PREVENTION OF FALLS IN THE
SUBACUTE HOSPITAL SETTING

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Australia
I dedicate this thesis to my family, especially my wife Emma and children Mitchell, Brooke, and Eliza, who continue to bless my life with their love every day.
ABSTRACT.

Falls are a relatively frequent occurrence amongst older people. Rates of falls amongst patients in subacute care are substantially higher than amongst people living in the community. Falls have been reported to cause physical and psychological injury, increase the likelihood of being discharged to nursing home, and are associated with longer lengths of stay in hospital. Thus, minimisation of falls in the subacute hospital setting is of high public health importance.

Much research has been conducted to identify factors associated with falls in the subacute setting, with several being identified. Similarly, several studies have reported developing tools to predict risk of falls, and evaluating interventions to minimise falls. However, few of these latter studies have employed rigorous methodologies to minimise sources of bias, and many have only included small sample sizes. Despite this, some evidence suggests that use of targeted, multiple intervention falls prevention programs may be successful in minimising falls.

A targeted, multiple intervention falls prevention program was designed, including a novel falls risk screening tool, three falls prevention interventions and a harm minimisation intervention. The screening tool was investigated to assess its predictive accuracy in a temporal validation study, and in comparison to a gold standard tool. Results indicated that the tool was readily completed by nursing, physiotherapy, and occupational therapy staff, and had comparable accuracy to the gold standard tool.

The falls prevention program was then investigated in a randomised controlled trial involving 626 subacute hospital patients. The targeted interventions were provided in addition to usual care and compared to usual care alone. The program significantly reduced the rate of falls by 30%, and is the first study to have demonstrated this in the subacute setting. Intervention subgroup analyses indicated that the education and additional exercise program components of the falls prevention program were especially effective in minimising falls. Limitations of the current research program and future directions for research in this field were discussed.
STATEMENT OF AUTHORSHIP.

Except where reference is made in the text, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis presented by me for another degree or diploma.

No other person’s work has been used without due acknowledgement in the main text of the thesis.

This thesis has not been submitted for the award of any other degree or diploma in any other institution.

All research procedures involving humans reported in this thesis were approved by the Human Research Ethics Committee of the Peter James Centre.

Financial support for this research project was received from the Victorian Department of Human Services, Aged Care Division.

Excluding references and appendices, this thesis contains no more than 100,000 words.

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Publications
The following manuscripts were derived fully or partly from work contained in this thesis:


• Haines T, Hill K, Bennell K, Osborne R (under review). Advancing the concepts of sensitivity and specificity to account for recurrent events and other features of the clinical research setting.

• Haines T, Osborne R, Bennell K, Hill K (under review). Predictive accuracy of a subacute hospital falls risk screening tool with comparison to gold standard.

**Conference presentations**

The following conference presentations (oral and poster) were derived from work contained in this thesis:


• *36th Annual Conference of the Australian Association of Gerontology. November 12-14 2003, Hobart Australia*

  Haines T, Osborne R, Bennell K, Hill K. Effectiveness of a targeted falls prevention program in a subacute hospital setting – a randomised controlled trial. Oral presentation.


  Haines T, Hill K, Bennell K, Osborne R. Advancing the concepts of sensitivity and specificity to account for recurrent events and other features of the clinical research setting. Poster presentation.

• *1st Australian Falls Prevention Conference. November 21-23, Sydney Australia*

• 1st Australian Falls Prevention Conference. November 21-23, Sydney Australia

Haines T, Bennell K, Osborne R, Hill K. Effectiveness of falls risk alert card, patient / family member information brochure and hip protector interventions for the prevention of falls in the subacute hospital setting – randomised controlled trial subgroup analysis. Poster presentation.

• 1st Australian Falls Prevention Conference. November 21-23, Sydney Australia

Haines T, Bennell K, Osborne R, Hill K. Effectiveness of an additional exercise program for the prevention of falls in the subacute hospital setting – randomised controlled trial subgroup analysis. Oral and poster presentation

UPCOMING

• 3rd National Conference of Emerging Researchers in Ageing. December 2, Brisbane Australia.

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<td>Area under the curve</td>
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<td>CI</td>
<td>Confidence interval</td>
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<td>ICC</td>
<td>Intra-class correlation coefficient</td>
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<td>MSS$^{ER}$S$^{ER}$</td>
<td>Maximum sum of sensitivity$^{ER}$ and specificity$^{ER}$</td>
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<td>FR</td>
<td>Functional reach</td>
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<tr>
<td>MSSS</td>
<td>Maximum sum of sensitivity and specificity</td>
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<td>Peter James Centre Falls Risk Assessment Tool</td>
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<td>NJ</td>
<td>Nursing judgement</td>
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<td>ROC</td>
<td>Receiver operating characteristic</td>
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Chapter 1: Review of literature on falls and falls prevention in the subacute care setting.

Part A: Epidemiology and outcomes of falls amongst patients in subacute care.
1.1 Introduction

Falls are a problem for many older (>65 years) Australians, with approximately 30% experiencing one or more falls over a 12 month period (Dolinis et al., 1997; Lord et al., 1993). These rates are similar to those from other countries including the United States of America (Tinetti et al., 1988), the United Kingdom (Prudham et al., 1981) and New Zealand (Campbell et al., 1981). Although less than 10% of falls result in serious physical injury (Tinetti et al., 1988), the cost to the Australian public for the management of injurious falls was $AUD 498 million annually in 2001 and with the ageing Australian population is expected to rise to $AUD 1,375 million annually by 2051 (Moller, 2003). Falls may also lead to serious psychological consequences that can reduce confidence, limit physical activity and subsequently lead to future falls and other complications of inactivity (Vellas et al., 1997).

Research into the epidemiology of and interventions to prevent falls have primarily been conducted with people living in three settings; community, residential care, and hospitals. Comparatively, a majority of randomised controlled trials of falls prevention interventions have been conducted in the community setting (Gillespie et al., 2004) with few randomised controlled trials in the hospital setting (Oliver et al., 2000). The hospital setting can be divided into acute and subacute care facilities. Patients in subacute hospitals are particularly vulnerable to falls as up to 47% have been reported to experience falls in this setting (Rapport et al., 1993).

To address this problem, a four step framework that has previously been applied to sports injury prevention has been proposed (van Mechelen et al., 1992). The framework involves:

1) Collection of incidence and severity data to identify the extent of the problem
2) Identification of factors and mechanisms associated with the problem
3) Implementation of measures to reduce the risk of the problem
4) Evaluation of the effectiveness of these measures

This process may repeat itself in an ongoing cycle. When considering previous falls research, much has been reported under each of these steps.
Part A of this chapter discusses the collection of falls data, the incidence and severity of falls, and risk factors related to them in the subacute hospital setting. Part B discusses what fall and fall-injury prevention measures have been developed for this setting and their effectiveness.
1.2 Subacute hospital care

1.2.1 Definition: Subacute hospital care

Despite a large amount of research that has been undertaken investigating patients receiving subacute care, there is no universally accepted or applied definition of subacute care that separates it from acute care. The term “subacute care” has been applied to a broad range of medical and rehabilitation services in settings that provide care to post-acute patients (Lewin - VHI Inc, 1994). Several brief definitions have been attempted, such as “Subacute care units treat patients too sick to go home but not sick enough to be hospitalized” (Barnett, 1993), or “Care provided to patients who do not meet established criteria for medically necessary acute care.” (Mannard et al., 1988). Several larger, more comprehensive definitions have been produced by organisations such as the American Subacute Care Association and the Joint Commission on Accreditation of Healthcare Organizations (Lewin - VHI Inc, 1994).

For the purpose of this thesis the definition adopted by the International Subacute Healthcare Association Incorporated will be used (International Subacute Healthcare Association Incorporated, 1994). This definition is:

“Subacute care is a comprehensive, cost-effective and outcome oriented approach to care for patients requiring short-term, complex medical and/or rehabilitation interventions provided by a physician directed interdisciplinary, professional team. Subacute services should be administered through defined programs without regard to setting. Subacute programs typically are utilized as an inpatient alternative to an acute hospital admission or an alternative to continued hospitalization, and may be a component of a vertically integrated health care system.”

Two primary aims of subacute care are to increase patient autonomy and reduce dependency, and to restore persons injured by disease or accident to their highest possible level of function. Both have been implicated as possible contributors to patient falls in this setting (Mayo et al., 1989; Oliver et al., 1997; Patrick et al., 1999). Patients admitted for subacute care more frequently display risk factors for falls such as disorientation, impaired physical function and altered bladder function (Grant et al.,
1987). Not surprisingly, fall rates among patients in subacute care have been found to be higher than those in acute care (Halfon et al., 2001; Mion et al., 1989b; Raz et al., 1987; Tuffnell, 1990). This indicates that the subacute care setting requires specific attention in establishing falls risk factors and prevention strategies.

This thesis addresses the prevention of falls and fall related injuries amongst patients in subacute care. In reviewing literature pursuant to this problem, studies that described inclusion of patients receiving care that could be classified as “subacute” under the definition adopted by the International Subacute Healthcare Association Incorporated (International Subacute Healthcare Association Incorporated, 1994) were included for analysis. Intervention and case-control exploratory studies that included a mixture of patients from acute and subacute, or subacute and residential care settings were also included, however, where available, data from the subacute setting in these studies was focused upon. Cohort studies where less than 20% of patients were under subacute care were excluded (discussed further in section 1.4.2). Some studies that did not include or included an insufficient proportion of patients in subacute care have been highlighted to articulate particular points that are applicable to patients in the subacute setting.
1.3 Falls

Falls have been the subject of much research in the subacute care setting, yet no consistent definition has been applied.

1.3.1 Definition: Falls

An internationally recognised definition for falls is that of the Kellogg International Working Group on Prevention of Falls by the Elderly, being an event which results in a person coming to rest inadvertently on the ground or other lower level and other than a consequence of the following: sustaining a violent blow, loss of consciousness, sudden onset of paralysis (as in stroke) or epileptic seizure (Kellogg International Working Group, 1987). These exclusion criteria are problematic for applying this definition to studies in the subacute care setting. Frequently falls in the subacute care setting are unwitnessed (Mion et al., 1989b) and are incurred by patients with cognitive impairment (Evans et al., 2001) making establishment of the cause of the fall difficult. Furthermore, falls regardless of cause may lead to patient injury and therefore should be of concern to health care providers, patients and families. Subsequently relatively few studies of falls in the subacute setting have employed this definition.

A definition of falls common to some hospital based studies has been:

“...an event in which the patient came to rest on the floor. This definition included patients slipping from the chair to the floor, patients found lying on the floor and assisted falls (ie., falls in which a nurse or bystander caught the patient and, although the impact of the fall was prevented, the assistant was unable to prevent the patient from being lowered onto the floor).” (Morse et al., 1987)

Some studies have refined this definition further by stating that the process of coming to rest on the ground must have been “inadvertent” or “involuntary”, presumably excluding incidents where patients had purposefully gone to the ground (Cohen et al., 1991; Hanger et al., 1999; Morris et al., 1980; Oliver et al., 1997; Vlahov et al., 1990). Other studies excluded “assisted falls” from their definition (Brady et al., 1993; Foster et al., 1996; Mion et al., 1989b).
Studies that reported investigating “falls” by patients under subacute care, their negative outcomes, or the patients who experience falls were included for analysis in the following review. It should be noted here that a standard definition of what a “fall” is has not been applied in these studies, which is a factor that may have introduced some of the variation in the outcomes reported.

1.3.2 Measuring falls

Falls incurred by patients in subacute care are widely considered to be an “adverse event” for which an “incident report” requires completion. Some studies have reported that completion of incident reports for falls is mandatory in their facility (Healey, 1994; Mayo et al., 1990; Vassallo et al., 2003) and in others the completion of an incident report is a component of the definition of a fall (Donald et al., 2000; Nurmi et al., 2002; Raz et al., 1987; Vlahov et al., 1990). One study claimed that their review of incident reports allowed for an analysis of their entire population of falls (DeVincenzo et al., 1987).

There is evidence however, that incident reporting is an imperfect method of falls surveillance in the hospital setting (Elnitsky et al., 1997; Sutton et al., 1994a; Sutton et al., 1994b). One study found that 1% - 12% of nurses over 15 health care facilities did not agree that it was important to report all incidents and did not report them all (Elnitsky et al., 1997). Another study found that patients reported incurring 35% more falls than what staff formally reported (Sutton et al., 1994b). However, fallers in this study had significantly poorer Mini-Mental State Examination results than non-fallers, indicating that patient recall may have been biased. In contrast, authors of another study reported finding no evidence of incomplete fall reporting, however the method by which these authors came to this conclusion was not described (Vassallo et al., 2003).

Despite its limitations, use of incident reports as the primary means for collating falls data is widespread. Several epidemiological studies (DeVincenzo et al., 1987; Grant et al., 1987; Mayo et al., 1989; Mayo et al., 1990; Nurmi et al., 2002; Nyberg et al., 1995; Vassallo et al., 2003), intervention studies (Donald et al., 2000; Hanger et al.,
1999; Healey, 1994; Mayo et al., 1994; Oliver et al., 2002; Tuffnell, 1990) and studies investigating fall risk screening tools in subacute care settings (Coker et al., 2003; Eagle et al., 1999; Halfon et al., 2001; Moore et al., 1996; Oliver et al., 1997; Rapport et al., 1993) have specified that auditing of incident reports was the means of collating falls data. Thus despite criticisms of its validity, measurement of falls through auditing of incident reports is widely accepted in subacute health care settings. Providing formal, standardised training to people taking measurements has been reported to improve the accuracy of measurements (Altman et al., 2001), and should be employed for falls studies in subacute settings to improve the reporting of falls incidents.

1.3.3 Classifications of falls and fallers

Although falls in general are the outcome of interest in most falls related studies, specific types of falls have also received attention. Falls have been classified according to their cause mechanism, situational factors surrounding their occurrence and their physical consequences.

Mechanisms of falls can be classified as intrinsic, such as where a health condition affects a patient's postural control, or extrinsic, where an environmental factor contributes to the fall to the largest extent (Masud et al., 2001; Nyberg et al., 1995). A more complex classification system that has been applied to the hospital setting proposes separating “anticipated physiological falls” from “unanticipated physiological falls” and “accidental falls” (Morse et al., 1989a). Anticipated physiological falls were defined as occurring in patients who have difficulty ambulating and are confused and accounted for 78% of falls in one study (Morse et al., 1987). Unanticipated physiological falls occur when a patient has a “drop attack”, faints or has a seizure, and accidental falls occur when a patient slips or trips. These classifications were used to describe the falls not correctly identified by a falls risk screening tool. The authors of this study implied greater predictive accuracy of the tool by claiming that some of the falls not predicted (unanticipated physiological and accidental) were “unpredictable events” (Morse et al., 1989a; Morse et al., 1989b). However the position that these falls are unpredictable has been criticised by
suggesting that intrinsic and extrinsic factors may still contribute to these falls (Masud et al., 2001).

Several epidemiological studies have classified falls according to situational factors surrounding their occurrence. For example, their location, time of day, week of patient hospitalisation, or if falls were witnessed (DeVincenzo et al., 1987; Foster et al., 1996; Grant et al., 1987; Halfon et al., 2001; Mion et al., 1989b; Morse et al., 1987; Nyberg et al., 1995; Pullen et al., 1999; Sweeting, 1994; Teasell et al., 2002; Tuffnell, 1990; Vlahov et al., 1990). The purpose of classifying falls in this way has been to identify situational factors that may contribute to falls. Alternately, falls studies may focus on interventions designed to prevent a specific type of fall in which case, the specific type of fall might become the primary outcome measure. For example, bedroom falls were the primary outcome measure in an investigation of bedrails as a falls prevention intervention (Hanger et al., 1999).

Falls have also been classified according to their relative outcomes. This will be discussed in section 1.5.

People who experience falls have also been the subject of investigation in epidemiological studies and intervention studies. Most frequently, a “faller” has been described as a person who experiences one or more falls during their hospital stay (Barr et al., 1999; DeVincenzo et al., 1987; Donald et al., 2000; Gluck et al., 1996; Grant et al., 1987; Grenier-Sennelier et al., 2002; Mayo et al., 1989; Mayo et al., 1990; Mion et al., 1989b; Nyberg et al., 1997; Patrick et al., 2001; Patrick et al., 1999; Teasell et al., 2002). One study compared the characteristics of “early” fallers (fall within the first week of hospitalisation) and “late” fallers (fall after the first week of hospitalisation) (Vassallo et al., 2003). Other studies have also described recurrent or multiple fallers as being patients who experience two or more falls during their hospital stay (Gaebler, 1995; Mion et al., 1989b; Oliver et al., 2002; Tuffnell, 1990). Justification for considering multiple fallers separately from single fallers has been based on the expectation that they have substantially different clinical characteristics and different likelihood of injury (Masud et al., 2001).
1.3.4 Describing falls rate data

The two most commonly described aspects of hospital falls data are the rate of fall events observed during the study period and the proportion of patients who experienced one or more falls during their hospitalisation. Using standard epidemiologic terminology to describe these data is problematic for two reasons. First, falls are singular events rather than disease processes, for example, a fall occurs in an instant and is then finished, whereas an infection can be present over an extended period. This means that terminology describing disease prevalence, being the number of cases of a disease at a given point in time (Portney et al., 2000), cannot be accurately employed (Cumming et al., 1990). Secondly, falls can also be recurrent events. Both the terms “cumulative incidence” and “incidence rate” refer to “new” occurrences of the condition (Portney et al., 2000), meaning that if a person has previously had the condition, their data should not be included. Given the definitions of falls discussed in 1.3.1 it would be difficult to find any patients who could participate in falls studies in subacute care settings who had not previously fallen at some stage in their life.

The term “event rate” has been defined as the number of events, possibly including multiple events per person, divided by the total person-years of experience (Glynn et al., 1996). Several authors have calculated their findings as event rates, although they have often referred to this as the incidence rate of falls. For consistency in this thesis, the terminology event rate will be used. The term event rate will also be applied to fall-related injuries.

Unfortunately there does not appear to be any equivalent terminology to describe the proportion of patients who experience one or more falls during their hospitalisation. Although the term “cumulative incidence” most closely resembles this measure, its use may be misleading (Cumming et al., 1990). Instead, in this thesis, these results will be referred to as the “proportion of patients who were fallers”. The term “proportion of patients who were recurrent fallers” will also be applied for patients who experience two or more falls.
1.3.5 Rates of falls

Studies in general subacute hospital wards have reported that between 14% and 37% of patients experienced one or more falls during their stay (Teasell et al., 2002; Vassallo et al., 2001). For stroke specific subacute settings, between 36% and 47% experienced falls (Mayo et al., 1990; Nyberg et al., 1997; Rapport et al., 1993). Between 25% and 61% of all fallers have also been reported as being recurrent fallers (two or more falls) (Donald et al., 2000; Nyberg et al., 1997).

Fall event rates are commonly described in terms of falls per 1000 patient days. It is a ratio measure where the number of fall events over a given time period in a defined sample is the numerator, and the sum of the number of days each patient was observed during the time period is the denominator. This ratio is then multiplied by 1000 to give the number of falls per 1000 patient days. Fall event rates have been reported between 2.9 and 18.2 falls per 1000 patient days in general subacute settings (Hanger et al., 1999; Morse et al., 1989a), and between 15.9 and 17.8 falls per 1000 patient days in stroke specific subacute settings (Nyberg et al., 1995; Nyberg et al., 1996; Teasell et al., 2002). Fall event rates have been less frequently reported than the proportion of patients who become fallers.

It is apparent that the proportion of patients who experience falls and fall event rates have varied widely. There are many possible reasons for this variance including differing falls definitions, incomplete reporting of falls, availability of falls prevention resources, whether a falls prevention program was being conducted at the time of data collection and patient casemix differences.
1.4 Falls risk factors

Information about the causes of falls and fall related injuries may be gleaned from their associated risk factors. Numerous studies in a variety of settings have identified over 400 potential risk factors for falling (Nuffield Institute for Health, 1996). Identification of important falls risk factors has been asserted to be a major component in the development of accurate falls risk factor assessment tools and effective falls prevention programs in the hospital setting (Evans et al., 2001).

1.4.1 Classifications of falls risk factors

Several methods for classifying falls risk factors have been described. A simple approach has been to divide a patient’s risk factors into intrinsic and extrinsic (Gillespie et al., 2003; Wilson, 1998). Intrinsic risk factors can be subdivided into physical, psychologic and pharmacologic (Wilson, 1998). Extrinsic factors are those in or related to the patient’s environment that may contribute to a fall. Factors such as patients not adhering to the recommendations of hospital staff could be considered to be “behavioural factors”. These factors are not clearly intrinsic or extrinsic factors, rather a combination. Another system divides falls risk factors into 5 categories; environmental, medication, medical conditions and changes associated with ageing, nutritional and lack of exercise (Nuffield Institute for Health, 1996). Alternate approaches have also been employed, for example, classifying risk factors as modifiable (reversible) or non-modifiable (Oliver et al., 2002). An example of a modifiable risk factor would be impaired quadriceps strength, which may be improved through knee extension exercises (Lord et al., 1995), and a non-modifiable risk factor would be age. A call has been made for greater emphasis on diagnosing and treating modifiable risk factors in future hospital falls prevention research (Oliver et al., 2002). However for descriptive purposes, falls risk factors will be classified as either being intrinsic or extrinsic in this discussion. Some behavioural factors that have been investigated and analysed in a similar manner to intrinsic factors have been classified as intrinsic risk factors. Similarly behavioural factors that have been investigated and analysed in a similar manner to extrinsic factors have been classified as extrinsic factors.
1.4.2 Statistical considerations – study designs and analysis techniques

There are three categories of research design available to researchers seeking to identify falls risk factors. Each has strengths and weaknesses in their ability to validly identify falls risk factors, and in their ease of application by researchers.

A retrospective review or audit of medical histories or falls incident reports over a given time period is the most common method for identifying fall event rates within an institution and the risk factors that contribute to the fall (Morse, 1993). Health care institutions may have a central collection point for fall related incident reports, making the information contained on these reports readily accessible (Gaebler, 1995; Grenier-Sennelier et al., 2002; Hanger et al., 1999; Oliver et al., 2002). Retrospective reviews allow for calculation of falls event rates providing that patient bed days or occupancy days data is gathered to be used for the denominator. Direct calculation of the proportion of patients who are fallers and identification of intrinsic falls risk factors is complicated in this research approach by an inability to clearly define the denominator, unless it is clearly specified in the methodology that only data from patients admitted after a certain date and discharged prior to a latter specific date were included. Patients at the commencement and completion of the audit period do not have all of their data considered. However, retrospective reviews are well placed to detect extrinsic falls risk factors, such as fall locations, times, and day of week. The limit to which extrinsic risk factors can be examined depends on what information is consistently recorded on incident reports or available in medical records.

Case-control studies endeavor to make a valid comparison through the selection of a control group. Both cases and controls must be clearly defined so that one can be clearly distinguished from the other (Portney et al., 2000). Unfortunately, consistent definitions of cases and controls have not been universally applied in this field. In most studies, a case has been defined as a patient who experienced one or more falls during their hospitalisation (Barr et al., 1999; Gluck et al., 1996; Mayo et al., 1989; Morse et al., 1987; Patrick et al., 2001), however fall definitions have varied. Controls have been patients from the same hospital who did not fall during their hospitalisation, selected through systematic sampling (Barr et al., 1999), random
selection (Morse et al., 1987), or based on matching for gender (Gluck et al., 1996; Mayo et al., 1989), age (Gluck et al., 1996), hospital ward (Gluck et al., 1996), admission date (Arbesman et al., 1999; Mayo et al., 1989), presence during a specified nursing shift (Arbesman et al., 1999) or patient type (Morse et al., 1987). Atypically in one study, a case was defined as a “fall”, allowing for individual patients to be the subject of several data sets (Oliver et al., 1997). The controls in this study were the patient in the next bed if they had not already fallen, but they could also provide information as a case if they subsequently fell (Oliver et al., 1997). This practice has been criticised, as duplication of data from the same source may introduce systematic bias (Altman, 1997). Case-control studies are unable to accurately identify falls event rates or the proportion of patients who were fallers unless additional information is gathered (Portney et al., 2000). Where cases and controls only contribute one set of data, the risk factors being investigated are those that predispose a patient to becoming a “faller” rather than those that are associated with “fall” events per se.

In cohort studies, a group of subjects are selected and followed over time to see if the condition develops (Portney et al., 2000). Generally in cohort hospital falls studies, all patients admitted to a ward during a pre-determined time period are followed to see if they fall during their hospitalisation. There is a danger when using this study design to collect data from a mixture of patients under subacute and acute care when trying to identify falls risk factors in the subacute setting. As previously mentioned, falls occur more frequently in the subacute than the acute setting (section 1.2.1). If a factor is more common to patients in subacute care, is disproportionately represented between acute and subacute care, yet is equally distributed between fallers and non-fallers under subacute care, it may still appear as a falls risk factor when the acute patients are added to the analysis. For this reason, cohort studies with an obviously greater proportion of acute patients were excluded from the following discussion unless findings specific to patients from the subacute setting were provided. Examples of two studies where general findings were excluded for this reason were those by Halfon et al 2001 and Passaro et al 2000. This is less of an issue for case-control studies as even if a greater proportion of eligible patients are under acute care, a greater proportion of falls are still more likely to be had by subacute patients,
increasing the relative amount of data they provide through being cases or their matched controls.

Cohort study designs can be used to determine the event rate of a condition (Portney et al., 2000), thus it can also be used to investigate factors relating to the “fall” event along with those related to whether the patient becomes a “faller”. Although many falls studies involving patients under subacute care have utilised a cohort design (Halfon et al., 2001; Izumi et al., 2002; Mayo et al., 1990; Mion et al., 1989b; Nyberg et al., 1997; Rapport et al., 1993; Vassallo et al., 2003), risk factors for fall events have rarely been described (Patrick et al., 2001; Rapport et al., 1993; Vlahov et al., 1990). Instead, the association between characteristics and the time to first fall have been described using Kaplan-Meier survival analysis and Poisson regression (Halfon et al., 2001; Nyberg et al., 1997; Vassallo et al., 2003). However, analysis of first events as a substitute for an analysis of overall fall event rates may lead researchers to miss insights that can be attained through a more thorough analysis of fall event rates (Glynn et al., 1996).

In considering the strength of an association between potential risk factors and the likelihood of a patient becoming a faller during their subacute hospitalisation, several things can be considered. Firstly, the association between the risk factor and becoming a faller in individual studies should be analysed to see if it is “significant”, statistically speaking. Due to chance differences in some subject characteristics, researchers are likely to see some differences between fallers and non-fallers. Conducting statistical “hypothesis testing” allows researchers to determine if these differences are probably due to chance or not (Portney et al., 2000).

There are two broad approaches that have been employed for describing the association between potential risk factors and whether patients become fallers or not. The first has been to conduct univariate analyses. A univariate approach accommodates analysis of only one risk factor at a time (Portney et al., 2000). Thus to analyse several potential risk factors, several separate univariate analyses must be undertaken. However the risk of committing a “Type 1” error (an incorrect decision to reject the null hypothesis, concluding that an association exists when in fact it does not) in an individual study increases where several risk factors have been investigated.
and multiple univariate tests have been employed (Portney et al., 2000). Thus although a risk factor may have been found to be “significant” in one study, there is a small chance that it is not “truly” related to a patient becoming a faller. Therefore it is important that “significant” risk factors investigated in this way in one study are compared across studies to see if the results have been consistent.

The “effect size” or strength of an association can also be taken into consideration. “Odds ratios” or “relative risks” can be used to describe effect sizes, for example, a risk factor with an odds ratio of 2.0 means that a patient with that risk factor is twice as likely to become a faller as a patient without it. Large studies may have the capacity to detect associations that are both strong and moderate. So although two risk factors could both be considered to be “significant”, one could also be argued as being stronger than another based on the effect size. Conversely, small studies may have very little potential for detecting significant associations at all. So instead of just focussing on whether a risk factor was found to be significant or not in such a study, one could also examine the effect sizes or trends in the associations investigated.

Caution must be applied with this approach though as an association that is not found to be significant has an increased probability of being the product of chance variation rather than a “true” association (Portney et al., 2000). Thus non-significant findings from small studies are often uninformative, unless they are pooled with the results from other similar studies in “meta-analyses” (Oliver et al., 2000; Portney et al., 2000).

Another approach has been to conduct multivariate analyses. A multivariate approach can be used to select from a number of observed variables those that are important risk factors for falls or patients becoming fallers. This collection of selected factors is referred to as a “model”. The model can be formed in a variety of ways, such as forwards, backwards, stepwise, or hierarchical selection using a variety of regression approaches (StataCorp, 2001). These approaches account for the potential interassociations of the risk factors included in the multivariate model (Portney et al., 2000). The problem with a multivariate approach comes in its interpretation as although the risk factors selected are important, the risk factors not selected are not necessarily unimportant (Huack et al., 1991). Furthermore, the risk factors selected in the model can be different depending on the risk factor selection approach (Simon et
al., 1994) and the number of variables included in a model will increase as the sample size increases (Harrell et al., 1985). This latter problem is not restricted to multivariate analysis though, as very large sample sizes can lead to many statistically significant associations between potential risk factors and falls using a univariate approach, however the strength of these associations may not be clinically significant (Portney et al., 2000). This is another important consideration when investigating falls risk factors, as infrequent characteristics will require much stronger associations with falls to be considered statistically significant falls risk factors than what common characteristics require.

1.4.3 Evidence of intrinsic falls risk factors

Several studies have described falls risk factors for hospital patients inclusive of those in subacute care. Details of the design of these studies are summarised in table 1.1. Intrinsic risk factors investigated in these studies are presented in table 1.2.
Table 1.1. Studies that investigated or provided information regarding falls risk factors among subacute hospital patients.

<table>
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<tr>
<th>Author, year</th>
<th>Design</th>
<th>Setting</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arbesman et al, 1999</td>
<td>Case-control</td>
<td>Acute hospital with a rehabilitation service</td>
<td>n = 504</td>
</tr>
<tr>
<td>Barr et al, 1999</td>
<td>Case-control</td>
<td>Rehabilitation ward</td>
<td>n = 174</td>
</tr>
<tr>
<td>Cannard, 1996</td>
<td>Retrospective audit</td>
<td>Care of the elderly ward</td>
<td>4 months x 49 beds</td>
</tr>
<tr>
<td>DeVincenzo et al, 1987</td>
<td>Retrospective audit, case-control</td>
<td>Rehabilitation centre</td>
<td>1 year x 150 beds (audit), n = 324</td>
</tr>
<tr>
<td>Foster et al, 1996</td>
<td>Retrospective audit</td>
<td>Rehabilitation ward</td>
<td>8 months x 46 beds</td>
</tr>
<tr>
<td>Gaebeler, 1993</td>
<td>Case-control</td>
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<td>n = 100</td>
</tr>
<tr>
<td>Gluck et al, 1996</td>
<td>Case-control</td>
<td>Mixed acute, rehabilitation, elderly care wards</td>
<td>n = 100</td>
</tr>
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<td>Grant et al, 1987</td>
<td>Retrospective audit</td>
<td>Rehabilitation centre</td>
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</tr>
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<td>Retrospective audit</td>
<td>Medical and rehabilitation unit</td>
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<tr>
<td>Izumi et al, 2002</td>
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<td>Rehabilitation centre</td>
<td>n = 277 (rehab. patients)</td>
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<td>Mayo et al, 1989</td>
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<td>n = 402</td>
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<td>Mayo et al, 1990</td>
<td>Cohort</td>
<td>Rehabilitation ward</td>
<td>n = 156 (stroke patients)</td>
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<tr>
<td>Mion et al, 1989</td>
<td>Cohort</td>
<td>General medical rehabilitation wards</td>
<td>n = 143</td>
</tr>
<tr>
<td>Morris et al, 1980</td>
<td>Retrospective audit</td>
<td>Subacute and residential aged care wards</td>
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<tr>
<td>Morse et al, 1987</td>
<td>Case-control</td>
<td>Acute, long term geriatric, veteran’s centre</td>
<td>n = 200</td>
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<tr>
<td>Nurmi et al, 2002</td>
<td>Prospective audit</td>
<td>Acute, subacute, nursing home wards</td>
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<td>Stroke rehabilitation ward</td>
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<td>Oliver et al, 1997</td>
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<td>n = 232</td>
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<td>Patrick et al, 2001</td>
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<td>Rehabilitation medicine service</td>
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<td>n = 238 (stroke patients)</td>
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<td>Vassallo et al, 2003</td>
<td>Cohort</td>
<td>General rehabilitation wards</td>
<td>n = 1025</td>
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<tr>
<td>Vlahov et al, 1990</td>
<td>Retrospective audit</td>
<td>Rehabilitation facility</td>
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## Table 1.2a. Intrinsic risk factors associated with patients becoming fallers.

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Table 1.2b. Intrinsic risk factors associated with patients becoming fallers (continued).

| Risk factor                  | Study (author, year) | Arbesman et al., 1999 | Barr et al., 1990 | DeVincenzo et al., 1997 | Glueck et al., 1996 | Grenier-Sennelder et al., 2002 | Izumi et al., 1999 | Mayo et al., 1990 | Mayo et al., 1990 | Mion et al., 1990 | Morris et al., 1997 | Morse et al., 1987 | Nummi et al., 2002 | Nyberg et al., 1997 | Oliver et al., 1997 | Patrick et al., 1993 | Rapport et al., 1993 | Teasell et al., 2002 | Vlahov et al., 1990 |
|------------------------------|----------------------|------------------------|-------------------|--------------------------|---------------------|-------------------------------|-------------------|-------------------|-------------------|-------------------|---------------------|-------------------|-------------------|-------------------|-------------------|--------------------|-------------------|
| Sensory impairment           |                      | ✓✓                     | ✓                 | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |
| Vision impairment            |                      | ✓                      |                   | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |
| Hearing impairment           |                      |                        |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Dizziness                    |                      |                        |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Aphasia/dysphasia            |                      | ✓                      |                   | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |
| Expressive                   |                      |                        |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Receptive                    |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Perceptual impairment        |                      | ✓                      |✓                 | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |
| Visuospatial hemineglect     |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Present medical condition    |                      | ✓                      |✓                 | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |
| High blood glucose           |                      |                        |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Intravenous therapy          |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Abnormal skin turgor         |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Respiratory assistance       |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Pulse rate                   |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Urinary tract infection      |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| High white blood cells       |                      | ✓                      |                   |                          |                     |                               |                   |                   |                   |                   |                     |                   |                   |                   |                   |                   |                   |
| Functional dependency        |                      | ✓                      |✓                 | ✓                        | ✓                   | ✓                             | ✓                 | ✓                 | ✓                 | ✓                 | ✓                   | ✓                 | ✓                 | ✓                 | ✓                 | ✓                  | ✓                 |

Legend: ✓ indicates the factor was found to be a risk factor, x indicates the factor was not found to be a risk factor.
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Table 1.2e. Intrinsic risk factors associated with patients becoming fallers (continued).

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✓ - Indicates risk factor was significantly associated with patient becoming a faller (univariate analysis).

☆ - Indicates risk factor was significantly associated with patient becoming a faller (multivariate analysis).

✗ - Indicates risk factor was investigated but found to not be significantly associated with patient becoming a faller (univariate analysis).

✗ - Indicates risk factor was investigated but found to not be significantly associated with patient becoming a faller (multivariate analysis).

❓ - Indicates risk factor was investigated but results were not clearly stated.

* - Indicates risk factor was protective against becoming a faller.

† - Risk factor excluded due to criteria for selection of controls in this study.
1.4.3.1 Age

Age has frequently been investigated as a potential falls risk factor, however studies of association between age and becoming a faller have revealed inconsistent results. Possible sources of discrepancy may lie in how this association has been analysed and setting. In three of the studies that found age to be a significant falls risk factor less than half of the patients examined were in sub-acute care (Arbesman et al., 1999; Grenier-Sennelier et al., 2002; Halfon et al., 2001; Morse et al., 1987). Two studies of the studies that investigated purely subacute patients measured age as a categorical variable with four and five categories of age respectively (DeVincenzo et al., 1987; Vlahov et al., 1990). Both of these studies demonstrated a curvilinear, inverse quadratic, association between falls and age. In one study, the proportion of patients becoming fallers started at 2.8% in the 10-29 age category, which rose to 21.8% in the 50-69 age category before dropping off slightly to 18.4% in the 70-89 age category (Vlahov et al., 1990). In another study, the proportion of patients becoming fallers commenced at 7% in the >49 category, peaked at 18% in the 60-69 category, before falling to <10% in the >80 category (DeVincenzo et al., 1987).

In comparison to studies that did not find age to be a significant risk factor, many analysed age as a continuous variable using t-tests, ANOVA, logistic or Cox regression analyses (Mayo et al., 1990; Mion et al., 1989b; Nyberg et al., 1997; Oliver et al., 1997; Patrick et al., 2001; Rapport et al., 1993). A curvilinear association between age and becoming a faller may produce a scenario where the mean age of fallers is similar to that of non-fallers. Thus, the association may not be detected using a t-test or ANOVA as these tests compare group means. Standard regression approaches are also unable to detect this association as they only test for a linear association between independent and dependent variables (Abrams, 2003).

Of the studies that did not find age to be a significant risk factor and divided age into categories, two utilised only three categories allowing fewer comparisons over the age range (Izumi et al., 2002; Mayo et al., 1989). Two demonstrated a curvilinear association with peak risk in the 75-84 year old age bracket where in one the association was weak (Izumi et al., 2002) and the other the association was strong but no statistical analysis was presented (Morris et al., 1980). Given the size and quality of the studies involved, there is little evidence of a linear association between age and
becoming a faller in the subacute care setting, and that if there is an association, a curvilinear one is more probable. This finding is in contrast to the community setting where increasing age has frequently been associated with increasing risk of falls (Close, 2001; Covinsky et al., 2001; Fletcher et al., 2002; Tinetti et al., 1988).

### 1.4.3.2 Gender

Gender has been investigated as a potential risk factor in several studies but a significant association has only been found in three. In these studies, men have been reported to be 1.6 (Nurmi et al., 2002) to 2.1 (Nyberg et al., 1997) times more likely to become a faller. A non-significant “trend” of men more frequently becoming fallers has been found in several studies (DeVincenzo et al., 1987; Halfon et al., 2001; Mayo et al., 1990; Morris et al., 1980; Morse et al., 1987). Only one study reported a trend of a greater risk of becoming a faller for women, yet after it adjusted these results for age, found a trend for men to become fallers more frequently (Vlahov et al., 1990). Thus there is evidence to suggest that gender (male) has a moderate association with becoming a faller.

These results conflict with those from the community setting where several studies have found females to be at a higher risk of falls than males (Campbell et al., 1990; Graafmans et al., 1996; Prudham et al., 1981; Wickham et al., 1989). It is possible that gender based differences in staff to patient interactions in the subacute setting contribute to this, although there are many other potential factors involved. It should also be noted that the women have not consistently been identified as being at a significantly increased risk of falling in community-based studies (Tinetti et al., 1988), and in one large epidemiological investigation, men were at a significantly increased risk for falls in this setting (Fletcher et al., 2002).

### 1.4.3.3 Previous history of falls

A previous history of falls has been frequently examined, however a uniform definition for this potential risk factor has not been employed. A “history of falls” without reference to a time period prior to admission has been used in several studies (Barr et al., 1999; Gluck et al., 1996; Nyberg et al., 1997; Patrick et al., 2001; Rapport et al., 1993). However, given the definitions of falls discussed in 1.3.1, having no
time frame reference makes the interpretation of this definition of a “history of falls” difficult.

Falls in the previous 2 years (Izumi et al., 2002) and falls as a presenting complaint to hospital (Oliver et al., 1997) have been used to define a history of falls. One case-control study examined previous falls during the same hospital admission, however excluded patients who had already had a fall during the admission from acting as control patients, thus invalidating the investigation of this potential falls risk factor (Morse et al., 1987). Where studies have found a significant association between a previous history of falls and becoming a faller while in subacute care, the increased risk has been reported to be 1.8 (Barr et al., 1999), 1.9 (Gluck et al., 1996) and 4.6 multivariate [2.7 univariate] (Oliver et al., 1997) times higher. The strength of association between past history of falls and becoming a faller during hospitalisation has not clearly been presented in studies that found a non-significant difference, other than one study describing these patients as being at 1.2 times greater risk (Nyberg et al., 1997). At present there is some evidence suggesting that falls in a period prior to hospital admission is associated with becoming a faller in the subacute setting, however the strength of this association is likely to be only weak to moderate in strength.

1.4.3.4 Cognitive impairment

Cognitive impairment, or aspects of cognitive impairment such as disorientation or confusion, have been identified as significant falls risk factors in many studies (Arbesman et al., 1999; Barr et al., 1999; Gluck et al., 1996; Mayo et al., 1989; Mion et al., 1989b; Morse et al., 1987; Nyberg et al., 1997; Teasell et al., 2002), which is consistent with findings from community based studies (Close, 2001; Fletcher et al., 2002; Tinetti et al., 1988). Of the five studies that did not find an association between cognitive impairment and falls, two were relatively small (n = 98 (Patrick et al., 2001) and n = 32 (Rapport et al., 1993)) and possibly underpowered. Another did not find a significant association following multivariate analysis although patients with “altered mentation” were twice as likely to become fallers following univariate analysis (Izumi et al., 2002).
Formalised measures of global cognitive impairment, such as the Mini-Mental State Examination (Folstein et al., 1975), have only occasionally been employed (Nyberg et al., 1997; Oliver et al., 1997; Patrick et al., 2001). One study found fallers to have higher mean Mini-Mental State Examination scores than non-fallers (Patrick et al., 2001). Alternative descriptions such as “altered mentation” (Izumi et al., 2002) or “cognitive deficits” (Teasell et al., 2002) however can leave clinicians and researchers little idea of how they can reliably reproduce these assessment procedures in their practice. Thus although there is much evidence supporting an association between cognitive impairment and becoming a faller during subacute hospitalisation, it is unclear how clinicians and researchers should best assess for this risk factor.

1.4.3.5 Physical impairment

Physical impairment, or aspects of physical impairment such as impaired balance, gait, or muscle weakness have been found to significantly increase the risk of becoming a faller in the majority of studies in which it has been investigated. This is consistent with findings from community based studies (Close, 2001; Covinsky et al., 2001; Graafmans et al., 1996; Tinetti et al., 1988). The studies that did not find physical impairment to be a significant risk factor had small sample sizes (range n = 32 to 143) (Gluck et al., 1996; Mion et al., 1989b; Patrick et al., 2001; Rapport et al., 1993), and the measurement scale or assessment techniques used to describe aspects of physical impairment were not described in three (Gluck et al., 1996; Mion et al., 1989b; Rapport et al., 1993). Thus it is difficult to know how these studies were assessing physical impairment and if they were sufficiently powered to detect even large effect sizes.

In comparison, the studies that found a significant association tended to be larger (range n = 135 to 504) (Arbesman et al., 1999; Barr et al., 1999; Izumi et al., 2002; Morse et al., 1987; Nyberg et al., 1997; Oliver et al., 1997; Teasell et al., 2002) and three used standardised assessment techniques such as the Berg Balance Scale (Berg et al., 1995), Fugl-Meyer Assessment (Fugl-Meyer et al., 1975) and the Barthel Index (mobility section) (Mahoney et al., 1965) to gauge aspects of physical impairment. The risk of falling was reported as being between 1.7 (Teasell et al., 2002) and 6 (Izumi et al., 2002) times greater for those with physical impairment, one reported
odds ratio (Oliver et al., 1997) was ignored as it was erroneous (the reported odds ratio was negative, however an odds ratio is a ratio of two positive integers, thus it must be positive) (Altman, 1993). Thus there is strong evidence of an association between physical impairment and becoming a faller in the subacute setting, and the presence of this risk factor can be gauged with a variety of standardised assessment techniques.

### 1.4.3.6 Functional dependency

Measures of functional independence gauge a patient’s ability to complete activities of daily living without physical aids or assistance. Five of seven studies that have investigated functional dependency have found that it is significantly associated with becoming a faller in the subacute setting (Mayo et al., 1989; Mayo et al., 1990; Mion et al., 1989b; Nyberg et al., 1997; Teasell et al., 2002). Four of these studies have used standardised measures of functional independence (Mayo et al., 1990; Mion et al., 1989b; Nyberg et al., 1997; Teasell et al., 2002); the Barthel Index (Mahoney et al., 1965), the Katz Activities of Daily Living Index (Katz et al., 1963), the Sister Kenny Self-Care Evaluation (Schoening et al., 1968) and the Functional Independence Measure (Ottenbacher et al., 1996). The strength of these associations have been reported as increasing the risk of falling between 1.6 (Mayo et al., 1989) and 6.4 (Nyberg et al., 1997) times. Of the studies that did not find a significant association, one study reported an erroneous (negative) odds ratio and was ignored (Oliver et al., 1997). The other did not employ a standardised measure of functional independence and only reported the results of a stepwise multiple logistic regression model (Barr et al., 1999). Thus there is strong evidence of an association between functional dependency and becoming a faller in the subacute setting, and this can be gauged with a variety of standardised assessment techniques. This association is consistent with findings from community based studies (Close, 2001; Covinsky et al., 2001; Graafmans et al., 1996; Tinetti et al., 1988).

### 1.4.3.7 Sensory impairment

Sensory impairment including hearing impairment, visual impairment and dizziness have been investigated in numerous studies. Visual impairment has only been found to have a significant association to becoming a faller in one study (Oliver et al., 1997).
Interestingly, the definition of visual impairment used in this study was “…visual impairment which seems to affect functioning on the ward.”. This functional impairment caveat was unique to this study and thus was theoretically only selecting a subset of the patients that would have been selected if only visual impairment was of interest. The risk of becoming a faller if visual impairment was present was reported as being 1.4 (Gluck et al., 1996; Nyberg et al., 1997) to 2.2 (Izumi et al., 2002) times higher compared to those with no impairment, but was not significant in studies that reported odds ratios. This is in contrast to community based studies where several have reported one or more aspects of visual impairment to be associated with falls (Close, 2001; Kamel et al., 2000; Tinetti et al., 1988). Dizziness (history of dizziness or vertigo, orthostatic hypotension, or syncope) was not significantly related to being a faller in one study (Rapport et al., 1993) and a subjective experience of vertigo or dizziness was higher amongst non-fallers (not significant) in another (Mion et al., 1989b). Available evidence suggests that visual impairments might have a weak association to becoming a faller in the subacute hospital setting whereas hearing impairment and dizziness do not appear to have any association. The association between falls and other aspects of sensory impairment, such as somatosensory impairment caused by peripheral neuropathy have not been investigated in the subacute setting.

1.4.3.8 Medications

A range of medications have been investigated as being potential falls risk factors (when taken on admission, routinely taken or preceding a fall), yet none have been consistently identified as having a significant association with patients who take them becoming a faller. Psychotropic medications affect the psychic functions, behaviour or experience of a person using them (Anderson, 1994), and include anti-depressants, sedatives, anti-psychotics, hypnotics, anti-convulsants and anti-Parkinsonian medications. This medication family has received the majority of attention in falls literature in the subacute setting. The strongest significant association between taking one of these medications and becoming a faller was a 2.5 times greater risk when taking hypnotics (Mayo et al., 1989), however another study found that only one third as many patients taking hypnotics became fallers compared to those who were not and this was a significant “protective factor” in that study (Mion et al., 1989b). A possible
contributor to this difference may have been that the former study considered those who had taken a hypnotic 24 hours prior to the fall, whereas the latter considered those who took medications routinely, however there is still likely to be considerable overlap. Taking anti-depressant medication was found to be a significant risk factor in one study (odds ratio = 2.1) when taken 24 hours prior to falling (Mayo et al., 1989), yet was found to be a significant protective factor in another when prescribed at the time of fall (Oliver et al., 1997). Overall three studies have found at least one class of psychotropic medication to be a significant (univariate) risk factor (Mayo et al., 1989; Mion et al., 1989b; Oliver et al., 1997), two have found one to be a significant (univariate) protective factor (ie. where taking this medication has been associated with a reduced risk of falling) (Mion et al., 1989b; Oliver et al., 1997), two have found at least one to be a significant risk factor in multivariate but not univariate analyses (Mayo et al., 1989; Nyberg et al., 1997) and one study found one class to be a protective factor and another a risk factor from a multivariate analysis (Barr et al., 1999). Thus, the taking of psychoactive medications does not yet have strong evidence supporting an association with becoming a faller in the sub-acute setting.

This picture does not sit in line with findings from other settings. One very large prospective cohort study (n = 7908) conducted across a number of predominantly acute settings (proportion of subacute patients < 20%) found that use of benzodiazepines (a sedative medication) with very short and short half-lives were significant risk factors for falls, adjusted odds ratios 1.9 and 1.8 respectively (Passaro et al., 2000). A meta-analysis of findings from community, hospital and residential care settings found psychotropic medications to be associated with an increased risk of falls (Leipzig et al., 1999). Further investigation is required to establish if psychotropic medications are related to falls in the subacute setting.

Medications affecting the cardiovascular system have also received some attention, but like psychotropic medications, there does not appear to be a consistently identified association. One study found taking anti-arrhythmics to be a significant risk factor (Oliver et al., 1997), however five others found no significant (univariate) association with any class of cardiovascular medication (Barr et al., 1999; Gluck et al., 1996; Mayo et al., 1989; Nyberg et al., 1997; Rapport et al., 1993). A similar picture is formed for polypharmacy (taking multiple medications). Taking three or more
medications was a significant risk factor in one study (Mayo et al., 1989), but taking seven or more was not a significant risk factor in the same study and taking six or more was protective (odds ratio = 0.33, non-significant) in another (Patrick et al., 2001).

1.4.3.9 Impaired continence

Elements of impaired continence such as frequency, urgency and nocturia have been found to be significant risk factors in six studies (Gluck et al., 1996; Mayo et al., 1989; Morse et al., 1987; Nyberg et al., 1997; Oliver et al., 1997; Rapport et al., 1993). In these studies, 1.7 (Gluck et al., 1996) and 8 (Mayo et al., 1989) times more patients have become fallers where cognitive impairment has been present. Of the two studies that did not find a significant association, one still indicated a strong trend towards impaired continence being a risk factor (odds ratio = 2.4) (Izumi et al., 2002) while the other only presented the results of a stepwise multiple logistic regression model. Thus impaired continence is likely to have a strong association to becoming a faller.

1.4.3.10 Behavioural difficulty

Some patient behaviours such as agitation and uncooperativeness have been found to be risk factors (Mion et al., 1989b; Oliver et al., 1997). However depression was found to be a protective (fewer falls) factor (non-significant) in two studies (odds ratios = 0.86 and 0.56) (Nyberg et al., 1997; Teasell et al., 2002) and a significant risk factor (more falls) in one (odds ratio = 1.75) (Mayo et al., 1990). One further study reported no significant association between all of the above and becoming a faller in a multivariate analysis (Barr et al., 1999). It is possible though that such a relationship would have been obscured through high correlation with the risk factor “confusion” which was included in the final model. This is because in a multivariate analysis where two factors are strongly associated with the each other and the outcome, one may be excluded (Abrams, 2003). Thus agitation and uncooperativeness may have an association with becoming a faller, whereas an association with depression is more unclear. This is in contrast to the community setting where depression has frequently been identified as a risk factor (Biderman et al., 2002; Close, 2001; Tinetti et al., 1988).
1.4.3.11 Admission diagnosis

An admission diagnosis of stroke has been found to be a risk factor in most studies where it has been investigated (Barr et al., 1999; DeVincenzo et al., 1987; Mayo et al., 1989; Patrick et al., 2001). It has been associated with a 2.7 (multivariate) (Barr et al., 1999) to 5.3 (univariate) (Mayo et al., 1989) times increased risk. A “neurological” admission diagnosis excluding stroke has also been associated with risk of falling by 7.4 times (Mayo et al., 1989), while another reported significantly more fallers had a neurological (including stroke) admission diagnosis (Grenier-Sennelier et al., 2002). An admission diagnosis of amputation has also been found to be a significant risk factor in one study (Barr et al., 1999). An admission diagnosis of arthritis was a significant protective factor in one study (Arbesman et al., 1999). Having multiple or secondary admission diagnoses have been found to significantly increase the risk of becoming a faller in three studies (Arbesman et al., 1999; Mayo et al., 1989; Morse et al., 1987), but not in three others with one finding it to be a (non-significant) protective factor (Barr et al., 1999; Gluck et al., 1996; Patrick et al., 2001). Thus, the primary admission diagnoses of stroke or other neurological diagnosis appears to be associated with becoming a faller. Having multiple or secondary admission diagnoses may also be weakly associated with increased risk.

1.4.3.12 Medical condition

Various aspects of a patient’s medical condition, both on admission and at the time of a fall, have been investigated. Postural hypotension was not found to be a risk factor. In two studies, it was found to be a (non-significant) protective factor (Mion et al., 1989b; Morse et al., 1989a). Other aspects of a patient’s medical condition have been found to be significant risk factors but only two individual studies, one that contained predominantly acute patients (Morse et al., 1987), the other only stroke patients (Nyberg et al., 1997). Thus it is unlikely that postural hypotension is related to becoming a faller and that other aspects of a patient’s medical condition as yet do not have a clearly demonstrated association primarily due to a lack of investigation in general sub-acute populations.

1.4.3.13 Miscellaneous factors
Other factors have also been investigated. Sleep disturbance was a significant risk factor in one study (Barr et al., 1999). Four studies have focused specifically on patients undergoing stroke rehabilitation, and have investigated several potential stroke specific risk factors that were not investigated in other studies (Mayo et al., 1990; Nyberg et al., 1997; Rapport et al., 1993; Teasell et al., 2002). Visuospatial hemineglect was a significant risk factor in only one of the four studies (Nyberg et al., 1997), dyspraxia was a significant risk factor in both studies that investigated it (Nyberg et al., 1997; Teasell et al., 2002), dysphasia was not significant in either (Nyberg et al., 1997; Teasell et al., 2002), while reduced reaction speed to left visual field stimuli and impulsivity were significant risk factors in the individual studies that investigated them (Mayo et al., 1990; Rapport et al., 1993). The site of the stroke lesion (left or right) was not significant in two studies (Mayo et al., 1990; Teasell et al., 2002), but bilateral stroke lesions were a significant risk factor in one (Nyberg et al., 1997). Thus it appears that some miscellaneous factors may be related to becoming a faller, although further investigation is required for many of them.

1.4.3.14 Intrinsic risk factors for fall events, early and recurrent fallers

This review has to this point focused on factors that increase or decrease the risk of a patient becoming a faller, however other investigations that focus on different types of outcome variable are present in the literature. Three studies have presented analyses of factors that predispose to fall events (Patrick et al., 2001; Rapport et al., 1993; Vlahov et al., 1990). One did not provide statistical analyses, while the other two used linear regressions that did not take into account exposure (length of stay) or the dependence of data when multiple falls per patient are analysed (the problem of data dependence is discussed in section 3.2.6). Despite this, a primary diagnosis of stroke was found to be a significant risk factor for falls in one study (Patrick et al., 2001), while impulsivity was significant in the other (Rapport et al., 1993).

“Early fallers” (those who fall within the first week of subacute hospitalisation) were more likely to have a past history of falls, less likely to have a lower limb fracture and be admitted from an orthopaedic ward than “later fallers” (those who fell for the first time after the first week of subacute hospitalisation) (Vassallo et al., 2003).
Recurrent fallers were not reported to be significantly more likely to have any intrinsic risk factors investigated than single fallers in the three studies that have made these comparisons (Gaebler, 1995; Tuffnell, 1990; Vlahov et al., 1990). However a trend was apparent for more single fallers to have been “clinically deteriorating” at the time of their fall than recurrent fallers (Gaebler, 1995). Given that first fall injury rates were found to be similar between recurrent fallers and single fallers (Gaebler, 1995), there appears to be little grounds for analysing these groups separately. However if investigation of causal factors for first falls finds them to be different to those of subsequent falls, or if preventative actions are different for first compared to subsequent falls, then this approach may still prove useful.

Overall, little information is available about risk factors for fall events, and no risk factors for being an “early faller” or a recurrent faller have been identified in more than one study.

1.4.4 Evidence of extrinsic risk factors

Extrinsic risk factors have been examined in several studies. Details of the design of these studies are summarised in table 1.1. Extrinsic risk factors investigated in these studies are presented in table 1.3. In comparison to analysis of intrinsic risk factors, statistical hypothesis testing has been much rarer and in some cases is very difficult to achieve logistically. Therefore it is difficult to determine the extent to which extrinsic risk factors are related to falls. Also in comparison to investigation of intrinsic factors, extrinsic factors are frequently related to the fall event rather than the individual.

1.4.4.1 Location

Fall locations or locations of patients prior to falls have been frequently investigated. When considered separately, a patient’s bedroom has been the location for falls on 61% (Nyberg et al., 1995) to 83% (Pullen et al., 1999), and their bathroom on 11% (Morris et al., 1980; Nyberg et al., 1995) to 21% (Vlahov et al., 1990) of occasions. When considered in combination, falls have occurred in the bedroom / bathroom on up to 97% of occasions (Foster et al., 1996). Clearly a greater proportion of falls
occur in the bedroom / bathroom, but it is still unclear if being in these locations predisposes patients to experience a higher rate of falls than other locations. To establish this, the proportion of time spent in these locations must serve as a denominator to the number of falls experienced there, however this information is difficult to obtain and has not yet been presented in a subacute hospital falls study. Similarly the location of patients prior to falling has been reported as being from bed on 25% (Teasell et al., 2002) to 59% (Foster et al., 1996) and from wheelchair on 10% (Foster et al., 1996) to 79% (Vlahov et al., 1990) (first falls only) of occasions. But again without an adjustment for the amount of time spent in these locations, it is difficult knowing if being in them increases the risk of falling.
Table 1.3. Extrinsic falls risk factors investigated in studies.

