The incidence of falls, prevalence of fear of falling and fall risk factors in adults with rheumatoid arthritis.

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Abstract
The objectives of the study were to determine the incidence of falls, the prevalence of fear of falling and fall risk factors and consequences in adults with rheumatoid arthritis (RA).

559 community dwelling adults with RA, aged 18 to 88 years (mean age 62; 69% female) participated in this prospective cohort study. Patients were recruited from four outpatient clinics in the Northwest of England and followed for 1 year after clinical assessment, using monthly falls calendars and telephone calls. Outcome measures included fall occurrence, reason for fall, type and severity of injuries, fractures, fall location, lie-times, use of health services and functional ability. Risk factors for falls included lower limb muscle strength, postural stability, number of swollen and tender joints, functional status, history of falling, fear of falling, pain, fatigue and medication. Data on demographics, vision, co-morbidities, history of surgery, fractures, and joint replacements were also recorded.

535 participants followed for one year had a total of 598 falls. 36.4% participants (95% CI 32% to 41%) reported falling with an incidence rate of 1313/1000 person-years at risk or 1.11 falls per person. Over one third of the falls were reportedly caused by hips, knees or ankle joints giving way. Over half of all the falls resulted in moderate injuries, including head injuries (n=27) and fractures (n=26). Univariate logistic regression showed that falls risk was independent of age and gender. A history of falls in the previous one year was a strong medical fall predictor with an odds ratio (OR) for a single fall=3.3 and for multiple falls OR=4.3. Fear of falling was an important self-reported psychological predictor, with the risk increasing by 10% with each point above 7 (up to 28) in the Short FES-I score. The inability to complete the Four Test Balance Scale due to poor balance was a strong postural fall predictor (OR 2.3). The most significant functional predictor of falls was the functional Health Assessment Questionnaire score, and each additional point attained in the score (1–4) nearly doubled the risk of further falls. Multivariate logistic regression revealed that when taken in combination with other factors, a history of multiple falls in the previous one year was the most significant predictive risk factor (OR=5.3) and overall the model accounted for 71% of variation. The most significant modifiable risk factors were swollen and tender lower limb joints (hip, knee and ankle) (OR=1.7), psychotropic medication (OR=1.8) and increasing fatigue (OR=1.13) with this model accounting for 68% of variation.

Adults of all ages with RA are at high risk of falls and fall-related injuries, fractures and head injuries. In clinical practice, high risk falls patients with RA can be identified by asking whether patients have fallen in the past year. The management of swollen and tender lower limb joints, fatigue and consideration of psychotropic medicines may be the most effective strategy to reduce falls in this group of patients. Fear of falling, pain, lower limb strength and poor balance are other useful clinical indicators that may be modified to prevent falls.
Declaration

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or institute of learning.

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The Author

The author is a registered nurse and registered district nurse who has worked in primary care for nearly 15 years. She gained a Bachelor in Nursing degree (Hons) in 1997 and completed a Masters in Research (Distinction) in 2003, both at the University of Manchester. Her master’s dissertation was a qualitative study of the patient and professionals’ views of a Rapid Response Service and resulted in service changes in the intermediate cares services, including a care homes training co-ordinator to promote evidence based practice, raise standards and ensure a rehabilitative approach to care in residential and nursing homes and a community nurse based in the Accident and Emergency (A & E) department to facilitate safe hospital discharges in East Cheshire.

Before working as a Lecturer in Nursing at the University of Manchester, the author worked as a Clinical Manager in East Cheshire Primary Care Trust and was the project manager for introducing Rehabilitation Assistants (a generic role, incorporating nursing, occupational therapy and physiotherapy skills) and other new services such as hospital at home for respiratory patients and community nursing support in A & E. An interest in research led to the external evaluation of the Rehabilitation Assistant project, supervised by Professor Heather Waterman and Professor Caroline Glendinning and the author. This experience and the encouragement of Heather and Caroline led to this PhD study.

The subject of falls and rheumatoid arthritis resulted from the authors experience in working with patients with arthritis and her interest in falls prevention due to the large number of older people requiring rehabilitation following a fall within the intermediate care services.
Publications
Publications arising from this thesis include:


CHAPTER 1

1. Introduction and background

This thesis reports a study of falls and rheumatoid arthritis (RA) and is organised into 13 chapters. Chapter 1 presents a concise introduction to the topic of falls and RA that includes the incidence and prevalence, causes and diagnosis of RA, economic costs, and an overview of fear of falling, fall risk factors and fall prevention programmes. Chapter 2 presents a literature review of falls and RA, chapter 3 reports the design and detailed methods used in the study. Chapter 4 gives a description of the data analyses utilised for the results of the study and chapter 5 reports the response rates and demographic results. Chapter 6 presents the incidence and prevalence of falls and fear of falling using both the prospective (one year follow-up) and retrospective (one year history of falls) data. Chapter 7 presents the fall risk factor data and uses the prospective results as these are of primary importance and interest in this study. Chapter 8 presents the retrospective history of falling and fall risk factor results and chapter 9 summarises and compares both the prospective and retrospective findings. Chapter 11 presents the self-reported data on fall consequences and chapter 12 reports the univariate and multivariate results of the study. The final chapter present a discussion of the findings and gives conclusions and recommendations from the findings in the study.
1.1 Introduction
This chapter provides a short introduction to the subject of RA and falls, which is further explored by reviewing the literature on this topic.

1.2 Rheumatoid arthritis
Rheumatoid arthritis (RA) is a chronic autoimmune disease that affects the joints causing inflammation, pain and can lead to the degeneration of bone and cartilage causing severe disability. It is considered a systemic disease, characterised by symmetric inflammation of the synovial joints and variable extra-articular features, which means it can affect a wide range of body systems (Pipitone and Choy, 2003). It is also believed to be an auto-immune disease whereby the body’s own immune system attacks the joint lining. This leads to the erosion of the cartilage of the joint and progressive deformities, which are visible on X-ray and by clinical examination.

1.2.1 Incidence and prevalence of RA
RA affects approximately 0.8% of the UK population and 1% worldwide, affecting three times more women than men (Silman and Pearson, 2002). RA is more prevalent among people aged over 65 years of age, but usually develops between the ages of 30 and 50 years (NAO, 2009). The National Audit Office (NAO, 2009) has estimated that 580,000 adults in England have RA, and an estimated 26,000 new cases are diagnosed annually. The occurrence of RA is different throughout the world. It is rare in less developed countries and more common in the USA and the UK, however there is evidence that the incidence
and prevalence of the disease is falling in the developed world (Symmons, 2002a).

### 1.2.2 Causes and diagnosis

Although the cause of RA is unclear, there appear to be a genetic link within families and risk factors include infection, trauma and environmental factors. The severity of the disease usually fluctuates with some people experiencing remission; however for many the condition can damage joints, cause disabling pain with stiffness and reduced functioning. This contributes to a substantial reduction in people’s quality of life.

The diagnosis of early RA is very difficult due to many of its symptoms being similar to a number of other disorders (such as viral arthritis, sickle cell disease and connective tissue disease to name a few). Initially, the patient may present with inflammatory polyarthritis which may go into remission or persist, resulting in chronic rheumatoid arthritis (Symmons, 2002b). Early disease usually presents with tender, swollen joints often affecting the small wrist and finger joints or both the small and large joints in the body. The symptoms of RA include morning joint stiffness, joint swelling, poor sleep, pain, fatigue, loss of weight and a feeling of having flu like symptoms. However, the disease and symptoms appear to affect people in differing degrees with rapid or steady progression again depending on the individual.
Diagnosis of RA is dependant upon a number of clinical criteria that have been modified over recent years. Currently, the standard and accepted means of defining RA is by use of the 2010 American College of Rheumatology (ACR) classification criteria (Table 1). These criteria are well accepted as providing the benchmark for disease definition (Aletaha et al., 2010).
Table 1. The 2010 American College of Rheumatology/European League Against Rheumatism classification criteria for rheumatoid arthritis

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Score</th>
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<tr>
<td><strong>Target population:</strong> Patients who</td>
<td></td>
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<tr>
<td>1) have at least 1 joint with definite clinical synovitis (swelling)</td>
<td></td>
</tr>
<tr>
<td>2) with the synovitis not better explained by another disease</td>
<td></td>
</tr>
<tr>
<td><strong>Classification criteria for RA (score-based algorithm: add score of categories A–D; a score of ≥6/10 is needed for classification of a patient as having definite RA).</strong></td>
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</table>

**A. Joint involvement***

1 large joint (Shoulders, elbows, hips, knees, ankles) 0
2-10 large joints 1
1-3 small joints (with or without involvement of large joints)** 2
4-10 small joints (with or without involvement of large joints) 3
>10 joints (at least 1 small joint) 5

**B. Serology (at least 1 test result is needed for classification)††

Negative Rheumatoid Factor and negative ACPA 0
Low-positive Rheumatoid Factor or low-positive ACPA 2
High-positive Rheumatoid Factor or high-positive ACPA 3

**C. Acute-phase reactants**
(at least 1 test result is needed for classification)‡‡

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<table>
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<tr>
<td>Normal CRP and normal ESR</td>
<td>0</td>
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<tr>
<td>Abnormal CRP or abnormal ESR</td>
<td>1</td>
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D. Duration of symptoms

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<tr>
<td>&lt;6 weeks</td>
<td>0</td>
</tr>
<tr>
<td>≥6 weeks</td>
<td>1</td>
</tr>
</tbody>
</table>

* Joint involvement refers to any swollen or tender joint on examination, which may be confirmed by imaging evidence of synovitis.

***"Small joints" refers to the metacarpophalangeal joints, proximal interphalangeal joints, second through fifth metatarsophalangeal joints, thumb interphalangeal joints, and wrists.

†† ACPA = anti-citrullinated protein antibody.

‡‡ CRP = C-reactive protein; ESR = erythrocyte sedimentation rate.

(Source: Adapted from Aletaha et al., 2010, pg 2574)

1.2.3 Economic costs of RA

It is estimated that the annual cost for RA treatment to the UK is £557 million. Other costs include loss of employment and incapacity benefit for RA amounting to £122 million in 2007/8 (NAO, 2009). Indeed, nearly a third of primary care consultations are due to musculoskeletal conditions and they are the most common reason for recurring GP visits (DH, 2006).
1.2.4 Treatment and prognosis

In recent years a number of clinical guidelines have been developed to assist with the treatment of people with RA including, “The Management of Rheumatoid Arthritis in Adults” (NICE 2009) and “Standards of Care. Inflammatory Arthritis” (ARMA 2004). These guidance agree that in order to prevent the progression of RA and to reduce the likelihood of developing severe disability, early diagnosis and intervention (primarily through the use of disease-modifying anti-rheumatic drugs) is required alongside close monitoring and support to minimize the damage to joints. To enable this optimum treatment to occur, prompt referrals are required to specialists for diagnosis. The NICE guidelines also recommend access to a named member of the multidisciplinary team to co-ordinate care provided by physiotherapists, occupational therapists and psychologists (NICE, 2009). However, the evidence suggests that the management of patients with RA is not always consistent with the guidelines (Goodwin et al., 2010). A recent report found that less than 50% of patients with RA were referred by their GP to a specialist within three months (NAO, 2009). There have also been reports on the lack of knowledge and ability of GP’s in making a diagnosis of RA (NAO, 2009).

It is notable that the major focus of the management of patients with RA is on the optimum use of medicines with little reference to the management of the physical and psychological aspects of the condition (such as muscle weakness, fatigue, pain and loss of confidence leading to social isolation). This is despite RA featuring in the widely used World Health Organisation’s FRAX fracture risk
assessment tool (Kanis et al., 2010) and the evidence that RA is a key risk factor for osteoporotic fractures due to low bone mass (Huusko et al., 2001; Cooper et al., 1995).

Despite these shortfalls, the prognosis for RA patients today, if diagnosed and treated early, is considerably better than it was 20 years ago due to earlier treatment and improved management of the condition.

1.3 Falls

Falls and their associated problems have gained much prominence in the research literature over recent years at least in part due to the increasing numbers of older people and the acknowledged costs associated with falls such as fractures, disability, reduced independence and increased healthcare utility. Over the last 30 years, a wealth of literature on the epidemiology and prevention of falls has been published that has led to improvements in services and practice for older people.

1.3.1 Definition of falls

According to the Prevention of Falls Network Europe (ProFaNE) consensus group (Lamb et al., 2005) a fall should be defined as ‘an unexpected event in which the participants come to rest on the ground, floor, or lower level.’ The use of a standard definition is important when investigating/managing falls to ensure that misinterpretation does not occur between older people and health professionals or researchers. For some older people a fall may be described as a
trip or loss of balance, whilst health professionals tend to refer to events that result in injuries and treatment (WHO, 2007). Inconsistencies in fall definitions may have led to differences in epidemiological studies of incidence and prevalence as well as risk factors that predict falls (Zecевич et al., 2006). Therefore it is important that all researchers, health professional, policy makers and persons at risk/fallers use a standard definition such as that outlined by ProFaNE to prevent such inconsistencies.

1.3.2 Incidence and prevalence of falls
Approximately one third (28-35%) of people aged 65 and over fall each year and this rate increases to 32-42% for those over 70 years of age (WHO, 2007; Blake et al., 1988; Campbell et al., 1981) and is higher for those in nursing homes. Around 30-50% of older people living in long-term care institutions fall each year, with 40% falling recurrently (Tinetti et al., 1987).

1.3.3 Prevalence of fear of falling in community dwelling population
Fear of falling (FOF) can be as debilitating as falling and can result in activity restriction, reduced quality of life, increased use of medication, institutionalisation and can increase the risk of falling (Scheffer et al., 2008; Lord et al., 1994; Arfken et al., 1994). The prevalence of fear of falling in the literature varies substantially from 12% to 65% and is higher in women than men (Legters, 2002; WHO, 2007). Fear of falling is not exclusively determined by physical weakness; many people with poor balance or a history of previous falls remain confident, whilst fear of falling is not uncommon among those who have never fallen (Yardley & Smith, 2002; Chandler et al., 1996). In some people, fear of
falling may result in greater caution and lead to some preventative effect against further falls but for most, this fear can be debilitating and compromise their quality of life (Delbaere et al., 2004).

1.3.4 Direct and indirect cost of falls
The economic cost of falls are a substantial burden on limited healthcare resources and without intervention these costs are likely to grow with the increasing numbers of older people. In England, older people aged 65 and over spend 4 million days in hospital each year as a result of falls and fractures (RCP, 2010) and falls are the leading cause of accidental death in this age group (Rubenstein, 2006). One in five falls may require medical attention, however less than one in 10 results in a fracture (Gillespie et al., 2009). The risks associated with fractures are high and are a significant source of mortality and morbidity (Gillespie et al., 2009; Keene, 1993; Sattin, 1992). The death rates from falls among older men and women have risen sharply over the past decade (CDC, 2011). It is estimated that over 90% of hip fractures are caused by falls. In the U.S. in 2007, there were 264,000 hip fractures and the rate for women was almost three times the rate for men (NAO, 2009). Therefore, the physical and psychological consequences of falls greatly reduce the quality of life for the affected person and can impact hugely on healthcare resources.

Direct costs associated with falls include inpatient care and treatment, home care, medications, equipment, rehabilitation/therapy and home modification. Of these, hospital inpatient treatment is most expensive and accounts for approximately
50% of the total cost of falls (Roudsari et al., 2005). The underlying causes for hospital admission as a result of falls are hip fracture, traumatic brain injuries and upper limb injuries (WHO, 2007). The long term support that also may be required contributes to 9.4% to 41% of all health service costs (The University of York, 2000). As much as 20% to 30% of fallers suffer moderate to severe injuries that reduce independence, mobility and increase risk of institutionalization and premature death (CDC, 2011).

Indirect costs are less easily quantified but include work days lost for both the faller and associated carer(s) due to the injuries and disability caused by falls. Falls are also an independent predictor of nursing home admission (Tinetti, 1997).

1.3.5 Fall risk factors
The literature describe falls as occurring due to a complex interaction or cumulative effect of multiple risk factors. These risk factors have been identified by epidemiological studies and have been summarised by the American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention (AGS/BGS, 2010). Around 15% of falls result from an external event that would cause most people to fall, a similar proportion may be due to a single cause, and the remainder may result from the interaction of multiple factors (La Grow et al., 2006). Fall risk factors can be categorised as biological, behavioural, environmental and socioeconomic factors (WHO, 2007) as demonstrated in Figure 1.
Biological risk factors are those that concern the human body and its physiology. They encompass non-modifiable risk factors such as age, gender, race, medical conditions and the number of co-morbidities. It is well known that ageing is a risk factor for falls due to the interplay between increased sedentary behaviour resulting in reduced muscle strength and impaired balance/gait, increased co-morbidities and therefore medications and physiological changes such as reduced reaction response times (therefore more difficulties in avoiding falls) (Lord et al. 1994). Women are more likely to fall and reasons for this are attributed to their greater use of psychotropic medications, multiple medications (polypharmacy) and higher prevalence of living alone (Ebrahim, 1996; Campbell et al., 1989). Caucasians living in the U.S. appear to have higher rates of falling than other races such as Japanese, Indian or Chinese ethnicities however further research is needed to clarify the racial differences (Ellis et al., 2001). Certain medical conditions have also been associated with increased falls. These include: postural hypotension; Stroke; Parkinson’s Disease; arthritis; congestive heart failure/cardiac arrhythmia/syncope; osteoporosis; diabetes; urinary incontinence; chronic obstructive pulmonary disease and anaemia. The risk of falling increases with the number of co-morbidities (Tinetti et al., 1988).

Behavioural risk factors are those involving human actions, choices or emotions and many have the potential to be modified e.g. sedentary behaviour can be modified through increased exercise or excess alcohol can be reduced to the recommended amounts (WHO, 2007). Multiple medication use can be classed as
both a biological risk factor and a behavioural risk factor as a person has choice over their management of medicines (e.g. over the counter or use of painkillers) or may require prescribed medicines for specific medical conditions.

Environmental risk factors cover a multitude of areas such as hazards inside or outside the home (e.g. uneven pavements, slippery floors, insufficient lighting) as well as situational factors such as getting onto a bus which may challenge a person’s balance and muscle strength.

Socioeconomic risk factors are those connected to the social and economic status of the person such as inadequate housing, low income and limited access to health and social care or a lack of resources. These areas may be modified by the individual or the health or social service providers.

There is some overlap between the categories of risk factors and their outcomes, for instance a person may choose not to exercise which may result in decreased muscle strength and reduced function and then be more at risk of falling due to environmental hazards such as walking on an uneven pavement.
1.3.6 Fall prevention programmes and their implementation
Over the last three decades, researchers have attempted to modify either a single risk factor or multiple risk factors in clinical trials, and both strategies have been shown to be effective in reducing the rate of falling. Gillespie et al., (2009) recently assessed the effects of interventions to reduce the incidence of falls in older people living in the community and included 111 clinical trials. They concluded that exercise is an effective intervention to reduce falls if delivered
using:

- Multiple-component group exercise
- Tai chi as a group exercise
- Individually prescribed exercise carried out at home (but no evidence to support this in patients with severe visual impairment, mobility problems after a stroke, Parkinson’s disease, or after a hip fracture)

They also found that a falls assessment and multi-factorial intervention reduced the rate of falls but not the risk of falling. Home safety interventions did not reduce falls but were effective in people with severe visual impairment and in others at higher risk of falling. The review identified from trials involving medication that vitamin D did not reduce falls but that gradual withdrawal of psychotropic medication reduced the rate of falls, but not risk of falling. A prescribing modification programme for primary care physicians was found to significantly reduce the risk of falling. For people with carotid sinus hypersensitivity, pacemakers were found to have reduced the rate of falls and first eye cataract surgery also reduced the rate of falls. The reviewers concluded overall that falls’ prevention strategies can be cost saving.

There have also been many trials to investigate interventions for preventing falls in nursing care facilities and hospitals. A Cochrane systematic review by Cameron et al., (2010) included 41 trials of varying quality with 25,422 participants. They concluded that multi-factorial interventions reduce falls and risk of falling in hospitals and may do so in nursing care facilities. Vitamin D
supplementation appears to be effective in reducing the rate of falls in nursing care facilities and exercise in sub-acute hospital settings appears effective but its effectiveness in nursing care facilities remains uncertain.

In terms of prescribing the optimum dose and timing of exercise programmes for reducing falls, the criterion for a minimal effective exercise dose equates to a twice weekly programme over 24 weeks (Sherrington et al., 2008).

Interestingly, despite the good evidence base for falls prevention programmes, a Royal College of Physicians’ survey indicated that many NHS providers are not delivering evidence-based interventions for reducing falls and there is a lack of long term follow-up classes for reducing falls in the community (RCP, 2010).

Therefore the risks and consequences of falls are well-researched in older people and are recognised to be a high priority in current policy. Increased life expectancy and an ageing society means that falls will continue to be a significant burden on finite healthcare resources. The falls prevention literature portray some positive messages in that it may not be possible to prevent falls completely, but people who tend to fall frequently may be enabled to fall less often.

To summarise, this initial chapter has provided a short introduction to the areas of rheumatoid arthritis and falls. The following chapter will systematically explore the literature on falls and rheumatoid arthritis.
2. **Introduction to the literature review**

There has been remarkable scientific progress over recent years that have vastly improved the quality of life for many people suffering with rheumatoid arthritis (RA). Pharmacological advances and earlier detection and treatment have been paramount in improving the long-term outcomes for patients. However, there appears to be some way to go to ensure equal and consistent standards in the management and care of all people with RA. A report by the King’s Fund, identified, “unacceptably wide variation” in the levels and quality of access to specialists available to the 450,000 people with RA in the UK, (King’s Fund, 2009). Indeed, the motivation for this study arose from the recognition that there are few health services available for patients with RA, at risk of falls, other than mainstream physiotherapy and occupational therapy. This is despite RA being highlighted as a key risk factor for osteoporotic fractures in research studies (Huusko et al., 2001; Cooper et al., 1995) and in the widely used World Health Organisation’s FRAX risk assessment tool (Kanis, 2007). Although falls prevention services have grown rapidly since their recommendation in the National Service Framework for Older People, they have remained a service for the elderly whilst falls can affect people of all ages with RA (Jamison et al., 2003). The following chapter will review studies (written in English) that have investigated falls and/or fear of falling in people with RA.
2.1 Literature review search strategy

In order to conduct a rigorous review of the literature the NHS Centre for Reviews and Dissemination’s (NHSCRD, 2001) guidance for undertaking systematic reviews was utilised. A preliminary check of the literature revealed a dearth of literature concerning falls and rheumatoid arthritis; therefore few restrictions were applied to the search strategy.

The following search criteria were incorporated; “*rheumatoid arthritis” and “arthritis” combined with “falls”, “accidental falls”, “fallers”, “falling”, “fear of falls” and “fear of falling” to identify studies that examined the association between falls and rheumatoid arthritis. Searches were restricted to English language publications but no date restrictions were imposed.

Inclusion criteria for papers included in the literature review:

- Papers including all age groups of people with rheumatoid arthritis.
- Papers written in English (due to translation costs).
- All types of research designs carried out in any health service setting.
- Published or unpublished studies.

Exclusion criteria:

- Papers not written in English
- Papers that focused on other types of rheumatic disease
An electronic literature search was performed through Ovid Embase, Ovid Medline, Cinahl, Evidence Based Medicine Reviews, British Nursing Index and PsycInfo (all from inception to 29th April 2012) to ensure a broad and thorough coverage of the relevant literature was conducted. These searches highlighted 8 articles. Additionally, The Cochrane Library (Issue 3, 2012) was searched and included: Databases of Reviews of Effectiveness; Cochrane Database of Systematic Reviews; Cochrane Central Register of Controlled Trials; Cochrane Methodology Register; Health Technology Assessment Database and the NHS Economic Evaluation Database. This highlighted 3 systematic reviews of exercise related to rheumatoid arthritis (Tai chi, dynamic exercise and balance training) with limited relevance to this study (Hurkmans et al., 2009; Han et al., 2004; Silva et al., 2010) and so were discarded for the literature review but utilised for background information.

The Health Management Information Consortium (HIMC) databases were searched covering the Department of Health publications, King’s Fund Database and the Helmis Database produced by the Nuffield Centre. The Helmis database ceases at 1998. Searching across these databases, no reports were found to have rheumatoid arthritis and falls as their subject description or within their title.

Other useful sources are the Arthritis Research Campaign website, the National Rheumatoid Arthritis Society website and the Arthritis Care website. These websites hold a number of publications and resources, written by leading academics and health professionals in the field of rheumatology. The British
Society for Rheumatology (BSR), The American College of Rheumatology and the European Congress of Rheumatology (EULAR) websites from 2002 – 2012 were also scrutinised for meetings abstracts which may be relevant to this study (Appendix 1). The majority of the scientific abstracts related to falls were studies in people with osteoporosis. However, two abstracts were found that were relevant and revealed a small, unpublished prospective study into falls in people with RA. The authors were contacted for further information on this study, and an unpublished article was obtained, that has since been published and the results from this study are included in the literature review.

Further available sources included contacting researchers in the field, which resulted in obtaining an unpublished Masters thesis, (Armstrong, 2001). Hand searching citations of included studies and rheumatology journals uncovered an additional relevant study.

The principle of appraising research evidence has developed considerably over recent years and the methodological standards have grown with the use of appraisal tools to assist with this process. Such useful tools can be found on the EQUATOR Network website (see http://www.equator-network.org/resource-centre/library-of-health-research-reporting/library/ accessed on 29th April, 2012). This is an international initiative that provides resources for researchers and seeks to enhance reliability and value of medical research literature by promoting clear and accurate reporting of research studies. It has a digital library that provides a collection of reporting guidelines for experimental, observational and
diagnostic accuracy studies amongst many other study types. The studies identified in the literature review are mainly observational studies and so the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) checklist tool for cohort, cross-sectional and case-control studies was chosen from the EQUATOR network as a guiding framework for the critical appraisal of the studies. STROBE is an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies. The group have produced the STROBE Statement, a checklist of items that should be included in reports of observational studies (see http://www.strobe-statement.org/ accessed on 29/04/12). The 22 question appraisal tool assists with considering the validity of the study. The questions focus on areas such as the limitations of the study, taking into account sources of potential bias or imprecision which might compromise the study, or confounding factors that may affect the results. The advantage of using such a framework is that each study within the literature can be appraised in a systematic and rigorous manner.

Appendix 2 summarises the ten studies identified from the literature search and outlines the main results respectively. The strengths and weaknesses of these studies are discussed in more detail within this chapter.
2.2 Rheumatoid arthritis and falls

Rheumatoid arthritis (RA) is linked to an increased risk of falls resulting in osteoporotic fractures (Kaz Kaz et al., 2004; Huusko et al., 2001; Lems et al., 1998; Cooper et al., 1995; Hooyman et al., 1984). This may be due to lower limb joint involvement resulting in impaired mobility, balance and postural stability (Armstrong et al., 2005; Huusko et al., 2001). People with RA frequently experience high levels of pain due to inflamed joints, moderate to severe fatigue and early morning stiffness, which may also detrimentally affect their physical abilities and contribute to a higher risk of falls than their healthy counterparts. A number of cross sectional and prospective studies have associated rheumatoid arthritis with lower bone mass and therefore greater risk of fractures. (Haugeberg et al., 2000; Kroot & Laan, 2000; Deodhar & Woolf, 1996). However, there are few scientific studies investigating the occurrence and predictors for falls or the factors associated with fear of falling among adults with RA.

This chapter summarises and critically reviews the current evidence related to falls and adults with RA. The studies are grouped into the areas of incidence of falls, prevalence of falls, risk factors associated with falls and fear of falling in people with RA.
2.2.1 Incidence of falls in people with RA

Since the commencement of this study, two studies have been published that have prospectively examined the incidence of falls in people with RA. A small study in the Netherlands of 84 adults (Smulders et al., 2007) reported an incidence rate of 0.82 falls/person per year (41% participants reported one or more fall(s)). This study assessed fall incidence rate and determined fall risk factors in RA patients with lower extremity problems (mean age=59.3 years, SD=12.0, range=24-86). Falls were monitored for one year by means of monthly fall registration cards. At the start of the study the participants completed several questionnaires to assess their potential fall risk factors that included medication, co-morbidity, visual impairment, fear of falling and history of falls in the prior year. Validated questionnaires included the Arthritis Impact Measurement Scales (AIMS), the Health Assessment Questionnaire (HAQ, Ramey et al., 1996), Activities-specific Balance Confidence scale (ABC). Visual Analogue Scale scores were used to measure pain during rest, stance and walking. Only 84 patients completed the study (1 died and 3 did not return the questionnaire) and so the results are statistically questionable in terms of significance and could be misleading. P-values rather than 95% confidence intervals are reported which tells us little of the size of the effect or the direction of it. Moreover, as this was a postal survey, selection bias may be present as the participants may be persons who have been affected by falls or fear of falling and therefore more likely to take part in the study.
In Japan, Hayashibara et al., (2010) also conducted a small prospective study that investigated the incidence of falls and associated risk factors in 84 (sic) women with RA. Participants were consecutively recruited from hospital outpatient clinics and were included in the study if they were aged between 50 and 84 years old, ambulatory, without dementia or stroke and had the ability to give informed consent. It was not clear why younger patients were excluded and a definition of falls was given although this is not the recommended version from the ProFaNE consensus group (Lamb et al., 2005). Participants were followed up using fall calendar cards that were mailed each month and non-responders were contacted by telephoned. Data was collected on RA history, duration of disease, function (using the HAQ), disease activity (using the DAS28, see section 3.7 for further information), medication, number of tender or swollen joint(s), foot deformity, bone mineral density (including fat and muscle volume), physical performance, balance and physical activity. Again, this is a small study, only 80 participants (mean age 64 years) completed the one year follow-up and 50% (n=40) reporting a fall with 33% falling twice or more during the year.

Despite the limitation of small sample sizes, Hayashibara et al., (2010) and Smulders et al., (2009) provide the only prospective studies in this area, and so the results are interesting as a comparison to the other studies.

2.2.2 Prevalence of falls in people with RA
A small number of clinic-based studies have examined the one year prevalence of falls in adults with RA by asking patients if they had fallen over the previous
These studies report strikingly similar results (despite different sample sizes) with numbers of falls in people with RA recorded as 35%, 33% and 31% respectively.

Yamagiwa et al’s (2011) cross-sectional study on falls and fear of falling in Japanese patients with RA (also reported in Furuya et al., 2009), utilised patients from a larger observational cohort study and used postal questionnaires to investigate falls in the previous 6 months. Among the 765 men (median age 63 years) and 4,231 women (median age 60 years) who responded to questions on falls, 9% men and 11% women reported one or more falls during the previous six months. Falls were more frequent in men over the age of 65 years and in women over the age of 75 years. Despite the advantages of a large sample, this study has a number of limitations. No definition of falls was used in the postal questionnaire which may have led to different interpretations of a fall by participants and researchers. The recruitment of the participants was from one site only which restricts the ability of the data to be generalised to the wider population. The prevalence of falls is lower in this study than in other reports, however this may reflect the six month history of falls data collection as opposed to the 12 months timeframe used in other studies.

In Turkey, a small cross-sectional, case control study by Çakıt et al., (2009) also investigated falls, fear of falling and falls risk but the RA sample only included women with RA. Eighty-four women with RA (mean age 56) and 44 healthy women (mean age 54) participated in this study, however it is not clear how
patients were recruited or the place of assessment. Detailed data were collected on disease duration and activity, function (using the HAQ), fear of falling (using the validated Falls Efficacy Scale), balance and gait, hand grip strength and depression. Twelve patients (14.3%) with RA reported falling in the previous year compared to no falls in the healthy control group. The authors explain the lower frequency of falls to be due to the recruitment younger participants (age range 41-70 years), however the small sample size were women only and the lack of a fall definition mean that caution should be taken in the interpretation of the results and the findings should not be generalised to the wider population.

Oswald et al’s (2006) UK based, cross sectional study on falls and associated factors utilised a community-based cohort of women with established inflammatory polyarthritis (IP). Participants were examined for active and inactive joint involvement and completed the validated Health Assessment Questionnaire (HAQ) to measure functional ability. Subjects (n= 316) completed a questionnaire with questions on history of falls in the previous 12 months, quality of vision, general health status, current exercise level, age at menarche, menopause and use of hormone replacement therapy. Patients were assessed for pain using a 100 mm visual analogue scale (VAS). Similar to the clinic-based studies, 34% of the 316 women reported a fall in the previous year, those aged 75 and over had an increased risk of falls at 49% (OR 2.0; 95% CI 1.0 to 4.1). Swollen joints (per 10 joints, odds ratio (OR) 1.7; 95% Confidence Intervals (CI) 1.0 to 1.2) and increased VAS pain score were associated with an increased risk of falls. Those who fell had higher HAQ scores (OR 1.7; 95% CI 1.3 to 2.3) and
lower levels of outdoor physical activity. However, the authors identify that there are several limitations that may affect these results. Only forty seven per cent of the invited subjects completed the falls questionnaire, therefore it is possible that the frequency of falls among women who completed the questionnaire may differ from those who refused. For instance, those who had experienced a fall may be more inclined to take part in the study. Due to the retrospective nature of the design it is possible that some patients may not have reported a history of a fall due to poor recall. In a study by Cummings et al., (1988) 13% of people over the age of 65 who reported a fall during weekly assessments did not report having had a fall at the end of a 12 month period. Selection bias is also present in this study as it only includes Caucasian women living in Norfolk with inflammatory polyarthritis and so the results cannot be extrapolated beyond this group except as a comparison with other studies.

Another UK based cross-sectional study that examined the one year prevalence of falls in patients with RA attending hospital outpatient clinics found that one in three patients aged 35 years and older reported falling during the previous year (Armstrong et al., 2005). A consecutive sample of 253 rheumatoid patients aged 35 years and over, attending hospital outpatient clinics at Salford Royal NHS Foundation Trust, completed an interview-assisted questionnaire. The questionnaire asked about the occurrence and number of falls in the previous 12 months, however, no formal definition of falls was given, although falls caused by road accidents or violence were excluded. Participants were asked about current treatment with anti-hypertensive agents, diuretics, sedatives or hypnotics,
antidepressants, and a history of previous hip/knee surgery due to their association as risk factors for falls in the general population. They also completed the validated health assessment questionnaire (HAQ). Out of the 253 men and women, (mean age 62 years) 84 (33%) reported falling in the previous year (36% of women and 26% of men). Of these, 52% (CI not given) had fallen on more than one occasion. However, the authors again recognise the limitations of a retrospective design due to possible poor recall of falls and the lack of a control group to compare results in people without RA. Similar to the other studies, the cross-sectional design prohibits the assessment of causal factors or changes in behaviour following the falls.

A case-control study was identified in the UK that investigated the prevalence of falls in women with RA (n=103) compared to controls (n = 203) (Kaz Kaz, 2004). However, similar to Oswald et al., (2006) this study did not include men with RA. Cases and controls were asked about previous falls and more women with RA gave a history of a previous fall since the diagnosis of RA compared with matched controls (54% v 44%), but this just failed to reach statistical significance (difference 10%, 95% CI –2 to 22). Cases and controls were matched by age, (within 5 years) and body mass index, (within 2 units) nevertheless, only Caucasian women were recruited and so the results are not relevant to other races or men. An advantage of this study is that the researchers were able to demonstrate that participants and non- participants were similar in age, duration of RA, ESR (Erythrocyte Sedimentation Rate, a blood test that measures inflammation in the body), swollen and tender joint count and HAQ.
Similar to the other aforementioned studies, the cross-sectional design reduces the strength of the results.

An American, cross-sectional study by Jamison et al., (2003) also included a history of falls during the previous year. In a small sample of 128 surveyed adults with RA (aged between 40-70, 82% were Caucasian females) attending a community outpatient clinic, 35.2% fell at least once during the previous one year. Of those who fell (mean age 52.4), 80% reported injuries from bruising, cuts or sprains and 4.4% reported a fracture. This study examined how fear of falling affects activities among adults with RA. Outcomes measures related to falls and fall risk factors included numbers of falls, fear of falling, modified activities, coexisting morbidity’s, pain, emotional status, walk time, grip strength, joint count and predicted maximum oxygen uptake as a measure of physical fitness. Although the methods section in this paper appears comprehensive, it is unclear whether questions were questionnaire or interview based. A definition of falls was given but not substantiated and the small sample size limited the representativeness, generalisability and statistical significance of the study. P-values were reported but 95% confidence intervals were not used. Another limitation similar to the other studies is the cross-sectional design that prevents the assessment of causality of the falls.

Another American cross-sectional study into fear of falling and activity limitation among persons with RA also included a series of questions on previous falls (Fessel and Nevitt, 1997). Approximately 31% of the sample of 570 (mean
age 64.9) patients with RA reported falling at least once during the previous year. Of these, 16% reported falling twice or more and nearly 87% of those who fell, reported some type of injury, most commonly bruising or bleeding. This study included a definition of a fall unlike Armstrong et al., (2005); Oswald et al., (2006) and Kaz Kaz (2004) but similar to Jamison et al., (2003) who also gave a definition, these definitions of a fall have been superseded by the recommended definition by the Prevention of Falls Network Europe (ProFaNE) (Lamb et al. 2005). This study also acknowledges the limitations of a cross-sectional design and possible recall bias due to its retrospective nature.

A brief conference abstract reported the findings from another small cross-sectional study, set in Turkey. Baskan et al., (2009) investigated risk factors related to falls, fear of falling and activity limitation in 100 patients with RA. Validated measures were used to collect data on fear of falling (Falls Efficacy Scale), function (HAQ) and depression (Hamilton Depression Rating Scale). No definition of falls appears to have been used and it is not clear how the data was collected. The authors report that 50% of participants reported falling at least once in the previous three years. It was not possible to fully critique this study due to the sparse details given in the report however, it is limited again by its cross-sectional, retrospective design and its small sample size as outlined in previous studies.
2.2.3 Risk factors associated with falls in people with RA

As highlighted in the introduction to this thesis, a fall is a multi-causal event that can result from complex interactions between behavioural, biological, environmental and socioeconomic factors (WHO, 2007). The risk of falls may be higher in people with RA due to muscle weakness, impaired mobility and balance, pain and joint abnormalities however there are few studies that have investigated the contribution of disease related factors alongside other potential risk factors in people with RA.

There are some interesting results within the literature relating to the biological risk factor of ageing. Advancing age is a common risk factor associated with the incidence of falls in the older population (WHO, 2007; Gillespie et al., 2009), however Çakıt et al., (2011), Yamagiwa et al., (2010), Furuya et al., (2009), Hayashibara et al., (2009), Smulders et al., (2009), Armstrong et al., (2006) and Jamison et al., (2003) found no relationship between age and falls in adults with RA. Oswald et al., (2006) found that falls were significantly more frequent in women with RA over 75 years of age compared to younger groups, but overall there was no trend toward an increase in risk of falls with age.

According to recent studies in falls prevention in community dwelling adults and older people, falls occur due to multiple interacting factors but leg muscle weakness and balance contribute to most falls (Campbell et al., 1999). In the RA falls literature, falls were more common in women with impaired walking and
rising in Armstrong et al.’s (2006) study and in women with lower levels of physical activity reported by Kaz Kaz et al., (2004) and Oswald et al., (2006). Jamison et al., (2003) associated longer walk times with falling as did Fessel and Nevitt, (1997) but with fear of falling in their small study on 128 adults. Hayashibara et al., (2010) found that fallers had lower postural stability and reduced physical performance compared to non-fallers in their recent study. Similarly, Çakit et al., (2011) found that impaired gait and balance were the most prominent risk factors in their case-control study.

Therefore risk factors associated with physical performance, balance and lower limb muscle strength that could be both classed as biological and behavioural, may play an important role in increasing the risk of falls in the RA population.

Functional disability, as measured by the eight domain Health Assessment Questionnaire (HAQ) was significantly associated with falls in a number of studies (Furuya et al., 2009; Çakit et al., 2011; Oswald et al., 2006; Kaz Kaz et al., 2004; Fessel & Nevitt, 1997). Likewise, poor general health scores were associated with a high risk of fall in both Furuya et al’s (2009) and Çakit et al’s (2011) studies.

High pain intensity was noted to be associated with a higher risk of falls in several studies (Smulders et al., 2009; Oswald et al., 2006; Jamison et al., 2003) and pain in the lower extremities was associated with fear of falling in Fessel and Nevitt’s (1997) study on 570 adults with RA.
Interestingly, Oswald et al., (2006) report higher swollen joint counts in women fallers in comparison to Kaz Kaz et al. (2004) who rated tender joint counts as a significant risk factor in women who had fallen in the previous year. Kaz Kaz et al., (2004) also included details of lower limb joint symptoms and records higher numbers of falls in women with knee and ankle/foot problems associated with RA. Oswald et al., (2006) found no association between falls and swollen and tender joint counts, whilst Hayashibara et al., (2010) found swollen joint counts were associated with fallers and Furuya et al., (2009) found tender joint counts associated with fallers. This raises the issue of the validity in recording swollen and tender joint counts. There is much discussion in the RA literature about the subjectivity of undertaking swollen and tender joint counts and whether these should be assessed by a trained clinician or self-reported by the patient (Radner et al., 2010). It should also be acknowledged that the disease activity levels and consequently swollen and tender joint counts, fluctuate on a weekly or sometime even daily basis for people with RA and this may also affect the consistency of the results.

A small number of studies demonstrated a relation between falls and drug use in people with RA. Hayashibara et al., (2010) reported that use of diuretics and/or antihypertensive medication were significant fall risk factors in their study of 84 women with RA. Armstrong et al., (2006) found that those who had fallen in the previous year were more likely to report taking multiple medications and antidepressant treatment (odds ratio (OR) = 2.09). Again, this is consistent with
non-rheumatoid literature (Leipzig et al., 1999), the reasons thought to be due to the sedative side effects of these drugs affecting postural control, slower reaction time and slower gait speed (Lord et al., 1995).

Other significant fall risk factors for people with RA include a one year history of falls (Smulders et al., 2009), impaired vision (Oswald et al., 2006), number of co-morbidities (Jamison et al., 2003), and these are all highlighted as risk factors for falls in community dwelling older people (WHO, 2007; Gillespie et al., 2009).

Overall, there are large differences between methods, sample sizes and outcomes measures in the studies and so it is difficult to make a comprehensive comparison between the risk factors associated with falls and rheumatoid arthritis. Some factors appear to be disease related and intrinsic to people with RA (swollen and tender joint counts, pain, poor functional levels, pain intensity and pain in lower extremities and impaired balance, gait and walking and rising) whilst other have been noted in community dwelling adults without RA (history of previous falls, use of psychotropic drugs, polypharmacy, decreased lower extremity strength).

As already discussed, caution should be taken when interpreting the results of the reviewed studies due to small sample sizes and the cross-sectional retrospective designs. This impacts the interpretation of the risk factors associated with falls as it is impossible to determine the temporal nature of any associations (e.g. lower levels of physical ability may be due to the fall or may be present before the fall) and so causality cannot be resolved at present. Only Smulders et al., (2009) and
Hayashibara et al., (2010) utilised a prospective design but both had small sample sizes of 84 persons (sic) which limits the significance of their results.

2.2.4 Fear of Falling and RA

Fear of falling is not limited to older people but may affect adults of all ages with RA (Yamagiwa et al., 2011; Smulders et al., 2009; Furuya et al., 2009; Jamison et al. 2003). Five studies in this review (with one study resulting in two published papers) have been identified as including fear of falling as an outcome in their research into falls in people with RA (Yamagiwa et al., 2011; Furuya et al., 2009; Çakit et al., 2009; Smulders et al., 2009; Jamison et al. 2003; Fessel and Nevitt, 1997).

Fessel and Nevitt (1997) were the first researchers to examine fear of falling in people with RA. In a sample of 570 adults (aged 50 and over) with RA, using self-report questionnaires, they found that female gender, depressive symptoms, poor physical functioning, minor injuries following falls, and high number of painful joints were associated with fear of falling. This study also highlighted that avoidance of activities, in particular walking or climbing steps was associated with fear of falling. As this study was cross-sectional, it cannot attribute causality, or determine whether significant risk factors preceded, accompanied or were the result of fear of falling or activity limitation.

More recently, Çakit and colleagues (2011) included a measure of fear of falling in their small case-control study of 84 women with RA and 44 healthy controls.
The validated ten-item Falls Efficacy Scale (Tinetti et al., 1990) was used to assess self-confidence in avoiding a fall while performing daily activities.

Yamagiwa et al.’s large cross-sectional survey of 4,996 adults with RA found that 16% of men and 22% of women reported fear of falling. They used a single question, “Do you have a fear of falling” rather than a validated fear of falling measure and this may have led to a lower prevalence of fear of falling due to differing participant interpretations of the question. They also found that men over the age of 65 tended to report more fear of falling than men under the age of 65 year and the prevalence of fear of falling in women also increased with advancing age. The other paper regarding this study (Furuya et al., 2009) reports that HAQ functional disability, tender joint counts and poor general health were independent predictors for fear of falling. Again, this study shares the limitations of Fessel and Nevitt’s due to its cross-sectional design and recruitment from a single institution that limits the generalisability.

Smulders et al., (2009) included the assessment of fear of falling in their small prospective study of 84 adults with RA but did not disclose how this was assessed in their brief article. They reported that fallers had significantly higher fear of falling (37%) than non-fallers (18%) but did not do any further analyses to assess gender or age differences or potential risk factors for fear of falling. The small sample size and recruitment in a single institution reduces the validity of the findings in this study.
A small study by Jamison et al. (2003) further examined how fear of falling affects activities among adults with RA in a convenience sample of 128 adults (mean age 59.2 years) with RA. Participants’ self-reported any fear of falling by answering a question on whether they could identify if they were not fearful, a little fearful, somewhat fearful, or very fearful of falling. Of the 60% who reported fear of falling, 27.3% acknowledged avoiding activities due to fear of falling. Fearful subjects reported greater pain intensity, reduced physical fitness demonstrated by longer walk time and more co-morbid conditions than non-fearful participants, similar to the earlier research conducted by Fessel and Nevitt (1997). Again the study limitations of small sample size, recruitment from a single institution and lack of a validated fear of falling measure may also negatively affect the validity of the findings in this study.

Therefore, there is some evidence to suggest that fear of falling in adults with RA is an important concern, with almost 67% of patients reporting fear of falling (Çakit et al., 2011) and 40% reporting modified activities due to fear of falling (Fessel and Nevitt, 1997). Prevalence of fear of falling in cross-sectional RA studies show high variability (range:16-67%) due to the sample selection (women only, small samples or frail older patients), inconsistent definitions of fear of falling and use of different assessment measures (Çakit et al., 2011; Yamagiwa et al., 2010; Jamison et al., 2003; Fessel and Nevitt, 1997). Fear of falling is not exclusively determined by physical weakness; many people with poor balance or a history of previous falls remain confident, whilst fear of falling is not uncommon among those who have never fallen (Yardley & Smith, 2002;
Chandler et al., 1996). All of the published studies to date that consider fear of falling share the limitations of being retrospective and cross-sectional in design. No study has utilised validated fear of falling measures such as the Short Falls Efficacy Scale-International (Short FES-I, Kempen et al., 2008) and prospectively investigated fear of falling and associated risk factors in a sufficiently powered study of RA patients of all ages.

2.3 **Summary of literature review**
These earlier studies are limited by methodological weaknesses, in particularly their retrospective designs and small samples sizes. Therefore it is not possible to draw robust conclusions from these studies, although the findings suggest that falls and fear of falling are important health problems for people with rheumatoid arthritis. The search yielded twelve articles, two were excluded according to defined inclusion criteria (as one was not written in English) and one not relevant to RA. Therefore ten articles (as well as the limited evidence from five conference abstracts) were included in the literature review. The systematic analysis of the methodology applied disclosed substantial variations in the definition and methods used to measure and document injurious falls. The limited standardisation of a fall definition hampered comparability of study results. Estimates of the proportion of people who fall annually with RA range from to 10% to 50% and this high variability may be due to the sample selection (women only, small samples or frail older patients), inconsistent definitions or no definitions of falls and use of different assessment measures. The risk factors for falls in patients with RA that have been drawn from previous studies include:
HAQ functional score (Furuya et al., 2009; Oswald et al., 2006; Kaz Kaz et al., 2004; Fessel & Nevitt, 1997); tender joint counts (Furuya et al., 2009; Kaz Kaz et al., 2004); swollen joint count (Hayashibara et al., 2010; Oswald et al., 2006) pain in lower extremities (Fessel & Nevitt, 1997) or pain intensity (Smulders et al., 2009; Jamison et al., 2003; Oswald et al., 2006); low levels of physical activity (Oswald et al., 2006); impaired general health (Furuya et al., 2009; Oswald et al., 2006), antidepressant use (Armstrong et al., 2005), impaired vision (Oswald et al., 2006), impairment in both walking and rising (Armstrong et al., 2005), walk time (Jamison et al., 2003), impaired balance (Hayashibara et al., 2010), number of medicines (Armstrong et al., 2005), number of co-morbidities (Jamison et al., 2003) and one year history of falls (Smulders et al., 2009).

To conclude, both the literature review and previous studies recommend that a large prospective study is needed to address the deficits in previous studies and to further investigate the interrelationship between falling and associated risk factors in people with rheumatoid arthritis.
CHAPTER 3

3. Methodology and research design

3.1 Methodology and research design

This chapter presents the aim and objectives of the study, the research design and a description of the sampling procedure and data collection. The planned data analysis approach is briefly covered and ethical considerations for the study are discussed.

3.1.1 Study aim and objectives.

The overall aims of this study are to determine the incidence of falls and prevalence of fear of falling and their effects on people with rheumatoid arthritis.

The research objectives related to these aims are:

1. To determine the incidence of falls in people with RA.
2. To determine the prevalence of fear of falling in people with RA.
3. To investigate fall risk factors, in particular balance and muscle strength in people with RA.

3.1.2 Why the study is needed now.

This study is needed now as there are currently no large prospective studies that have confirmed that falls in people with rheumatoid arthritis are a problem and if so, the extent, risks and consequential effects. It is thought that people with rheumatoid arthritis may be at greater risk of falls and potential fractures due to
altered gait, poor mobility and balance, muscle weakness, bone fragility, pain and fatigue (Oswald et al., 2006; Armstrong et al., 2005; Huusko et al., 2001). Improved muscle strength has been associated with a reduction in falls (Lindemann et al., 2003; Robertson et al. 2002) which may also influence the ability to balance effectively, therefore this study also explored the influence of muscle strength and balance on people with RA. This evidence will indicate whether muscle weakness and instability are important risk factors for falls in people with RA. There have been recent advances in fall prevention programmes, such as strength and balance programmes that have been shown to significantly reduce falls in the community dwelling population by 35-40% (Robertson et al, 2001). Thus if falls in people with rheumatoid arthritis are a significant problem, adapted falls prevention programmes could be targeted at those at risk and may lead to significant individual and economic health gains.

3.1.3 Choice of research design

In order to meet the study objectives, a prospective cohort study was considered to be the most appropriate research design. Patients with RA were followed up for one year after the initial measurements, using self-reported falls calendars, fall event forms and follow-up telephone calls (Campbell et al., 1989). Other designs for the study were considered, in particular a case-control design with groups of people with RA compared to groups without the disease. However, after exploring the feasibility of recruiting people with and without the disease in primary care, it was deemed to be beyond the scope of a lone researcher, particularly in terms of the time required to obtain a matched control group. A
single GP practice may only have a small number of people with RA and so a
great deal of time would have needed to be spent on recruiting a sample of cases
with the disease and then the subsequent age, sex matched control group. A
longitudinal design was deemed appropriate with the use of monthly falls
calendars for one year. The calendars (in the form of a pre-paid postcard, see
Appendix 8) enabled the participant to log each day whether they had fallen or
not and these were returned at the end of the month. Non-responders and fallers
were telephoned at the end of the month (once calendars had been received) to
investigate the reasons for the falls and any injuries sustained. This prevents the
problem of poor recall that may have occurred in previous studies on falls in
people with RA (e.g. Armstrong et al., 2005).

3.1.4 Sampling principles and procedures
The participants were subjected to eligibility criteria, to ensure that they were
suitable for this study. A consecutive sample of eligible patients were referred
from four rheumatology clinics at Salford Royal NHS Foundation Trust, the
Manchester Royal Infirmary, University Hospital of North Staffordshire and the
Haywood Hospital, Stoke-on-Trent and invited to participate in the study. The
rheumatology clinics were decided upon as the most appropriate setting to recruit
the sample due to the wide diversity and number of participants attending. A
variety of different clinics were accessed to ensure people with different levels of
severity of disease could be invited to participate. For instance at the Haywood
Hospital, there are evening clinics with large numbers of people with RA
attending from primary care, who are working and living independently.
Nurse-led clinics were attended with patients who were mainly fit and well but require a monthly blood-monitoring test to check for any adverse effects from the disease-modifying anti-rheumatic drugs and other beneficial drugs. The consultant-led clinics usually include patients with more severe disease, complications or those newly diagnosed. Therefore, by attending a wide choice of clinics from four different hospitals there is a greater likelihood of obtaining a more representative and generalisable sample of the RA population.

**Participant inclusion criteria:** Community-dwelling people with chronic RA, (based on the 2010 American College of Rheumatology classification criteria for RA, confirmed by a Consultant Rheumatologist) over the age of 18, with the ability to give informed consent.

**Participant exclusion criteria:** Patients under the age of 18 or without the mental or physical capacity to give informed consent.

3.1.5 **Access arrangements**

The participants were recruited from the four rheumatology outpatients’ clinics under the direction of the Consultant Rheumatologists. Time was spent at each clinic, getting to know the clinic staff and learning about the different types of clinics, databases and access to rooms. An honorary contract was attained for the lead investigator to undertake the research at the four hospitals and a Greater Manchester researcher passport was obtained for the duration of the study. An up-to-date CRB check was also required to fulfil further research governance
procedures to ensure the safety of patients and Good Clinical Practice training was undertaken prior to the commencement of data collection.

3.2 **Involvement of users**

Three patients with rheumatoid arthritis were involved in the planning of the study. Two were patients who wrote to the lead investigator following the advertisement of the study in the arthritis press and one was a relative of a colleague. They assisted with decisions such as what would be a feasible length of time for completion of the questionnaire, the language used in the questionnaire and information sheets and were consulted throughout the study for independent lay user advice.

3.3 **Peer review and Research Management Group**

During the preparatory stages, the study benefited from substantial peer review. It was critically appraised by an expert review committee at the Arthritis Research Campaign, from senior colleagues at the University of Manchester and from the supervisors and advisors to the study; Professor Jackie Oldham, Professor Chris Todd, Professor Dawn Skelton and Professor Terry O’Neill. External advice was given from a New Zealand research group with expertise on falls trials (led by Professor John Campbell) and the Scientific Advisory Board at the Wellcome Trust Clinical Research Facility (WTCRF) also reviewed and approved the study. The study continued to be monitored by the research management group at the WTCRF and monthly meetings took place with the supervisors and advisors to the study.
3.4 **Piloting the questionnaire and research process**

Piloting aspects of the study was important to check the feasibility and acceptability of the recruitment process, the understanding of the invitation letter, information sheets, consent forms and data collection tools. A pilot study on 10 participants was initially carried out to ensure that the recruitment process was feasible and the questionnaires were suitable for participants to complete. The questionnaire, assessments (such as a tender and swollen joint count) and face-to-face questions were found to take the patient approximately 35-40 minutes. Following the pilot, the medical history and medication of the patient was checked both verbally with the patient and on the patient’s records due to patients having difficulties remembering medical terminology and the types of prescribed medications. An additional question was also added, on whether the participant had painful feet or not, as the joints in the feet were not included in the data collection measures but painful feet could be an important predictor of falls.