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† - Indicates risk factor investigated in this study.
1.4.4.2 Patient activity / compliance with recommendations

Patient activity at the time of a fall could be considered to be an intrinsic risk factor, however as these activities often involve hospital equipment such as wheelchairs or hospital beds, it is being discussed as an extrinsic risk factor. Attempting to use the toilet has been reported in approximately 30% of falls (Foster et al., 1996; Mion et al., 1989b; Rogers, 1994), and transferring, such as standing up from sitting, in between 21% and 63% of occasions (Cannard, 1996; Grant et al., 1987; Mion et al., 1989b; Morse et al., 1987; Nyberg et al., 1995). Possibly of greater importance than the activity itself is whether a hospital staff member was present to assist the patient at the time of the activity. Despite the presence of nursing, allied health and medical staff on subacute wards, between 61% and 98% of falls have been reported as being unwitnessed (Mion et al., 1989b; Morris et al., 1980; Morse et al., 1987; Nyberg et al., 1995; Pullen et al., 1999).

A factor related to this is whether the patient required assistance to perform their activity at the time of the fall. A balance between encouraging independent activity and restricting activities to only those that a patient can perform safely during subacute hospitalisation has previously been recognised (Morris et al., 1980; Oliver et al., 2000). Thus patients may be instructed by a staff member to ask for assistance with an activity until they have been assessed as being safe to perform it. Non-compliance with this recommendation results in a patient attempting to perform an activity that they have not been assessed as being safe to perform independently. As a risk factor for falls, this non-compliance has been found to be present in 58% and 71% of fall occasions in two studies that reported this (Nyberg et al., 1995; Rogers, 1994). All of the patients who fell in another were classified as “up with assistance only” (Foster et al., 1996) which when one considers the proportion of falls that are unwitnessed by staff in the subacute setting (although not specifically stated in this study) indicates that a large proportion of patients had not adequately followed instructions.

Many reasons have been hypothesised as contributing to patient non-compliance with safety advice. Unavailability of nursing staff due to alternate activities (Morse et al.,
nursing staff reprimanding patients for using the call buzzer (Morse et al., 1987), urinary urgency (Morse et al., 1987), patients overestimating their ability relative to the task they were undertaking (Morse et al., 1987; Turkoski et al., 1997), impaired patient cognition resulting in patients being unaware of how and when to use the call buzzer (Morse et al., 1987; Nyberg et al., 1995; Turkoski et al., 1997), hospital staff positioning the call buzzer out of sight or reach of the patient (Morse et al., 1987), a patient’s strong sense of independence (Turkoski et al., 1997), a desire to maintain a positive association with nursing staff (Turkoski et al., 1997) and staff response times that do not meet patient expectations (Turkoski et al., 1997) have been cited as possible contributing factors. Nursing staff not communicating instructions effectively to patients could also be a possible contributing factor. No studies have specifically compared these possibilities, however one study found that of the 83% of patients who fell after not asking for help, 59% reported that they believed that they could manage on their own (Mion et al., 1989b). Another study found that a significantly greater proportion of “non-compliant” fallers had cognitive impairment (Mini-Mental State Examination <24 / 30) than patients who fell but were compliant (Nyberg et al., 1995).

Although logically it follows that patients who do not comply with safety instructions are more likely to be unsafe and experience falls, it is difficult to measure this association. Researchers would have to be able to measure the total number of occasions that patients were compliant or non-compliant with the activities they attempted, and determine the relative frequency of falls with each. This would entail an extremely intensive observational research design, and not surprisingly this is yet to be reported.

1.4.4.3 Time of day / day of week

Peak times of patient falls have also been investigated, however no consistent pattern has emerged across studies. The times of 8 a.m. (DeVincenzo et al., 1987), 9 a.m. (Tuffnell, 1990), 5 p.m. (Nyberg et al., 1995) and 6 till 8 p.m. (Mion et al., 1989b) have all been found to be “peak” times. Some authors have reported several peak times within their own study (Grenier-Sennelier et al., 2002; Sweeting, 1994). The “morning” nursing shift (approximately 7 a.m. to 3 p.m.) has been found to have a
majority of falls in some studies (DeVincenzo et al., 1987; Foster et al., 1996; Nyberg et al., 1995), whereas the “evening” nursing shift (approximately 3 p.m. to 11 p.m.) was found to have most falls in others (Grant et al., 1987; Mion et al., 1989b). Fridays have been identified as peak days for falls in two studies (DeVincenzo et al., 1987; Grenier-Sennelier et al., 2002), but another found an even distribution of falls during the week (Nyberg et al., 1995). The peaks in both days and times have not been compared statistically. The only picture that seems to emerge is that falls happen less frequently overnight, with only 12% of falls in one study occurring between the hours of 8pm and 8am. One could argue that this is due to patients (generally) being asleep at this time and that it is not the (numerical) time of day that is related to falls but the amounts and types of activities undertaken at various times of day that are. In support of this, falls have previously been observed to occur more frequently during days and times of high ward activity (Rogers, 1994).

1.4.4.4 Length of hospitalisation

Length of subacute hospitalisation has been found to be significantly associated with becoming a faller (Grenier-Sennelier et al., 2002; Halfon et al., 2001; Mion et al., 1989b; Patrick et al., 2001). This is consistent with findings from mixed acute/subacute populations (Halfon et al., 2001; Passaro et al., 2000), but is not a surprising finding. Through simple probability, if two patients tend to experience one fall every ten days, and one patient has a two day stay while the other a 50 day stay, it is the latter patient who is more likely to become a faller during the hospitalisation. Another aspect of this association is that a patient fall might cause a setback in a patient’s rehabilitation, delaying their discharge.

1.4.4.5 Time since hospitalisation

The time period since commencement of sub-acute care has been investigated as a risk factor for falls. Most studies have reported that in terms of the raw frequency of falls, the first and second weeks have the greatest number which then descends in a linear fashion over subsequent weeks, making this a time of particular importance for falls prevention during a patients stay (DeVincenzo et al., 1987; Mion et al., 1989b; Morse et al., 1987; Rogers, 1994; Vassallo et al., 2003). Some have hypothesised that this is due in part to patient unfamiliarity with the hospital environment (Morse et al.,
1.4.4.6 Environmental hazards

Environmental hazards have infrequently been investigated in subacute hospital studies, despite being widely accepted as a possible contributor to patient falls (Campbell et al., 1995; Masud et al., 2001). One study reported that fallers were not wearing their glasses on 43% of fall occasions, 20% wore poor footwear, 18% had insufficient lighting and 8% tripped on environmental obstacles (Mion et al., 1989b). Another found that an environmental factor was the primary precipitant to a fall in only 11% of falls (Nyberg et al., 1995).

1.4.4.7 Restraint

Some research has focused on the use or non-use of restraints and their association with falls from an epidemiological perspective. However this subject is better discussed in terms of it being a falls prevention intervention in Part B of this chapter rather than as an epidemiological factor in Part A.

1.4.4.8 Flooring
Flooring types have seldom been examined in exploratory studies. One study randomly selected 213 accident forms from a care of the elderly unit that had taken place in the preceding four years (Healey, 1994). Only 27 of these falls occurred on carpet compared to 186 on vinyl. The authors of this study rightly acknowledged though that as they did not observe the relative amounts of time that patients spent on each of these surfaces, they could not comment on whether one type of flooring was more likely to contribute to falls than the other.
1.5 Fall-related injury

As mentioned in the introduction to this chapter, falls may have many serious consequences of which physical injury is one. This section discusses fall-related injuries and their associated risk factors in the subacute setting.

1.5.1 Classifications of fall-related injury

In attempting to quantify fall-related injury, no classification system has been universally applied between studies. Some studies have simply considered falls with some form of injury or “injurious falls” separately from “non-injurious” falls. A definition of what constituted an injurious fall was not described in some studies (Coker et al., 2003; Foster et al., 1996; Oliver et al., 2002) but clearly described in others (Healey, 1994; Rogers, 1994). The clear definition in one was:

“For the purpose of this study injury was defined as any graze, bruise, laceration or fracture, and also any fall that resulted in the patient complaining of pain, even if there was no visible lesion” (Healey, 1994).

Other studies have described the number of injurious falls and then listed the types of injuries incurred (Gaebler, 1995; Morris et al., 1980; Morse et al., 1985; Nurmi et al., 2002; Teasell et al., 2002). Although this approach does inform readers of what injuries occurred and were included in their definition, it does not describe any potential injuries that were excluded. Some studies only described the number of fractures that occurred (Grenier-Sennelier et al., 2002; Sweeting, 1994; Vassallo et al., 2003).

Another approach has been to divide falls into particular levels of physical injury such as no injury, minor injury and serious or major injury. Fractures have been described as major or serious injuries in most studies using this system (Grant et al., 1987; Hanger et al., 1999; Mion et al., 1989b; Nyberg et al., 1995; Tuffnell, 1990). Joint damage (Tuffnell, 1990), joint dislocations (Hanger et al., 1999), head injuries requiring neurological observations (Hanger et al., 1999), lacerations that require suturing, skin grafts or plastic surgery (Hanger et al., 1999; Nyberg et al., 1995), hip pain limiting mobilisation (Hanger et al., 1999) and death (Nyberg et al., 1995) have
also been included in major injury definitions. Minor injuries have been described as lacerations that do not require suturing (Hanger et al., 1999; Nyberg et al., 1995), lacerations (Cannard, 1996), bruises (Cannard, 1996; Grant et al., 1987; Hanger et al., 1999; Nyberg et al., 1995; Rapport et al., 1993), soft tissue injury (Cannard, 1996), head injury (Cannard, 1996), soreness or tenderness (Nyberg et al., 1995; Rapport et al., 1993), minor abrasions (Rapport et al., 1993) and scrapes (Grant et al., 1987). Minor injuries were not defined in three studies (Mion et al., 1989b; Morse et al., 1989a; Vlahov et al., 1990) and major injuries were not defined in one (Morse et al., 1989a).

1.5.2 Recording fall-related injury

Even when studies list particular types of injuries that occurred, few have defined what severity of injury was necessary to act as a recording threshold. For example, bruising was classified as a minor injury in several studies, however none described how much bruising was needed for this injury to be recorded. The inter-rater reliability of hospital staff in recording bruising was not stated in any of these studies, nor any attempts to standardise the recording of fall-related injury. Without clear definitions of each injury included under the injurious falls definition, it remains unclear whether inter-study variation in reported rates of injurious falls is due to true variation or variation due to different injury recording thresholds between studies. It is likely though that this is more of a problem for minor injuries than for some major injuries such as fracture where a diagnosis is made following radiological investigation.

Seldom have publications included a description of who assessed patients for fall related injuries. Nursing staff were responsible for recording fall-related injury in some studies (Healey, 1994; Morris et al., 1980; Teasell et al., 2002). It is also possible though that medical staff have been involved in recording fall-related injury. Two authors have suggested that recording of fall-related injuries is more reliable than that of falls overall (Morse, 1993; Uden et al., 1999), however some evidence suggests that the reporting of fall-related injuries can be just as incomplete as reporting of falls in general can be incomplete (Sutton et al., 1994b).
1.5.3 Statistical considerations – units of analysis and describing rates

Many studies have reported data on injuries resulting from falls (Gaebler, 1995; Hanger et al., 1999; Oliver et al., 2002; Vassallo et al., 2003; Vlahov et al., 1990), falls in which the patient was injured (Cannard, 1996; Foster et al., 1996; Grant et al., 1987; Mion et al., 1989b; Morris et al., 1980; Nyberg et al., 1995; Rapport et al., 1993; Rogers, 1994; Teasell et al., 2002), both injuries and falls leading to injuries (Morse et al., 1989a; Nurmi et al., 2002) and patients who experienced an injury due to falls (Coker et al., 2003; Gaebler, 1995; Healey, 1994; Nyberg et al., 1995; Sweeting, 1994; Tuffnell, 1990). When comparing fall-related injury rates one could assume that these studies are essentially reporting the same data and have just used different terminology to describe it. This would indeed be the case if only one injury was incurred per fall and each patient only incurred one injury. However in reality, a patient who falls and breaks their neck of femur, is also likely to have bruising and possibly a laceration. If a researcher was truly counting “injuries”, then this fall would have contributed three injuries, whereas a researcher counting falls in which injury occurred would only have counted one fall. Similarly one patient may experience two separate falls and sustain one injury in each. A researcher counting injuries would have counted two injuries, but a researcher counting patients who experienced an injury due to falls would have counted only one patient. Thus it is clear that reported fall-related injury rates vary depending on whether the researcher counted injuries, falls in which the patient was injured or patients who experienced an injury due to falls.

In the same way that the raw number of falls should be converted into a rate for comparison between studies (Morse et al., 1988), comparing fall-related injuries also requires that raw numbers be converted into rates. When counting the number of patients who incurred fall-related injury, using the total number of patients as the denominator produces a proportion of all patients who experienced fall-related injury. When counting the number of falls that caused injury, using the total number of falls the denominator produces the proportion of all falls in which the patient incurred injury. This has been presented in several studies (Cannard, 1996; Foster et al., 1996;
Mion et al., 1989b; Morse et al., 1989a; Morse et al., 1985; Nyberg et al., 1995; Rapport et al., 1993; Teasell et al., 2002). Only one study has clearly indicated that in describing fall-related injury, they have counted multiple injuries per fall where this was the case (Nurmi et al., 2002). In adjusting this data, the authors used the amount of patient observed time as the denominator producing an injury event rate.

### 1.5.4 Rates of fall related injury

The proportion of falls in which the patient incurred an injury has been reported to range between 14% (Vlahov et al., 1990) and 81% (Healey, 1994). Interestingly the former study contained a broad definition of what injuries were and included complaints of pain in this definition, whereas the latter divided injuries into minor and “other” but did not provide any description of what a minor or other injury was. This highlights the strong possibility that a proportion of variation in reported injury rates could be attributable to different definitions employed to describe fall-related injury. Although the range in reported injury rates is wide, the majority of studies have reported that a patient incurs an injury in between 20% and 30% of falls (Cannard, 1996; Morris et al., 1980; Morse et al., 1989a; Nurmi et al., 2002; Nyberg et al., 1995; Oliver et al., 2002; Rapport et al., 1993; Teasell et al., 2002; Vassallo et al., 2003).

In terms of specific types of injury, fractures have been reported to occur in between 10% (Grenier-Sennelier et al., 2002) and less than 1% of falls (Cannard, 1996; Grant et al., 1987; Mion et al., 1989b; Teasell et al., 2002). Fractured neck of femur injuries have been reported in up to 1.4% of falls (Nurmi et al., 2002). Head injuries have been reported in between 3% (Cannard, 1996) and 19% (Nurmi et al., 2002) of falls. Soft tissue injuries have been reported in between 6.5% (Cannard, 1996) and 23% (Morris et al., 1980) of falls. Skin injuries were reported in up to 41% of falls (Tuffnell, 1990).

When expressed in terms of an injury event rate, one study reported 533 injuries overall per 1000 patient years, 20 hip fractures per 1000 patient years and 270 head injuries per 1000 patient years (Nurmi et al., 2002).
1.5.5 Evidence of risk factors for fall-related injury

A small amount of evidence has been gathered to describe associations between potential intrinsic and extrinsic risk factors and injurious falls. Finding statistical significance in these associations has proven to be more difficult than when examining the association between falls and their risk factors because of the lower frequency of fall-related injury (Vlahov et al., 1990). Statistically, this means that a risk factor will require a larger effect size of association with fall-related injury than with falls in order to attain the same p value for a given sample size.

Only one study has reported conducting statistical evaluation of an association between fall-related injury and potential risk factors (Healey, 1994). This study found that patients who fell on carpet were significantly less likely to be injured than those who fell on vinyl. From data presented in this study, an overall odds ratio effect size can be approximately calculated as being 6.1. However, these results need to be considered with caution, for while the reported injury rate on carpeted surfaces (15%) approximated those recorded in many other studies, the injury rate on vinyl surfaces (91%) was 57 percentage points higher than the next highest recorded rate of injurious falls in the subacute setting, being 34% (Coker et al., 2003). This extraordinarily high percentage of injurious falls does appear to be quite out of place with those rates recorded from other subacute settings some of which presumably may also have used vinyl flooring.

Other studies have only been able to identify trends in associations between fall-related injuries and risk factors. Male patients incurred twice as many head injuries and 1.5 times more fall-related injuries overall when adjusted for exposure time in one study (Nurmi et al., 2002). However males also had a 1.6 times higher event rate of falls indicating that the risk of incurring an injury “per fall” was closer to being equal between the genders. Similarly, recurrent fallers have been found to be more likely to incur fall-related injuries than single fallers (Gaebler, 1995; Tuffnell, 1990), yet their injury per “first fall” rates were also found to be similar (Gaebler, 1995). Fractures have been found to only occur in recurrent fallers in one study (Gaebler, 1995), and “late” fallers (those whose first fall is after the first week of hospitalisation) in another (Vassallo et al., 2003). Weak trends for higher incidence of injury per fall have also
been noted in falls that are “anticipated physiological falls” (Morse et al., 1989a), amongst patients who are wheelchair or bed bound, amongst those who are disoriented, and in falls that occur outside the bedroom and bathroom (Vlahov et al., 1990).

Possibly, the only factor that appears to be associated with fall-related injury are falls themselves in that the risk of becoming a patient who experiences a fall-related injury during a subacute hospitalisation increases with recurrences of falls (Gaebler, 1995; Tuffnell, 1990). This association is not surprising as through simple probability if the risk of sustaining a fall-related injury for each individual patient remains constant throughout a hospitalisation, then each patient is more likely to experience an injury if they have multiple falls than if they only had one. One study did report though that the risk of incurring an injury “per fall” reduced gradually with subsequent falls (Gaebler, 1995). The association between surface and injury was significant however due to the inconsistencies in injury rate recording between the study that examined this (Healey, 1994) and others, further investigation is required before conclusive statements can be made.

In the absence of other direct evidence examining potential risk factors for fall-related injury in the subacute setting, it may be reasonable for clinicians at present to rely on indirect evidence from other settings. For example, increasing age and the female gender are associated with an increased risk of osteoporosis which itself is associated with an increased risk of fracture (Cumming et al., 1985; Melton et al., 1987). It is possible that this association may hold in the subacute setting even though we currently have no direct evidence of this.
1.6 Other negative outcomes from falls

Purely physical descriptions of injurious falls neglect other potential consequences of falls that may be of harm to a patient. There are also other negative consequences that flow from falls for subacute health care providers and patient’s family members and carers.

1.6.1 Other negative outcomes for patients

A non-physical consequence of falls for patients may be the development of fear of falling. Fear of falling has previously been defined as “low perceived self-efficacy at avoiding falls during essential, non-hazardous activities of daily living” (Tinetti et al., 1990). Fear of falling may result in a self-imposed decline in activity and function not necessitated by physical disabilities or injury, which may in turn lead to deconditioning, reduced strength and balance, predisposing to further falls (Kellogg International Working Group, 1987). In the subacute care context, authors have contended that curtailment of activity due to fear of falling translates to patients becoming more dependent on staff and running the risk of complications of inactivity which can be life-threatening (Cannard, 1996). Reduced patient confidence has also anecdotally led to delays in hospital staff allowing patients to return home, increasing the patients length of hospitalisation (Teasell et al., 2002).

In terms of direct evidence from the subacute setting that falls may lead to a fear of falling, no studies have yet reported investigating this association. However there is much indirect evidence from other settings from which it would be reasonable to expect that there is an association between falls and fear of falling in the subacute setting (Friedman et al., 2002; Liddle et al., 1995). However, some evidence suggests that fear of falling present at the start of a hospitalisation does not affect rehabilitation outcomes (Liddle et al., 1995).

It is plausible that other patient outcomes may also be affected by falls. It has been suggested that falling may prevent patients from realising their full rehabilitation potential (Teasell et al., 2002). As discussed previously, fallers have been found to require longer lengths of stay in hospital. An increased dependency on nursing staff has been observed by 31% of recurrent fallers after falls (Tuffnell, 1990). Fallers
have been found to be more likely to be discharged to a nursing home (Grenier-Sennelier et al., 2002) and recurrent fallers 2.5 times more likely than single fallers to be discharged to a nursing home (Gaebler, 1995). These consequences of falls are likely to have a negative impact on a patient’s quality of life. Questions over causal associations remain however over most of these outcomes. For example, it may not be that falling increases the risk of being discharged to a nursing home, rather that patient characteristics that predispose patients to being discharged to nursing home are similar to those that increase the risk of falling, leading to their statistical association. The practical implication of this alternative is that even if staff were able to prevent such patients from falling, this would not change their discharge destination.

### 1.6.2 Negative outcomes for subacute health care providers

The cost of patient falls to subacute health care providers is in some respects difficult to quantify. Two studies in the subacute setting have attempted to measure the financial burden of falls. An average cost of 944 Euro ($US 850 at time of study) per injurious fall was calculated in one recent study that focused on patients in acute, subacute and nursing home care (Nurmi et al., 2002). The factors taken into account when making this calculation were the number of emergency room visits, outpatient visits, inpatient days in regional hospitals and health centres, surgical costs, costs for conservative treatment, treatment in hospitals and health centres, radiological investigations and transportation. Interestingly in this study, 70% of total fall costs were attributable to the management of hip fractures, highlighting that although the incidence of this injury may be low, their severity, at least in financial terms, is high.

In comparison to the factors included by the above study for consideration when calculating fall costs, a second study detailed the costs of six injurious falls and included time spent by nursing, medical and “portering” staff in the calculations (Sweeting, 1994). Another possible source of increased costs for subacute care providers is a fall-induced increase in length of stay. As discussed earlier, the causal association between length of stay and falls is unclear, and thus one can question whether it should be included as a fall-related cost. Length of stay is of high importance though in considering the costs of hospitalisation overall as these figures
can be incorporated into funding systems for subacute hospitals (Webster, 1996). Length of hospitalisation was included in an investigation of resource utilization in the acute setting (Bates et al., 1995). Patients who fell with serious injury were cases in this study and controls were selected and matched for age, gender and length of stay up to time of case fall. By matching controls to cases in this way there was some small adjustment for the length of stay that may have occurred without the fall. Cases in this study were found to have a 12.3 day longer length of stay and $US 4,233 more in total charges. Subsequent authors converted this figure to a cost of $US 351 per fall, while making the assumption that non-injurious falls incurred no cost (Boswell et al., 2001). One could question whether this was a reasonable assumption as it is possible that even non-injurious falls may reduce a patient’s confidence, delay their rehabilitation and increase their length of hospitalisation. It may have been preferable though for this study or an equivalent one in the subacute setting to match cases and controls on admission “estimated length of stay” calculations or other factors strongly related to length of stay, if length of stay was to be included in the cost calculations.

Potential costs of falls not included in cost calculations in the above articles (Bates et al., 1995; Nurmi et al., 2002; Sweeting, 1994) were legal costs. Patients who fall may feel that the hospital was negligent in their duty of care and claim compensation for the injuries and suffering incurred (Bates et al., 1995). Subsequent to this hospitals may incur higher insurance premiums (Raz et al., 1987). Trying to incorporate these data into a costing calculation for falls is likely to be impractical for researchers, but again, this is a factor that cannot be ignored.

1.6.3 Negative outcomes for family members and carers

There are also many potential negative consequences of falls for family members and carers. If it is true that falls can interfere with patients realising their full rehabilitation potential, then there would be serious consequences for the family members and carers of the patient. A patient who can perform more of their activities of daily living independently will require less support and be less of a burden on their family and carers. Family members may also have greater fear and anxiety of future falls for the patient (Liddle et al., 1995). However, to date there has been little
investigation of the effect of falls in the subacute setting on patients’ family members and carers.

Given the relatively small amount of investigation that all these “other negative fall outcomes” have received, further investigation is warranted to establish the nature of their association to falls in the subacute setting.
1.7 Summary: Epidemiology and outcomes of falls amongst patients in subacute care

Falls are clearly a problem for subacute hospital patients, their family members and carers, hospital staff and administrators. Fall event rates are higher among patients in subacute hospitals than those in acute hospitals and community dwelling people over the age of 65 years. These falls lead to considerable morbidity through physical injury and psychological consequences, and are associated with increased financial costs of hospitalisation.

Factors associated with patients becoming fallers during their subacute hospitalisation have been widely investigated. Present evidence indicates that several intrinsic risk factors including gender (males at higher risk), previous history of falls, cognitive impairment, physical impairment, functional dependency, incontinence, and admission diagnosis of stroke or other neurological impairment are related to patients becoming fallers. Evidence supporting extrinsic risk factors is less clear, however increased length of hospital stay and behaviour that does not comply with hospital staff recommendations do appear to increase the likelihood that patients will become fallers. Identification of risk factors for patients becoming multiple fallers, fall events and fall related injuries has received less attention with no risk factors consistently being identified for these outcomes. Efforts to consistently identify risk factors for fall outcomes in the subacute setting have been retarded by differing definitions of falls and fall related injuries, and varying procedures for assessing the same risk factor. Yet despite this, a profile of factors associated with patients becoming fallers during their subacute hospitalisation has emerged.
Part B: Falls prevention interventions in the subacute setting
1.8 Introduction

Numerous studies have investigated the effectiveness of falls prevention interventions in the subacute setting. These studies have varied in terms of the number of interventions investigated, the types of interventions employed, the study designs used to investigate them and the outcome measures used to gauge their success. As this thesis is concerned with the prevention of falls and fall-related injury, studies that included at least one of falls, fallers or fall-related injury as an outcome measure were included for discussion to describe the effectiveness of previously described falls prevention interventions in the subacute setting.

Studies that included only “surrogate” outcome measures for falls without inclusion of falls, fallers or fall-related injury were not focused upon in terms of falls prevention effectiveness. An example of use of a surrogate measure instead of falls to gauge falls risk has been use of the Berg Balance Scale (Berg et al., 1995) among other measures to gauge a reduction in falls risk attributable to an exercise program (Shumway-Cook et al., 1997). Some discussion of the proposed method of action of interventions discussed in this chapter has been included from which some information has been drawn from secondary or surrogate outcome measures. However, an improvement in surrogate measures does not provide direct evidence of the effectiveness of the intervention on the outcome of interest (Gotzsche et al., 1996).

For the many falls prevention programs that have been described in the hospital population, it has been previously identified that the first step in a majority of these programs is the “falls risk assessment” (Oliver et al., 2000; Perell et al., 2001; Whedon et al., 1989). Two categories of falls risk assessment tool have been described (Morse, 1993). The first are tools that aim to identify a patient’s probability or risk of falling, which in this thesis are referred to as “falls risk screening tools”. They tend to be quick to administer, easy to use, and may reflect changes in a patient’s condition through repeated application (Morse, 1993). The second type are referred to as “falls risk factor assessment tools” in this thesis. These tools assist staff in identifying patient characteristics that increase falls risk and are often linked to interventions that address the risk factors identified. The contributions of falls risk screening and risk factor assessment tools to preventing falls have been evaluated
differently than other falls prevention interventions. Thus the following discussion will examine falls risk screening tools, falls risk factor assessment tools, and then progress to other falls prevention interventions that may have been implemented in isolation or as a part of a larger falls prevention program.
1.9 Falls risk screening tools

Tools discussed in this section are those that contain a specific mechanism for discriminating different patients’ “falls risk”, have either been designed for or validated using patients in the subacute care setting, and are those referred to as falls risk screening tools in this thesis.

1.9.1 Definition: Falls risk

In attempting to measure falls risk, researchers must first determine what they view “falls risk” as being. Falls risk has previously been described as a patient’s probability of falling (Morse, 1993). This definition though, does not adequately encompass all potential aspects of “falls risk” that may be of interest. For example, a more specific definition of falls risk may be; the probability of a patient experiencing one or more falls during their subacute hospitalisation. This could more accurately be described as the risk of becoming a faller. When using a “survival analysis” approach to handling falls data, falls risk could be defined as the instantaneous rate of experiencing falls, which could also be referred to as a “falls hazard” (Cleves et al., 2002). Alternately one could describe falls risk in terms of the risk of incurring a particular type of injury, or experiencing a particular type of fall. Although one could reasonably argue that these concepts are closely related, the strength of an association between a factor and a patient becoming a faller or experiencing fall events may be different. Thus it can also be argued that these concepts may be sufficiently different to require specific description. One could also argue that fall-related injuries are of greater importance than falls themselves, thus a fall-related injury risk could also be the focus of a screening tool. Choosing to focus a falls risk screening tool specifically on either falls, fallers or fall-related injuries may lead to compromises that limit the effectiveness of the tool in predicting the remaining two.

In this thesis, the term “falls risk” will be used as a generic term to refer to a patient’s probability of experiencing falls. Where a particular study refers to the probability of a patient becoming a faller, this will be mentioned specifically. Where a particular study refers to a patient’s probability of incurring fall-related injury, this will also be mentioned specifically.
1.9.2 Structure of falls risk screening tools

Falls risk screening is essentially an attempt to measure a particular aspect of “falls risk”. Measurement has been defined as “the process of assigning numerals to variables to represent quantities of characteristics according to certain rules” (Nunally, 1978). The measurement scales chosen to describe falls risk have most commonly been ordinal, although some could argue that many have interval measurement scale properties (Portney et al., 2000). The simplest scales employ only two (high vs low risk) or three (high vs medium vs low risk) categories. Others give patients a “falls risk score”, between zero and 125 in one tool (Morse et al., 1989a).

No matter how many categories falls risk screening tools divide “falls risk” into, the “clinical” question these tools are being used to answer is whether a particular falls prevention intervention should be deployed or not (Perell et al., 2001). Therefore, from the patient’s perspective, the exact score they received on the falls risk scale is of lesser importance than whether they were provided with the falls prevention intervention or not. Frequently falls risk scales with a large range of possible scores often merge score ranges into categories to be left with only two or three from which clinical decisions are made (Cannard, 1996; Donald et al., 2000; Morse et al., 1989b; Nyberg et al., 1996; Oliver et al., 1997; Sweeting, 1994). The borders at which categories are merged together are often referred to as “cut-off” points. For example, the STRATIFY falls risk screening tool measures falls risk using a zero to five scale, but then uses a cut-off threshold of two or more out of five to describe those at “high” risk (Oliver et al., 1997).

A consistent feature of falls risk screening tools is that they have been applied on a patient’s admission to subacute care. Less consistently described have been their review processes. Falls risk screening tools have been applied only on admission in a majority of cases (Aditya et al., 2003; Coker et al., 2003; Eagle et al., 1999; Izumi et al., 2002; Nyberg et al., 1996; Oliver et al., 2002; Rapport et al., 1993), but also on an eight hourly (Brady et al., 1993), daily (Cohen et al., 1991; Morse et al., 1989a) or weekly (Moore et al., 1996; Oliver et al., 1997) basis in others. Reapplication of falls risk screening tools is thought to make them sensitive to changes in the patient’s condition (Morse, 1993).
1.9.3 Construction of falls risk screening tools

An approach common to the construction of many falls risk screening tools has been to select a number of factors associated with falls which are then assigned various weights to reflect their relative strength of association with falls, producing a “mathematical” model. Designing a tool to include the factors that are important to the construct being measured, while ignoring those that are not, provides the tool with content validity (Portney et al., 2000). However there has been little consistency in the selection or omission of factors in published tools, or in the weightings ascribed to them. This is not surprising given the inconsistency with which various factors have been found to be significant falls risk factors, and the different methods used to construct risk factor lists and ascribe weightings.

One approach for the selection of factors and ascribing of weights for “mathematical” models has been to rely on expert opinion. Three scales have been constructed by authors, usually following a review of relevant falls literature (Donald et al., 2000; Izumi et al., 2002; Rapport et al., 1993). Another approach has been to select factors based on analysis of local data (Gaebler, 1995; Gluck et al., 1996; Halfon et al., 2001; Morse et al., 1989b; Nyberg et al., 1996; Oliver et al., 1997; Sweeting, 1994), however the analysis approach chosen has varied. Factors and weightings have been selected based on univariate analyses (Gluck et al., 1996), multivariate analyses (Gaebler, 1995; Nyberg et al., 1997) and unspecified analyses (Sweeting, 1994). Multivariate analyses may be preferable here as they can adjust for interassociations between selected factors (Portney et al., 2000). Weightings suggested by statistical analyses have also been ignored in one instance in order to make falls risk scoring easier for nurses (Oliver et al., 1997). A variance on this approach has been to describe falls risk profiles into which staff attempt to place their patients (Patrick et al., 1999) or to list numerous falls risk factors and state that patients with any one or two are at high risk (Brady et al., 1993; Foster et al., 1996; Tuffnell, 1990). This latter approach is the same as assigning a weight of one point to each factor and selecting a cut-off point for high risk at one or two.
An alternative to this approach has been to rely on the clinical judgement of hospital staff in measuring falls risk. Nursing staff have previously been asked to classify patients’ risk of falling today as being at high, medium or low risk (Moore et al., 1996), as being fallers or non-fallers (Izumi et al., 2002), if they were likely to have a fall in the near future (Eagle et al., 1999) and in the acute setting have been asked to grade a patient’s falls risk on a scale from zero to ten (Price et al., 1999). A possible advantage of this approach is that the number of possible risk factors that can be taken into account is only limited by the awareness of these factors by hospital staff. Staff can also weigh up the potential importance of each risk factor to each patient, for example, although two patients may both have gait instability, one may be significantly more impaired than the other. A reciprocal potential disadvantage is that staff who have poor awareness of risk factors or insight into how they can contribute to patient falls will be very limited in their clinical decision making processes.

Figure 1.1 conceptualises the structural similarities and differences between “mathematical model”, “staff clinical judgement” and “patient profile” falls risk screening tools and falls risk factor assessment tools.

A hybrid approach of both the “clinical judgement” and “mathematical” models has been described (Foster et al., 1996). In this tool a checklist of falls risk factors was produced for nursing staff, but the final decision as to whether the patient was at risk rested with the clinical judgement of nursing staff. This was tempered however by a printed guideline on the tool that if a patient had any two categories of risk factor, then they should be classified as high falls risk. Another hybrid approach included nurse clinical judgement in a “mathematical” model, weighting it with one point out of a total of eight points (Izumi et al., 2002). These approaches are still best described as “mathematical” models however as the final decision as to whether the patient is classified as high or low falls risk appears to rest with the mathematical models outcome more-so than the hospital staff member’s clinical judgement.
Figure 1.1. Structural similarities and differences between “mathematical”, “patient profile” and “staff clinical judgement” falls risk screening tool models, and falls risk factor assessment tools.
1.9.4 Content of falls risk screening tools

Table 1.4 demonstrates the risk factors included in published falls risk screening tools intended for patients in the subacute setting. As can be seen from this table, the content and number of items selected for inclusion in these tools varies widely. Some factors with good evidence supporting their association to becoming a faller were included near routinely. Other factors with good to moderate evidence were less consistently included. Further still some with very little or conflicting evidence were near routinely included.

Aspects of cognitive, physical, mobility and continence impairment were included in most tools. This appears to be quite reasonable, for, as discussed earlier, there is good evidence that indicates these factors are associated with patients becoming fallers. Interestingly though most tools rely on unstandardised approaches to collect this data. For example, only one study relied on Mini-Mental State Examination scores (Folstein et al., 1975), in preference to using a nurses clinical judgement of cognitive impairment, disorientation or confusion. Medical conditions were also included in many tools. Neurological conditions (such as stroke or Parkinson’s disease) predominantly were the focus of this factor, reflecting well the evidence supporting the association between them and becoming a faller. However other medical conditions with lesser evidence were also given attention.

Behavioural problems, age and gender were less frequently included in tools. Behavioural problems identified included agitation, unwillingness to call for help, overestimation of abilities and uncooperativeness. Each of these problems can potentially impede the compliance of patients with staff mobility instructions, which as previously discussed may be a factor in a high proportion of falls. Age was included in four tools, but in only one was it given non-proportional weighting to provide a curvilinear association to falls risk with a peak risk in the 71 – 80 year old age group (Cannard, 1996). As discussed previously this type of association may more accurately reflect that between age and becoming a faller in subacute care. Gender was also infrequently included despite evidence supporting a moderately increased risk for male patients. A history of falls was also included in many tools,
but in similarity to epidemiological studies, there was little consensus in regards to the time frame of this history.

Despite several screening tools being designed to screen patients’ risk of falling, there appears little consensus as to which factors should be included in a falls risk screening tool and how heavily they should be weighted. From a theoretical perspective, one could presume that only those factors consistently identified as being falls risk factors in epidemiological studies from the subacute setting should be included. However due to methodological imperfections and inconsistencies within that body of research, one could also argue that risk factors consistently identified across a variety of settings should be included. This may have been the reasoning behind the inclusion of sensory impairments and medications in several tools. These factors did not have strong evidence of association with becoming a faller during subacute hospitalisation (section 1.4), yet have frequently been identified as risk factors in other settings.

There are other possible reasons for the discrepancies between the lists of factors included in tools and the amount of evidence supporting their inclusion from the subacute setting. First, some tools were not solely designed for use in the subacute setting, and authors may have taken into account literature or data from other settings when designing the tool (Izumi et al., 2002). Second some tools may have been constructed from local data only, and include items that are specific to that hospital. For example, the STRATIFY (Oliver et al., 1997), included a visual impairment item in their tool. An epidemiological investigation at their hospital was the only study to demonstrate a significant association between visual impairment and falls. Thus for their hospital population, this inclusion could be justified at the expense of reduced applicability to other settings.
<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Tool name, author, year, study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive impairment</td>
<td>Local, Brady et al, 1993, 1</td>
</tr>
<tr>
<td>Confusion</td>
<td>FRASE, Cannard, 1996, 2</td>
</tr>
<tr>
<td>Disorientation</td>
<td>Local, Cohen et al, 1991, 3</td>
</tr>
<tr>
<td>Poor memory</td>
<td>ACCIDENTS, Donald et al, 2000, 4</td>
</tr>
<tr>
<td>Physical impairment</td>
<td>Local, Foster et al, 1996, 6</td>
</tr>
<tr>
<td>Poor endurance</td>
<td>Functional Reach, Eagle et al, 1999, 5</td>
</tr>
<tr>
<td>Poor strength</td>
<td>Local, Gaebler, 1993, 7</td>
</tr>
<tr>
<td>Hemiplegia</td>
<td>Local, Gluck et al, 1996, 8</td>
</tr>
<tr>
<td>Poor balance</td>
<td>Local, Izumi et al, 2002, 10</td>
</tr>
<tr>
<td>Mobility impairment</td>
<td>Heslin, Moore et al, 1996, 11</td>
</tr>
<tr>
<td>Gait impairment</td>
<td>Morse Fall Scale, Morse et al, 1989, 12</td>
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<tr>
<td>Transfers impairment</td>
<td>Downon Index, Nyberg et al, 1997, 13</td>
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<tr>
<td>Requires gait aid</td>
<td>STRATIFY, Oliver et al, 1993, 15</td>
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<tr>
<td>Functional impairment</td>
<td>FAQ, Rapport et al, 1994, 16</td>
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<tr>
<td>Continence impairment</td>
<td>Harrogate, Sweeting, 1990, 17</td>
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<tr>
<td>Frequency</td>
<td>Barbieri, Tuffnell, 1990, 17</td>
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<tr>
<td>Urgency</td>
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</tr>
<tr>
<td>Nocturia</td>
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<tr>
<td>Postural hypotension</td>
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</tr>
<tr>
<td>Restraint</td>
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</table>

Each study has been numbered to allow identification on other sections of this table on subsequent pages.
Table 1.4b. Falls risk factors included in previously described falls risk screening tools (continued).

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<td></td>
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<tr>
<td>Sensory impairment</td>
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<tr>
<td>Vision</td>
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<td>Hearing</td>
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<tr>
<td>Dizziness</td>
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<td>Visuospatial neglect</td>
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<td>Gender</td>
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<tr>
<td>Age</td>
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<tr>
<td>Falls history</td>
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<td>Since hospitalisation</td>
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<tr>
<td>Medications</td>
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</tr>
<tr>
<td>Cardiovascular</td>
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</tr>
<tr>
<td>Diuretics</td>
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<tr>
<td>Laxatives</td>
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<td>Recent surgery</td>
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<td>Foot abnormality</td>
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Table 1.4c. Falls risk factors included in previously described falls risk screening tools (continued).

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<tr>
<td>Uncooperative</td>
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<tr>
<td>Overestimates or forgets limitations</td>
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<tr>
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<td></td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Morbidity predisposition</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<td>✓</td>
</tr>
</tbody>
</table>

✓ - Indicates that risk factor was included in the falls risk screening tool indicated.
1.9.5 Statistical considerations – “validating” falls risk screening tools

Measurement validity concerns the extent to which an instrument measures what it is intended to measure (Portney et al., 2000). There are many types of measurement validity including face validity, content validity, criterion-related validity, and predictive validity. As the primary purpose of a falls risk screening tool is to direct interventions to patients who are at higher falls risk, it is the predictive validity of screening tools which is of key importance and is going to be focused upon in this discussion.

To determine if a falls risk screening tool is a valid measure, authors must define what falls risk is in order to measure it. This has rarely been done. Most authors have evaluated the predictive validity of their falls risk screening tools in terms of their ability to discriminate fallers from non-fallers, thus it is assumed in these cases that the definition of falls risk was the probability of a patient becoming a faller during their subacute hospitalisation.

Describing the accuracy of falls risk screening tools in discriminating fallers from non-fallers has primarily been done using sensitivity and specificity statistics. Sensitivity is the proportion of fallers who were correctly predicted to become fallers. Specificity is the proportion of non-fallers who were correctly predicted to remain as non-fallers. Calculations of sensitivity and specificity can be made from data entered into a 2 x 2 contingency table (Portney et al., 2000), demonstrated in figure 1.2.
**Figure 1.2.** Calculation of sensitivity and specificity from a 2 x 2 contingency table.

<table>
<thead>
<tr>
<th>Actual outcome:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive (faller)</td>
<td>Negative (non-faller)</td>
</tr>
<tr>
<td>A (true positive)</td>
<td>C (false positive)</td>
</tr>
<tr>
<td>B (false negative)</td>
<td>D (true negative)</td>
</tr>
</tbody>
</table>

Screening tool prediction:  
- Positive (faller)
- Negative (non-faller)

Sensitivity = \( \frac{A}{A + B} \)
Specificity = \( \frac{D}{D + C} \)
For screening tools with multiple possible “cut-off” points, moving the choice of cut-off point up or down the range will either increase the sensitivity and decrease the specificity of the measure, or vice versa. These different points can be graphed to form a receiver operating characteristic (ROC) curve, with sensitivity on the “Y” axis and specificity (or conventionally 1 – specificity) on the “X” axis. This curve can assist in identifying an optimal cut-off point, possibly where the sum of sensitivity and specificity (SSS) are at a maximum (Bairagi et al., 1989), or by calculating the area under the ROC curve (AUC) it can be used to represent the overall accuracy of the tool over the entire range of possible cut-off points (Portney et al., 2000). AUC and SSS can be used to make comparisons of predictive accuracy between screening tools, however to do this, variance estimates should be calculated and hypothesis tests performed (DeLong et al., 1988; Emir et al., 2000; Mossman, 1995; Zou, 2001). As a reference, a SSS of 100% and AUC of 0.5 represent what would theoretically be found by random predictions. The Youden Index is also a statistic that could be used, however this is no different from SSS except that in the Youden Index a constant value (100%) is subtracted from the SSS (Connell et al., 1985).

In the “standard” calculation of sensitivity and specificity, each patient contributes only one unit of measurement regardless of how many falls they have or how long they stay in hospital. Thus, sensitivity and specificity are ideally suited to describe the predictive accuracy of a falls risk screening tool where the tool has been applied once, each faller only falls once (or that fall recurrences are considered irrelevant), and that patients are followed for the same period of time (or that unequal periods of patient observation are considered irrelevant). However, some alternative techniques to the standard calculation of sensitivity and specificity have been described to cater for repeated screening tool measurements (Emir et al., 2000; Zou, 2001).

Alternatives to using sensitivity and specificity to describe the predictive accuracy of falls risk screening tools have been to comment on the calibration of the tool, overall accuracy, a regression model odds ratio or the correlation of tool results with the number of falls by each patient. An instrument that is not calibrated will select a much greater or lesser proportion of patients to be fallers than actually is the case, thus reducing its practical applicability in most situations. Overall accuracy represents the total proportion of fallers and non-fallers that were correctly classified.
The use of overall accuracy is limited in falls studies where the proportion of fallers is low and the screening tool is poorly calibrated to select an excessively high proportion of non-fallers. Despite a high overall accuracy that would result from such a situation, the tool would be of little practical use for discriminating fallers from non-fallers. Describing the association between a risk screening tool and the probability of being a faller using a regression model odds ratio does provide evidence as to the strength and variance in that association. However these odds ratios are closely related to the measurement scales of tools as an odds ratio represents the change in risk with a one unit change in the scale (Portney et al., 2000), thus leading to difficulties when comparing tools that have different measurement scales. Correlating screening tool results with the number of falls experienced by patients describes the strength of this association. However, the magnitude of a correlation coefficient can be affected by the distribution of falls per subject or range in falls screening tool outcome scales (Portney et al., 2000). Thus these values are of little use for comparing screening tools in different studies (with different distributions of falls per patient), and even in the same study where screening tools have different measurement scales.

Following consideration of how the accuracy of a screening tool has been described, consideration must also be given to the study design. Some studies construct a screening tool based on data drawn from a particular sample, and then re-apply that tool to the same data to describe its “apparent” predictive accuracy (Gluck et al., 1996; Morse et al., 1989b). Such attempts at validating a model are retrospective and provide little evidence of generalisability outside the sample from which the tool was constructed as very few tools will not fit the data for which they were tailor-made (Harrell et al., 1996). Better approaches (hierarchically) are to conduct internal validation, temporal validation or external validation (Altman et al., 2000). An internal validation collects the data and divides the sample into two groups before the tool is constructed, constructs the tool on one set and then tests its validity on the other. Although this approach is still retrospective, the data the tool is being validated with is independent from the data it was constructed with. Temporal validation uses a set of patients from the same location at a later time to that from which the tool was constructed to validate the tool. This is a prospective evaluation independent of the original data. External validation addresses the wider issue of generalisability by
collecting new data from an appropriate patient population in a different centre. Data from an external validation provides the best indication of likely screening tool performance in a hospital other than the one it was developed in. Studies investigating tools developed through expert opinion (without consideration of local data) or are based on staff clinical judgement are poorly classified by the terms internal, temporal and external validation designs. Thus these tools will be discussed in terms of whether they were evaluated prospectively or retrospectively, and if they were validated in a variety of locations.

A final consideration in “validating” a falls risk screening tool relates to its use in practice. No matter how accurate a screening tool is, if hospital staff do not complete it in the clinical setting, it will not assist in the prevention of falls of any patient. It is reasonable to expect that tools that take a long time or are difficult to complete may have higher non-completion rates than shorter, simpler tools. Similarly staff may also be less inclined to complete tools they perceive as being inaccurate or irrelevant to patient care. Thus it is important to consider how practically applicable a tool appears to be and how regularly it is completed by hospital staff.
1.9.6 Predictive accuracy of falls risk screening tools

Falls risk screening tools that have reported their predictive accuracy are demonstrated in table 1.5 along with their measurement scale, cut-off score, validation approach and number of patients involved in the study.

The Morse Fall Scale was one of the earliest falls risk screening tools and was developed from a combination of acute, rehabilitation and residential care facility data. Initially its predictive accuracy was reported as SSS = 161% (Morse et al., 1989b). The authors followed up this retrospective analysis with a prospective study, but made no mention of sensitivity and specificity, nor did they provide sufficient information for them to be calculated (Morse et al., 1989a). Another research group examined the Morse Fall Scale’s predictive accuracy in an external validation study in rehabilitation and general medical wards (Eagle et al., 1999). These authors found its predictive accuracy to be SSS = 123%, perhaps demonstrating the effect of setting specificity or of a more rigorous validation approach. Of note was another external validation of the Morse Fall Scale in the acute setting, which found its’ predictive accuracy to be SSS = 112% (O’Connell et al., 2002). This provides greater weight to the effect of a more vigorous validation approach as a reason behind the reduction in predictive accuracy, indicating that the Morse Fall Scale may only be of moderate use in predicting fallers in the subacute setting.

The STRATIFY (St. Thomas’s Risk Assessment Tool in Falling Elderly Patients), was developed from local hospital data in the United Kingdom and was then investigated for predictive accuracy in temporal and external validation studies (Oliver et al., 1997). The temporal validation reported an accuracy of maximum SSS = 181%, while the external validation led to a predictive accuracy of maximum SSS = 160%. A subsequent study completed an external validation in a subacute hospital in Canada and achieved a predictive accuracy of maximum SSS = 113% (Coker et al., 2003). The predictive accuracy of a “modified” STRATIFY (STRATIFY score plus previous ward fall) has also been reported as SSS = 140% from an intervention study (Oliver et al., 2002). This latter result is difficult to interpret as it appears that patients who were identified as high risk received falls prevention
Table 1.5a. Reported predictive accuracy of falls risk screening tools.

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Screening tool</th>
<th>Setting</th>
<th>Size</th>
<th>Study design</th>
<th>Predictive accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannard, 1996</td>
<td>FRASE</td>
<td>Nursing development unit</td>
<td>n = 141</td>
<td>Unknown</td>
<td>“...effective in predicting likelihood of falls.”</td>
</tr>
<tr>
<td>Coker et al, 2003</td>
<td>STRATIFY</td>
<td>Geriatric assessment, rehabilitation unit</td>
<td>n = 581</td>
<td>External validation</td>
<td>Sensitivity (Sen) = 66%, specificity (Spec) = 47%</td>
</tr>
<tr>
<td>Donald et al, 2000</td>
<td>ACCIDENTS</td>
<td>Elder rehabilitation</td>
<td>n = 54</td>
<td>Prospective cohort, single location</td>
<td>Mean score of fallers equal to non-fallers</td>
</tr>
<tr>
<td>Eagle et al, 1999</td>
<td>Morse Fall Scale (Morse), Functional Reach (FR), Nurse judgement (NJ)</td>
<td>Rehabilitation unit and general medical ward</td>
<td>n = 98</td>
<td>External validation</td>
<td>Morse: Sen = 72%, Spec = 51%, FR: Sen = 76%, Spec = 34%, NJ: Sen = 76%, Spec = 49%</td>
</tr>
<tr>
<td>Foster et al 1996</td>
<td>Local</td>
<td>Rehabilitation unit</td>
<td>46 beds x 8 months</td>
<td>Prospective cohort, single location</td>
<td>Poor calibration, 98% high risk</td>
</tr>
<tr>
<td>Gluck et al, 1996</td>
<td>Local</td>
<td>Acute and rehabilitation wards</td>
<td>n = 100</td>
<td>Retrospective validation</td>
<td>Sen = 68%, Spec = 88%.</td>
</tr>
<tr>
<td>Izumi, et al, 2002</td>
<td>Local, Nurse Judgement (NJ)</td>
<td>Rehabilitation wards</td>
<td>n = 277</td>
<td>Prospective cohort, multiple locations</td>
<td>Local: Accuracy not stated NJ: Sen = 79%, Spec = 40%</td>
</tr>
<tr>
<td>Moore et al, 1996</td>
<td>Heslin Nurse judgement (NJ)</td>
<td>Geriatric unit of community hospital</td>
<td>n = 39</td>
<td>External validation</td>
<td>Heslin: Sen = 50%, Spec = 52% NJ: Sen = 50%, Spec = 81%*</td>
</tr>
<tr>
<td>Morse et al, 1989(b)</td>
<td>Morse Fall Scale</td>
<td>Acute, subacute, and residential care setting</td>
<td>n = 200</td>
<td>Retrospective validation</td>
<td>Sen = 78%, Spec = 83%</td>
</tr>
</tbody>
</table>
Table 1.5b. Reported predictive accuracy of falls risk screening tools (continued).

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Screening tool</th>
<th>Setting</th>
<th>Size</th>
<th>Study design</th>
<th>Predictive accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nyberg et al, 1997</td>
<td>Downton Fall Index</td>
<td>Stroke rehabilitation</td>
<td>n = 135</td>
<td>Retrospective validation</td>
<td>Odds ratio = 1.46, p &lt; 0.001 relationship with being a faller Index significantly associated with patient being faller</td>
</tr>
<tr>
<td>Nyberg et al, 1996</td>
<td>Downton Fall Index</td>
<td>Stroke rehabilitation</td>
<td>n = 135</td>
<td>Retrospective validation</td>
<td>Sen = 91%, Spec = 27%</td>
</tr>
<tr>
<td>Oliver et al, 1997</td>
<td>STRATIFY</td>
<td>Elderly care units, Elderly acute, subacute</td>
<td>n = 217, n = 331</td>
<td>Temporal validation, external validation</td>
<td>Sen = 93%, Spec = 88%, Sen = 92%, Spec = 68%†</td>
</tr>
<tr>
<td>Oliver et al, 2002</td>
<td>STRATIFY + ward fall</td>
<td>Elderly care units</td>
<td>Unknown</td>
<td>Retrospective validation</td>
<td>Sen = 70%, Spec = 70%</td>
</tr>
<tr>
<td>Rapport et al, 1993</td>
<td>Local, Modified local</td>
<td>Rehabilitation ward (male, right sided stroke patients only)</td>
<td>n = 32</td>
<td>Local: Prospective cohort Modified local: Retrospective validation</td>
<td>Local: Correlation with falls r = 0.52, p &lt; 0.001, modified local: Sen = 80%, Spec = 82%</td>
</tr>
<tr>
<td>Vassallo et al, 2002</td>
<td>Downton Fall Index</td>
<td>Geriatric wards</td>
<td>n = 200</td>
<td>External validation</td>
<td>Sen = 92%, Spec = 36%</td>
</tr>
</tbody>
</table>

intervention, thus contaminating predictive accuracy results. It also appears that the modification of the STRATIFY was *post hoc* making this a retrospective validation.

It is difficult to interpret the conflicting results of the two external validation studies of the STRATIFY. Both were conducted with predominantly subacute patients, who experienced falls at a similar rate and both recruited relatively large sample sizes. However, they did differ in their application of the STRATIFY. The earlier external validation study applied the STRATIFY on admission and then weekly, as prompted by the researchers through interviews with nursing staff (Oliver et al., 1997). In the later external validation, nurses were responsible for completing the tool on patient admission only (Coker et al., 2003). A second point of difference was in the statistical analysis. As a consequence of having a review process, the earlier study could not use a “standard” calculation for sensitivity and specificity, and chose to calculate sensitivity based on the proportion of falls correctly predicted without specifying how specificity was calculated. In contrast, the later study employed a standard calculation of sensitivity and specificity. Admirably, both studies were the only two to present 95% confidence intervals for their sensitivity and specificity measures, although the “exact” binomial confidence intervals used in the earlier study did not take into account the dependence of falls data when multiple falls are recorded for individual patients. This approach may have produced results that were insufficiently conservative, and use of falls instead of fallers to calculate sensitivity may also produce overoptimistic results (Altman, 1997). Thus it is unclear whether the superior results found in the earlier external validation study were due to the different application process of the STRATIFY, different outcome of interest, different statistical approach or just due to random differences in the samples being examined. Despite this the STRATIFY has been the most widely investigated tool to date and appears to have a good ability to predict falls when applied with a weekly review process, but a more limited ability to predict fallers.

The only other “mathematical” model screening tool to be subjected to multiple investigations in the subacute setting was the Downton Fall Index (Nyberg et al., 1997). This tool was developed using only “stroke” patients. It was initially investigated retrospectively, and had its accuracy described in one study as having a significant correlation with first falls (odds ratio = 1.46) (Nyberg et al., 1997), while
another publication from the same data described its predictive accuracy as $SSS = 118\%$ in predicting fallers (Nyberg et al., 1996). A external validation study of the Downton Fall Index on a general geriatric ward with little other description in a peer reviewed journal found this tool to have a predictive accuracy of $SSS = 128\%$ (Vassallo, 2002) in (Vassallo et al., 2004). Despite this result, the authors were not sufficiently confident in this tool’s ability to discriminate fallers from non-fallers for the purpose of their intervention study (Vassallo et al., 2004). Again, the evidence describing the predictive accuracy of this tool is unclear, as it appears to be of lesser value in discriminating fallers from non-fallers amongst stroke patients (which it was designed for) than what it does for general subacute patients.

The clinical judgement of nursing staff in predicting fallers has been prospectively investigated in three studies, each also collecting predictive accuracy data for a “mathematical” model screening tool. The accuracy of nursing judgement has been relatively modest however it has also been comparable to the “mathematical” model being compared against in each instance. For example, in one study the predictive accuracy of the Heslin tool was $SSS = 102\%$ for predicting falls in the first week of hospitalisation, compared to nurse judgement $SSS = 131\%$ (Moore et al., 1996). In another study the predictive accuracy of the Morse Fall Scale was $SSS = 123\%$ whereas nurse judgement was $SSS = 125\%$. Unfortunately no hypothesis testing was performed on this data, so it is unclear if these differences were statistically significant. The third study presented predictive accuracy data for nurse judgement ($SSS = 119\%$) however described the predictive accuracy of components of a retrospectively validated logistic regression model in terms of adjusted odds ratios (Izumi et al., 2002). Another “mathematical” model that was being prospectively evaluated in that study after being constructed through the “expert opinion” of the primary author, did not have its sensitivity and specificity presented. It is a concern that the predictive accuracy of these three different approaches were not described in a consistent manner that allowed for comparison between them. None of these three studies described providing nursing staff with any education on falls risk prediction prior to data collection, raising the possibility that prediction accuracy could be improved from the reported levels. A difficulty inherent to assessing the predictive accuracy of nursing judgement is that the nurse caring for the patient is also the one making the judgement, thus they cannot be blinded to this judgement. Subsequently,
even when a specific falls program is not in place it is likely that hospital staff will intervene in some way for patients they perceive as being at high falls risk (Moore et al., 1996). If the intervention they implement is effective, the patient will have a reduced risk of falling, thus contaminating the data such that the predictive accuracy of the nurse will appear poorer.

Several other falls risk screening tools have been investigated in the subacute setting, but have only had predictive accuracy results published once. Two were developed following analyses of local data and evaluated retrospectively producing predictive accuracy of SSS = 156% (Gluck et al., 1996) and SSS = 162% (Rapport et al., 1993). However, without a prospective validation of these tools there is little evidence that they will be useful outside the data sample they were constructed from. Four received a prospective evaluation but authors did not report sensitivity and specificity measures, nor provide sufficient data for them to be calculated. From data that was reported though, it was clear that two of these were not particularly useful. One was poorly calibrated (98% of patients were predicted to be at high risk when only 15% fell) (Foster et al., 1996), and for the other, the average falls risk score for fallers was equal to that for non-fallers (Donald et al., 2000). The third reported that the tool was effective in predicting falls, and that the number of falls and patients falling increased as the risk score increased (Cannard, 1996). The fourth reported a significant correlation between their falls risk score and falls (Rapport et al., 1993). These remarks and correlation analysis are not useful though for comparison to data from other screening tools.

From this discussion it appears that there are several unresolved issues pertaining to the development and content of an accurate falls risk screening instrument. First, it is unclear whether a “mathematical” model provides more accurate classifications than the clinical judgement of nursing staff. Predictive accuracy scores taken from studies where tools have been evaluated in isolation suggest that this may be the case. However in studies where they were compared directly, thus removing inter-subject differences, the nurse judgement appeared to be slightly better. Second, benefits from integrating nurse judgement into a “mathematical” model remain unclear. Third, it is unclear which method of constructing a “mathematical” model is most effective. Although several models based on statistical analysis of local data have produced
strong results through retrospective validation, few have maintained their accuracy following prospective investigation. Fourth, it is unclear whether a review protocol would improve the predictive accuracy of a falls risk screening tool. Obviously a tool based on factors that do not vary throughout an in-patient stay (such as admission diagnosis and gender) would not require review. However other factors, such as patient mobility and behaviour, may vary. Results for the STRATIFY when applied only on admission were certainly poorer than those when it had a review protocol, but it was unclear if this change was the sole reason for the difference observed (Coker et al., 2003; Oliver et al., 1997).

1.9.7 Completion of falls risk screening tools

Despite the essential contribution of completion rates data to understanding the global practical applicability of a falls risk screening tool, these data have rarely been reported. A number of factors may have contributed to this. When tools are developed and evaluated retrospectively, hospital staff have not had the opportunity to use the tool yet and thus these data cannot be collected. When examined prospectively, some tools have been completed by researchers, or hospital staff have been prompted by researchers to complete the tool (Eagle et al., 1999). These conditions do not reflect clinical practice, thus even if data were presented, it would not be generalisable.

When applied by hospital staff, non-completion rates of falls risk screening tools have been found to be 26% (Coker et al., 2003) and 36% (Oliver et al., 2002) for the STRATIFY tool, and 25% and 12% for the Barbieri tool (Tuffnell, 1990). Given the relative lack of reporting of falls risk screening tool completion rates, little can be concluded from this data at this stage. Future investigations may demonstrate that certain characteristics of falls risk screening tools may promote or retard completion rates, however it will be difficult to separate these effects from those of the culture of medical record completion in the setting where it is being tested. Another potential confounding factor is that staff may be reluctant to complete falls risk screening tools for patients whom they believe to be clearly at low risk of falling. Ideally, comparison of screening tool completion rates should be made using the same staff.
and patient samples to control for these confounding variables, however this approach may prove to be burdensome for hospital staff in the clinical setting.
1.10 Falls risk factor assessment tools

The tools discussed in this section differ from those discussed in the previous section in that they do not contain a specific mechanism for discriminating different patients’ “falls risk” (see figure 1.1). Comparatively few of these tools have been described and evaluated in the subacute setting with only one tool previously described that could be considered to be a “pure” falls risk factor assessment tool that does not contain a mechanism for gauging a patient’s overall risk of falling (Uden et al., 1999). Other “pure” falls risk factor assessment tools have been described for the acute setting which may be transferable to the subacute setting.

1.10.1 Structure and construction of falls risk factor assessment tools

Conceptually, use of falls risk factor assessment tools in falls prevention programs is different to that of falls risk screening tools. On one hand, a falls risk screening tool aims to identify a patient who is highly likely to fall due to certain characteristics. On the other hand, a falls risk factor assessment tool aims to identify certain characteristics that a patient may have which may contribute to increasing their risk of falling. This difference, although subtle, produces two approaches for provision of interventions. Interventions specifically related to a falls risk factor, for example, a balance exercise program to address impaired balance, may be more suitably deployed using a falls risk factor assessment approach than a falls risk screening approach as not all high risk patients will have balance impairment. Conversely, interventions that are not specifically related to a falls risk factor, for example, employment of a patient “sitter”, may be targeted to those at the highest risk of falling regardless of which specific risk factors they possess. Thus the structure of a falls risk factor assessment tool may have different requirements to those of a falls risk screening tool.

In similarity to construction of falls risk screening tools, falls risk factor assessment tools require inclusion of risk factors with strong associations between falls, fallers or fall-related injuries. However, where a falls risk screening tool needs to focus on one of these particular aspects as its definition of falls risk (as discussed in section 1.8.1), a falls risk factor assessment tool can encompass factors related to all three without
compromise. The selection of risk factors included in the “Uden” falls risk factor assessment tool was “…based on findings reported by the nurse researchers.” in the author’s doctoral thesis (Uden et al., 1999). It was unclear however whether these “findings” were from an epidemiological study the authors conducted or from a review of the literature. Other tools from the acute setting have included risk factors based on a combination of findings from literature reviews and analyses of local data (Spellbrig, 1992; Tack et al., 1987).

1.10.2 Content of falls risk factor assessment tools

Inclusion of factors that do not have direct evidence of an association to falls in the subacute setting in falls risk factor assessment tools is less of a problem than what it is for falls risk screening tools. Despite the presence of what might be unrelated risk factors, as long as a falls risk factor assessment tool contains some factors that are related, they will be identified and some benefit will flow from the completion of the tool. However falls risk screening tools that contain unrelated factors will have the entire result of the screening confounded by their presence, reducing its effectiveness. Thus when evaluating the content validity of a falls risk factor assessment tool, relatively greater focus should be given to whether a sufficient number of risk factors with strong direct evidence of association were included, rather than whether factors with questionable associations were excluded.

Risk factors included in the Uden falls risk factor assessment tool include balance impairment, medications (sedative, neuroleptic, hypnotic, diuretic, laxatives), gait impairment (requires aid or assistance while walking), dizziness, disturbed sleep at night, aggressiveness, confusion and a history of falls in the previous three months (Uden et al., 1999). Staff using this document were then instructed to write an “individualised nursing-care plan” based on the findings from the falls risk factor assessment (Uden et al., 1999). Although not all of these factors have strong direct evidence of an association to falls in the subacute setting, arguably a sufficient number of factors with direct evidence of an association have been included. Factors with some direct evidence absent from this list include impaired continence, admission diagnosis, gender and possibly age. However, as little can be done by staff
to modify the impact of admission diagnosis, gender and age (they are non-modifiable risk factors), their exclusion is arguably appropriate.

1.10.3 Evaluation of falls risk factor assessment tools

Falls risk factor assessment tools are evaluated differently from falls risk screening tools. The primary purpose of a falls risk factor assessment tool is not to measure a patient’s probability of falling, thus there is no need to use sensitivity and specificity measures to calculate their accuracy. One could instead measure its direct effect on falls. However, in similarity to falls risk screening tools, the purpose of a falls risk factor assessment tool is to deploy falls prevention interventions. This complicates attempts to isolate the contribution that a falls risk factor assessment tool makes to an overall falls prevention program. If a falls risk factor assessment tool, or for that matter a falls risk screening tool, were to be implemented on a hospital ward without an associated intervention program, the most likely means by which it may contribute to a reduction in the incidence of falls would be through increased staff awareness of patients with elevated falls risk. Such a study in the subacute setting is yet to be reported. Thus the contribution of falls risk factor assessment tools needs to be evaluated concurrently with that of the intervention program it is linked to. These will be discussed in section 1.11.4. Other areas that may be of interest in evaluating falls risk factor assessment tools include the range of risk factors included, the operational definitions used to define each factor, and the grading of each factor where different levels of risk for that factor are applicable.

1.10.4 Completion of hospital falls risk factor assessment tools

An initial falls risk factor assessment was completed for 96% of patients using the Uden tool (Uden et al., 1999). Repeat assessments subsequent to the initial assessment were completed for 9% of patients in that study sample (Uden et al., 1999). These results compare favorably to those of falls risk screening tools the STRATIFY [completion rates of 74% (Coker et al., 2003) and 64% (Oliver et al., 2002)] and the Barbieri tool [completion rates of 75% and 88% (Tuffnell, 1990)]. It is unclear how much prompting was provided by researchers in each of these studies to facilitate the completion of these documents by hospital staff, which may have
biased these results. Given that there is relatively little evidence regarding completion rates of each type of tool, it is difficult to make a fair comparison at this stage regarding which type of tool is more likely to be consistently completed by hospital staff.
1.11 Evaluation of effectiveness of falls prevention interventions

A wide range of study designs, outcome measures and statistical analysis techniques have been employed to describe the effectiveness of particular falls prevention interventions in the subacute setting and have been summarised in table 1.6. Various characteristics of falls prevention studies can influence how the results from these studies should be interpreted. Three such characteristics - study design, outcome measure selection and statistical analysis technique - will now be discussed.

1.11.1 Study designs

In attempting to reduce either the incidence of falls, fall-related injury or the proportion of patients who become fallers during their subacute hospitalisation, researchers and clinicians need to identify interventions that “cause” a reduction in the occurrence of these problems. An experimental research design provides a means for evaluating the “cause-and-effect” association between a set of independent and dependent variables (Portney et al., 2000). Both “true experimental designs” and “quasi-experimental designs” have been used to investigate the effectiveness of falls prevention interventions.

1.11.1.1 True experimental designs

True experimental designs require that independent variables must be manipulated by the researcher (the independent variable must be active), that subjects be assigned randomly to groups, and that a control group must be incorporated into the research design (Portney et al., 2000). Two previous falls prevention studies in the subacute setting have used a randomised controlled trial study design. One individually randomised patients to receive a falls risk alert bracelet (intervention group) or no falls risk alert bracelet (control group) (Mayo et al., 1994). The other employed a 2 x 2 design, whereby patients received either an additional exercise program or no additional exercise program, and vinyl flooring or carpet flooring (Donald et al., 2000). The independent variable(s) in both of these cases was active as the researcher could manipulate which patients received it. Comparison (control) groups were incorporated into both study designs. Patients were also randomly allocated in both
circumstances. Thus both of these study designs fulfilled the three essential requirements of true experimental designs.

1.11.1.2 Quasi-experimental designs

Quasi-experimental designs do not meet all three criteria required to be described as a true experimental design, yet are not adequately classified as being either descriptive or exploratory research (Portney et al., 2000). This study design has been frequently used where it has been difficult or impractical to randomise patients to a control or an intervention group, such as when interventions are deployed at a ward based level (Oliver et al., 2000). As a consequence however, quasi-experimental designs are less able to rule out threats to the internal validity of a study design with the same confidence as true experimental designs. This limits the confidence we can have in concluding that any effect on falls (or any other dependent variable) observed in the study was truly due to the effect of the intervention being investigated.

An example of a quasi-experimental design used to evaluate the effectiveness of a falls prevention intervention has been a “parallel control group” design (Vassallo et al., 2004). A parallel control group design indicates that patients in the control group were present in the study at the same time as those in the intervention group. In this study patients were admitted to either the “intervention” ward or one of two “control” wards in the sequence in which they were put on a waiting list and in the order in which beds became available. Patients on the intervention ward received more comprehensive falls risk screening and intervention plans than those on control wards and also received weekly multidisciplinary falls specific case-conferences not provided on the control wards. Thus an active intervention (independent variable) was investigated, a control group was incorporated into the design, but patients were not randomly allocated making this a quasi-experimental study.

Three considerable threats to the internal validity of such a study are “selection”, “instrumentation” and unequal provision of treatment. By not randomly allocating patients to receive the intervention, the distribution of falls risk factors among patients in both groups is less likely to be balanced (Portney et al., 2000). This was evident in the example provided as gender, length of hospital stay and use of anti-depressant
medications were not evenly distributed between groups (Vassallo et al., 2004). Perhaps of greater concern though were potential differences in instrumentation, namely, different practices by hospital staff in recording falls on different wards. The reliability of fall reporting has previously been questioned (Elnitsky et al., 1997; Sutton et al., 1994a; Sutton et al., 1994b), and it is plausible that different wards even within the same hospital may have different “cultures” for reporting fall incidents which could bias results. Also of concern is the possibility that hospital staff did not provide “equal” usual care to patients in both groups. This does not require conscious involvement by researchers or hospital staff, yet may either have obscured or exaggerated the apparent effect of the intervention on falls depending on whether the control group received better or worse care than usual (Portney et al., 2000).

Another quasi-experimental design more frequently used has been the “historical control group” design, also referred to as the “pre-post intervention” design (Brady et al., 1993; Foster et al., 1996; Grenier-Sennelier et al., 2002; Hanger et al., 1999; Oliver et al., 2002; Rogers, 1994; Sweeting, 1994; Tuffnell, 1990; Uden et al., 1999). The term historical control indicates that the control group was observed prior to the intervention group, usually employing the same setting for both groups to control for some of the variances in fall recording practices and provision of usual care that may exist between wards. This design is quite appealing for occasions where an intervention needs to be implemented across an entire hospital or ward at the same time. However, there is still little guarantee that the two groups will be comparable at baseline, and it is also possible that fall recording practices and provision of usual care may change over time on the same ward. Authors of one study attributed an increase in falls during the intervention period to a perceived increase in reporting rates rather than the actual number of falls (Uden et al., 1999). Naturally occurring cyclical fluctuations in fall event rates may also be a threat to the internal validity of studies using a historical control group design unless the time period for both control and intervention groups covers the same proportion of that cycle. Therefore, both the historical control group and parallel control group designs have practical benefits that may make them more appealing than pursuing a randomised controlled trial design, yet both suffer from threats to their internal validity that limits the level of confidence researchers and clinicians can have in their results.
Many threats to the internal validity of both true experimental and quasi-experimental studies can be traced back to patients, hospital staff or researchers being aware of patients’ group allocation. Blinding, where patients, hospital staff and even researchers handling data collation and analysis, are kept unaware of patient’s group allocation can provide protection against these biases (Portney et al., 2000). Unfortunately, using ward based interventions dictates that hospital staff are often unable to be blinded, and the nature of other interventions, such as falls risk alert bracelets (Mayo et al., 1994), dictates that patients often cannot be blinded either. To date only one falls prevention study in the subacute setting has employed some form of blinding in their study design (Vassallo et al., 2004). In this instance, blinding was only of a researcher collating data upon a patient’s discharge from hospital. Thus the potential bias that this addressed was that of inappropriate recording of patient data from histories. Patients and hospital staff were unable to be blinded in this study design.

1.11.1.3 Systematic review and meta-analysis

As a growing number of falls prevention studies are conducted in the subacute setting, there is a growing likelihood that similar falls prevention approaches may be used in different studies, yet produce different results. “Review” articles have previously been published that summarise findings from the literature and generate conclusions regarding the prevention of falls in hospitals (Lambert et al., 1998; Rawsky, 1998; Whedon et al., 1989; Wilson, 1998). The selection of studies and relative importance that each has in forming the paper’s conclusions is left in the hands of the authors and may vary from review paper to review paper.

A “systematic review” is an overview of primary studies which contain an explicit statement of objectives, materials, and methods and has been conducted according to explicit and reproducible methodology (Greenhalgh, 1997). Explicit and pre-determined research methodologies of systematic reviews limits bias in the identification and rejection of studies producing conclusions that are more reliable and accurate (Greenhalgh, 1997).
A meta-analysis is different again from a review or a systematic review. It is a statistical approach that provides a way of making sense of sometimes conflicting results by pooling the results of different studies that have used the same or similar intervention, and then producing a single estimate of the intervention effect (Portney et al., 2000). Meta-analyses increase power to find significant differences by increasing sample size, improve estimates of effect size, improve generalisability of findings, and resolve uncertainty when conflicting results occur (Sacks et al., 1987).

Only a handful of systematic reviews with meta-analyses of falls prevention studies have been published. One has been produced by the Cochrane Collaboration which included results only from randomised controlled trials and separated studies in the community setting from those in the hospital and residential care settings (Gillespie et al., 2004). Another focused on experimental and quasi-experimental studies (separate meta-analyses provided) in the hospital setting, but did not separate acute from subacute settings (Oliver et al., 2000). Another excluded trials from the hospital setting (Chang et al., 2004).

1.11.1.4 Levels of evidence

Determining how to interpret various studies of different design and procedure requires a mechanism for rating the level of evidence that different studies provide. The Australian National Health and Medical Research Council has provided guidelines to rate the levels of evidence provided by various research designs (National Health and Medical Research Council, 1998). These guidelines are shown in table 1.7.
Table 1.6a. Summary of subacute care falls prevention intervention study designs, outcome measures, analysis techniques, interventions, and results.

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Size</th>
<th>Setting</th>
<th>Design</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brady, (1993)</td>
<td>n = 25</td>
<td>Rehabilitation centre</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Donald et al, (2000)</td>
<td>n = 54</td>
<td>Elder care rehabilitation ward</td>
<td>Randomised controlled trial (2x2 design)</td>
<td>II</td>
</tr>
<tr>
<td>Foster et al, (1996)</td>
<td>16 months x 46 beds</td>
<td>Rehabilitation unit</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Grenier-Sennelier et al, (2002)</td>
<td>4 years x 160 beds</td>
<td>Rehabilitation units</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Hanger et al, (1999)</td>
<td>1 year x 135 beds</td>
<td>Geriatric rehabilitation wards</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Mayo et al, (1994)</td>
<td>n = 134</td>
<td>Rehabilitation facility</td>
<td>Randomised controlled trial</td>
<td>II</td>
</tr>
<tr>
<td>Oliver et al, (2002)</td>
<td>1 year x 78 beds</td>
<td>Acute / rehabilitation geriatric unit</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Rogers, (1994)</td>
<td>6 months x 160 beds</td>
<td>Rehabilitation hospital</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Sweeting, (1994)</td>
<td>12 months x 231 beds</td>
<td>Acute and rehabilitation wards</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Tuffnell, (1990)</td>
<td>12 months x 280 beds</td>
<td>General hospital including rehabilitation ward</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
<tr>
<td>Uden et al, (1999)</td>
<td>n = 379</td>
<td>Geriatric care wards</td>
<td>Historical control</td>
<td>III-3</td>
</tr>
</tbody>
</table>
Table 1.6b. Summary of subacute care falls prevention intervention study designs, outcome measures, analysis techniques, interventions, and results (continued).

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Primary outcome measures (analysis technique)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brady, (1993)</td>
<td>Fall without injury event rates (comparison of event rates but no variance estimates provided)</td>
</tr>
<tr>
<td>Donald et al, (2000)</td>
<td>Fallers (relative risk with 95% CIs)</td>
</tr>
<tr>
<td>Foster et al, (1996)</td>
<td>Fallers [assisted falls excluded] (chi-square)</td>
</tr>
<tr>
<td>Grenier-Sennelier et al, (2002)</td>
<td>Fall event rates (chi-square), fallers (chi-square), recurrent fallers (chi-square)</td>
</tr>
<tr>
<td>Hanger et al, (1999)</td>
<td>Fall event rates (unpaired t test), fall by bedside event rates (unpaired t test), number of “serious” injuries (chi-square)</td>
</tr>
<tr>
<td>Mayo et al, (1994)</td>
<td>Time until first fall (Cox regression)</td>
</tr>
<tr>
<td>Oliver et al, (2002)</td>
<td>Fall event rates (not stated), fallers (comparison of proportions but no variance estimates provided), injuries (comparison of raw numbers but no variance estimates provided), recurrent fallers (not stated)</td>
</tr>
<tr>
<td>Rogers, (1994)</td>
<td>Falls during first week of hospitalisation (comparison of raw numbers but no variance estimates provided)</td>
</tr>
<tr>
<td>Sweeting, (1994)</td>
<td>Number of falls (comparison of raw number of falls but no variance estimates provided)</td>
</tr>
<tr>
<td>Tuffnell, (1990)</td>
<td>Fall event rates (comparison of event rates but no variance estimates provided)</td>
</tr>
<tr>
<td>Uden et al, (1999)</td>
<td>Fallers (comparison of proportions but no variance estimates provided)</td>
</tr>
<tr>
<td>Vassallo et al, (2004)</td>
<td>Fall event rates (Mann-Whitney U-test), fallers (multiple logistic regression, chi-square), patients injured through falls (multiple logistic regression chi-square), recurrent fallers (chi-square)</td>
</tr>
</tbody>
</table>
Table 1.6c. Summary of subacute care falls prevention intervention study designs, outcome measures, analysis techniques, interventions, and results (continued).

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Intervention</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brady, (1993)</td>
<td>Falls risk screen and nursing intervention protocol checklist, falls risk bracelets and signs, patient education, use of side rails</td>
<td>50% reduction in falls without injury</td>
</tr>
<tr>
<td>Donald et al, (2000)</td>
<td>Carpet versus vinyl flooring, regular therapy versus regular therapy plus additional exercise program</td>
<td>Carpet relative risk (95%CI) = 8.3 (0.95-73), additional exercise = 0.21 (0.04-1.2)</td>
</tr>
<tr>
<td>Foster et al, (1996)</td>
<td>Falls risk screen, nursing intervention protocol checklist, falls analysis, falls risk stickers, toileting program</td>
<td>35% reduction in fallers, P&lt;0.05</td>
</tr>
<tr>
<td>Grenier-Sennelier et al, (2002)</td>
<td>Falls risk screen, “improved” procedures for transporting patients, falls analysis, falls reporting and education of patients and families</td>
<td>30% reduction in falls between years 1 (pre-intervention) and 4 (post-intervention) (P&lt;0.001), fallers no difference, significant 45% reduction in recurrent fallers between years 1 and 4.</td>
</tr>
<tr>
<td>Hanger et al, (1999)</td>
<td>Bed rail reduction policy and staff education program</td>
<td>16% increase in falls (P=0.18), 19% increase in falls by bedside (P=0.12), serious injury reduced (P&lt;0.01)</td>
</tr>
<tr>
<td>Mayo et al, (1994)</td>
<td>Falls risk alert bracelet</td>
<td>Increased risk of falling with intervention (hazard ratio = 1.33 – not significant)</td>
</tr>
<tr>
<td>Oliver et al, (2002)</td>
<td>Staff education, falls risk screen, falls risk alert labels, nursing and medical checklists</td>
<td>24% increase in falls (P=0.015), 11% reduction in fallers (not significant), injuries similar, increase in repeat fallers (P=0.06)</td>
</tr>
<tr>
<td>Rogers, (1994)</td>
<td>Staff reminders to patients of recommended levels of assistance for mobilising.</td>
<td>20% reduction in falls in first week of hospitalisation</td>
</tr>
<tr>
<td>Sweeting, (1994)</td>
<td>Falls risk screen, staff education, communication procedure with radiology department, fall data review, intervention checklist, falls risk alert bracelet</td>
<td>41% reduction in falls</td>
</tr>
<tr>
<td>Tuffnell, (1990)</td>
<td>Falls risk screen., post fall review, staff education, individualised falls prevention plan</td>
<td>38% reduction in falls</td>
</tr>
<tr>
<td>Uden et al, (1999)</td>
<td>Falls risk factor assessment, staff education, individualised falls prevention plan</td>
<td>29% increase in fallers</td>
</tr>
<tr>
<td>Vassallo et al, (2004)</td>
<td>“More comprehensive” falls risk screening and intervention plans, multidisciplinary falls specific case conferences</td>
<td>7% increase in falls (P=0.045), 30% reduction in fallers (P=0.033), 51% reduction in patients who sustained a fall injury (P=0.025)</td>
</tr>
</tbody>
</table>
Table 1.7. National Health and Medical Research Council designated levels of evidence.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case series, either post-test or pre-test and post-test</td>
</tr>
</tbody>
</table>
1.11.2 Choice of outcome measures and definition of falls

Both the fall definition employed and outcome measures chosen to evaluate the effectiveness of reported falls prevention programs have varied widely. Falls without injury event rates (Brady et al., 1993), proportion of patients who became fallers (Donald et al., 2000; Foster et al., 1996; Grenier-Sennelier et al., 2002; Oliver et al., 2002; Uden et al., 1999; Vassallo et al., 2004), falls event rates (Grenier-Sennelier et al., 2002; Hanger et al., 1999; Oliver et al., 2002; Tuffnell, 1990), the proportion of patients who became recurrent fallers (Grenier-Sennelier et al., 2002; Oliver et al., 2002; Vassallo et al., 2004), falls by bedside event rates (Hanger et al., 1999), number of injuries or serious injuries resulting from falls (Hanger et al., 1999; Oliver et al., 2002), the proportion of patients experiencing an injurious fall (Vassallo et al., 2004), time until first fall (Mayo et al., 1994), falls during the first week of hospitalisation (Rogers, 1994), and the raw number of falls (Sweeting, 1994) have all been used as outcome measures in falls prevention studies in the subacute setting. Falls definitions used in these studies included assisted falls in many (Brady et al., 1993; Donald et al., 2000; Hanger et al., 1999; Mayo et al., 1994; Rogers, 1994; Vassallo et al., 2004), excluded assisted falls in one (Foster et al., 1996), and were undefined in others (Grenier-Sennelier et al., 2002; Sweeting, 1994; Tuffnell, 1990; Uden et al., 1999).

The variation in outcome measures selected and in fall definitions employed may be responsible for some variation in reported outcomes where similar interventions were used.

By selecting different outcome measures, researchers are trying to answer slightly different questions through their research, although all could be said to be addressing the problem of “falls” generally. In selecting falls event rates as an outcome measure, researchers are seeking to find if their intervention will reduce the frequency with which falls occur. In selecting the proportion of patients who become fallers as an outcome, researchers are seeking to find if their intervention will increase the proportion of patients who go through their subacute hospitalisation without experiencing any falls. Both of these outcomes appear to have merit, as each fall event carries with it consequences for patients, their families and health care facilities, and each faller is a person from whom falls during their subacute hospitalisation may have had a negative impact on their life.
The proportion of patients who became recurrent fallers has also been employed in a few studies, however as discussed in section 1.4.3.14, there appears to be little grounds for conducting separate analyses for fallers and recurrent fallers. Fall without injury event rates have been used once, however the exclusion of injurious falls from this analysis is questionable and the authors did not justify why they decided to do this (Brady et al., 1993). The raw number of fall events was used for comparison in one study, however without adjustment for the relative periods of patient observation, these results can be misleading (Morse et al., 1988). The time to first fall was used as an outcome in one study, the merits of which will be discussed in the next section (1.10.3). Other unusual outcomes such as fall by bedside event rates and falls during the first week of hospitalisation have also been employed. One could question whether these falls are any more serious than other falls. However one study did justify the use of their outcome (falls by bedside) by stating that their intervention (bedrail policy) was most likely to influence these types of falls (Hanger et al., 1999).

Fall injuries and patients who experience a fall-related injury during their hospitalisation have also been selected as outcome measures in some studies. It is arguable that this aspect of falls is of high importance and should be considered in falls prevention studies. However, as discussed in sections 1.5.1 and 1.5.3, varying definitions of fall injuries and different ways of counting fall injuries can influence how this data appears. To prevent duplication of data (where a single fall leads to multiple injuries), it could be argued that each fall in which an injury occurred should be counted as one unit of data, and where of interest, the severity of that fall classified by the most serious injury sustained in that fall. These should also be considered as a rate using patient observation time as a denominator, in the same way that fall event rates are constructed. By considering also the proportion of patients who experience a fall-related injury during their stay, one has an analysis analogous to considering both fall event rates and the proportion of patients who became fallers in that both events and people are analysed. However, this should be only be viewed as one component of the total consequences of a fall to the patient, their family and the health care facility, as was discussed in section 1.6.
1.11.3 Statistical considerations - analysis techniques for outcome measures selected

In similarity to conducting hypothesis tests to determine if the association between risk factors and falls is unlikely to be due to chance (as discussed in 1.4.2), intervention studies must also demonstrate that differences in fall outcomes observed between groups are unlikely to be due to chance. Inappropriate use of statistical analysis techniques can lead to invalid conclusions regarding the nature of an association between falls prevention interventions and the selected outcome (Portney et al., 2000). Therefore it is of importance that before a study’s conclusion is accepted, the statistical analysis technique employed is scrutinised to identify any threats to the statistical conclusion validity of the article. The types of data that have been analysed in subacute hospital falls prevention intervention studies have been related to patients, events, and time.

1.11.3.1 Analysing patients (fallers, patients injured through falls)

When comparing the proportion of patients who became fallers between groups, no variance estimates or statistical analysis were presented in two studies (Oliver et al., 2002; Uden et al., 1999). As the differences between groups in both studies were not negligible, the opportunity to find a significant difference between groups may have been missed in both. The chi-square statistic was used in three (Foster et al., 1996; Grenier-Sennelier et al., 2002; Vassallo et al., 2004) with a multiple logistic regression also being used in one (Vassallo et al., 2004), and relative risks with 95% confidence intervals in one other (Donald et al., 2000). Chi-square and multiple logistic regression were also used to analyse the proportion of patients who experienced an injurious fall during hospitalisation in one study (Vassallo et al., 2004). Recurrent fallers were analysed using chi-square in two studies (Grenier-Sennelier et al., 2002; Vassallo et al., 2004), but the technique employed in one other was not stated (Oliver et al., 2002). For each of these outcomes the patient was the focus of the analysis and was classified under a dichotomous scale, namely, they were a faller or non-faller. Logistic regression, chi-square and relative risk analyses are all appropriate techniques for analysing these data (Portney et al., 2000).
1.11.3.2 Analysing events (falls, injurious falls)

Unlike the relatively straightforward manner in which “patient” focused outcome data can be analysed, analysing “events” is a more complicated process. Analysing raw numbers of events should take into account the relative periods of time over which they were observed to adjust for variances in patient observation periods. Raw numbers of falls during the first week of subacute hospitalisation (Rogers, 1994) and falls resulting in injury (Oliver et al., 2002) have been compared between groups with no variance estimates provided, although in the latter study, raw datum provided clearly indicated no difference between groups. Comparison of fall event rates has been presented with no variance estimates in two studies (Brady et al., 1993; Tuffnell, 1990), the analysis technique employed has not been identified in one (Oliver et al., 2002), a Mann-Whitney U test was used in one (Vassallo et al., 2004), chi-square in one (Grenier-Sennelier et al., 2002), and an unpaired t-test in another (Hanger et al., 1999). The other “event rate” datum examined has been fall by the bedside event rates, which was analysed using an unpaired t-test (Hanger et al., 1999).

The use of t-tests to establish if there is a difference in fall event rates between groups is problematic. The t-test is a parametric statistic that tests hypotheses based on the assumption that the samples come from populations that are normally distributed (Key, 2004). A difficulty with subacute hospital fall event rates data is that a majority of patients have no falls, introducing a severe skew into the data distribution. This data distribution would therefore be poorly approximated by the normal distribution. Hence a t-test is unlikely to be an appropriate tool for hypothesis testing of falls event rate datum.

Another approach used in historical control studies has been to pool falls data across a ward over time to produce normally distributed data (Dempsey, 2004; Hanger et al., 1999). The observations in this analysis become the number of falls on a ward over a specified time period. This approach is inappropriate for two reasons. First, the number of observations and degrees of freedom involved in the analysis can vary depending on the choice of length of time per observation period, producing different results when using the same data and statistical technique. Second, this approach
violates the assumption of independence of observations, a requirement that should be met for a t-test (Portney et al., 2000).

The chi-square statistic, although a non-parametric test, still has some restrictions that limit its use. Of importance when considering falls event rate data is the assumption that individual observations must be independent of each other (Key, 2004). If one were to use a one-way chi-square analysis to compare the number of fall events between two groups, one would use the formula:

\[
\chi^2 = \sum \frac{(\text{observed} - \text{expected})^2}{\text{expected}}
\]

Adapted from Portney and Watkins (2000)

In considering fall events, one would have to sum the total number of fall events in one group to calculate the number of observed fall events. In doing this, if one or more patients had more than one fall, then the data used to calculate this chi-square statistic would not be fully independent, thus violating one of the assumptions underpinning its use. Hence the use of the chi-square statistic to compare fall event rates between groups appears to be inappropriate.

The Mann-Whitney U test is another non-parametric approach to the analysis of fall event rates. In this technique, data from both groups are assigned a rank in order of their increasing size, which are then used to calculate the U statistic (Portney et al., 2000). The null hypothesis dictates that we would expect the mean of these ranks to be equal and any differences to have occurred by chance. A disadvantage of using this technique is that by ranking data, there is potential for some of it to be “lost”. To illustrate this I will now discuss the hypothetical data presented in figure 1.3. For simplicity, this figure presents only raw fall event data rather than fall event rates, however the concept discussed is equally applicable. The ranks presented for each subject in each comparison have been calculated following the procedure for ranking scores for non-parametric analysis (Portney et al., 2000). In comparison 1, there are 2.0 times as many falls in group 2 compared to group 1, yet the mean rank for scores
in group 1 is 10, compared to 11 for group 2. The resultant probability that the
number of falls for group 2 is greater than group 1 calculated using the Mann-
Whitney U is $p = 0.55$ [calculated using Stata version 8.0 software (StataCorp, 2003)].
In comparison 2, the difference between the data in this comparison and the first is
that subject 10 in group 1 had 11 falls instead of 4. As a result, group 2 has now only
had 1.18 times more falls than group 1, which is substantially lower than in
comparison 1. However, the ranks of this data have remained the same and the
resultant $p$-value calculated by the Mann-Whitney U test has remained at $p = 0.55$.
Thus it has been demonstrated that the Mann-Whitney U test may not appropriately
model falls and fall event rates as it converts them into ranks prior to analysis, making
its use for this data questionable. In defence of the Mann-Whitney U statistic, these
problems reduce as the size of the data set increases, the number of fallers increases,
and the range in number of falls per patient reduces, though even in these
circumstances it is unable to model differing exposure periods in patients who
experience no falls.

Analysing the time to a “first fall” has been the only other statistical analysis approach
to be used to analyse falls event rate data. This approach has been used widely in
medical literature in fields where recurrent events are of interest (Glynn et al., 2001).
Conceptually, the times from the start of participant observation until first fall/s in one
group are compared to those of another. Patients who do not fall can be appropriately
taken into account in such analyses, and are referred to as “right censored”
observations (Cleves et al., 2002). However, to generalise a result of a reduced rate
(or time until) first falls into a conclusion of a reduction in overall fall event rates is
difficult. It assumes that fall event rates are unrelated random events that will
continue at the same rate after the first fall for all subsequent falls. Some authors
have argued that individual patients may have different susceptibility for recurrent
events, and that they are rarely independent of each other in that the advent of one
event can affect the rate of subsequent events (Glynn et al., 1996). This indicates that
a conclusion drawn from such analyses should be restricted to first events and not
generalised to overall event rates. Conducting a “first fall” analysis is questionable
unless the author can justify why first falls are more important than other falls in their
particular study.
Figure 1.3. Hypothetical falls event data.

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Comparison 1

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Comparison 2

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A question confronting readers attempting to review literature on the minimisation of fall event rates on sub-acute hospital wards is how to interpret the findings of studies that have either included no statistical analysis or have used a questionable technique for their analysis. One could argue that the statistical conclusion validity of these articles has been compromised, and that the results should be discarded or written off as being background variation. However, this could be considered to be proverbially throwing the baby out with the bath-water. Instead, it is probably more prudent to consider the overall effect size reported, keeping in mind that without an accurate description of the probability of this result occurring by chance, less confidence can be placed upon these results. In contrast, reported approaches used to analyse the proportion of patients who became fallers during their hospitalisation have been more suitable, with greater confidence able to be placed upon these results due to the appropriate analysis of this data.

1.11.3.3 Number of analyses

Many studies have included multiple primary outcome measures in their analyses (Grenier-Sennelier et al., 2002; Hanger et al., 1999; Oliver et al., 2002; Vassallo et al., 2004). Conducting multiple comparison tests with the same alpha criterion level increases the probability of committing a type I error (rejecting the null hypothesis when the null hypothesis is true) over the entire analysis (Portney et al., 2000). Limiting an analysis to only one outcome measure would eliminate this problem. However it is often of interest to see if a falls prevention intervention can reduce falls, fallers and fall injuries. Often the effect of an intervention on other secondary outcome measures (such as length of stay, quality of life, functional independence) is also of interest. However if only one association was examined per study, much time, energy and public money would be wasted (Perneger, 1998). Thus in many circumstances, it would be inappropriate to restrict an analysis to only one of these outcome measures.

Bonferroni’s correction is a statistical adjustment that employs a familywise error rate that is dependent upon the number of planned comparisons, to reduce the risk of committing a type I error (Portney et al., 2000). Effectively this reduces the alpha criterion level for each comparison by the number of comparisons. As a consequence
however, the risk of committing a type II error (not rejecting the null hypothesis when the alternate hypothesis is true) is increased. It has been argued that type II errors are just as false as type I errors, and that the use of Bonferroni’s correction does not ensure a “prudent” interpretation of results (Perneger, 1998). Yet even opponents of the Bonferroni correction concede that it is appropriate in circumstances where: (i) a universal null hypothesis (that separate groups are identical on all variables considered) is of interest, (ii) where the same test is repeated in many subsamples, and (iii) when searching for significant differences without pre-established hypotheses (Perneger, 1998).

Should Bonferroni corrections be employed in subacute hospital falls prevention studies that make multiple comparisons? In falls prevention intervention studies, the universal null hypothesis is rarely of the same interest as the effect of the intervention on falls, fallers or fall injuries, indicating that Bonferroni corrections are not necessary. Pre-established hypotheses for multiple comparisons have also been presented, for example, authors of one study hypothesised that their bed-rail reduction policy may affect both falls in the bedroom and patient injuries from falls around the bed (Hanger et al., 1999). In studies of this nature where the multiple comparisons are driven by pre-specified hypotheses, the Bonferroni correction may not be necessary. Thus unless authors are searching for significant differences by completing the same test amongst many sub-samples without pre-specified hypotheses, the Bonferroni correction does not appear necessary. However, even when a Bonferroni correction could have been employed and was not, consideration should be given to whether the findings were likely to be “chance” findings or not by integrating prior clinical beliefs with the existing evidence base (Perneger, 1998).

1.11.4 Evidence of effectiveness of falls prevention interventions

Several falls prevention interventions have been investigated in the sub-acute setting (table 1.6). Although few interventions have been investigated in isolation (ie. most studies have investigated multiple interventions), the following discussion will consider each individually, followed by a discussion of the effectiveness of multiple (3 or more) compared to dual or single intervention programs.
1.11.4.1 Falls risk screening and falls risk factor assessment tools

Falls risk screening tools have been a component of the falls prevention intervention program in several studies (Brady et al., 1993; Foster et al., 1996; Grenier-Sennelier et al., 2002; Oliver et al., 2002; Sweeting, 1994; Tuffnell, 1990; Vassallo et al., 2004). Their use in isolation has not been investigated. They were linked to staff initiated falls prevention plans and checklists in all but one study (Grenier-Sennelier et al., 2002). The falls risk screening tools employed have been the Downton falls risk index (Vassallo et al., 2004), the Barbieri falls screening tool (Tuffnell, 1990), the Harrogate falls assessment chart (Sweeting, 1994), the STRATIFY (Oliver et al., 2002), and three local tools, two described (Brady et al., 1993; Foster et al., 1996) and one not (Grenier-Sennelier et al., 2002).

The success of programs that have utilised these tools have ranged from a 38% reduction (Tuffnell, 1990) to a 24% increase (Oliver et al., 2002) in fall event rates. Two studies had statistically significant increases in fall event rates (Oliver et al., 2002; Vassallo et al., 2004) although the statistical conclusion validity for these analyses in both studies was questionable (for reasons discussed in section 1.10.3.2). The evidence rating provided by these two studies were levels III 2 and III 3. In terms of minimising the number of fallers, the success of these programs has ranged from “no trend” (Grenier-Sennelier et al., 2002) to a significant 30% reduction (Vassallo et al., 2004). Only this latter study demonstrated a significant change, providing level III 2 evidence. If only significant findings were taken into account, a puzzling conclusion that programs which include a falls risk screening tool appear to reduce the risk of becoming a faller, yet increase the fall event rate, could be made. Given the conflicting results between and within individual studies, it is difficult to conclude that inclusion of falls risk screening tools in falls prevention programs has an effect on falls. As these tools conceptually add value to falls programs through accurate identification of fallers for the deployment of other interventions, it is possibly better to evaluate these tools in terms of their predictive accuracy, as in section 1.8.6. However, falls risk screening tools may still have a direct association to falls as nursing staff who complete a falls risk screen for a high risk patient may become
more aware of that patients risk of falling (Uden et al., 1999). This may consciously or subconsciously cause that staff member to provide additional care for that patient, lowering their risk of falling.

Introduction of a falls risk factor assessment tool has also been investigated in the subacute setting using a historical control group design (evidence level III 3) (Uden et al., 1999). This tool was designed as a stamp that staff could print into medical records to facilitate its use. Introduction of this intervention led to a 29% increase in the reported proportion of patients who became fallers (no statistical hypothesis testing presented). This evidence suggests that introduction of this falls risk factor assessment tool increased the risk of patients becoming fallers. However, authors of this study cited a higher proportion of injurious falls reported in the control group as evidence that introduction of the falls risk factor assessment tool led to more diligent recording of falls, particularly of non-injurious falls, among patients in the intervention group. The hypothesis that recording of fall-related injuries is more reliable than that of falls overall had earlier been proposed by another author (Morse, 1993), yet some evidence suggests that this is not the case (section 1.5.2).

1.11.4.2 Staff checklists / intervention plans

The content of intervention checklists and plans has varied from study to study, though not all have been fully described. Frequently they include items relating to the patient’s immediate environment (Brady et al., 1993; Foster et al., 1996; Sweeting, 1994; Uden et al., 1999), use of risk alert bracelets, stickers and signs (Brady et al., 1993; Foster et al., 1996), patient supervision (Foster et al., 1996; Uden et al., 1999), patient and family education (Brady et al., 1993; Foster et al., 1996; Sweeting, 1994; Uden et al., 1999), toileting (Foster et al., 1996; Sweeting, 1994), footwear (Foster et al., 1996; Sweeting, 1994), and the need for restraint (Foster et al., 1996; Sweeting, 1994). These checklists and plans have commonly been completed by nursing staff, however one study also included a checklist for medical staff (Oliver et al., 2002).

This intervention has not been evaluated in isolation, as in each study they have followed on from a falls risk screening tool. One could then consider this to be a joint (screening tool and checklist) intervention that has been investigated in isolation. It
has been unclear in many studies however, as to whether the interventions on the checklist were available prior to the commencement of use of the checklist. Thus even if the approach of analysing screening tools and checklists together as a joint intervention were used, the likely confounding contribution of “new” interventions on the checklist cannot be estimated. If a study was to document that the interventions listed on the checklist were available to the control group, then it would be clearer that the observed effect was due to the presence of the screening tool / checklist combination. A hypothesised mechanism of action would be through improved allocation of the available falls prevention resources, possibly by reminding staff of their availability or through directly linking the findings of the screening to specific interventions. However, as this level of clarity on the availability of interventions on the checklist to the control group has not been provided, the success of programs that included staff checklists or intervention plans should be considered to be the same as that for programs that included falls risk screening tools (section 1.10.4.1) in that it is unclear as to whether this intervention has an effect on falls.

Data pooled from four community based programs that evaluated the use of falls intervention prevention plans that have been related to falls risk screening and risk factor assessment tools has shown that this approach successfully reduces falls (Gillespie et al., 2004). This provides added justification for further investigation in this area, to see if the success of this approach will translate to the subacute setting.

Falls prevention checklists and plans often provide a means for clearly documenting and communicating to other staff members what falls prevention interventions have been implemented. This is an important function considering the litigious nature of many western societies, whereby a perceived failure in duty of care through insufficient documentation can lead to legal problems for hospital staff and administrators. Thus from a practical perspective, even if these checklists and plans had no effect on falls, they may still perform a valuable, indeed central, role in hospital based falls prevention programs.

1.11.4.3 Staff education
Unlike many community based intervention programs where health professionals may see patients infrequently during the intervention period, patients in the subacute setting are constantly surrounded by nursing, medical and allied health staff. Further to this, a patient’s ability to perform personal activities of daily living in this setting, for example, getting dressed, toileting, eating, may be more or less dependent upon hospital staff. Thus the extent to which hospital staff education may have an impact on the rate of falls is arguably greater in the subacute setting than in the community.

Hospital staff education programs have been a component of several falls prevention programs investigated (Hanger et al., 1999; Oliver et al., 2002; Sweeting, 1994; Tuffnell, 1990; Uden et al., 1999). The reported content of these programs has included the effects on patients of bedrail use (Hanger et al., 1999), alternatives to use of bedrails (Hanger et al., 1999), falls risk assessment (Uden et al., 1999), falls prevention interventions (Sweeting, 1994; Tuffnell, 1990; Uden et al., 1999), nurse care planning (Uden et al., 1999), and “pre-study” staff education (Oliver et al., 2002). The style of education has also varied, from discussion sessions (Uden et al., 1999) to provision of resource packs that act as “self-learning guides” (Sweeting, 1994; Tuffnell, 1990).

The direct effect of staff education on falls has not been evaluated in isolation. For a staff education program to be effective in reducing falls, it must not only be effective in translating its message into the clinical thought processes and practice of staff, but it must also be the “correct” message (i.e. it is of no benefit to effectively educate staff about the incorrect way to prevent falls). A majority of studies that have incorporated staff education have also included use of falls risk screening or falls risk factor assessment tools along with staff checklists and care plans (Oliver et al., 2002; Sweeting, 1994; Tuffnell, 1990; Uden et al., 1999). The success of these programs has varied. Two reported decreases in falls of 41% (raw number) (Sweeting, 1994) and 38% (event rate) (Tuffnell, 1990) but did not present further statistical analysis. One reported a 29% increase in the proportion of fallers with no further statistical analysis provided (Uden et al., 1999). Another reported a significant 24% increase in falls event rate, and a non-significant 11% reduction in fallers (Oliver et al., 2002). The only other study used their education program to assist in the implementation of a
new bedrail reduction policy, which led to a non-significant 16% increase in falls event rate (Hanger et al., 1999).

Several factors make forming a conclusion on the effectiveness of staff education in the prevention of falls difficult. First, only five studies of moderate design quality (level of evidence rating level III 3) have reported use of staff education. Only two studies reported results of hypothesis testing (Hanger et al., 1999; Oliver et al., 2002). Staff education has been one component of a multifactorial intervention program in these studies, and not examined in isolation. Results from different studies have not shown a consistent effect on falls. Last, the content and mode of delivery of these education programs has varied widely making it difficult to consider “staff education” across the literature as a homogenous approach. Thus it cannot be concluded that staff education has a clear effect on falls. Evaluation of secondary outcomes may provide some insight into the effect of the education in translating the message to staff. For example, following staff education on bedrail reduction in one study, a >50% reduction in bedrail use was noted (Hanger et al., 1999). It may have been that the education provided in this study was effective in informing staff of its message, yet it was the message itself that was not conducive to reducing falls.

1.11.4.4 Review of falls and those at high risk for falls

Reviewing falls, fallers and patients at high risk of falls has been a component in a moderate number of falls prevention programs (Grenier-Sennelier et al., 2002; Sweeting, 1994; Tuffnell, 1990; Vassallo et al., 2004). Review of individual falls, including identification of possible contributing factors and modification of care plans to reduce risk of similar falls recurring, have been included in three programs (Grenier-Sennelier et al., 2002; Sweeting, 1994; Tuffnell, 1990). The other approach was to have a dedicated, multidisciplinary falls case conference conducted weekly for discussion of patients’ falls risk factors and individualised management plans (Vassallo et al., 2004).

Some studies have indicated that patients who experience recurrent falls tend to experience similar types of falls and in similar locations (Gaebler, 1995; Morse et al., 1987). It would thus appear that attempting to analyse individual fall events for
contributing factors and implementing relevant strategies to address these factors would appear a logical approach to preventing fall recurrences. However, just having a review process in place does not necessarily mean that the fall will be accurately analysed or that appropriate interventions will be instituted. Two studies did incorporate a form of staff education along with post fall analysis in their overall program, which may have provided hospital staff with the appropriate education to perform an accurate post fall analysis (Sweeting, 1994; Tuffnell, 1990).

The effectiveness of post fall analysis has not been investigated in isolation. Programs that incorporated a post fall analysis resulted in a 41% reduction in falls (raw number) (Sweeting, 1994), and a 30% to 38% reduction in fall event rates (Grenier-Sennelier et al., 2002; Tuffnell, 1990). Interestingly, one of these studies also reported a significant 45% reduction in recurrent fallers (Grenier-Sennelier et al., 2002). This is perhaps the most valid outcome measure to describe the effectiveness of a post fall analysis as this intervention is unlikely to influence first fall event rates or who becomes a faller. Given this evidence, though in the context of the low quality of studies involved (all studies level III 3) and the absence of isolated investigation, it appears fair to conclude that post fall analysis may assist in reducing the rate of falls, particularly those of recurrent fallers.

In the study with the falls prevention case-conference, this intervention was a central component of the program investigated, though it too cannot be considered to have been investigated in isolation. This program led to a significant 7% increase in fall event rates, although this result had questionable statistical conclusion validity (as discussed in section 1.10.3.2) (Vassallo et al., 2004). Adjustment for length of stay in this study indicated that there was no significant effect of the intervention on fallers or recurrent fallers. It appears that weekly, multidisciplinary, falls prevention case-conferences do not assist in reducing falls.

**1.11.4.5 Falls risk alert items**

Falls risk alert bracelets placed on patients’ wrists (Brady et al., 1993; Mayo et al., 1994; Sweeting, 1994; Vassallo et al., 2004), labels stuck to medical files (Foster et al., 1996; Oliver et al., 2002) and signs on top of patient bed heads and outside rooms
(Brady et al., 1993) have all been used to raise patient awareness and staff awareness of patients with an elevated risk of falling. Each time that this intervention has been investigated, it has been deployed by a falls risk screening tool. Thus if one were considering its effectiveness as an intervention in the context of an entire sample of patients (not just those at high risk who were deemed appropriate for the intervention), it relies upon an accurate falls risk screening tool in order for it to be deployed to the appropriate patients.

In contrast to many other interventions investigated, falls risk alert bracelets have been the subject of isolated investigation. Patients with a “primary” risk factor for falls (admission diagnosis of stroke or ataxia, history of multiple falls, an episode of incontinence) were analysed in a randomised controlled trial design (level II evidence) (Mayo et al., 1994). However, interim analyses in this study indicated that the risk of first falls was elevated among patients receiving this intervention (hazard ratio (95% CI) = 1.34 (0.76, 2.38). This study was ceased prematurely by the authors after 134 patients were analysed (600 were initially intended to be recruited). Despite the difference between groups not being statistically significant at the point of the interim analysis, the authors maintained that there was “reasonable certainty” that the intervention was not beneficial and could no longer justify the costs of continuing the study (Mayo et al., 1994).

Other studies that have incorporated falls risk alert bracelets, labels and signs have not investigated these interventions in isolation and have been of lower quality in design (evidence level III 2 or lower) (Brady et al., 1993; Foster et al., 1996; Oliver et al., 2002; Sweeting, 1994; Vassallo et al., 2004). In all of these studies, the falls risk alert has been listed as a part of a larger intervention program, but it has been unclear if this intervention was available to members of the study control groups. If it was available to members of the control group, then it is arguably the new checklist or screening tool that has prompted the deployment of this intervention that was under investigation. Thus despite reported outcomes ranging between a 50% reduction in rate of falls without injury (Brady et al., 1993) and a significant 35% reduction in fallers (Foster et al., 1996) to a significant 24% increase in falls event rate (Oliver et al., 2002), little clear evidence has been generated from these trials in understanding the effectiveness of this intervention.
Considering the contrast in quality of studies that have investigated this intervention and the evidence they have presented, it must be concluded that the highest quality evidence available indicates that use of falls risk alert bands may increase the risk of falls. However it has been argued that although these patients may have had a greater proportion reported to have had a fall, they may not necessarily have had more falls. A potential consequence of wearing a falls risk alert band is that nurses caring for them become more diligent in reporting falls, and relatively less so for control group patients (Mayo et al., 1994). Other falls risk alert interventions such as labels stuck in histories and signs placed above bedheads and behind doors have little clear evidence that they have a beneficial effect on reducing falls. Due to their greater visibility for staff, it is possible that their primary mechanism of action is through raised staff awareness rather than raised patient awareness as with falls risk alert bracelets (Mayo et al., 1994). There is some evidence from isolated investigation of falls alert signs placed on patient’s doors in the acute setting that this intervention is a successful means for reducing falls (Zepp, 1991). This indicates that further research is required to determine if the effect of falls risk alert signs on falls in the subacute setting may be different to that of falls risk alert bracelets.

1.11.4.6 Patient / family member education

Education targeted at patients and family members has been incorporated into larger falls prevention programs investigated on three occasions (Brady et al., 1993; Grenier-Sennelier et al., 2002; Rogers, 1994). This has taken the form of discussion between nursing staff and patients (Brady et al., 1993; Rogers, 1994), and discussion between nursing staff, patients and family members (Grenier-Sennelier et al., 2002). The content of these discussions has been re-enforcement of recommended levels of assistance required, particularly for transferring and toileting (Rogers, 1994), re-enforcement of need to call for assistance (every four hours as necessary) (Brady et al., 1993), and discussion of risk of falls with emphasis on organisational aspects of daily activities (Grenier-Sennelier et al., 2002). In similarity to the staff education intervention, effectiveness of this intervention relies not only on the mode of information delivery being appropriate and effective for the target audience to take this information on board, but the information being conveyed must also be the
“correct” information that will be useful for the prevention of falls. As previous studies have found non-compliance with mobility instructions to be present in 58% and 71% of fall occasions (Nyberg et al., 1995; Rogers, 1994), it is likely that the education programs that have focused upon this area have selected an appropriate message.

One study has indicated that this intervention was investigated in isolation (Rogers, 1994). Authors of this study stated that “…a concerted staff effort took place to remind patients of the recommended levels of assistance…” using a historical control group study design (evidence level III 3). This led to a 20% reduction in falls during the first week of a patient’s hospitalisation over a 6 month period. However, this investigation took place while a broader falls prevention program was being implemented. Authors of this paper did not clarify if there was overlap between the time of the implementation of the broader falls prevention program and the control and intervention periods of the patient education intervention. Also of consideration was that no statistical analyses of this data were presented, a relatively obscure primary outcome measure (falls during first week of hospitalisation) was selected without specific justification, and no baseline characteristics of patients in each group were presented to determine if adjustments for inter-group variation in falls risk factors should have been made.

The remaining programs that have incorporated some form of patient / family education have reported successful outcomes. These were a 50% reduction in falls without injury (Brady et al., 1993) and a significant 30% reduction in falls event rate (Grenier-Sennelier et al., 2002). Both of these studies used historical control group designs (evidence level III 3) and did not present baseline characteristics of control and experimental groups for comparison. As it is unlikely that no patient / family education was provided to the control group of these two studies and the one discussed earlier, it is again unclear to determine if it was more the education program or the screening tool deploying this intervention that was responsible for the observed effect on falls.

Given that each of the three studies that have examined patient / family education as a part of their falls prevention program have demonstrated some success, it is likely that
this intervention may be useful in reducing falls. However due to the low quality of
evidence available, and the presence of other interventions confounding these
investigations, it cannot be said with much certainty that this intervention is
beneficial.

1.11.4.7 Flooring
The association between flooring type, falls and fall injuries has been the focus of two
studies in the sub-acute setting. The first has previously been described in section
1.4.4.8 (Healey, 1994). This study focused on the association between flooring and
experiencing a fall related injury. Although this study described a randomisation
process and use of a control group, the study was retrospective, the intervention was
not able to be manipulated by the researchers, and the randomisation was not that of
random allocation of patients to groups but random selection of incident reports. This
study is possibly best described as an exploratory study rather than an experimental
one. Its findings indicated that patients who fell on carpet were less likely to injure
themselves than those who fell on vinyl, which support findings from a study in the
residential care (nursing home) setting that falls on carpet resulted in a lower rate of
hip fracture (Simpson et al., 2004). However these findings may have poor
generalisability to other subacute settings due to the extremely high rate of reported
injury in comparison to other studies (discussed in section 1.5.5).

The second investigated the risk of becoming a faller on carpet compared to vinyl,
along with the effect of additional exercise versus no additional exercise in a 2x2
factorial randomised controlled trial (evidence level II) (Donald et al., 2000). This
study design is considered to enhance the generalisability of results by allowing the
effect of flooring type to be analysed over both levels of the additional exercise
intervention separately (interaction effects) and in combination (main effect) (Portney
et al., 2000). The main effect of carpet versus vinyl flooring was that the relative risk
of becoming a faller was 8.3 times higher on carpet (not significant) than on vinyl.
Statistical analyses of interaction effects were not presented in this study. Due to the
low proportion of fallers (n = 8) and of patients recruited (n = 54), these interaction
effects were unlikely to be significant. Given the particularly small sample size
involved, this failure to reject the null hypothesis (ie. no effect of flooring on falls) is uninformative.

Little can currently be concluded regarding the usefulness of carpet versus vinyl flooring for the prevention of falls and fall injury in the subacute setting. Even if the effect sizes reported in the two studies discussed were accepted, disregarding their methodological and statistical shortcomings, one would conclude that carpet, although safer to fall on from an injury perspective may be a causative factor for a greater number of falls. This would provide health administrators no clear direction as to whether they should place carpet or vinyl on their floors from a falls perspective.

1.11.4.8 Additional exercise

Therapeutic exercise through provision of physiotherapy services can be viewed as a common element of “rehabilitation interventions” identified in several definitions of subacute care (Lewin - VHI Inc, 1994). Conceptually, if it is assumed that therapeutic exercise is a standard component of subacute care, a perceived need for the provision of “additional exercise” as a part of a falls prevention program implies that “usual care” exercise undertaken is sub-optimal for the prevention of falls. Exercise prescription involves four broad principles; the mode (type) of exercise, frequency of participation, duration of each exercise session, and the intensity of each exercise session (Wilmore et al., 1994). To modify an exercise regimen, one or more of these principles must be addressed. Provision of “additional exercise” obviously implies that it is the frequency of exercise that is altered (increased), however depending on the nature of the exercises provided during these additional exercise sessions, the mode, intensity, and duration of these exercises may also be changed.