3.5 **Sample size required to estimate fall incidence**

Based on data from retrospective studies (Oswald et al., 2006; Armstrong et al., 2005; Jamison et al., 2003) it was calculated that to estimate a fall rate of 0.3 to a precision of (0.26, 0.35) with an exact 95% confidence interval (Clopper-Pearson, using Statdirect version 2.6.5, Statsdirect Ltd) a sample size of 550 was required (i.e. 495 participants after an assumed 10% drop-out rate). The sample size was large enough to estimate the rate with a margin of error of ±5%.
3.6 Detailed methods

1. Patients were sent a letter and information sheet by the Consultant rheumatologist two weeks before their clinic appointment advising them of the content of the study (see Appendix 3 and 4). The letter also had an opt-in/opt-out form for patients to complete and bring to their routine appointment in a sealed envelope. The hospital database was checked to ensure that potential participants had a consultant diagnosis of RA and that their contact details were up-to-date.

2. Patients were seen at their routine appointment at the rheumatology clinic. The lead investigator met the patients who opted to take part in the study (by completing the opt-in form) either before or after their planned appointment (depending on the patients’ time of arrival and any delays in appointment times at the clinic). The lead investigator checked that participants had received and understood the information leaflet.

3. Patients were given the opportunities to talk about the study and ask further questions before written consent was obtained (see Appendix 4). If patients completed the form, as opting out of the study, then no further mention of the study was made to the patient except to explain that not taking part would not affect their care in any way.

4. Patients were asked questions about their medication, eyesight and whether they had any co-morbidities, previous fractures, surgery or joint replacement(s)
(See RA Assessment in Appendix 6). A joint assessment was then undertaken by the lead investigator to measure current RA disease activity. This involves counting the number of swollen or tender joints and obtaining the most recent ESR blood test result to calculate the DAS28 (disease activity score using 28 joints, Van Riel and Schumacher, 2001).

5. Patients were assisted to perform two simple physical assessments, the Chair Stand Test and the Four Test Balance Scale (taking approximately five minutes for both tests) to give an indication of their lower limb strength and balance. The Chair Stand Test involves timing in seconds the participant standing up and sitting down five times as quickly as possible with their arms folded and has been widely used and validated (Guralnik et al., 1994). The Four Test Balance Scale includes four timed static balance tasks of increasing difficulty using different positioning of the participants’ feet and has also been extensively tested for validity and reliability (Rossiter-Fornoff et al., 1995). These physical checks have been safely performed on thousands of patients, many with severe arthritis (Robertson et al., 2002).

6. The participants were asked to complete a questionnaire with assistance given by the lead investigator as necessary (see Appendix 5). If time did not permit, they were asked to post the questionnaires back in a stamped addressed envelope. This methodology has been used successfully with patients with chronic fatigue syndrome and rheumatoid arthritis (Moss–Morris and Chalder, 2003).
7. Following completion and checking of the questionnaires, the falls calendars were individually explained to the patients and they were asked to complete prepaid, preaddressed calendars to be filled in daily and returned at the end of each month. For those not able to complete or post the calendars, arrangements were made to telephone monthly. Those who reported a fall were also telephoned to gather information on any injuries.

8. At recruitment, participants were asked if they required a summary of the findings and if so, address details were taken. The National Research Ethics Service was informed of any amendments to the study and time was allowed in the schedule for potential delays such as sickness and holidays.

9. The study was set in Manchester where there is a mixed ethnic and socio-demographic population, so consideration was given to the recruitment of people who do not speak English. During the piloting of the questionnaire, it was ascertained that NHS translators were available to assist with non-English speaking patients. In addition, the clinic staff were aware of the attendance of non-English speaking patients and so English-speaking relatives were encouraged to attend to assist the patient.

3.7 Data collection methods

Measurements were taken at baseline between the months of August 2008 and March 2009. Patients were followed up for one year for falls, injuries and other
consequences using daily calendars and telephone calls. Variables considered important in causing or predicting falls were included in the baseline assessment.

**Assessments** included demographic data (age, gender, ethnicity, socio-economic status), Rheumatoid Arthritis Disease Activity Score (DAS28, Van Riel and Schumacher, 2001) including number of swollen and tender joints, Stanford Arthritis Centre Health Assessment Questionnaire (HAQ, Ramey et al., 1996), history of falling, fear of falling questionnaire (Short FES-I, Kempen et al., 2008), lower limb muscle strength, balance and falls risk using the Assessment of Falls Risk Tool (FRAT, Nandy et al., 2004). Data on medication (including steroid use), pain, fatigue, vision, co-morbidities, and history of surgery, fractures and joint replacements were also recorded.

**Rheumatoid arthritis** status was measured by an assessment of the number of swollen/tender joints (shoulders, elbows, wrists, metacarpophalangeal, proximal interphalangeal and knee joints), the Disease Activity Score (DAS28) and the Stanford Arthritis Centre Health Assessment Questionnaire (HAQ). The DAS28 is a disease activity score for people with rheumatoid arthritis that has been extensively validated for use in clinical trials and in clinical practice (Van Riel and Schumacher, 2001). It provides scores for the number of swollen and tender joints, Erythrocyte Sedimentation Rate (ESR) and a VAS global disease scale. The DAS28 provides a number on a scale from 0-10 indicating the current activity of the rheumatoid arthritis of the patient. The total DAS28 range between 0-10 and indicates the current activity of rheumatoid arthritis. Accepted cut offs
are above 5.1 for high disease activity, below 3.2 indicates low disease activity.

The HAQ is a self-administered arthritis-specific instrument that measures patients’ perceptions of difficulties in performing activities in daily living, the need for equipment and physical assistance to perform tasks and has been extensively tested for validity and reliability (Ramey et al., 1996).

**Falls and injuries** were recorded during the one year follow-up, using the ProFaNE fall definition of “an unexpected event in which participants come to rest on the ground, floor, or other lower level” (Lamb et al. 2005). A one year history of falling was also obtained at the baseline assessment by asking, “During the past year, how often have you had any fall including a slip or trip in which you lost your balance and landed on the floor, ground or lower level?” with the response set of, “never, once or twice or more”. Monitoring was undertaken through the use of monthly, prepaid preaddressed calendars filled in daily by participants. Those not able to complete the calendars were telephoned monthly, as were those reporting a fall, to gather information about the fall and any injuries. Data on falls and injuries were documented using Campbell et al’s (1981) methodology as recommended by Schwenk et al., (2012).

**Lower limb muscle strength and balance** were assessed using two simple, valid and reliable tests: the Chair Stand Test (Guralnik et al. 1994) and the Four Test Balance Scale (Rossiter et al. 1995). For the Chair Stand Test, participants were instructed to stand up and down from a chair as quickly as possible five times, with their arms folded. The time taken to complete was recorded.
Participants unable to complete the test within two minutes were scored as unsuccessful. The Four Test Balance Scale comprised four timed static balance tasks of increasing difficulty using different positioning of the participants’ feet. Participants were scored 0 for unsuccessful, 1 if they could only stand with their feet together, 2 if they could only complete a semi-tandem stand, 3 if they could complete a tandem stand and 4 for participants who could complete a one-leg stand. The participant must hold each position for 10 seconds before progressing to the next more challenging task. These measures have been widely tested and validated and have previously been used in four randomised controlled trials in falls prevention (Robertson et al., 2002).

**Fear of falling** was recorded at baseline (interviewer assisted questionnaire) and at one year follow-up (postal survey) using the Short Falls Efficacy Scale-International (Short FES-I) to measure confidence in performing a range of activities of daily living without falling. Activities include getting dressed or undressed, taking a bath or shower, getting in or out of a chair, going up or down stairs, reaching, walking up or down a slope, going out to a social event. A score is obtained by adding all the scores on all items together to give a total that ranges from 7 (no fear of falling) to 28 (severe concern about falling) (Kempen et al, 2007). Cut points are defined which differentiate between lower and higher levels of fear of falling concern (7-10=low concern, 11-28=high concern) (Delbaere et al., 2010).
**Falls risk** was measured with the use of the Assessment of falls risk tool (FRAT). This validated measure (Nandy et al., 2004) has five items which include; history of any fall in the previous year, four or more prescribed medications, diagnosis of stroke or Parkinson’s disease, reported problems with balance, and inability to rise from a chair without using arms. These are all strong indicators for risk of falling.

In addition, vision was assessed using a self-reported question, “At the present time, would you say that your eyesight using both eyes (with glasses or contact lenses if you wear them) is” (response set: Excellent, Good, fair, Poor, Very poor, Registered blind which gives a score 0-6) (Mangione et al., 2001). Patients were also asked questions about levels of pain and fatigue using visual analogue scales (VAS) (Murphy et al., 1988; Pollard et al., 2006) and about any co-morbidities, previous fractures, surgery or joint replacement(s) (Oswald et al., 2006) and verified using medical records. Medical records were utilised to check previous history and medication, including steroid use (Kaz Kaz et al., 2004).

**Follow-up:** Participants were requested to complete and return a postcard calendar each month for one year (with falls recorded as, “F” and no falls as, “NF” on each day). All fallers were contacted by telephone and the description of the fall was checked with the participants using the ProFaNE fall definition (Lamb et al. 2005). Stumbles, trips or near misses were regularly described by participants but not recorded in this study. Information on incident falls was collected by telephone each month using a pre-coded fall event form (Appendix
7). This is a pre-tested form that has been used successfully in fall prevention trials in New Zealand involving older people (La Grow et al, 2006) and has been recently recommended in a ProFaNE systematic review of methods of measuring injurious falls (Schwenk et al., 2012). Information included; date of fall, participant description of how the fall occurred, self-reported consequences (e.g. use of health services) and injuries (injuries coded by the lead investigator as 0=no injury for minor bruising not requiring medical assessment, 1=moderate injury for sprains, cuts, bruising, abrasions that may require medical assessment or intervention, 2=severe injury for medical treatment, fractures, stitches, hospital assessment/ treatment/ admission), and length of time before the participant was able to get up or help arrived (lie time in minutes). The participants’ functional status after the fall was assessed with the use of three questions; “As a result of this fall, did you have any difficulty walking around your home?”, and “As a result of this fall, did you have any difficulty walking outside or away from your home?”, and “As a result of this fall, did you have any difficulty doing things around your home like cooking or cleaning?” (response set=could not do before the fall, could not do because of the fall, able to do but had more difficulty than before the fall, could do after the fall without difficulty).

3.8 Ethical issues
Ethical approval was gained from the National Research Ethics Committee. Approval (reference 08/H1009/41) for the study and co-operation for its implementation was also gained from the Salford Royal Foundation NHS Trust, The Manchester Royal Infirmary, The University Hospital of North Staffordshire
and the Haywood Hospital’s management and outpatients’ staff, as well as their
respective Research and Development departments. Additionally, as the research
took place as part of an academic qualification, approval was sought and given
by the University of Manchester’s Senate Ethics Committee before the study
commenced. Participation of the patients was voluntary, and no harm to the
participants was expected throughout the study. Consideration was given to the
possibility that participants may become distressed when recalling a previous
fall. It was planned in advance that if any participants showed signs of distress,
they would be asked if they wished the interview/questionnaire to be
discontinued. If any participant showed signs of significant distress the research
would be stopped. Although this did not occur, it was planned that the lead
investigator would inform the patient’s consultant if this took place in hospital or
the patient’s GP if the falls took place in the community. It was apparent during
the study that a small number of patients were at high risk of injurious falls or
had been repeatedly falling, consequently the hospital consultant was informed if
the patient was in attendance at an outpatients’ clinic, or their GP if they were in
the community. This information was included in the patient’s information sheet.
Confidentiality and care was taken to ensure all participants fully understood that
information was solely for the purpose of the study. Anonymity was ensured, as
the results were not linked to particular subjects through the use of coding.
Information was repeated and reinforced orally once the subjects were recruited.
Only information relevant to the study was extracted from patient records in
order to ascertain which patients fitted the eligibility criteria and to obtain the
data to make up an anonymous patient profile. Patients were assigned a study
identification number when they consented to take part and only that number was used on study records. The consent form was filed separately from the completed questionnaires as this bears the patient’s name. No identifying information was inputted into the database at any point. All records were kept in locked filing cabinets with the School of Nursing, Midwifery and Social Work and confidential waste was shredded.

3.9 Pilot study in lower limb muscle strength and postural stability in 30 patients with RA.
In addition to the main study, a small pilot study of lower limb muscle strength and postural stability in 30 patients with RA was conducted at the Wellcome Trust Clinical Research facility (WTCRF). A complete description of the methods and results of this additional study can be found in Appendix 9. The findings from the pilot study in muscle strength and balance will be used to inform power calculations, feasibility and practical issues for a larger, future study in falls prevention.

3.10 Summary of the methodology and research design
This chapter has described the aims, methodology and choice of design for this study. Extensive peer review and a pilot of the research process were useful in fine tuning the methods for this study and ensuring that the measures were not too onerous for participants to complete. Variables considered important in causing or predicting falls were assessed at baseline and the research process has
been described in detail. The next chapter considers the statistical methods for analysis of the data and then the results will be presented in detail.
CHAPTER 4

4. Analysis of data

Statistical analysis was conducted using SPSS (V. 16.0). The main steps in the preparation of the data for analysis in this study were the design of the SPSS datasets (one for the baseline data and one for the follow-up data that were merged following the completion of the one year follow-up), data entry, data checking and the transformation of some of the data into a different format. Statistical advice and assistance was given for the complex task of merging the baseline dataset with the follow-up dataset and throughout the various stages of analysis. The data analysis methods in line with the research objectives, are described in the following chapter.

4.1 Preparation and data checking.

4.1.1 Data entry, checking, missing data and transformation.

The questionnaires and clinical assessments were checked at the end of each clinic (at the stage of recruitment) for completeness and accuracy to minimise missing data or errors. All baseline questionnaires and clinical assessments (linked by study number) were inputted into a prepared SPSS dataset with a sample of 10% double entered to detect errors in data entry. The input error rate after comparing the sample with the completed data inputting was 1.6%. Additional data cleaning and checking was carried out in order to further minimise any errors. Any missing values (e.g. ESR blood results, five
questionnaires not completed at baseline) were inserted by referring back to primary sources i.e. participant or hospital database.

For the fear of falling Short FES-I survey (at baseline and at the end of the one year data collection) guidelines are given for the handling of missing data (Kempen et al., 2008). If data is missing on more than one item then that questionnaire cannot be used. If data is missing on no more than one of the seven items then the sum score of the six items that have been completed (i.e. add together the responses to each item on the scale) should be calculated, divided by six, and multiplied by seven. The new sum score should be rounded up to the nearest whole number to give the score for an individual. At baseline any missing items were checked at the end of the assessment and inserted or the participant was telephoned as soon as possible to check the missing entries. For the one year follow-up postal survey, there were two Short FES-I questionnaires with one item that had two responses ticked by the participant. After looking at the responses for the other item it was decided to use the lower response variable for one of the questionnaires and the higher response for the other as these appeared to be more in line with the other responses. There were also two questionnaires with one item missing that could also be used following the missing data guidelines.

The HAQ questionnaire (used to assess functional ability) involves 20 activities of daily living, divided into categories with possible responses graded as 0 = without any difficulty; 1 = with some difficulty; 2 = with much difficulty; and 3
Participants were also asked about the use of aids and devices, and if they needed help from another person for activities in any of the eight categories. The highest response within each category was used as a score for that function. The total HAQ score was calculated as follows; the sum of the highest response in each category is divided by 8 to form a score within the range 1 to 4. The total HAQ score is the mean of the highest scores for the eight categories.

Some of the variables needed to be transformed into a different format. Date of birth was converted to age in years and months at the time of assessment; the final HAQ scores (0-3) were calculated, as were the DAS28 score, using the ESR blood result, number of swollen/tender joints and the global health score. The socio-economic status of the participants was categorised using the National Statistics Socio-Economic Classification system (ONS, 2005).

Following the data entry process, further checks for errors and inaccuracies were made by visually checking the SPSS dataset and looking at summary frequencies. It was possible to refer back to primary sources (telephoning participants and checking medical records) to ensure accurate data had been inputted.

The follow-up data (number of falls and data from fall event forms) was consecutively entered into a separate SPSS dataset, linked by subject study number for the detailed analysis of fall incidence and injuries sustained. Fall injuries self-reported during the follow-up calls were categorised according to the
International Classification of Diseases, 10th revision, as recommended by the ProFaNE consensus group (Lamb et al., 2005).

The one year follow-up data was linked to the baseline data to enable analyses of associations of risk factors with fallers.

4.2 Data Analysis

4.2.1 Types of data
The first step in data analysis was to decide on the data types (e.g. discrete or continuous) or measurement levels of the variables. This was in order to make a decision regarding the use of the most appropriate statistical method to draw conclusions from the data.

4.3 Descriptive statistics
Descriptive statistics and univariate analyses were initially used to summarise the basic features of the data.

The participant demographic, disease and risk factor characteristics were summarised using means, standard deviations or frequencies and percentages or medians and interquartile ranges depending on skewness.

Comparisons of the means and standard deviations between those with a one year history of falls and those without were made. Differences between gender and age were also investigated.
4.4 **Hypothesis tests and confidence intervals**

Each statistical test makes particular assumptions about the data, which should also be taken into account when deciding the most appropriate test (Vowler, 2007). For the continuous data this depends on the shape of the frequency distribution (whether symmetrical, positively skewed or negatively skewed when displayed as a histogram). The distribution of the continuous data was assessed before deciding the type of statistical test to be used. The mean and standard deviation of each continuous variable was estimated and the shape of the distribution was examined by presenting the data as a histogram. For continuous data with an approximately normal distribution, parametric tests were utilised and the mean, standard deviation and 95% confidence intervals reported. Confidence intervals were used to indicate the clinical importance of the result and represent the range within which the true magnitude of effect lies (Petrie & Sabin, 2007; Wright, 2003). A wide interval indicates that the estimate is imprecise, whereas a narrow one indicates a precise estimate.

For data with other distributions, non-parametric tests (e.g. the Kruskal-wallis test) and the inter-quartile range were used to show variability. Before tests of significance for the data were applied, the null hypothesis was defined; namely stating that there is no difference between the groups that are being compared (e.g. males compared with females) in the distribution of the outcome variable.
Hypothesis tests such as the chi-square test for dichotomous or nominal variables by group was used, as was the chi-square test for trend and the Mann-Whitney test for skewed continuous variables by group. T-tests were used to compare the means of non-skewed continuous variables by group. Analysis of variance (ANOVA) was used to test for differences between the groups of non-fallers, single fallers and multiple fallers. Levene’s test of homogeneity of variance was undertaken and Tukey’s post-hoc tests were used to compare the differences between pairs of groups. In cases when Levene’s test was not met (p<=0.05) the non-parametric Welch test was used to determine overall significance between the groups, and Dunnett’s T3 post-hoc tests were used to compare between pairs of groups. Appendix 10 outlines a summary table of all the ANOVA tests used within the study to give an overview.

These tests will indicate the significance level of the results with a P-value less than 0.05 (5%) set as sufficiently small to reject the null hypothesis.

4.5 Incidence of falls (objective 1)
In epidemiology, the incidence rate is the frequency of new onsets of an event in a population at risk, in a period of time (Bhopal, 2008). The incidence of falls is the number of new falls in the sample population of adults with RA within the period of study. The incidence rate divides the incidence of the event by the person-years of observations and is usually multiplied by a constant (e.g. 1000) to aid interpretation (Silman & Macfarlane, 2002).
To calculate the person-time incidence rate, the following formula is used:

\[
\text{Person time incidence rate} = \frac{\text{New occurrences of outcome over a period of time}}{\text{time spent by the study population at risk over this period}} \quad (\text{Bhopal, 2008})
\]

To determine the incidence rate, the number of person months/years must initially be calculated. The number of person months in the study is the total number of months that participants returned a falls postcard. The incidence of falls over one year was estimated by calculating the number of new onsets of falls in the sample within the one year.

Fall data was summarised as recommended by the ProFaNE consensus group (Lamb et al., 2005) using number of falls, number of non-fallers/single fallers/multiple fallers, and fall rate per person year. Age and sex specific rates were also calculated. Confidence intervals were reported for the incidence rate of falls.

Numbers of non-fallers, single fallers and multiple fallers were compared at baseline and after the one year follow-up. The frequency of falls was also compared in groups of age band and gender, reporting 95% confidence intervals for differences between proportions where applicable.
4.6 Prevalence of fear of falling (objective 2)

The seven–item Short FES-I (via interviewer assisted questionnaire) was completed at the baseline assessments by all participants to measure confidence in performing a range of activities of daily living without falling as recommended by Lamb et al., (2005). As explained in the methods, activities include getting dressed or undressed, taking a bath or shower, getting in or out of a chair, going up or down stairs, reaching, walking up or down a slope, going out to a social event. A score was obtained by adding all the scores on all items together to give a total that ranges from 7 (no fear of falling) to 28 (severe concern about falling) (Kempen et al, 2007).

Chi squared tests of trend were used as appropriate for categorical data to examine differences in groups of those with low and high levels of fear of falling. Independent t-tests were used to test for differences among continuous variables. A paired t-test was used to compare Short FES-I mean scores between baseline and follow-up for participants. Analysis of variance (ANOVA) was used to test for differences in mean FES-I scores between the groups of non-fallers, single fallers and multiple fallers. Confidence intervals were reported for the fear of falling data.

4.7 Fall risk factors and fall related consequences (objective 3)

Binary logistic regression enables the calculation of odds ratios (OR) and 95% CI for age and gender and all fall risk associated variables with a significance level above 0.25 (Hosmer, 2000). The OR is the ratio of exposure odds among cases
(fallers) relative to exposure odds among controls (non-fallers) and is the best single estimate of the effect in an unbiased study (Silman & Macfarlane, 2005). It should not be confused with relative risk, which is the ratio of probabilities rather than odds (LaValley, 2008). The CI not only informs of an effect of an exposure or event but also indicates the precision of the estimate of the effect size. However with small sample numbers, there may not be enough power to detect a small effect. Binary logistic regression allows the analysis of dichotomous outcomes with a two-level outcome of interest (in this case faller or non-faller). It can be used with continuous or categorical predictors (LaValley, 2008).

To gain a good understanding of the associations between the selected variables and falls, binary logistic regression was initially performed on all groups of non-fallers, single fallers and multiple fallers by selecting two groups (e.g. single fallers and non-fallers) at a time until all comparisons and variations had been carried out. Univariate odds ratios with 95% CI of all selected variables were individually calculated for comparing the groups of: all fallers and non-fallers; single fallers and non-fallers; multiple fallers and non-fallers; and single fallers and multiple fallers.

Selection of variables and confounders
A relationship between falls and fall predictors can potentially be affected by the presence of a third factor which is associated with the predictor(s) of falls but also independently affects falls. Such an extraneous factor is known as a
confounder and can be a major source of bias in epidemiological studies (Bhopal, 2008). Age and gender were also included in the univariate analysis as potential variables that may affect falls.

Multivariate analysis of data takes into account associations between two or more variables simultaneously. Problems can occur when too few (under-specification) or too many variables are entered into a multivariate analysis model (over-specification). Over-specification can affect the precision and accuracy of the results and produce misleading associations due to a lack of generalisability of the result. Guidelines have been suggested that recommend the minimum number of events per variable as ten (Peduzzi et al., 1996). Following the initial analysis of the different pairwise combinations of the predicted groups (e.g. non-fallers and multiple fallers), the participants were grouped into just two categories (non-fallers and all fallers) to use the maximum amount of data and without losing significant variables. Each clinically relevant variable with a significance level less than 0.25 from the previous hypotheses tests were then selected to be entered into the multivariate logistic regression analysis, as recommended by Peduzzi et al., (2008) to estimate the best predictors of falls. The higher cut-off was chosen to reduce the possibility of missing important risk factors, not previously identified.

Descriptive statistics were used to summarise self-reported explanations for falls, locations and outcomes of falls (categorical, nominal data). Absolute risk differences between the injuries of fallers and non-fallers were also calculated as
recommended by the ProFaNE consensus group (Lamb et al., 2005), again reporting confidence intervals for differences between proportions where applicable.

4.8 Summary of data analysis plan

The purpose of this analysis plan was to guide the data management, analytical process and the statistical methods that were used to present the results of the study. It also ensured that the results relevant to the primary aims to the study were addressed and that the analysis was not biased by self-selected enquiries following the data collection. The next chapter will present the response rates and demographic results with subsequent chapters reporting the incidence of falls, prevalence of fear of falling baseline characteristics and risk factor data, using the prospective fall data and history of falling retrospective data.
CHAPTER 5

5. Results

5.1 Study participation
The 559 study participants were recruited from four rheumatology outpatient clinics in Salford, Central Manchester, Stoke-on-Trent and Newcastle-under-Lyme, in the Northwest of England. In the following chapter, participants were divided into 3 categories according to the number of falls: no fall (non-fallers), one fall during the follow-up period (single fallers), and two or more falls during the follow-up period (multiple fallers).

5.2 Participation rates
Eight hundred and forty five letters were sent to participants a month before their clinic appointment (Figure 2). Of the 656 who attended the clinics and were assessed for eligibility, 31 were excluded and 66 refused to take part. There was a high recruitment rate for participants (85%) and 535/559 (96%) participants took part in the one year follow-up. Twenty-four participants did not complete the follow-up, reasons included: death (n=7), felt too unwell (n=14) or wished to discontinue sending the postcards as too onerous (n=3).
5.3 Calendar postcard responses

The majority of participants (n = 323, 60%) completed one year's worth of postcards (i.e. 12). However, there were still many participants who missed one month or more at some point in the study. Sixty per cent of participants completed all of the 12 calendar returns within the one year follow-up. Participants were telephoned if they reported a fall(s), or if a calendar postcard was not received or filled in incorrectly to enable as complete a record of falls as possible.

5.4 Fear of falling response rates

The seven–item Short FES-I (via interviewer assisted questionnaire) was completed at the baseline assessments by all 559 participants to measure confidence in performing a range of activities of daily living without falling as recommended by Lamb et al., (2005).

The Short FES-I was repeated again as close as possible after the participants had completed one year data collection on falls (via postal questionnaire). After one year, 47% (n = 254) of the participants completed the second FES-I questionnaire.
5.5 Outliers

Outliers are observations that are distinct from the main body of data and are incompatible with the rest of the data (Petrie & Sabin, 2005). In this study, there were a small number of individuals who fell repeatedly, with one person falling 44 times throughout the study. However, it was felt to be important to include all of these falls in the descriptive analysis to gain as much information about the types of falls in adults with RA as possible. The monthly follow-up phone calls included self-reported descriptions about how the fall occurred and whether it was related to the RA. This enabled comprehensive descriptions of each fall to be recorded, fairly close in time to the event. The data was grouped into non-fallers, single fallers or multiple fallers and so the inclusion of the more frequent fallers (36 people fell 4 or more times) did not affect the statistical techniques used.