One study has examined the effect of exercise in addition to usual care exercise undertaken in reducing falls, using a 2x2 factorial randomised controlled trial design (evidence level II) (Donald et al., 2000). This additional exercise program consisted of a strengthening program for hip flexor and ankle dorsiflexor muscle groups. The exercises were performed twice daily, for three sets of ten repetitions of each exercise performed in sitting and with weights set at the “…maximum the patient could manage.” (Donald et al., 2000). Usual care exercise was described as one to two
sessions per day of function-based therapy (eg. transfers, walking exercises, dynamic balance) administered by a senior physiotherapist or physiotherapy assistant. This description implies that the types of exercises performed as a part of the additional exercises were not a component of the usual care exercise. Thus it appears that at least the frequency, mode and duration of the exercise program completed by the intervention group was different to that of the control group.

Eight of the 30 patients allocated to receive additional exercise were either considered too frail or refused to participate. It was not stated whether those who were willing and able to participate with the additional exercise were fully compliant. Patients receiving additional exercise in this study had approximately one fifth (not significant) the risk of becoming a faller. This analysis was similarly limited to that of the flooring factor investigated in this study (section 1.10.4.7) by the low number of patients recruited (n = 54). No difference in changes to ankle dorsiflexor strength and hip flexor strength were noted between the two groups, yet handgrip strength had significantly greater improvement for those receiving the additional therapy. As the additional exercises only focused on the hip flexor and ankle dorsiflexor muscle groups, there appears to be little physiological rationale for this observation, raising the possibility that it was a type I error.

It is impossible to firmly conclude that additional exercise has an effect on falls based on non-significant findings from one underpowered study (Donald et al., 2000). However, this study did demonstrate that 73% of patients involved were able to participate to some extent in an exercise program that was broader and more frequent than that provided under usual care. Thus, if nothing else, it does appear to be an intervention that can be integrated into the care routine of a reasonably high proportion of patients.

1.11.4.9 Restraint

There have been several types of restraint described in hospital and residential care literature, including mechanical restraint such as bedrails, patented leather and linen devices, pharmacological (medication) restraint, and covert restraint (chair selections, positioning of furniture, tucking bedclothes in too tight) (Arbesman et al., 1999;
Use of restraint in health care settings is a contentious issue. In favor of using restraint, previous authors have argued that nurses are more likely to be held liable for failing to restrain a patient who should have been restrained than vice versa, that this was especially so for patients who had fallen prior to the fall that led to the injury and that this represents a reasonable standard of care (Cohen et al., 1991; Fiesta, 1985). In contrast to this, recent reports have indicated that there have been more successful lawsuits in the United States of America as a result of morbidity caused by use of bedrails and restraints than from a failure to employ them. Furthermore, some forms of restraint have been directly implicated as a cause of patient mortality (Parker et al., 1997), and they have been cited as infringing the dignity and autonomy of patients (Oliver, 2002). Recently, some health care accreditation organisations have added their viewpoint to the debate, emphasising that restraint use in hospitals should be minimised (Boswell et al., 2001).

Prevention of falls has been reported as the reason for patients requiring restraint for 33% of restrained rehabilitation patients in one study (Mion et al., 1989a). But how successful is this intervention in preventing falls and fall injury? To address this, one would have to evaluate a form of restraint-free care to other forms of care that incorporate restraint. This has not been reported in subacute hospitals, however has received some attention in the residential care setting (Joanna, 2002). Rather, one subject of investigation has been a bedrail reduction policy (with an accompanying staff education program discussed in section 1.10.4.3) in a historical control group study (evidence level III 3) (Hanger et al., 1999). This policy “discouraged” the use of bedrails by requiring staff to document reasons and approval for use when required, conduct regular review of effectiveness, conduct regular monitoring and toileting of any patient for whom bedrails are employed, and to remove bedrails from any bed when not in use. A >50% reduction in the number of beds with bedrails attached, a 19% increase (not significant) in falls by the bedside, and a 45% (significant) reduction in the number of injurious falls followed the introduction of this policy. The authors of this study and subsequent authors who have reviewed this article have concluded that this bedrail reduction policy caused no significant change in the fall event rates and led to fewer serious injuries, bringing into question the use of bedrails for the prevention of falls (Hanger et al., 1999; Hill et al., 2000; Oliver, 2002).
Before this bed-rail reduction policy can be fully supported, there are four methodological concerns that require attention. First, although there was no statistically significant increase in the rate of falls by the bedside, it was unclear whether this study was sufficiently powered to detect the observed 19% increase. Second, the statistical test used on this data was a t-test, which has already been discussed as being inappropriate for analysing falls data (see section 1.10.3.2). Third, the only type of “serious injury” substantially reduced by this interventions was head injuries requiring neurological observations to be taken (27 in pre-intervention phase, 11 in post-intervention phase). This component of the operational definition of serious injury leaves a historical control group design study open to the potential bias of differing interpretations of what severity of head injury requires neurological observations to be taken. Other “serious injuries” remained relatively unchanged with three fractures and three hip pain (no fracture) injuries in both the pre and post intervention periods. Forth, the raw number of minor injuries was greater (not-significant) in the post-intervention period (43 to 60). Hence, more research is required to determine whether this bed-rail reduction policy is beneficial for the prevention of falls and their negative consequences.

Other studies to have included restraint in their falls prevention program, have included it on a nursing care plan or falls prevention checklist, but have not stated that the control group received more or less of this intervention than the intervention group (Brady et al., 1993; Foster et al., 1996; Vassallo et al., 2004). Thus no firm conclusions regarding the effectiveness of restraint in preventing falls and fall injury can be made from these studies.

1.11.4.10 Miscellaneous interventions

Several other interventions have been included in falls prevention programs investigated. These have included interdepartmental patient transportation protocols (Grenier-Sennelier et al., 2002; Sweeting, 1994), patient supervision (Foster et al., 1996), checking bedside environment (Brady et al., 1993; Foster et al., 1996), checking patient footwear (Foster et al., 1996), orienting patient (Foster et al., 1996), a toileting regimen (Foster et al., 1996), and bed alarms (Vassallo et al., 2004). None
have been investigated in isolation, the highest evidence rating from any of these studies is level III 2, and all were available to both control and experimental group patients with no evidence indicating that one group received a different amount than the other with the exception of the interdepartmental patient transportation protocols. No firm conclusions can be drawn regarding the effectiveness of these interventions from studies conducted in the subacute setting. This highlights that there are many interventions for which there has been little research to date that require investigation to determine whether they should play a role in falls prevention in the subacute setting. Other interventions that have not yet received any exposure in this setting, such as hip protectors and medication review protocols, may also be appropriate for investigation.

1.11.4.11 Findings from meta-analyses and systematic reviews

Several systematic reviews of the effectiveness of falls prevention interventions in the hospital setting have been reported (Evans et al., 1999; Gillespie et al., 2004; Hill et al., 2000; Kenny et al., 2001; Oliver et al., 2000). None have specifically examined the effectiveness of interventions in the subacute hospital setting. Despite this none have been able to conclude that there is sufficient evidence from randomised controlled trials in the hospital setting (acute and subacute) to support the use of either any single intervention or multifactorial intervention program strategy in the prevention of falls (Evans et al., 1999; Gillespie et al., 2004; Hill et al., 2000; Kenny et al., 2001; Oliver et al., 2000; Whedon et al., 1989). One randomised controlled trial of a bed alarm system did produce encouraging results however this trial was quite small (n = 70) (Tideiksaar et al., 1993). A meta-analysis that included studies with historical controls also found no significant effect on falls of education programs, equipment checks, falls risk alert labels or bracelets, bed alarms, physical restraint or nursing care plans / checklists were found (Oliver et al., 2000). These findings would not be surprising coming from the subacute setting alone, however when even the acute setting is considered, this absence of direction is considerable.
1.12 Summary: Falls prevention interventions in the subacute setting

Despite the numerous studies that have investigated the effectiveness and practical implementation of falls prevention interventions in the subacute setting, there appears to be no clear evidence of high quality supporting any interventions as being effective for the prevention of falls or fall injuries. Several different approaches have been trialed, most commonly incorporating a falls risk screening process followed by an intervention checklist or care plan protocol. Some evidence indicates that falls risk screening tool models based on hospital staff clinical judgement are of comparable accuracy to mathematical models, though higher levels of predictive accuracy have been reported for mathematical models when investigated in isolation. Little has been reported about the completion of falls risk screening tools by hospital staff in the clinical setting. Meta-analyses of results from studies investigating other falls prevention interventions have failed to identify any effective falls prevention interventions in the hospital setting. However it has been demonstrated that several interventions have been successfully incorporated into the “usual care” of subacute hospital wards.

Studies investigating falls prevention interventions in the subacute hospital setting have generally been of limited methodological quality. Only two randomised controlled trials have been reported, with small sample sizes and little reference to blinding of patients or hospital staff. Statistical procedures used to investigate the effect of an intervention on the outcome of fall event rates has also been questionable. Where multiple intervention programs have been implemented, little clarification about the availability of interventions contained in the program to control group patients has been provided. Overall, it is clear that further investigation is urgently required to establish the effectiveness of falls prevention interventions in the subacute setting using studies of high methodological quality.
1.13 General aims of thesis

This thesis aims to address the problem of falls and their negative outcomes in the subacute hospital setting. As has been discussed in this chapter, the current body of evidence in this field leaves clinicians and hospital administrators with little clear direction as to how the problem of falls in the subacute hospital setting should best be addressed. Thus there is a clear need to develop a falls prevention program that can be integrated into the subacute care setting, and that can also be investigated using a methodologically rigorous research design approach, such as the randomised controlled trial research design.

Thus the aims of this thesis are to:

1) Describe the development of a falls prevention program designed to be integrated into the subacute care setting.

2) Evaluate the accuracy and practical applicability of a falls risk screening tool used to deploy interventions as a part of the falls prevention program.

3) Evaluate the effectiveness of this program in minimising fall event rates, the proportion of patients who become fallers, and fall injury event rates using a methodologically rigorous research design approach.

4) Evaluate the effectiveness of this program on secondary outcome measures.

5) Evaluate the effectiveness of individual components of this program in minimising fall event rates, the proportion of patients who become fallers, and other secondary outcome measures.
Chapter 2: General methods
2.1 Introduction

The research program described in this thesis consists of two major studies to:

1) Evaluate the accuracy and clinical applicability of the Peter James Centre Falls Risk Assessment Tool (PJC-FRAT) in deploying interventions from the falls prevention program.

2) Examine the effectiveness of the falls prevention program in reducing fall event rates, the proportion of patient who become fallers, fall injury event rates, and its effect on other secondary outcome measures.

The contribution of data from these studies to each of the following chapters of this thesis is presented in figure 2.1. Study one used a prospective longitudinal cohort design, while study two was a randomised controlled trial that randomised individuals, not clusters.

This chapter outlines the general methodology of both studies. Specific methods will be described in each chapter. This chapter will also describe in detail the selection of interventions included in the falls prevention program and the construction of the PJC-FRAT.

Ethical approval for both studies conducted in this research program was granted by the Human Research Ethics Committee of the Peter James Centre in September 2001 (study one) and February 2002 (study two).

Terminology used in this thesis:

- Investigator – Author of thesis who collated and analysed data in study one, was involved in participant recruitment, deployment of interventions, measurement of secondary outcome measures, data collation and analysis in study two, and who designed the PJC-FRAT and the falls prevention program.

- Study supervisor – Thesis supervisor

- Research assistant – Assistant who was involved in participant recruitment and measured secondary outcome measures in study two.

- Research physiotherapist – Physiotherapist who was involved in participant recruitment and conducted the falls prevention program exercise program in study two.
• Research program – Two studies described in this thesis (studies one and two).
• Research occupational therapist – Occupational therapist who was involved in participant recruitment and conducted the falls prevention program education program in study two.
Figure 2.1. Distribution of data from studies one and two into chapters of this thesis.

<table>
<thead>
<tr>
<th>Study one: Predictive accuracy of the PJC-FRAT</th>
<th>Study two: Effectiveness of the falls prevention program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 3: Predictive accuracy of the Peter James Centre Falls Risk Assessment Tool</td>
<td>✓</td>
</tr>
<tr>
<td>Chapter 4: Predictive accuracy of the Peter James Centre Falls Risk Assessment Tool in comparison to a gold standard</td>
<td>✓</td>
</tr>
<tr>
<td>Chapter 5: Effectiveness of the targeted falls prevention program in the subacute hospital setting</td>
<td></td>
</tr>
<tr>
<td>Chapter 6: Effectiveness of the “additional exercise” intervention in reducing falls and improving balance, strength, and mobility amongst subacute hospital patients</td>
<td></td>
</tr>
<tr>
<td>Chapter 7: Effectiveness of the education program, falls risk alert card, patient / family member information brochure, and hip protectors in the prevention of falls amongst subacute hospital patients</td>
<td></td>
</tr>
<tr>
<td>Chapter 8: Summary</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ - Indicates that data from this study was used for analysis in this chapter.
2.2 Setting

The Peter James Centre was the setting for this research program. It is a metropolitan aged care hospital with three subacute (inpatient) care wards (98 beds), one aged psychiatry ward, one residential aged care (nursing home) ward, one dialysis unit and one community (outpatient) rehabilitation centre. This hospital is located in the eastern suburbs of Melbourne, Australia.

Usual care on the subacute care wards of this hospital includes assessment by medical, nursing, physiotherapy and occupational therapy staff members within 24 hours of admission. This is followed by weekly medical reviews (more frequent reviews provided where necessary), 24 hour nursing assistance, one hour sessions of occupational therapy and physiotherapy each weekday per week for each discipline, social work assessment and management, and input from other allied health staff (speech pathologists, dieticians, podiatrists) as required. Physiotherapists provide patients with an admission mobility assessment. Rehabilitation goals and mobility recommendations (for example, which gait aid a patient should use and how much assistance they require to mobilise) are formed at this time by members of the rehabilitation team in collaboration with the patient and / or their family members or carers. Physiotherapy and occupational therapy treatment sessions take place in specialised physiotherapy and occupational therapy department areas, separate from ward areas.

There was infrequent use of physical restraint equipment such as restraining belts or vests. Where this form of restraint was considered necessary by nursing staff, a medical review would be requested. The final decision as to whether a patient would be restrained in this manner or not rested with medical staff, however this would be in consultation with the patient’s family members / carers. Adjustable bedrails were present on every bed in the hospital, patients could request or decline their use. Where physical restraint equipment such as restraining belts or vests were being used when a patient was out of bed, bedrails were used when the patient remained in bed.
This description of usual care was formed by the investigator through personal experience from two years of employment as a physiotherapist on the subacute wards of the Peter James Centre, and through personal communication with department heads at the Peter James Centre (Lynch et al., 2003).

In 2001, the Peter James Centre successfully applied for a “Falls Prevention Program Grant” from the Victorian Department of Human Services, Aged Care Division. This grant was initially $50,000 for the financial year of 2001-2002. The investigator was appointed as Project Officer of this project commencing this position from October 2001. A steering committee of hospital administration representative, allied health department heads, nursing staff administration representative, medical staff administration representative, patient advocate representative, and a Department of Human Services representative oversaw and approved the use of this grant.

A supplementary grant of $15,000 from the Victorian Department of Human Services, Aged Care Division was successfully applied for by the investigator to be used at the Peter James Centre. Thus the total funds provided to the Peter James Centre was $65,000. Through negotiation with the Department of Human Services, Aged Care Division and the steering committee of the falls prevention project at the Peter James Centre, these funds were able to be used for the research program described in this thesis.
2.3 Participants

The participants in this research program are referred to using the term “patients” throughout this thesis. Patients were admitted to the subacute wards of the Peter James Centre primarily from acute hospitals in the surrounding area. Data from the 2001 national Australian census indicated that English was the predominant language spoken at home in this area (approximately 75% -80% of households in the catchment areas), followed by Chinese languages, Greek, and Italian (each less than 5%) (Australian Bureau of Statistics, 2004). Patients admitted required the level of care described under the International Subacute Healthcare Association definition of subacute care (International Subacute Healthcare Association Incorporated, 1994) discussed in section 1.2.

In study one, 122 patients were consecutively recruited from admissions to the subacute (inpatient) care wards of the Peter James Centre. They were recruited over a six week period commencing in November 2001. Patients could only be admitted to this study once (ie. if a patient had two or more admissions during this period, only their first admission was included). There was no other exclusion criteria.

In study two, consecutive patients admitted to the subacute (inpatient) care wards of the Peter James Centre were eligible to provide informed consent to participate in this study. Recruitment occurred over a 10 month period from the start of March until end of December 2002. A total of 626 patients were recruited to participate. Where subjects were assessed by medical staff as having impaired cognition (admission abbreviated mental test score of less than seven) or if there was a communication barrier that prevented clear explanation of the study, then a family member was approached to provide informed consent on the patient’s behalf. Informed consent was required to be provided in writing prior to patients being included in this study. There was no other exclusion criteria.
2.4 Measurements

Demographic, screening tool, primary and secondary outcome measurements collected in both studies are now presented. The chapters that present results from these measures are indicated. Measures used in only one study are discussed in the methods section of the chapter in which their data are presented.

2.4.1 Demographic information

Several demographic variables were collected. These data were available from admission medical staff assessment reports for all patients involved in the study except where specified. They are useful for considering the generalisability of results from these studies into other subacute hospitals, and for possible statistical adjustments during data analysis. Each measurement was routinely collected information recorded in patients’ medical records at the Peter James Centre.

2.4.1.1 Age (chapters 3 and 5)

Age may possibly have a curvilinear association with risk of a patient falling in the subacute setting (section 1.4.3.1).

2.4.1.2 Gender (chapters 3 and 5)

Male patients are more likely to fall in the subacute setting than female patients (section 1.4.3.2).

2.4.1.3 Primary admission diagnosis (chapters 3 and 5)

Various diagnose categories have been identified as having an association to falls in the subacute setting (section 1.4.3.11). The consultant geriatrician on each ward of the Peter James Centre determines and records in patients’ medical histories their primary admission diagnostic category. The categories available were specified by the VICREHAB classification system used by public hospitals in Victoria, Australia (Victorian Department of Human Services, 2002).

- Stroke
- Head injury
• Neurological
• Spinal cord
• Amputation of limb
• Arthritis
• Pain
• Orthopaedic conditions
• Cardiac
• Pulmonary
• Burns
• Musculoskeletal
• Major multiple trauma
• Other disabling impairment
• Other geriatric management

The category “elective joint replacement” was also used (previously a part of orthopaedic conditions) as it appeared to be unreasonable to group together patients of a generally healthy background (in that they were considered by an orthopaedic surgeon to be healthy enough to undergo elective joint replacement surgery), with those who have been admitted primarily following a fall related fracture.

2.4.1.4 Living arrangements prior to hospitalisation (chapters 3 and 5)

Living arrangements prior to hospital admission were categorised as:
• living at home alone
• living at home with a family member or carer
• living in a low level residential care facility (hostel)

This information has received little prior attention in hospital based falls prevention literature. It is required as a baseline for “discharge living arrangements”, a secondary outcome measure in study two. It is also be a “surrogate” measure of prior functional dependency may be related to falls in this setting.
2.4.1.5 Previous medical history (chapters 3 and 5)

Previous medical diagnoses of stroke, neoplasm, congestive heart failure, Parkinson’s disease, osteoporosis and fall related fracture were collected to describe the medical background of patients in these studies. These prior diagnoses have not received as much attention as admission diagnostic categories in subacute hospital falls prevention literature. Despite this they are global indicators of health prior to hospitalisation that may be related to falls or fall injuries in the subacute setting.

2.4.1.6 Cognitive impairment (chapters 3 and 5)

Cognitive impairment has been shown to be associated with an increased risk of a patient falling in the subacute setting (section 1.4.3.4). The Mini-Mental State Examination (MMSE) is a global indicator of cognitive function that was originally developed to differentiate organic from non-organic dementia in older people (Folstein et al., 1975). The test-retest reliability of this measure has been evaluated in many studies, where reliability coefficients have generally varied between 0.80 and 0.95 in both cognitively intact and impaired subjects (Tombaugh et al., 1992). For studies one and two of this thesis, a hospital occupational therapist conducted this assessment for all patients on the weekday following their admission, and recorded the result in patients’ medical records. This assessment scale as used by the Peter James Centre is displayed in appendix A, and has a scoring range between zero and 30 where higher scores represent better cognitive functioning. In previous research a score of less than 24 out of 30 on the Mini-Mental State Examination has been found to be indicative of cognitive impairment (Tombaugh et al., 1992).

2.4.1.7 Functional independence (chapters 3 and 5)

Reduced functional independence (or increased functional dependency) has been shown to be associated with increased of a patient falling in the subacute setting (section 1.4.3.6). The Barthel Index has previously been used to demonstrate this association (Mion et al., 1989b) and is a global measure of functional independence with personal activities of daily living and mobility (Mahoney et al., 1965). It is considered to have good face validity (Donaldson et al., 1973), and the inter-tester agreement of adjusted Barthel Index components has previously been reported as 97% using a direct observational approach in the hospital setting (Dorevitch et al., 1992).
The Barthel Index has been modified several times with several variations of the original index being tested for reliability and validity (Wade et al., 1988). The modified Barthel Index used by the Peter James Centre (appendix B) combines weighted scores from 12 categories to form a score range of zero to 100 with higher scores representing a greater level of functional independence. This version of the Barthel Index was prescribed by the Victorian Department of Human services for use as a part of the VICREHAB casemix funding system for Victorian public hospitals (Victorian Department of Human Services, 2002). Nursing, physiotherapy and occupational therapy staff completed sections of this assessment and entered the result into the patient’s medical record within 48 hours of patient admission.

2.4.1.8 Physical impairment (chapters 3, 5, and 6)

Physical impairment has been shown to be associated with increased risk of falling in the subacute setting (section 1.4.3.5). The “Timed Up and Go” test is a measure of mobility, independence with transfers, and balance. It is a modification of the “Get Up and Go” test in which a patient stands from a 45cm chair, walks three metres and returns to sit in the chair (Mathias et al., 1986). But in the modified test, this activity is timed. The Timed Up and Go test has been reported to have excellent intra-rater reliability (ICC = 0.99), inter-rater reliability (ICC = 0.99) and a moderate correlation (log transformed r = -0.81) with the Berg Balance Scale (Podsiadlo et al., 1991). This measure was conducted by the physiotherapist on the weekday following patient admission and was entered into patients’ medical records.
2.4.2 Falls risk screening tool

2.4.2.1 The Peter James Centre Falls Risk Assessment Tool (PJC-FRAT) (chapters 3 to 7)

This tool (appendix C) was developed by the investigator for the purpose of deploying the interventions of the falls prevention program investigated in study two. The principles underlying the construction of this tool are described in detail in section 2.5.4. The predictive accuracy of this tool is described in chapters 3 and 4 of this thesis. During studies one and two, individual patient’s PJC-FRAT was located in their medical record. Medical, nursing, occupational therapy and physiotherapy staff were involved in the completion of this document.

2.4.3 Primary outcome measures

Primary outcome measures recorded for both studies are described in this section. These data were routinely recorded and available for retrieval from patients’ medical records at the Peter James Centre.

2.4.3.1 Falls (chapters 3 to 7)

The definition of a fall used in this research program was:

“Any event when the patient unexpectedly came to rest on the ground, floor or another lower level” (Wolf et al., 1996).

This definition does not contain exclusion criteria that are difficult to apply in the hospital setting, such as those of the Kellogg falls definition (Kellogg International Working Group, 1987). It is inclusive of “assisted falls”, and like many other previously employed definitions, excludes incidents where patients purposefully place themselves on the ground (Cohen et al., 1991; Hanger et al., 1999; Morris et al., 1980; Oliver et al., 1997; Vlahov et al., 1990).

The procedure for documenting falls at the Peter James Centre was that following a fall, a fall related incident report needs to be completed either by a hospital staff member who witnessed the incident or the hospital staff member who was first to
arrive at the scene following the fall. A senior member of staff was to “witness” the incident report once completed. A copy of the report was then sent to the nursing administration office, the hospital administration office, and the original filed in the patient’s medical record.

Hospital falls incidents reports have the limitation of potentially providing an underestimation of the true number of falls, however are still the most widely used standard for measuring fall incidents in the hospital setting (section 1.3.2). Steps were taken prior to studies one and two to improve the reliability and validity of this falls measurement. This included discussion with hospital staff of the importance of recording fall incidents in pre-study education sessions and the provision of the standard definition of a fall used in this research program in writing to all hospital staff.

2.4.3.2 Fallers (chapters 3 to 7)
In this research program, a faller was defined as being any patient who experienced one or more falls (as measured using hospital fall incident reports and the definition of a fall described in section 2.3.3.1) during the time in which they were under observation. For study one, this meant that if a patient fell one or more times during their hospitalisation, they were considered to be a faller. For study two, if they fell one or more times following their consent to participate in the study during their subacute hospitalisation, they were considered to be a faller. Non-fallers for each study were all patients under observation who were not classified as being fallers.

2.4.3.3 Fall related injuries (chapters 5 and 7)
All patients who fell at the Peter James Centre during the research program were assessed by a medical staff member as soon as practicable following the fall. Any fall related injuries were recorded on the incident report along with any recommendations for radiological investigations, medical interventions or other future management plans.

For the purpose of analysing fall injuries in the research program, a four level classification scale (severe injury, moderate injury, minor injury or no injury) was
used. A fall with severe injury included falls that resulted in a fracture, confirmed by radiological investigation. A fall with moderate injury included falls that resulted in a laceration that required suturing, a head injury that required neurological observations to be taken, damage to dentures, or soft tissue injury for which a radiological investigation was ordered but no fracture found. A fall with minor injury included falls that resulted in a laceration that did not require suturing. A fall with no injury was a fall that did not involve any of the above injuries.

Using the above classification approach, a fall that results in multiple injuries is counted only once (avoiding duplication of data) and is classified by the most serious fall sustained. Falls that resulted only in mild pain or bruising were not included as falls with injury due to concerns with their reliability of recording. It is possible that minor bruising that existed prior to the fall may be falsely attributed to the fall in some cases, and in other. This is not the case for lacerations included under the definition of minor injury as fresh blood or serous ooze would provide evidence of the recency of this injury. Conversely, minor bruising may not have yet been evident when the medical staff member assessed the patient shortly after the fall. Cases where bruising or pain were moderate to severe were likely to have been referred for radiological investigation to rule out a fractured bone as the cause of the pain and bruising, thus falls resulting in these injuries were classified as being falls with moderate injury.
2.4.4 Secondary outcome measures
Secondary outcome measures recorded for both studies are described below. These data were routinely documented and available for collation from patients’ medical records at the Peter James Centre unless otherwise stated. Other secondary outcome measures not analysed in both studies are described in relevant chapters.

2.4.4.1 Discharge living arrangements (chapters 3 and 5)
Living arrangements following discharge from the subacute hospital were categorised as:
- living at home alone
- living at home with a family member or carer
- living in a low level residential care facility (hostel)
- living in a high level residential care facility (nursing home)
- transfer to an acute hospital
- deceased

This variable was examined as falls during hospitalisation have been associated with an increased risk of being discharged to a nursing home (Gaebler, 1995; Grenier-Sennelier et al., 2002).

2.4.4.2 Functional independence (chapters 3 and 5)
Functional independence upon discharge from the Peter James Centre was measured using the modified Barthel Index (described in section 2.4.1.7). Hospital nursing, physiotherapy, and occupational therapy staff recorded the results of this test within three days of a patient’s discharge in the same manner in which it was recorded when the patient was admitted. This information was collected as it has previously been argued that falling may prevent patients from realising their full rehabilitation potential in terms of functional independence (Teasell et al., 2002).

2.4.4.3 Physical impairment (chapters 3 and 5)
The Timed Up and Go test was used as it is a measure of mobility, independence with transfers, and balance (described in section 2.4.1.8). This test was administered by a hospital physiotherapist on the day of or day prior to patient discharge from the Peter
James Centre, and was administered in the same manner as at the patient’s admission. As with functional independence, this information was collected as it has previously been argued that falling may prevent patients from realising their full rehabilitation potential in terms of mobility and balance (Teasell et al., 2002).
2.5 Intervention (falls prevention program) procedure

The falls prevention program used as the intervention in study two will now be described. This falls prevention program was made up of five interventions, two of which were grouped into one intervention. The criteria used to select these interventions, a description of the falls prevention program model selected, followed by a detailed description of the interventions that met the selection criteria and how they were implemented in study two are now presented.

2.5.1 Selection criteria for falls prevention program interventions

One of the aims of this thesis was to evaluate the effectiveness of a falls prevention program in minimising fall event rates, the proportion of patients who become fallers, and fall injury event rates using a methodologically rigorous research design. Achieving this would increase the relatively small amount of evidence (level II or better) presently available on the effectiveness of falls prevention interventions in the subacute hospital setting. A randomised controlled trial research design, where patients are individually randomised to intervention or control groups, provides this level of evidence (National Health and Medical Research Council, 1998) and has been selected for evaluating the falls prevention program described in this chapter. Briefly, the reason for selecting a randomised controlled trial design instead of a “cluster” randomised controlled trial design (which could also be considered to provide level II evidence) is that the latter design faces the biases associated with parallel control group designs as discussed in section 1.11.1.2. The potential influence these biases may have on results could be lessened by having a large number of “clusters”.

Funding limited the project to the Peter James Centre, where there are only three wards at the Peter James Centre and thus only three “clusters” upon which ward based interventions could be implemented within this hospital. A randomised controlled trial study design with individual patient randomisation overcomes these biases, and therefore was selected. For this reason, the first intervention selection criteria was that interventions must be able to be provided to individual patients, and not on a “ward-by-ward” basis.
Undertaking research in the hospital setting is problematic as many falls prevention initiatives are already undertaken as a part of “usual care” in the hospital setting. For example, a nursing staff member assisting a patient with unsteady gait to the toilet could be considered a part of “usual care” in the subacute setting. Intuitively it is also a falls prevention intervention in that if they were not assisting the patient, the patient’s risk of falling would be increased. As was discussed in section 1.11.4.5, evaluation of interventions where patients in both the control and intervention groups have access to the intervention does not provide a clear indication of the effect of the intervention. In order to truly evaluate the effectiveness of such an intervention one would have to remove it from “usual care” for one group of patients and retain it for another. Offering a level of care less than “usual care” to this vulnerable population of patients may be considered unethical, as researchers are asking patients to participate in a study where they may be less safe than what they would be had they not participated in the study. Hospitals may also consider these interventions to be a core part of their service that are not able to be removed for research purposes.

One could counter-argue however that an intervention that is costly and hypothesised to provide little benefit needs to be removed from “usual care” in order to lower costs, justifying such a study. Such a study would aim to streamline the costs of providing subacute care without increasing the rate of adverse events, rather than addressing the topic of this thesis (ie. two similar topics but with different foci). Thus, such interventions will not be the focus of studies in this thesis, and the second intervention selection criteria was that interventions outside the “usual care” at the Peter James Centre be selected.

As this research program is trying to establish a model for preventing falls in subacute care, interventions will also be selected on the basis of expected efficacy. As there has been limited investigation of falls prevention interventions in the subacute setting, evidence of efficacy from other settings will also be taken into account. However, it must also be anticipated that these interventions will be able to be successfully incorporated in conjunction with “usual” subacute care.
Different falls prevention interventions have different amounts of financial cost associated with their implementation. Some interventions also take up less tangible resources in order to be implemented. An essential component of planning a research program is to consider the feasibility of the research being proposed (Portney et al., 2000). Thus interventions selected must be able to be investigated effectively within the financial constraints of the research program and implemented within the financial constraints of a program of subacute care.

A characteristic of subacute care is the intensive multidisciplinary input to patient care (American Subacute Care Association, 1994). This team approach allows hospital staff from different disciplines and backgrounds to each contribute expertise in their specific areas, for example, physiotherapists and occupational therapists may provide gait and functional task assessment and retraining respectively. Considering interventions that promote this team approach may promote the existing framework of subacute care, facilitating its integration with usual care.

In summary, general selection criteria for interventions to be included in the program were:

a) Intervention must be able to be deployed to individual patients
b) Intervention cannot be currently a part of “usual care” on participating subacute hospital wards
c) Intervention anticipated to be successfully integrated into “usual care” on participating subacute hospital wards
d) Intervention anticipated as likely to reduce falls or fall related injuries in the subacute setting
e) Intervention able to be effectively investigated given financial constraints of research program
f) Interventions to complement multidisciplinary team approach to subacute care

2.5.2 Falls prevention program model

There are many different possible “models” for the implementation of falls prevention interventions. One could implement a single intervention in isolation. One could then choose to provide that intervention to all patients, or just to a selected subset,
thus “targeting” the intervention. One could implement two interventions, both provided simultaneously, or in a 2 x 2 factorial design, a model that has previously been employed (Donald et al., 2000). Or one could implement a greater number of interventions, some or all of which may be targeted to selected subsets of patients.

Investigation of interventions in isolation provides an excellent evaluation of the contribution that this intervention may make to the prevention of falls if implemented in isolation. However they do not provide an indication of how the intervention behaves when implemented along with other interventions as a part of a larger program, which is perhaps a more clinically relevant picture. It is possible that some interventions may prove to be more or less effective when implemented with other interventions. Conversely, investigation of many interventions allows consideration of how well they combine in an overall program, and through intervention specific subgroup analyses, an indication of the effectiveness of an individual intervention can be gained. This picture may become clouded though with too many interventions being implemented producing a degree of overlap that does not allow a clear picture of an individual intervention’s effectiveness to be formed. Furthermore, if one is interested in the fastest development of understanding in this field, investigating multiple intervention models that allow individual intervention subgroup analyses may progress the understanding at a faster rate per study than conducting individual intervention studies. For these reasons, a multiple intervention model was selected.

One potential problem with multiple intervention models is that resources may be deployed to patients who are at low risk of falls. Similarly, many patients may not benefit from a specific intervention despite being at high risk of falls. For example, a patient who is at risk of falls due to their cognitive and balance impairments, yet has no foot problems, may not benefit from podiatry intervention whereas other patients with foot problems might. To minimise resource wastage, “blanket” provision of the interventions selected was not employed. Rather the interventions were selectively deployed to patients who were most likely to benefit from the intervention. This required that a falls risk screening tool, with specific links to the interventions involved needed to be employed.
Targeted multiple intervention programs have previously been used, aiming to prevent falls in the subacute hospital setting in studies using historical or parallel control group designs (Brady et al., 1993; Foster et al., 1996; Grenier-Sennelier et al., 2002; Oliver et al., 2002; Sweeting, 1994; Tuffnell, 1990; Vassallo et al., 2004). They have also been used to successfully reduce the incidence of falls in some studies in the community setting that have employed a randomised controlled trial design (Close et al., 1999; Fabacher et al., 1994; Lightbody et al., 2002; Tinetti et al., 1994). Similar programs have also been used successfully in the residential care setting, but evaluated using a cluster-randomised controlled trial approach (Becker et al., 2003; Jensen et al., 2002). Given the success of this approach in community based randomised controlled trials and those in the subacute setting of lesser methodological quality, there appears to be clear justification for the investigation of this model of falls prevention program in the subacute hospital setting using a randomised controlled trial design.

2.5.3 Falls prevention interventions

For each of the following interventions selected for inclusion in the falls prevention program, a description is provided of:

i) The intervention as it was employed in the research described in the latter chapters of this thesis

ii) How this intervention meets the selection criteria (section 2.5.1)

iii) Any particular issues relating to implementing this intervention specifically at the Peter James Centre

iv) The association between this intervention and others previously described that were included in the program

2.5.3.1 Falls prevention education program

i) The education program used in study two had a structured curriculum intended to be covered over four sessions. The booklet provided to patients (appendix D) served as a safety information resource for patients during and between education sessions. The curriculum consisted of:

a) A patient completed falls risk factor screening, allowing patients to identify their own falls risk factors
b) Information regarding to the nature of falls at the Peter James Centre, including potential consequences of falls, when falls occurred, where falls occurred, and why falls were considered to have occurred

c) General information on mechanisms of falls, including slips, trips, overbalancing, having legs give way, becoming dizzy or losing consciousness

d) Steps that patients could take to prevent falls, specifically relating to hospital organisational processes and general mechanisms of falls

e) A patient quiz containing questions relating to how, when, where and why patients have previously fallen at the Peter James Centre

f) A patient quiz of how patients hypothesise that they may fall, if they were to fall during their hospitalisation

g) Goal setting and selection of specific strategies to prevent future falls

h) Review of goals and compliance with strategies to prevent future falls

The information regarding the epidemiology of falls at the Peter James Centre was taken from a retrospective audit of fall incident reports over 6 months from July to December 2001 conducted by the author of this thesis. The methodology and finding of this audit are summarised in appendix E.

Education was provided at patients’ bedsides twice a week. The length of these sessions was at the discretion of the occupational therapist providing the education, but generally ranged from 15 to 35 minutes per session. The curriculum was intended to be covered over 4 sessions however, more sessions could be provided at the discretion of the research occupational therapist. These sessions were not intended to be didactic in nature, rather they were intended to facilitate discussion between the patient and the research occupational therapist. The program was initially intended to be inclusive of group discussion sessions facilitated by the research occupational therapist for up to four patients. However, there were rarely enough patients involved in the study at the same stage in the education process during study two to make this viable. The falls prevention education program and information booklet were designed by the investigator, who trained the research occupational therapist as to how the sessions were to be conducted prior to study commencement.
The content of discussion points was guided by concepts related to adherence to rehabilitation programs and behaviour change. The first concept was that of “threat appraisal”, which, for this thesis, relates to the perceived susceptibility to falls and severity of fall outcomes by patients. Threat appraisal has previously been identified as a motivating process in adherence to home based exercise programs (Taylor et al., 1996). Sections a), b), c), e), and f) of the education program above, each focused on the threat appraisal by patients of falls. These sections not only aimed to inform patients as to how frequently falls occurred, their consequences, how, where, when, and why they occurred, but also to assist the patient identify for themselves the specific risks that they faced personally. The intent was not to impose a fear of falling upon the patient, rather it was to assist the patient to appraise their own personal threat or risk of falls at an appropriate level.

Threat appraisal is the first step in a wider theoretical approach to promoting adherence referred to as Protection Motivation Theory (Maddux et al., 1983). In this theoretical framework, adherence is affected by threat appraisal, a perception of how likely the recommended course of action will reduce or prevent the threat, and an expectancy that the individual can perform the desired behaviour. Sections d), g), and h) of the above education program aimed to address the latter two components of the Protection Motivation Theory. The steps that patients can take to prevent falls under section d) were presented as straightforward instructions. These and other steps that patients could take to prevent falls are discussed and reviewed in sections g) and h). The foci of these sections were to enhance the patient’s expectancy that they would be able to take these steps and that they would enhance the patient’s safety.

Goal setting and review was involved in sections g) and h). This process involved the patient and research occupational therapist working together to set positive and realistic goals that were written down and kept where the patient could see them, similar to processes for sports injury rehabilitation previously advocated (Wiese et al., 1987). Provision of written material was intended to facilitate adherence, as this has previously been demonstrated to be beneficial for achieving behaviour change (Schneiders et al., 1998).
ii) This intervention did not preclude individual patient randomisation. Although falls prevention advice was provided to patients on an ad hoc basis at the Peter James Centre, “usual care” did not include the provision of any formal falls prevention education or literature to patients. Three previous subacute hospital falls prevention programs incorporating a patient education component have been integrated into usual subacute care procedures and have demonstrated some success in reducing falls (Brady et al., 1993; Grenier-Sennelier et al., 2002; Rogers, 1994).

The cost of implementing the patient education program (from the research program perspective) was the wage of the research occupational therapist providing the education, along with the cost of the education booklet provided. The research occupational therapist was paid at the grade II level (wage rate range at time of study: $23 to $27 AUD per hour) and was employed for 8 hours per week for the duration of the data collection period of study 2 (wage cost range = $8,832 to $10,368 AUD – based on 48 weeks of employment). The education booklet provided with this intervention was constructed from four pages of A4 sized paper, with information photocopied onto it (two sided) and stapled together. The estimated cost of producing each booklet was less than $2 AUD each. The overall cost of this intervention was considered to be reasonable given the overall research program budget.

Formal education provision has previously been a responsibility of occupational therapists at the Peter James Centre. Given that they also conduct cognitive screening assessments [the Mini-Mental State Examination (Folstein et al., 1975)] at the Peter James Centre, this cognitive / behavioural intervention was considered of greatest relevance to their discipline.

iii) An anticipated problem with implementing this intervention at the Peter James Centre was that patients were known to often be busy at physiotherapy, occupational therapy or other allied health treatment sessions. At times they may also have been out of the hospital at medical specialist’s review appointments. Thus it was anticipated that it would be difficult for the research occupational therapist to gain access to patients on all occasions. A daily patient program was produced at the Peter James Centre for each ward specifying when patients would be off the ward that day.
The research occupational therapist used this program to plan when they would visit each patient during their shift.

2.5.3.2 Family member / patient information brochure

i) The family member / patient information brochure used in this study (appendix F) contained similar information to that covered by the patient education program (section 2.5.3.1). In contrast to the patient education program, this resource also contained sections specifically targeted at family members and carers of the patient. The content of the falls prevention information brochure included:

a) The nature of falls at the Peter James Centre, including how frequently falls have occurred, potential consequences of falls, when falls occurred, where falls occurred, and why falls were felt to have occurred.

b) General information on mechanisms of falls, including slips, trips, overbalancing, having legs give way, becoming dizzy or losing consciousness.

c) Steps that patients could take to prevent falls, specifically relating to hospital organisational processes and general mechanisms of falls.

d) Steps that family members and carers could take to minimise the risk of falls for the patient in the subacute setting.

e) A checklist of safety steps for the family member or carer.

The content of this brochure was similar to that provided in the education program intervention and was selected for similar reasons (discussed in section 2.5.3.1). This intervention was intended to involve patient’s family members and other significant members of their social support in the falls prevention process. Previous investigations have found a positive association between rehabilitation adherence (sports injury programs) and social support (Wiese et al., 1991). This intervention was designed and produced by the investigator.

ii) This intervention did not preclude individual patient randomisation. Although falls prevention advice was provided to family members and patients on an ad hoc basis at the Peter James Centre, “usual care” did not include the provision of any falls prevention literature to patients, their family members or carers. Patient education has previously been integrated into usual care in the subacute setting (Brady et al., 1993;
Grenier-Sennelier et al., 2002; Rogers, 1994), however family member education has been described in only one study which did report a successful reduction in falls (Grenier-Sennelier et al., 2002). In this trial, staff discussed with patients and family members the risk of falls, with emphasis given to organisational aspects of daily activities.

The cost of employing this intervention (from the research program perspective) was limited to the costs of producing this document. The brochure used was constructed from three pages of A4 paper that had information photocopied onto them (2 sided), which were then stapled together. The estimated cost of producing each brochure was less than $2 AUD each, a negligible amount in the context of the research program budget. In the context of how this intervention could be implemented in the “real life” situation, it would appear to be an intervention that nursing staff could handout to at risk patients and their family, and provide follow-up answers to their questions. In study two however, it was the investigator who handed out this intervention to patients. The investigator did not provide follow-up to questions raised, though the brochure did encourage patients to discuss their safety with hospital staff.

iii) A foreseeable difficulty with using this intervention was that family members and carers may not see and subsequently read the information brochure. For this reason, the brochure cover was designed to grab the attention of family members. The cover was printed on pink paper to stand out from other brochures the patient may have received from the hospital. The words “Family members: PLEASE READ THIS with your relative who is staying with us at the Peter James Centre” were printed on the cover in large font sizes. When the brochure was provided to the patient, it was placed on top of the patient’s bedside table, not in a draw, and the patient was advised to read the brochure with their family members or carer when they came to visit. The brochure was also printed in large font sizes (as was the education program information booklet) in case the patient or family member / carer had mildly impaired vision.

iv) This intervention, along with the patient education program, formed the two arms of the education approach to the falls prevention program. The patient education program focused on the patient and took place in the context of a therapist to patient
association. It was a relatively resource intensive approach to providing this education. The falls prevention information brochure focused on both the patient and their family members or carers. This intervention took place in the context of a patient to family member or carer association and was relatively inexpensive. From the perspective of patient education, having a two tiered approach allows for an inexpensive intervention to be provided to a large number of patients, but also allows for more thorough yet resource intensive intervention to be selectively provided to a smaller number of patients. The falls prevention information brochure has the added advantage of involving family members and carers, who are a group of key stakeholders interested in patient safety. It would have been difficult for the falls prevention education program to involve this group as family members and carers tend to visit patients outside of regular working hours. Thus it would be difficult to have a dedicated research staff member consistently involve family members in this program during regular working hours. Alternately, hospital nursing staff could have provided the education, however, this would have ensured the unblinding of group allocation in the randomised controlled trial, and increased the risk of this education inadvertently being provided to control group patients’ families, diluting the observed intervention effect.

2.5.3.3 Falls risk alert card

i) The design of the card used in study two is included in appendix G. The central symbol of this design was a character used in the staff education program at the Peter James Centre called “UpRight Rodney”. This character was pictured to be falling over with a “no-entry” symbol (red circle with red diagonal line) placed over him indicating that falls are not allowed. This symbol was designed to be immediately recognisable by hospital staff but not readily recognisable by family members or patients, as it was also similar to “no smoking” (cigarettes) signs seen elsewhere around the hospital. A symbol immediately recognisable by patients and family members was not used as it may have been distressing to them and it could be considered to compromise the privacy of the patient. This falls risk alert card was designed and produced by the investigator.
ii) This intervention did not preclude individual patient randomisation and was not a part of usual care at the Peter James Centre. Falls risk alert systems have been frequently integrated into care provided in subacute settings (section 1.11.4.5). Some evidence from historical control group studies suggests that falls risk alert signs or labels may be effective in minimising falls (Brady et al., 1993; Foster et al., 1996), but a randomised controlled trial indicated that falls risk alert bracelets were not (Mayo et al., 1994).

The cost of this intervention (from the research program perspective) was limited to the materials used to produce the card. These materials were two pages of A4 sized paper, stuck together with an adhesive soft plastic covering. The estimated cost of producing each card was less than $2 AUD per card, which in the context of the research program budget, was negligible. Again, in the “real world” situation, this intervention would be of greatest relevance to nursing staff, as they enter patients’ rooms most frequently.

iii) At the Peter James Centre, each bed has a small board above their bedhead where signs of this nature were hung. For example, a “nil orally” sign could also be placed on this board for patients not allowed to eat or drink by mouth. Thus one concern for this intervention was that the falls risk alert card could become obscured by other signs. For this reason, the investigator pinned falls risk alert cards at the bottom of the notice-board, so that it would be difficult for other signs to obscure it from view.

iv) This intervention was a relatively low cost intervention, and therefore it could readily be applied to a large number of patients. One concern though would be that if too many patients received this intervention, it would no longer serve to highlight individuals with increased risk of falls. Although one could argue that all patients in a subacute hospital are at a high risk for falls, if every patient had a falls risk alert card, then no patients would be identified as being at higher risk than others.

2.5.3.4 Additional exercise program

i) The exercise program consisted of three 45 minute sessions per week conducted by the research physiotherapist in addition to regular physiotherapy provided by their
hospital physiotherapist. These sessions were conducted in a location away from the hospital physiotherapy department and away from the view of hospital physiotherapists. The exercises preformed incorporated therapeutic principles of Tai Chi (Wolf et al., 1993) combined with functional activities such as transferring from chair to chair, stepping, reaching and weight shifting. Modified forms of Tai Chi have previously been used in the rehabilitation of patients with acquired brain injury (Shapira et al., 2001). The exercises in the program were tailored to meet individual abilities of patients, however a 1:3 to 1:5 work to rest ratio was aimed to be achieved for all patients. A maximum number of four patients participated in an exercise class at any one time. A manual of exercises conducted is included as appendix H.

The additional exercise classes added to the overall frequency of exercise participation by patients. In the experience of the investigator, it also included exercises different to those included in usual care physiotherapy. Both of these factors may have contributed to a greater “overload” of patients, facilitating greater improvements in balance, leg strength and endurance (Wilmore et al., 1994). This exercise program was developed by the investigator, who educated the research physiotherapists prior to study commencement.

ii) This intervention did not preclude individual patient randomisation. By definition the additional exercise program was not a part of usual care. An additional exercise program has previously been integrated into subacute care (Donald et al., 2000), although it was recognised in this study that some patients were unwilling or too frail to participate. The exercise program investigated in that study could be considered to be less intense than the additional balance exercise program undertaken in study two, yet was still associated with a trend for reducing the risk of falling, providing reasonable evidence that this intervention had potential to be successful.

The cost of implementing the additional exercise program (from the research program perspective) was the wage of the research physiotherapist providing the education. The research physiotherapist was paid at the grade II level (wage rate range at time of study: $23 to $27 AUD per hour) and was employed for 12 hours per week (3 x 4 hour sessions) for the duration of the data collection period of study 2 (wage cost range = $13,248 to $15,552 AUD– based on 48 weeks of employment). The overall
cost of this intervention was considered to be reasonable given the overall research program budget.

Balance and lower limb strength exercise prescription was a responsibility of physiotherapists at the Peter James Centre. Given that they also conduct admission balance, strength and mobility assessments at the Peter James Centre, this exercise intervention was considered of greatest relevance to their discipline.

iii) As with the patient education program intervention, a foreseeable difficulty with implementing this intervention was that patients would be busy at alternate appointments as a part of usual care at the Peter James Centre. Unlike the education program, this intervention was an exercise group that meant that patients who were a part of that group had to be available at the same time. The research physiotherapist conducted three official sessions in each one of their shifts. One session was dedicated to each ward, although two of the wards were geographically located next to each other, allowing patients from either ward to participate in the other ward’s exercise session. These sessions were conducted at the same time on Monday, Wednesday and Friday afternoons, as these times would not interfere with weekly medical rounds on each ward. This also allowed hospital staff to be aware of the times that patients whom they recommended for this intervention could be participating in it, so that they could appropriately schedule their usual care physiotherapy session for the patient in on that day.

iv) From a practical perspective, both the patient education program and the additional exercise program were competing for patient time outside of regular therapy times for some patients. To minimise direct competition for this time, the research occupational therapist conducted their sessions on Tuesdays and Thursdays. Combining an exercise with an education intervention has previously been shown to be successful in reducing falls in the community setting (Hornbrook et al., 1994). This indicates that although these interventions had to be specifically arranged so that they did not directly compete for patient time, they can be successfully implemented in combination.
2.5.3.5 Hip protectors

Hip protectors are aids that have recently been the focus of considerable investigation for the prevention of fall related hip fracture (Parker et al., 2004). Most types of hip protector consist of specially designed underwear that contain pockets in which protective shields or foam pads are placed. Hip protectors that contain firm shields work on the concept of deflecting the force of a blow onto the lateral aspect of the hip away from the greater trochanter and into the surrounding soft tissues (Lauritzen, 1996). Hip protectors that contain foam pads work on the concept of shock absorption, attenuating the force of the impact before it is transmitted to the greater trochanter and neck of femur (Wiener et al., 2002). The hip protectors used in study two were those with firm shields. They were “Safehip” hip protectors with removable shields produced by Abena-Sanicare Limited.\(^1\) A picture of the hip protector used in study two is shown in appendix I.

ii) This intervention did not preclude individual participant randomisation and were not used as a part of usual care at the Peter James Centre. This intervention has been successfully integrated into usual care in residential care facilities (van Schoor et al., 2002). Pooled analysis of five individually randomised controlled trials evaluating the effectiveness of this intervention in preventing hip fracture in residential care facilities indicated that it did not result in a significant reduction in the incidence of hip fracture, though the effect size was a 17% reduction (Parker et al., 2004). Pooled results from five cluster randomised trials however did support the use of this intervention (Parker et al., 2004). Admittedly these results are conflicting, and the overall incidence of hip fracture is low in the hospital setting bringing into question the selection of this intervention. However, there is a great need to establish the effectiveness of interventions specifically targeted at preventing hip fracture as 70% of the total cost of hospital and residential care falls have been found to be attributable to hip fractures (Nurmi et al., 2002).

Acceptance of and compliance with wearing hip protectors has previously been identified as a problem. Initial acceptance by people in residential care facilities has

\(^1\) Abena –Sanicare Limited, Unit 4/1-7 Friars Road, Moorabbin, Victoria
ranged between 37% to 72%, and prolonged compliance among people initially accepting of wearing these items has ranged between 20% and 92% (van Schoor et al., 2002). Compliance with wearing these items has been as low as 5% in community dwelling older people following discharge from hospital (Hopper et al., 1999). Previous initiatives suggested to enhance compliance with use of hip protectors in the residential care setting include providing nurses with education (who then educate residents) (Meyer et al., 2003), and modification of the undergarments to make them more appealing to residents (Tracey et al., 1998).

The cost of this intervention (from the research program perspective) was $75 per pair of underwear with removable shields and $33 per pair of additional underwear without shields. A bulk purchase discount of 20% was negotiated with the hip protector company. Seventy pairs of varying sizes and gender styles with shields and an equivalent number of pairs without shields were purchased at the commencement of study two, with provision to purchase more as individual gender style and size stock levels ran low. This addressed infection control concerns by allowing each participant to have two pairs of underwear and one pair of shields so that these garments did not have to be shared. Thus the initial cost was $6,050. A further order of hip protectors was made towards the end of the data collection period, however only two pairs were required from this stock for study patients, the remainder were used for hospital patients following completion of the study, thus the total cost for purchasing this equipment was $6,140.

As nursing staff were responsible for assisting patients with their dressing and undressing on the ward, this intervention was considered to be of greatest relevance to this discipline.

iii) At the Peter James Centre, patients and their families were responsible for the washing of clothes, however a hospital based washing service was available at a cost. A foreseeable concern for this intervention was that if a family member took the garments home to wash and did not bring them back by the time the patient’s other garment required washing, then the patient would have to be allocated additional underwear. A washing machine was available at the Peter James Centre for the washing of these garments along with clothes washing detergent and clothes dryer.
Nursing staff members placed the soiled garments into a specially labeled container in the ward “bedpan” room. The investigator washed and dried the garments during study two. Each garment was able to be returned to the appropriate patient once dried through use of a labeling system where each pair of underwear was marked with a unique code, and the code of the underwear provided to each patient was recorded by the investigator. As the investigator did not require funding from the research project grant allocation and the other washing facilities were provided by the hospital, this process did not contribute any additional costs to the research program budget. However, staff time and effort spent maintaining and assisting patients to use this equipment should be included when considering the costs of this intervention from a societal perspective (Drummond et al., 1993). A notice (appendix J) was attached to the patient’s bedside cupboard door providing them and their families with information regarding the washing and use of the hip protectors.

iv) This intervention is best described as a “harm minimisation” intervention. It complements the other interventions included in this program which could be considered to primarily target the prevention of falls and then secondarily a reduction in fall injuries as mediated through a reduction in falls.

2.5.4 Falls risk screening tool – the PJC-FRAT

The interventions selected as a part of the falls prevention program investigated in study two could potentially be targeted to different groups of patients, yet with some overlap. The falls risk alert card and family member / patient information brochure could both be deployed to patients considered to be at high risk of falls. The hip protector was targeted to patients at high risk of fracturing their hip. The additional exercise program was targeted to patients at high risk of falling for whom impaired balance, leg strength or mobility were contributing risk factors, and who were considered by the hospital physiotherapist to be able to participate in a group exercise environment. The education program for patients at high risk of falling who would be suitable to receive such education (for example, patients not aggressive or agitated). Thus to deploy these interventions appropriately, the screening tool selected needs not only to measure falls risk, but also be sensitive to requirements specific to individual interventions.
The predictive accuracy of hospital staff clinical judgement has previously been demonstrated to be comparable to that of mathematical models in measuring falls risk (section 1.9.6). Additionally, using hospital staff clinical judgement would potentially provide flexibility to take into account the specific requirements of individual interventions, while eliminating the need for staff to complete sometimes complicated and abstract mathematical calculations. For these reasons, the falls risk screening tool model selected to deploy the falls prevention interventions was based primarily on the clinical judgement of hospital staff.

No existing tool which met the requirements for study two were identified in the published research literature. Therefore a new tool was specifically designed for this purpose. The tool was named the Peter James Centre Falls Risk Assessment Tool (PJC-FRAT) and is presented in appendix C. Using the terminology of this thesis, this tool does not clearly fit within the definitions adopted for this thesis of a falls risk screening tool or a falls risk factor assessment tool. Although the tool requires a measurement of generalized falls risk it does not clearly grade this (making it difficult to classify as a falls risk screening tool), and although interventions related to specific risk factors are identified (eg. the additional exercise program for balance impairment), potential benefit from the intervention is the criteria identified. Thus, in search of terminology to most adequately describe its function and properties, the phrase “falls prevention intervention deployment tool” may be most fitting. However due to requirements of the medical records department at the Peter James Centre, it was necessary to name this document as an assessment tool. The term “project officer” used in the PJC-FRAT referred to the investigator.

Both the falls risk alert card and family member / patient information brochure interventions were targeted by nursing staff to patients who they determined to be at high risk of falls. Nursing staff were selected as these interventions were considered to be of greatest relevance to this discipline. They were provided with the clinical decision making prompt of “Would this patient benefit from a falls risk alert card and patient information brochure in order to prevent falls at the Peter James Centre?” Combining the referral of these interventions was intended to reduce the amount of paperwork for nursing staff however it also meant that effectively they could only be
analysed as a single (combined) intervention. This decision was made early on in the research program, however upon later reflection, it may have been more appropriate to refer these interventions separately. The additional nursing staff time costs would have been minimal, and the family member / patient information brochure could have been targeted to a larger number of patients than the falls risk alert card without substantial negative consequence.

Deployment of the falls prevention education program intervention was the responsibility of hospital occupational therapy staff. Occupational therapists completed initial cognitive assessments at the Peter James Centre and were in a good position to determine if a patient who was at high risk for falls would also be suitable to receive this information. Patients who were aggressive, agitated, delirious, or unwilling to participate in therapeutic activities were generally deemed not to be suitable for this intervention, though the final decision was left with the hospital occupational therapists. A clinical decision making prompt of “Would this patient benefit from attending a falls prevention intervention program in order to prevent falls at the Peter James Centre?” was provided for this intervention.

The additional exercise program was deployed by hospital physiotherapy staff. Physiotherapists at the Peter James Centre completed mobility, strength and balance assessments for all patients, and were thus in a good position to determine if individual patients were at high risk of falls and that impaired balance, leg strength and mobility were a component of that elevated risk. Again, these therapists also had to determine if individual patients were suitable for this intervention. Patients who were unlikely to be able to participate in a group exercise environment for behavioural, cognitive or communicative reasons, and those who required physical assistance to stand from a chair were generally considered not to be suitable for this intervention, although the final decision rested with the hospital physiotherapists. A clinical decision making prompt was again provided, being “Would this patient benefit from attending a balance exercise program in order to prevent falls at the Peter James Centre?”.

In contrast to the falls risk alert card (with information brochure) intervention, the hip protectors were considered to be relatively more expensive per patient, and to have
substantial ongoing costs in terms of staff time completing laundering. Thus the potential to waste resources by over-recommending this intervention was greater than for the falls risk alert card intervention. The hip protector intervention had a dual mechanism for deployment. First, patients who experienced frequent unanticipated physiological falls (Morse et al., 1989a) such as syncope episodes, or “drop attacks” due to cerebral vascular occlusion would potentially receive little benefit from other interventions in this program. In the context of the overall falls prevention program, these patients would potentially have received little benefit from other interventions, so it appeared reasonable to target the hip protector intervention at this patient group.

Second, patients who displayed or who were strongly anticipated to display behaviour that was non-compliant with safety instructions were also targeted. Frequently these patients display some degree of confusion or delirium which could preclude them from participating in or limit the benefit they might receive from other interventions in the falls prevention program. This group of patients were also identified as being at particularly high risk of falls as not only has this behaviour been identified as a risk factor in previous literature (section 1.4.4.2), but this behaviour was being displayed by over 70% of patients who fell at the time of their fall from data gathered at the Peter James Centre (Appendix E). The deployment of this intervention depended on medical staff identifying if patients were at increased risk of unanticipated physiological falls or if any staff member witnessed or strongly suspected patient behaviour that was non-compliant with safety instructions. This latter criteria required that physiotherapy, occupational therapy and nursing staff members record what the prescribed levels of aids, assistance or supervision were with various activities that patients performed commonly on the wards. A modified version of the Functional Independence Measure (Linacre et al., 1994) rating scale was used for this purpose and was printed on the PJC-FRAT (appendix C). Thus this intervention was targeted at a group of patients who were considered to be at a very high risk of falls, and who may have received little benefit from other interventions offered in the falls prevention program.

The PJC-FRAT was intended to be completed on admission, with the intervention recommendations generated reviewed on an “as required” basis throughout a patient’s hospitalisation. This allowed staff to change the number or combination of falls prevention interventions recommended for a patient where appropriate. The PJC-
FRAT “amendment Sheet” (appendix C) facilitated this. Recommendations for the falls risk alert card with information brochure, exercise program and education program interventions could be made at any time using this review process. A recommendation for hip protectors could be made or taken away. The hip protector intervention could be taken away once provided as, in contrast to the other interventions, it was considered reasonable that the effect of this intervention would not persist once the patient was no longer considered suitable for it (for example, if a patient with delirium recovered good cognition).

In summary, the PJC-FRAT was designed to deploy the interventions of the falls prevention program. It primarily relied on the clinical judgement of hospital staff to make referrals for the interventions. It contained an “admission” sheet along with an “amendment” sheet so that changes to patient intervention recommendations could be made when required.
2.6 Statistical analyses

All statistical analyses were conducted using Intercooled Stata Version 8.0 (StataCorp, 2003) and Microsoft Excel Version 97 SR-2 (Microsoft Corporation, 1997).

A two tailed alpha significance criterion of 0.05 was used for all tests.

Data measured on continuous scales of measurement (interval or ratio) were examined for kurtosis and skew to identify potential violations of the assumption of normality of distribution using the Shapiro-Wilk test prior to use of parametric statistics based on the normal distribution. Non-parametric statistics were used to examine data measured on categorical scales of measurement (nominal or ordinal) and continuous data that was not normally distributed. Normally distributed continuous data were summarised using mean and standard deviation (SD) statistics. Continuous data not normally distributed were summarised using median and inter-quartile range statistics. Nominal data were presented as counts and percentages. Time until and between fall events were considered to be survival time data (Cleves et al., 2002).

Specific statistical analyses undertaken in each study will be detailed in relevant chapters.
Chapter 3: Predictive accuracy of the Peter James Centre Falls Risk Assessment Tool, with comparison to a gold standard.
3.1 Introduction

Use of clinical judgement to measure (or predict) a patient’s risk of falling during hospitalisation has received some attention in previous literature (Eagle et al., 1999; Izumi et al., 2002; Moore et al., 1996; Price et al., 1999). The results from these studies have been encouraging (section 1.9.6), forming a partial basis for the use of clinical judgement in the design of the PJC-FRAT. However, many questions remain as to whether this tool would be an appropriate mechanism for the deployment of interventions from the falls prevention program. Specifically this tool needed to be evaluated to see if it would lead to the deployment of falls prevention resources to those who require them, if it would do this without directing interventions to those who do not require them, and to see if it would be completed by hospital staff.

A determination as to whether the accuracy of the PJC-FRAT was acceptable could have been made through comparison with previous results from a “gold standard” alternate screening tool which could theoretically be used instead of the PJC-FRAT. However, to just compare the published accuracy of various tools when administered to separate patient samples would be inappropriate as there are subject-to-subject variations that cannot be controlled. This makes comparisons based on the same sample preferable for establishing relative superiority of one particular tool over another (Zou, 2001). Few studies have prospectively and concurrently administered alternative tools, and none have specifically focused on the PJC-FRAT. Thus to determine if the PJC-FRAT was an appropriate tool for the deployment of falls prevention interventions in the subacute setting, a direct comparison was required between the accuracy of the PJC-FRAT and that of a “gold standard” using the same patient sample.

3.1.1 Aims and hypotheses

The aims of the research described in this chapter are to:

- Evaluate the calibration of the PJC-FRAT.
- Evaluate the predictive accuracy of the PJC-FRAT.
- Determine if the calibration and accuracy of the PJC-FRAT are maintained over a prolonged period of time.
- Investigate the rate and speed of completion of the PJC-FRAT.
• Compare the predictive accuracy of the recommendation of the falls risk alert card intervention using the PJC-FRAT to that of a “gold standard”.
• Compare the predictive accuracy of recommendation of the hip protector intervention using the PJC-FRAT to that of a “gold standard”.
• To determine if the PJC-FRAT was an appropriate tool to deploy the interventions of the falls prevention program.

The hypotheses of the research described in this chapter are that:
• The predictive accuracy of the PJC-FRAT will be high and comparable to previous clinical judgement model falls risk screening tools.
• The predictive accuracy of the PJC-FRAT will be maintained over the course of a clinical trial.
• Hospital staff compliance with and speed of completion of the PJC-FRAT will be high and at least at levels equivalent to those previously reported.
• The predictive accuracy of the PJC-FRAT in deploying the falls risk alert card intervention would be superior to that of a “gold standard”.
• The predictive accuracy of the PJC-FRAT in deploying the hip protector intervention would be superior to that of a “gold standard”.
• The PJC-FRAT will be of sufficient accuracy to warrant its use in the deployment of interventions from the falls prevention program in the clinical setting.
3.2 Methods

3.2.1 Study design

The investigation of the PJC-FRAT described in this chapter took place in two phases. Data for phase one was generated from study one of the research program (the prospective longitudinal cohort), and data for phase two was generated from study two (the randomised controlled trial).

3.2.2 Participants

A general description of patients involved in phase one (n = 122) has been provided (section 2.3). Patients involved in phase two were those randomly allocated to the control group (n = 316) of study two. A general description of the patients involved in this study has been provided (section 2.3). Unlike patients involved in phase one, patients involved in phase two were required to provide written informed consent. For patients with cognitive impairment (abbreviated mental test score of less than seven out of ten), or with a communication impairment, a family member or carer were approached to provide consent on their behalf. A specific description of baseline characteristics of these patients has been provided in table 3.1.

3.2.3 Sample size

Given the exploratory nature of study one, no sample size target was set based on a specific power calculation. The median (IQ) size of studies reviewed that have investigated the predictive accuracy of falls risk screening tools in the subacute setting (table 1.5) was 138 (76 to 239) participants. The sample sizes of the two studies that have previously prospectively compared predictive accuracy statistics of two or more separate falls risk screening tools in the subacute setting have been 98 (Eagle et al., 1999), and 39 patients (Moore et al., 1996). Thus the sample size of 122 for phase one (comparison of two screening tools) was of reasonable size and greater than previous studies of this nature in this setting. The overall sample size [phases one and two combined (n = 438)] was substantial. The sample size of phase two was governed by a power analysis for the randomised controlled trial (chapter 5).
3.2.4 Screening tools

3.2.4.1 The PJC-FRAT

The design, content and construction of the PJC-FRAT has been described in section 2.5.4 and is included as appendix C of this thesis.

3.2.4.2 “Gold standard” – the STRATIFY

The STRATIFY (appendix L) was developed to identify older inpatients at high risk of falls. Further detail on the development and predictive accuracy of this tool has been described previously (section 1.9.6). In summary, the accuracy of this tool when initially prospectively validated [MSSS = 181% (Oliver et al., 1997)] has been the highest recorded accuracy of any screening tool that has been used to measure falls risk in the subacute setting. It is also one of the few tools to undergo secondary investigation (temporal and external validation studies). The nearest competitor for selection as a gold standard was the Morse Fall Scale (Morse et al., 1989b). This scale was initially validated retrospectively, yet its accuracy [MSSS = 161% (Morse et al., 1989b)] was less than that of the STRATIFY which was initially evaluated prospectively, thus lending greater external validity to the results of this latter study. For these reasons, the STRATIFY was selected as the “gold standard” falls risk screening instrument.

3.2.5 Blinding

Patients in both phases of this study were blinded to the PJC-FRAT recommendations made by hospital staff. As the hospital staff members who made PJC-FRAT recommendations for patients were the same as those who provided their care, it was not possible to blind hospital staff caring for patients as to their PJC-FRAT recommendations. Patients were also blind to both their STRATIFY “scores” recorded by the investigator. Hospital staff were blinded to patients’ STRATIFY scores as recorded by the investigator. The investigator, who recorded STRATIFY scores, collated data from patient histories and completed data analyses, was not blinded to PJC-FRAT or STRATIFY recommendations.
3.2.5 Procedure

3.2.5.1 Pre-study staff education

Prior to phase one, staff were provided with two separate half hour training sessions. The first session was an interactive discussion on falls risk factors in the sub-acute hospital setting and how staff can use their clinical judgement to gauge a patient’s falls risk. It was repeated 10 times during the first week of October 2001 during the day and at night so that night staff could have access to this education. A handout was provided to all staff attending (appendix K). This handout contained a list of several falls risk factors that were discussed during the first education session. During the discussion session, staff were asked to formulate ways in which these risk factors could directly contribute to a fall, and how various factors could combine to increase a patient’s risk of falling. In the second session, staff were instructed on how to use the PJC-FRAT. This session was repeated 10 times during the second week of October 2001. The investigator facilitated both education sessions. This education was provided to all new staff during their orientation to the hospital throughout phases one and two. Medical staff did not attend these sessions. In response, the investigator met with medical staff on an individual basis to discuss how falls risk factors could be used to help predict which patients are likely to fall, and to introduce the PJC-FRAT. These sessions lasted for approximately 15 minutes. When new junior medical staff commenced working at the Peter James Centre, these education sessions were repeated for the incoming junior medical staff by the investigator.

3.2.5.2 Introduction of the PJC-FRAT

The PJC-FRAT was introduced into medical histories of all patients newly admitted to the sub-acute wards of the Peter James Centre from the commencement of the third week of October 2001. Hospital staff were encouraged to discuss with the investigator any concerns or difficulties that they had in completing the PJC-FRAT from this point until the commencement of the data collection period of study one two weeks later.

Hospital nursing, physiotherapy, occupational therapy and medical staff were instructed to complete the “admission sheet” of the PJC-FRAT for every patient following their admission to the Peter James Centre. They were also instructed to
complete the “amendment sheet” on an “as required” basis. That is to say, that if staff felt that a patient’s condition changed such that they would now benefit from one of the interventions for which they previously had not been recommended, or that if they had previously been recommended for the hip protector intervention but now were thought to not require it, then the “amendment sheet” should be completed.

3.2.5.3 Participant flow

The recruitment of patients for phases one and two of this study was described previously (section 2.3). Figures 3.1 and 3.2 demonstrate the participant flow during both phases of this study.

3.2.5.4 Measurements

Baseline measures selected and the procedure for their recording were described in section 2.4.1. The outcome measures selected (falls and fallers) and the procedure for their recording have been described in section 2.4.3. These measures were collated by the investigator from patient medical records following their discharge from the Peter James Centre.

The compliance of staff members completing the PJC-FRAT was determined by whether each individual hospital staff discipline involved in completion of the PJC-FRAT did so for each patient. Thus, for each patient the compliance of medical, nursing, occupational therapy, and physiotherapy staff in completing the PJC-FRAT was individually recorded. The number of days between patient admission and completion of a discipline specific section of the PJC-FRAT was also recorded separately for each discipline.

STRATIFY scores were recorded by the investigator through interviews with nursing staff and reviewing patients’ medical records one the day of their admission, and then every seven days subsequent to that, as was the originally described process (Oliver et al., 1997).
Figure 3.1. Participant flow in phase one (study one).

122 admissions during the participant recruitment period.

All admissions eligible to participate

PJC-FRAT completed by hospital staff. STRATIFY completed by investigator through direct nursing staff interview and review of patient medical records.

Participants discharged from the Peter James Centre

Baseline, PJC-FRAT recommendations and outcome measures collated from medical history by the investigator following participant discharge from the Peter James Centre
Figure 3.2. Participant flow in phase two (control group of study two).

1040 admissions during the participant recruitment period.

47 previously enrolled in the study excluded
367 did not provide informed consent

Randomisation

310 intervention group participants
Data not included in phase two

316 control group participants
PJC-FRAT completed by hospital staff

Participants discharged from the Peter James Centre
Baseline, PJC-FRAT recommendations and outcome measures collated from medical history by the investigator following participant discharge from the Peter James Centre
3.2.5.5 Provision of “usual care”

Usual care, described in section 2.2, was provided to patients involved in phases one and two. Interventions included in the falls prevention program (section 2.5.3) were not provided, despite them being recommended through the PJC-FRAT. These interventions were not yet available during phase one, and during phase two, these patients had been allocated to the control group of a randomised controlled trial which received usual care alone. The absence of these interventions meant that predictive accuracy measures were not contaminated by effectiveness of these interventions.

3.2.6 Statistical analysis

The distribution of baseline characteristics of phase one and phase two patients were compared using chi-square tests for nominal data and unpaired t-tests (equal variance) for normally distributed continuous data.

Completion rates and speed of completion of the PJC-FRAT by hospital staff were compared between phases one and two. PJC-FRAT completion rates and frequencies of recommendation were compared between phases for individual disciplines using chi-square tests. Where significant differences existed, odds ratios were also calculated so that 95% confidence intervals could be presented (Altman, 1993). Speeds of completion were compared between phases for individual discipline using unpaired t-tests (equal variance). However, sample sizes and variances were unequal when comparing speed of PJC-FRAT completion between phases one and two by medical, nursing and physiotherapy staff (Levene’s test, p < 0.05). For these comparisons, unpaired t-tests (unequal variance) were used.

The calibration of the PJC-FRAT in identifying patients at risk for falls within each phase was evaluated by examining the difference in proportion of patients referred for recommendations and the proportion that became fallers using chi-square tests.

The outcome of the PJC-FRAT was considered to be a binary (yes/no) answer to four discrete questions, one for each intervention. The predictive accuracy of the PJC-FRAT was described using sensitivity and specificity statistics, and the sum of
sensitivity and specificity (SSS) for each intervention. The calculation of these statistics has been described in section 1.9.5 and demonstrated in figure 1.2. As was previously noted in these discussions, standard calculations of sensitivity and specificity are unable to be adapted to situations where there are repetitions of screening tool application. They are also unable to be adapted when the outcome of interest is a recurrent event, when there are delays in screening tool application, and when patients involved in the study are observed for unequal periods of time as each patient contributes only one unit of data to a 2x2 contingency table. Therefore, admission PJC-FRAT classifications only were used in analyses using standard calculations of sensitivity and specificity. Each patient was classified as being a faller or a non-faller. Fall recurrences were ignored along with unequal patient follow-up periods.

Variance estimates of sensitivity, specificity, and SSS were calculated using the bootstrap resampling approach (Efron et al., 1993). Bootstrap resampling is an approach for constructing variance estimates by randomly “resampling” the original data set with replacement. The first bootstrap “repetition” draws a sample of data from the original data set with replacement of data once drawn. The statistic is calculated from that first bootstrap sample and retained. The process then repeats itself, with the statistic being constructed from each bootstrapped sample of the data and retained. The distribution of these statistics drawn from the bootstrap replications is then used to construct the variance estimate of the original statistic. This approach is similar to the theoretical process that gives rise to the commonly used “standard error of the mean” statistic (Portney et al., 2000). The bootstrap approach to calculating variance estimates has been applied to sensitivity and specificity previously (Emir et al., 2000; Mossman, 1995).

To include information on multiple falls, use of the PJC-FRAT amendment sheet, delays in screening tool completion, and unequal follow-up periods, sensitivity$_{ER}^{ER}$, specificity$_{ER}^{ER}$, and their sum (SS$_{ER}^{ER}$S$_{ER}^{ER}$) were calculated (ER denotes event rate). Sensitivity$_{ER}^{ER}$ and specificity$_{ER}^{ER}$ are predictive accuracy statistics based on how effectively the screening tool predicts the falls event rate rather than proportion of patients who were fallers. Sensitivity$_{ER}^{ER}$ is the number of events (falls) by patients predicted to be event positive at the time of the event, divided by the total number of
events. Specificity$^{ER}$ is the period of participant time while predicted to be event negative, divided by the total amount of participant time. The calculation of these statistics is further illustrated in figure 3.3.

Calculating variance estimates for sensitivity$^{ER}$, specificity$^{ER}$, and SS$^{ER}$ was also undertaken using the bootstrap resampling approach (Efron et al., 1993). An important consideration when calculating variance estimates based on dependent data (where individuals contribute more than one unit in the dataset), is that standard approaches do not produce appropriately conservative variance estimates. For this reason, “robust” variance estimates have been recommended (Williams, 2000). The bootstrap approach to variance estimation has been demonstrated to produce results comparable to other “robust” approaches (Guan, 2003) and has been applied to other dependent data (Cowling et al., 1996). By resampling individuals and not events (thereby maintaining the dependence structure of this data) the confidence intervals constructed for sensitivity$^{ER}$, specificity$^{ER}$, and SS$^{ER}$ statistics were anticipated to be sufficiently conservative.

The accuracy of the PJC-FRAT in phase one was compared with phase two. Again bootstrap resampling techniques were used to test the null hypothesis of no difference in predictive accuracy between the two phases. Specifically this null hypothesis could be written as:

$$H_0: \text{[PJC-FRAT accuracy (phase one)]} = \text{[PJC-FRAT accuracy (phase two)]}$$

However the presentation of this hypothesis as:

$$H_0: \text{[PJC-FRAT accuracy (phase one)]} - \text{[PJC-FRAT accuracy (phase two)]} = 0$$

more accurately represents how the bootstrap approach was used to compare the predictive accuracy of the PJC-FRAT in the two study phases. For each phase, a statistic was selected to represent the accuracy deployment of one of the PJC-FRAT interventions. This same statistic from phase two was subtracted from that of phase one. The 95% confidence intervals of this difference were then used to test the null hypothesis. These confidence intervals were constructed by creating 2000 bootstrap
replications of the original sample size as this number has previously been advocated for hypothesis testing (Efron et al., 1993). Where the 95% confidence intervals of [PJC-FRAT accuracy \text{(phase one)}] – [PJC-FRAT accuracy \text{(phase two)}] did not include the value zero, then the null hypothesis of no difference was rejected. Comparing predictive accuracy statistics using bootstrap resampling in the manner described above has previously been described (Mossman, 1995).

The accuracy of the PJC-FRAT (falls risk alert card and hip protector interventions) expressed in terms of SSS and SS\text{ERS} was compared directly to that of the STRATIFY (prospective cut off of ≥ 2 out of 5). Theses statistics were chosen to compare the screening tools in preference to area under the receiver operating characteristic curve statistic as this latter approach has been shown to bias towards screening tools that have multiple possible outcome scores over screening tools that have binary outcomes (Beam et al., 1991). A prospectively selected cut-off of ≥ 2 out of 5 was chosen as the decision making point to indicate high falls risk using the STRATIFY tool. Previous studies have confirmed this point for maximising the SSS of the STRATIFY (Coker et al., 2003; Oliver et al., 1997). The null hypotheses for these comparisons were:

\begin{align*}
H_0: \ [\text{SSS (PJC-FRAT falls risk alert card)}] – [\text{SSS (STRATIFY ≥ 2 / 5)}] &= 0 \\
H_0: \ [\text{SSS (PJC-FRAT hip protector)}] – [\text{SSS (STRATIFY ≥ 2 / 5)}] &= 0 \\
H_0: \ [\text{SS\text{ERS} (PJC-FRAT falls risk alert card)}] – [\text{SS\text{ERS} (STRATIFY ≥ 2 / 5)}] &= 0 \\
H_0: \ [\text{SS\text{ERS} (PJC-FRAT hip protector)}] – [\text{SS\text{ERS} (STRATIFY ≥ 2 / 5)}] &= 0
\end{align*}

Bootstrap resampling was used to test these null hypotheses of no difference in predictive accuracy between the two screening tools. A “difference” statistic for each of the four comparisons stated above was calculated for each bootstrap replication of the original data set. A total of 2000 bootstrap repetitions were performed from which 95% confidence intervals were constructed. Where the 95% confidence intervals of a difference statistic did not include the value zero, this difference was considered statistically significant.

Two bootstrap resampling procedures were used to calculate the 95% confidence intervals for each statistic included in these analyses (one bootstrap resampling
procedure for comparing phase one and phase two PJC-FRAT results, another for comparing PJC-FRAT and STRATIFY results from phase one). Stata version 8.0 software was used for these calculations. The Stata “do” files used to generate these statistics were written by the investigator and can be viewed in appendices M and N.
Figure 3.3. Calculation of sensitivity\(^{ER}\) and specificity\(^{ER}\) from two 1 x 2 tables.

Table 1: Number of events of condition of interest

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>In those predicted</td>
<td></td>
</tr>
<tr>
<td>to be event positive</td>
<td>A</td>
</tr>
<tr>
<td>In those predicted</td>
<td></td>
</tr>
<tr>
<td>to be event negative</td>
<td>B</td>
</tr>
</tbody>
</table>

Table 2: Period of patient observed time

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>While predicted to</td>
</tr>
<tr>
<td>be event positive</td>
</tr>
<tr>
<td>While predicted to</td>
</tr>
<tr>
<td>be event negative</td>
</tr>
</tbody>
</table>

\[ \text{Sensitivity}^{ER} = \frac{A}{A + B} \]
\[ \text{Specificity}^{ER} = \frac{D}{D + C} \]

\[ \text{Sum of sensitivity}^{ER} \text{ and specificity}^{ER} = \frac{A}{A + B} + \frac{D}{D + C} \]
3.3 Results

Demographic characteristics of the two samples along with completion rates of the PJC-FRAT are presented in table 3.1. No statistically significant differences were found in these variables between phases one and two (table 3.1). For completion of the PJC-FRAT, lowest completion rates were evident for medical staff (59% and 57%), whereas completion rates were greater than 80% for other staff. Ten patients (8%) in phase one and 24 (8%) in phase two had PJC-FRAT reviews completed during their sub-acute hospitalisation. Length of delays in PJC-FRAT completion were comparable between phases.

In phase one (n=122), a total of 59 falls were recorded during 4004 patient-days (15 falls per 1,000 patient-days). Twenty-six (21%) were fallers. In phase 2 (n=316), 149 falls were observed during 9239 patient-days (16 falls per 1,000 patient-days), with 71 participants (22%) being fallers.

Assessment outcomes for the PJC-FRAT (phase one), STRATIFY (phase one) and PJC-FRAT (phase two) are reported in table 3.2. Frequency of recommendations for PJC-FRAT interventions were slightly higher across all interventions in phase 2 compared with phase 1, and were significantly higher (Chi-square p<0.05) for admission recommendations to the exercise [odds ratio (95% CI): 1.77 (1.01, 3.11)] and hip protector interventions [odds ratio [95% CI]: 1.83 (1.04, 3.21)]. Calibration testing of the PJC-FRAT indicated that in both phases, the proportion of patients who were recommended for the falls risk alert card and education program interventions were greater than the proportion of patients who fell (Chi-square: p < 0.05).

Sensitivity, specificity, SSS, sensitivity$^{ER}$, specificity$^{ER}$, and SS$^{ER}$S$^{ER}$ statistics along with their 95% confidence intervals for individual PJC-FRAT intervention recommendations for both phases are presented in table 3.3. The highest SSS value was obtained for the PJC-FRAT for the falls risk alert card recommendation [SSS = 148 (127 – 167)] in phase one. The SS$^{ER}$S$^{ER}$ which provides the more valid estimate of diagnostic accuracy of fall event rates, was also highest for this recommendation [SS$^{ER}$S$^{ER}$ = 141 (128 – 154)].
The difference in accuracy between phase one and two PJC-FRAT intervention recommendations are presented in table 3.4. The reduction in accuracy of falls risk alert card recommendation between phases one and two was significant using SS\textsuperscript{ER}S\textsuperscript{ER} statistics [phase one – phase two SS\textsuperscript{ER}S\textsuperscript{ER} (95%CI) = 17% (2%, 24%)], but was not when using SSS statistics [phase one – phase two SSS (95% CI) = 25% (-1%, 47%)].

Sensitivity, specificity, SSS, sensitivity\textsuperscript{ER}, specificity\textsuperscript{ER}, and SS\textsuperscript{ER}S\textsuperscript{ER} statistics along with their 95% confidence intervals for potential STRATIFY cut-off points are presented in table 3.3. These results indicate that the prospectively selected “≥ 2 out of 5 to indicate high falls risk” cut-off point for the STRATIFY was the most accurate cut-off point able to be selected for this tool both in terms of SSS and SS\textsuperscript{ER}S\textsuperscript{ER}.

Results of the direct comparison of SSS and SS\textsuperscript{ER}S\textsuperscript{ER} statistics between the PJC-FRAT and the STRATIFY are presented in table 3.5. These results indicated that there was a trend for superior predictive accuracy of hospital nursing staff through use of the PJC-FRAT in recommending the falls risk alert card intervention than that of the STRATIFY in terms of both SSS and SS\textsuperscript{ER}S\textsuperscript{ER}. The 95% confidence intervals of these difference statistics did not exclude the value zero however, thus the null hypothesis for these comparisons was not rejected. No significant difference was present either when the accuracy of recommendation for the hip protector intervention was compared to that of the STRATIFY.
Table 3.1. Baseline characteristics and PJC-FRAT completion rates.

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 (n = 122)</th>
<th>Phase 2 (n = 316)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>80 (73.75, 86)</td>
<td>81 (75, 86)</td>
</tr>
<tr>
<td>Gender – male (n)</td>
<td>38 (31%)</td>
<td>105 (33%)</td>
</tr>
<tr>
<td>Modified Barthel Index (0-100)*</td>
<td>44.5 (37, 58.25)</td>
<td>47 (37, 57)</td>
</tr>
<tr>
<td>Mini-mental state examination (0-30)*,†</td>
<td>23.5 (19, 28)</td>
<td>25 (20, 27)</td>
</tr>
<tr>
<td>Primary admission diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>18 (15%)</td>
<td>40 (13%)</td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>30 (25%)</td>
<td>95 (30%)</td>
</tr>
<tr>
<td>Other geriatric management</td>
<td>30 (25%)</td>
<td>53 (17%)</td>
</tr>
<tr>
<td>Days from admission to completion of discipline specific PJC-FRAT section</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>0 (0, 2.75)</td>
<td>3 (0, 5)</td>
</tr>
<tr>
<td>Nursing</td>
<td>0 (0, 0)</td>
<td>0 (0, 0)</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>3 (2, 5)</td>
<td>3 (1.75, 5)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>0 (0, 0)</td>
<td>0 (0, 0)</td>
</tr>
<tr>
<td>Number of discipline specific PJC-FRAT sections completed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>72 (59%)</td>
<td>178 (57%)</td>
</tr>
<tr>
<td>Nursing</td>
<td>116 (95%)</td>
<td>284 (90%)</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>100 (82%)</td>
<td>276 (87%)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>118 (97%)</td>
<td>302 (96%)</td>
</tr>
</tbody>
</table>

Scores are median (interquartile range) or absolute number (percentage).

* - Higher score better
† - 6 missing values phase 1, 13 missing values phase 2, imputed using best subset regression (StataCorp, 2001).
Table 3.2. Number of patients, fallers, patient-days and falls identified by PJC-FRAT and STRATIFY in both study phases.

In phase 1; patients (n) = 122, fallers (n) = 26, days (n) = 4004 and falls (n) = 59.
In phase 2; patients (n) = 316, fallers (n) = 71, days (n) = 9239, and falls (n) = 149.

<table>
<thead>
<tr>
<th>Patients*</th>
<th>Fallers†</th>
<th>Days‡</th>
<th>Falls¶</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (% of patients in phase)</td>
<td>n (% of fallers in phase)</td>
<td>n (% of days in phase)</td>
<td>n (% of falls in phase)</td>
</tr>
<tr>
<td><strong>Phase 1: PJC-FRAT recommendations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falls Risk Alert Card</td>
<td>43 (35%)</td>
<td>19 (73%)</td>
<td>1798 (45%)</td>
</tr>
<tr>
<td>Exercise program</td>
<td>18 (15%)</td>
<td>3 (12%)</td>
<td>600 (15%)</td>
</tr>
<tr>
<td>Education program</td>
<td>38 (31%)</td>
<td>7 (27%)</td>
<td>1145 (29%)</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>18 (15%)</td>
<td>7 (27%)</td>
<td>753 (19%)</td>
</tr>
<tr>
<td><strong>Phase 1: STRATIFY classifications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1 / 5</td>
<td>102 (84%)</td>
<td>25 (96%)</td>
<td>3134 (78%)</td>
</tr>
<tr>
<td>≥ 2 / 5</td>
<td>66 (54%)</td>
<td>20 (77%)</td>
<td>1630 (41%)</td>
</tr>
<tr>
<td>≥ 3 / 5</td>
<td>28 (23%)</td>
<td>9 (35%)</td>
<td>644 (16%)</td>
</tr>
<tr>
<td>≥ 4 / 5</td>
<td>22 (18%)</td>
<td>0 (0%)</td>
<td>190 (5%)</td>
</tr>
<tr>
<td><strong>Phase 2: PJC-FRAT recommendations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falls Risk Alert Card</td>
<td>125 (40%)</td>
<td>41 (58%)</td>
<td>4359 (47%)</td>
</tr>
<tr>
<td>Exercise program</td>
<td>74 (23%)#</td>
<td>18 (25%)</td>
<td>2215 (24%)</td>
</tr>
<tr>
<td>Education program</td>
<td>109 (34%)</td>
<td>22 (31%)</td>
<td>3007 (33%)</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>76 (24%)#</td>
<td>27 (38%)</td>
<td>2396 (26%)</td>
</tr>
</tbody>
</table>

* - Includes only participants for whom the admission screen produced this recommendation / classification. Subsequent reviews of screening tools disregarded.
† - Includes only patients who experienced one or more falls during their hospital stay and for whom the admission screen produced this recommendation / classification. Subsequent reviews of screening tools disregarded.
‡ - Period of time (days) spent by participants under this recommendation / classification. Reviews of screening tools incorporated.
¶ - Number of falls by participants under this recommendation / classification at time of individual falls. Reviews of screening tools incorporated.
# - Significantly higher frequency of recommendation for exercise program and hip protector interventions in phase 2 compared to phase 1 (Chi-square, p < 0.05).
Table 3.3. Diagnostic accuracy measures of PJC-FRAT and STRATIFY from phases one and two with bootstrap 95% confidence intervals.*

<table>
<thead>
<tr>
<th>Screening tool</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>SSS (%)</th>
<th>Sensitivity&lt;sup&gt;ER&lt;/sup&gt; (%)</th>
<th>Specificity&lt;sup&gt;ER&lt;/sup&gt; (%)</th>
<th>SS&lt;sup&gt;ER&lt;/sup&gt;S&lt;sup&gt;ER&lt;/sup&gt; (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1: PJC-FRAT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falls risk alert card</td>
<td>73 (55, 90)</td>
<td>75 (66, 83)</td>
<td>148 (127, 167)</td>
<td>85 (71, 94)</td>
<td>56 (45, 66)</td>
<td>141 (128, 154)</td>
</tr>
<tr>
<td>Exercise program</td>
<td>12 (3, 27)</td>
<td>84 (77, 91)</td>
<td>96 (84, 112)</td>
<td>14 (1, 39)</td>
<td>85 (77, 92)</td>
<td>99 (86, 120)</td>
</tr>
<tr>
<td>Education program</td>
<td>27 (12, 46)</td>
<td>68 (58, 77)</td>
<td>95 (77, 116)</td>
<td>29 (10, 51)</td>
<td>71 (61, 81)</td>
<td>100 (84, 119)</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>31 (14, 48)</td>
<td>90 (83, 95)</td>
<td>120 (102, 139)</td>
<td>46 (28, 60)</td>
<td>81 (73, 88)</td>
<td>127 (113, 141)</td>
</tr>
<tr>
<td><strong>Phase 1: STRATIFY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ to 1 / 5</td>
<td>96 (86, 100)</td>
<td>20 (12, 29)</td>
<td>116 (104, 126)</td>
<td>97 (90, 100)</td>
<td>22 (15, 31)</td>
<td>119 (111, 128)</td>
</tr>
<tr>
<td>≥ to 2 / 5</td>
<td>77 (59, 92)</td>
<td>51 (41, 61)</td>
<td>128 (109, 146)</td>
<td>71 (53, 87)</td>
<td>59 (51, 67)</td>
<td>130 (115, 146)</td>
</tr>
<tr>
<td>≥ to 3 / 5</td>
<td>42 (24, 63)</td>
<td>78 (70, 86)</td>
<td>120 (101, 141)</td>
<td>34 (18, 52)</td>
<td>84 (77, 89)</td>
<td>118 (104, 135)</td>
</tr>
<tr>
<td>≥ to 4 / 5</td>
<td>4 (0, 14)</td>
<td>93 (88, 98)</td>
<td>98 (90, 107)</td>
<td>5 (0, 11)</td>
<td>95 (90, 98)</td>
<td>100 (96, 105)</td>
</tr>
<tr>
<td><strong>Phase 2: PJC-FRAT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falls risk alert card</td>
<td>58 (45, 68)</td>
<td>66 (60, 71)</td>
<td>123 (110, 136)</td>
<td>71 (59, 81)</td>
<td>53 (47, 60)</td>
<td>124 (114, 133)</td>
</tr>
<tr>
<td>Exercise program</td>
<td>25 (16, 36)</td>
<td>77 (72, 82)</td>
<td>102 (91, 114)</td>
<td>32 (14, 53)</td>
<td>76 (70, 82)</td>
<td>108 (92, 127)</td>
</tr>
<tr>
<td>Education program</td>
<td>31 (21, 42)</td>
<td>64 (58, 70)</td>
<td>95 (83, 108)</td>
<td>32 (15, 53)</td>
<td>67 (61, 74)</td>
<td>100 (84, 118)</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>38 (27, 50)</td>
<td>80 (75, 85)</td>
<td>118 (105, 131)</td>
<td>50 (30, 68)</td>
<td>75 (69, 80)</td>
<td>124 (107, 141)</td>
</tr>
</tbody>
</table>

* - Bootstrap confidence intervals were bias corrected estimates based on 2000 repetitions of original sample size.

SSS – Sum of sensitivity and specificity

SS<sup>ER</sup>S<sup>ER</sup> – Sum of sensitivity<sup>ER</sup> and specificity<sup>ER</sup>
Table 3.4. Difference between phase 1 and phase 2 predictive accuracy results (SSS and SS<sup>ERS</sup><sup>ER</sup>). Data presented are phase 1 minus phase 2.

<table>
<thead>
<tr>
<th>Observed difference (bootstrap 95% confidence intervals)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SSS</strong></td>
</tr>
<tr>
<td>Falls risk alert card</td>
</tr>
<tr>
<td>Exercise program</td>
</tr>
<tr>
<td>Education program</td>
</tr>
<tr>
<td>Hip protectors</td>
</tr>
<tr>
<td><strong>SS&lt;sup&gt;ERS&lt;/sup&gt;&lt;sup&gt;ER&lt;/sup&gt;</strong></td>
</tr>
<tr>
<td>Falls risk alert card</td>
</tr>
<tr>
<td>Exercise program</td>
</tr>
<tr>
<td>Education program</td>
</tr>
<tr>
<td>Hip protectors</td>
</tr>
</tbody>
</table>

* - Bootstrap confidence intervals were bias corrected estimates based on 2000 repetitions of original sample size.
† - The difference between screening tools was significant if the 95% confidence interval did not include the value zero.

SSS – Sum of sensitivity and specificity
SS<sup>ERS</sup><sup>ER</sup> – Sum of sensitivity<sup>ER</sup> and specificity<sup>ER</sup>
Table 3.5. Comparison of PJC-FRAT and STRATIFY predictive accuracy results.
Data presented are PJC-FRAT (accuracy statistic) minus STRATIFY (accuracy statistic).

<table>
<thead>
<tr>
<th>Observed difference (bootstrap 95% confidence intervals) (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SSS</strong></td>
</tr>
<tr>
<td>(Falls risk alert card) – (cut-off ≥ 2 / 5)</td>
</tr>
<tr>
<td>(Hip protectors) – (cut-off ≥ 2 / 5)</td>
</tr>
<tr>
<td><strong>SS^ER S^ER</strong></td>
</tr>
<tr>
<td>(Falls risk alert card) – (cut-off ≥ 2 / 5)</td>
</tr>
<tr>
<td>(Hip protectors) – (cut-off ≥ 2 / 5)</td>
</tr>
</tbody>
</table>

* - Bootstrap confidence intervals were bias corrected estimates based on 2000 repetitions of original sample size.

SSS – Sum of sensitivity and specificity

SS^ER S^ER – Sum of sensitivity^ER and specificity^ER
3.4 Discussion

The results from this study indicated that the PJC-FRAT was generally applicable in the clinical setting. The PJC-FRAT also demonstrated reasonable calibration while facilitating hospital staff to predict patients who were going to fall with accuracy comparable to levels established in other hospitals and with other tools. The hypotheses that the predictive accuracy of the PJC-FRAT in deploying the falls risk alert card and hip protector interventions would be superior to that of the STRATIFY (the “gold standard”) were not supported. Only a trend of superior accuracy for the clinical judgement of hospital nursing staff in recommending the falls risk alert card intervention in comparison to the STRATIFY was noted, though the STRATIFY did record marginally better predictive accuracy statistics than the hip protector intervention recommendations. The hypothesis that the predictive accuracy of the PJC-FRAT would be comparable to those of previous clinical judgement model falls risk screening tools was supported. The hypothesis that the predictive accuracy of the PJC-FRAT would be maintained over a prolonged period of time was supported but less so for hospital nursing staff. The hypothesis that hospital staff compliance with and speed of completion of the PJC-FRAT would be at levels equivalent to those previously reported was strongly supported, though less so for medical staff.

Although the PJC-FRAT was not demonstrated to be significantly more accurate than the STRATIFY, it was also not demonstrated to be significantly less accurate. Thus, the question of whether the PJC-FRAT would be appropriate for use in the clinical setting, must then rely also on the relative practical applicability of the tool. Completion rates of the PJC-FRAT remained high over both phases of the study for nursing, physiotherapy and occupational therapy staff. As was discussed in section 1.9.7, completion rates of falls risk screening tools has rarely been reported in the clinical context. Non-completion rates of the STRATIFY screening tool have been 26% (Coker et al., 2003) and 36% (Oliver et al., 2002) when applied clinically, and 25% and 12% for the Barbieri tool (Tuffnell, 1990). Thus completion rates of the PJC-FRAT, particularly by nursing and physiotherapy staff appear to be particularly good. Conclusive remarks regarding relative superiority of the practical applicability of these tools should not be made on this data alone, as there were many potential confounding factors involved.
Review assessments were completed for 8% of participants in both study phases which is comparable to the 9% previously reported for an alternate falls risk factor assessment tool (Uden et al., 1999). Employing staff clinical judgement in the PJC-FRAT and having direct links to interventions may have enhanced the relevance and staff ownership of this system, contributing to higher completion rates. It is also possible that hospital staff, knowing that a research project was taking place, were additionally motivated to complete the screening tool.

The completion rates of the PJC-FRAT by hospital medical staff were relatively poor when compared with other disciplines. There were many factors that may have contributed to this:

i) Although the staff-to-patient ratios for hospital medical staff are similar to those of allied health staff at the Peter James Centre, their responsibility structure is quite different. As a point in case, two of the wards at the Peter James Centre have 30 patients, and each had two physiotherapists who were responsible for completing admission assessments and other paperwork for their own set of 15 patients. This was the same for occupational therapists. However, the junior medical staff on each ward were responsible for 30 patients and were supervised by the ward geriatrician. This may have generated confusion between junior and senior medical staff as to whose responsibility it was to complete the medical section of the PJC-FRAT.

ii) The medical section of the PJC-FRAT did not lead to the deployment of an intervention deployed by them solely, as the hip protector intervention had a dual recommendation mechanism. This may have reduced the perceived “ownership” or sense of responsibility that medical staff had for the deployment of this intervention.

iii) The medical section did not rely purely on the clinical judgement of medical staff to identify falls risk, rather the presence or absence of three potential falls risk factors.

iv) The education that medical staff had received regarding how to complete the PJC-FRAT was briefer than what was provided to other disciplines.
v) There was greater variability in junior medical staffing as individual doctors were rotated in and out of the Peter James Centre to acute hospitals every six weeks to three months.

vi) Medical staff may have had a lower level of enthusiasm to address this problem through this research project as evidenced by their lack of attendance at the general education sessions provided. However, it was also possible that they felt that they were too busy to attend, or that the times these sessions were conducted were inconvenient for them.

This indicates that either strategies to facilitate medical staff involvement in PJC-FRAT completion require development and investigation, or one could reassign the section completed by medical staff to another discipline, such as nursing staff.

The time between admission and completion of the PJC-FRAT demonstrated that nursing and physiotherapy staff were completing their sections very promptly following patient admission. Occupational therapy staff did not complete the PJC-FRAT as promptly as other disciplines (when completed). During the pre-study education sessions, occupational therapy staff had expressed a desire to complete initial cognitive screening (Mini-Mental State Examination) before deciding if patients were suitable to be recommended for the education program intervention. This screening was generally conducted on the second weekday following admission for each patient, and sometimes later if an interpreter was required. This may explain the delay in PJC-FRAT completion by occupational therapy staff.

The investigation of screening tool calibration indicated that a significantly greater proportion of patients were initially being recommended for the falls risk alert card intervention and the education program intervention than the proportion of patients who went on to become fallers. Table 3.2 demonstrates that 35% of patients in phase one and 40% of patients in phase two were recommended to receive the falls risk alert card intervention following admission PJC-FRAT completion. The education program intervention was recommended for 31% of patients in phase one and 34% of patients in phase two. This was in comparison to the 21% of patients who became fallers in phase one and the 22% who became fallers in phase two.
The importance of perfect calibration in this study is questionable though. Where the consequence of “over recommending” a certain intervention is limited to a small financial cost which is considered minimal in comparison to the cost of falls and fall injuries, this would not be inappropriate. Perhaps of greater concern were the low levels of recommendation for the hip protector and additional exercise program interventions (both 15%) in phase one. In such a situation, a greater proportion of patients were falling than what would have been given the opportunity to use these interventions, had they been available. However, recommendation rates for both of these interventions significantly increased in phase two. It is possible that the more “hypothetical” nature of the interventions in phase one (as they were not being deployed to any patients) made therapists less comfortable with recommending them than in phase two (when patients in the intervention group received them).

Examination of the accuracy of recommendation for each intervention from the PJC-FRAT (table 3.3), revealed that the falls risk alert card was the most accurately recommended intervention in both phases in terms of SSS and SS, though in phase two, its SS was equal to that of recommendation for the hip protector intervention. This result was not surprising however, as this intervention was targeted at patients at high risk for falls, whereas the additional exercise and education program interventions were targeted at subgroups of this theoretical patient group. Thus when considering sensitivity and specificity, within the group of patients who were not recommended these interventions, there would have been some who were recognised as being at high risk for falls yet deemed not suitable to participate in these particular interventions. Hence it would be unfair to use the sensitivity and specificity of these recommendations to represent the accuracy with which they were recommended. In hindsight, it may have been preferable to ask hospital physiotherapy and occupational therapy staff which patients they deemed as being at high risk for falls, and then ask which would benefit from their respective interventions. The hip protector intervention was recommended for those at very high risk who may have received limited benefit from the other interventions. As a consequence, the specificity of recommendation for this intervention was relatively high and sensitivity relatively low. Given the higher initial and ongoing costs of this
intervention in comparison to the falls risk alert card intervention, this was considered to be an appropriate outcome.

The $SS_{ER}^{ER}$ of recommendation for the falls risk alert card intervention was 17% higher in phase one than phase two. This could represent inter-subject variances between patient groups that made predicting fallers more difficult, or a true reduction in the predictive accuracy of hospital nursing staff. A true loss in predictive accuracy may have come about due to a loss of “education effect”. No “refresher” education sessions were provided to existing hospital staff following the initial education at the start of the study periods. The continuing education that was provided during the study period was instead provided to all new staff at their hospital orientation sessions. Thus, some staff may have gradually lost some of the information they had absorbed and used during phase one. However, the accuracy of other disciplines recommendations in phase two were relatively similar or better than that in phase one. It is also possible that the “education effect” may be of particular relevance to nursing staff.

The accuracy of nursing staff clinical judgement, facilitated by the PJC-FRAT in this research, was comparable to that previously reported. As discussed in section 1.9.6, previous levels of predictive accuracy of hospital nursing staff clinical judgement has ranged from $SS = 131\%$ in predicting fallers during the first week of hospitalisation (Moore et al., 1996) to $SS = 119\%$ in predicting fallers (Izumi et al., 2002). Phase one accuracy of the PJC-FRAT in recommending the falls risk alert card intervention ($SS = 148\%, SS_{ER}^{ER} = 141\%$) was above these levels, however phase two accuracy ($SS = 123\%, SS_{ER}^{ER} = 124\%$) was within the range previously established.

The comparison of the present study with previous ones is somewhat difficult because of several differences between study conditions. The studies have focused on different outcomes (particularly the Moore et al, 1996 article) and each employed different methods for harnessing the clinical judgement of nursing staff. In contrast to other studies, hospital staff were not specifically prompted to complete the PJC-FRAT apart from the pre-study staff education program. This introduced non-completions of the PJC-FRAT not present in the studies compared above. Due to the structure of the PJC-FRAT, non-completions were classified as a non-recommendation for the
intervention, as clinically this would result in non-deployment of the intervention if available. This potentially reduced the apparent accuracy of the PJC-FRAT, especially the SS_{ER}^{SSER}. This statistic was also sensitive to delays in screening tool completion, another factor not taken into account in previous studies. Harnessing staff clinical judgement has been done in different ways across these studies. Staff have been asked to globally rate patients as being at high, medium or low risk (Moore et al., 1996), record if they ‘feel’ the patient will fall in the near future (Eagle et al., 1999) or if the patient would benefit from a specific falls prevention intervention as in the present study. Thus there have been several differences between this and previous investigations into the predictive accuracy of hospital staff clinical judgement, though arguably, the results generated in this investigation are more conservative and may be more generalisable to typical clinical settings.

For the direct comparison of the PJC-FRAT and STRATIFY tools, the design and analysis of this study disadvantaged the direct comparison of the PJC-FRAT with the STRATIFY in two ways. First, hospital staff were not blinded to the results of the PJC-FRAT, but were to STRATIFY results. Despite the interventions being recommended not being deployed, it is likely that staff may have intervened in some other way for patients they identified as being at high risk of falling (Moore et al., 1996). If additional care was provided to these patients due to their being identified as high falls risk through the PJC-FRAT, this may have reduced their risk of falling. This in turn would have reduced the number of patients correctly identified as being at high risk who fell, assuming that the additional care provided was effective in reducing falls risk. Subsequently, the predictive accuracy statistics generated had the potential to be lower than if hospital staff been blinded to their recommendations, as they had been for STRATIFY scores.

The second way in which the comparison was compromised was through the PJC-FRAT being completed by hospital staff whereas the STRATIFY was calculated by a dedicated project researcher. As a result, non-completions of the PJC-FRAT were present which may have reduced its diagnostic accuracy, but were not for the STRATIFY (100% completion). Therefore, although the tools were compared on the same sample, the PJC-FRAT was evaluated in a manner almost analogous to “intention-to-treat” analyses for intervention studies, producing results more likely to
represent those seen in clinical practice. In comparison, the STRATIFY was evaluated under purely “research” conditions that do not fully reflect those seen in clinical practice.

A comparison of the predictive accuracy of recommendations for the additional exercise and education programs to STRATIFY results was not undertaken in this analysis. As was briefly discussed in section 3.4, both of these interventions were targeted at subgroups of the “high” risk population who were deemed suitable to participate in them by hospital physiotherapy and occupational therapy staff. Thus there was a proportion of patients who may have been identified as being at high falls risk by these staff yet not recommended for their respective interventions. Indeed the characteristics that made them unsuitable for participating in these interventions may have been the same as those that placed these patients at very high risk for falls. So despite potentially being appropriately identified as being at high risk for falls by the hospital staff involved, the falls that these patients incurred would have adversely affected the sensitivity, specificity, sensitivity\(^{ER}\), and specificity\(^{ER}\) results calculated.

In order to have appropriately compared the predictive accuracy of hospital physiotherapy and occupational therapy staff clinical judgement to that of the STRATIFY, the investigator should have first asked these staff to record if they considered a patient to be at high falls risk on the PJC-FRAT before asking them if the patient would benefit from receiving the relevant interventions. The falls risk alert card and hip protector intervention recommendations did not have similar exclusion criteria to those of the additional exercise and education program interventions, thus the recommendations for these interventions were able to be compared to those of the STRATIFY.

This study not only compared the PJC-FRAT to the STRATIFY, but was another of a growing number of studies that have directly compared a “clinical judgement” model to a “mathematical” model of screening tool. A trend common to these studies has been that the accuracy of the clinical judgement of nurses was only found to be moderate to good but in all cases was at least comparable to the “mathematical” model screening tools they were compared with (Eagle et al., 1999; Izumi et al., 2002; Moore et al., 1996; Price et al., 1999). Also of note from this study was the lower diagnostic accuracy of the STRATIFY than what was reported when it was first
investigated (Oliver et al., 1997). Difficulty reproducing initial predictive accuracy results of the STRATIFY have been reported elsewhere (Coker et al., 2003). The Morse Falls Scale is another falls risk screening tool that had impressive initial results which have not been replicated to the same level through subsequent investigation (Eagle et al., 1999; Morse et al., 1989b; O'Connell et al., 2002). Both the Morse Falls Scale and the STRATIFY are “mathematical” model screening tools that sum weighted falls risk factors to produce a falls risk score. The inability to reproduce initial results suggests that such tools may be sample-specific.

Falls risk screening tools of a “mathematical” model tools are still likely to be of importance. As was discussed in chapter 3, the reduction in predictive accuracy of hospital nursing staff in recommending the falls risk alert card intervention may have been as a result of a loss of the “education” effect brought about by the staff education prior to study one. Thus in situations where hospital staff have little previous clinical experience or education to aid their clinical judgement of falls risk, a “mathematical” model of screening tool may prove to be a more accurate means of falls risk screening. It is also possible that a combination of both could be used effectively.

The study designs used for this investigation had some limitations. As has been discussed, blinding hospital staff to PJC-FRAT results would have made for a fairer comparison of the screening tools. It was possible to do this had only the initial (admission) screening been important. One could have employed a hospital staff member from a separate ward to complete the screening following some limited interaction with the patient. The screening test results could have been concealed and the staff member not involved in that patient’s care for the remainder of their stay. This would create the ideal situation for evaluating hospital staff clinical judgement as the hospital staff member caring for the patient would be blinded to the result of the falls risk screen based on another hospital staff member’s clinical judgement. However, it was impractical to use this approach in the evaluation of the PJC-FRAT given this tool’s reliance on the clinical judgement of staff directly caring for the patient for its review process (the PJC-FRAT “amendment sheet”).

The sample size involved in this study could also have been considered to be small, despite it being larger than previous studies of similar design. It was unknown
whether this study was powerful enough to detect a minimum clinically significant difference in the predictive accuracy of the two screening tools. In order to have ensured that it was, a power analysis based on this minimum clinically significant difference would need to have been undertaken. Thus, from a theoretical perspective, it would have been preferable had the investigator undertaken a power analysis prior to study commencement. However from a practical perspective, the investigator has as yet been unable to locate a power analysis formula to calculate sample sizes based on the difference of SSS or SS$^S$ER$^S$ statistics using the bootstrap resampling approach to calculate 95% confidence intervals of the “difference” statistics.

A third potential limitation of this study design was that recommendations for interventions were ‘hypothetical’ due to the interventions not yet being available during this pre-implementation phase. This may limit the external validity of the study findings. When the outcomes from the PJC-FRAT were compared in chapter 3, some significant differences were noted. The hip protector and additional exercise program intervention recommendations increased when these interventions became available. There was also a decline in the accuracy of hospital nursing staff in predicting falls event rates through recommendations of the falls risk alert card. One could question whether the trend for superior predictive accuracy of the PJC-FRAT in recommending the falls risk alert card intervention discussed in this chapter would in fact be generalisable to clinical (real world) situations where the interventions were really available. To have evaluated this, the investigator should have continued to apply the STRATIFY to control group patients during study two of the research program.

Although this study did have limitations, it also had significant methodological strengths and made new advances in this field. Of the comparative studies of falls risk screening tools published to date, this is the first to perform hypothesis testing between the diagnostic accuracy of the tools examined. It is also the first to compare screening tools’ abilities to correctly classify fallers and non-fallers (through sensitivity and specificity) and the falls event rate (through sensitivity$^E^R$ and specificity$^E^R$). The results from this study demonstrated similarity in difference between tools regardless of the analysis approach taken, indicating that neither of the tools were better suited to classify fallers from non-fallers than the falls event rate. By recommending interventions that were not instituted, an appropriate evaluation of
the accuracy of these recommendations could be undertaken without the confounding influence of the interventions had they been implemented. This is in contrast to previous studies that have evaluated the accuracy of screening tools in the context of “intervention” studies (Cannard, 1996; Donald et al., 2000; Foster et al., 1996; Oliver et al., 2002).

Some areas requiring further investigation have been highlighted by this study. Reasons for relatively poor compliance by hospital medical staff with participating in the multidisciplinary falls risk screening protocol would be valuable to identify. This should be followed by formulation and evaluation of strategies to facilitate greater participation. The association between staff education and accuracy in predicting falls also requires further examination. Specifically, investigations of different modes of education program delivery, different quantities of education, and different frequencies of education delivery to promote and maintain predictive accuracy of staff clinical judgement are required. Further investigation is required to determine the relative merits of using hospital staff clinical judgement in comparison to “mathematical” model falls risk screening tools. The study design of such investigations should be prospective, encompass as much blinding of hospital staff involved as practical, and consist of a sufficiently large sample size as to be able to detect a minimum clinically significant difference between the screening tools. The inter-rater reliability of staff clinical judgement in predicting falls risk both between and within disciplines requires examination. Sensitivity\textsuperscript{ER} and specificity\textsuperscript{ER} statistics should be employed in conjunction with standard calculations of sensitivity and specificity, along with a statistical approach to hypothesis testing such as the bootstrap resampling approach used for this study. Attention should also be given to screening tools that consist of both clinical judgement and mathematical model elements.

The PJC-FRAT appears to be an appropriate approach to facilitating the use of hospital staff clinical judgement for the deployment of falls prevention interventions. It allows clear documentation of the deployment of specialised multidisciplinary falls prevention interventions. Harnessing hospital staff clinical judgement by asking staff if particular patients would benefit from specific falls prevention interventions appears to have contributed to the overall accuracy of the tool and possibly the high levels of completion by nursing, physiotherapy, and occupational therapy staff. There
was also no requirement to undertake any numeric calculations or adherence to
cutoffs to undertake deployment, allowing a flexible approach to individualised falls
prevention planning. Following this comparison to a “gold standard”, there appears to
be sufficient justification to use this tool for the deployment of the interventions from
the falls prevention program in the clinical (real world) setting.
Chapter 4: Effectiveness of the targeted falls prevention program in the subacute hospital setting.
4.1 Introduction

Interventions to reduce in hospital falls have received little attention. In this area only three RCT’s have been published (Donald et al., 2000; Mayo et al., 1994; Tideiksaar et al., 1993). Two investigated single interventions [bed alarms (Tideiksaar et al., 1993) and alert bracelets (Mayo et al., 1994)] in conjunction with usual care compared to usual care alone. The third investigated two interventions (additional exercise and flooring type) in a two-by-two design in conjunction with usual care (Donald et al., 2000). Only two of these studies were conducted in the subacute hospital setting (Donald et al., 2000; Mayo et al., 1994). None of these studies demonstrated a statistically significant reduction in fall event rates, however all were relatively small (between 54 and 134 participants).

Previous randomised controlled trials in community and residential care settings have reduced fall event rates in randomised and cluster randomised controlled trials using multiple intervention strategies (Becker et al., 2003; Close et al., 1999; Fabacher et al., 1994; Jensen et al., 2002; Lightbody et al., 2002; Tinetti et al., 1994). Several of the interventions involved in these studies have been targeted at selected participants. Given the effectiveness of the targeted, multiple intervention approach in these settings, an investigation of its effectiveness in the subacute hospital setting is clearly in need of investigation. The targeted falls prevention program constructed for this research program was designed specifically for patients in subacute care and is the subject of investigation in this chapter.