In addition, participants reported reasons why they thought the fall had taken place. Within these fall descriptions, there were neurological reasons for falling, such as a transient ischaemic attack (T.I.A.) and epilepsy (Table 33). As there were only four participants (n=535) affected by epilepsy or T.I.A.’s that caused 12 falls in total (out of 635 total falls), it was concluded as unnecessary to exclude such small numbers. The analytical results would not be affected and it was important for the descriptive results to include all of the self-reported reasons for falling.
Figure 2. Flow diagram of the research process

Enrolment

Study invitation letters sent (n=845)

Assessed for eligibility (n=656)

Excluded (n=97)
  - Not meeting inclusion criteria (n=31)
    - Too unwell (n=23)
    - Unclear diagnosis (n=8)
  - Declined to participate (n=66)

Data collection

Baseline assessments completed (n=559, 85%)

Calendar postcards and telephone follow-up
  Agreed (n=559)

One year follow-up

Lost to follow-up (n=24)
  - Too unwell (n=14)
  - Died (n=7)
  - Reported too time consuming to complete and return postcards (n=3)

Analysis

Analysed (n=535, 96%)
Demographics of participants.

The demographics of the participants are presented in detail in Table 2. In short, there were twice as many women (n=373, 69.7%) recruited to the study than men, which was unsurprising as RA affects approximately three times as many women as men in the UK (Symmons et al., 2002a). The majority of participants were married or living with a partner (71%) and were of white British ethnicity and born in the UK (96%). Over half of the participants were retired (59%), and 14% were unable to work due to their disabilities. Twenty-four percent of the participants continued to be employed. The eight-category version of the National Statistics Socio-Economic Classification (ONS 2005) was utilised to classify the socio-economic status of participants, based on their occupation (or previous, if retired), employment status and size of organisation. The socio-economic status of the participants was mainly spread between the middle groups. A large proportion of the participants were classified as lower supervisory and technical persons (32%), followed by small employers and own-account workers (23%). The two other major categories were the intermediate (16%) and lower managerial and professional groups (16%).
Table 2. Demographics and characteristics of study participants (n=535)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>162 (30.3)</td>
</tr>
<tr>
<td>Female</td>
<td>373 (69.7)</td>
</tr>
<tr>
<td><strong>Ethnic origin</strong></td>
<td></td>
</tr>
<tr>
<td>African/Caribbean</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>White British/white Irish/other white background</td>
<td>521 (97.4)</td>
</tr>
<tr>
<td>Asian/British Indian/British Pakistani</td>
<td>7 (1.3)</td>
</tr>
<tr>
<td>Mixed ethnicity</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>Other ethnicity</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>127 (23.7)</td>
</tr>
<tr>
<td>Retired</td>
<td>315 (58.9)</td>
</tr>
<tr>
<td>Full time student/voluntary work/unemployed</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>At home doing housework/caring for family</td>
<td>13 (2.4)</td>
</tr>
<tr>
<td>Unemployed due to sickness/disability</td>
<td>77 (14.4)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>47 (9.1)</td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>367 (70.7)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>65 (12.5)</td>
</tr>
<tr>
<td>Widowed</td>
<td>40 (7.7)</td>
</tr>
<tr>
<td>(not recorded = 17)</td>
<td></td>
</tr>
<tr>
<td><strong>Socio-economic classification (ONS, 2005)</strong></td>
<td></td>
</tr>
<tr>
<td>Higher managerial and professional occupations</td>
<td>11 (2.2)</td>
</tr>
<tr>
<td>Lower managerial and professional</td>
<td>83 (16.4)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>82 (16.2)</td>
</tr>
<tr>
<td>Small employers and own-account workers</td>
<td>116 (22.9)</td>
</tr>
<tr>
<td>Lower supervisory and technical</td>
<td>160 (31.6)</td>
</tr>
<tr>
<td>Semi-routine/routine</td>
<td>53 (10.5)</td>
</tr>
<tr>
<td>Never worked and long-term unemployed</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>(not recorded = 30)</td>
<td></td>
</tr>
</tbody>
</table>
5.6 Age at initial interview (years)

The mean age of participants was 62 years (Standard deviation=12.8, Median=63). The youngest participant was 18 years and the oldest participant 88 years. The mean age of men was 62.4 years (SD=11.0) and the mean age of women was 61.9 years (SD=13.5). The independent samples t-test was used to compare the mean ages between the male and female participants. There were no significant gender differences in terms of age (t=0.67, p=0.63, 95% CI of difference –1.62 to 2.64).

5.7 Summary of response rates and demographics

To summarise, 845 letters were sent to participants prior to their clinic appointment (Figure 2). Of the 656 who attended the clinics and were assessed for eligibility, 31 were excluded and 66 refused to take part. There was a high recruitment rate for participants (85%) and 96% participants took part in the one year follow-up. Sixty per cent of participants completed all of the 12 calendar returns within the one year follow-up. Twenty-four participants did not complete the follow-up and there were twice as many women recruited to the study compared to men and the majority of the participants were married and of white British ethnicity. The mean age of participants was 62 years and over half were retired from employment, although 24% continued to work. The following chapter will present the incidence and prevalence of falls and any associations with gender or age using the prospective data and the retrospective data.
CHAPTER 6

6. Falls: incidence and prevalence

This chapter will report the prospective data initially on the one year follow-up of falls and any associations with gender or age as this is of primary importance in the study. The retrospective data will then be presented to enable comparisons to be made between the one year follow-up data and the one year history of falls data.

6.1 Follow-up fall episodes in one year and incidence rate

Over a third of the participants experienced one or more falls (36.4%, 95% CI 32% to 41%) during the one year follow-up. Ninety-four people fell once, and one hundred and one people fell twice or more. There were 598 falls reported during the one year follow-up data. The one year incidence rate can be calculated as follows:

Total number of person months = 5467

\[ \frac{5467}{12} = 455.58 \text{ person years} \]

Total number of falls in one year = 598

**Crude incidence rate** = \[ \frac{598}{455.58} = 1.31 \]

\[ = 1312.6/1000 \text{ person-years at risk} (95\% \text{ CI 1209.5, 1422.2}). \]

The faller incidence rate in one year was \[ \frac{598}{535} = 1.12 \text{ falls per person} \]

\( (95\% \text{ CI 1.3, 1.21}). \)
6.2 Absolute risk differences between fallers and non-fallers

To explore the differences between those who did not fall in the one year follow-up but did fall in the previous year (Table 3), the absolute risk differences between the groups were calculated.

Table 3 History of falls by one year follow-up

<table>
<thead>
<tr>
<th></th>
<th>No fall(s) in 1 year follow-up</th>
<th>Fall(s) in 1 year follow-up</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No 1 year history of fall(s)</td>
<td>232 (76.6)</td>
<td>71 (23.4)</td>
<td>303</td>
</tr>
<tr>
<td>1 year history of fall(s)</td>
<td>108 (46.6)</td>
<td>124 (53.4)</td>
<td>232</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>340</strong></td>
<td><strong>195</strong></td>
<td><strong>535</strong></td>
</tr>
</tbody>
</table>

The absolute risk of falling during the study for participants without a one year history of falls was 23% whilst for participants who did have a one year history of falls the absolute risk of falling during the study was 53%. Using a chi-square test there was evidence to reject the hypothesis that there was no association between past falls and study falls ($\chi^2 = 51.1$, df=1, p<0.000001).

6.3 Falls by outpatient department

To check for any participant differences in history of fall according to attendance at the different outpatient clinics, the proportion of fallers and non-fallers were examined (Table 4). This checking was deemed important as participants at
different clinics could have different treatments or much more severe disease activity that could affect the falls data. However, there were no significant differences noted between the areas of recruitment and history of falling ($\chi^2$ Trend=0.7, df=1, p=0.4).

Table 4. Recruitment location of participants and history of falls in previous one year at baseline.

<table>
<thead>
<tr>
<th>Outpatient department</th>
<th>Number of participants (%)</th>
<th>1 year history of no-falls (%)</th>
<th>1 year history of 1 fall (%)</th>
<th>1 year history of 2 or more falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Staffs Hospital/ Haywood Hospital</td>
<td>248</td>
<td>141 (56.9)</td>
<td>44 (17.7)</td>
<td>63 (25.4)</td>
</tr>
<tr>
<td>Salford Royal Hospital</td>
<td>228</td>
<td>126 (55.3)</td>
<td>61 (28.8)</td>
<td>41 (18.0)</td>
</tr>
<tr>
<td>Manchester Royal Infirmary</td>
<td>83</td>
<td>50 (60.2)</td>
<td>15 (18.1)</td>
<td>18 (21.7)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>559</strong></td>
<td><strong>317 (56.7)</strong></td>
<td><strong>120 (21.5)</strong></td>
<td><strong>122 (21.8)</strong></td>
</tr>
</tbody>
</table>
6.4 Falls by age and gender (1 year follow-up)

In the prospective data, falls were fairly evenly reported between the age groups (Table 5).

Table 5. One year follow-up of falls by age group

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>No falls (%/95% CI)</th>
<th>1 fall (%/95% CI)</th>
<th>&gt;1 fall (%/95% CI)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 34</td>
<td>12 (63.2/41.0, 80.9)</td>
<td>2 (10.5/2.9, 31.4)</td>
<td>5 (26.3/11.8, 48.8)</td>
<td>19 (100.0)</td>
</tr>
<tr>
<td>35 - 44</td>
<td>25 (71.4/54.9, 83.7)</td>
<td>4 (11.4/4.5, 25.9)</td>
<td>6 (17.1/8.1, 32.7)</td>
<td>35 (100.0)</td>
</tr>
<tr>
<td>45 - 54</td>
<td>56 (64.4/53.9, 73.6)</td>
<td>13 (14.9/8.9, 23.9)</td>
<td>18 (20.7/13.5, 30.4)</td>
<td>87 (100.0)</td>
</tr>
<tr>
<td>55 - 64</td>
<td>103 (62.4/54.8, 69.5)</td>
<td>30 (18.2/13.0, 24.7)</td>
<td>32 (19.4/14.1, 26.1)</td>
<td>165 (100.0)</td>
</tr>
<tr>
<td>65 - 74</td>
<td>99 (63.9/56.1, 71.0)</td>
<td>26 (16.8/11.7, 23.4)</td>
<td>30 (19.4/13.9, 26.3)</td>
<td>155 (100.0)</td>
</tr>
<tr>
<td>Over 75</td>
<td>45 (60.8/49.4, 71.1)</td>
<td>19 (25.7/17.1, 36.7)</td>
<td>10 (13.5/7.5, 23.1)</td>
<td>74 (100.0)</td>
</tr>
<tr>
<td>Total</td>
<td>340 (63.6)</td>
<td>94 (17.4)</td>
<td>101 (18.9)</td>
<td>535 (100.0)</td>
</tr>
</tbody>
</table>

The clustered bar chart in Figure 3 demonstrates that most of the falls occurred fairly evenly between the age groups in the one year follow-up data except for a small rise in single fallers in the over 75 year age group. A one-way analysis of
variance (ANOVA) showed no significant differences between the mean age in
the groups of non-fallers (mean age=61.6, SD =12.7), single fallers (mean
age=64.7, SD=11.7) or multiple fallers (mean age = 61.1, SD=13.0) ($F=2.64,
df=2, 532, p=0.07$). The box plot in Figure 4 demonstrates the similar median
ages between the three groups.
Figure 3. Clustered bar chart of 1 year follow-up of falls by age group

<table>
<thead>
<tr>
<th>Age band</th>
<th>No falls reported</th>
<th>1 fall reported</th>
<th>&gt;1 fall reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 75</td>
<td>40%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 to 74</td>
<td>30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55 to 64</td>
<td>20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45 to 54</td>
<td>10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35 to 44</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 34</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age band</th>
<th>No falls reported</th>
<th>1 fall reported</th>
<th>&gt;1 fall reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 75</td>
<td>19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 to 74</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55 to 64</td>
<td>87</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45 to 54</td>
<td>165</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35 to 44</td>
<td>155</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 34</td>
<td>74</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 4. Box plot of non-fallers and fallers in 1 year follow-up by age.
As Table 6 demonstrates, there were no significant gender differences found in the prospective reporting of falls ($\chi^2=0.04$, p=0.83).

Table 6. One year follow-up falls by male or female gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>No fall (%, 95% CI)</th>
<th>1 fall (%, 95% CI)</th>
<th>2 or more falls (%, 95% CI)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>105 (64.8, 57.2 to 71.8)</td>
<td>26 (16.0, 11.2 to 22.5)</td>
<td>31 (19.1, 13.8 to 25.8)</td>
<td>162 (100.0)</td>
</tr>
<tr>
<td>(n=162)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>235 (63.0, 57.9 to 67.8)</td>
<td>68 (18.2, 14.6 to 22.5)</td>
<td>70 (18.8, 15.1 to 23.0)</td>
<td>373 (100.0)</td>
</tr>
<tr>
<td>(n=373)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>340 (63.6)</td>
<td>94 (17.6)</td>
<td>101 (18.9)</td>
<td>535 (100.0)</td>
</tr>
</tbody>
</table>

6.5 Age–specific and sex-specific incidence rates in one year follow-up

Table 7 presents the age-specific incidence rates in one year follow-up for the participants. It can be seen that a small number of younger fallers (n=7) are falling more frequently which gives the 0-34 age-band a high incidence of falls. However, due to the small number in this group confidence intervals are wide. There was also an increase in the incidence of falls in the 65-74 age-band but this drops again in the >75 age group.
Table 7. Age-specific incidence rates in one year follow-up

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Fallers (n)</th>
<th>Fall events (n)</th>
<th>Person-years at risk</th>
<th>Incidence rate of falls / 1000 person years</th>
<th>95% Confidence intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-34 (n=19)</td>
<td>7</td>
<td>34</td>
<td>13.7</td>
<td>2481.6</td>
<td>1718.7, 3468.0</td>
</tr>
<tr>
<td>35-44 (n=35)</td>
<td>10</td>
<td>34</td>
<td>28.3</td>
<td>1201.4</td>
<td>832.0, 1678.9</td>
</tr>
<tr>
<td>45-54 (n=87)</td>
<td>31</td>
<td>67</td>
<td>69</td>
<td>971.0</td>
<td>752.5, 1233.2</td>
</tr>
<tr>
<td>55-64 (n=165)</td>
<td>62</td>
<td>251</td>
<td>150</td>
<td>1673.3</td>
<td>1472.7, 1893.7</td>
</tr>
<tr>
<td>65-74 (n=155)</td>
<td>56</td>
<td>149</td>
<td>49.8</td>
<td>2991.9</td>
<td>2530.9, 3512.8</td>
</tr>
<tr>
<td>Over 75 (n=74)</td>
<td>29</td>
<td>63</td>
<td>61.5</td>
<td>1024.4</td>
<td>787.2, 1310.6</td>
</tr>
<tr>
<td>All ages (n=535)</td>
<td>195</td>
<td>598</td>
<td>455.9</td>
<td>1312.6</td>
<td>1208.7, 1420.0</td>
</tr>
</tbody>
</table>

There were no significant differences in the percentage of men and women who fell in the one year. Two thirds of the participants in the study were women, and 70.2% of the fallers were women, but the sex-specific incidence rates (Table 8) show that men fell proportionally more than the women and had a statistically significant higher incidence rate of falls per 1000 person years (p=<0.0001).
Table 8. Sex-specific incidence rates in one year follow-up

<table>
<thead>
<tr>
<th>Gender</th>
<th>Fallers (n)</th>
<th>Fall events (n)</th>
<th>% Fallers per year</th>
<th>Person-years at risk</th>
<th>Incidence rate of falls per 1000 person years</th>
<th>95% Confidence intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>57</td>
<td>240</td>
<td>35%</td>
<td>136.6</td>
<td>1756.9</td>
<td>1541.7, 1993.9</td>
</tr>
<tr>
<td>Female</td>
<td>138</td>
<td>358</td>
<td>37%</td>
<td>318.9</td>
<td>1122.6</td>
<td>1009.3, 1245.1</td>
</tr>
</tbody>
</table>

6.6 Baseline period prevalence of fallers using retrospective data

In the previous year 120 participants (21%) reported falling once and 122 participants (22%) reported two or more falls, whilst 317 (57%) did not report any falls in the previous one year. The self-reported one year period prevalence of fallers for people with RA was 443 cases per 1000 people per year (44%, 95% CI 39%, 47%). This was slightly higher than the one year follow-up incidence of falls (36.4%, 95% CI 32% to 41%), which may be due to year on year differences, recall bias (participants recalling falls prior to the one year history) and/or reporting fatigue. However, the 95% confidence intervals show some overlap between the two rates for the one year follow-up and the one year history of falls, demonstrating some consistency in the results.

6.7 Prevalence of falls by age and gender

In both the prospective data and retrospective data, falls were fairly evenly reported between the age groups of participants similar to the prospective data which is interesting due to the number of participants under the age of 65. A one-way analysis of variance (ANOVA) showed no significant differences between
the mean age in the groups of non-fallers, single fallers or multiple fallers (F=1.1, df 2,556, p=0.33) reported in the previous year. The box plot in figure 5 demonstrates the similarities in age between the groups of non-fallers, single fallers and multiple fallers within the one year history of falls data. This corresponds with the finding that adults of all ages with RA have a similar risk of falling.

Table 9 Self-reported one year previous history of falling by age

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Up to 34 years (%)</th>
<th>35-44 years (%)</th>
<th>45-54 years (%)</th>
<th>55-64 years (%)</th>
<th>65-74 years (%)</th>
<th>Over 75 years (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No 1 year history of fall</td>
<td>10 (47.6)</td>
<td>21 (58.3)</td>
<td>45 (50.0)</td>
<td>104 (60.1)</td>
<td>95 (60.1)</td>
<td>42 (51.9)</td>
</tr>
<tr>
<td>1 year history of a single fall</td>
<td>3 (14.3)</td>
<td>8 (22.2)</td>
<td>23 (25.6)</td>
<td>31 (17.9)</td>
<td>34 (21.5)</td>
<td>21 (25.9)</td>
</tr>
<tr>
<td>1 year history of 2 falls or more</td>
<td>8 (38.1)</td>
<td>7 (19.4)</td>
<td>22 (24.4)</td>
<td>38 (22.0)</td>
<td>29 (18.4)</td>
<td>18 (22.2)</td>
</tr>
<tr>
<td>Total</td>
<td>21 (100.0)</td>
<td>36 (100.0)</td>
<td>90 (100.0)</td>
<td>173 (100.0)</td>
<td>158 (100.0)</td>
<td>81 (100.0)</td>
</tr>
</tbody>
</table>
There were no significant gender differences found in the prospective reporting of falls, but in the retrospective data there were significantly more female participants who reported falls in the previous year than males ($\chi^2 = 8.2$, p=0.02, 95% CI –1.79, 2.81, Table 10).

Table 10 Self-reported one year previous history of falling by gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>No fall (%)</th>
<th>1 fall (%)</th>
<th>2 falls or more (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>113 (65.3%)</td>
<td>27 (15.6%)</td>
<td>33 (19.1%)</td>
<td>173 (100.0%)</td>
</tr>
<tr>
<td>Female</td>
<td>204 (52.8%)</td>
<td>93 (24.1%)</td>
<td>89 (23.1%)</td>
<td>386 (100.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>317 (56.7%)</td>
<td>120 (21.5%)</td>
<td>122 (21.8%)</td>
<td>559 (100.0%)</td>
</tr>
</tbody>
</table>
6.8 Summary of fall incidence and prevalence

It appears that adults of all ages with RA fall frequently. The crude incidence rate of falls in adults with RA was high at 1313/1000 person-years and during the one year follow-up 36.4% (95% CI 32% to 41%) participants reported one or more falls. Increasing age was not associated with increased falls in both the prospective and retrospective data, adults of all ages with RA have a similar risk of falling. The incidence of falls was higher in men than women due largely because men who fell were more likely to fall more than once during the study period. However there were no significant differences in the percentage of men and women who fell in the one year follow-up period. The one year period
prevalence (using retrospective history of falling data) of fallers for people with RA (44%) was slightly higher than the one year follow-up incidence of falls (36.4%), which may reflect year on year differences. More women than men reported a one year history of falls whilst there were no gender differences in the follow-up reporting of falls. A number of reasons could be given to explain these differences such as under-reporting by men. However further studies are required to investigate this area further. The next chapter will present the fear of falling data at baseline and at one year follow-up.
CHAPTER 7

7. Fear of falling and fall risk factors
The fear of falling results at baseline and at one year follow-up will be presented in the following chapter. The prospective fall data was utilised for the analytical results to examine the associations between potential risk factors or patient characteristics and fear of falling.

7.1 Fear of falling
The Short Falls Efficacy Score – International ((Short FES-I) administered via interviewer assisted questionnaire) was completed at the baseline assessments by all 559 participants and repeated again as close as possible after the participants had completed one year data collection on falls. After one year, 47% (n = 254) of the participants completed the second Short FES-I questionnaire (administered via postal survey). Table 11 shows the characteristics of the participants who responded to the baseline assessment and to the one year follow-up survey of the Short FES-I questionnaire. It can be seen that the proportions in the demographic characteristics for the baseline and follow-up groups are similar.
Table 11. Participants (who completed the Short FES-I) characteristics at baseline (n=559) and 1 year follow-up (254)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n=559)</th>
<th>1 year follow-up (n=254)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%) or mean (SD)</td>
<td>n (%) or mean (SD)</td>
</tr>
<tr>
<td>Female</td>
<td>373 (69.7) 4.7 (6.3)</td>
<td>174 (68.5) 4.3 (5.9)</td>
</tr>
<tr>
<td>White British</td>
<td>521 (97.4) 5.3 (6.9)</td>
<td>245 (96.5) 5.4 (7.0)</td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>367 (70.7) 4.7 (6.3)</td>
<td>199 (78.3) 4.0 (1.0)</td>
</tr>
<tr>
<td>Employed</td>
<td>127 (23.7) 4.0 (1.0)</td>
<td>55 (21.7) 4.0 (2.0)</td>
</tr>
<tr>
<td>Swollen joints (0-28)</td>
<td>4.7 (6.3) 4.3 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Tender joints (0-28)</td>
<td>5.3 (6.9) 5.4 (7.0)</td>
<td></td>
</tr>
<tr>
<td>DAS28 score (0 -10)</td>
<td>4.0 (1.0) 4.0 (2.0)</td>
<td></td>
</tr>
<tr>
<td>Psychotropic medication</td>
<td>105 (18.8) 3.85 (2.7)</td>
<td>53 (20.9) 3.8 (2.6)</td>
</tr>
<tr>
<td>Four or more types of medicines</td>
<td>431 (77.1) 4.7 (2.8)</td>
<td>196 (77.2) 4.5 (2.8)</td>
</tr>
<tr>
<td>Taking steroids at baseline</td>
<td>117 (20.9) 3.85 (2.7)</td>
<td>47 (18.5) 3.8 (2.6)</td>
</tr>
<tr>
<td>History of stroke/Parkinson’s</td>
<td>38 (6.8) 4.7 (2.8)</td>
<td>20 (7.9) 4.5 (2.8)</td>
</tr>
<tr>
<td>VAS pain score (0-10)</td>
<td>3.85 (2.7) 4.5 (2.8)</td>
<td></td>
</tr>
<tr>
<td>VAS fatigue score (0-10)</td>
<td>4.7 (2.8) 142 (43.3)</td>
<td></td>
</tr>
<tr>
<td>History of fall in previous year</td>
<td>109 (43.0) 55 (21.7)</td>
<td></td>
</tr>
<tr>
<td>History of no falls in previous year</td>
<td>145 (57.1) 55 (21.7)</td>
<td></td>
</tr>
<tr>
<td>History of single fall in previous</td>
<td>116 (21.7) 55 (21.7)</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>History of multiple falls in previous year</td>
<td>116 (21.7)</td>
<td>54 (21.3)</td>
</tr>
<tr>
<td>History of fractures</td>
<td>228 (40.8)</td>
<td>107 (42.1)</td>
</tr>
<tr>
<td>History of injuries from previous falls</td>
<td>1.6 (1.5)</td>
<td>1.6 (1.4)</td>
</tr>
<tr>
<td>Poor vision (reg. blind, v poor or poor)</td>
<td>46 (8.6)</td>
<td>19 (7.5)</td>
</tr>
<tr>
<td>Number of co-morbidities</td>
<td>2.0 (1.9)</td>
<td>1.9 (1.9)</td>
</tr>
<tr>
<td>Previous surgery</td>
<td>408 (73.1)</td>
<td>187 (73.6)</td>
</tr>
<tr>
<td>Painful feet</td>
<td>432 (77.3)</td>
<td>191 (75.2)</td>
</tr>
<tr>
<td>Previous joint replacements</td>
<td>125 (22.5)</td>
<td>55 (21.7)</td>
</tr>
<tr>
<td>Complaints of feeling dizzy or unsteady</td>
<td>370 (66.2)</td>
<td>167 (65.7)</td>
</tr>
<tr>
<td>Short FES-I score (7-28)</td>
<td>15.3 (6.5)</td>
<td>15.5 (6.1)</td>
</tr>
<tr>
<td>HAQ score (1-4)</td>
<td>2.4 (0.9)</td>
<td>2.4 (0.8)</td>
</tr>
<tr>
<td>Four test balance scale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fail at each level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsuccessful</td>
<td>39 (7.0)</td>
<td>13 (5.1)</td>
</tr>
<tr>
<td>Feet together stand</td>
<td>13 (2.2)</td>
<td>7 (2.8)</td>
</tr>
<tr>
<td>Semi-tandem stand</td>
<td>216 (38.6)</td>
<td>93 (36.6)</td>
</tr>
<tr>
<td>Tandem stand</td>
<td>116 (20.8)</td>
<td>55 (21.7)</td>
</tr>
<tr>
<td>One leg stand</td>
<td>175 (31.3)</td>
<td>86 (33.9)</td>
</tr>
</tbody>
</table>
The majority of participants (n=459, 82.1%) reported some fear of falling at baseline (reported as somewhat fearful, fairly fearful or very fearful in one or more of the seven item categories). At one year follow-up, 88.6% (n=225) reported at least some fear of falling in one or more of the seven item categories of the Short FES-I indicating that only small proportions of participants were unaffected by concerns about falling during activities of daily living such as taking a bath, shower or going up or down stairs.

7.2 Individual fear of falling scores at baseline and follow-up
At baseline, within the individual fear of falling categories (Table 12), participants were less concerned about getting dressed or undressed and getting in and out of chairs. However, taking a bath or shower, going up or down stairs, reaching for something, walking up or down a slope, and going out for a social event, were of much greater concern to the participants.

The one year follow-up item mean scores (Table 13) were very similar to the baseline individual fear of falling scores (Table 12). Within the individual fear of falling categories, participants were again less concerned about getting dressed or undressed and getting in and out of chairs. However, taking a bath or shower,
going up or down stairs, reaching for something, walking up or down a slope, and going out for a social event, were of much greater concern to the participants.

Table 12. Baseline fear of falling categories for Short FES-I (item range 1-4)

<table>
<thead>
<tr>
<th>Short FES-I item</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting dressed or undressed</td>
<td>1.70</td>
<td>0.91</td>
<td>1.0</td>
</tr>
<tr>
<td>Taking a bath or shower</td>
<td>2.32</td>
<td>1.15</td>
<td>2.0</td>
</tr>
<tr>
<td>Getting in or out of a chair</td>
<td>1.64</td>
<td>0.85</td>
<td>1.0</td>
</tr>
<tr>
<td>Going up or down stairs</td>
<td>2.46</td>
<td>1.16</td>
<td>2.0</td>
</tr>
<tr>
<td>Reaching for something above your head or on the ground</td>
<td>2.44</td>
<td>1.17</td>
<td>2.0</td>
</tr>
<tr>
<td>Walking up or down a slope</td>
<td>2.59</td>
<td>1.15</td>
<td>3.0</td>
</tr>
<tr>
<td>Going out to a social event</td>
<td>2.19</td>
<td>1.15</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Item range: 1=not at all concerned, 2=somewhat concerned, 3=fairly concerned, 4=very concerned.
Table 13. One year follow-up fear of falling categories for Short FES-I (item range 1-4)

<table>
<thead>
<tr>
<th>Short FES-I item</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting dressed or undressed</td>
<td>1.91</td>
<td>0.97</td>
<td>2.0</td>
</tr>
<tr>
<td>Taking a bath or shower</td>
<td>2.49</td>
<td>1.12</td>
<td>2.0</td>
</tr>
<tr>
<td>Getting in or out of a chair</td>
<td>1.78</td>
<td>0.92</td>
<td>1.0</td>
</tr>
<tr>
<td>Going up or down stairs</td>
<td>2.47</td>
<td>1.13</td>
<td>2.0</td>
</tr>
<tr>
<td>Reaching for something above your head or on the ground</td>
<td>2.41</td>
<td>1.08</td>
<td>2.0</td>
</tr>
<tr>
<td>Walking up or down a slope</td>
<td>2.41</td>
<td>1.09</td>
<td>2.0</td>
</tr>
<tr>
<td>Going out to a social event</td>
<td>2.05</td>
<td>1.00</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Item range: 1=not at all concerned, 2=somewhat concerned, 3=fairly concerned, 4=very concerned.