Subsequent to the research program described in this thesis and publication of results stemming from it, another randomised controlled trial of a falls prevention program in the subacute setting has been published (Healey et al., 2004). This study investigated the effectiveness of a nursing falls care plan for the prevention of falls in a cluster randomised controlled trial. The nursing falls care plan was administered to patients who were admitted with a history of falls, and those who had fallen or had a near miss during their current admission. The checklist covered areas of vision impairment, use of psychoactive medications, postural hypotension, urine abnormalities, mobility impairment, environmental hazards, use of bedrails, footwear, ward bed position, and nurse call bell position. Each area had a targeted intervention linked to it.
The authors of this trial reported that baseline characteristics of patients admitted to control and intervention wards were broadly similar with the exception of a slightly longer length of stay on the intervention wards, and that the rate of falls was significantly less on intervention wards during the 6 month intervention period than on control wards [relative risk (95% CI): 0.59 (0.49-0.70)]. Also reported was that significantly fewer falls occurred on the intervention wards during the 6 month pre-intervention period [relative risk (95% CI): 0.83 (0.70-0.98)]. The discussion identified several potential biases that may have confounded these results, including inter-subject differences. The problem of inter-ward differences was not discussed, however this may have potentially biased the outcomes of this study. The randomised controlled trial is considered the “gold standard” of experimental designs, partly because of its ability to ensure that groups being compared are relatively comparable from the outset providing sufficient numbers have been recruited (Portney et al., 2000). This trial was described as a cluster randomised trial of matched pairs of wards, yet there was a significant difference in fall rates during the pre-intervention phase between control and intervention wards. If patient characteristics were “broadly similar” then differences between control and experimental wards should be considered as a reason for this non-equivalence. This is a difficulty of randomising wards rather than individuals. Randomising hundreds of patients to control and intervention groups within same wards not only ensures relative consistency of baseline patient characteristics, but also levels of patient exposure to differing ward characteristics, for example, levels of “usual care” and fall reporting practices. Randomising only eight wards (despite attempts to match them) means that inter-ward differences have a much larger potential to bias results. For this reason, it is difficult to say with confidence that the intervention was responsible for the observed difference in fall rates between intervention and control wards.

A second difficulty in interpreting these results lies in the statistical analysis and use of the relative risk approach to analyse the primary outcome. When using relative risk statistics to compare fall rates, one must consider the units that time is measured in. In that study (Healey et al., 2004), 319 control group falls over 16,577 patient-days were compared to 180 intervention group falls over 15,951 patient days during the post-intervention period producing a relative risk (95% CI) of 0.59 (0.49-0.70).
However, had the same time data been measured in patient-years (1 patient-year = 365 patient-days), the relative risk (95% CI) would have been 0.92 (0.85 – 0.99) using the formula provided in the cited text (Altman, 1993). In fact, the larger the units that time is measured in, the closer to the null the result becomes, and vice versa. For this reason, interpretation of the relative risks (95% CI) presented is difficult, which further complicates the interpretation of the conclusions provided by the authors. As data was not available on an individual patient level in that study, approaches such as recurrent event survival analysis or negative binomial regression could not be employed. A suitable alternative may have been to use a time-series analysis approach.

Taking into account the positive aspects of this trial (large sample size, randomisation, comparable baseline patient characteristics) and the negative (such as those listed above) it would be fair to conclude that this trail adds to the growing number of trials that support a targeted multiple intervention strategy as being beneficial for the reduction of falls in the hospital setting, though further evidence from well constructed and analysed trials is still needed.

### 4.1.1 Aims and hypotheses

The aims of the research described in this chapter are to:

- Evaluate the effectiveness of the targeted falls prevention program in minimising falls, fall injuries and the proportion of patients who fell.
- Evaluate the effect of the targeted falls prevention program on patient length of stay in subacute care, discharge destination, mobility, and functional independence.
- Examine whether a targeted, multiple intervention falls prevention program can be implemented in conjunction with usual care in the subacute hospital setting.

The hypotheses of the research described in this chapter are that:

- Patients allocated to receive the targeted, multiple intervention falls prevention program in addition to usual care will incur fewer falls, fall-injuries, and have a lower proportion who fall, than patients allocated to receive usual care alone.
• Patients allocated to receive the targeted, multiple intervention falls prevention program in addition to usual care will have shorter lengths of stay, better mobility, and functional independence than patients allocated to receive usual care alone.

• Patients allocated to receive the targeted, multiple intervention falls prevention program in addition to usual care will be less likely require more supportive discharge accommodation relative to pre-admission accommodation than patients allocated to receive usual care alone [eg. less likely to move from pre-admission community living to a residential care facility, or to move from low (hostel) to high (nursing home) levels of care].

• The targeted, multiple intervention falls prevention program will be implemented in conjunction with usual care without causing a reduction in the number of “usual care” physiotherapy sessions provided (indicating that program did not interfere with provision of “usual care”).
4.2 Methods

4.2.1 Study design
Data analysed in this chapter have been taken from study two of the research program. This study used a randomised controlled trial design with randomisation of individuals.

4.2.2 Participants
Patients eligible to participate in this study were inpatients of the subacute wards of the Peter James Centre. A general description of these patients has been provided in section 2.3.

4.2.3 Sample size
A sample size of 626 patients was calculated for this study. This was based on a 33% reduction in the proportion of patients who were fallers, an alpha of 0.05, beta of 0.80 (Fleiss, 1981), and a summary of hospital falls data from the Peter James Centre in March 2001 indicating that 30% of their patients fell at least once during their hospitalisation.

4.2.4 Intervention program
The targeted, multiple intervention falls prevention program was implemented in addition to usual care for patients randomly allocated to the intervention group. Patients allocated to the control group received usual care alone. The interventions included in the falls prevention program were described in section 2.5. The construction of the screening tool used to target these interventions to specific patients (the PJC-FRAT) was described in section 2.5.4. The predictive accuracy of this tool was described in chapters 3 and 4.

4.2.5 Procedure
4.2.5.1 Participant recruitment and consent
The participant recruitment period was from March to December 2002. The investigator, research physiotherapist, research occupational therapist, and research assistant approached patients for consent as soon as practical after admission to the
hospital. Patients were provided with an information sheet about the study, and had the study explained to them before being asked to sign a written informed consent form. The information sheet and informed consent forms are presented in appendix O. Family members or carers of patients were provided with this information and approached for consent if the patient had communication difficulties or cognitive impairment (admission Abbreviated Mental Test Score < seven).

### 4.2.5.2 Randomisation

Random group allocation was employed using a random number table held at the Peter James Centre by the investigator (Portney et al., 2000). The investigator allocated a patient to the intervention or control group using this table following receipt of informed consent. The research physiotherapist, research occupational therapist, and research assistant did not have access to the allocation sequence and were thus fully blinded from the allocation sequence when recruiting patients. Although no official figures were maintained, these staff approached a clear majority of patients for consent to participate in this study. The investigator maintained the random number table in his office and although not consciously aware of the allocation sequence at the time of recruiting patients, cannot be classified as being blinded to the allocation sequence in the same way that other research staff were.

### 4.2.5.3 Participant flow

Research team members approached 1040 patients during the subject collection period, of whom 626 (60%) consented to participate. The flow of participants in this trial is demonstrated in figure 5.1. No participants withdrew from the trial during the study period.

### 4.2.5.4 Completion of screening tool

Hospital staff completed the PJC-FRAT for all patients admitted to the Peter James Centre from the commencement of the participant recruitment period (March 2002) until the end of the data collection period for this study (April 2003). This tool was thus completed for patients in the intervention and control groups, along with patients not participating in the study. If a staff member recommended that a patient receive an intervention from the falls prevention program, then staff contacted the investigator
and informed him of their recommendation, as was indicated on the PJC-FRAT, appendix C. The investigator had an answering machine to record these recommendations if he was not by the phone to receive the call.

4.2.5.5 Provision of usual care

Usual care, as described in section 2.2, was provided to patients regardless of group allocation.

4.2.5.6 Provision of the intervention

Patients participating in this study who were randomly allocated to the intervention group were provided with interventions from the falls prevention program as recommended by hospital staff through use of the PJC-FRAT. The interventions were provided as described in section 2.5.3.

The falls risk alert card (with patient / family member information brochure) intervention was provided by the investigator. The additional exercise program intervention was provided by two physiotherapists employed in the research physiotherapist position during the study period. One conducted the exercise sessions on Monday afternoons, the other conducted sessions on Wednesday and Friday afternoons. The investigator conducted sessions when these staff were unable to attend. The education program intervention was provided by three occupational therapists employed in the research occupational therapist position during the study period. Unlike the research physiotherapists, these staff were employed in series rather than in parallel. The investigator conducted the education sessions during periods of transition between employment of the separate occupational therapists. The first occupational therapist left this position due to maternity leave, the second due to being offered a full-time position within the hospital, however the third saw out the remainder of the study duration. Each was involved in the project for between 3 and 4 months. The hip protector interventions were provided and maintained (washed) by the investigator.

There were delays between intervention recommendations being made and communicated to the investigator, and the provision or commencement of the
interventions. These were generally considered to be minimal, however some extreme examples could have occurred. For example, had a hospital physiotherapist recommended that a patient in the intervention group be provided with the additional exercise intervention late on a Friday afternoon, that patient would not have attended an additional exercise group until the Monday afternoon almost 72 hours later. Similarly if a patient in the intervention group was recommended for hip protectors after working hours on a Friday, they also would not have received that intervention until the Monday morning almost 65 hours later when the investigator had returned to the research location after the weekend. This limitation reflects the inability of a research project with little funding to provide “seven day a week” coverage of a hospital that provides health services seven days per week.

4.2.5.7 Measurements

The majority of baseline measures used for this study, and the procedure for their measurement and recording, have been described previously (section 2.4.1). The primary outcome measures selected (falls, fall injuries and fallers) and the procedure for their recording have been described (section 2.4.3). Falls occurring prior to patient consent were not included. Many of the secondary outcome measures (discharge modified Barthel Index, discharge Timed Up and Go scores, discharge living arrangements) and the procedure for their recording have been described previously (section 2.4.4). Changes in living arrangements between admission and discharge were classified as;

- return to previous residence
- newly admitted to low level residential care
- newly admitted to high level residential care
- transfer to an acute hospital
- other (for example, death).

The procedure for recording and classifying compliance rates of hospital staff in completion of the PJC-FRAT has been previously described (section 3.2.5.4).

Length of patient stay in hospital was considered to be a secondary outcome measure in this study as previous studies have identified an association between falls and longer hospital stays (Grenier-Sennelier et al., 2002; Halfon et al., 2001; Mion et al.,
1989b; Passaro et al., 2000; Patrick et al., 2001). Length of stay is important from an economic perspective as the costs of caring for an individual patient will rise the longer they stay in subacute care (Phelan et al., 1998; Webster, 1996). To calculate the overall length of stay, the investigator counted the number of days between admission and discharge, inclusive of discharge day. Thus a patient admitted on a Monday and discharged the next day (Tuesday) had a length of stay of one day. However, as the intervention program could only be implemented following patient consent, the number of days between date of consent and discharge was the outcome analysed.

Attendances at usual care physiotherapy sessions were used as an indicator of provision of usual care. At the end of each day hospital physiotherapists recorded the number of “attendances” each patient had. A standard attendance was a one hour physiotherapy session. Monthly summaries of this data were produced by the hospital physiotherapy department. The investigator used these summaries to count the number of physiotherapy attendances each study participant had. Equivalent data for hospital occupational therapy attendances was not available.

4.2.5.8 Blinding

Complete blinding of hospital staff and participants was impossible in this study given the nature of the interventions employed. This was of particular relevance for hospital staff as their awareness of participant group allocation may have introduced several sources of bias such as altered fall incident recording practices or inconsistent provision of usual care. “Resentful demoralization” or “compensatory rivalry” may also have been introduced from the patients’ perspective (Portney et al., 2000), and were also of concern.

Patients were not intentionally made aware of their group allocation. However patients who were allocated to the intervention group and received interventions from the falls prevention program would potentially have been unblinded to their group allocation. To gain an indication of the level of “un-blinding” of patients involved in the study, a “blinding survey” was conducted following completion of two thirds of
the data collection period (James et al., 1996). Just prior to patient discharge, the investigator asked patients;

“During your stay in this hospital you have been participating in a study of falls prevention interventions. In this study there were two groups of patients. One group were only eligible to receive “usual care”. The other group were eligible to receive the falls prevention interventions on top of their “usual care” if staff recommended that they would benefit from them. Do you think that you were allocated to the group eligible to receive “usual care” only, or the group that could also have received the additional falls prevention interventions if staff members recommended them?”

There was a binary outcome response (intervention or control group) to this question. This survey was not a part of the original research proposal, however was deemed to be a valuable addition by the investigator and study supervisors thus prompting its initiation part-way into the data collection period.

Hospital staff were not made aware of the group allocation of their patients. For patients in the intervention group, hospital staff may have been made aware of their group allocation if they became aware that the patient had a falls prevention intervention (such as a falls risk alert card) provided to them. If patients in this group had not been recommended for an intervention, hospital staff did not have an opportunity to be unblinded to their group allocation. For patients in the control group, hospital staff may have been made aware of their group allocation if the hospital staff member was aware that they had been recommended for an intervention using the PJC-FRAT yet they had not received it. Though to clarify, the staff would only know that the patient was not in the intervention group as the patient may not have consented to participate in the study.

To gain an indication of the level of “un-blinding” of hospital staff, a centre wide one-off blinding survey was conducted following two thirds of the data collection period (James et al., 1996). On one afternoon, the investigator asked the primary care nurse for each patient participating in the study at that time which group they felt that patient was allocated to. Hospital physiotherapy and occupational therapy staff were given an envelope labeled “to open at 4:00 pm today”. Inside the envelope was the
list of patients that therapist was caring for who were participating in the study at that stage. Also inside was a letter explaining the blinding survey and that the therapist needed to record which group they felt each of their patients had been allocated to. The letter also explained that they were not to discuss this with other staff, as this would warn them of the survey prior to completing it. This would have been a problem had pre-warned staff attempted to unblind themselves in order to guess more group allocations correctly. Hospital staff were then informed that this survey was only going to be administered once so that they would not try to deliberately un-blind themselves in preparation for future surveys. The investigator administered the survey to nursing, physiotherapy, and occupational therapy staff and collated their responses within a three hour period.

4.2.6 Statistical analysis

Continuous baseline measures were initially examined for normality of distribution using the Shapiro-Wilk test (StataCorp, 2001). Analysis indicated that data for each variable examined were not to be normally distributed (Shapiro-Wilk: p<0.05), thus between group comparisons were performed using the Wilcoxon rank-sum (Mann-Whitney) test for independent samples (StataCorp, 2001). Nominal, binary baseline measures were compared using chi-square tests. Comparison of prior living arrangements was made using a 3x2 chi-square contingency table test (Portney et al., 2000). Comparison of admission diagnostic categories was made using a 7x2 chi-square contingency table test (Portney et al., 2000), where diagnostic categories selected were; stroke, neurological, elective joint replacement, orthopaedic, other disabling impairment, other geriatric management, and remaining categories (combined due to low cell frequencies – see section 2.4.1.3 for complete list).

Analyses of primary outcomes were on an intention-to-treat basis. Data were regarded as recurrent events survival data, allowing all falls and variable participant study observation periods to be accounted for in the analysis. In standard (single or first event) survival time analyses, the outcome of interest is the time until an event. This outcome is continuous, though linear regression residuals generated from this data are rarely normally distributed necessitating that statistical approaches specifically designed for this data be used (Cleves et al., 2002). Recurrent events
survival analyses are an extension to single or first event approaches. The outcome of interest is again “time”, however in the recurrent events case it is the time between events. In this study, the first outcome for each patient is the period of time between their entry to the study and their first fall, or if they did not fall, their discharge from hospital. Patients who were discharged prior to experiencing the outcome of interest are referred to as being “right” censored, and then contribute no more data to the analyses (Cleves et al., 2002). For patients who experienced at least one fall, the second outcome is the period of time between their first fall and their second fall, or if they had no further falls, their discharge from hospital. Again these patients that were discharged are “right” censored. This process continues until the greatest number of falls by any one patient, such that every patient is eventually “right” censored. Thus the number of time outcomes each patient contributes to the analysis is one greater than the total number of falls they individually experienced.

When entering and analysing this data, time was entered as discrete units (days), following the data entry approach described for ordered failure events (Anderson-Gill) used with Stata statistical software (Cleves, 1999). Where two events were experienced by an individual on the same day, the “epsilon” approach of separating this data was used (Gould, 1999). Using this approach, the time between the first fall and the second fall on the same day was recorded as being 0.1 days (this magnitude of time is referred to as “epsilon”). In non-parametric and semi-parametric survival analyses, the value of epsilon is inconsequential providing that it is consistent between individuals and smaller than the smallest unit value of time otherwise used. In this analysis, time was otherwise recorded in 1.0 day units.

The cumulative incidence of falls over time for each group was compared graphically using the Nelson-Aalen cumulative hazard estimator (Nelson, 1972). This estimator is a “step” function. Each participant’s observation time started at time = 0 (the X axis) regardless of what date they were admitted to the hospital. The length of horizontal components is determined by the length of time between falls within a group. The height of vertical components is determined by the number of falls that occurred on that day number since study entry for each patient, divided by the number of patients remaining in that group.
To compare the rate of falls between groups, the logrank statistic for recurrent events was used (Pepe et al., 1993). It was developed as an analogue of the non-parametric logrank statistic for time to first events. This test combines the results of separate chi-square tests conducted at each point in time that an event took place. This approach, along with others, avoids having to specify the dependence structure among recurrent events (Miloslavsky et al., 2004). The logrank test requires the assumption of proportional hazards be met, in that fall event rates between groups maintain a proportional association over time. This association was analysed visually, by examining the Nelson-Aalen cumulative hazard estimates (figure 5.2). These estimates did not appear to maintain a purely proportional association over time (the estimates were not parallel). The Schoenfeld residuals test was also used (Grambsch et al., 1994; StataCorp, 2001). This test also indicated that the assumption of proportional hazards may have been violated (Schoenfeld residuals test: p=0.015). To account for this, the Peto extension to the logrank test was also used (Peto et al., 1972). This approach is considered to be useful when the proportional hazards assumption is not met and when “censoring” patterns between groups are not equal by weighting chi-square tables of the logrank test (Cleves et al., 2002; StataCorp, 2001).

The incidence of falls with injuries was compared between groups using the log-rank test for recurrent events (Pepe et al., 1993). The proportional hazards assumption for this comparison did not appear to be violated (Schoenfeld residuals test: p=0.96), thus the Peto extension of the logrank test was not required. The proportion of participants who experienced one or more falls was compared between groups using relative risk with 95% confidence intervals (Altman, 1993).

Length of stay following consent was compared between groups using the Wilcoxon rank-sum (Mann-Whitney) test as data were not normally distributed (Shapiro-Wilk test: p<0.05). The number of attendances at usual care physiotherapy sessions were divided by length of stay for each individual patient, thus becoming intensity rates of physiotherapy attendance. These rates were compared between groups using the Wilcoxon rank-sum (Mann-Whitney) test as this data was not normally distributed (Shapiro-Wilk: p<0.05).
Other continuous outcome measures (modified Barthel Index scores and Timed Up and Go test scores) were examined as change scores between admission and discharge for each individual patient. These change scores were then divided by the length of time patients spent in hospital. Thus rate of change scores were generated for each patient for each outcome. Both of these outcomes were analysed between groups using the Wilcoxon rank-sum (Mann-Whitney) test as data were not normally distributed (Shapiro-Wilk test: p<0.05). Changes in living arrangements between pre-admission and discharge were analysed between groups using a 4x2 chi-square test where the transfer to an acute hospital category and the “other” (for example, death) category were collapsed into a single outcome due to low frequencies in the “other” category.

The agreement between patient group allocation and hospital staff estimation of group allocation, and that between patient estimation of group allocation and actual group allocation, were analysed using the kappa statistic (Fleiss, 1981).
Figure 4.1. Participant flow and distribution of recommendations for intervention subgroups during study two.

1040 admissions during the participant recruitment period.

47 previously enrolled in the study excluded
367 did not provide informed consent

Randomisation

**Intervention group**
310 participants
9356 participant days

**Recommendations**
- Falls risk alert card: 151 participants, 5065 days
- Exercise program: 93 participants, 2596 days, 595 attendances by participants
- Education program: 115 participants, 3190 days, 473 attendances by participants
- Hip protectors: 89 participants, 2692 days, 57% wore hip protectors ≥ 12 hours/day, 25% refused to wear at all

**Control group**
316 participants
9239 participant days

**Recommendations**
- Falls risk alert card: 135 participants, 4359 days, 0 cards provided
- Exercise program: 80 participants, 2215 days, 0 attendances by participants
- Education program: 111 participants, 3007 days, 0 attendances by participants
- Hip protectors: 84 participants, 2396 days, No hip protectors worn by participants

Baseline and outcome measures collated from medical history by investigator following participant discharge from sub-acute hospital
4.3 Results

Baseline characteristics of patients in the intervention and control groups are demonstrated in table 4.1. Rates of completion and delays in completion of the PJC-FRAT are demonstrated in table 4.2. No significant differences between control and intervention groups were found.

Compared with the control group, the intervention group had 30% fewer falls (control: 149 falls, intervention: 105 falls), and a lower proportion of participants who experienced one or more falls [control: 71 fallers, intervention: 54 fallers, relative risk (95% CI): 0.78 (0.56 to 1.06)]. There were 35 single fallers in the intervention group compared to 49 in the control group. Both groups had 10 who fell twice, three who fell three times, but the intervention group only had six participants incur four or more falls compared to nine for the control group. No adverse events attributable to the intervention were identified.

The Nelson-Aalen cumulative hazard estimate for both groups were similar until about day 45, where the control group marginally increased its fall rate and the intervention group appeared to have a sudden reduction in its fall rate (figure 4.2). The rate of falls was significantly lower in the intervention group (control: 16.1 falls / 1000 patient-days, intervention: 11.2 falls / 1000 patient-days, log-rank test: p = 0.004, Peto extension logrank test: p = 0.045).

Table 4.3 shows the number of patients under specific PJC-FRAT recommendations at one point in time during the study, the amount of patient time recommended for each intervention / intervention combination, and the number of falls that took place during these periods. It should be noted that as an individual patient could have fallen under more than one PJC-FRAT intervention / intervention combination recommendation during their stay, there was double counting of this data and thus the numbers displayed do not sum to equal the true number of participants (n).

Table 4.4 displays the distributions of fall related injuries between the two groups. There was a 28% reduction in the incidence of falls with injury overall in the intervention group (log-rank test: p = 0.20). Two participants from each group
incurred a fall-related fracture. One participant fractured their neck of femur while wearing hip protectors. Nursing staff reporting this incident stated that the patient was wearing the hip protectors correctly, and that the patient had tripped forwards, and landed on the anterior aspect of her knee.

Median and interquartile range statistics, along with raw frequencies of secondary outcome measures for each group are demonstrated in table 4.5. There was no significant difference in the rate of change in modified Barthel Index scores (Rank-sum: $z = -1.07$, $p = 0.29$), Timed Up and Go scores (Rank-sum: $z = 1.07$, $p = 0.29$), in the rate of attendance at usual care physiotherapy sessions (Rank-sum: $z = 0.39$, $p = 0.70$), or in the distribution of discharge destinations [$df = 3$, chi-square$_{(critical\ value)} = 7.82$, chi-square$_{(obtained)} = 1.35$].

Hospital staff correctly identified the group allocation of 90 out of 172 participants they were caring for, Kappa = 3% chance corrected agreement. Similarly, 54 out of the 87 participants who were surveyed and able to provide a response correctly identified their group allocation, Kappa = 24%. It should also be noted that an additional 13 patients were approached but unable to provide an answer due to a communication barrier (language), and another 21 were approached but did not answer the question when asked (primarily due to cognitive impairment).
**Table 4.1.** Patient characteristics at baseline.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days from admission until consent</td>
<td>1 (0, 2)</td>
<td>1 (0, 3)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>81 (75, 86)</td>
<td>82 (75, 87)</td>
</tr>
<tr>
<td>Gender – male (n)</td>
<td>105 (33%)</td>
<td>101 (33%)</td>
</tr>
<tr>
<td>Admission modified Barthel Index (/100)*</td>
<td>47 (37, 57)</td>
<td>42 (37, 57)</td>
</tr>
<tr>
<td>Admission mini-mental state examination (/30)*</td>
<td>25 (20, 27)</td>
<td>25 (20, 27)</td>
</tr>
<tr>
<td>Primary Admission Diagnosis (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>40 (13%)</td>
<td>32 (10%)</td>
</tr>
<tr>
<td>Neurological</td>
<td>12 (4%)</td>
<td>13 (4%)</td>
</tr>
<tr>
<td>Elective joint replacement</td>
<td>44 (14%)</td>
<td>33 (11%)</td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>95 (30%)</td>
<td>104 (34%)</td>
</tr>
<tr>
<td>Other disabling impairment</td>
<td>33 (10%)</td>
<td>34 (11%)</td>
</tr>
<tr>
<td>Other geriatric management</td>
<td>53 (17%)</td>
<td>57 (18%)</td>
</tr>
<tr>
<td>Remaining diagnoses</td>
<td>39 (12%)</td>
<td>37 (12%)</td>
</tr>
<tr>
<td>Previous medical history (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>70 (22%)</td>
<td>65 (21%)</td>
</tr>
<tr>
<td>Parkinson's disease</td>
<td>18 (6%)</td>
<td>18 (6%)</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>49 (16%)</td>
<td>45 (15%)</td>
</tr>
<tr>
<td>Congestive cardiac failure</td>
<td>40 (13%)</td>
<td>49 (16%)</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>36 (11%)</td>
<td>43 (14%)</td>
</tr>
<tr>
<td>Fall related fracture</td>
<td>55 (17%)</td>
<td>68 (22%)</td>
</tr>
<tr>
<td>Prior living (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home alone</td>
<td>120 (38%)</td>
<td>118 (38%)</td>
</tr>
<tr>
<td>Home with family</td>
<td>143 (45%)</td>
<td>144 (46%)</td>
</tr>
<tr>
<td>Low level residential care facility</td>
<td>52 (16%)</td>
<td>47 (15%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.3%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

Scores are median (inter-quartile range) or absolute number (percentage).

* - Higher score better

† - 25 missing values (13 control, 12 intervention) imputed using best subset regression (StataCorp, 2003).
Table 4.2. Rates of PJC-FRAT completion and delays in completion.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Days from admission to completion of discipline specific PJC-FRAT section</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>3 (5)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Nursing</td>
<td>1 (7)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>4 (3)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td><strong>Number of discipline specific PJC-FRAT sections not completed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>138 (43%)</td>
<td>112 (36%)</td>
</tr>
<tr>
<td>Nursing</td>
<td>32 (10%)</td>
<td>27 (9%)</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>40 (13%)</td>
<td>44 (14%)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>14 (4%)</td>
<td>6 (2%)</td>
</tr>
</tbody>
</table>

Scores are median (inter-quartile range)
Figure 4.2. Nelson-Aalen cumulative hazard estimates, by group.
Table 4.3. Distribution of patients, patient-time, and falls incurred while under specific PJC-FRAT intervention / intervention combination recommendations.

<table>
<thead>
<tr>
<th>PJC-FRAT intervention / intervention combination recommendation</th>
<th>Number of patients*: Control / intervention</th>
<th>Patient-time (days): Control / intervention</th>
<th>Falls: Control / intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>145 / 133</td>
<td>2695 / 2060</td>
<td>15 / 17</td>
</tr>
<tr>
<td>Falls risk alert card only</td>
<td>63 / 73</td>
<td>1132 / 1289</td>
<td>26 / 12</td>
</tr>
<tr>
<td>Additional exercise only</td>
<td>35 / 34</td>
<td>479 / 392</td>
<td>4 / 2</td>
</tr>
<tr>
<td>Education program only</td>
<td>32 / 40</td>
<td>648 / 1018</td>
<td>9 / 4</td>
</tr>
<tr>
<td>Hip protector only</td>
<td>20 / 14</td>
<td>362 / 247</td>
<td>3 / 1</td>
</tr>
<tr>
<td>Falls risk alert card and additional exercise</td>
<td>21 / 29</td>
<td>423 / 452</td>
<td>6 / 9</td>
</tr>
<tr>
<td>Falls risk alert card and education program</td>
<td>24 / 22</td>
<td>755 / 684</td>
<td>7 / 2</td>
</tr>
<tr>
<td>Falls risk alert card and hip protector</td>
<td>35 / 39</td>
<td>878 / 1096</td>
<td>35 / 31</td>
</tr>
<tr>
<td>Additional exercise and education program</td>
<td>23 / 18</td>
<td>490 / 470</td>
<td>7 / 3</td>
</tr>
<tr>
<td>Additional exercise and hip protector</td>
<td>5 / 9</td>
<td>23 / 94</td>
<td>1 / 1</td>
</tr>
<tr>
<td>Education program and hip protector</td>
<td>5 / 1</td>
<td>95 / 10</td>
<td>0 / 0</td>
</tr>
<tr>
<td>Falls risk alert card, additional exercise and education program</td>
<td>10 / 14</td>
<td>221 / 309</td>
<td>0 / 1</td>
</tr>
<tr>
<td>Falls risk alert card, additional exercise and hip protector</td>
<td>12 / 22</td>
<td>240 / 545</td>
<td>11 / 6</td>
</tr>
<tr>
<td>Falls risk alert card, education program and hip protector</td>
<td>18 / 12</td>
<td>459 / 365</td>
<td>7 / 12</td>
</tr>
<tr>
<td>Additional exercise, education program and hip protector</td>
<td>5 / 0</td>
<td>88 / 0</td>
<td>4 / 0</td>
</tr>
<tr>
<td>All interventions</td>
<td>8 / 17</td>
<td>251 / 325</td>
<td>14 / 4</td>
</tr>
</tbody>
</table>

* Each patient may have contributed data to more than one PJC-FRAT intervention / intervention combination recommendation, thus the numbers displayed do not sum to equal the true number of participants.
Table 4.4. Classification and distribution of falls that led to injury (fall rated by worst injury sustained).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe</td>
<td>2*</td>
<td>2†</td>
</tr>
<tr>
<td>Moderate</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Minor</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Nil</td>
<td>117</td>
<td>82</td>
</tr>
</tbody>
</table>

* One neck of femur and one shaft of femur fracture
† Two neck of femur fractures
Table 4.5. Secondary outcome measures for patients in control and intervention groups.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay following consent (days)</td>
<td>24 (14, 37)</td>
<td>24 (14, 40)</td>
</tr>
<tr>
<td>Rate of change in modified Barthel Index scores (index points per day)</td>
<td>1.08 (0.32, 1.92)</td>
<td>0.95 (0.21, 1.87)</td>
</tr>
<tr>
<td>Rate of change in Timed Up and Go scores (seconds per day)</td>
<td>0.64 (0.19, 1.56)</td>
<td>0.50 (0.19, 1.30)</td>
</tr>
<tr>
<td>Rate of attendance at usual care physiotherapy sessions (attendances per day)</td>
<td>0.76 (0.62, 0.95)</td>
<td>0.75 (0.61, 0.92)</td>
</tr>
</tbody>
</table>

Scores are median (inter-quartile range).
4.4 Discussion

This is the first large randomised controlled trial to show a significant effect in reducing falls in the hospital setting. The targeted multiple intervention program employed in this study led to a 30% reduction in the incidence of falls. A reduction of this magnitude is important not only for individual patients and their families, but for hospital management in dealing with the associated costs and additional care brought about by falls (Brandis, 1999; Grenier-Sennelier et al., 2002; Liddle et al., 1995). Sub-acute hospital falls prevention programs have been based on the little evidence available from the hospital setting or by transferring results from other settings. This study provides a valuable evidence base for health care administrators and practitioners to reduce falls in sub-acute hospitals where falls are a frequent and dangerous occurrence.

In contrast to earlier studies (Donald et al., 2000; Mayo et al., 1994; Tideiksaar et al., 1993), the present study demonstrated a significant effect in reducing falls which may be a result of a targeted multiple intervention strategy where each intervention intentionally addressed one or more of a variety of falls risk factors. There may also have been some unintended benefits, such as increased surveillance while participating in the exercise or education programs. Tailoring of falls prevention strategies to individual patients was also made possible through targeting of interventions. The observed relative benefit of the intervention program became pronounced after 45 days hospitalisation (figure 4.2), indicating that the program may have had a cumulative effect over time and be of greatest benefit to those who have more complex presentations that necessitate greater lengths of stay in hospital.

A 22% reduction in the proportion of patients who fell and a 28% reduction in the overall number of falls with injuries were also noted. Though these results were encouraging they were not statistically significant. The proportion of patients who were fallers in the control group (22.5%) was less than the projected proportion used for the power analysis (30%). This study was insufficiently powered to detect a difference in the incidence of fall-related injury under the assumption that the change in rate of injury would have been proportional to that of falls. This is because fall-related injuries only occur in approximately 20 to 30% of falls (Cannard, 1996;
In terms of preventing femoral neck fractures, of those recommended for hip protectors, one patient from each group incurred this injury. Fractures in the subacute setting have previously been reported in 10% of falls as a maximum, though generally in less than 2% of falls (Cannard, 1996; Grant et al., 1987; Mion et al., 1989b; Teasell et al., 2002), and femoral neck fractures have been reported in up to 1.4% of falls (Nurmi et al., 2002). The nature of the fall by the intervention group patient who fractured their femoral neck itself raises important considerations for the prevention of hip fractures. Upon interview by the investigator following this incident, the patient reported tripping on their walking frame, falling forwards and landing on the anterior aspect of their knee. This is not the first time that a patient has been reported to sustain a femoral neck fracture while wearing hip protectors (Cameron et al., 1997; Specht-Leible et al., 1999). The point raised by this particular fracture is that despite much focus in biomechanical literature on the role that a blow to the lateral aspect of the hip plays in femoral neck fractures (Ford et al., 1996), hip fractures can be caused by other mechanisms (Dias, 1987; Sloan et al., 1981). Carpeted (or padded) flooring has been suggested as an alternative to patient-worn protective devices (Rowe, 2002). Theoretically, this might protect against femoral neck fractures of varying aetiology as well as fractures to other parts of the body (Healey, 1994), along with potentially improving gait in older inpatients (Willmott, 1987). Issues of cleaning, and infection control would be of concern with such an intervention, though these concerns also exist for the hip protector intervention. Theoretically, neither would be able to protect against “spontaneous” femoral neck fractures, which have been cited as the cause of up to 11% of femoral neck fractures (Dias, 1987). Thus, despite demonstrable effectiveness of hip protectors in attenuating forces transmitted to the lateral aspect of the hip during a fall (Kannus et al., 1999; Wiener et al., 2002), it is clear that not all femoral neck fractures are preventable by hip protectors, even when worn appropriately.

The present study focused on falls, fallers and falls with injury as separate end-points. Although a significant reduction was only observed for the falls outcome, examining each is important. Falls is an important end-point as each individual fall potentially
leads to negative outcomes (physical and psychological) for participants and places additional demands on hospital resources. Thus detection of a reduction in both falls and falls with physical injury would be indicative of improved safety for participants and less drain on hospital resources due to falls. In examining fallers, patients are the unit of analysis rather than events (falls). A reduction in fallers would also be indicative of improved health care delivery through a greater proportion of patients being treated without incurring falls and their potential consequences.

No significant differences were identified in secondary outcome measures. Despite the reduction of falls in this study, and the previously described links between falls and increases in length of hospital stay (Teasell et al., 2002), poorer rehabilitation outcomes (Teasell et al., 2002; Tuffnell, 1990), and an increased likelihood of being discharged to a nursing home (Grenier-Sennelier et al., 2002), no significant reductions in these areas were noted. It is possible that this study was insufficiently powered to detect clinically meaningful differences in these outcomes. For example, the intervention group would had to have had a minimum of 8% reduction in length of stay, 30% increase in rate of Timed Up and Go improvement, and 55% increase in rate of modified Barthel Index improvement, in order to have been detected in this trial (assuming alpha = 0.05, power = 0.80, and observed control group results and variances remain the same). However, even if this trial was insufficiently powered to detect these differences, there was no evidence of a strong trend away from the null hypothesis in any of these variables. One would have to hypothesise that although there are associations between falls and increases in length of stay, poorer rehabilitation outcomes, and an increased likelihood of being discharged to a nursing home, a causal role of falls in these outcomes cannot be supported by the results of this study. It is possible that another variable, perhaps impaired cognition, is a confounding factor in these associations, in that patients with this characteristic are at increased risk for falls due to this characteristic, and also for incurring the other outcomes. It is also possible that a causal association exists, but that it is an association between a particular “theoretical” subset of falls that were not the ones prevented by this intervention program. Clinically, an obvious subset of falls that would be hypothesised to meet this role would be the subset of “injurious” falls. However, table 4.2 demonstrates that the proportion of injurious falls incurred by
intervention group patients to control group patients, was similar to the reduction in
falls overall. Thus this theory is not well supported by the data from this trial.

This study had some limitations. In gaining patient consents, a minority of patients
were recruited by the investigator who, although not consciously aware of the
allocation sequence, did have the random allocation sequence maintained in his office
and thus could not be classified as being blinded in the same way that other research
staff who recruited patients were. This may have biased the distribution of baseline
falls risk factors between groups. However, the impact of this potential bias is likely
to have been minimal though due to the small proportion of patients recruited by the
investigator. This is further evidenced by the comparability of baseline patient
characteristics between groups.

The inability to completely blind all staff and participants was another limitation that
is a difficulty commonly encountered by researchers in the hospital setting. This may
have influenced fall incident recording practices or have altered elements of usual
care such as provision of regular physiotherapy services. By randomising individual
participants, hospital ward-to-ward variances in these recording behaviours would not
have influenced the results. The staff and participant blinding surveys also indicated
that both were relatively unaware of patient group allocation. Lastly, usual care
physiotherapy session attendances (table 4.5) were similar between groups suggesting
that usual care provision was unaffected.

Some ethical dilemmas were present in this study. Firstly, family members / carers of
patients with cognitive impairment were approached to provide consent. Although
this challenges their autonomy, it is important to be able to recruit patients with
cognitive impairment into research that may benefit this population. Patients were not
forced to participate in any intervention and were free to withdraw from the study at
any stage thus preserving a large degree of participant autonomy. Secondly, the falls
risk alert card potentially may violate patient privacy and cause distress to patients
and their families. A falls alert symbol identifiable by hospital staff was used rather
than a sign with words to minimise this risk. During the study no official complaints
or requests to remove falls risk alert cards were received.
The intervention program examined in this study could potentially be incorporated into the usual care of acute, other sub-acute and residential care facilities. Modifications to the exercise program in the acute setting may be required to cater for patients with drips, drains or other attachments. The description of the nature of falls provided in the written educational material could be modified and based on local facility falls data. These results may well be generalisable to other sub-acute settings. Although we recruited only 60% of eligible patients, their characteristics were consistent with those examined during study one of this research program which suggests our sample was reasonably representative. Many patients involved in this study had diagnoses of dementia or stroke and were recommended for the falls prevention interventions indicating that the program could be implemented on wards that deal specifically with patients with these diagnoses. However, generalising the findings to acute hospitals may be problematic as the reduction in fall event rates was noticeable after 45 days, a period after which few acute patients would still be in hospital. Further to this, some subacute hospitals would not cater for many patients with a length of stay longer than 45 days and generalisation to these hospitals may also be limited. The Nelson-Aalen cumulative hazard estimate of data from this trial (figure 4.3) suggests that patients with longer lengths of stay benefited from the intervention to a larger extent than those with shorter lengths of stay. However, it would be inappropriate to conclude that the benefit of this program is restricted to these patients solely. Even graphical survival analysis curves such as the Nelson-Aalen cumulative hazard estimate have theoretic confidence intervals within which the “true” distribution of falls over time is likely to fall within. Further similar research is indicated with pre-specified subgroup analyses to determine if the benefits of the intervention program are restricted to only those with longer lengths of stay, and to see if any protective effect of the program endures beyond the inpatient stay.

In this study, usual care at the Peter James Centre was compared to usual care plus the targeted falls prevention program. Subsequently many falls prevention interventions, such as review of sedative medication prescription, were not able to be investigated using this approach as they were already incorporated into usual care. These interventions, along with evaluation of the relative effectiveness of individual interventions from this program and the cost effectiveness of targeted multiple intervention strategies are worthy of further investigation.
Chapter 5: Secondary evaluation of the education program, additional exercise program, and hip protector interventions.
5.1 Introduction

Several multiple intervention falls prevention programs of varying sizes have been trialed in the subacute setting (Brady et al., 1993; Donald et al., 2000; Foster et al., 1996; Grenier-Sennelier et al., 2002; Oliver et al., 2002; Rogers, 1994; Sweeting, 1994; Tuffnell, 1990; Vassallo et al., 2004). Investigating a multifactorial intervention approach is clinically relevant as falls have a multifactorial aetiology. However, at the end of these analyses researchers have infrequently pursued the question of which components of the multifactorial program were effective and which were not. Trimming ineffective interventions from a larger program of interventions would reduce the resources used to implement the program for the achievement of the same outcome.

During study two, outcomes of relevance to three of the individual components of the falls prevention program other than those described in chapter four were measured. This chapter presents results from these additional measurements, so that a further understanding can be gained of the effectiveness of the individual components of the falls prevention program.

5.1.1 Aims and hypotheses

The aims of the research described in this chapter are to:

- Evaluate the effectiveness of the “education program” in providing patients with falls prevention information that they were not previously aware of, and whether patients perceived that they changed their behaviour in response to this information.
- Evaluate the effect of the “additional exercise” component of the targeted falls prevention program on the rate of improvement in leg strength, balance and mobility.
- Evaluate the compliance of patients recommended for the “hip protector” intervention in wearing this equipment.

The hypotheses of the research described in this chapter are that:

- Patients recommended for the “education program” intervention would identify that they learnt new information regarding their safety (falls prevention), and modified some of their actions in accordance with this.
• Intervention group patients recommended for the “additional exercise” component of the targeted falls prevention program in addition to usual care will improve their balance, strength, and mobility at a greater rate than the equivalent subset of patients from the control group who received usual care alone.

• Patients recommended for the “hip protector” intervention would display a high level of compliance relative to previously recorded levels in wearing this equipment.
5.2 Method

5.2.1 Participants and study design
Data analysed in this chapter were taken from patients in study two of the research program. For the secondary evaluation of the additional exercise intervention, patients who were recommended for the additional exercise intervention from both the intervention and control groups contributed data. For the secondary evaluation of the education program, patients who were recommended for the education program intervention from the intervention group only, contributed data. Similarly, patients who were recommended for the hip protector intervention from the intervention group only, contributed data.

5.2.2 Sample size
As these comparisons are secondary evaluations from a larger randomised controlled trial, no specific sample size was specified for their analysis prior to study commencement.

5.2.3 Intervention
The education program, additional exercise program, and hip protector interventions have previously been described (sections 2.5.3.1, 2.5.3.4 and 2.5.3.5 respectively). A copy of the education booklet, manual of exercises used in this program, and a picture of the hip protectors have also been presented in appendices D, H, and I respectively.

Briefly, the education program consisted of one-to-one bedside education sessions with an occupational therapist, up to 35 minutes in duration, conducted twice weekly. An education booklet was also provided which contained the curriculum of the program, intended to be covered over four sessions. Individual patients could receive more than four education sessions when deemed necessary by the research occupational therapist. The exercise program was developed by the investigator and was based on combining the therapeutic elements of Tai Chi (Wolf et al., 1993) with functional exercises. The program was conducted three times per week with sessions lasting approximately 45 minutes. Once recommended for this intervention, patients usually continued attendance until discharge unless unwell or refusal to continue. The hip protector intervention consisted of two pairs of hip protector pants and one pair of
removable hip protector shields. Intervention group patients recommended for this intervention were encouraged to wear them throughout the day and night.

5.2.4 Procedure

5.2.4.1 Participant recruitment, consent, randomisation, screening tool completion, provision of usual care, and provision of the intervention.

The procedure for recruiting and gaining consent from patients to participate in this study (section 4.2.5.1), randomisation procedure (section 4.2.5.2), screening tool completion (section 4.2.5.4), provision of usual care (section 2.2), provision of the education program, additional exercise program, and hip protector interventions have all previously been described previously (sections 2.5.3.1, 2.5.3.4 and 2.5.3.5 respectively).

5.2.4.2 Measurements

i) Education program secondary evaluation

Patients recommended for the education program interventions were surveyed at their final education program session. The questionnaire was administered by the research occupational therapist. It contained six statements, namely:

1) The written educational material was easy to understand.
2) The written educational material provided me with information that I was previously unaware of.
3) I felt comfortable to participate in the discussions / discussion groups.
4) The discussions / discussion groups provided me with information that I was previously unaware of.
5) As a result of reading the written material and the discussions / discussion groups, I tried to modify my actions to reduce my risk of falling over whilst in hospital.
6) Please list any actions that you took to reduce your risk of falling.

For statements one to five, patients were asked to select the most appropriate response from a Likert scale (Mogey, 1999). These response options were strongly agree, agree, undecided, disagree, strongly disagree. For the final question, the research
occupational therapist recorded verbatim patient responses. As discussion “groups” were not successfully integrated into the education program, the components of questions three, four, and five above referring to the discussion groups were removed after the first four weeks of the data collection period.

**ii) Additional exercise program secondary evaluation**

The procedure for recording demographic and baseline patient characteristics has been described (section 2.4). A battery of balance, strength, and mobility outcome measures were also collected from patients from both the intervention and control groups following their recommendation for the additional exercise intervention. They were measured again just prior to patient discharge. A research assistant was employed for four hours per week to conduct these measurements for the duration of study two. This took place at the same time each week (Wednesday afternoons). The research assistant had several years of experience as a physiotherapy assistant and was trained in completing the measures by the investigator prior to study commencement. Due to the number of patients referred for this intervention, and the fluctuations in the number of patients recommended each week, the investigator was required to conduct some of both the initial testing and discharge testing. Furthermore, as some of the discharges were arranged rapidly, for example, where a hostel bed became available for the patient, there was insufficient notice for the research assistant or the investigator to conduct some or all of the discharge measures. In these circumstances, discharge measures administered by the hospital physiotherapist as a part of their routine discharge summary were collated. Discharge follow-up measures were not collected for patients for whom initial measures were not collected (for example, if the patient had refused).

The measurements taken were the Timed Up and Go test, gait velocity over six metres, mean step length while walking six metres, the Step Test with both right and left legs, the Functional Reach test, the Six Minute Walk test, and maximal isometric muscle strength tests using a spring gauge dynamometer for the quadricep, hamstring, ankle dorsiflexor, and hip abductor muscle groups of both left and right legs.

Gait velocity and step length are temporal measures of gait that are considered to be key outcome measures in neurological rehabilitation (Hill et al., 2001). Gait velocity
has shown significant improvement during inpatient care for a mixed rehabilitation sample of stroke and orthopaedic patients (Weiner et al., 1993). Several researchers have examined the reliability of gait speed measurements over distances of five, six and eight metres and have consistently established high test-retest and intrarater reliabilities (reliability coefficients > 0.89) (Bohannon et al., 1990; Colleen et al., 1990; Evans et al., 1997; Holden et al., 1984; Salbach et al., 2001; Wade et al., 1987). These measurement in this study was taken using a 10 metre walkway with two metre acceleration and deceleration sections, thus making the distance over which the measurements were taken six metres (Hill et al., 2001). The assessor instructed the patient to walk at a comfortable speed without stopping or talking until they reached the end of the walkway. The assessor counted the number of steps over the six metre section and used a stopwatch to measure the time taken to walk this section.

Step length was calculated by dividing six by the number of steps taken (over the six metre test section), to equal step length with units of metres per step. Gait velocity was calculated by dividing six by the time taken (over the six metre test section), to equal gait velocity with units of metres per second.

The Timed Up and Go test is a measure of physical impairment that has been described previously (section 2.4.1.8).

The six minute walk test is a measure of gait endurance. Patients with stroke have demonstrated poorer six minute walk test results than healthy older people (Dean et al., 2001). This test has high retest reliability amongst people with chronic lung and heart disease (ICC = 0.92) (Guyatt et al., 1985), patients with acquired brain injury (ICC = 0.94) (Mossberg, 2003), along with community dwelling people, frail elderly people, and people with Parkinson’s disease (Hadara et al., 1999; King et al., 2000; Schenkman et al., 1997). The procedure for conducting this test was originally described using an indoors walk-way, 33 metres in length (Guyatt et al., 1985). The walk-way used in this investigation was indoors and 40 metres in length. Apart from this, the procedure for conducting this test was in line with what has been previously described (Guyatt et al., 1985). Patients were instructed to walk as far as they could in six minutes, but if they needed to rest, they could sit down in one of the several chairs adjoining the walkway for as long as necessary. When a patient reached the
end of the 40 meter walkway, they were told to turn around and continue walking back in the opposite direction. The recorded outcome was total distance traveled.

The Step Test is a measure evaluating the speed of performing a dynamic single limb stance balance task (Hill et al., 2001). The patient stands in front of a 7.5 centimetre block and lifts one foot up onto the step and then back down again repeatedly during a 15 second period. This test was conducted for both legs. This test has been found to be significantly correlated with other tests of balance and gait such as the Functional Reach test, gait velocity and stride length, has been found to have high retest reliability in both healthy older people and stroke subjects (Hill et al., 1996), and has been found to discriminate between non-fallers, single, and multiple fallers in the community setting (Dite et al., 2002).

The Functional Reach test measures the patient’s ability to reach forwards in bilateral limb stance (Duncan et al., 1992; Duncan et al., 1990; Weiner et al., 1993). The patient initially stands facing along a wall in a comfortably relaxed stance with one arm straight out in front, shoulder at 90 degrees flexion. A tape measure is attached to the wall at the level of the acromion. The initial position was marked, and the patient was then asked to reach forwards as far as they could without overbalancing. Two practice trials were used, followed by three “test” trials. The mean of the three test trials was used as the outcome measure (Duncan et al., 1992). The Functional Reach score of older male war veterans who experienced one or more falls over a six month period were significantly lower than those who did not fall when measured at the start of the six month follow-up period (Duncan et al., 1992). Retest reliability in older healthy subjects has been found to be high (ICC = 0.89) (Weiner et al., 1992), and also for those with Parkinson’s Disease (Schenkman et al., 1997).

Lower limb muscle strength was measured using a spring gauge dynamometer. Spring gauge dynamometer equipment has previously been used to test muscle strength amongst older people (Lord et al., 2003; Lord et al., 1991), and their measurements have a high correlation with those attained through strain gauge (hand-held) dynamometres (Bohannon et al., 1989). As spring gauge dynamometers have previously been considered to lose calibration with repeated use (Bohannon et al., 1989), the calibration of equipment used in this study is presented as a part of
appendix P. This investigation revealed the equipment used in this study to be appropriately calibrated (agreement by blinded reader with randomly placed weights of one kilogram increments = 100%). Though not yet identified as a risk factor for falls in the subacute setting, it was important to collect this information as impaired lower limb strength has been identified as a falls risk factor in the community setting (Lord et al., 1992; Lord et al., 1994), and has been recommended as an outcome measure for clinical trials with exercise interventions (Lord et al., 2003).

Quadriceps strength was assessed following a method from that has been previously described with moderate retest reliability (reliability coefficient = 0.75) (Lord et al., 2001; Lord et al., 1994; Lord et al., 1991). In our study, the patient was seated on a bench (so that feet were free from floor) with knees at 90 degrees of flexion, with an ankle strap fastened proximal to the ankle joint using a leather strap and buckle attachment. The strap was tightened sufficiently in this position to limit any movement proximally or distally along the length of the tibia during the testing procedure, yet not so tight as to cause discomfort. The distance between the strap and the lateral epicondyle of the femur was recorded. The spring gauge dynamometer² was attached to the ankle strap and secured directly posterior to the leg using a chain with adjustable link positions, perpendicular to the shaft of the tibia. Tension was placed through the chain at this point so that no visible “slack” in the chain was evident, yet less than 1 kilogram of strain was measured on the dynamometer. The patient was then asked to extend their knee “as hard as you can”. The best of three trails was taken as the measurement, with 30 seconds rest between each trial. For the discharge test, the ankle strap was placed in the same position as it was during the initial test so that raw dynamometer scores (in kilograms) could be subtracted from each other to form “change” scores without having to convert raw dynamometer scores into torque scores.

Hamstrings and ankle dorsiflexor strength were also tested as strength in these muscle groups has previously been found to be different between nursing home residents who were fallers and non-fallers (Whipple et al., 1987), and have been included in other standardised strength testing batteries for falls risk assessment (Lord et al., 2003; Lord

² F H Prager Pty Ltd, 16 – 26 Wentworth Place, Banyo, Queensland
et al., 2001). Hamstrings muscle strength was tested with the same procedure as the quadriceps strength test, however the spring gauge dynamometer was secured directly anterior to the tibia and the patient was asked to pull backwards instead of forwards. The patient was again sitting on a bench for this testing procedure so that the movement of their foot was not limited by testing equipment. Ankle dorsiflexor strength was tested using a procedure based on one previously described (Lord et al., 1994), with the patient seated, foot resting on a platform in the plantargrade position, and a strap attached across the dorsum of the foot at the level of the head of the fifth metatarsal. The ankle was then actively dorsiflexed by the patient, stretching a spring gauge dynamometer orthogonally perpendicular to the plantar aspect of the foot. A measurement of the distance between the strap and the lateral malleolus was added though, similar to the procedure used for quadriceps and hamstrings strength assessment. This was to ensure reproducibility of the strap position, and to allow raw dynamometer scores to be used in comparisons between admission and discharge scores.

Hip abductor strength was measured using a procedure outlined in appendix P, and was measured due to the importance of this muscle group to lateral movement balance tasks and gait (Brauer et al., 2000; Giles et al., 1999). The intra-rater reliability of the research assistant when using this measurement procedure using measures taken 24 hours apart was ICC model (3,1) = 0.71. The inter-rater reliability between the investigator and another physiotherapist using measures taken 24 hours apart was ICC model (2,1) = 0.60. These reliabilities could be considered to be moderate though similar to results gained for testing the strength of other lower limb muscle groups using spring gauge dynamometry equipment (Lord et al., 1991).

iii) Hip protector intervention secondary evaluation

Patient compliance with wearing hip protectors was recorded through audits conducted by the investigator and research physiotherapist every five weeks during the study period. Information was gathered in these audits for all intervention group patients who were in the hospital and recommended to the hip protector intervention. Where the patient was unable to provide this information (for example, due to communication impairment), the patient’s primary care nurse was interviewed. The information collected in these audits was:
1) Were the hip protectors presently being worn?
2) How many hours over the past 24 had the hip protectors been worn?
3) If the hip protectors had been removed for one hour or more over the past 24 hours, why were they removed?
4) If the hip protectors had been removed for one hour or more over the past 24 hours, was there a particular time of day that they were not worn.
5) What were the nursing staff ratings of patient toileting using the modified Functional Independence Measure (Linacre et al., 1994) when the patient was and was not wearing the hip protectors?

This audit was administered on five weekdays of the audit week, however to restrict duplication of data for question 5, only results from the first day of data collection were used for statistical analysis. Where a patient refused to wear the hip protectors on all audited days, they were classified as “refusing outright” to wear the hip protectors.

### 5.2.5 Blinding

For the secondary evaluation of the education program and hip protector interventions, both patients and research staff administering this survey and audit were not blinded to group allocation, however these analyses did not involve comparisons between groups. For the secondary evaluation of the additional exercise program, blinding of patients and hospital staff was incomplete. Procedures for and results of blinding surveys for both patients and hospital staff have been discussed (chapter 4). The investigator was aware of participant group allocation. The research assistant was blinded to participant group allocation. It was the initial intent of the investigator that the research assistant be the only person to conduct initial and discharge strength, balance, and mobility outcome measures with the patients. This would have produced complete assessor blinding for these measures. However, due to the unforeseen difficulties in gathering this data, the investigator assisted with this data collection and there was also some reliance on data collected by hospital physiotherapists from their routine discharge assessments. Measures collected for this research that were also routinely collected by hospital physiotherapists were gait velocity, step length, Step Test, and the six minute walk. Thus blinding of the
assessors for these outcome measures was incomplete, however the research assistant did collect a majority of initial and discharge measures, ensuring blinding of assessor for a majority of measurements.

5.2.6 Statistical analyses

i) Education program secondary evaluation

Education program evaluation survey results were analysed descriptively.

ii) Additional exercise program secondary evaluation

Continuous baseline measures from the battery of balance, strength, and mobility specifically selected for this subgroup analysis were initially examined for normality of distribution using the Shapiro-Wilk test (StataCorp, 2001). Data for each variable examined were considered not to be normally distributed (Shapiro-Wilk: p < 0.05), thus they were compared between groups using the Wilcoxon rank-sum (Mann-Whitney) test for independent samples (StataCorp, 2001). Due to incomplete datasets, baseline results were also compared between groups using only data from patients that had both initial and discharge measures recorded. Wilcoxon rank-sum (Mann-Whitney) tests were used for these comparisons with the exception of data from the Functional Reach measure. This data was compared using an unpaired t-test (equal variances) as it did not violate normality of distribution (Shapiro-Wilk: p > 0.05) or equality of variance assumptions (Levene’s test: p > 0.05).

Analyses of outcomes were on an intention-to-treat basis. Change scores between initial and discharge assessments of the battery of balance, strength and mobility tests (gait velocity, step length, Step Test, Timed Up and Go, six minute walk, Functional Reach, and strength tests of the quadriceps, hamstring, hip abduction and ankle dorsiflexor muscle groups) were calculated. These change scores were then divided by the length of time between initial assessment and discharge assessment. Thus rate of change scores were generated for each outcome. Rate of change data between groups were compared using Wilcoxon rank-sum (Mann-Whitney) tests as data were not normally distributed (Shapiro-Wilk: p < 0.05).
To examine if patients for whom discharge (follow-up) data was collected were different from those for whom it was not but did have initial data recorded, a comparison of admission scores between these two groups was conducted. As there appeared to be a relatively lower proportion of patients from the control group who had a follow-up completed, this comparison was made separately between control and intervention groups. Data from intervention group patients was compared using Wilcoxon rank-sum (Mann-Whitney) tests with the exception of Functional Reach data as it did not violate normality of distribution (Shapiro-Wilk: p > 0.05) or equality of variance assumptions (Levene’s test: p > 0.05). Thus an unpaired t-test was used. Data from control group patients was compared using Wilcoxon rank-sum (Mann-Whitney) tests with the exception of Functional Reach, six minute walk, dorsiflexion strength (left leg), and quadriceps strength test (right and left) data as it did not violate normality of distribution (Shapiro-Wilk: p > 0.05) or equality of variance assumptions (Levene’s test: p > 0.05). Again unpaired t-tests were used for comparison of these data.

iii) Hip protector intervention secondary evaluation

Hip protector compliance audit results were analysed descriptively. The comparison between patient independence in toileting with and without the hip protectors being worn was analysed using the Wilcoxon match-pairs signed-rank test (StataCorp, 2001).
5.3 Results

A summary of baseline characteristics of patients who were recommended for the education program, additional exercise program, and hip protector interventions is presented in table 5.1.

i) Education program.

During the study period, there were a total of 473 education sessions provided to patients [median (inter-quartile range) = 4 (2 to 5) sessions per patient]. A total of 64 education program surveys, of a possible 115 were completed. Reasons for non-completion were not collected. A summary of responses is presented in table 5.2. A majority of patients agreed or strongly agreed that the written education material was easy to understand and provided information that patients were previously unaware of. A majority also agreed or strongly agreed that they felt comfortable to participate in discussions, that discussion sessions provided patients with information that they were previously unaware of, and that as a result of the education program, the patients modified their actions to reduce their risk of falling. Most frequently, patients reported (percentage of surveys that included this item as one of the listed responses to this question):

- Being more careful (generally) - 28 responses (44%)
- Reducing or avoiding a specifically mentioned “risky” activity - 13 responses (20%)
- Asking for help from staff – 11 responses (17%)
- No changes – 10 responses (16%)
- Using gait and reaching aids appropriately – 8 responses (13%)
- Planning ahead – 7 responses (11%)
- Increased awareness of falls risks (generally) – 7 responses (11%)
- Follow staff instructions – 5 responses (8%)
- Modify environment – 3 responses (5%)
- Perform more exercises – 3 responses (5%)
- Monitor own fatigue levels – 3 responses (5%)

ii) Additional exercise program.
During the data collection period, 93 intervention group patients were recommended for the additional exercise intervention for a total of 2596 days. Similarly, 80 control group patients were recommended for this intervention for a total of 2215 days. No significant differences were found between groups for baseline characteristics (table 5.1) or the initial assessment of balance, strength, and mobility tests (table 5.3). The six minute walk test had the lowest number of initial assessments completed (62 for the intervention group, 57 for the control group). Thus data was recorded for at least two thirds of all participants recommended for this intervention. Reasons for full non-completion of measurements included patient refusal (3 patients control, 4 patients intervention), administrative error (3 patients control, 2 patients intervention), patient discharge (to an acute hospital, for example) between time of recommendation and intended date of testing (9 patients control, 9 patients intervention), and patient being medically unwell (2 patients intervention). Partial non-completions [ie. non-completion of specific test(s)] were contributed to by patient skin conditions (such as ulcer) preventing use of strap for strength testing, and patient report of being too fatigued to complete test battery.

During the study period, there were 792 possible exercise session attendances of which 595 (75%) were attended. The median (inter-quartile range) number of attended sessions per patient was 4 (3 to 10). There were also 197 (25%) occasions of non-attendance, 103 (13% of total possible) due to patient refusal, 42 (5%) due to patient ill-health, and 53 (7%) due to the patient being at an alternate appointment (such as an occupational therapy home visit).

Discharge balance, strength, and mobility outcome measures and rates of improvement are presented in tables 5.4 and 5.5. A relatively lower proportion of patients had both initial and discharge measurements completed than those who had initial measurements completed. Reasons for full non-completion of these measurements included; sudden patient discharge to nursing home, hostel, acute hospital, or other location (control: 14 patients, intervention: 4 patients), administrative error (control: 12 patients, intervention: 11 patients), patient refusal (control: 6 patients, intervention: 4 patients). Partial non-completions were contributed to by patient report of being too fatigued to complete test battery and patient being discharged during follow-up assessment. Patients in the intervention
group experienced a significantly greater rate of improvement in the Functional Reach balance test (Wilcoxon rank-sum: p = 0.004). There were no other significant differences between groups. There were also no significant differences between groups in initial assessment results for patients who had both admission and discharge measurements completed, nor within groups in initial assessment results between those who had discharge measurements completed and those who did not.

The hip protector audit was completed on 203 occasions (maximum of 5 audit occasions per patient per audit week) for intervention group patients recommended for this intervention, with 8 patients audited during two separate audit weeks. The hip protectors were being worn at the time of the audit on 57% of occasions (115 of 203 audit occasions). The audited patient had worn the hip protectors for ≥ 12 hours over the preceding 24 hours on 57% of occasions (115 of 203 audit occasions), while they were worn for all 24 hours on 18% (37 of 203 audit occasions). Reasons provided for patients not wearing hip protectors for the full 24 hours (percentage of 166 total audit occasions) included:

- Discomfort wearing hip protectors in bed – 41 audit occasions (25%).
- Impaired continence while wearing hip protectors – 32 audit occasions (19%).
- Immobility / not getting out of bed at night – 35 audit occasions (21%).
- Patient perception of not requiring hip protectors – 16 audit occasions (10%).
- Refusal with no specific reason provided – 23 audit occasions (14%).
- Other reasons – 19 audit occasions (11%).

Hip protectors were not worn at night on 82% of occasions (166 of 203 audit occasions). Patients refused outright to wear the hip protectors (no use at all during the audit week) in 25% of patient audit-weeks (13 of 53 patient audit-weeks).

Modified Functional Independence Measure scores were recorded for 36 patients (using first audit occasions only). The median (inter-quartile range) score for patients to use the toilet when not wearing hip protectors was 4.5 (3 to 6). When wearing hip protectors was 4 (3 to 6). There was a reduction by 1 modified Functional Independence Measure score level in 10 patients, and by 2 levels in one patient. This difference was significant (Sign-rank test: p = 0.001).
Table 5.1. Baseline characteristics of patients in the intervention and control groups upon recommendation for the education program, additional exercise, and hip protector interventions.

<table>
<thead>
<tr>
<th></th>
<th>Education program</th>
<th>Additional exercise</th>
<th>Hip protectors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Gender – male</td>
<td>40 (36%)</td>
<td>35 (30%)</td>
<td>31 (39%)</td>
</tr>
<tr>
<td>Age</td>
<td>82 (75, 86)</td>
<td>83 (77, 88)</td>
<td>81 (75, 86)</td>
</tr>
<tr>
<td>Admission modified Barthel Index ( /100)*</td>
<td>47 (39, 59)</td>
<td>44 (37, 54)</td>
<td>52 (41, 62.8)</td>
</tr>
<tr>
<td>Prior living arrangements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home alone</td>
<td>51 (46%)</td>
<td>49 (43%)</td>
<td>37 (46%)</td>
</tr>
<tr>
<td>Home with family</td>
<td>45 (41%)</td>
<td>49 (43%)</td>
<td>34 (42%)</td>
</tr>
<tr>
<td>Low level residential care facility</td>
<td>15 (14%)</td>
<td>17 (15%)</td>
<td>9 (11%)</td>
</tr>
<tr>
<td>Admission diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>36 (32%)</td>
<td>40 (35%)</td>
<td>18 (23%)</td>
</tr>
<tr>
<td>Other geriatric management</td>
<td>22 (20%)</td>
<td>24 (21%)</td>
<td>19 (24%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>11 (10%)</td>
<td>9 (8%)</td>
<td>18 (23%)</td>
</tr>
</tbody>
</table>

† Missing values (13 falls risk alert card, 3 education program, 10 hip protector) imputed using best subset regression

- Higher scores better.
Table 5.2. Summary of education program survey responses.

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>The written educational material was easy to understand.</td>
<td>39</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>The written educational material provided me with information</td>
<td>21</td>
<td>31</td>
<td>3</td>
<td>5</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>that I was previously unaware of.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt comfortable to participate in the discussions /</td>
<td>34</td>
<td>21</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>discussion groups.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The discussions / discussion groups provided me with information</td>
<td>22</td>
<td>26</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>that I was previously unaware of.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The discussions / discussion groups provided me with information</td>
<td>32</td>
<td>19</td>
<td>1</td>
<td>11</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>that I was previously unaware of.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5.3. Baseline balance, strength, and mobility measurements of patients recommended for the additional exercise intervention.

<table>
<thead>
<tr>
<th>Completed measurements (n): Control (%) / intervention (%)</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait velocity (m/sec)</td>
<td>68 (85%) / 79 (85%)</td>
<td>0.47 (0.28, 0.63) / 0.45 (0.28, 0.63)</td>
</tr>
<tr>
<td>Step length (m)</td>
<td>67 (84%) / 79 (85%)</td>
<td>0.33 (0.26, 0.43) / 0.32 (0.22, 0.43)</td>
</tr>
<tr>
<td>Timed Up and Go (sec)*</td>
<td>66 (83%) / 78 (84%)</td>
<td>29 (21, 48) / 34 (23, 48)</td>
</tr>
<tr>
<td>Step Test – left (steps)</td>
<td>68 (85%) / 80 (86%)</td>
<td>1 (0, 8) / 1.5 (0, 6.8)</td>
</tr>
<tr>
<td>Step Test – right (steps)</td>
<td>68 (85%) / 80 (86%)</td>
<td>2.5 (0, 7.8) / 0 (0, 7)</td>
</tr>
<tr>
<td>Functional Reach (cm)</td>
<td>66 (83%) / 76 (82%)</td>
<td>10.8 (2.8, 19) / 10 (6, 14.8)</td>
</tr>
<tr>
<td>Strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee extension – right</td>
<td>64 (80%) / 77 (83%)</td>
<td>11 (9, 15) / 10 (7, 16)</td>
</tr>
<tr>
<td>Knee extension – left</td>
<td>63 (79%) / 77 (83%)</td>
<td>12 (9, 16) / 10 (8, 15)</td>
</tr>
<tr>
<td>Knee flexion – right</td>
<td>63 (79%) / 77 (83%)</td>
<td>8 (6, 11) / 8 (6, 11)</td>
</tr>
<tr>
<td>Knee flexion – left</td>
<td>63 (79%) / 77 (83%)</td>
<td>8 (6, 10) / 8 (6, 10)</td>
</tr>
<tr>
<td>Hip abduction – right</td>
<td>62 (78%) / 74 (80%)</td>
<td>6 (5, 8) / 6 (4, 8)</td>
</tr>
<tr>
<td>Hip abduction – left</td>
<td>64 (80%) / 74 (80%)</td>
<td>5 (4, 7) / 5 (3.8, 6)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – right</td>
<td>64 (80%) / 75 (81%)</td>
<td>7 (5, 8.8) / 6 (4, 9)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – left</td>
<td>64 (80%) / 75 (81%)</td>
<td>6 (5, 8) / 6 (4, 8)</td>
</tr>
<tr>
<td>Six minute walk (m)</td>
<td>57 (71%) / 62 (67%)</td>
<td>140 (85, 204) / 130 (80, 203)</td>
</tr>
</tbody>
</table>

* Lower score better.

Scores are median (inter-quartile range)
Table 5.4. Discharge balance, strength, and mobility measurements of patients recommended for the additional exercise intervention.

<table>
<thead>
<tr>
<th>Completed measurements (n): Control (%) / Intervention (%)†</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait velocity (m/sec) 42 (62%) / 64 (81%)</td>
<td>0.69 (0.47, 0.88)</td>
<td>0.61 (0.52, 0.78)</td>
</tr>
<tr>
<td>Step length (m) 41 (61%) / 63 (80%)</td>
<td>0.43 (0.38, 0.50)</td>
<td>0.40 (0.35, 0.46)</td>
</tr>
<tr>
<td>Timed Up and Go (sec)* 40 (61%) / 63 (81%)</td>
<td>19 (13, 29)</td>
<td>21 (17, 30)</td>
</tr>
<tr>
<td>Step Test – left (steps) 43 (63%) / 65 (81%)</td>
<td>8 (0, 10)</td>
<td>7 (0, 10)</td>
</tr>
<tr>
<td>Step Test – right (steps) 43 (63%) / 65 (81%)</td>
<td>8 (0, 11)</td>
<td>7 (4, 9)</td>
</tr>
<tr>
<td>Functional Reach (cm) 36 (55%) / 60 (79%)</td>
<td>14 (8, 21)</td>
<td>19 (13, 24)</td>
</tr>
<tr>
<td>Strength (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee extension – right 35 (55%) / 63 (82%)</td>
<td>12 (9, 18)</td>
<td>13 (10, 17)</td>
</tr>
<tr>
<td>Knee extension – left 35 (56%) / 63 (82%)</td>
<td>10 (13, 19)</td>
<td>12 (9, 17)</td>
</tr>
<tr>
<td>Knee flexion – right 34 (54%) / 63 (82%)</td>
<td>7 (10, 14)</td>
<td>10 (8, 12)</td>
</tr>
<tr>
<td>Knee flexion – left 35 (56%) / 63 (82%)</td>
<td>8 (10, 12)</td>
<td>10 (8, 13)</td>
</tr>
<tr>
<td>Hip abduction – right 34 (55%) / 62 (84%)</td>
<td>6 (5, 9)</td>
<td>8 (5, 10)</td>
</tr>
<tr>
<td>Hip abduction – left 36 (56%) / 62 (84%)</td>
<td>6 (5, 8)</td>
<td>7 (5, 10)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – right 34 (53%) / 63 (84%)</td>
<td>7 (6, 10)</td>
<td>8 (6, 11)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – left 34 (53%) / 63 (84%)</td>
<td>8 (6, 10)</td>
<td>8 (6, 11)</td>
</tr>
<tr>
<td>Six minute walk (m) 34 (60%) / 52 (84%)</td>
<td>220 (140, 306)</td>
<td>160 (140, 200)</td>
</tr>
</tbody>
</table>

† Percentage equals number of patients proportion of patients with admission measures completed who also had discharge measures completed.

* Lower scores better.

Scores are mean (interquartile range)
Table 5.5. Rates of improvement in balance, strength, and mobility outcome measures, comparison between groups.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait velocity (m/sec/day)</td>
<td>0.03 (0, 0.08)</td>
<td>0.04 (0.01, 0.12)</td>
</tr>
<tr>
<td>Step length (cm/day)</td>
<td>0.03 (0, 0.07)</td>
<td>0.03 (0, 0.07)</td>
</tr>
<tr>
<td>Timed Up and Go (sec/day)</td>
<td>0.40 (0.11, 1.01)</td>
<td>0.58 (0.2, 1.41)</td>
</tr>
<tr>
<td>Step Test – left (steps/day)</td>
<td>0.14 (0, 0.33)</td>
<td>0.13 (0, 0.3)</td>
</tr>
<tr>
<td>Step Test – right (steps/day)</td>
<td>0.08 (0, 0.37)</td>
<td>0.14 (0, 0.28)</td>
</tr>
<tr>
<td>Functional Reach (cm/day)*</td>
<td>0.04 (-0.13, 0.51)</td>
<td>0.4 (0.18, 0.83)</td>
</tr>
<tr>
<td>Strength (kg/day)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee extension – right</td>
<td>0.07 (-0.05, 0.21)</td>
<td>0.14 (0, 0.33)</td>
</tr>
<tr>
<td>Knee extension – left</td>
<td>0 (-0.11, 0.29)</td>
<td>0.05 (-0.03, 0.23)</td>
</tr>
<tr>
<td>Knee flexion – right</td>
<td>0.04 (-0.07, 0.21)</td>
<td>0.06 (0, 0.29)</td>
</tr>
<tr>
<td>Knee flexion – left</td>
<td>0.05 (0, 0.19)</td>
<td>0.09 (0, 0.21)</td>
</tr>
<tr>
<td>Hip abduction – right</td>
<td>0.06 (-0.05, 0.16)</td>
<td>0.07 (0, 0.2)</td>
</tr>
<tr>
<td>Hip abduction – left</td>
<td>0.03 (-0.03, 0.18)</td>
<td>(0, 0.29)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – right</td>
<td>0.02 (0.07, 0.13)</td>
<td>0.09 (0, 0.2)</td>
</tr>
<tr>
<td>Ankle dorsiflexion – left</td>
<td>0.05 (-0.01, 0.14)</td>
<td>0.09 (0, 0.3)</td>
</tr>
<tr>
<td>Six minute walk (m/day)</td>
<td>4 (1.7, 7.5)</td>
<td>2.3 (0.37, 5)</td>
</tr>
</tbody>
</table>

Positive data reflect improvement, negative figures decline.

* - Statistically significant difference (Wilcoxon rank-sum: p = 0.004)
5.4 Discussion

These secondary evaluations have provided some evidence that individually, the education program, additional exercise program, and hip protector interventions may be useful additions to future falls prevention programs for the subacute hospital setting. However, some potentially negative consequences of their inclusion have also been highlighted.

The education program intervention was intended to work by modifying “high risk” patient behaviours. Questionnaire responses indicated that this may have been the case, with a majority of patient surveys indicating that they modified their behaviour in response to the education sessions. However patients did not as frequently indicate a specific activity that they modified, rather many stated that they were more careful generally. This raises the question as to whether a more generalized awareness raising intervention which could be implemented at lower cost could make a similar contribution. A small proportion of patients indicated that the education did not provide them with any new information and that they did not modify their actions. If this intervention did have an impact on the overall rate of falls, it is likely to have come about due to specific changes in patient behaviour amongst some and a general increase in awareness of falls in others (which may have led to behaviour change sub-consciously, or behaviour change that could not be recalled at the time of questionnaire completion).

The questionnaire responses may have been influenced by two factors. First, there was a large number of patients who did not complete the questionnaire (51 patients - 44%). The proportion of patients who viewed the education program favorably amongst those not surveyed may have been different to that among those who were. Reasons for questionnaire non-completion were not collected. Second, the questionnaire was administered by the research occupational therapist who conducted the program. This may have caused patients to respond more favorably than if a third person not involved in the program administered the questionnaire.

The education program investigated in this trial differed from programs previously investigated in the subacute setting (Brady et al., 1993; Grenier-Sennelier et al., 2002;
Rogers, 1994). It encompassed a curriculum focused on the problem of falls in the subacute setting and was based upon the theoretical frameworks of threat appraisal (Taylor et al., 1996), protection motivation theory (Maddux et al., 1983), and goal setting and review (Wiese et al., 1987). It was also conducted by a research occupational therapist, not a hospital nursing staff member. This may have allowed patients to discuss more openly, any potential difficulties they were having with nursing staff that may have affected their safety. For example, patients were able to discuss with the research occupational therapist if they felt their nursing “buzzers” were not answered as promptly as they would have liked, without fear of offending their primary care nurse. This allowed the research occupational therapist to discuss with the patient constructive approaches to dealing with this issue, which may not have been accomplished had the patient not felt comfortable to raise the issue initially.

The mode of education was a one-to-one discussion approach. Group discussion sessions were intended to be a part of the education program but, due to several factors, were unable to be implemented. Had the group discussion sessions been conducted, patients may have experienced a greater level of social support (ie. from other group participants), which may have promoted greater adherence to safety instructions contained within the education (Wiese et al., 1991). A previous trial of one-to-one versus group education for the prevention of falls amongst community dwelling women found no difference between the two approaches (Ryan et al., 1996). This was only a pilot study however (n = 45) amongst a relatively different set of subjects (community dwelling, >65 years, ambulatory) than those investigated in this trial. Further investigation is required to determine the most efficacious and cost-effective method of providing falls prevention education to patients in the subacute setting. Possible options should include one-to-one education, group education, combination of group and one-to-one education, and written material only (such as the patient / family member information brochure intervention).

The rates of change in balance, strength, and mobility outcome measures for patients recommended for the additional exercise program intervention showed some variation. A significant difference between groups found was for the functional reach test where the median rate of improvement for intervention patients tested was ten times higher than that for control group patients tested. Significant differences in the
rate of improvement between groups were not detected using other balance measures employed (the Step Test and Timed Up and Go test), strength, or gait measures. Possible trends for a greater rate of improvement in Timed Up and Go test results (Wilcoxon rank-sum: p = 0.12), but for a lesser rate of improvement in six minute walk results (Wilcoxon rank-sum: p = 0.10) were apparent.

When interpreting the difference in Functional Reach test results, one must consider the possibility of a type I statistical error. A difficulty with analysing the effect of an intervention on multiple outcomes is that the family-wise type I error rate is increased above the alpha level set for each individual test. Previous criteria have been identified to determine whether apparent differences in subgroup or secondary endpoints can be considered “real” in the context of multiple comparisons (Freemantle, 2001; Oxman et al., 1992). These criteria are:

• Is the magnitude of difference clinically important?
• Was the difference statistically significant?
• Did the hypothesis precede rather than follow the analysis?
• Was the subgroup analysis one of a small number of hypotheses tested?
• Was the difference suggested by comparison within rather than between studies?
• Was the difference consistent across studies?
• Is there indirect evidence that supports the hypothesised difference?

The magnitude of difference in this outcome does appear to be of clinical importance and statistically significant (using a standard alpha = 0.05). The hypothesis that patients receiving additional exercise may improve their balance at a faster rate preceded the analysis. A moderate number of other subgroup analysis tests were performed for other outcomes. Previous research has not suggested that targeting specific muscle groups or activities for exercise additional to usual care results in faster improvements in related outcomes (Donald et al., 2000). There is also little other indirect evidence to support this difference.

If one were to assume that this difference was “real”, then one must also question why differences in other outcomes investigated were not detected. The Functional Reach test measures a patient’s ability to bring their weight forwards and reach in front of themselves without overbalancing (Duncan et al., 1992). Many of the exercises used
in the additional exercise program incorporated movements of the upper limb about the trunk and multidirectional weight shifting (appendix H), thus movements similar to the Functional Reach test were a focus of the additional exercise program intervention. However several “stepping” and lateral weight shift movements were also included in the exercise program, and it was surprising that greater improvements were not also detected for the Step Test. It is possible that the speed at which these movements were performed during the program (slowly) may not have assisted in improving performance at the Step Test for which quick stepping is important. Instead of concluding that the observed difference in the Functional Reach outcome was “real”, it is perhaps more prudent to conclude that this result provides some evidence of a potential mechanism of action by which the additional exercise program intervention may reduce falls, and that this should be the subject of future investigations.

Previous studies have demonstrated the value of exercise programs in improving the strength, balance, mobility, and safety of both healthy older people and those with a variety of medical conditions (Day et al., 2002; Delagardele et al., 2002; Duncan et al., 2003; Foley et al., 2003; Gillespie et al., 2004; Hauer et al., 2001; Lord et al., 1995; Newton et al., 2002; Shumway-Cook et al., 1997; Wolf et al., 1993). In the hospital setting however, only one previous randomised controlled trial has investigated the effect of an additional exercise intervention on the prevention of falls, and improvement in strength and mobility (Donald et al., 2000). The additional exercise program investigated in that trial was a strength training regimen for the hip flexor and ankle dorsi-flexor muscle groups. However, this trial did not find a significant reduction in falls, or improvements in gait velocity, hip flexor or ankle dorsiflexor strength attributable to the exercise program. The additional exercise program investigated in the present study was different to that particular program. It consisted of exercises based upon the therapeutic principles of t’ai chi (Wolf et al., 1993) combined with functional activities such as transferring from chair to chair, stepping, reaching and weight shifting. These activities were designed to represent activities that patients might perform by their bedside that might contribute to a fall, possibly making them more functionally relevant for the prevention of falls than hip flexor and ankle dorsiflexor exercises.
This also, raises the issue of whether an alternative additional exercise program may have been more effective than that investigated in this study. Exercises that promote quick stepping may have more readily facilitated greater improvement in step test results and arguably would be important in situations where a patient needs to step quickly in order to prevent a fall. An exercise program with a higher work to rest ratio may have facilitated greater improvement in patient endurance which would arguably be important in situations where patient fatigue contributes to a fall. Clearly, there are many alternate directions that the additional exercise program could have taken, each with a theoretical argument as to why it would be useful for the prevention of falls. One approach to designing an alternate program could be to conduct a post-fall analysis of falls in the subacute hospital setting with the physiologic aspects of the falls specifically under investigation. This would help to identify components of balance and mobility that are strongly associated with falls by establishing the relative proportion of falls that involved a reaching task, a quick stepping task, a patient fatigue component or any other movement task that may potentially be the focus of an additional exercise intervention. Additional exercise programs could then be designed to address the movements and then be evaluated through randomised controlled trials.

Many of the patients involved in this subgroup analysis were recommended for other interventions from the falls prevention program. The amount of intervention overlap is demonstrated in table 4.3. However, these other interventions were unlikely to have had a direct effect on the balance, strength, and mobility of patients in receipt of them. It is possible though that falls and particularly fall injuries which may have been prevented by the other interventions could have indirectly led to better physical outcomes for these intervention group patients.

The collection of balance, strength, and mobility measurements in this study was relatively unsuccessful with several measures having incomplete data on both initial and discharge follow-up assessments. The intention for assessment of this battery of tests was that a blinded research assistant would complete the tests for all patients upon their recommendation for the additional exercise intervention. This goal was not achieved for several reasons, including; the size and content of the test battery
selected, insufficient and inflexible staffing of the research assistant position, administrative errors on behalf of the investigator, and the refusal of several patients to undergo these tests.

The least amount of data was available for six minute walk test results with only 43% of control group and 56% of intervention group participants having both initial and discharge measures completed. This measure was completed at the end of the assessment battery by which time more patients may have reported that they were too tired to complete the full testing battery. Other tests could not be completed on specific patients. For example the hip abduction strength test required that patients be able to lie supine, however some reported shortness of breath or discomfort in this position, precluding the patient from participating in this test. Frequently patients reported being quite tired following the initial assessment. Memory of this may have caused several to refuse the discharge follow-up assessment, particularly if they did not want to feel tired upon return to their home environment. The consequence of this was a reduced power to detect change in statistical analyses, and the potential bias that missing data from patients who did not have both assessments completed may have substantially altered results had their data been collected.

The staffing approach employed for the research assistant position may also have contributed to the high proportion of incomplete assessments. Employing the research assistant for only one four hour block per week limited the flexibility with which assessments could be conducted at different times during the week to meet individual patient discharge circumstances. Modifying this approach was difficult as the human resources department at the research location specified the minimum shift duration for this position to be a four-hour period. A possibility not taken up by the investigator was to employ the research assistant for an additional four-hour shift each week, though this would have consumed additional (limited) research funds.

Administrative error was also responsible for several patients not having both their initial and discharge measurements completed. To arrange dates and times for these assessments, the investigator would periodically check the ward diary on each ward for impending patient discharges (up to one week in advance). However, patients may have been having a home visit or some other appointment on the date and at the
time with which the assessment had been scheduled, thus the patient was not scheduled appropriately. Pure administrative mistakes were also made by the investigator in failing to arrange either for an initial or discharge assessment to be completed in a small number of instances. Investing in a greater level of administrative support for this trial may have assisted in minimising this occurrence.

These problems with completing and recording measurements should be given some perspective however. There were no significant differences in admission measures between those who had initial and discharge measures collected and those who had only initial measures collected, indicating that the group of patients for which data was available may have been representative of the entire group. It may also have been unrealistic to expect that a high completion rate would be observed. The hospital setting has previously been identified as a difficult environment in which to undertake falls prevention research (O'Connell et al., 2001; Oliver et al., 2002). Where measures of this type have previously been attempted in a falls prevention trial investigating an additional exercise intervention, only 54% of control group patients and 66% of intervention group patients had both initial and discharge measurements completed (Donald et al., 2000). As with the present trial, several patients in that particular trial were too ill or on the ward for too short a time to have the assessments completed. Thus although the data recording completion levels in this analysis were obviously sub-optimal, it may have been unreasonable to expect that levels substantially better should have been attained without additional resources to support their collection. Furthermore, the gathered data has still provided some useful evidence of reasonable quality that has given insight into how the additional exercise intervention may contribute to a reduction in falls.

From a practical perspective, it appears that the additional exercise was successfully implemented in conjunction with usual care. Of a possible 792 exercise session attendances, patients attended 595 (75%), with patients either refusing to attend (103 sessions [13%]), being too unwell to attend (42 sessions [5%]), or being at an alternate appointment (53 sessions [7%]). Some patients indicated in their refusals that they were “too tired” to perform the additional exercise on that day. This may indicate that the amount of exercise (frequency, duration, intensity) being provided to
these patients was above the threshold that they were able to physically or psychologically cope with during these periods of their rehabilitation.

Subacute care facilities typically provide a level of care quite different to that in acute and residential care settings (American Subacute Care Association, 1994; Lewin-VHI Inc, 1994). In the acute setting, a lower proportion of patients tend to be medically stable than in the subacute setting (Hyatt, 1994). This means that a lower proportion of patients would be able to participate in such an exercise program due to illness. It may also mean that the “less demanding” exercises and sessions of shorter duration be used within the program to adapt to patients’ generally poorer physical status. The presence of bodily attachments such as urinary catheters, intravenous drips, and drains could increase the difficulty of leading such a program safely. However, it is more likely that this additional exercise program could be practically implemented in the residential care setting where group exercise programs have successfully and safely been trialed previously (Becker et al., 2003; Gillespie et al., 2004).

The findings from this analysis indicate that varying the amount and type of exercise provided to some subacute hospital patients may result in differing rates of improvement in some balance outcomes. To employ such a program in isolation in the clinical setting, one would have to weigh up the costs of implementing an additional exercise program with likely savings brought about from potentially a greater rate of improvement in some aspects of balance and possibly the prevention of falls. Future research of the additional exercise program in isolation and an economic evaluation of this program is required to shed greater light on this issue from the perspective of the health facility administrator and health policy decision-maker. Alternately, one could attempt to integrate elements of the additional exercise program into the provision of usual care. The difficulty here is that in order to add to usual care, one must either increase the amount of work that is done under usual care, or replace a previous component of usual care with this new one. This type of decision is one that should be made on a facility-by-facility basis given that the content and capacity of usual care provision in each facility is likely to vary to some extent.
Patient acceptance of and compliance in wearing hip protectors has frequently been a criticism of this equipment (McAughey et al., 2002; Thompson et al., 2002; van Schoor et al., 2002). A meta-analysis of hip protector studies across various settings that reported compliance levels found a median compliance rate of 57% with wearing hip protectors, yet the definition of compliance used in these studies differed (van Schoor et al., 2002). The present study found that patients had worn the hip protectors for ≥ 12 hours over the preceding 24 hours on 57% of audit occasions, and for all 24 hours on 18% of audit occasions. Thus it appears that the compliance of patients in wearing hip protector garments in this study was similar to that previously established.

Patients in “institutional” settings who require assistance to dress may have little choice in deciding whether to wear hip protectors or not (Parker et al., 2004). There was some evidence of this in the present study as hospital nursing staff decided that some patients were so immobile in general or immobile at night that the patient did not require hip protectors at that time. When reporting compliance levels, it is questionable whether investigators are truly identifying patient’s attitudes towards and subsequent actions in wearing this equipment, or if they are measuring the zeal with which nursing staff encourage and assist patients to wear them. Investigators and clinicians should ensure that patient autonomy remains a central concern during evaluations of hip protector compliance, and that patient choice is not over-ridden in an attempt to secure a favorable research finding.

Previously cited reasons for not wearing hip protectors have frequently included: not being comfortable (too tight / poor fit), the extra effort (and time) needed to wear the device, urinary incontinence, and physical difficulties / illness (van Schoor et al., 2002). In the present study, a range of hip protector sizes were available for patients to be fitted with and the investigator was aware of only one situation where a patient recommended for this intervention was not able to be appropriately fitted (the largest hip protector garment available was too small). Patient discomfort when wearing these garments (particularly at night) was still evident in the present study however. This is possibly more related to the firmness of the protector shield, and the discomfort that it may cause when a patient lies on their side, rather than the pants. It is therefore possible that a softer shield may have been more widely worn at night.
Impaired continence was also given as a reason for hip protector removal. The analysis of toileting independence revealed that some patients required more assistance when wearing the hip protectors than when not. This may have caused both these patients (who lost some independence with this activity) and their nurses (who had to compensate for this by providing additional assistance) to view the hip protector equipment negatively.

Future research should be conducted to determine the effectiveness of each of the components of the intervention program in isolation with fall event rates as a primary end-point. Factorial research designs could be employed where hypothesised interactions between interventions are of interest. For the additional exercise program, future research should identify whether potential improvements in balance are maintained following patient discharge. The applicability of this intervention to the acute and residential care settings requires investigation. Also, an economic evaluation for each of these interventions is necessary to aid clinicians and health facility administrators in their decision making as to whether to implement these interventions in their facilities.
6.1 Thesis summary

This thesis was a comprehensive investigation of the prevention of falls in the subacute hospital setting. A review of the literature found fall event rates to be higher in this setting than in acute care and the community for people over the age of 65. Falls in subacute hospitals were identified as a cause of considerable physical and psychological morbidity, along with increased costs to the health care system. Patient characteristics associated with those who fell were gender (male), previous history of falls, cognitive impairment, physical impairment, functional dependency, incontinence, and an admission diagnosis of stroke or other neurological impairment. Extrinsic factors associated with patients becoming fallers were increased length of hospital stay and behaviour that does not comply with hospital staff recommendations.

Many interventions to minimise the number of falls occurring in the subacute setting have been examined, though few with methodologically rigorous study designs. Several falls risk screening tools that measure individual patient’s risk of falling and assist in the deployment of falls prevention interventions have been developed and evaluated. The accuracy of these tools in measuring risk of falling in settings other than those in which they were developed, and effectiveness of these tools in assisting to reduce the incidence of falls was unclear. Other interventions investigated have included falls risk alert items, staff education, patient / family member education, additional exercise, restraint reduction, flooring variations, post-fall reviews, bed alarms, and nursing intervention checklists. None of these interventions were clearly identified as being beneficial for the prevention of falls. Given the extent of the problem of falls in the subacute setting and the lack of direction provided by current literature as to its effective management, a firm justification for the need to develop and appropriately evaluate effective interventions for the prevention of falls was established.

This thesis aimed to address the prevention of falls and their negative outcomes in the subacute hospital setting. Specifically it aimed to:

1. Describe the construction of a falls prevention program that could be integrated into the subacute care setting.
2. Evaluate the accuracy and practical applicability of a falls risk screening tool used to deploy interventions from the falls prevention program.

3. Evaluate the effectiveness of this program in minimising fall event rates, the proportion of patients who became fallers, and fall injury event rates using a methodologically rigorous research design approach.

4. Evaluate the effectiveness of this program on secondary outcome measures.

5. Evaluate secondary outcomes for three of the falls prevention intervention interventions included in the program.

The falls prevention program used to investigate these aims consisted of falls risk alert card, patient / family member information brochure, additional exercise program, patient education program, and hip protector interventions. These interventions were targeted to selected patients by use of the PJC-FRAT, a falls risk screening tool that facilitated hospital staff to use their clinical judgement in order to guide intervention deployment. This tool had direct links to falls prevention interventions, an “as required” re-application protocol, and input from a multidisciplinary team making it a novel tool for the subacute hospital setting.

The first study was a prospective longitudinal cohort design study investigating the predictive accuracy and practical applicability of the PJC-FRAT. The findings from this study indicated that:

- The PJC-FRAT was of comparable accuracy to the STRATIFY (gold standard) falls risk screening tool.
- The PJC-FRAT could be applied to a “real life” subacute hospital setting, as completion rates and speeds of completion were good to excellent for hospital nursing, physiotherapy, and occupational therapy staff.
- Hospital medical staff did not complete the screening tool as readily as the other disciplines involved.

The second study was a randomised controlled trial of the effectiveness of the targeted falls prevention program in prevention of falls in the subacute setting. The findings from this study indicated that:

- The program was effective for reducing fall event rates in the subacute setting.
• The falls prevention program interventions could be incorporated with “usual care” in the subacute setting.
• The additional exercise program intervention may have contributed to a faster rate of improvement on an important domain of balance (reaching) though did not have a demonstrable effect on other domains of balance, strength, or mobility.
• The education program presented patients with new, understandable information that they were comfortable to discuss with the research occupational therapist, and led to specific behaviour change in a moderate proportion.
• Hip protectors were reasonably well accepted and worn by patients in this setting, particularly during the day.
• The PJC-FRAT did not maintain its predictive accuracy over time and that hospital staff may require ongoing education to maintain predictive accuracy levels of the PJC-FRAT.
6.2 Strengths and limitations of present research

The primary strength of the current research program was that it addressed a significant public health problem for which previous research had provided little clear direction for it’s management.

The first study of this research program had several methodological strengths. The evaluation was prospective, and for the PJC-FRAT, the screening tool was completed by hospital staff. Both of these factors made the results gained more representative of what one could expect to observe upon using this tool in the “real world” setting than results provided by retrospective evaluations, or evaluations where screening tools were completed by research staff. There was a direct comparison between two screening tools on the same sample. This provides a more valid insight into the relative superiority of either tool in a particular setting, rather than comparing the results produced by the tools when applied to different samples. The interventions being recommended through the PJC-FRAT were not actually deployed and thus did not interfere with subsequent predictive accuracy statistics. Statistically, the use of sensitivity and specificity statistics based upon fall event rates in conjunction with standard calculations of sensitivity and specificity provided a clearer comparison of the accuracy of the tools than what would have been provided had the standard calculation alone been used. In addition to this, statistical hypothesis testing was also presented for the first time when comparing falls risk screening tools from the subacute setting. These attributes of the first study of this research program combine to make this study a true methodological advancement over previous studies in this field.

The second study of this research program also had several strengths. From the outset of this research program, including the selection and development of interventions included in the falls prevention program, this study was intended to be a randomised controlled trial with individual participant randomisation. This prevented many confounding factors inherent to cluster randomised, quasi-randomised, and non-randomised study designs from affecting this study. This served to strengthen the validity of the results attained. The patient sample was relatively heterogenous promoting generalisability of results particularly to other subacute settings. Applying
the PJC-FRAT to control group patients allowed a secondary investigation of the predictive accuracy of the PJC-FRAT, and the formation of an intervention specific control group which allowed for individual evaluation of each intervention in the falls prevention program. This also reduced the possible effect that completion of a falls risk screening tool by hospital staff may have had on fall rates. This approach has not previously been employed in falls prevention trials in the subacute setting, thus the intervention subgroup analyses presented in chapters 6 and 7 are the first investigations of individual interventions from larger targeted multiple intervention programs. The statistical analysis of primary outcome data took into account all fall events and all patient-time observed in the comparison of fall event rates. It also revealed when the fall event rates between groups began to diverge relative to the time since each patient consented to participate in the study. In this study, a cumulative effect of the intervention over time was detected, particularly after 45 days of patient-observed time. Such information would not have been detected had only analysis techniques from previous falls prevention studies in the subacute setting been used. Secondary evaluation outcome measures collected for the education program and additional exercise program interventions supported to some extent “a priori” hypothesised mechanisms of action of these interventions for the prevention of falls. Compliance and toileting independence data collected for the hip protector intervention also served to highlight potential problems with the practical applicability of this intervention.

While many strengths and methodological advancements were present in this research program, some weaknesses were also present.

Study one of the research program may have produced a type II error due to insufficient patient recruitment. Although this comparison was larger than previous studies that have compared and presented the predictive accuracy of two or more screening tools applied to the one patient sample, a potentially clinically significant effect size in difference between predictive accuracy statistics was not found to be statistically significant. Hospital staff were not blinded to PJC-FRAT screening tool results, though to do this would have been impractical given the nature of the tool and available research resources. Only direct comparisons could be made between the predictive accuracy of hospital nursing staff and the STRATIFY, despite the
involvement of three other disciplines in the completion of the tool. This was a consequence of the chosen structure for the PJC-FRAT at the commencement of the research program. The nature of the intervention recommendations being made (in study one) by hospital staff was purely hypothetical as the interventions being recommended were not yet available. Had the interventions been available for implementation, the recommendation patterns may have been different.

Study two also contained some weaknesses. The nature of the interventions included in the falls prevention program dictated that hospital staff and patients could not be completely blinded from group allocation. Hospital staff and patient blinding surveys however indicated that this may have had little impact on the overall results. The observed reduction in fall rates may not be transferable to the acute setting, not only because of the patient sample consisted only of subacute patients, but also because the overall observed difference in fall rates did not appear until after 45 days of patient-observation time, a period after which few acute patients would remain in acute hospital. The effect of the falls prevention program following patient discharge was not observed. Had it been done it may have illuminated further “medium term” benefits of the program. Measuring secondary outcome measures for the additional exercise program intervention, education program intervention, and even the patient blinding surveys was incomplete. Issues of sudden patient discharge, patient reluctance or ill-health, administrative error, and insufficient research resource allocation to these areas were some of the contributing factors to this problem. Despite reducing the incidence of falls by 30% through this program, it is unclear whether the benefits associated with the 30% reduction offset the additional costs involved with implementing and sustaining the program.
8.3 Future directions

In the area of falls risk screening, the present research program has highlighted several potential areas for future research. Further investigation should be undertaken in comparing the accuracy of hospital staff clinical judgement with externally developed mathematical model falls risk screening tools using prospective study designs which encompass as much blinding of hospital staff involved as practical, and consist of a sufficiently large sample size as to be able to detect minimum clinically significant differences between the screening tools. The inter-rater reliability of staff clinical judgement in predicting falls risk both between and within disciplines requires examination. The association between ongoing staff education and accuracy in predicting falls requires further examination, particularly for nursing staff. Methods to promote medical staff participation in the falls risk screening process should also be investigated.

In the area of falls prevention interventions, several other areas have been highlighted. In regards to the additional exercise program, investigation should be made to see if potential improvements in balance and safety can be maintained following patient discharge. This intervention should be further investigated to see if it can be applied to the acute and residential care settings. For the education program intervention, investigation can be made into determining the relative effectiveness of this intervention across patients with differing levels of cognitive impairment. Both this and the exercise program interventions require comparison to an appropriate patient-sitter (socialisation group) intervention to eliminate the effect of increased patient supervision time. A comparison of alternate means for harm minimisation, shock absorptive flooring could be compared to hip protector (hard and soft shields) interventions. The effectiveness of falls risk alert cards and patient / family member information brochures could be investigated individually to evaluate their relative effectiveness. For each of these interventions and the program as a whole, an economic evaluation of this approach to falls prevention is required. Finally, as the program appeared to have minimal effect on fall event rates during the first 45 days of patient-observed time in study two, other interventions that may address the problem of falls in the early stages of a patient’s stay require development and investigation.
6.4 Conclusion

In conclusion, this thesis has provided a summary of the available literature regarding the epidemiology of falls in the subacute hospital setting, along with methods to both predict and prevent these falls. The program investigated a novel falls prevention program which demonstrated the first significant reduction in fall event rates while using a randomised controlled trial study design. These findings shed new light on managing the problem of falls in the subacute hospital setting, an area of substantial public health importance. It is hoped that publications arising from this thesis will stimulate further investigation in areas of falls risk screening, falls prevention intervention development, and evaluation of falls prevention programs in the hospital setting.
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Appendix A. The Mini-Mental State Examination.

I am going to ask you some questions and give you some problems to solve. Please try to answer them as best as you can.

1. (Allow 10 seconds for each reply)

   a) What year is this?  
      (accept exact answer only)  
      SCORE  MAX
      ( )  1

   b) What season is this?  
      (during last week of the old season or first week of a new season, accept either season)  
      ( )  1

   c) What month of the year is this?  
      (on the first day of new month, or last day of the previous month, accept either)  
      ( )  1

   d) What is today's date?  
      (accept previous or next date, e.g. on the 7th accept 6th or 8th)  
      ( )  1

   e) What day of the week is this?  
      (accept exact answer only)  
      ( )  1

2. (Allow 10 seconds for each reply)

   a) What country are we in?  
      (accept exact answer only)  
      ( )  1

   b) What province/state/county are we in?  
      ( )  1

   c) What city/town are we in?  
      (accept exact answer only)  
      ( )  1

   d) (in clinic) What is the name of this hospital/building?  
      (accept exact name of hospital or institution only)  
      (in home) What is the street address of this house?  
      (accept street name and house number or equivalent in rural areas)  
      ( )  1

   e) (in clinic) What floor of the building are we on?  
      (accept exact answer only)  
      (in home) What room are we in?  
      (accept exact answer only)  
      ( )  1

3. I am going to name three objects. After I have said all three objects, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. (say them slowly, at approximately one second intervals)

   BALL  CAR  MAN

   For repeated use:
   BELL  JAR  FAN
   BILL  TAR  CAN
   BULL  WAR  PAN

   Please repeat the three items for me  
   (score 1 point for each correct reply on the first attempt)  
   (allow 20 seconds for reply, if subject did not repeat all three,  
   repeat until they are learned or up to a maximum of five times)  
   ( )  3

   NAME OF CLINICIAN:  DISCIPLINE:  SIGNATURE:

   DATE: ..........................
(Allow 10 seconds for each reply)

4. Spell the word "WORLD"
   (you may help subject to spell word correctly)
   Say "Now spell it backwards please"
   (if the subject cannot spell "world" even with assistance - score 0)
   ( ) 5

5. Now what were the three objects that I asked you to remember?
   BALL CAR MAN
   (score one point for correct response regardless of order)
   ( ) 3

6. Show wristwatch. Ask "What is this called?"
   (score 1 point for correct response)
   Accept "wristwatch" or "Watch". Do not accept "Clock", "Time" etc. (allow 10 seconds)
   ( ) 1

7. Show pencil. Ask, "What is this called?"
   (score 1 point for correct response, accept pencil only - score 0 for pen)
   ( ) 1

8. I'd like you to repeat a phrase after me: "No ifs, ands or buts"
   (Allow 10 seconds for response. Score 1 point for correct repetition)
   Must be exact e.g. no ifs or buts - score 0
   ( ) 1

9. Read the words on this page and then do what it says.
   (take page 4, fold page in half, show subject half with "CLOSE YOUR EYES" on it)
   CLOSE YOUR EYES
   (if subject just reads the words and does not then close eyes - may repeat "read the words on this
   page and then do what it says" to a maximum of 3 times. Allow 10 seconds. Score one point only
   if the subject closes eyes. Subject does not have to read aloud)
   ( ) 1

10. Ask if the subject is right or left-handed. Alternate right/left hand in statement e.g. if the subject is Right
    handed say "Take a piece of paper in your left hand..." Take a piece of paper - hold it up in front of
    subject and say the following:

    "Take this paper in your right/left hand, fold the paper in half once with both
    hands and put the paper down on the floor"

    Takes paper in the correct hand ( ) 1
    Folds it in half ( ) 1
    Puts it on the floor ( ) 1
    (allow 30 seconds. Score 1 point for each instruction correctly executed) ( ) 3

11. (Hand subject a pencil and paper) - see page 3
    Write any complete sentence on that piece of paper
    (allow 30 seconds. Score 1 Point. The sentence should make sense. Ignore spelling errors)
    ( ) 1

12. Place page 3, folded in half with design showing, a pencil and paper in front of subject.
    Copy this design please
    Allow multiple tries until subject is finished and hands it back. Score 1 point for correctly copied
    diagram. The subject must have drawn a 4 sided figure between the two 5 sided figures.
    (Maximum Time - 1 minute)
    ( ) 1

TOTAL TEST SCORE

( ) 30
CLOSE YOUR EYES

Write a sentence:

DATE: NAME OF CLINICIAN: SIGNATURE:
Appendix B. The modified Barthel Index.

<table>
<thead>
<tr>
<th>SELF CARE</th>
<th>Can do without aids</th>
<th>Can do with aids</th>
<th>Can do with help of someone else</th>
<th>Cannot do at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drinking from a cup</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Eating</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dressing upper body</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Dressing lower body</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Putting on a brace or artificial limb</td>
<td>0</td>
<td>0</td>
<td>-2</td>
<td>0 (if not applicable)</td>
</tr>
<tr>
<td>Grooming</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Washing or bathing</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Getting in &amp; out of shower</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

OT: Admission Barthel (self-care) Completion Date: Subtotal:

| Controlling urination         | 10                  | 10               | 5 (accidents)                     | 0                |
| Controlling bowel movements   | 10                  | 10               | 5 (accidents)                     | 0                |
| Care of perineum/clothes at toilet | 4                   | 4                | 2                                | 0                |

NURSING: Admission Barthel (self-care) Completion Date: Subtotal:

<table>
<thead>
<tr>
<th>MOBILITY</th>
<th>Can do without aids</th>
<th>Can do with aids</th>
<th>Can do with help of someone else</th>
<th>Cannot do at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting in and out of chair</td>
<td>15</td>
<td>15</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Getting on and off toilet</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Walking 50 yards on the level</td>
<td>15</td>
<td>15</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Walking up or down one flight of stairs</td>
<td>10</td>
<td>10</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>If NOT walking: pushing or propelling wheelchair</td>
<td>15</td>
<td>5</td>
<td>0 (if not applicable)</td>
<td>0</td>
</tr>
</tbody>
</table>

PT: Admission Barthel (mobility) Completion Date: Subtotal:

Total:
Appendix C. The Peter James Centre Falls Risk Assessment Tool.
# Falls Risk Assessment Tool (Admission)

**Medical**

Does the patient suffer from frequent falls with no diagnosed cause?

- [ ]

Is the patient suffering an established medical condition that is currently unable to be adequately managed, that may cause a fall during their inpatient stay (e.g. drop attacks due to vertebro-basilar artery insufficiency)?

- [ ]

Is the patient taking any medications/medication amounts/medication combinations that you anticipate may directly contribute to a fall (e.g. sedatives)?

- [ ]

**Nursing**

Toileting (day) F.I.M.

- [ ]

Toileting (night) F.I.M.

- [ ]

Would this patient benefit from a Falls Risk Alert Card and a Falls Prevention Information Brochure in order to prevent falls at PJC?

- [ ]

**Physiotherapy**

Gait F.I.M. (Gait aid + distance)

- [ ]

Transfer (bed < - > chair) F.I.M.

- [ ]

Would this patient benefit from attending a Balance Exercise Class in order to prevent falls at PJC?

- [ ]

**Occupational Therapy**

Bathing F.I.M.

- [ ]

Dressing F.I.M.

- [ ]

Would this patient benefit from attending a Falls Prevention Education Program in order to prevent falls at PJC?

- [ ]

**All Disciplines**

Has this patient demonstrated non-compliance or do you strongly anticipate non-compliance with the above prescribed level of aids / assistance / supervision such that the patient becomes unsafe?

- [ ]

### The Modified Functional Independence Measure (F.I.M.)

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Fully dependent (patient performs less than 25% of the task).</td>
</tr>
<tr>
<td>(2)</td>
<td>Maximal assistance required (patient performs between 25% and 50% of the task).</td>
</tr>
<tr>
<td>(3)</td>
<td>Moderate assistance required (patient performs between 50% and 75% of the task).</td>
</tr>
<tr>
<td>(4)</td>
<td>Minimal assistance required (patient performs greater than 75% of the task).</td>
</tr>
<tr>
<td>(5)</td>
<td>Supervision / prompting.</td>
</tr>
<tr>
<td>(6)</td>
<td>Independent with aids.</td>
</tr>
<tr>
<td>(7)</td>
<td>Independent with nil aids.</td>
</tr>
</tbody>
</table>

---

*Forms:Falls Risk AxTool2 (rg) 28/06/01*
This amendment section of the Falls Risk Assessment Tool is to be used when a patient’s condition changes such that the employment of interventions is now indicated or now no longer indicated. For example, if a patient’s confusion due to a UTI that caused them to be non-compliant is now resolved, they may no longer require a hip protector.

Has this patient’s condition changed such that the patient:

- Does now require a hip protector:
- Does no longer require a hip protector:
- Would now benefit from balance exercise class:
- Would now benefit from falls prevention education class:
- Would now benefit from a falls risk alert card and information brochure:

Date: .................................................................

Signature: .................................................................

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.

Alert Project Officer of change.
Appendix D. The falls prevention information booklet for the education program intervention.
FALLS PREVENTION

INFORMATION BOOKLET

DEVELOPED FOR THE FALLS PREVENTION PROJECT AT THE PETER JAMES CENTRE.
INTRODUCTION

This is an information booklet designed for the Falls Prevention Project at the Peter James Centre.

You have received this booklet because you may be able to use the information provided to reduce your risk of falling over while at the Peter James Centre.

IS “FALLING OVER” A PROBLEM AT THE PETER JAMES CENTRE?

Previously one in four people who have come to the Peter James Centre have experienced a fall during their stay.

This rate is approximately ten times greater than that for people who live at home.
AM I AT RISK OF "FALLING OVER"?

Your risk of falling over is increased if:

☐ You have previously had falls.
☐ Your legs are weak, balance is poor or walking is unsteady.
☐ You need to go to the toilet frequently or urgently.
☐ You have reduced vision.
☐ You take many medications.
☐ You have a chronic medical disorder such as Parkinsons Disease, congestive heart failure, cancer or have had a stroke.
☐ You have bouts of dizziness.
☐ You have difficulty with concentration or memory.
☐ You have reduced activity levels.
WHAT HAPPENS TO PEOPLE WHO FALL OVER?

One in six falls at the Peter James Centre results in a “significant injury” such as broken bones, cuts, lacerations or requires an x-ray.

People who fall over may also develop a fear of falling that restricts their confidence and activity levels.

WHERE DO FALLS OCCUR?

Two thirds of all falls at our centre occur at a patients bedside!

Falls also tend to occur in passageways, bathrooms and toilets.
WHY DO FALLS OCCUR?

Falls occur for a variety of reasons however, 80% of falls occur when patients are not in view of a staff member. From this we know that one common factor in many falls is that patients are attempting to perform activities on their own.

We believe that most people are trying to go to the toilet or get back into bed on their own when they have a fall.

At the Peter James Centre, we are aiming to make you as independent with your mobility and daily activities as possible, so that you can perform activities on the ward on your own.

However this must only be done once you are told by a staff member that it is SAFE to perform these activities on your own.
When do falls occur?

In the morning, many falls occur between **7:00 and 10:00 AM**. This is when staff are often busy showering and dressing individual people.

We believe that many people who fall at this time are trying to get themselves out of bed and go to the toilet without assistance.

In the afternoon, many falls occur between **5:30 and 7:00 PM**. Staff are often busy bringing people back from the dining room, and taking other people to the toilet.

We believe that many people who fall at this time are trying to get themselves into bed or go to the toilet without assistance.

**Please be patient when requesting assistance at these times!**
3 SIMPLE STEPS TO STOPPING FALLS.

1) KNOW IF YOU NEED HELP TO WALK AROUND.

Your physiotherapist will tell you if it is safe for you to walk around on your own.

You can also tell by the number of red stripes on your walking aid:

- One red stripe means you can walk on your own.

- Two red stripes means you must wait for someone to supervise your walking.

- Three red stripes means you must wait for someone to physically help you with your walking.
2) **ASK FOR HELP IF YOU NEED IT.**

If you have two red stripes (supervision) or three red stripes (assistance) you must press the nurses buzzer to gain the attention of a staff member before you walk anywhere.

If you have one red stripe (independent) but you are tired and feel as if you need some help, you are free to ask for it also.

The nursing staff member looking after you will show you how to use your buzzer.
3) **WAIT FOR A STAFF MEMBER TO ARRIVE.**

Staff are often busy with other patients and have difficulty coming straight away, but it is very important that you wait for them.

Do not be afraid to ask for assistance when you need it. Our staff will be only too happy to try to help you to move around the ward safely.

It is important to follow this procedure for even the shortest of walks. Remember two thirds of falls occur beside a patients bed!
HOW DO FALLS OCCUR?

1) Losing your balance.

CAUSES:
- Poor balance.
- Not using your walking aid.
- Not waiting for assistance if you need it.
- Using furniture to assist with walking around the bedside instead of your walking aid.
- Reaching to pick something up or to open and close doors.

HOW TO STOP THIS FROM HAPPENING:
- Follow the 3 simple steps to stopping falls.
- Exercise to improve your balance!
- Do not use furniture to assist with walking around your bedside.
- Buzz for a staff member if you want something picked up or opened.
- Keep things that you want to use often (e.g., Nurses buzzer, television control) close to you so that you do not have to reach for them when you want to use them.
HOW DO FALLS OCCUR?

2) Slipping.

CAUSES:
- Wet surfaces (especially in the toilet / bathroom / shower area).
- Footwear (Poor grip, non-supportive heel).
- Leaning back too far when standing up.

HOW TO STOP THIS FROM HAPPENING:
- Scan the environment you are walking into for wet surfaces, if you see a potential problem, call for assistance.
- Ensure you are wearing appropriate eyewear.
- Turn lights on before entering the area.
- Ensure you have and are wearing appropriate footwear with a supportive heel and a non-slip grip.
- Lean forwards when standing up and always use the walking aid provided for you.
HOW DO FALLS OCCUR?

3) Tripping over objects.

CAUSES:
• A cluttered bedside environment.
• Consider especially the placement of your television table, bedside table and if there is enough room for you to push your frame between your bed and your chairs.
• Television or radio power cords, and nurses buzzers being left across a passageway.
• Not scanning the passageway that you are about to walk through for potential obstacles.

HOW TO STOP THIS FROM HAPPENING:
• Scan your bedside environment and the passageways that you walk along for any potential obstacles.
• If there is a potential obstacle there, ask a staff member to remove it.
• Wear appropriate eyewear and “scan ahead” on the path you are walking for potential obstacles.
• Ensure there is adequate lighting in the area that you are walking into.
HOW DO FALLS OCCUR?

4) Your legs give way beneath you.

CAUSES:
- Weak or tired muscles (especially in front of the thigh).
- Is a common occurrence following knee and hip surgery (eg. A joint replacement), a stroke or a long period of inactivity.
- Can also occur in people with painful joints (especially the knee).
- Trying to walk around without the walking aid or the assistance that you have been told that you need.

HOW TO STOP THIS FROM HAPPENING:
- Follow the 3 simple steps to stopping falls.
- Exercise to strengthen those muscles!
- If your muscles do feel tired, rest or ask for assistance if required. Even people who are allowed to walk around on their own can become tired by the end of the day.
HOW DO FALLS OCCUR?

5) Becoming dizzy or fainting.

CAUSES:
• A drop in blood pressure when moving from lying to sitting or sitting to standing.
• This tends to occur more often in people with heart problems, following meals, on hotter days or when dehydrated.
• Other medical conditions such as problems with the inner ear or a stroke can also cause dizziness or fainting.

HOW TO STOP THIS FROM HAPPENING:
• Rise from lying to sitting and sitting to standing in stages. Take plenty of time to allow your body to adjust to the change in position.
• Be especially careful if you have heart problems, following meals, on hotter days or if you are dehydrated.
• If you do experience dizziness or fainting, please discuss this with your doctor who may be able to help you.
FALLS PREVENTION QUIZ

1) Are you at risk of falling over while at the Peter James Centre?