7.3 Prevalence of fear of falling
At baseline (n=559) the mean FES-I score was 15.34, which fell in the fairly fearful score category (median=15.00). The follow-up mean FES-I score was very similar to the baseline score at 15.52 (median=15.00). However these descriptive measures are not comparing the same number of participants and could be misleading. However, after excluding the participants who did not complete the follow-up Short FES-I, the means, medians and percentiles appear to be very similar (Table 14).
Table 14. Comparison of descriptive results in baseline Short FES-I score with follow-up Short FES-I score and change in FES-I score between baseline and follow-up

<table>
<thead>
<tr>
<th></th>
<th>Baseline Short FES-I score (7-28) (SD/95% CI) (n = 253)</th>
<th>Follow-up Short FES-I score (7-28) (SD/95% CI) (n = 253)</th>
<th>Mean change in Short FES-I score (SD/95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD)</strong></td>
<td>14.76 (6.33/13.98, 15.54)</td>
<td>15.52 (6.11/14.77, 16.28)</td>
<td>0.79 (5.06/0.16, 1.42)</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>14.00</td>
<td>15.00</td>
<td>-</td>
</tr>
<tr>
<td><strong>Percentiles</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>9</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>50</td>
<td>4</td>
<td>15</td>
<td>-</td>
</tr>
<tr>
<td>75</td>
<td>21</td>
<td>21</td>
<td>-</td>
</tr>
</tbody>
</table>

The distributions between the baseline and follow-up Short FES-I scores appear similar when comparing only the participants who completed both measures. There appears to be a small increase in the mean FES-I score in the follow-up group that in clinical practice would be classed as very small. However, using a paired t-test, this difference was found to be statistically significant ($t=-2.5$, $df=252$, $p=0.013$, 95% CI -1.4, -0.17).

Using an independent t-test to analyse differences between FES-I scores by gender, women (mean FES-I score = 16.0) were found to have significantly
higher fear of falling scores at baseline than men (mean FES-I score =13.9) (t=-3.7, p = <0.001, 95% CI –3.23, -1.01).

A one-way analysis of variance (ANOVA) was used to compare the baseline FES-I score by the one year follow-up groups of non-fallers, single fallers and multiple fallers to explore variability between the means. Levene’s F statistic had a significance value of 0.39. Therefore the assumption of homogeneity of variance was met and the ANOVA analysis was undertaken. This confirmed that there were significant differences between groups (f = 12.37, df = 2, 531, p = <0.001). The Tukey post-hoc test was used to test the differences between the groups. Multiple fallers had a significantly higher mean FES-I score than single fallers (mean difference= 2.2, p = 0.03, 95% CI 0.13, 4.34) and non-fallers (mean difference= 3.5, p = <0.001, 95% CI 1.83, 5.16). There were no significant differences between the mean FES-I score in the groups of single fallers and non-fallers.

To check for any differences in fear of falling at baseline compared to follow-up for non-fallers, single fallers and multiple fallers, a one-way ANOVA was repeated using the change in FES-I score (the difference between follow-up FES-I score and baseline FES-I score). This analysis would indicate whether fear of falling increased following a fall. Levene’s F statistic had a significance value of 0.43. Therefore the assumption of homogeneity of variance was met and the ANOVA was undertaken. There were no significant differences in the change in fear of falling found between the groups of non-fallers, single fallers and
multiple fallers at baseline or follow-up \((f = 0.697, \text{ df} = 1, 249, p = 0.41)\).

Therefore, having a fall or not in the one year follow-up did not appear to significantly change levels of fear of falling in this group of participants. We know from the results that those who fell in the previous one year were also more likely to fall again in the following one year. Therefore, those who fell in the previous one year may already experience higher levels of fear of falling that remain constant whether they fell again or not in the following one year.

**7.4 Fear or anxiety reported at follow-up phone calls**

In addition, any self-reported fear, anxiety or psychological concerns due to falls reported by participants during the telephone follow-up calls (without prompting and categorising as, “yes” or “no”, rather than using the Short FES-I) was also recorded (Table 15).

**7.4.1 Fear after a fall**

Over two thirds (69\%) of the falls, resulted in the participants reporting fear or anxiety after the fall. It is not possible to grade the degree of this fear without the use of the Short FES-I, but it can be interpreted as rational fear related to the fall and its consequences. There were significant differences in the reporting of fear according to the level of injury experienced by the participants. Participants who reported no fear were more likely to report no injuries in comparison to those who reported fear and experienced moderate or serious injuries \( \chi^2 \text{Trend}=49.7, \text{ df}=1, p=<0.001 \) (Table 15).
Table 15. Fallers’ self-reported fear of falling

<table>
<thead>
<tr>
<th>Fear/anxiety due to falls</th>
<th>Number of falls</th>
<th>No injury</th>
<th>Moderate injury (%)</th>
<th>Serious injury (%)</th>
<th>Total injury/non-injury (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>414</td>
<td>126</td>
<td>247 (60.0)</td>
<td>39 (9.5)</td>
<td>412 (100.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(30.6)</td>
</tr>
<tr>
<td>No</td>
<td>185</td>
<td>119</td>
<td>62 (33.5)</td>
<td>4 (2.2)</td>
<td>185 (100.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(64.3)</td>
</tr>
<tr>
<td>Total</td>
<td>599</td>
<td>245</td>
<td>309 (51.8)</td>
<td>43 (7.2)</td>
<td>597 (100.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(41.0)</td>
</tr>
</tbody>
</table>

7.5 Summary of fear of falling results

The Short FES-I was completed by all 559 participants at the baseline assessment and by 254 (47%) participants after one year. The characteristics of both the baseline and follow-up sample appear to be very similar (Table 11). The mean Short FES-I score were also comparable at baseline and one year follow-up and both groups were classed as being fairly fearful. Having a fall or not in the one year follow-up did not appear to significantly change levels of fear of falling for the participants and over two thirds of those who reported a fall also self-reported experiencing fear/anxiety as a result of the fall. The next chapter will present the baseline patient characteristics in detail and the fall risk factor results using the prospective one year follow-up data. The retrospective data will be reported after the prospective data for comparisons to be made between the one year follow-up and one year history of falls data.
CHAPTER 8

8. Baseline participant characteristics and fall risk factors using the prospective data

This chapter presents the results from the fall risk factor data using the one year follow-up data and reports any significant or non-significant associations with falls or gender. As prospective data is considered to be of higher quality than retrospective data (Bhopal et al., 2008), this data is initially presented and the subsequent chapter utilises the retrospective data with a summary of the consistencies and differences in the data presented in chapter 10.

8.1 Falls risk assessment tool results using the prospective data

As outlined in the methods chapter, the Falls Risk Assessment Tool (FRAT) includes five items: history of any fall in the previous year, four or more prescribed medications, diagnosis of stroke or Parkinson’s disease, reported problems with balance and inability to rise from a chair without using arms. Complaints of feeling dizzy or unsteady were included as part of the balance assessment. However, the clinical balance assessment (Four-Test Balance Scale) and the ability to rise from a chair without using arms (Chair Stand Test) are reported in detail under the heading, “strength and balance assessments, section 8.5”. The presence of three or more of the FRAT risk factors has a positive predictive value for a fall in the next six months of 0.57 (95% CI 0.43, 0.69). Less than three risk factors had a negative predictive value of 0.86 (95% CI 0.82, 0.89), a sensitivity of 0.59 (95% CI 0.48, 0.70) to 0.15 (95% CI 0.09, 0.26), and a specificity of 0.92 (95% CI 0.88, 0.94) (Nandy, et al., 2004).
Table 16 summarises the self-reported responses to the FRAT.

Table 16. Self-reported responses to the Falls Risk Assessment Tool (n=559)

<table>
<thead>
<tr>
<th>Response</th>
<th>Positive response (%)</th>
<th>Negative response (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four or more types of medicine each day</td>
<td>431 (77.1)</td>
<td>128 (22.9)</td>
</tr>
<tr>
<td>Medicines for sleeping, anxiety or depression (psycho-tropic)</td>
<td>105 (18.8)</td>
<td>454 (81.2)</td>
</tr>
<tr>
<td>Complaints of feeling dizzy or unsteady</td>
<td>370 (66.2)</td>
<td>189 (33.8)</td>
</tr>
<tr>
<td>History of stroke or Parkinson’s disease</td>
<td>38 (6.8)</td>
<td>521 (93.2)</td>
</tr>
</tbody>
</table>

There were no significant gender differences found in taking four or more types of medicine each day ($\chi^2=3.3$, df=1, p=0.07) or in the history of stroke or Parkinson’s disease ($\chi^2=0.01$, df=1, p=0.93). However, female participants were significantly more likely to be taking medicines for sleeping, anxiety or depression ($\chi^2=7.6$, df=1, p=0.006) and to complain of feeling dizzy or unsteady ($\chi^2=5.9$, df=1, p=0.02).

Pearson’s chi–square analysis for non-fallers, single fallers and multiple fallers showed significant differences between the groups when testing the associations with taking four or more types of medicines. Single fallers and multiple fallers were more likely to be taking four or more types of medicines ($\chi^2=11.4$, df =2, p=0.003). Positive associations were found between single fallers and multiple
fallers and participants with a history of stroke or Parkinson’s disease ($\chi^2$ Trend=7.48, df=2, p=0.02). There was also a positive linear association between single fallers and multiple fallers and taking medicines for sleeping, anxiety or depression ($\chi^2$ Trend=20.12 df=2, p=<0.001) and complaints of feeling dizzy or unsteady ($\chi^2$ Trend=10.14, df=2, p= 0.01).

### 8.2 Medication

Participants were asked details regarding their current medication (Table 17). These details were verified with their medical records. Due to the potential side effects of taking steroids that may have an effect on potential falls (e.g. osteoporosis may be associated with increased fracture rates), current and previous type and frequency of usage were recorded. Particular types of medications and poly-pharmacy have been linked to an increased risk of falls in community dwelling adults. Medicines were categorised as psychotropic or cardiovascular and participants reported whether they took four or more types of medicines each day and whether they took medicines for sleeping difficulties, anxiety or depression using the British National Formulary to categorise medicines (BNF, 2009). Drugs specific to RA (disease-modifying anti-rheumatic drugs) were categorised as either non-biologic or biologic medicines.

### 8.3 Number of medicines taken at baseline

The mean number of medicines taken by participants at the time of the baseline assessment was 6.3 (median=6.0, Std. Dev. 3.5). Only eight participants took no medicines and 10 participants took one type of medicine. Over half of the
participants took between five and nine different types of medicines (n=284, 50.8%). There were no significant gender differences in the number of medications as both men and women took a mean number of six different types of medicines (t=-0.2, df=557, p=0.32).

Table 17. Number of medicines taken at baseline

<table>
<thead>
<tr>
<th>Number of medicines</th>
<th>Number or participants at baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>195 (34.5)</td>
</tr>
<tr>
<td>5-9</td>
<td>284 (50.8)</td>
</tr>
<tr>
<td>10-14</td>
<td>66 (11.8)</td>
</tr>
<tr>
<td>15-19</td>
<td>10 (1.8)</td>
</tr>
<tr>
<td>20-24</td>
<td>3(0.5)</td>
</tr>
<tr>
<td>&gt;25</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>559</strong></td>
</tr>
</tbody>
</table>

A one-way ANOVA was undertaken to compare the number of medicines taken at baseline by non–fallers, single fallers and multiple fallers, using the follow-up data. As Levene’s F statistic was significant (p=<0.001), the assumption of homogeneity of variances was not met. The Welch test showed that there were significant differences between the groups means (Statistic=7.9, p=<0.001) and Dunnett T3 posts-hoc comparisons showed that multiple fallers had a higher baseline mean number of medicines than non–fallers (mean difference=1.8, p=<0.001, 95% CI 0.6, 3.0), but this was not significantly higher than single
fallers (mean difference=1.1, p=0.1, 95% CI 0.3, 2.4). There were also no significant differences between non-fallers and single fallers (mean difference=0.7, p =0.07, 95% CI -0.04, 1.5).

### 8.4 Use of steroid medication at baseline

Eighty-four percent of participants recorded that they had at some point taken steroid medication in either tablet or injection form. A smaller proportion of the participants were taking steroids at the time of the baseline assessment (21%). Of those who had a history of taking steroids (n=471, 84.3%), 33% had taken them for over one year, which increases the risk of side effects such as osteoporosis, visual problems and muscle weakening which in turn could have an effect on fall risk and associated injuries.

Using Pearson’s Chi-square test, there were no significant gender differences in the self-reported current use of steroids ($\chi^2=1.37$, df=1, p=0.24), or history of steroid use at baseline ($\chi^2=0.03$, df=1, p=0.95). There was a linear association found between use of steroids at baseline and single and multiple fallers ($\chi^2$ Trend=4.8, df=1, p=0.03) in the follow-up data.

Eighty-five percent of participants were taking non-biologic disease-modifying anti-rheumatic drugs at the baseline assessment in comparison to only 10% who were taking biologic disease-modifying anti-rheumatic drugs. Cardiovascular drugs were taken by 47%, whilst 19% were classified as taking psychotropic type
medicines. Seventy-seven percent of participants were recorded as taking four or more types of medicines per day (Table 18).

Table 18. Types of prescribed medicines at baseline assessment

<table>
<thead>
<tr>
<th>Type of medicine</th>
<th>Number at baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic disease-modifying anti-rheumatic drugs</td>
<td>57 (10.2)</td>
</tr>
<tr>
<td>Non biologic disease-modifying anti-rheumatic drugs</td>
<td>475 (85.0)</td>
</tr>
<tr>
<td>Use of steroids at baseline</td>
<td>117 (20.9)</td>
</tr>
<tr>
<td>History of steroid use</td>
<td>471 (84.3)</td>
</tr>
<tr>
<td>Cardiovascular drugs</td>
<td>260 (46.5)</td>
</tr>
<tr>
<td>Four or more types of medicine each day</td>
<td>431 (77.1)</td>
</tr>
<tr>
<td>Psychotropic medicines</td>
<td>106 (19.0)</td>
</tr>
</tbody>
</table>

At the baseline assessment there was a significant effect for gender (p=0.004, 95% CI 0.15, 0.3) with females (22%) taking more psychotropic drugs than males (12%). The frequency of participants that self-reported the use of cardiovascular drugs did not differ by gender (p=0.31). There were no significant gender differences in the use of biologic ($\chi^2=1.2, \text{df}=1, p=0.27$) or non-biologic ($\chi^2=2.4, \text{df}=1, p=0.13$) disease-modifying anti-rheumatic drugs.
There were no significant differences in the use of cardiovascular drugs ($\chi^2=0.3$, df=2, p=0.98), non-biologic ($\chi^2=0.8$, df=2, p=0.68) or biologic disease-modifying anti-rheumatic drugs ($\chi^2=1.8$, df=2, p=0.96) in the prospective data on falls between groups of non-fallers, single fallers and multiple fallers.

8.5 Strength and balance baseline assessments

Lower limb muscle strength was measured at baseline using the Chair Stand Test (Guralnik et al., 1994). At the initial assessment, 13% (n=75) were unable to move from sitting to standing in a straight-backed chair without using their arms, whilst 87% (n=484) were able to sit to stand without support.

Participants who were able to move from sitting to standing without support were asked to complete five chair stands as fast as they could and the time to complete this test was recorded (Table 19). The time taken to complete the test was divided into intervals of 10 seconds. Only 39% of the participants (n=188) were able to complete the Chair Stand Test in less than 15 seconds. However most participants (98%) were able to complete the test in under one minute. The mean time taken to complete five chair stands was 20.96 seconds (median=17.9, SD=12.2) with the fastest participant able to complete the test in four seconds and the slowest taking 104 seconds. There were no gender differences found in the ability to complete the Chair Stand Test ($\chi^2$ Trend=0.1, df =1, p=0.7). However men (mean time=19.3 seconds) were significantly faster at completing the five chair stands than women (mean time=21.3 seconds) ($t=-2.3$, p=0.02).
Using the prospective data, the ability to complete the Chair Stand Test was analysed using the groups of non-fallers, single fallers and multiple fallers. It was found that single fallers and multiple fallers were less likely to be able to complete the Chair Stand Test than non-fallers ($\chi^2$ Trend=13.85, df=2, p=<0.001).

Table 19. Time taken to perform five chair stands (seconds) at baseline

<table>
<thead>
<tr>
<th>Time (Seconds)</th>
<th>Unable to complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15</td>
<td>188</td>
</tr>
<tr>
<td>15-25</td>
<td>173</td>
</tr>
<tr>
<td>26-35</td>
<td>72</td>
</tr>
<tr>
<td>36-45</td>
<td>31</td>
</tr>
<tr>
<td>46-55</td>
<td>12</td>
</tr>
<tr>
<td>5-65</td>
<td>3</td>
</tr>
<tr>
<td>&gt;65</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>75</td>
</tr>
</tbody>
</table>

Using the prospective fall data, the time taken to perform five chair stands was analysed using a one-way ANOVA. As Levene’s F statistic was significant (p=0.04), the assumption of homogeneity of variances was not met and the Welch test was used. This showed that there were significant overall differences between the groups’ means (Statistic=4.3, p=0.015). Dunnett T3 post hoc tests showed that non-fallers took significantly less time to complete the five chair stands than multiple fallers (mean difference=4.4, p=0.03) but not single fallers (p=0.2). This suggests that those participants who were able to complete the five chair stands in less time (indicating good lower limb strength) were less likely to fall during the one year follow-up.
8.6 Balance at baseline assessment

Balance was assessed using the Four Test Balance Scale (Rossiter-Fornoff et al., 1995). This involves four timed static balance tasks of increasing difficulty that are completed without assistive devices (such as walking sticks). It is scored from 0-4, with 0 being unable to complete the test and 4 representing a high balance level (being able to stand on one leg). Thirty-nine participants (7.0%) were unable to stand with their feet together unaided and only 31.1% of participants were able to stand on one leg for 10 seconds (Table 20).

Table 20 Four Test Balance Scale at baseline and non-fallers, single fallers and multiple fallers at one year follow-up

<table>
<thead>
<tr>
<th>Balance ability Fail at each level</th>
<th>Total Baseline n (%)</th>
<th>Non-fallers n (%)</th>
<th>Single fallers n (%)</th>
<th>Multiple fallers n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuccessful</td>
<td>39 (7.0)</td>
<td>19 (5.6)</td>
<td>6 (6.4)</td>
<td>11 (10.9)</td>
</tr>
<tr>
<td>Feet together stand</td>
<td>13 (2.3)</td>
<td>5 (1.5)</td>
<td>2 (2.1)</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>Semi-tandem stand</td>
<td>216 (38.6)</td>
<td>127 (37.4)</td>
<td>42 (44.7)</td>
<td>38 (37.6)</td>
</tr>
<tr>
<td>Tandem stand</td>
<td>116 (20.8)</td>
<td>69 (19.7)</td>
<td>20 (21.3)</td>
<td>25 (24.8)</td>
</tr>
<tr>
<td>One leg stand</td>
<td>175 (31.3)</td>
<td>122 (35.9)</td>
<td>24 (25.5)</td>
<td>24 (23.8)</td>
</tr>
<tr>
<td>Total</td>
<td>559</td>
<td>340</td>
<td>94</td>
<td>101</td>
</tr>
</tbody>
</table>
Further analyses to test for gender differences showed that males were significantly more successful in completing the Four Test Balance Scale than females ($\chi^2 = 14.8$, df=1, p=0.005).

The Chi-square test for trend showed that single fallers and multiple fallers were significantly less likely to be able to complete the semi-tandem stand, the tandem stand or the one-leg stand than non-fallers ($\chi^2$ Trend=6.9, df=1, p=0.008).

### 8.7 Comparison of follow-up falls data with baseline characteristics

Participant’s joints were examined to assess for swelling and tenderness based on the 28 joint count (Van Riel and Schumacher, 2001). Although 78% of participants were found to have 7 or less affected joints out of the 28 assessed at baseline (Table 21), the effect on functional ability varied according to the location of the swollen or tender joints. Swollen and tender metacarpophalangeal (MCP), shoulders, knees and wrists appeared to be the most commonly affected joints for participants in this study (Table 22).

**Table 21. Swollen and tender joints at baseline assessment**

<table>
<thead>
<tr>
<th>Number of affected joints</th>
<th>Number with swollen joints (%)</th>
<th>Number with tender joints (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-7</td>
<td>433 (77.5)</td>
<td>436 (78.0)</td>
</tr>
<tr>
<td>8-14</td>
<td>84 (15.0)</td>
<td>64 (11.4)</td>
</tr>
<tr>
<td>15-21</td>
<td>18 (3.2)</td>
<td>24 (4.3)</td>
</tr>
<tr>
<td>22-28</td>
<td>24 (4.3)</td>
<td>35 (6.3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>559 (100.0)</strong></td>
<td><strong>559 (100.0)</strong></td>
</tr>
</tbody>
</table>
Table 22. Types of swollen and tender joints at baseline assessment

<table>
<thead>
<tr>
<th>Type of joint</th>
<th>Swollen joint(s) (%)</th>
<th>Tender joint(s) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoulder joint</td>
<td>155 (27.8)</td>
<td>317 (56.7)</td>
</tr>
<tr>
<td>Elbow joint</td>
<td>93 (16.7)</td>
<td>168 (30.1)</td>
</tr>
<tr>
<td>Wrist joint</td>
<td>255 (45.6)</td>
<td>299 (53.5)</td>
</tr>
<tr>
<td>MCP* (s) joints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>64 (11.4)</td>
<td>86 (15.4)</td>
</tr>
<tr>
<td>2</td>
<td>76 (13.6)</td>
<td>51 (9.1)</td>
</tr>
<tr>
<td>3</td>
<td>90 (16.1)</td>
<td>39 (6.9)</td>
</tr>
<tr>
<td>4</td>
<td>41 (7.3)</td>
<td>60 (10.7)</td>
</tr>
<tr>
<td>5</td>
<td>93 (16.7)</td>
<td>96 (17.1)</td>
</tr>
<tr>
<td>PIP** (s) joints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>35 (6.2)</td>
<td>24 (4.3)</td>
</tr>
<tr>
<td>2</td>
<td>38 (6.8)</td>
<td>22 (3.9)</td>
</tr>
<tr>
<td>3</td>
<td>16 (2.9)</td>
<td>14 (2.6)</td>
</tr>
<tr>
<td>4</td>
<td>38 (6.8)</td>
<td>38 (6.8)</td>
</tr>
<tr>
<td>5</td>
<td>35 (6.2)</td>
<td>50 (8.9)</td>
</tr>
<tr>
<td>DIP*** (s) joints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>26 (4.7)</td>
<td>25 (4.5)</td>
</tr>
<tr>
<td>2</td>
<td>32 (5.2)</td>
<td>16 (2.9)</td>
</tr>
<tr>
<td>3</td>
<td>5 (0.9)</td>
<td>6 (1.1)</td>
</tr>
<tr>
<td>4</td>
<td>16 (2.9)</td>
<td>16 (2.3)</td>
</tr>
<tr>
<td>5</td>
<td>19 (3.4)</td>
<td>24 (4.3)</td>
</tr>
<tr>
<td>Hip joint</td>
<td>2 (0.4)</td>
<td>10 (1.8)</td>
</tr>
<tr>
<td>Knee joint</td>
<td>208 (37.2)</td>
<td>270 (47.3)</td>
</tr>
</tbody>
</table>

*MCP = metacarpophalangeal
**PIP = proximal interphalangeal
***DIP = distal interphalangeal

The number of tender and swollen joints per person were analysed by gender using an independent samples t-test. There were no significant differences in tender (t=-1.6, p=0.1) or swollen joints (t=-1.6, p=0.1), between female and male participants.
A one-way analysis of variance (ANOVA) was used to compare the number of swollen and tender joints in non-fallers, single fallers and multiple fallers enabling the variability between the means to be explored. There were no significant differences in mean number of swollen joints between the three groups (f=2.7, df=2, 532, p=0.07). However there were significant differences found between the three groups in the mean number of tender joints. As the assumption of homogeneity of variance was not met, the Welch test was undertaken and confirmed a significant group difference for the number of tender joints (Statistic=4.2, p=0.017). Using the Dunnett T3 comparison tests, multiple fallers were just short of significance in having higher number of tender points than non-fallers (mean difference=1.9, p=0.07, 95% CI -0.1, 4.1). Participants who reported multiple falls at one year follow-up had a significantly higher number of tender joints at baseline than single fallers (mean difference=2.8, p=0.01, 95% CI 0.5, 5.1). There were no significant differences between the number of tender joints at baseline in single fallers and non-fallers (mean difference=-0.8, p=0.5, 95% CI –2.5, 0.7). This suggests that having greater numbers of tender joints may be associated with falling frequently in people with RA.

8.8 Levels of pain and fatigue at baseline assessment

Participants were asked to score their current level of pain at the baseline assessment on a 10 cm line (VAS), with zero representing no pain to ten representing extreme pain. As fatigue is also an important characteristic of RA and may affect the risk of falls, a fatigue VAS was similarly undertaken at
baseline. The VAS pain mean score and VAS fatigue mean score were analysed by gender of participants using an independent sample t-test (Table 23). There were no significant differences in pain measures between the men and women participants however fatigue was significantly worse in women than men.

Table 23. VAS Pain and fatigue baseline differences by gender in one year follow-up

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Mean (SD)</th>
<th>Mean difference</th>
<th>95% CI for mean difference</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Visual Analogue</td>
<td>Male</td>
<td>3.67 (2.6)</td>
<td>-0.27</td>
<td>-0.74, 0.21</td>
<td>0.270</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>3.94 (2.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue Visual Analogue</td>
<td>Male</td>
<td>4.11 (2.8)</td>
<td>-0.87</td>
<td>-1.37, -0.37</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>5.0 (2.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Using the prospective data, a one-way ANOVA was undertaken to compare baseline pain in the groups of non-fallers, single fallers and multiple fallers. As Levene’s F statistic was not significant (p=0.07), the assumption of homogeneity of variances was met. The ANOVA analysis showed that there were significant
differences between the groups means (p=<0.001). Tukey’s post-hoc test showed that pain scores were significantly higher in multiple fallers (mean difference=1.5, p=<0.001, 95% CI 0.83, 2.20) than non-fallers and compared to single fallers (mean difference=1.1, p=0.006, 95% CI 0.28, 2.01). However, there were no significant differences between single fallers and non-fallers in baseline pain scores (mean difference=0.4, p=0.44, 95% CI –0.34, 1.28).

Fatigue scores were compared using a one-way ANOVA for the prospective data. As Levene’s F statistic was significant (p=<0.001), the assumption of homogeneity of variances was not met. The Welch Test showed that there were significant differences between the group means (Statistic=20.4, p=<0.001). Using Dunnett T3 tests, fatigue scores were shown to be significantly higher in single fallers (mean difference=1.1, p=0.005, 95% CI 0.27, 1.87) and multiple fallers (mean difference=1.6, p=<0.001, 95% CI 1.0, 2.3) than non-fallers. However, there were no significant differences between single fallers and multiple fallers in fatigue scores (mean difference=0.6, p=0.34, 95% CI –1.5, 0.3).

8.9 Painful feet at baseline.

Painful feet were also recorded as a variable that may have an affect on falls risk. The DAS28 swollen and tender joint count did not include the assessment of joints in the feet. Seventy-seven per cent of the participants (n=432) reported painful feet due to RA. Females (n=310, 80.3%) were significantly more likely to report painful feet than males (n=122, 70.5% (χ²=6.7, df=1, p=0.01).
The prospective follow-up data on the groups of non-fallers, single fallers and frequent fallers did not show any significant associations with painful feet ($\chi^2=2.0$, df=2, p=0.36).

### 8.10 Previous joint replacements at baseline.

Overall, 125 (22%) out of the 559 participants had undergone joint replacement surgery prior to the baseline assessment (Table 24). The majority of these were knee and hip replacements with small numbers of participants reporting shoulder, elbow, ankle, wrist and foot or hand surgery to replace damaged joints. Female participants were significantly more likely to have a history of joint replacement surgery than males ($\chi^2=9.9$, df=1, p=0.002).

Using the Chi-square for Trend test, there were no significant differences found between the three groups of non-fallers, single fallers and multiple fallers in the prospective fall data (p=0.6).

<table>
<thead>
<tr>
<th>Joint replacements</th>
<th>Number at baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>430 (77.5)</td>
</tr>
<tr>
<td>Yes</td>
<td>125 (22.5)</td>
</tr>
<tr>
<td>Total</td>
<td>555 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>559</strong></td>
</tr>
</tbody>
</table>
8.11 Disease Activity Scores at baseline

The DAS28 is a measure of the activity of RA and its calculation includes the number of tender and swollen joints out of 28 joints, an erythrocyte sedimentation rate (ESR) and a patient assessment of disease activity (100mm VAS). As described in more detail in the methods, the DAS28 provides pts with a number on a scale from 0 to 10 indicating the current activity of the RA. A DAS28 above 5.1 means high disease activity whereas a DAS28 below 3.2 indicates low disease activity. Remission is achieved by a DAS28 lower than 2.6 (comparable to the American College of Rheumatology remission criteria, Prevoo et al., 1996). Table 25 shows the results of participants within the DAS28 score range.

Table 25. Disease Activity Scores (DAS28) at baseline

<table>
<thead>
<tr>
<th>DAS28 score range</th>
<th>Number of participants at baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.6 (disease remission)</td>
<td>93 (16.6)</td>
</tr>
<tr>
<td>2.6 to 3.2 (low disease activity)</td>
<td>67 (12.0)</td>
</tr>
<tr>
<td>3.3 to 5.1 (moderate disease activity)</td>
<td>256 (45.8)</td>
</tr>
<tr>
<td>&gt; 5.1 (severe disease activity)</td>
<td>143 (25.6)</td>
</tr>
</tbody>
</table>

Both the mean DAS28 score (4.07) and the median score (3.95) of the participants fall within the moderate disease activity range (Std. dev. 1.58).
### Table 26. Disease Activity Score 28 by follow-up fall data

<table>
<thead>
<tr>
<th>DAS28Band</th>
<th>No fall in 1 year follow-up (%)</th>
<th>1 fall in 1 year follow-up (%)</th>
<th>2 falls or more in 1 year follow-up (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 2.6 disease remission</td>
<td>73 (21.5)</td>
<td>8 (8.5)</td>
<td>8 (7.9)</td>
<td>89 (16.6)</td>
</tr>
<tr>
<td>2.6 - 3.2 low disease activity</td>
<td>45 (13.2)</td>
<td>13 (13.8)</td>
<td>7 (96.9)</td>
<td>65 (12.1)</td>
</tr>
<tr>
<td>3.3 - 5.1 moderate disease remission</td>
<td>139 (40.9)</td>
<td>54 (57.4)</td>
<td>52 (51.5)</td>
<td>245 (45.8)</td>
</tr>
<tr>
<td>More than 5.1 severe disease activity</td>
<td>83 (24.4)</td>
<td>19 (20.2)</td>
<td>34 (33.7)</td>
<td>136 (25.4)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>340 (100)</strong></td>
<td><strong>94 (100)</strong></td>
<td><strong>101 (100)</strong></td>
<td><strong>535 (100)</strong></td>
</tr>
</tbody>
</table>

Using an independent samples *t*-test to compare the means between women and men, women were found to have significantly higher DAS28 scores at baseline than men (*t*=-2.4, *p*=0.02, 95% CI – 0.63, - 0.06).

A one-way ANOVA was undertaken to compare the DAS28 mean score between non–fallers, single fallers and multiple fallers using the follow-up data. As Levene’s F statistic was significant (*p*=0.006), the assumption of homogeneity of variances was not met. The Welch test showed that there were significant differences between the group’s means (Statistic=6.4, *p*=0.002). The Dunnett T3 post–hoc test showed that multiple fallers had significantly higher
mean DAS28 scores (mean difference=0.6, p=0.001, 95% CI 0.2, 1.05) than non-fallers. However, there were no significant differences between single fallers and multiple fallers (mean difference=0.5, p=0.07, 95% CI -0.03, 0.9) and single fallers and non–fallers in DAS28 scores (mean difference=0.2, 95% CI -0.2, 0.6, p=0.61). In this sample of participants it appears that follow-up falls are associated with a higher baseline DAS28 score (Table 26).

8.12 Global Health Score (0-100) at baseline

The participants reported their overall health status by marking a 100mm line (0=very bad, 100=very good). The mean global health score for the participants was 41.89 (median=40.00, SD=22.458, range 0-95) indicating overall moderate health. An independent sample t-test showed no significant differences in global health between males and females (t=0.08, p=0.12, 95% CI –2.21, 0.25).

A one-way ANOVA was used to compare global health scores between the groups of non-fallers, single fallers and multiple fallers. As Levene’s F statistic was not significant (p=0.22) the assumption of homogeneity of variance was met. The ANOVA results indicated significant differences between the groups (p=<0.001). Using Tukey comparison tests, it was found that there were no significant differences between the global health scores of non-fallers and single fallers (mean difference=5.5, p=0.08, 95% CI -0.5, 11.5). However global health scores were significantly lower in multiple fallers in comparison to non-fallers (mean difference=13.9, p=<0.001, 95% CI 8.7, 19.7) and single fallers (mean difference=8.4, p=0.02, 95% CI 1.0, 15.7).
8.13 Number of co-morbidities (not including RA) at baseline

The majority of participants suffered from more than one co-morbidity in addition to RA (Table 27). The mean number of co-morbidities was 1.98 (median=2.00). The number of co-morbidities did not significantly differ between gender groups \((t=0.4, \text{ df}=553, p=0.68)\).

Table 27 Types of co-morbidities reported at baseline

<table>
<thead>
<tr>
<th>Type of co-morbidity</th>
<th>Number at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>33 (5.9)</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>82 (14.7)</td>
</tr>
<tr>
<td>Respiratory disease</td>
<td>92 (16.5)</td>
</tr>
<tr>
<td>Depression</td>
<td>22 (4.3)</td>
</tr>
<tr>
<td>Diabetes (Type I or II)</td>
<td>62 (12.3)</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>12 (3.9)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>149 (26.7)</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>40 (7.2)</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>78 (13.9)</td>
</tr>
<tr>
<td>Other rheumatic</td>
<td>38 (6.8)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>21 (3.7)</td>
</tr>
<tr>
<td>Thyroid disease</td>
<td>34 (6.1)</td>
</tr>
</tbody>
</table>

Using a one-way ANOVA test, there were no significant differences found in the number of co-morbidities in the follow-up groups of non-fallers and single fallers \((\text{mean difference}=0.2, p=0.69, 95\% \text{ CI}-0.4, 0.7)\), non-fallers and multiple fallers \((\text{mean difference}=0.3, p=0.29, 95\% \text{ CI}-0.2, 0.9)\) and single fallers and multiple fallers \((\text{mean difference}=0.2, p=0.86, 95\% \text{ CI}-0.5, 0.8)\).
8.14 Vision at baseline

Participants self-recorded the status of their vision (with glasses or contact lenses) as falling within the categories of registered blind, very poor, poor, fair, good or excellent. A small proportion reported their eyesight as either registered blind, very poor or poor (n=46, 8.2%), with the majority of participants reporting their vision as fair (n=145, 25.9%), good (n=313, 56.0%) or excellent (n=55, 9.8%). There were no significant differences in eyesight between males and females ($\chi^2=4.6$, df=5, $p=0.47$). However older age groups were associated with poorer vision than younger age groups ($\chi^2$ Trend=29.4, df=1, $p=<0.001$). There were no significant differences found between the groups of non-fallers, single fallers and multiple fallers in the prospective data ($\chi^2$ Trend=3.1, df=1, $p=0.08$).

8.15 Previous surgery at baseline

The history of previous surgery was recorded by 73% of participants. There was no significant difference found between the history of previous surgery in the male and female participants ($\chi^2=1.8$, df=2, $p=0.18$). There were also no significant differences in the history of previous surgery in the prospective data on non-fallers, single fallers and multiple fallers ($\chi^2=1.7$, df=2, $p=0.44$).

8.16 History of fractures at baseline

Over a third of participants (41%) reported a history of fracture, with upper and lower limbs most affected (Table 28). There were eight fractures of the pelvis (1.4%) and four hip fractures (0.7%) that would have been severely debilitating
for persons with RA and may have led to further muscle weakness and increased the risk of falling.

Table 28. Self-reported types of previous fracture

<table>
<thead>
<tr>
<th>Type of fracture</th>
<th>Number of participants at baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skull</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>Clavicle</td>
<td>9 (1.7)</td>
</tr>
<tr>
<td>Neck</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Shoulder</td>
<td>9 (1.6)</td>
</tr>
<tr>
<td>Ribs</td>
<td>16 (2.9)</td>
</tr>
<tr>
<td>Elbow</td>
<td>10 (1.8)</td>
</tr>
<tr>
<td>Arm</td>
<td>43 (7.7)</td>
</tr>
<tr>
<td>Wrist</td>
<td>59 (10.5)</td>
</tr>
<tr>
<td>Hand</td>
<td>33 (5.9)</td>
</tr>
<tr>
<td>Pelvis</td>
<td>8 (1.4)</td>
</tr>
<tr>
<td>Hip</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>Leg</td>
<td>45 (8.0)</td>
</tr>
<tr>
<td>Ankle</td>
<td>37 (6.6)</td>
</tr>
<tr>
<td>Foot</td>
<td>29 (5.2)</td>
</tr>
</tbody>
</table>

The variable, “history of fractures” was analysed by gender of participants using Pearson’s Chi-square test. Males were found to be significantly more likely to have a history of fracture(s) than females, ($\chi^2=9.4$, df=1, p=0.002). An association was found with single and multiple fallers more likely to have a history of fracture than non-fallers ($\chi^2$ Trend=4.3, df=1, p=0.008).

8.17 Health Assessment Questionnaire (HAQ) total score at baseline

Participants completed the HAQ as part of the assessment of their functional capacity in their daily activities. In the total sample the total HAQ score mean
was 2.44 (median=2.43, SD=0.852), this indicates overall moderate difficulty for the participants in performing activities of daily living (overall HAQ score range = 1.00 – 4.00, low scores indicate the person can function without difficulty).

Table 29 demonstrates the level of ability in the individual category scores with the mean scores reflecting that participants have at least some, and largely much difficulty in performing the various activities of daily living. Fine motor skills such as being able to open a milk carton or to turn taps on and off caused much difficulty in this group of patients, explained by swollen and tender hand joints. The ability to independently take a bath, carry out errands and do chores in the house and garden was also a problem for the majority of the participants.

The independent samples t-test was used to analyse the total HAQ score means between the groups of males and females. There were no gender differences in mean HAQ scores (t=-4.9, p=0.98, 95% CI –0.54, -0.23).

In the prospective data, a one-way ANOVA was used to compare total HAQ score by groups of non-fallers, single fallers and multiple fallers to explore variability between the means. As Levene’s F statistic had a significance value of 0.8, the assumption of homogeneity of variance was met and the ANOVA analysis showed that there were significant differences between the groups (p=<0.001). The Tukey post-hoc test was used to test the differences between the groups. Single fallers had a just short of significantly higher mean HAQ score than non-fallers (mean difference=0.2, p=0.06, 95% CI -0.44, – 0.01) and multiple fallers had a significantly higher mean HAQ score than single fallers.
(mean difference=0.3, p=0.001, 95% CI 0.29, 0.72) and non-fallers (mean difference=0.5, p=0.04, 95% CI 0.01, 0.56).

Table 29. Mean, SD and median HAQ scores for individual response items (0-3)

<table>
<thead>
<tr>
<th>HAQ item score</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing score</td>
<td>2.32</td>
<td>0.98</td>
<td>2.00</td>
</tr>
<tr>
<td>Rising score</td>
<td>1.88</td>
<td>0.94</td>
<td>2.00</td>
</tr>
<tr>
<td>Eating score</td>
<td>2.71</td>
<td>1.03</td>
<td>3.00</td>
</tr>
<tr>
<td>Walking score</td>
<td>2.10</td>
<td>0.94</td>
<td>2.00</td>
</tr>
<tr>
<td>Hygiene score</td>
<td>2.83</td>
<td>1.15</td>
<td>3.00</td>
</tr>
<tr>
<td>Gripping score</td>
<td>2.25</td>
<td>0.93</td>
<td>2.00</td>
</tr>
<tr>
<td>Activity score</td>
<td>2.70</td>
<td>1.15</td>
<td>3.00</td>
</tr>
</tbody>
</table>

8.17.1 Use of aids or assistance from carers

The majority of the participants required the use of assistive devices or help from carers for dressing, grooming, eating or walking (Table 30 and Table 31). Assistance was also notably required from carers in areas of gripping, bathing and for errands. Some kind of walking aid was used by 43.8% of the participants such as a walking stick, walking frame, crutches or a wheelchair.
Table 30. Individual responses to questions on aids

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special or built up chair</td>
<td>146 (26.3)</td>
<td>410 (73.7)</td>
</tr>
<tr>
<td>Built up or special utensils</td>
<td>114 (20.5)</td>
<td>442 (79.5)</td>
</tr>
<tr>
<td>Stick</td>
<td>155 (27.9)</td>
<td>401 (72.1)</td>
</tr>
<tr>
<td>Walking frame</td>
<td>15 (2.7)</td>
<td>541 (97.3)</td>
</tr>
<tr>
<td>Crutches</td>
<td>26 (4.7)</td>
<td>530 (95.3)</td>
</tr>
<tr>
<td>Wheelchair</td>
<td>47 (8.5)</td>
<td>509 (91.5)</td>
</tr>
<tr>
<td>Raised toilet seat</td>
<td>127 (22.8)</td>
<td>429 (77.2)</td>
</tr>
<tr>
<td>Bath seat</td>
<td>98 (17.6)</td>
<td>458 (82.4)</td>
</tr>
<tr>
<td>Bath rail</td>
<td>121 (21.8)</td>
<td>435 (78.2)</td>
</tr>
<tr>
<td>Long-handled appliances</td>
<td>51 (9.2)</td>
<td>505 (90.8)</td>
</tr>
<tr>
<td>for bathroom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-handled appliances</td>
<td>138 (24.8)</td>
<td>418 (75.2)</td>
</tr>
<tr>
<td>for reaching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jar opener</td>
<td>249 (44.8)</td>
<td>307 (55.2)</td>
</tr>
</tbody>
</table>


Table 31. Individual responses to questions about carers

<table>
<thead>
<tr>
<th></th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any help from another person with dressing, grooming, rising or walking</td>
<td>278 (50.0)</td>
<td>278 (50.0)</td>
</tr>
<tr>
<td>Any help from another person with dressing, grooming</td>
<td>236 (42.4)</td>
<td>320 (57.6)</td>
</tr>
<tr>
<td>Any help from another person with eating</td>
<td>187 (33.6)</td>
<td>369 (66.4)</td>
</tr>
<tr>
<td>Any help from another person with rising</td>
<td>106 (19.1)</td>
<td>450 (80.9)</td>
</tr>
<tr>
<td>Any help from another person with walking</td>
<td>121 (21.8)</td>
<td>435 (78.2)</td>
</tr>
<tr>
<td>Any help required by another person with bathing, using the toilet etc</td>
<td>411 (73.8)</td>
<td>146 (26.2)</td>
</tr>
<tr>
<td>Any help from another person with hygiene</td>
<td>169 (30.3)</td>
<td>388 (69.7)</td>
</tr>
<tr>
<td>Any help from another person with reaching</td>
<td>229 (41.1)</td>
<td>328 (58.9)</td>
</tr>
<tr>
<td>Any help from another person with gripping</td>
<td>368 (66.1)</td>
<td>189 (33.9)</td>
</tr>
<tr>
<td>Any help from another person with errands</td>
<td>354 (63.6)</td>
<td>203 (36.4)</td>
</tr>
</tbody>
</table>

8.18 Summary of baseline patient characteristics and fall risk factor and prospective data analyses

In summary, there were large numbers of participants (77%) taking four or more types of medication, with 19% taking psychotropic medicines and 84% reporting a history of taking steroids. Sixty-six percent of participants complained of
feeling dizzy or unsteady at the baseline assessment and only 39% participants were able to complete five chair stands in less than 15 seconds. Just 31% participants were able to successfully complete all of the levels for the Four Test Balance Scale (one-leg stand) and these tests indicate that lower limb strength and balance may be considerably impaired in people with RA. Pain, fatigue, DAS28 and global health scores were all in the moderate range and over two thirds of participants reported painful feet (77%) at the baseline assessment. Over a third of participants reported a history of fracture (41%) and the mean HAQ scores indicated moderate functional ability.

Chapter 10 provides a full summary of the fall risk factor and gender/prospective/retrospective data analyses to enable a clear and comprehensive overview of the findings. Prior to this, the next chapter reports the retrospective data and risk factor analyses
CHAPTER 9

9. Retrospective falls data results

This chapter presents the retrospective data (one year history of falls) to investigate any differences or consistencies in comparison to the one year history of falls and risk factors for falls data.

9.1 Fear of falling and retrospective data

An ANOVA test (Levene’s F statistic was not significant (p=0.32) therefore the assumption of homogeneity of variances was met), showed that there were significant differences between the three groups means (p=<0.001). It was found that participants with a one year history of a single fall did not significantly differ in mean baseline FES-I score than participants without a one year history of falls (mean difference=1.7, p=0.10, 95% CI -0.3, 3.8). Participants with a one year history of multiple falls had a significantly higher mean baseline FES-I score than those who reported single falls (mean difference=2.9, p=0.01, 95% CI 0.5, 5.4) and no falls (mean difference=4.7, p=<0.001, 95% CI 2.6, 6.7), but clinically these differences are small. The box plot in Figure 6 clearly demonstrates these results.
An ANOVA test was repeated using the one year follow-up mean FES-I score and the one year history of falls data. As Levene’s F statistic was not significant (p=0.49) the assumption of homogeneity of variances was met. The ANOVA analysis again showed that there were significant differences between the three groups means (p=<0.001) and it was found that participants with a one year history of a single fall did not significantly differ in mean follow-up FES-I score than participants without a one year history of falls (mean difference=1.8, p=0.20, 95% CI -0.4, 4.0). Participants with a one year history of multiple falls did not differ significantly in mean follow-up FES-I score than those who
reported single falls (mean difference=1.9, p=0.22, 95% CI -0.8, 4.6). However, participants with a one year history of multiple falls has a significantly higher mean one year follow-up mean FES-I score than those with a one year history of no falls (mean difference=3.7, p=<0.001, 95% CI 1.5, 5.9). This last result was the only small difference between the history of falls data and the follow-up falls data when analysed by baseline and follow-up Short FES-I mean scores.

9.2 Falls Risk Assessment Tool (FRAT) and one year history of falls

The chi–square test for trend analysis for those with a one year history of no-falls, single falls and multiple falls was just short of significance when testing the associations with taking four or more types of medicines ($\chi^2$ Trend=3.6, df=1, p=0.058). There were no significant associations found between a history of stroke or Parkinson’s disease and one year history of falling ($\chi^2$ Trend=2.9, df=1, p=0.09). However, there was a positive linear association between those with a one year history of single falls and multiple falls and taking medicines for sleeping, anxiety or depression ($\chi^2$ Trend=20.2, df=1, p=<0.001) and complaints of feeling dizzy or unsteady at the baseline assessment ($\chi^2$ Trend=41.9, df=1, p=<0.001).

9.3 Lower limb strength assessment – ability to complete and time taken for the Chair Stand Test with retrospective fall data

It was found that participants reporting a one year history of a single fall and multiple falls were less likely to be able to complete the Chair Stand Test than non-fallers ($\chi^2$ Trend=13.5, df=1, p=<0.001). In addition, the non-parametric
Kruskal–Wallis test showed that participants with no history of falls were able to complete the Chair Stand Test in significantly less time than those who fell once or more (H=26.5, df=2, p=<0.001). These results were consistent with the prospective results and suggest that poor lower limb strength may be associated with falls.

9.4 Balance at baseline assessment with retrospective fall data

The chi-square test for trend showed that participants with a one year history of falling once or more were significantly less likely to be able to complete the semi-tandem stand, the tandem stand or the one-leg stand for the Four Test Balance Scale ($\chi^2$ Trend=19.4, df=1, p=<0.001), than participants who did not report a fall in the previous year. This is consistent with the prospective results and suggests that poorer balance may be associated with falls.

9.5 Swollen and tender joints at baseline and retrospective fall data

A one-way analysis of variance (ANOVA) was repeated using the retrospective data to compare any differences in the groups (one year history of non-fallers, single fallers and multiple fallers). There were no significant differences in mean number of swollen joints between the three groups (p=0.07) and this was consistent with the prospective data.

However, there were significant differences found between the three groups in the mean number of tender joints. As the assumption of homogeneity of variances was not met the Welch test was undertaken which showed that there
were significant differences between the three groups means (Statistic=4.2, p=0.004). The Dunnett T3 post–hoc tests showed that those with a one year history of single falls were just short of significance in having a higher number of tender points than non–fallers (mean difference=1.7, p=0.06, 95% CI -3.6, 0.7). Participants with a one year history of multiple falls had a significantly higher number of tender joints than those non-fallers (mean difference=2.2, p=0.01, 95% CI 0.4, 4.1). There were no significant differences between the number of tender joints in single fallers and multiple fallers (mean difference=0.5, p=0.95, 95% CI –1.8, 2.8).

9.6 **Levels of pain and fatigue at baseline and retrospective fall data**

Using the retrospective data, a one-way ANOVA was undertaken to compare baseline pain in the groups (one year history of non-fallers, single fallers and multiple fallers). The ANOVA analysis showed that there were significant differences between the group’s means (p=0.001). The Tukey’s post–hoc test showed that the pain scores were significantly higher in multiple fallers (mean difference=1.2, p=0.001, 95% CI 0.58, 1.88) than non-fallers. There were no significant differences between single fallers and multiple fallers in baseline pain scores (mean difference=0.6, p=0.23, 95% CI –1.34, 0.24), similar to the prospective data. However, unlike the prospective data, those with a one year history of a single fall (mean difference=0.7, p=0.04, 95% CI 0.02, 1.33) were also found to have significantly higher pain score than non-fallers, although clinically this difference was small.
Fatigue scores were compared using a one-way ANOVA for the retrospective data. The retrospective data showed similar results to the prospective data: Fatigue scores were significantly higher in participants with a one year history of a single fall (mean difference=1.0, p=0.02, 95% CI -1.71, -0.31) and multiple falls (mean difference=1.7, p=<0.001, 95% CI -2.4, -1.1) than non-fallers. Again, there were no significant differences between those with a one year history of single falls and multiple fallers in fatigue scores (mean difference=0.7, p=0.09, 95% CI –1.5, 0.1).

9.7 Painful feet and one year history of falls

However, when analysing the one year history of falls by painful feet, the Chi-square for Trend was just short of significance level at the 0.05 level, as the percentage of participants with painful feet increased in both groups of single fallers and multiple fallers ($\chi^2$ Trend=3.8, df=1, p=0.05), similar to the prospective data.

9.8 Previous joint replacements and one year history of falls.

Using the Chi-square for Trend test, there were no significant differences found between the three groups (one year history of non-fallers, single fallers and multiple fallers) in the number of previous joint replacements in the retrospective fall data ($\chi^2$ Trend= 0.5, df=1, p=0.51) and this was also found in the prospective data.
9.9 Disease Activity Scores and one year history of falls

The analysis was repeated using the retrospective fall data to check for
differences or consistencies in the results. In this case, Levene’s F statistic was
not significant (p=0.48) and so the assumption of homogeneity of variances was
met. The ANOVA analysis showed that there were significant differences
between the three groups means (p=<0.001). Unlike the prospective data, the
Tukey’s post–hoc test showed that the DAS28 mean scores were significantly
higher in single fallers (mean difference=0.6, p=<0.001, 95% CI 0.16, 0.95) than
non-fallers. However, consistencies were found with multiple fallers associated
with higher DAS28 scores (mean difference=0.7, p=<0.001, 95% CI 0.29, 1.06)
than non-fallers. Similar to the prospective data, there were no significant
differences between single fallers and multiple fallers in DAS28 scores (mean
difference=0.1, p=0.82, 95% CI -0.4, 0.6).

9.10 Number of medicines and one year history of falls

Using the retrospective data on one year history of falls, as Levene’s F statistic
was significant (p=<0.001) the assumption of homogeneity of variances was not
met. However, unlike the prospective data, the Welch test showed that there were
no significant differences between the group means (Statistic=2.5, p=0.09)
between those with a one year history of no–fall and single fallers (mean
difference=0.1, p=0.9, 95% CI -0.9, 0.7) or non-fallers and multiple fallers (mean
difference=0.9, p=0.1, 95% CI -0.2, 2.1) or between single and multiple fallers
(mean difference=1.1, p=0.1, 95% CI -0.2, 2.4). In the prospective data, the mean
difference between the non-fallers and multiple fallers was 1.8 (p=<0.001) and although this was statistically significant, a difference of less than two medicines was clinically small.

9.11 Use of steroid medication and one year history of falls

There were found to be no significant differences in the baseline use of steroids and the one year history of falling data ($\chi^2=1.57, \text{ df}=2, p=0.46$), which was different to the prospective results. However, comparable to the prospective results, there were no associations found between participants with a history of steroid use ($\chi^2=1.47, \text{ df}=2, p=0.48$) in the groups of one year history of non-fallers, single fallers and multiple fallers.

9.12 Types of prescribed medicines at baseline assessment and retrospective fall data

In the retrospective data on falls, there were no significant differences in the use of cardiovascular drugs ($\chi^2=3.99, \text{ df}=2, p=0.14$) or biologic disease-modifying anti-rheumatic drugs ($\chi^2=2.8, \text{ df}=2, p=0.25$) and this was consistent with the prospective results.