2) What activity are you most afraid of falling over doing?

3) How do you think that you might fall over doing this?

4) How can you stop this type of fall from occurring?

5) Where do most people who fall over at the Peter James Centre fall?

6) When do most people who fall over at the Peter James Centre fall?

7) What do you think most people are trying to do when they fall over?

8) What 3 steps can people follow to stop falling over?

9) If you were to have a fall at the Peter James Centre, where would you be most likely to fall?
10) If you were to have a fall at the Peter James Centre, what activity would you be most likely to be doing when you fall?

11) How could you prevent this type of fall from occurring?

Set a goal for the next week to help prevent yourself from falling over.

Did you achieve this goal? Yes / No

Did you have a fall in the last week? Yes / No

Set a goal for the next week to help prevent yourself from falling over.

Did you achieve this goal? Yes / No

Did you have a fall in the last week? Yes / No
Appendix E. Retrospective audit of fall incident reports at the Peter James Centre.

Background:
A review of current literature on the epidemiology of falls in the subacute hospital setting in chapter 1 of this thesis revealed some inconsistencies in the identification of factors associated with falls. Some of these inconsistencies may be attributable to variability in intrinsic characteristics of the patient population in different hospitals, but also extrinsic factors such as environmental structure, policies and procedures that may also vary between hospitals.

The present research program will employ education strategies in an attempt to reduce falls at the Peter James Centre. For these strategies to be effective, it is important that the information they provide is accurate and relevant to patients at this hospital. This study aims to describe epidemiological factors associated with falls at the Peter James Centre, from which an appropriate education program intervention can be structured.

Method:
Study design: Retrospective audit of fall related incident reports between 1st July and December 31st, 2001.

Participants and setting: Patients of three subacute wards (98 beds total) at the Peter James Centre, a metropolitan hospital in Melbourne, Australia.

Measurements: Falls were measured by incident reports completed by nursing staff following patient falls. Potential risk factors investigated were taken from information routinely available on the incident report. All fall-related incident reports contained:
- Name, age, gender and UR (identification) number of patient
- Cognitive condition of patient before the incident (as assessed by staff member completing incident report)
- Location of incident
− Date and time of incident
− A description of the incident by the member of staff reporting (from which it could be determined whether the fall was witnessed by a staff member)
− Statement of doctor

“Patient ambulation status” sheets were collected over this time period. These sheets were updated each weekday by the physiotherapy department and contained the prescribed gait aid, level of assistance (assistance of one person, two persons, supervision only, or independent) required and ambulatory endurance for each patient.

Comparison data for patients’ age and gender data were taken from data collected by the Peter James Centre’s health information service for patients discharged between July 1st and December 31st, 2001.

**Procedure:** Each incident report was completed in triplicate (one original and two carbon copies). One copy of each incident report was sent to a central location (the assistant to the director of nursing’s office) and collated there. The investigator collected data directly from this file of incident reports.

Patient ambulation status sheets were collected by an administrative assistant to the physiotherapy department. Two of the three wards had an incomplete collection of these sheets for one month (July) each. The investigator used cross-referenced these patient ambulation status sheets with the information provided by the fall description on each incident report to determine whether patients had complied with their prescribed level of ambulatory assistance, gait aid, or walking distance at the time of the fall.

**Statistical analysis:**
The proportion of patients becoming fallers was approximated by using the number of patients discharged during the 6 month audit period as the denominator. The relationship between age (separated into 5 year intervals) and gender to falls was also approximated by using the characteristics of patients discharged during the 6 month audit period as the denominator. Statistical hypothesis testing was not conducted as
these ratios were only crude approximations of the true ratios. The rate of falls per 1000 patient days was calculated assuming 100% occupancy of all 98 beds during the audit period. The relationship between falls and day of week, time of day, witnessing of fall by hospital staff, compliance with advice for ambulation, and fall location were analysed descriptively.

**Results:**

During the 6 month period under review, there were 633 patients discharged from the Peter James Centre, from which 230 falls were incurred by 133 fallers. Thus the approximation of the proportion of patients becoming fallers was 21% and falls rate was 12.8 falls per 1000 patient-days.

There were 398 female patients discharged and 235 male patients discharged, while there were 79 female fallers to 54 male. Thus the approximation of the proportion of patients who became fallers was 20% of female patients and 23% of male patients.

The 46 to 50 year-old, 81 to 85 year-old, and 91 to 95 year old age groups each had the highest ratio of fallers to discharges (25% fallers). However the 96 to 100 year old age group had the highest ratio of falls to discharges (0.6 falls per discharge), followed by the 81 to 85 year-old age group (0.5 falls per discharge), and the 91 to 95 year-old age group (0.43 falls per discharge).

Staff members witnessed 28 (12%) falls, did not witness 196 (85%), with 6 (3%) being unclear. Patients clearly did not follow their prescribed level of ambulatory assistance, gait aid, or distance on 131 (57%) occasions, clearly did follow recommendations on 57 (25%) occasions, with 42 (18%) occasions being unclear. Staff reported that the cognitive condition of patients who fell was “normal” on 133 (58%) occasions, “disorientated” on 54 (23%) occasions, “sedated” or “senile” on 7 (3%) occasions each, and “other” on 26 (11%) occasions.

Patients most frequently fell onto their bedside floor (63%), followed by the bathroom/toilet/shower floor (10%), and ward passageways and doorways (7%). They fell most frequently on Sundays (19%), then Tuesdays (16%) and Mondays (14%). Falls
most frequently occurred between the hours of 9:01 to 10:00 am (10%), 6:01 to 7:00 pm (9%), and 7:01 to 8:00 am (7%). The fewest number of falls occurred during patients’ lunch time, between 12:01 and 1:00 pm (<1%).

**Discussion:**

This investigation has demonstrated some similarities between the epidemiology of falls in this setting compared to other subacute settings. The estimation of the proportion of patients becoming fallers (21%) and the rate of falls (12.8 per 1000 patient-days) were within the boundaries of previously reported rates (section 1.3.5). There was little evidence of a linear relationship between increasing age and becoming a faller (section 1.4.3.1). A majority of falls were unwitnessed and amongst patients not complying with their recommendations for ambulation at the time of the fall (section 1.4.4.2), and also occurred by patients’ bedsides (section 1.4.4.1).

However, this study also highlighted some differences. Female patients appeared to be at a higher risk of experiencing falls, in comparison to a slightly higher risk for males in previous studies (section 1.4.3.2). Falls predominantly occurred in morning (7:00 to 10:00 am) and evening (5:30 pm to 7:00 pm) clusters with a dramatic drop at lunchtime. A slight trend was also noted for falls to occur more frequently over the Sunday to Tuesday day bracket.

Of concern was the difference in fall rates estimated in this audit and those of the hospital reported figures upon which the power analysis for study two were based upon. The hospital reported figures for the month of March 2001 indicated that 30% of patients had experienced one or more falls during this period. This discrepancy may have existed for several reasons. March 2001, may have been a particularly “bad” month for patients to experience falls. Some fall incident reports may not have been sent to the nursing administration office appropriately during the period audited, or they may have been “mis-filed”. Using the number of discharges over the 6 month audit period as the denominator to estimate the proportion of patients becoming fallers may have produced a moderate level of inaccuracy into the estimate. Nursing administrators may have “double counted” individual patients for experiencing falls in their earlier audit. In contrast, falls by the same patient over two separate admissions would have only been counted as coming from one faller in the present audit, but
would likely have been counted as coming from two fallers had six separate one monthly audits been conducted instead of one six month audit. The counting approach used to estimate falls rates would have produced an under-estimation as 100% occupancy was assumed, though in the investigators experience when working in this institution, an estimate of 98% occupancy would still have been realistic. A lack of data available to the investigator over this period made employing the 100% occupancy assumption necessary for calculations in this audit.

Despite the limitations inherent in attempting to calculate fall rates and proportions from retrospective audit data, this study has still provided sufficient information from which to tailor an education program for the prevention of falls to the Peter James Centre subacute ward setting. It has also demonstrated that falls in this setting share many similar characteristics to those in other subacute settings, and that any reductions in falls achieved by a falls prevention program in this setting may be generalisable to other subacute hospitals.
Appendix F. Patient / family member falls prevention information brochure intervention.

FAMILY MEMBERS:

PLEASE READ THIS

with your relative who is staying with us at the Peter James Centre.

This is a falls prevention information brochure produced for the “Falls Prevention Project” at the Peter James Centre.
INTRODUCTION

Falls amongst the elderly presents a very large public health problem.

This brochure has been designed to help prevent falls amongst patients at the Peter James Centre.

This brochure will tell you how and when some falls occur, and what patients and family members / carers can do to stop falls from occurring.

IS “FALLING OVER” A PROBLEM AT THE PETER JAMES CENTRE?

Previously, 25% of patients have been recorded as having at least one fall during their stay at the Peter James Centre.

As a result of falling over, patients have incurred injuries such as cuts, bruises and broken bones.
3 SIMPLE STEPS TO STOPPING FALLS.

1) KNOW IF YOU NEED HELP TO WALK AROUND.

Your physiotherapist will tell you if it is safe for you to walk around on your own.

You can also tell by the number of red stripes on your walking aid:

- One red stripe means you can walk on your own.
- Two red stripes means you must wait for someone to supervise your walking.
- Three red stripes means you must wait for someone to physically help you with your walking.

2) ASK FOR HELP IF YOU NEED IT.

If you have two red stripes (supervision) or three red stripes (assistance) you must press the nurses buzzer to gain the attention of a staff member before you walk anywhere.
If you have one red stripe (independent) but you are tired and feel as if you need some help, you are free to ask for it also.

The nursing staff member looking after you will show you how to use your buzzer and where you can find it.

3) **WAIT FOR A STAFF MEMBER TO ARRIVE.**

Staff are often busy with other patients and have difficulty coming straight away, but it is very important that you wait for them.

It is important to follow this procedure for even the shortest of walks. Remember two thirds of falls occur beside a patients bed!
WHY DO FALLS OCCUR?

A majority of falls at the Peter James Centre are preventable.

80% of falls occur when patients are not in view of a staff member.

From this we know that many falls occur when patients are attempting to perform activities on their own.

We believe that most people are trying to go to the toilet or get back into bed on their own when they have a fall.

WHERE DO FALLS OCCUR?

Two thirds of all falls at our centre occur at a patients bedside!

Falls also tend to occur in passageways, bathrooms and toilets.
HOW DO FALLS OCCUR?

1) Losing Your Balance.

2) Slips and Trips.

3) Your Legs Give Way Beneath You.

4) Dizziness and Fainting.
HOW PATIENTS CAN STOP THEM.

Use the walking aid provided to you EVERY TIME you want to walk somewhere.

Press your buzzer and WAIT for assistance.

Look at the path you are about to walk for any obstacles.

Ensure you are wearing correct eyewear and footwear (not socks!) when you walk.

If you see an obstacle, press the buzzer and wait for a staff member to move it.

Even people who are allowed to walk around on their own can get tired by the end of the day. Use the walking aid provided to you and please ask for help if you feel that you may need it.

Get up from the bed or the chair slowly and in stages. Be especially weary if you sometimes feel dizzy when standing up or if you have a heart condition.

Becoming dizzy when standing up is often worse on hot days, after meals or if you are dehydrated.
When do falls occur?

Falls can occur at any time, day or night.

In the morning, most falls occur between 7:00 and 10:00 AM. This is when staff are often busy showering and dressing individual people.

We believe that many people who fall at this time are trying to get themselves out of bed and go to the toilet without assistance.

In the afternoon, most falls occur between 5:30 and 7:00 PM. Staff are often busy bringing people back from the dining room, and taking other people to the toilet.

We believe that many people who fall at this time are trying to get themselves into bed or go to the toilet without assistance.

Please be patient when requesting assistance at these times!
HOW FAMILY MEMBERS CAN STOP PATIENTS FROM FALLING.

1) WHEN VISITING THE PATIENT

Ensure the patient knows where to find the buzzer and how to use it.

Check how many stripes the patient has on their walking aid. Do they know how many they have and what that means?

If patients are bored and restless, ask nursing staff to see if you can take the patient for a walk.

Check the patients bedside environment to see if it is free from potential obstacles.

Nurses buzzers or television cords are sometimes obstructing a pathway at the side of a patients bed.

2) WHEN LEAVING AFTER VISITING.

If you bring in a chair during visiting hours, please remove it when you leave.

Ask your relative if they are tired and require assistance to return to bed. If so, please ask one of the nursing staff to assist.
3) CLOTHING, FOOTWEAR + EYEWEAR.

Ensure the patient has appropriate clothing to wear while walking around the ward. Long dressing gowns and nightwear are potentially hazardous if they are caught beneath a patient’s foot while they are walking.

Ensure the patient has appropriate footwear (fits securely, flat or low supportive heel, non-slip grip). If in doubt of the appropriateness of the patients clothing or footwear, please check with a nurse.

Ensure the patient has appropriate eyewear to use while walking. Bifocal glasses have been associated with an increased risk of falling over. If you have concerns about the patient’s vision or if they are due for a checkup with their optometrist, please inform the doctor looking after the patient.
4) FAMILY SUPERVISION OUTSIDE OF VISITING HOURS

The primary approach to falls prevention at the Peter James Centre is based upon patients correctly following the 3 SIMPLE STEPS TO STOPPING FALLS.

Sometimes patients have difficulty following the 3 SIMPLE STEPS TO STOPPING FALLS. This is quite often the case in people who are confused, have poor memory, are disorientated, or have had a stroke.

These patients may benefit from having additional supervision from a family member. This supervision would be especially valuable during peak periods of falls (ie. 7:00 - 10:00 AM, 5:30 - 7:00 PM) and during the afternoon (1:00 - 5:00 PM). If you or one of your family members would be able to supervise your relative at one of these times, please speak to the nurse in charge to see if this would be appropriate.
Checklist for Family Members:

☐ Have you read through this brochure with your relative staying with us at the Peter James Centre?

☐ Does the patient understand the 3 simple steps to stopping falls?

☐ If your relative is unable to follow the 3 simple steps to stopping falls, are you or another family member able to help supervise your relative during the peak periods of falls?

☐ Have you checked your relatives clothing, footwear and eyewear to ensure that it is suitable for use around the wards?

☐ Have you scanned around your relatives bedside for any potential obstacles?

☐ Is there enough room for them to push their frame safely around their bedside.

Before leaving:

☐ Does your relative have their nurses buzzer and walking aid within reach (if they are allowed to use it on their own).

☐ Have you taken out any chairs or potential obstacles that you may have brought in with you.
Appendix G. The falls risk alert card intervention design.
Appendix H. Additional exercise program intervention manual.
Manual of exercises to be used in study
“Effectiveness of a targeted falls prevention
program in the sub-acute hospital setting – a
randomised controlled trial”.

Contents:

Underlying principles of exercise program……………………Page 2

Description of starting positions and abbreviations………………Page 4

Sample exercises………………………………………………Page 6

Concluding remarks and reference……………………………..Page 16
Underlying principles of exercise program

This program is intended to consist of 3 exercise sessions of 45 minutes duration per week. The exercises are to incorporate the therapeutic elements of Tai Chi (below) with functional activities such as transferring from chair to chair, stepping reaching and weight shifting. In conducting exercise with sub-acute hospital patients, therapists must be sensitive to fatigue levels of individual participants within the exercise group and tailor the intensity of the program accordingly.

7 therapeutic elements of Tai Chi exercise
1. Continuous movement performed SLOWLY
2. Small to large degrees of motion
3. Knee flexion and weight shifting
4. Straight and extended head and trunk
5. Combined rotation of head, trunk and extremities
6. Asymmetrical arm and leg movements about the waist
7. Unilateral weight bearing and constant shifting

One or more of these elements should be incorporated into every exercise performed, especially knees bent, upright posture, slow movement and weight shifting.

Functional context: Many of the exercises in this manual resemble activities that may be undertaken in everyday life. Where possible, visual imagery may be used to assist the patient to perform the exercises.

Hand support: Additional support should be provided where required. This can take the form of rails or the back of sturdy chairs. However contact between upper limbs and a supporting surface should be discouraged where safe to do so. In circumstances where patients are hesitant to attempt an activity without being able to hold onto something, the therapist may initially wish to offer their hands. They should be relaxed at all times and never serve as a supporting surface. If a patient places downwards pressure through your hands, do not apply an equal force in the opposite direction, rather allow your hands to be pushed down (this is of course unless the hand
pressure is a protective balance reaction where the patient will fall if you do not push back). This will teach the patient that they must rely on their lower limbs for their balance reactions.

**Format of group:** For simpler exercises, the therapist can have all participants performing simultaneously. However for complex exercises or exercises where the participants struggle to perform the movement without losing balance, the therapist may wish to have participants perform exercises one at a time.
**Basic starting position (BSP)** – to be incorporated into most exercises.

Knees bent

Upright posture (esp. head arms trunk)

Feet shoulder width apart

---

**Basic starting position – upper limbs (BSPUL):** Shoulders at 90 degrees flexion, wrists extended, fingers pointing up. This will move centre of gravity anteriorly, requiring lumbar spine and hip extensors to do more work.
Narrow basic starting position (NBSP): BSP + feet together
Wide basic starting position (WBSP): BSP + feet wide apart

Abbreviations:
In this manual you will notice some abbreviations such as BSP (basic starting position), BSPUL (basic starting position upper limbs) and WBSP (wide basic starting position).
Where you see (W)BSP(UL) this means that you could use the basic starting position alone, the wide basic starting position, the basic starting position – upper limbs or the combination of wide basic starting position and basic starting position – upper limbs.
Basic standing exercises

1. (W)BSP(UL) + lateral weight shift
   Slowly move from side to side with no rotation in horizontal plane

![Diagram of lateral weight shift]

2. BSP(UL) + trunk rotation
   Slowly rotate HAT as a unit in horizontal plane

![Diagram of trunk rotation]
3. (W)BSP(UL) + lateral weight shift + trunk rotation
Use both rotation and lateral weight shift (ipsilateral or contralateral to the side of the rotation)

4. (W)(N)BSP + toe / heel lift
Slowly raise heel / toes of one foot, or combinations with both feet.
Stepping exercises

1. Uni-direction foot slide
Start in NBSP, slowly slide one foot forwards / sideways / backwards then return. Emphasise, contralateral weight shift first, then smooth sliding motion of foot. If foot moves incrementally then foot is taking too much weight and must emphasise more contralateral weight shift. Only expect small step when going forwards or backwards. To effectively slide foot further away from body, the contralateral knee must bend further.

Variation: Move foot on a diagonal forwards or backwards – this progresses to chair transfers later.
Once patient is more confident in single limb support, foot slide may no longer be necessary, use instead SLOW steps. If stepping forwards / forwards diagonal try to completely extend knee and dorsiflex ankle before initial contact. If stepping laterally, back diagonal, try to fully evert ankle before initial contact.
Variation: Incorporate use of upper limb in movement. Eg. Lateral foot slide moving left foot, abduct right arm to 90 degrees slowly during slide. Could also have flexed shoulder or used ipsilateral arm in either manner. Might choose to incorporate hand positioning such as thumb touching finger-tips, fingers straight and wrist flexed.

2. Combination foot slide
Sequentially perform two uni-direction foot slides with the same foot in different directions.

Variation: After initially sliding foot away from body (eg. backwards), use a slide that is like an arc to move to a position 90 degrees away (eg. sideways), then return to NBSP.
Transferring exercises

1. Sit to stand.

Sit to stand in BSP then stand to sit. Do not allow use of hands for stand to sit, even for beginners. Must emphasise slowness of movement and control of descent. Progress to no / minimal use of hands for ascent. Then emphasise slowness of movement for ascent.
2. Chair to chair transfer.
Important to progress to this quickly due to its functional importance even if previous moves cannot be performed perfectly. Set up chairs with arms of chairs touching at 90 degree angle.

Sit to stand, BSP(UL), with foot closer to target chair forwards diagonal foot slide towards distant front leg of target chair. Weight shift onto this foot, rotate head arms and trunk away from this side (so that patient is now facing away from chair). Slide foot that is closer to the original chair towards the opposite foot, ending up in BSP(UL). Sit down without using hands very slowly.
Complex movements

1. Charleston

NBSP(V), lateral foot slide, weight shift towards that side, lateral foot slide of contralateral leg to return to NBSP(V) however now one step lateral from original starting position. Return to the original position using the same technique in reverse.

Variation: From NBSPV, horizontally extend ipsilateral shoulder of lead foot
2. Pushing the car
(N)BSPV, forward foot slide, weight shift onto front foot, forward foot slide, forward weight shift onto new front foot. All steps performed slowly with knee bend maintained. Can repeat for many steps and use therapist hands for minor support if necessary.

Variation: Car is too heavy – as above but backwards foot slides.
3. Stinky baby

(N)(W)BSP(V), first half of Charleston, rotate upper body towards this direction, reach into imaginary baby’s cot, lift imaginary baby to chest, ½ Charleston back in other direction, rotate upper body towards this direction, push baby out to mum / dad (for nappy change).
4. Watering flower pots

(N)(W)BSP(V), forward foot slide, back weight shift as much as possible and imagine filling up watering pot from ground level tap (can reach down with both hands to do this), imagine picking up watering pot, forwards weight shift, lift arms right up and pour water into hanging pot plant.

Variation: Can imagine that flower pots are diagonally forward, across a step or any where you like. Can use real watering pot as a prop for this one.
Closing remarks

This manual is not intended to be an exhaustive description of all exercises that can be included in this program. The exercises described provide sufficient content to conduct many sessions with, however therapists may wish to add other particular exercises of their own design. It is important though that they preserve the underlying principles of the program outlined in pages 2 and 3 of this manual.

Reference

Appendix I. Hip protector intervention picture.
Appendix J. Hip protector intervention patient notice.

HIP PROTECTOR INFORMATION SHEET:

You are currently in possession of:

2 x hip protector pants
2 x hip protector shields

These are designed to reduce your risk of hurting your hips if you happen to experience a fall during your stay at the Peter James Centre.

We encourage you to wear these pants with the shields inserted during the day and at night.

These pants are to be worn on the outside of your underwear, like a pair of shorts.

Please change hip protector pants every two days. Please give the old pants to the nurse looking after you. These will then be laundered for you here at the Peter James Centre.

These pants and shields remain the property of the Peter Hames Centre and should remain at the Peter James Centre at all times. Please Do Not take them home with you when you leave our centre or have them sent home to be washed.

If you would like to purchase a pair for when you leave our centre, you can arrange this through your treating occupational therapist or physiotherapist.
Appendix K. Staff education handout.
<table>
<thead>
<tr>
<th>Falls Risk Factors</th>
<th>Explanatory Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of recent falls</td>
<td>Especially falls in the hospital setting</td>
</tr>
<tr>
<td>Impaired mental state</td>
<td>Confusion, Disorientation, Poor memory, Poor Judgement, Receptive aphasia, Depression</td>
</tr>
<tr>
<td>Impaired physical condition</td>
<td>Unsteady gait, Reduced lower limb strength, Poor co-ordination, Poor balance, Difficulty transferring (sit to stand)</td>
</tr>
<tr>
<td>Impaired sensory feedback</td>
<td>Reduced vision, Dizziness / Vertigo</td>
</tr>
<tr>
<td>Medications acting upon the central nervous system</td>
<td>Sedatives, Tranquilizers, Hypnotics</td>
</tr>
<tr>
<td>Special toileting needs</td>
<td>Bladder and bowel incontinence, Frequency, Urgency</td>
</tr>
<tr>
<td>Presence of a chronic medical disorder</td>
<td>Stroke, Parkinsons disease, Neoplasm / cancer, Congestive heart failure</td>
</tr>
<tr>
<td>Other risk factors</td>
<td>Presence of infection, Postural drop (&gt;10 mmHg), Increasing age, Wandering behavior</td>
</tr>
<tr>
<td>Multiple risk factors</td>
<td>Consider combinations of the above risk factors, Consider the importance of each individual risk factor</td>
</tr>
</tbody>
</table>

Consider environmental risk factors: Footwear, bedside clutter, lighting, surfaces.

References:
UpRight RODney at the Peter James Centre.

- Centre of gravity.
- Base of support.

What happens when UpRight RODney's centre of gravity falls outside his base of support?

- What could cause this to happen?

How can we help UpRight RODney to stand more safely?

- How else can we help him?
- What might stop those strategies from working?

How else might UpRight RODney fall over?

- What might cause this to occur?
- How can we prevent this?

Remember that UpRight RODney is at risk because he is trying to do things.

- What are the common activities performed by patients at the Peter James Centre?
- Are some activities more risky than others?
- How do we make these activities safer?
Appendix L. Stata “do” file program to calculate variance estimates of predictive accuracy statistics – Chapter 3a.

summarize a if(phase==1), mean
scalar a1 = r(mean)*122
summarize a if(phase==2), mean
scalar a2 = r(mean)*316
summarize b if(phase==1), mean
scalar b1 = r(mean)*122
summarize b if(phase==2), mean
scalar b2 = r(mean)*316
summarize c if(phase==1), mean
scalar c1 = r(mean)*122
summarize c if(phase==2), mean
scalar c2 = r(mean)*316
summarize d if(phase==1), mean
scalar d1 = r(mean)*122
summarize d if(phase==2), mean
scalar d2 = r(mean)*316
scalar fracSSSdiff = (a1/(a1+c1)+d1/(d1+b1))-
    (a2/(a2+c2)+d2/(d2+b2))
summarize e if(phase==1), mean
scalar e1 = r(mean)*122
summarize e if(phase==2), mean
scalar e2 = r(mean)*316
summarize f if(phase==1), mean
scalar f1 = r(mean)*122
summarize f if(phase==2), mean
scalar f2 = r(mean)*316
summarize g if(phase==1), mean
scalar g1 = r(mean)*122
summarize g if(phase==2), mean
scalar g2 = r(mean)*316
summarize h if(phase==1), mean
scalar h1 = r(mean)*122
summarize h if(phase==2), mean
scalar h2 = r(mean)*316
scalar exSSSdiff = (e1/(e1+g1)+h1/(h1+f1))-
(e2/(e2+f2)+h2/(h2+f2))
summarize i if(phase==1), mean
scalar i1 = r(mean)*122
summarize i if(phase==2), mean
scalar i2 = r(mean)*316
summarize j if(phase==1), mean
scalar j1 = r(mean)*122
summarize j if(phase==2), mean
scalar j2 = r(mean)*316
summarize k if(phase==1), mean
scalar k1 = r(mean)*122
summarize k if(phase==2), mean
scalar k2 = r(mean)*316
summarize l if(phase==1), mean
scalar l1 = r(mean)*122
summarize l if(phase==2), mean
scalar l2 = r(mean)*316
scalar edSSSdiff = (i1/(i1+k1)+l1/(l1+j1))-
(i2/(i2+k2)+l2/(l2+j2))
summarize m if(phase==1), mean
scalar m1 = r(mean)*122
summarize m if(phase==2), mean
scalar m2 = r(mean)*316
summarize n if(phase==1), mean
scalar n1 = r(mean)*122
summarize n if(phase==2), mean
scalar n2 = r(mean)*316
summarize o if(phase==1), mean
scalar o1 = r(mean)*122
summarize o if(phase==2), mean
scalar o2 = r(mean)*316
summarize p if(phase==1), mean
scalar p1 = r(mean)*122
summarize p if(phase==2), mean
scalar p2 = r(mean)*316
scalar hipSSSdiff = (m1/(m1+o1)+p1/(p1+n1))- (m2/(m2+o2)+p2/(p2+n2))
summarize frac if(phase==1), mean
scalar fracm = r(mean)*122
summarize los if(phase==1), mean
scalar losm = r(mean)*122
summarize ex if(phase==1), mean
scalar exm = r(mean)*122
summarize ed if(phase==1), mean
scalar edm = r(mean)*122
summarize hp if(phase==1), mean
scalar hpm = r(mean)*122
summarize frac if(phase==2), mean
scalar fracn = r(mean)*316
summarize los if(phase==2), mean
scalar losn = r(mean)*316
summarize ex if(phase==2), mean
scalar exn = r(mean)*316
summarize ed if(phase==2), mean
scalar edn = r(mean)*316
summarize hp if(phase==2), mean
scalar hpn = r(mean)*316
summarize fracfall if(phase==1), mean
scalar fracfallm = r(mean)*122
summarize falls if(phase==1), mean
scalar fallsm = r(mean)*122
summarize exfall if(phase==1), mean
scalar exfallm = r(mean)*122
summarize edfall if(phase==1), mean
scalar edfallm = r(mean)*122
summarize hipfall if(phase==1), mean
scalar hipfallm = r(mean)*122
summarize fracfall if(phase==2), mean
scalar fracfalln = r(mean)*316
summarize falls if(phase==2), mean
scalar fallsn = r(mean)*316
summarize exfall if(phase==2), mean
scalar exfalln = r(mean)*316
summarize edfall if(phase==2), mean
scalar edfalln = r(mean)*316
summarize hipfall if(phase==2), mean
scalar hipfalln = r(mean)*316
scalar fracSSAdiff = (fracfallm/fallsm+(losm-fracm)/losm)-(fracfalln/fallsn+(losn-fracn)/losn)
scalar exSSAdiff = (exfallm/fallsm+(losm-exm)/losm)-(exfalln/fallsn+(losn-exn)/losn)
scalar edSSAdiff = (edfallm/fallsm+(losm-edm)/losm)-(edfalln/fallsn+(losn-edn)/losn)
scalar hipSSAdiff = (hipfallm/fallsm+(losm-hpm)/losm)-(hipfalln/fallsn+(losn-hpn)/losn)
Appendix M. The St Thomas’s risk assessment tool in falling elderly inpatients.

<table>
<thead>
<tr>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES = 1</td>
</tr>
<tr>
<td>NO = 0</td>
</tr>
</tbody>
</table>

1. Did the patient present to the hospital with a fall or has s/he fallen on the ward since admission?

2. Do you think the patient is agitated?

3. Do you think the patient is visually impaired to the extent that everyday function is affected?

4. Do you think the patient is in need of especially frequent toileting?

5. Does the patient have a **combined** transfer and mobility score of 3 or 4?
   (transfer score ___ + mobility score ___ = total ___)
   - if total is 3 or 4 (answer is yes) = 1 ➤
   - if total is 0, 1, 2, 5, 6 (answer is no) = 0 ➤

   **TOTAL STRATIFY SCORE**

Transfer and Mobility score (0-6) by combining the transfer and mobility sections of the Barthel index:

<table>
<thead>
<tr>
<th>transfer score: (transfer means from bed to chair and back)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = unable - no sitting balance; two people to lift</td>
</tr>
<tr>
<td>1 = major help (one strong/skilled helper or two normal people, physical); can sit</td>
</tr>
<tr>
<td>2 = minor help (one person easily or needs supervision for safety)</td>
</tr>
<tr>
<td>3 = independent (use of aids to be independent is allowed)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>mobility score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = immobile</td>
</tr>
<tr>
<td>1 = wheelchair independent including corners, etc.</td>
</tr>
<tr>
<td>2 = walks with help of one person (verbal or physical)</td>
</tr>
<tr>
<td>3 = independent (but may use any aid, eg, stick)</td>
</tr>
</tbody>
</table>
Appendix N. Stata “do” file program to calculate variance estimates of predictive accuracy statistics – Chapter 3b.

```stata
summarize a, mean
scalar a1 = r(mean)*_N
summarize b, mean
scalar b1 = r(mean)*_N
summarize c, mean
scalar c1 = r(mean)*_N
summarize d, mean
scalar d1 = r(mean)*_N
summarize e, mean
scalar e1 = r(mean)*_N
summarize f, mean
scalar f1 = r(mean)*_N
summarize g, mean
scalar g1 = r(mean)*_N
summarize h, mean
scalar h1 = r(mean)*_N
summarize i, mean
scalar i1 = r(mean)*_N
summarize j, mean
scalar j1 = r(mean)*_N
summarize k, mean
scalar k1 = r(mean)*_N
summarize l, mean
scalar l1 = r(mean)*_N
summarize m, mean
scalar m1 = r(mean)*_N
summarize n, mean
scalar n1 = r(mean)*_N
summarize o, mean
scalar o1 = r(mean)*_N
```
summarize p, mean
scalar p1 = r(mean)*_N
scalar senpjcfrac = a1/(a1+c1)
scalar specpjcfrac = d1/(d1+b1)
scalar senpjcem = e1/(e1+g1)
scalar specpjcem = h1/(h1+f1)
scalar senpjced = i1/(i1+k1)
scalar specpjced = l1/(l1+j1)
scalar senpjchp = m1/(m1+o1)
scalar specpjchp = p1/(n1+p1)
scalar SSSpjcfrac = (a1/(a1+c1))+(d1/(d1+b1))
scalar SSSpjcem = (e1/(e1+g1))+(h1/(h1+f1))
scalar SSSpjced = (i1/(i1+k1))+(l1/(l1+j1))
scalar SSSpjchp = (m1/(m1+o1))+(p1/(n1+p1))
summarize sa, mean
scalar sal = r(mean)*_N
summarize sb, mean
scalar sbl = r(mean)*_N
summarize sc, mean
scalar scl = r(mean)*_N
summarize sd, mean
scalar sdl = r(mean)*_N
summarize se, mean
scalar sel = r(mean)*_N
summarize sf, mean
scalar sfl = r(mean)*_N
summarize sg, mean
scalar sgl = r(mean)*_N
summarize sh, mean
scalar shl = r(mean)*_N
summarize si, mean
scalar sil = r(mean)*_N
summarize sj, mean
scalar sjl = r(mean)*_N
summarize sk, mean
scalar skl = r(mean)*_N
summarize sl, mean
scalar sl1 = r(mean)*_N
summarize sm, mean
scalar sm1 = r(mean)*_N
summarize sn, mean
scalar snl = r(mean)*_N
summarize so, mean
scalar sol = r(mean)*_N
summarize sp, mean
scalar spl = r(mean)*_N
scalar senstratify1 = sa1/(sa1+sc1)
scalar specstratify1 = sd1/(sd1+sb1)
scalar senstratify2 = se1/(se1+sg1)
scalar specstratify2 = sh1/(sf1+sh1)
scalar senstratify3 = si1/(si1+sk1)
scalar specstratify3 = sl1/(sl1+sj1)
scalar senstratify4 = sm1/(sm1+so1)
scalar specstratify4 = sp1/(sp1+sn1)
scalar SSSstratify1 = (sa1/(sa1+sc1)+sd1/(sd1+sb1))
scalar SSSstratify2 = (se1/(se1+sg1)+sh1/(sh1+sf1))
scalar SSSstratify3 = (si1/(si1+sk1)+sl1/(sl1+sj1))
scalar SSSstratify4 = (sm1/(sm1+so1)+sp1/(sp1+sn1))
scalar dfrac2 = (se1/(se1+sg1)+(sh1/(sh1+sf1)))-(a1/(a1+c1)+d1/(d1+b1))
scalar dhp2 = (se1/(se1+sg1)+(sh1/(sh1+sf1)))-(m1/(m1+ol)+p1/(pl+nl))
scalar dfrac3 = (si1/(si1+sk1)+(sl1/(sl1+sj1)))-(a1/(a1+c1)+d1/(d1+b1))
scalar dhp3 = (si1/(si1+sk1)+(sl1/(sl1+sj1)))-(m1/(m1+ol)+p1/(pl+nl))
summarize frac, mean
scalar frac1 = r(mean)*_N
summarize ex, mean
scalar ex1 = r(mean)*_N
summarize ed, mean
scalar edl = r(mean)*_N
summarize hp, mean
scalar hp1 = r(mean)*_N
summarize fracfall, mean
scalar fracfall1 = r(mean)*_N
summarize exfall, mean
scalar exfall1 = r(mean)*_N
summarize edfall, mean
scalar edfall1 = r(mean)*_N
summarize hipfall, mean
scalar hipfall1 = r(mean)*_N
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summarize stratify2, mean
scalar stratify2l = r(mean)*_N
summarize stratify3, mean
scalar stratify3l = r(mean)*_N
summarize stratify4, mean
scalar stratify4l = r(mean)*_N
summarize stratify1orfalls, mean
scalar stratify1orfalls1 = r(mean)*_N
summarize stratify2orfalls, mean
scalar stratify2orfalls1 = r(mean)*_N
summarize stratify3orfalls, mean
scalar stratify3orfalls1 = r(mean)*_N
summarize stratify4orfalls, mean
scalar stratify4orfalls1 = r(mean)*_N
summarize los, mean
scalar los1 = r(mean)*_N
summarize falls, mean
scalar falls1 = r(mean)*_N
scalar senAfrac = fracfall1/falls1
scalar specAfrac = (los1-frac1)/los1
scalar SSAfrac = senAfrac+specAfrac
scalar senAex = exfall1/falls1
scalar specAex = (los1-ex1)/los1
scalar SSAex = senAex+specAex
scalar senAed = edfall1/falls1
scalar specAed = (los1-ed1)/los1
scalar SSAed = senAed+specAed
scalar senAhp = hpfall1/falls1
scalar specAhp = (los1-hp1)/los1
scalar SSAhp = senAhp+specAhp
scalar senAstratify1 = stratify1orfalls1/falls1
scalar specAstratify1 = stratify11/los1
scalar SSAstratify1 = senAstratify1+specAstratify1
scalar senAstratify2 = stratify2orfalls1/falls1
scalar specAstratify2 = stratify21/los1
scalar SSAstratify2 = senAstratify2+specAstratify2
scalar senAstratify3 = stratify3orfalls1/falls1
scalar specAstratify3 = stratify31/los1
scalar SSAstratify3 = senAstratify3+specAstratify3
scalar senAstratify4 = stratify4orfalls1/falls1
scalar specAstratify4 = stratify41/los1
scalar SSAstratify4 = senAstratify4+specAstratify4
scalar dAfrac2 = SSAfrac-SSAstratify2
scalar dAhp2 = SSAhp-SSAstratify2
scalar dAfrac3 = SSAfrac-SSAstratify3
scalar dAhp3 = SSAhp-SSAstratify3
Appendix O. Information sheet and informed consent form for study two.
Falls Prevention Project: “Effectiveness of a Targeted Falls Prevention Program in the Rehabilitation Setting – A Randomised Controlled Trial.”

Participant Information Sheet

We invite you to participate in our research project titled “Effectiveness of a Targeted Falls Prevention Program in the Rehabilitation Setting – A Randomised Controlled Trial”. We would like to give you some background information on why we think this project is important and on what we would like you to do if you decide to join us in this research.

What is the purpose of this study?

Falls and injuries incurred as a result of falls are a major problem for people who undertake rehabilitation. A “Falls Prevention Program” has been developed at the Peter James Centre to try to address this problem. This program is intended to introduce a harm minimisation strategy and four falls prevention strategies that are not currently used at our centre. These interventions will be targeted to the patients who require them the most as assessed by our staff members. This is intended to reduce the number of falls and minimise the severity of injuries resulting from falls by patients at the Peter James Centre. In this research we seek to establish the effectiveness of this program in reducing the number of falls and minimise the severity of fall related injuries incurred by patients at the Peter James Centre.

Who can participate?

You can participate in this study if you:

1. Have been admitted to the rehabilitation wards at the Peter James Centre.

What will I have to do?

If you agree to take part in this study, the researcher will provide you with a code number and you will either receive the “Falls Prevention Program” in conjunction with “standard care” during your stay at the Peter James Centre, or “standard care” alone. This means that by participating in this study you will receive at least the same amount of rehabilitation as what you would receive if you did not wish to participate. You will have a 50% chance of being allocated to the “Falls Prevention Program” group. If you are allocated to the “Falls Prevention Program” group, you may be asked to wear, attend or receive the Hip protector garment – designed to reduce the risk of fracturing a patient’s hip if the patient has a fall while wearing this garment. Patients who are
1. selected to receive this intervention will have the correct use of these garments demonstrated by the researcher and be fitted for an appropriately sized pair. Staff members will determine how long each patient will benefit from this intervention during their stay at the Peter James Centre. These will be provided free of charge to the patient while they are at the Peter James Centre.

2. A balance exercise class – designed to improve a patient’s balance and reduce the risk of falling over during their stay. This class will be conducted three times a week and last for approximately 45 minutes each session. Patients will only be referred to this group once their physiotherapist deems it safe to participate.

3. An education class – designed to improve a patient’s knowledge of falls and falls prevention strategies. The class leader, an occupational therapist, will determine how many times each patient will need to attend this class.

4. A falls risk alert card to be placed by a patient’s bedside – designed to increase staff awareness of a patient’s possible increased risk of falling over.

5. A falls prevention information brochure – designed for patients and family members to discuss falls prevention strategies that may be used while at the Peter James Centre.

These interventions are targeted to those who require them most as assessed by our staff members. Therefore, even if you are allocated to the “Falls Prevention Program” group, you may receive none, one, two, three, four or all five of these new interventions. You will not be forced to wear or attend any of these interventions if you do not wish to. Staff members will merely suggest to you that you would benefit from attending or wearing the particular intervention.

To aid the evaluation of the “Falls Prevention Program”, you will be asked some questions regarding your quality of life and fear of falling upon admission and discharge from the Peter James Centre. If you are asked to participate in an education class or be given a falls prevention information brochure, you will be asked to complete a short survey regarding if you changed any of your behaviours as a result of attending the class or reading the information brochure. You may also be asked to complete some balance and strength tests if you are selected to attend the balance exercise class.

Are there any potential side effects?

There are potential side effects of some of the particular interventions involved in the “Falls Prevention Program”:

Hip protectors – Patients will be encouraged and assisted not to fall at all times during this study. In the event of a fall however, hip protectors are designed to deflect the force of a fall away from the side of the hip so that
1. the likelihood of fracturing that hip is reduced. This force however is
deflected into the soft tissues surrounding the hip, which may result in
damage to those soft tissues. Although this is an outcome that results in
injury to the participant, it is anticipated to be a much less harmful one than
that if the hip protector were not being used.

- Balance Exercise Class – Patients will be encouraged to improve their
  strength and balance during these classes. During these activities it is
  possible that a patient may lose balance and fall to the ground. We consider
  this likelihood to be similar to that when performing exercises in the
  physiotherapy department as a part of “standard care”. There will be less
  opportunity however for one to one assistance to be provided by a staff
  member to assist patients with their balance. To limit the impact of this, a
  number of strategies have been put in place:

  - Patients will be provided with hand support that they may use
    to steady themselves in the event of a loss of balance.

  - Each patient’s treating physiotherapist has been instructed to only refer
    patients to this class if they feel it would be safe for them to do so.

1. The class itself has been designed by physiotherapists and will be
   conducted by a physiotherapists who will be guiding patients as to an
   appropriate difficulty level of exercises so that they will still make
   improvements while remaining relatively safe.

We would like to remind you though, that even if you are allocated to the
“Falls Prevention Program” group, you will not necessarily be referred to the
above interventions and at no stage will you be forced to use or attend the
above interventions.

**What if I have concerns during this study?**

The researcher, Mr. Terry Haines will be available throughout the study if you
have any questions. The other investigators will also be available if required.

If you are not happy with or have concerns about the way the study is being
conducted you should contact the researcher, Mr. Terry Haines, or Dr. Peter
Lynch, Director of Aged Care Services at the Peter James Centre.

**Can I withdraw from the study if I wish?**

Your participation in this study is voluntary.

It is important that you are under no obligation to participate in this study. If
you do not wish to take part you are under no obligation to do so. Also, if you
Eastern Health
The Peter James Centre

Consent form for persons participating in research projects

Name of participant: __________________________________________________________

Project title: Effectiveness of a Targeted Falls Prevention Program in the Rehabilitation Setting – A Randomised Controlled Trial.

Name of investigators: Mr Terry Haines, Dr. Keith Hill, Associate Professor Kim Bennell.

1. I consent to participate in the above project, the particulars of which – including details of programs and procedures – have been explained to me and are appended hereto.

2. I authorise the researcher or his assistant to use with me the programs and procedures with me referred to under (1) above.

3. I acknowledge that:
   • The possible effects of the programs and procedures have been explained to me to my satisfaction;
   • My participation is voluntary and I have been informed that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied;
   • The project is for the purpose of research and / or teaching and not for treatment;
   • I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.

I, ______________________________________________________________
consent to participate in the above project.

Signature __________________________________________ Date ____________
(Participant)

OR

I, ______________________________________________________________
consent for ______________________________________________________
Who is my family member / For whom I am a care giver, to participate in the above project.

Signature __________________________________________ Date ____________
(Family member or care giver of patient)
Appendix P. Reliability of a hip abduction strength measure amongst older hospital patients using a spring gauge dynamometer.

BACKGROUND:
Clinical assessment tools are commonly used to describe level of impairment, assist in formulation of diagnosis and gauge changes in performance over time. Measures that are chosen need to be reliable. Reliability is the extent to which a measurement is consistent and free from error, and is fundamental to all aspects of measurement, because without it we cannot have confidence in the data we collect (Portney and Watkins 2000).

A measure of importance in research projects examining balance is that of hip abduction strength. Muscle groups responsible for hip abduction play an important role in the maintenance of balance. The gluteus medius and minimus muscles function to abduct the hip and to stabilise the pelvis in unilateral stance. If there is weakness in these muscle groups, during gait the pelvis accompanied by the trunk will fall excessively on the “swing” side of the body resulting in a loss of balance (Norkin and Levange 1992).

Previously, reliability studies of hip abduction strength have been completed using isokinetic dynamometers, hand held dynamometers, fixed dynamometers and with manual muscle testing.

Isokinetic dynamometers (such as the Kincom) have previously been demonstrated to have an intraclass correlation coefficient (ICC) for concentric hip abduction of 0.59 (Kea et al 2001) when tested on elite sportsmen. ICC values lower than 0.75 can be considered to be a poor to moderate result (Portney and Watkins 2000). Further to this result, the cost of this equipment, $18,000 US (Wish List Incorporated 2002) can place the use of this equipment outside of the reach of financially restricted research projects and physiotherapy departments.
The reliability of maximal isometric hip abduction strength measures using a hand
held dynamometer has previously been examined (Wang et al 2002, Purser et al 1999,
Agre et al 1987) ICC values for intra-rater reliability ranged from 0.7 in community
dwelling elders (Purser et al 1999) to 0.98 in community dwelling elders with a past
history of falling in the previous year (Agre et al 1987). In a separate study, Pearson’s
r correlation co-efficients of inter-rater reliability were found to be 0.74 (Wang et al
2002). Authors of this study commented that examiners using the hand held
dynamometer had great difficulty in maintaining the specific position for isometric
muscle testing which may have contributed to their poor results. To combat this,
subsequent studies have employed dynamometers that have been attached to fixed
apparatus in order to eliminate difficulties encountered by examiners in using this
equipment (Nadler et al 2000). Despite some encouraging results, the cost of this
equipment can also place the use of this equipment outside the reach of financially
restricted research projects and physiotherapy departments. Prices for hand held
dynamometers have been quoted at $925.93 US for the Micro FET2 Digital Muscle
Tester (Rehab Outlet Incorporated 2002).

Manual muscle testing is a method of strength assessment that is quick, inexpensive,
requires no equipment and is in common use in the clinical setting (Frese et al 1987).
Using a 13 point scale for grading of hip abduction muscle strength, a previous study
involving patients of a physiotherapy clinic found that two separate examiners agreed
on the muscle strength grade of a particular patient on 45-47% of occasions (Frese et
al 1987). However there was disagreement by 3 or more points on the 13 point scale
on 18–26% of occasions which led to authors of this study to conclude that the
reproducibility of manual muscle testing of hip abduction may not be adequate
enough for clinical decision making. Other authors have noted that manual muscle
testing suffers from a severe ceiling effect and is not accurate enough to detect subtle
but significant muscle weakness in older people (Lord et al 2001). Due to the poor
levels of agreement in the use of this assessment technique and its insensitivity to
subtle deficits, it is unsuitable for use in a research capacity.

Spring gauge dynamometers have previously been demonstrated to be a reliable
instrument for the measurement of isometric strength in lower limb musculature (Lord
et al 1991). However this has focussed on muscle groups other than those used for
hip abduction. The use of spring gauge dynamometers has previously been cautioned against as it is possible that the gauge will lose its calibration with fatigue of the spring upon repeated use (Bohannon and Andrews 1989). However the relative cost of this device [$40.00 US for the Salter Model 3 Tubular Balance with Hook (Salter Weigh Products Incorporated 2002)] makes its potential use in research projects with limited funding more attractive than that of other forms of dynamometer.

A protocol for measuring isometric hip abduction strength using a spring gauge dynamometer (see figures 1 - 4) has been devised and may provide a reliable measure of hip abduction strength amongst subacute hospital patients. This study seeks to document the intra-rater and inter-rater reliability of this hip abduction strength assessment protocol.
Figure 1. Protocol for testing maximum isometric hip abduction strength using a spring gauge dynamometer.

1) **Starting position** (to test left hip abductors): See figures 2 - 3.
Position patient in supine with the head supported by 1-2 pillows. Support right lower leg on a 20 cm stool with a pillow between the stool and the lower leg for comfort. Beneath the left leg place a masonite board and beneath the left heel place a “doughnut” to reduce friction.
Attach a thigh strap (5.5 cm in width) to the left leg so that it remains in the horizontal plane and that the inferior border of the thigh strap runs alongside the superior border of the left patella.
Attach the spring gauge dynamometer to a mobile bedside attachment, and then connect it to the thigh strap using additional links of chain if necessary. The chain and dynamometer should pass beneath the right leg that is elevated on the stool.
Care should be taken to ensure at this point that the dynamometer is attached at 90 degrees to the thigh, and that the thigh is in a neutral position of flexion/extension, abduction/adduction and internal/external rotation.

2) **Instructions:**
Patients are informed that this is a test of maximum muscle strength. They are then instructed to slide their left leg out to the side with as much force as they can, without letting their foot turn out to the side (external hip rotation) or lifting their knee into the air (hip flexion). Three attempts are made, following each attempt the patient is allowed to rest for 30 seconds. If the examiner observes that a “trick” movement is being performed (for example, hip flexion or external rotation), that attempt is ceased and the patient is corrected as to the movement required.

3) **Recording:**
The strength (kg) of all three trials is recorded, however the highest score is that which represents maximum voluntary isometric muscle strength. A measurement is then taken of the distance (m) from the superior margin of the left greater trochanter to the middle of the lateral aspect of the strap attaching to the thigh. This measurement represents the lever arm for the calculation of torque.

4) **Torque:**
Torque can be calculated by multiplying the length of the lever arm (m) by the magnitude of the greatest contraction (kg).
Figure 2. Starting position, lateral view.

Δ = Knee

Ø = Strap attachment

= Donut
Figure 3. Starting position, birds-eye view.

$\bigtriangleup$ = Knee

$\bigcirc$ = Strap attachment

$\bullet$ = Donut

Spring gauge dynamometer with fixed point of attachment to edge of bed

Masonite slide board

Pillow on top of stool

Chain
METHOD:

Participants and setting:
Patients of the subacute wards of the Peter James Centre, a metropolitan hospital in Melbourne, Australia, were approached for consent to participate in this study. Patients were excluded if:

- they had recent (<6 weeks) total or partial hip joint replacement surgery using a Hardinge approach due to the disruption of the gluteus medius musculature.
- They had a restricted weight bearing status due to a femoral fracture.
- They had severe pain or shortness of breath in the supine position.
- They were unable to follow instructions appropriately or have an abbreviated mental test score of less than 7 indicating cognitive impairment.

Instrument:
A spring gauge dynamometer that measured weight in 1 kilogram increments was used for this study.

Procedure: Participant recruitment -
The investigator approached patients for informed consent to participate from three days prior to the initial date of testing. Demographic data (patient age, gender, height, admission diagnosis, mini-mental state examination results) was collected by the investigator.

Instrument calibration –
Prior to testing, the spring gauge dynamometer was calibrated to ensure instrument accuracy. The dynamometer was loaded by the investigator with pre-weighed loads of up to 15 kilograms in 1 kilogram increments. A research assistant was blinded by a curtain from seeing the amount of weight that has been loaded onto the spring gauge dynamometer, yet was able to see the measurement displayed by the instrument (figure 4). The order in which the loads were applied was randomly determined (the investigator pulled numbers between 1 and 15 out of a hat without replacement).
Following placement of each load, the chief investigator recorded the weight placed on the scale separately to the measurement recorded by the research assistant.

**Figure 4.** Instrument and assessor positioning for calibration testing.

**Inter-rater reliability –**

Testing day one: The investigator (assessor one) measured the maximal isometric strength of the right hip abductors for eight participants. The data collection sheet was then kept in a secure location, away from view of the research physiotherapist involved in testing on day two.

Testing day two (followed immediately from day one): A research physiotherapist (assessor two) measured the isometric strength of the right hip abductors of all participants.

Testing day three (followed immediately from day two): The investigator measured the isometric strength of the right hip abductors for the remaining nine participants who had not already had two measurements on this side.
**Intra-rater reliability** -
Testing day two: The research assistant (who conducted strength testing for study two of the present research program) measured maximal isometric strength of the left hip abductors for each participant. The data collection sheet was then removed from the research assistant by the investigator and kept in a separate location.

Testing day three: The research assistant repeated the testing procedure for each participant using the left hip abductor muscle group. One participant was unwell on this day and thus measurements were performed on only 16 participants.

**Re-calibration** -
At the completion of the testing protocol, the spring gauge dynamometer used for these measurements was re-calibrated following the same procedure as when the instrument was initially calibrated.

**Statistical analysis:**

**Calibration** –
Agreement between the observations recorded by the research assistant and the weight loading applied by the investigator was expressed as percent agreement (number of exact agreements divided by number of possible agreements [1]).

**Reliability** –
Intra and inter-rater reliability was evaluated with the intra-class correlation coefficient (ICC) model (3,1) for intra-rater reliability and model (2,1) for inter-rater reliability using raw force (kilograms) measurement data. A paired t-test was used to compare mean results from first tests to second tests to examine a possible maturation effect for each leg.
RESULTS:
Baseline characteristics of the 17 patients who consented to participate in this study are presented in table 1. These characteristics were very similar to those of patients recommended for the additional exercise intervention in study two of the research program and to whom this hip abduction measure was applied (table 6.1 of main thesis body).

There was 100% agreement between load applied and research assistant reading of load (to the nearest 1 kilogram increment) in both the pre-testing and post-testing calibration investigations of the spring gauge dynamometer.

Raw force scores from maximal isometric hip abduction strength measurements for each participant are presented in table 2. The intra-rater reliability ICC model (3,1) = 0.71 (F = 5.87, p < 0.001) and inter-rater reliability ICC model (2,1) = 0.60 (F = 3.96, p = 0.005) both indicated a significant relationship between tests and assessors, however the strength of the relationship for inter-tester reliability was below the “clinically meaningful” target of r = 0.70. Mean raw scores for the first assessment for each leg (left = 6.3 kilograms, right = 6.8 kilograms) were lower than those for the second assessment (left = 7.0 kilograms, right = 7.8 kilograms) but not significantly so.
Table 1. Participant (n = 17) baseline characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (standard deviation) or absolute number (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>81 (8)</td>
</tr>
<tr>
<td>Gender</td>
<td>5 (29%) male</td>
</tr>
<tr>
<td>Height (cms)</td>
<td>160 (12)</td>
</tr>
<tr>
<td>Admission modified Barthel Index ( / 100)*</td>
<td>57 (16)</td>
</tr>
<tr>
<td>Admission mini-mental state examination ( / 30)*</td>
<td>24 (4)</td>
</tr>
<tr>
<td>Admission diagnosis</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>4 (24%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>3 (18%)</td>
</tr>
<tr>
<td>Other geriatric management</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>Other diagnoses</td>
<td>2 (12%)</td>
</tr>
</tbody>
</table>

* - Indicates higher score better.
Table 2. Raw force scores (kilograms) for maximal isometric hip abductor strength testing.

<table>
<thead>
<tr>
<th>Intra-rater reliability (left leg)</th>
<th>Inter-rater reliability (right leg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Day 2</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
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<td>6</td>
<td>9</td>
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<td>4</td>
<td>5</td>
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<td>5</td>
<td>Missing</td>
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<td>4</td>
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<tr>
<td>6</td>
<td>7</td>
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<tr>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
DISCUSSION:
The results of this study indicate that the intra-rater reliability of this testing procedure was comparable to previously established testing procedures that have used more expensive testing equipment (Kea et al 2001, Wang et al 2002, Purser et al 1999). The inter-rater reliability of this testing procedure was not as accurate when scores between two physiotherapists were compared.

In contrast to previous hip abduction strength test reliability studies, this testing procedure was performed on a group of subacute hospital patients. As was demonstrated in chapters 5 and 6 of this thesis, many of these patients undergo rapid change during their hospital stay. When test results for “first tests” were compared to those of “second tests” 24 hours later, there was an increase in strength of 0.7 and 1.0 kilograms for the left and right legs respectively. Though this difference was not significant, this study was not constructed to be sufficiently powered to detect a difference of this magnitude. This difference may indicate that there may have been a learning effect with the testing procedure or a maturation effect among the participants in the 24 hours between tests. A maturation effect would have caused the testing procedure to appear less reliable than what would have been found had a participant group unlikely to experience change over a brief period of time (such as a community-dwelling population) been selected.

Muscle strength testing conducted with a spring gauge dynamometer should possibly not be referred to as being isometric. This term implies that the limbs involved maintain a static position during the testing procedure, however this was not observed to be the case in this study. As participants applied greater force to the testing apparatus, the elongation of the spring inside the spring gauge dynamometer increased, allowing the limb to move into an abducted position to a small extent. This was of concern as the further the lower limb being tested moved away from the neutral position of hip flexion / extension, the further the angle of the strap attachment to the thigh moved away from the 90 degree starting position. The effect of this would have been to exaggerate the magnitude of test results for higher results to a greater extent than lower results. Had the chain and strap attachment been allowed to
be “slack” at the commencement of the testing procedure, this problem would have been accentuated.

In the context of the rapid change in physical functioning of the patients participating in this study, it appeared that this strength testing protocol was acceptable for use in the subacute setting. Therapists using this protocol should pay particular attention to ensuring that any slack in the testing strap or chain should be removed prior to test commencement, and discourage “trick” movements such as hip flexion and external rotation during the test.
REFERENCES:
Author/s:
Haines, Terrence Peter

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2004

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