However, participants with a one year history of single or multiple falls were significantly more likely to be taking non-biologic disease-modifying anti-rheumatic drugs at baseline than non–fallers ($\chi^2=7.9, \text{ df}=2, p=0.02$) which was different to the prospective results.
9.13 **Global Health Score (0-100) and retrospective fall data**

The ANOVA analysis was used with the global health score data and one year history of non-fallers, single fallers and multiple fallers groups to check for differences with the prospective falls data. The results were consistent, with no significant differences between the global health scores of participants with a one year history of no-falls and single falls (mean difference=5.2, \( p=0.06 \), 95% CI=-0.1, 10.6). Global health scores were significantly higher in participants with a one year history of multiple falls in comparison to non-fallers (mean difference=12.1, \( p=<0.001 \), 95% CI 6.0, 18.1) and were borderline significantly higher in single fallers (mean difference=6.8, \( p=0.05 \), 95% CI -0.03, 13.7).

9.14 **Co-morbidities (not including RA) and retrospective fall data**

Differences in the number of co-morbidities were explored in the one year history of falling data. As Levene’s F statistic was significant (\( p=0.002 \)) the assumption of homogeneity of variance was not met. The Welch test indicated significant differences between the groups (Statistic=5.2, \( p=0.006 \)). There were no significant differences between the number of co-morbidities for participants with a one year history of no falls and single falls (mean difference=0.1, \( p=0.93 \), 95% CI -0.4, 0.6). However there were significantly higher numbers of co-morbidities in multiple fallers in comparison to non-fallers (mean difference=0.8, \( p=0.004 \), 95% CI 0.2, 1.3) but not with single fallers (mean difference=0.7, \( p=0.06 \), 95% CI -0.03, 1.3), although these differences (less than 1 co-morbidity) are not clinically large and the type of disease may have more clinical
importance if it was associated with falls (e.g. Stroke). These results are slightly different than the prospective data where no significant differences were found between the follow-up non-fallers, single fallers and multiple fallers and the number of co-morbidities.

9.15 Vision and retrospective fall data
Those with very poor, poor or fair eyesight were significantly more likely to have recorded a one year history of falling once or more, than those with good or excellent eyesight ($\chi^2$ Trend=4.3, df=1, p=0.04). These findings were not present in the prospective data where there were no significant differences between the groups.

9.16 Previous surgery and retrospective fall data
There were no significant differences in the history of previous surgery with participants with a one year history of no falls, single falls or multiple falls ($\chi^2$=2.6, df=2, p=0.26) and this was found to be consistent with the prospective data.

9.17 History of fractures and one year history of falls
There were no significant differences found between participants with a history of fracture(s) when analysed by groups of one year history of non-fallers, single fallers and multiple fallers ($\chi^2$ Trend=4.7, df=2, p=0.10). This was different to the prospective data where single and multiple fallers were associated with a history of fracture(s).
9.18 Health Assessment Questionnaire (HAQ) total score and retrospective fall data

A one-way ANOVA analysis was used to compare with total HAQ score by groups of one year history of non falls, single falls and multiple falls. The assumption of homogeneity was met (p=0.21) and the ANOVA analysis confirmed that there were significant differences between the groups (p=<0.001). Previous one year single fallers had a significantly higher mean total HAQ score than previous one year non-fallers (mean difference=0.25, p=0.01, 95% CI 0.04 – 0.46) and previous one year multiple fallers had a significantly higher mean total HAQ score than previous one year single fallers (mean difference=0.4, p=0.001, 95% CI 0.42, 0.84) and non-fallers (mean difference=0.6, p=<0.001, 95% CI 0.13, 0.63). These results were consistent with the prospective results.

To summarise, this chapter has reported the results from the fall risk factor and retrospective fall data analyses and compared these results with the prospective data findings. The following chapter will provide a clear summary of these findings to present a comprehensive outline of these detailed results.
10. Summary of prospective and retrospective fall risk factor results

This chapter provides a summary of the consistencies and differences in the prospective and retrospective fall risk factor results.

It is striking and encouraging that there are so many similarities in the prospective and retrospective fall risk factor results. Many of the results are also in line with previous research and what would be reasonably expected in a group of participants with a disabling condition. The results from the following variables gave the same results in both the prospective and retrospective data analyses:

- Ability to complete the Chair Stand Test – non-fallers were significantly more likely to be able to complete the 5 chair stands than single or multiple fallers.
- Time taken to complete the Chair Stand Test – non-fallers were significantly faster at completing the 5 chair stands than single and multiple fallers.
- Four test balance scale – single and multiple fallers were significantly less likely to be able to complete the more difficult semi-tandem, tandem and one-leg stands than non-fallers.
- Fear of falling FES-I Score was significantly higher in multiple fallers than single and non-fallers.
• Taking psychotropic medicines were significantly more prevalent in single and multiple fallers than non-fallers.

• Feeling dizzy or unsteady at the baseline assessment was significantly more prevalent in single and multiple fallers than non-fallers.

• VAS fatigue scores were significantly higher with single and multiple fallers than non-fallers.

• Global health scores were significantly higher with multiple fallers than non–fallers.

• Painful feet were prevalent in the sample but not significantly associated in any one group of single, multiple or non–fallers.

• Number of joint replacement(s) was not significantly associated with any one group of single, multiple or non–fallers.

• Taking biologic disease-modifying anti - rheumatic drugs at baseline assessment was also not significantly associated with any one group of single, multiple or non–fallers.

• Taking cardiovascular medication at baseline assessment was not significantly associated with any one group of single, multiple or non–fallers.

• History of previous surgery was not significantly associated with any one group of single, multiple or non–fallers.

• Health Assessment Questionnaire (HAQ) functional scores were significantly higher in single and multiple fallers than non-fallers.
10.1 **Minor differences between prospective and retrospective data.**

There were some small differences between some of the prospective and retrospective data that still gave overall very similar results.

- In the prospective data multiple fallers had significantly more tender joints than single fallers but were just short of significance for the non-fallers. However, in the retrospective data multiple fallers had significantly more tender joints than the non-fallers, but not the single fallers.

- Pain levels were significantly higher in the multiple fallers than single and non-fallers in the prospective data, whilst in the retrospective results pain was higher in the single and multiple fallers compared to the non-fallers.

- Mean disease activity scores (DAS28) were significantly higher in the multiple fallers than non-fallers in the prospective data, but were significantly higher in both the single and multiple fallers in the retrospective results. However overall these differences were clinically small.

10.2 **Associations found in prospective but not retrospective results**

There were significant associations found in the prospective results for four variables that were not found to be significant in the retrospective results.

- In the prospective data single and multiple fallers were more likely to have a history of Parkinson’s disease or stroke whilst no significance was found in the retrospective data. The small numbers of participants
affected by Parkinson’s disease or stroke may have resulted in the results being under powered to detect differences in this variable.

- A history of fractures was found to be significantly higher in single and multiple fallers in the prospective data, but no significant differences were found in the retrospective data. Again, the small number of participants affected by previous fractures may have affected these results.

- Multiple fallers were significantly more likely to have a mean higher numbers of medications than single and non-fallers in the prospective data but no significant associations were found in the retrospective data.

- Single and multiple fallers were more likely to be taking steroid medication at baseline than non-fallers but no significant associations were found in the retrospective results.

10.3 **Associations found in retrospective but not prospective results**

There were just three variables with significant associations found in the retrospective results but not in the prospective data.

- Participants with a one year history of a single or multiple falls were more likely to be taking non-biologic disease-modifying anti-rheumatic drugs (DMARDs), but no associations were found in the 12 month follow–up data.

- Participants with a one year history of multiple falls had higher numbers of co-morbidities than those with a one year history of single or no falls but again this was not confirmed in the prospective data.
- Participants with very poor, poor or fair eyesight were significantly more likely to have a one year history of fall(s) than those with good or excellent eyesight but these associations were not found in the follow-up data.

The smaller numbers of participants affected by these variables may have affected the validity and reliability of the results and so further studies with larger sample are required to confirm these results.

10.4 Summary of significant gender differences

There were significant differences between gender for ten of the measured variables in the study.

- Women had higher levels of fear of falling in both the prospective and cross-sectional/retrospective data.
- Women also had higher levels of fatigue and were more likely to feel dizzy or unsteady at the baseline assessment.
- Women were more likely to be taking psychotropic drugs and had a history of more joint replacements than males.
- Women were also more likely to suffer from painful feet and have higher disease activity scores (DAS28) than males.
- Men were more likely to be able to complete the four test balance scale (but were equally as good as the females at reaching the levels of varying degrees of difficulty).
- Men were also more likely to have a history of fracture(s).
In summary, chapter ten has provided a clear overview of the consistencies and differences between the prospective and retrospective data and fall risk factor analyses. The following chapter will present the self-reported fall event circumstances and consequences that were recorded during the one year follow-up telephone calls.
11. Self-reported fall event circumstances and consequences

The following descriptive results summarise the one year follow-up data that was collected on the self-reported falls to gain as much detail as possible on the possible causality, consequences and types of falls affecting adults with RA.

11.1 Fall event descriptions

The self-reported fall descriptions (n=598) were recorded and later categorised into types of falls and reasons for falls. Seventeen participants could not remember the full details of the fall at the time of the follow-up telephone call.

The commonly reported types of falls were hips or knees or ankles, “giving way” (n=187, 31.3%) or slips/trips forward on a level (n=101, 17.7%) or uneven surface (n=96, 16.8%). Falls due to loss of balance were also a problem for 9.8% of participants (n=56), as were slips or trips going upstairs (n=25, 4.4%) or downstairs (n=21, 3.7%). Smaller proportions of falls were described as falls sideways, slips/trips backwards on level or rough surfaces and falls getting out of bed or the bath (Table 32).
### Table 32. Self-reported type of fall

<table>
<thead>
<tr>
<th>Type of fall</th>
<th>Number of falls (%)</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can't remember</td>
<td>33 (5.8)</td>
<td>3.9, 7.7</td>
</tr>
<tr>
<td>Slip/trip forward on level surface</td>
<td>101 (17.7)</td>
<td>14.1, 20.1</td>
</tr>
<tr>
<td>Slip/trip forward on rough surface</td>
<td>96 (16.8)</td>
<td>13.3, 19.2</td>
</tr>
<tr>
<td>Slip/trip backwards on level surface</td>
<td>6 (1.1)</td>
<td>0.5, 2.2</td>
</tr>
<tr>
<td>Slip/trip backwards on rough surface</td>
<td>13 (2.3)</td>
<td>1.3, 3.7</td>
</tr>
<tr>
<td>Slip/trip going upstairs</td>
<td>25 (4.4)</td>
<td>2.9, 6.1</td>
</tr>
<tr>
<td>Slip/trip going downstairs</td>
<td>21 (3.7)</td>
<td>2.3, 5.31</td>
</tr>
<tr>
<td>Fall sideways</td>
<td>15 (2.6)</td>
<td>1.5, 4.1</td>
</tr>
<tr>
<td>Hip/knee/ankle gave way</td>
<td>187 (31.3)</td>
<td>27.7, 35.1</td>
</tr>
<tr>
<td>Lost balance</td>
<td>56 (9.8)</td>
<td>7.3, 11.9</td>
</tr>
<tr>
<td>Fell getting out of bed</td>
<td>7 (1.2)</td>
<td>0.6, 2.4</td>
</tr>
<tr>
<td>Fell getting out of bath</td>
<td>11 (1.8)</td>
<td>1.0, 3.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>571 (100.0)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Missing</strong></td>
<td><strong>27</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 11.2 Falls reportedly due to joints giving way

A large proportion of falls related to reports of joints giving way (n=187, 31.3%). This category was investigated in more detail by going back to the primary data and recoding as a new variable. The most commonly affected joints were the knees (42%) with some participants reporting both hip and knee (3%) or ankle and knee joints (9%) giving way prior to the falls. Nearly half of the falls due to knee joints giving way resulted in moderate or serious injury (47%). Participants were unable to clearly describe the type of joint(s) affected in 25% percent of these falls and were only able to say that their, “legs gave way”. Ankle joints giving way affected 16% of these falls, with 76% of these fall resulting in
moderate or serious injury. Hip joints giving way affected the smallest proportion of participants at 5% with only 20% resulting in moderate injuries.

11.3 Self-reported reasons for falls

Table 33 summarises the self-reported reasons given by participants for their fall(s). The majority of the participants affected by falls blamed their RA for the underlying reason that caused the fall (n=356, 63.3%). Over half of these falls resulted in moderate injuries (n=182, 51.1%) and 7% (n=25) resulted in serious injuries (e.g. fractures or hospitalisation). Falls related to RA were described in different ways such as joint pain, weakness in joints or muscles, joints giving way or a flare-up of the condition. Some participants were unable to explain why they had fallen but felt that the fall was related to the RA.

Tripping over hazards was the next most commonly described reason for fall (n=105, 18.7%), and the majority of these types of falls resulted in moderate or serious injuries (n=61, 58.1%). A number of participants had recently undergone joint replacement surgery (n=9, 1.6%) and associated their fall with weakness following the surgery. Dizziness, feeling generally unwell and tripping over hazards were also commonly reported reasons for falls. Only one person related their fall to hypotension and it was not known whether the falls reported due to dizziness were actually hypotensive events. Neurological disorders such as epilepsy or transient ischaemic attacks were also reported by four participants with a total of 12 falls. Other falls not related to RA were slips on ice, rushing or
losing concentration, although in some cases the RA could be a contributory factor and affect response times and the ability to regain balance.

Table 33. Self-reported reason for fall in one year follow-up

<table>
<thead>
<tr>
<th>Reason for fall</th>
<th>Number of falls</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RA</td>
<td>356 (63.3)</td>
<td>55.5 to 63.4</td>
</tr>
<tr>
<td>Hypotension</td>
<td>1 (0.2)</td>
<td>0.0 to 0.95</td>
</tr>
<tr>
<td>Tripped over hazard</td>
<td>105 (18.7)</td>
<td>14.7 to 20.8</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>7 (1.2)</td>
<td>0.6 to 2.4</td>
</tr>
<tr>
<td>Transient ischaemic attack/Stroke</td>
<td>5 (0.9)</td>
<td>0.3 to 2.0</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>21 (3.7)</td>
<td>2.3 to 5.3</td>
</tr>
<tr>
<td>Slipped on ice</td>
<td>17 (3.0)</td>
<td>1.9 to 4.7</td>
</tr>
<tr>
<td>Feeling generally unwell</td>
<td>14 (2.5)</td>
<td>1.4 to 3.8</td>
</tr>
<tr>
<td>Recent surgery</td>
<td>9 (1.6)</td>
<td>0.8 to 2.9</td>
</tr>
<tr>
<td>Momentary lapse of concentration</td>
<td>8 (1.4)</td>
<td>0.7 to 2.6</td>
</tr>
<tr>
<td>Rushing</td>
<td>7 (1.2)</td>
<td>0.6 to 2.4</td>
</tr>
<tr>
<td>Difficulty with visibility at night</td>
<td>6 (1.1)</td>
<td>0.5 to 2.2</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5 (0.9)</td>
<td>0.3 to 2.0</td>
</tr>
<tr>
<td>Fainted</td>
<td>1 (0.2)</td>
<td>0.0 to 0.95</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>562 (100.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Missing</strong></td>
<td>36</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>598</td>
<td></td>
</tr>
</tbody>
</table>
The majority of the falls took place inside the participants’ houses on a level surface such as in the kitchen, or going up or down stairs (n=385, 68.5 %) and it is likely that this is where the participants spent most of their time carrying out daily activities, particularly as over half were retired from work. A substantial number of participants fell outside their home or outside going up or down steps (n=177, 31.5%). Table 34 shows the self-reported locations of the participants’ falls.

Table 34. Self-reported location of fall

<table>
<thead>
<tr>
<th>Location of fall</th>
<th>Number of falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fell inside house on flat surface</td>
<td>314 (55.9)</td>
</tr>
<tr>
<td>Fell outside house on flat surface</td>
<td>168 (29.9)</td>
</tr>
<tr>
<td>Fell in hospital/Nursing home inside</td>
<td>5 (0.9)</td>
</tr>
<tr>
<td>Fell on holiday indoors</td>
<td>14 (2.5)</td>
</tr>
<tr>
<td>Fell getting out of bed at home</td>
<td>7 (1.2)</td>
</tr>
<tr>
<td>Fell inside house going upstairs</td>
<td>21 (3.7)</td>
</tr>
<tr>
<td>Fell inside house going downstairs</td>
<td>21 (3.7)</td>
</tr>
<tr>
<td>Fell outside going upstairs</td>
<td>7 (1.2)</td>
</tr>
<tr>
<td>Fell outside going downstairs</td>
<td>2 (0.3)</td>
</tr>
<tr>
<td>At work inside</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Total</td>
<td>562 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>36</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
</tr>
</tbody>
</table>

After analysing the severity of injury by indoor or outdoor falls, it was found that significantly more outdoor falls resulted in moderate or severe injury (72%) in comparison to indoor falls (55%, χ²=14.1, df=2, p=<0.001). This may be due to
the more vigorous types of activities undertaken outdoors in comparison to indoors or the less predictable environment or hazards.

The participants were asked to recall the amount of time they spent on the floor or lower level following the fall, to enable the estimated lie-time to be calculated. Most lie–times were short with 89.3% (n=448) participants able to stand up again in less than 10 minutes. The median lie time was 2 minutes (mean=7 mins, interquartile range = 0 to 5 mins). There were small numbers of longer lie times (> 60 mins) where participants required further assistance from medical personnel due to the severity of the fall (n=6, 1.0%).

11.4 Injuries and consequences of falls
Injuries were recorded and then graded according to the severity as recommended by Schwenk et al., (2012), using Campbell et al.’s methods (1997)(Table 35). Many falls did not result in an injury or were so minor that they were categorised as no injury (n=231, 40.9%). However, over half (n=291, 51.5%) resulted in bruising, stiffness and exacerbated joint pains, sprains, head injuries (not requiring hospitalisation) and were recorded as moderate injuries. Severe injuries included fractures and injuries requiring further assessment and treatment in hospital (n=43, 7.6%).
Table 35. Severity of injury

<table>
<thead>
<tr>
<th>Grade of injury</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No injury</td>
<td>231 (40.9)</td>
</tr>
<tr>
<td>Moderate injury</td>
<td>291 (51.5)</td>
</tr>
<tr>
<td>Serious injury</td>
<td>43 (7.6)</td>
</tr>
<tr>
<td>Total</td>
<td>565 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>33</td>
</tr>
<tr>
<td>Total</td>
<td>598</td>
</tr>
</tbody>
</table>

The severity of injuries data were further analysed by lie-times (in bands of 0-5, 5-10, 10-30, 30-60, 60+ minutes) and it was found that the more serious the injury, the longer the lie times ($\chi^2$ Trend=29.8, df=1, p=<0.001) as would be clinically expected. Injuries were further classified using the International Classification of Diseases (10th edition) as recommended by ProFaNE (Lamb et al., 2005). Lower body injuries were most common (Table 36) and included hip, thigh, knee, lower leg, ankle and foot injuries (n=139, 24.6%). Shoulder, upper arm, elbow and forearms (n=66, 11.6%) were also frequently reported, but wrist and hand injuries were less common (n=8, 1.4%). The number of head injuries (minor bumps to more severe concussions) was relatively high (n=27, 5.1%) compared to other studies (Fessel and Nevitt, 1997). Injuries involving multiple body regions (n=81, 14.3%) were also relatively high.
Injury type according to International Classification of Diseases (10th Ed)

<table>
<thead>
<tr>
<th>Type of injury</th>
<th>Number of participant falls (%)</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>No injury</td>
<td>232 (41.0)</td>
<td>34.9 to 42.7</td>
</tr>
<tr>
<td>Injuries to head</td>
<td>15 (2.7)</td>
<td>1.5 to 4.1</td>
</tr>
<tr>
<td>Injuries to thorax</td>
<td>6 (1.1)</td>
<td>0.5 to 2.1</td>
</tr>
<tr>
<td>Injuries to abdomen, lower back, lumbar spine and pelvis</td>
<td>18 (3.2)</td>
<td>1.9 to 4.7</td>
</tr>
<tr>
<td>Injuries to shoulder and upper arm</td>
<td>37 (6.5)</td>
<td>4.5 to 8.4</td>
</tr>
<tr>
<td>Injuries to elbow and forearm</td>
<td>29 (5.1)</td>
<td>3.4 to 6.9</td>
</tr>
<tr>
<td>Injuries to wrist and hand</td>
<td>8 (1.4)</td>
<td>0.7 to 2.6</td>
</tr>
<tr>
<td>Injuries to hip and thigh</td>
<td>32 (5.5)</td>
<td>3.8 to 7.5</td>
</tr>
<tr>
<td>Injuries to knee and lower leg</td>
<td>28 (4.9)</td>
<td>3.3 to 6.7</td>
</tr>
<tr>
<td>Injuries to ankle and foot</td>
<td>79 (14.0)</td>
<td>10.7 to 16.2</td>
</tr>
<tr>
<td>Injuries involving multiple body regions</td>
<td>81 (14.3)</td>
<td>11.0 to 16.5</td>
</tr>
<tr>
<td>Total</td>
<td>565 (100.0)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>598</td>
<td></td>
</tr>
</tbody>
</table>

There were 26 fractures in total as a result of falls (n=20, 4%) (Table 37), which resulted in a fracture rate of 57.1 fractures per 1000 person-years at risk. Of these 15 were single fractures, three falls resulted in two fractures, and two falls
resulted in three fractures (bilateral hip fractures and a fractured pelvis for one participant, and three fractured toes in another participant).

Table 37. Self-reported injuries/fractures due to falls

<table>
<thead>
<tr>
<th>Injury/fracture</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury requiring stitches</td>
<td>6</td>
</tr>
<tr>
<td>Haemarthrosis</td>
<td>2</td>
</tr>
<tr>
<td>Head injury</td>
<td>27</td>
</tr>
<tr>
<td>Fractured ribs</td>
<td>2</td>
</tr>
<tr>
<td>Fractured back/vertebrae</td>
<td>2</td>
</tr>
<tr>
<td>Fractured lower arm/wrist/hand</td>
<td>6</td>
</tr>
<tr>
<td>Fractured pelvis/hip</td>
<td>4</td>
</tr>
<tr>
<td>Fractured knee/ankle/toe</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>56</strong></td>
</tr>
</tbody>
</table>

It was apparent from the follow-up telephone calls that many of the participants’ managed their own injuries following the falls, such as increasing their analgesic medication and resting for a few days. Some would wait until their next rheumatology appointment to discuss the fall with their doctor rather than use the primary health care services. However, there were, a considerable number of falls (n=86, 15.0%) that resulted in visits to the GP or required physiotherapy or nursing assistance for treatment or rehabilitation (Table 38). Furthermore, emergency services such as an ambulance or visit to the accident and emergency department were necessary for treatment for nearly 9% (n=50) of the falls, and 2.4% (n=14) of the falls resulted in hospital admissions.
Table 38. Use of health services/resources

<table>
<thead>
<tr>
<th>Health service/resource</th>
<th>Number of falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulance required</td>
<td>17 (3.0)</td>
</tr>
<tr>
<td>Attended A &amp; E</td>
<td>33 (5.8)</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>14 (2.4)</td>
</tr>
<tr>
<td>Admission to private rest home</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Permanent stay in rest home</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>GP or AHP visit</td>
<td>86 (15.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>152</strong></td>
</tr>
</tbody>
</table>

Of the participants who required a hospital admission, two persons were discharged without staying overnight. Four participants stayed for one night and two participants stayed for 21 days. Six participants required hospital stays of 5, 7, 14, 17, 30 and 140 days respectively. The 140 night stay in hospital was due to a participant suffering from a cerebrovascular accident resulting in a fall and multiple injuries. One participant required a short stay of four nights in a private rest home to recuperate following a fall.

11.5 **Functional ability following a fall**

Nearly a third (n=183, 31.9 %) of all falls resulted in the participants’ experiencing more difficulty in being able to walk around their home. A smaller proportion of the falls (n=47, 8.2%) resulted in the participants being unable to walk independently around their home (Table 39).
Table 39. Self-reported ability to walk around home following a fall

<table>
<thead>
<tr>
<th>Participant response</th>
<th>Number of falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not do before the fall</td>
<td>58 (10.1)</td>
</tr>
<tr>
<td>Could not do because of the fall</td>
<td>47 (8.2)</td>
</tr>
<tr>
<td>Able to do but had more difficulty than before the fall</td>
<td>183 (31.9)</td>
</tr>
<tr>
<td>Could do after the fall without difficulty</td>
<td>285 (49.7)</td>
</tr>
<tr>
<td>Total</td>
<td>573 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
</tr>
</tbody>
</table>

Nearly 38% of the falls resulted in participants having difficulty or being unable to walk outside or away from their home (Table 40). A smaller proportion could not walk outside before the fall occurred which indicates the general difficulty some of the participants faced in this area (n=77, 13.4%). Nearly half of the falls did not result in difficulties in walking outside.
Table 40. Self-reported ability to walk around outside or away from home following a fall

<table>
<thead>
<tr>
<th>Participant response</th>
<th>Number of falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not do before the fall</td>
<td>77 (13.4)</td>
</tr>
<tr>
<td>Could not do because of the fall</td>
<td>57 (9.9)</td>
</tr>
<tr>
<td>Able to do but had more difficulty than before the fall</td>
<td>160 (27.9)</td>
</tr>
<tr>
<td>Could do after the fall without difficulty</td>
<td>279 (48.7)</td>
</tr>
<tr>
<td>Total</td>
<td>573 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
</tr>
</tbody>
</table>

Similarly, nearly half of the falls resulted in the participants being able to continue to do activities around the home, although 15% already had difficulties and required help in the area. However, nearly 37% of the falls did lead to participants being unable or having difficulties in being able to continue with activities around the home such as cooking and cleaning (Table 41).
Table 41. Self-reported ability to be able to do things around home such as cooking or cleaning following a fall

<table>
<thead>
<tr>
<th>Participant response</th>
<th>Number of falls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not do before the fall</td>
<td>86 (15.0)</td>
</tr>
<tr>
<td>Could not do because of the fall</td>
<td>51 (8.9)</td>
</tr>
<tr>
<td>Able to do but had more difficulty than before the fall</td>
<td>158 (27.6)</td>
</tr>
<tr>
<td>Could do after the fall without difficulty</td>
<td>278 (48.5)</td>
</tr>
<tr>
<td>Total</td>
<td>573 (100.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>28</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
</tr>
</tbody>
</table>

11.6 Summary of fall events

Over a third of the falls reported by the participants, were reportedly caused by their hips, knees or ankles giving way. Trips forward on a level or rough surface were also commonly reported followed by reports of loss of balance. Over half of all the falls resulted in moderate injuries. Falls reportedly occurred mainly in the participants’ homes (63%). However, more moderate and severe injuries were caused by falls occurring outdoors. The severity of the injuries was fairly equal among all the age ranges of participants within the study. Lower body injuries were most commonly reported and the number of head injuries was high (n=27, 5.1%), possibly due to hand joint involvement causing difficulties in breaking the impact of falls. Treatment by general practitioners or other health professionals was required for 15% of the falls and emergency services were required after 9%
of the falls. The functional ability of participants was affected following over a third of the reported falls.
CHAPTER 12

12. Univariate and multivariate analysis

This chapter will initially consider the results using univariate logistic regression analysis (i.e. between one explanatory and one response variable), to estimate associations between falls and potential risk factors. Multivariate logistic regression analysis will then be used to create the best possible risk model to predict falls amongst people with RA based on this data set.

12.1  Univariate analysis

As with the previous chapter, participants were divided into 3 categories according to the number of falls: non-fallers, single fallers and multiple fallers. An alternative grouping was also formed by grouping the single fallers and multiple fallers together to form an all fallers group for the multivariate analysis.

12.2  Multivariate analysis

Multivariate logistic regression was used to estimate the best predictors of falls. After assessing the results from all of the different combinations of the groups (e.g. non-fallers and multiple fallers), it was reasonable to group the participants into just two groups (non-fallers and all fallers). This allowed all of the participants to be included in the multivariate analysis. There were adequate numbers of events for the significant variables that were selected for the multivariate analysis. Each variable with a significance level less than 0.25 from the previous hypothesis tests were selected to be entered into the analysis up to a
maximum number, as recommended by Peduzzi et al., (2008). The higher cut-off was chosen to reduce the possibility of missing important risk factors, not previously identified.

12.3 All fallers and non-fallers univariate binary logistic regression analyses: associations between fall risk factors and fallers.

The categories of single fallers and multiple fallers were grouped together to form one group classed as “all fallers” (n = 195) and were compared to non-fallers (n = 340) for the initial univariate analyses. The variables that were selected according to their clinical relevance and significant associations with falls were as follows: age, gender, number of tender joints, DAS28 score, use of psycho-tropic drugs, four or more types of medicines, taking steroids at baseline, history of fracture, history of injury from previous falls, ability to complete Chair Stand Test, time taken to complete Chair Stand Test, Four Test Balance Scale, complaints of feeling dizzy or unsteady, history of stroke or Parkinson’s disease, VAS pain score, VAS fatigue score, Short FES-I score, HAQ score and a history of fall(s) in previous one year.

These variables were further classified into groups of demographic, medical, psychological, self-report/functional ability, and postural risk factors to aid the reporting of the results.
Table 42 summarises the results of the all fallers and non-fallers univariate logistic regression analyses.

12.3.1 Demographic risk factors (all fallers versus non-fallers).

There were no associations found between age or gender with falls in the univariate analyses (Table 42). Both variables had little or no effect (p=<0.05). This was surprising as in the general population, adults over the age of 65, in particular women, have significantly more falls than younger adults (Rubenstein, 2006; Peden et al., 2002).

12.3.2 Medical risk factors (all fallers versus non-fallers).

There were no significant associations found between the number of tender joints and falls. A history of stroke or Parkinson’s disease had no significant effect (p=0.08), possibly due to the small number of participants who reported a positive response to this variable. However, all of the other medical related variables were individually predictive of falls. Reporting any swollen or tender lower limb joints (hip, knee or ankle joints only), doubled the risk of falling during the follow-up period. A positive self-reported history of falls in the previous one year was individually the best predictor of falls. Reporting a single fall in the previous year more than tripled the relative odds of falling during the reporting period of the study (OR=3.3, 95% CI 2.1, 5.1, p=<0.001) and reporting multiple falls more than quadrupled the odds (OR=4.3, 95% CI 2.7, 6.8, p=<0.001). Reporting injurious falls was also a strong predictor of falls (OR=1.3, 95% CI 1.1, 1.6, p=0.001). Taking psychotropic medicines more than doubled
the odds of falling (OR=2.4, 95% CI 1.5, 3.7, p=<0.001). Polypharmacy was a strong predictor of falls; taking four or more medicines more than doubled the risk of falling (OR=2.1, 95% CI 1.3, 3.3, p=0.002). Taking steroids at baseline increased the risk of falling by half, (OR=1.5, 95% CI 1.0, 2.4, p=0.049) as did a history of previous fracture(s) (OR=1.5, 95% CI 1.04, 2.1, p=0.03). Both the VAS pain (OR=1.2, 95% CI 1.1, 1.2, p=<0.001) and VAS fatigue score (OR=1.2, 95% CI 1.1, 1.3, p=<0.001) showed similar positive predictive values for falling. The DAS28 score was another predictor of falls that could be useful in clinical practice (OR=1.2, 95% CI 1.1, 1.3, p=0.004).

12.3.3 Self-report/functional ability risk factors (all fallers/ non-fallers).
The Short FES-I score values ranged from 7 (no fear of falling) up to 28 (very fearful of falling). For each value above 7 up to 28, there was a 10% increase in the odds of falls (OR=1.1, 95% CI 1.03, 1.1, p=<0.001), suggesting that the short FES-I is a good predictor of falls. The HAQ is a sensitive tool for the measurement of functional health status and is designed to assess the patient’s usual abilities using their usual equipment over the past week. The univariate analyses demonstrated that for each additional point attained in the final HAQ score (1.00 – 4.00), the risk of falling increased by 70% (OR 1.7, 95% CI 1.4, 2.1, p = <0.001).

12.3.4 Postural risk factors (all fallers/ non-fallers).
The Four Test Balance Scale was entered into the univariate analysis with a score of 0 for unsuccessful, 1 for participants who could only stand with their feet
together, 2 for participants who could stand with a semi-tandem stand, 3 for those who completed a tandem stand and 4 for participants who could complete a one-leg stand. The odds of falling was 2-3 times higher for participants who could not complete the Four Test Balance Scale at all (OR=2.3, 95% CI 1.1, 4.7, p=0.03) and 2.5 times higher for those who could only complete the feet together stand, however the 95% CI spanned unity in this scale, possibly due to smaller numbers of participants at this level (OR=2.5, 95% CI 0.7, 9.1, p=0.15). Both the levels of semi-tandem stand (OR=1.6, 95% CI 1.0, 2.5, p=0.03) and tandem stand (OR=1.7, 95% CI 1.0, 2.8, p=0.04) were also predictive of falls in comparison to those who could fully complete the one-leg stand for 10 seconds and therefore had good balance.

A complaint of feeling dizzy or unsteady was also a strong predictor of falls with participants with positive reports having an 80% greater risk of falling than those without (OR=1.8, 95% CI 1.2, 2.6, p=0.004).

Participants were asked to complete the Chair Stand Test to test their lower limb strength. There was an inverse association found with those who were able to complete the Chair Stand Test with an OR of 0.48 (95% CI 0.29, 0.8, p=0.004). Therefore, those able to complete the Chair Stand Test were half as likely to fall as those unable to complete the test. An explanation for these results may be that those unable to stand with their arms folded were people who were less mobile or wheelchair users which would negatively affect their muscle strength and postural stability. The time taken to complete the Chair Stand Test varied from 4
to 104 seconds. For every additional second taken to complete the test there was an increased risk of falling of 2% (OR 1.02, 95% CI 1.01, 1.04, p=0.003) and indicates that the Chair Stand Test could be a useful clinical predictor of falls.
Table 42 Univariate binary logistic regression – association between fall risk factors and fallers (all fallers n = 195/non-fallers n = 340).

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Score</th>
<th>Odds ratio (OR)</th>
<th>OR 95% Confidence Intervals</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic risk factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (referent)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.1</td>
<td>0.7, 1.6</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>18 - 88</td>
<td>1.0</td>
<td>0.99, 1.02</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Medical risk factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of tender joints</td>
<td>0 - 28</td>
<td>1.0</td>
<td>0.98, 1.04</td>
<td>0.3</td>
</tr>
<tr>
<td>Swollen or tender lower limb joints</td>
<td>No (referent)</td>
<td>Yes</td>
<td>2.0</td>
<td>1.3, 2.8</td>
</tr>
<tr>
<td>DAS28 Score</td>
<td>0.1 – 8.</td>
<td>1.2</td>
<td>1.1, 1.3</td>
<td>0.004</td>
</tr>
<tr>
<td>Psychotropic medicines</td>
<td>No (referent)</td>
<td>Yes</td>
<td>2.4</td>
<td>1.5, 3.7</td>
</tr>
<tr>
<td>Four or more types of medicines</td>
<td>No (referent)</td>
<td>Yes</td>
<td>2.1</td>
<td>1.3, 3.3</td>
</tr>
<tr>
<td>Taking steroids at baseline</td>
<td>No (referent)</td>
<td>Yes</td>
<td>1.5</td>
<td>1.0, 2.4</td>
</tr>
<tr>
<td>History of stroke or Parkinson’s disease</td>
<td>No (referent)</td>
<td>Yes</td>
<td>1.8</td>
<td>0.9, 3.6</td>
</tr>
<tr>
<td>VAS pain score</td>
<td>0 - 10</td>
<td>1.2</td>
<td>1.1, 1.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS fatigue score</td>
<td>0 - 10</td>
<td>1.2</td>
<td>1.1, 1.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>History of falls in previous 12 months</td>
<td>0 fall (referent)</td>
<td>1 fall</td>
<td>3.3</td>
<td>2.1, 5.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 or more falls</td>
<td>4.3</td>
<td>2.7, 6.8</td>
</tr>
<tr>
<td>History of fracture</td>
<td>No (referent)</td>
<td>Yes</td>
<td>1.5</td>
<td>1.04, 2.1</td>
</tr>
<tr>
<td>History of injuries from previous</td>
<td>0 - 6</td>
<td>1.3</td>
<td>1.1, 1.6</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Score</td>
<td>Odds Ratio</td>
<td>95% CI</td>
<td>p-value</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------</td>
<td>------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>Short FES-I score</td>
<td>7 - 28</td>
<td>1.1</td>
<td>1.03, 1.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HAQ score</td>
<td>1.00 – 4.00</td>
<td>1.7</td>
<td>1.4, 2.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Postural risk factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four Test Balance Scale:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsuccessful</td>
<td>0</td>
<td>2.3</td>
<td>1.1, 4.7</td>
<td>0.03</td>
</tr>
<tr>
<td>Feet together stand</td>
<td>1</td>
<td>2.5</td>
<td>0.7, 9.1</td>
<td>0.15</td>
</tr>
<tr>
<td>Semi- tandem stand</td>
<td>2</td>
<td>1.6</td>
<td>1.0, 2.5</td>
<td>0.03</td>
</tr>
<tr>
<td>Tandem stand</td>
<td>3</td>
<td>1.7</td>
<td>1.0, 2.8</td>
<td>0.04</td>
</tr>
<tr>
<td>One – leg stand</td>
<td>4 (referent)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complaints of feeling dizzy or</td>
<td>No (referent)</td>
<td>Yes</td>
<td>1.8</td>
<td>1.2, 2.6</td>
</tr>
<tr>
<td>unsteady</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to complete Chair Stand Test</td>
<td>No (referent)</td>
<td>Yes</td>
<td>0.48</td>
<td>0.29, 0.8</td>
</tr>
<tr>
<td>Time taken for Chair Stand Test</td>
<td>4 – 104 secs</td>
<td>1.02</td>
<td>1.01, 1.04</td>
<td>0.003</td>
</tr>
</tbody>
</table>
(n = 484)
12.4 Multivariate analyses

The aim of the multivariable logistic regression analyses was to identify the most predictive combination of factors that predict falls in this study and to assess their relative importance. The explanatory risk factors (i.e. those factors that possibly cause or contribute to the fall(s) taking place) were also further explored to investigate the variables that could be modified to prevent falls in clinical practice. To accomplish this goal, forward stepwise regression was initially used to explore and investigate the most significant variables from the univariate analyses. Multivariate logistic regression was then used to build the best predictive model and the best intervenable model that could be used in clinical practice.

After analysing and interpreting all the univariate results from 23 variables, the 19 variables that were statistically important were: Swollen or tender lower limb joints, the DAS28 score, taking psychotropic medicines, taking four or more types of medicine, taking steroids at baseline, a history of fracture, a history of injuries from previous falls, time taken to complete the Chair Stand Test, four test balance scale (as four variables), complaints of feeling dizzy or unsteady, VAS pain score, VAS fatigue score, Short FES-I score, the HAQ score and a 12 month history of single or multiple fall(s). These variables were entered into a SPSS forward stepwise logistic regression analysis.
12.4.1 Forward stepwise logistic regression analyses

Forward stepwise regression only enters a variable into the model when its inclusion increases the amount of explained variability by a “useful amount”. The order of entry of variables into the model reflects their relative importance in explaining variability. Nineteen variables were used. It was found that the single variables that were the best predictors of falls were the VAS fatigue score (OR 1.2, p = 0.001, 95% CI 1.1, 1.4) and a one year history of falling (OR 1.7, p = 0.002, 95% CI 1.2, 2.4). This analysis used one year history of falling as a continuous variable (0 = no falls, 1 = one fall, 2 = 2 or more falls). A model using both of these two variables gave a model with an overall prediction of falling that explained 65% of variability. From these results it was seen that the VAS fatigue score had a stronger p–value, but a history of falls has more clinical significance and a much larger effect size. These results are based on one study and would require replicating on an independent set of data to confirm the predictive usefulness of these two variables alone.

12.5 Multivariate logistic regression

Multivariate logistic regression uses all available data, and accounts for the confounding that can occur between variables by including relevant covariates. The following variables were included in this multivariate analysis because of their clinical utility and relevance, and based on their statistical significance in the univariate analysis: swollen or tender lower limb joints, taking psychotropic medicines, taking four or more medicines, a history of fracture or injuries, the ability and time taken to complete the Chair Stand Test, the ability to complete
the Four Test Balance Scale, feeling dizzy or unsteady, fear of falling (Short FES-I score), history of single fall, history of multiple fall, DAS28 score, taking steroids, pain, fatigue and HAQ score. The univariate results from the categorical Four Test Balance Scale (with values of 0 meaning poor balance, up to 4 meaning excellent balance) varied in significance, so this variable was treated as a single numerical variable and this reduced the total number of explanatory variables. Multivariate logistic regression analysis initially showed that the results from the ability to complete the Chair Stand Test variable were highly correlated with the other variables causing spurious model estimates, (VIF >10). Therefore, the ability to complete the Chair Stand Test variable was excluded from the analysis. The same variables (excluding the ability to complete the Chair Stand Test but not the time to complete the Chair Stand Test) were entered into a multivariate logistic regression analyses to build the best predictive model of falls (Table 43). After the initial examination and interpretation of the results, it was decided that changing the one year history of falls variable (0,1,2) to two categorical variables (a one year history of a single fall, a one year history of multiple falls) would usefully allow us to investigate separate OR estimates, and not assume the effect of ≤2 falls had twice the effect of one fall. This change increased the number of explanatory variables by one.

12.5.1 Predictive risk model

The final model included all 16 selected risk factor variables in predicting the occurrence of falls during the study, and accurately explained 71% of the variation in the data. Statistically and clinically significant variables were the 12
month history of a single (OR 3.6, \( p<0.001 \), 95% CI 1.8 to 7.3) or multiple fall(s) (OR 5.3, \( p<0.001 \), 95% CI 2.3 to 12.3), swollen or tender lower limb joints (OR 1.7, \( p=0.02 \), 95% CI 1.1 to 2.8) and increasing VAS fatigue (OR 1.11, \( p=0.03 \), 95% CI 1.0 to 1.3).
Table 43 Results from a multivariate analysis based on 16 predictive risk factors of all fallers (195) versus non-fallers (340) using prospective data.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% confidence intervals)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swollen or tender lower limb joints</td>
<td>1.7 (1.1, 2.8)</td>
<td>0.02</td>
</tr>
<tr>
<td>DAS28 score (0.1-8)</td>
<td>0.9 (0.8, 1.1)</td>
<td>0.29</td>
</tr>
<tr>
<td>Psychotropic medicines (Yes/No)</td>
<td>1.6 (0.9, 2.9)</td>
<td>0.09</td>
</tr>
<tr>
<td>Taking four or more types of medicine (Yes/No)</td>
<td>1.8 (1.5, 3.1)</td>
<td>0.30</td>
</tr>
<tr>
<td>Taking steroids at baseline (Yes/No)</td>
<td>1.3 (0.8, 2.3)</td>
<td>0.32</td>
</tr>
<tr>
<td>VAS pain score (0-10)</td>
<td>1.02 (0.9, 1.1)</td>
<td>0.73</td>
</tr>
<tr>
<td>VAS fatigue score (0-10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.11 (1.0, 1.3)</td>
<td>0.03</td>
</tr>
<tr>
<td>12 month history of a single fall (Yes/No)</td>
<td>3.6 (1.8, 7.3)</td>
<td>0.00</td>
</tr>
<tr>
<td>12 month history of multiple falls (Yes/No)</td>
<td>5.3 (2.3, 12.3)</td>
<td>0.00</td>
</tr>
<tr>
<td>A history of fracture (Yes/No)</td>
<td>1.3 (0.8, 1.9)</td>
<td>0.31</td>
</tr>
<tr>
<td>A history of injuries from previous falls (Yes/No)</td>
<td>0.8 (0.6, 1.1)</td>
<td>0.24</td>
</tr>
<tr>
<td>Short FES-I score (7 -28)</td>
<td>1.0 (0.9, 1.0)</td>
<td>0.57</td>
</tr>
<tr>
<td>HAQ score (1.00 -4.00)</td>
<td>1.2 (0.7, 2.0)</td>
<td>0.44</td>
</tr>
<tr>
<td>Four test balance scale (0-4)</td>
<td>1.0 (0.8, 1.3)</td>
<td>0.94</td>
</tr>
<tr>
<td>Complaints of feeling dizzy or unsteady (Yes/No)</td>
<td>0.9 (0.5, 1.5)</td>
<td>0.66</td>
</tr>
<tr>
<td>Time taken to complete the Chair Stand Test (Secs)</td>
<td>0.99 (0.98, 1.02)</td>
<td>0.94</td>
</tr>
</tbody>
</table>
12.6 Multivariate logistic regression of significant explanatory risk factors to predict future falls, excluding 12 month history of fall.

A multivariate logistic regression analysis of the risk factors excluding a 12 month history of fall was conducted to explore the potential reasons for falls. As well as understanding the best predictive risk factors, it is clinically important to understand the risk factors that can potentially be modified to enable an effective falls prevention strategy to be implemented. Although a history of a single or multiple fall was found to be the best independent predictor of falls this model does not help clinicians to prevent the initial fall and a history of a single or multiple fall(s) can be considered a marker of poor mobility or frailty (Campbell et al., 1989). Therefore a history of a single or multiple fall(s) was excluded from the analysis due to its lack of utility in designing an intervention. The 12 variables included in the multivariate logistic regression were chosen in advance from the 18 significant variables examined in the univariate analysis. DAS28 and VAS pain score were included as covariates and swollen or tender lower limb joints, taking four or more medicines, HAQ score, Short FES-I score, psychotropic medicines, taking steroids at baseline, time taken to complete the chair stand test, the four test balance scale, complaints of feeling dizzy or unsteady and VAS fatigue score were also included as the most clinically relevant for purposes of intervention.

Table 44 shows the multivariate analysis for explanatory risk factors.
12.6.1 **Explanatory risk model**

The multivariate logistic regression analysis for the explanatory fall risk factors showed that having any swollen or tender lower limb joints (hip, knee, ankle), taking psychotropic medicines and increasing VAS fatigue produced the best fitting risk factor model. The amount of variation explained by the explanatory risk factor model due to 12 variables was 68%.

Table 44. Results from a multivariate analysis based on 12 explanatory risk factors of all fallers (195) versus non-fallers (340) excluding history of falls.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% confidence intervals)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swollen or tender lower limb joints</td>
<td>1.7 (1.1, 2.7)</td>
<td>0.03</td>
</tr>
<tr>
<td>DAS28 score</td>
<td>0.9 (0.8, 1.1)</td>
<td>0.44</td>
</tr>
<tr>
<td>Psychotropic medicines</td>
<td>1.8 (1.1, 3.1)</td>
<td>0.03</td>
</tr>
<tr>
<td>Four or more types of medicines</td>
<td>1.6 (0.96, 2.8)</td>
<td>0.07</td>
</tr>
<tr>
<td>Taking steroids at baseline</td>
<td>1.2 (0.7, 2.1)</td>
<td>0.43</td>
</tr>
<tr>
<td>VAS pain score</td>
<td>1.02 (0.92, 1.1)</td>
<td>0.65</td>
</tr>
<tr>
<td>VAS fatigue score</td>
<td>1.13 (1.02, 1.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Fear of falling Short FES-I score</td>
<td>1.004 (0.95, 1.06)</td>
<td>0.89</td>
</tr>
<tr>
<td>HAQ score</td>
<td>1.11 (0.7, 1.8)</td>
<td>0.7</td>
</tr>
<tr>
<td>Four test balance scale</td>
<td>1.0 (0.8, 1.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>Complaints of feeling dizzy or unsteady</td>
<td>1.1(0.7, 1.7)</td>
<td>0.73</td>
</tr>
<tr>
<td>Time taken for Chair Stand Test</td>
<td>1.002 (0.08, 1.02)</td>
<td>0.87</td>
</tr>
</tbody>
</table>
12.7 Summary of multivariate analysis
Both the forward stepwise logistic regression and the multivariate logistic regression came to the consistent conclusion that a one year history of falls (both single or multiple) was required to produce the best fitting risk model both in terms of clinical effect and as a statistically significant predictor of falls. The final model included all 16 selected risk factor variables in predicting the occurrence of falls during the study, and accurately explained 71% of the variation in the data. Statistically and clinically significant variables were the 12 month history of a single or multiple fall(s), swollen or tender lower limb joints and increasing VAS fatigue. The multivariate logistic regression analysis for the explanatory fall risk factors showed that having any swollen or tender lower limb joints (hip, knee, and ankle), taking psychotropic medicines and increasing VAS fatigue produced the best fitting explanatory risk factor model. The accuracy for the causative risk factor model due to 12 variables is 68%. These are the best models for the observed data, and ideally these findings should be replicated in an independent dataset to confirm the strength of associations observed in this one study.
Chapter 13

13. Discussion and conclusions

The primary aim of this study was to determine the incidence of falls in adults with RA to identify the risk factors associated with falls in RA and to investigate the prevalence of fear of falling. This chapter will summarise the main findings and discuss the extent to which the objectives of the study have been met. A critique of the research methods will be given, including the strengths, limitations and representativeness of the research. The results of the study will be set within the wider context of findings in the literature and the originality and contribution to research knowledge will be considered. To conclude the thesis, the relevance of the findings for health professionals and managers in the health service will be highlighted and recommendations for further research will be summarised.

13.1.1 Incidence of falls: main findings

This is the largest prospective study of falls in RA patients to date, we have demonstrated that adults of all ages with RA fall frequently. In our study the crude incidence rate of falls in adults with RA was high at 1313/1000 person-years. During the one year follow-up 36.4% (95% CI 32% to 41%) participants reported one or more falls. These results are slightly higher than previous retrospective studies where one year fall frequencies (self-reported and previous year) have been found to be between 31-35% (Oswald et al., 2006; Armstrong et al., 2005; Jamison et al., 2003; Fessel and Nevitt, 1997). They are less than Hayashibara’s et al., (2010) and Smulders et al., (2009) small prospective
studies, who reported a 50% fall incidence in 84 older women with RA and a 42% fall incidence in 84 adults with RA respectively. However, limitations in the methodologies of these studies (for instance, small sample, mail response only, women only) reduce the reliability of their findings.

The incidence of falls in adults of all ages with RA identified in this study is similar to fall rates in community dwelling older people where 28-35% of people aged 65 years and over fall annually (Tinetti et al., 1988; Blake et al., 1988; Campbell et al., 1981). The difference found in this study is that adults of all ages with RA have a high risk of falls and not just those of 65 years of age and over.

Increasing age was not associated with increased falls. Hayashibara et al. (2010) and Smulders et al., (2009) also report that age was not associated with falls in their small prospective studies. This is different to community dwelling studies in falls in older people where age is considered to be one of the most important risk factors for falls (WHO, 2007; Blake et al., 1988; Tinetti et al., 1988). Older people in general are more frail (a marker of illness and decline) and have decreased activity leading to muscle weakness, poor gait, balance and other fall risk factors. These factors occur in all age groups with RA. Both younger and older people with RA appear to have muscle weakness (due to pain, fatigue or fear resulting in reduced activity) and this may lead to the similar fall rates and may override the risk factors usually associated with age and gender.
No relationship was found between frequency of falls and gender in adults in this study and by Smulders et al. (2009) which is also different to studies of community dwelling people where women are more likely to fall than men (Stevens et al., 2006; WHO, 2007). Reasons for fall gender differences in the general population are attributed to biological differences in muscle mass between men and women, more women living alone, with higher levels of polypharmacy amongst women (Ebrahim and Kalache, 1996). A general decline in muscle mass and similarities in polypharmacy between men and women with RA may result in the similar fall rates between the groups. The incidence of falls was higher in men than women due largely because men who fell were more likely to fall more than once during the study period, possibly reflecting differences in activities and risk taking behaviour.

Over a third of the falls reported by the participants were caused by their hips, knees or ankles’ giving way and this type of fall is common in the RA population. These falls may be due to muscle weakness and reduced proprioception, however further research is needed to confirm this.

Over half of all the falls resulted in moderate injuries (51.5%) which is greater than fall injuries reported by community dwelling older people (Scuffham et al., 2003). Falls mainly occurred in the participants’ home (68.5%) and it is likely that this is where the participants spent most of their time, particularly as over half were retired from work. However, more moderate and severe injuries were caused by falls occurring outdoors. This may be due to the more vigorous types
of activities undertaken outdoors. The severity of the injuries was similar among all the age ranges of participants. Lower body injuries were most common. The number of head injuries was high compared to other studies (Smulders et al., 2009), possibly due to hand joint involvement causing difficulties in breaking the impact of falls. Injuries involving multiple body regions were also high.

There were 26 fractures in total as a result of falls which resulted in a fracture rate of 57.1 fractures per 1000 person-years at risk. A large proportion of participants also had a previous history of fractures (41%). Patients with RA are at particular risk of fractures as they are more likely to develop osteoporosis as a result of their disease, medication (steroid use) and health behaviour (Haugeberg et al., 2000). This further highlights the importance of preventing falls in RA patients.

Treatment by general practitioners or other health professionals was required for 15.0% of the falls and emergency services were required after 8.8% of the falls (ambulance or visit to accident and emergency department). It is estimated that between10-15% of all emergency department visits are as a result of falls (Scuffham et al., 2003). The functional ability of participants was decreased after more than a third of the falls, which could affect levels of independence and requirements from care givers.
13.2 Prevalence of fear of falling: main findings and contribution to the research knowledge

To date, no study has utilised validated fear of falling measures such as the Short Falls Efficacy Scale-International (Short FES-I) nor prospectively measured fear of falling in adults with RA. This study has found that fear of falling is a significant problem for adults of all ages with RA and is not limited to older people. Mean fear of falling scores were in the fairly fearful category for participants at baseline and at one year follow-up and those who fell in the previous year or during the one year follow-up had significantly higher fear of falling scores than non-fallers. The prevalence of fear of falling appeared to increase with age and to be higher in women. This is consistent with community dwelling studies (Schefffer et al., 2008). Almost 89% of participants in this study reported at least some fear of falling at one year follow-up (82% at baseline) and this may affect the ability to carry out activities of daily living such as taking a bath or going out for a social event. The prevalence of fear of falling in this study is higher than other studies (Furuya et al., 2009; Smulders et al., 2009; Jamison et al., 2003; Fessel and Nevitt, 1997) but this may reflect the use of the Short FES-I that enables the measurement of some fear as well as severe fear rather than the use of a single item question of having fear or not. Having a fall or not in the one year follow-up did not appear to significantly change levels of fear of falling in this group of participants. Those who fell in the previous one year may already experience higher levels of fear of falling that remain constant whether they fell again or not in the following one year.
The impact of having high levels of fear of falling may lead to protective behaviours for some people (e.g. taking extra precautions when walking or using adaptive equipment) but for others can lead to a decline in quality of life due to reduced physical and social activities, loss of independence and the consequent negative effect on mental health (Yardley et al., 2002; Lachman et al., 1988). A reduction in physical activities can further reduce muscle strength, balance and lower confidence levels which can then further increase the risk of falls (Delbaere et al., 2004).

Intervention studies have shown that fall-related multi-factorial programs, home based exercises and community-based tai chi programs (in group format) have been effective in reducing fear of falling in community-living older people (Zijlstra et al., 2007). Therefore, it is important that fear of falling is taken into account in assessments of adults with RA and research based therapy to improve fear of falling in RA patients is recommended.

13.3 **Risk factors associated with falls: main findings and contribution to the research knowledge**

This study also shows that falls in adults with RA are not just random events but may be predicted and possibly prevented by assessing and treating a number of independent risk factors including: a history of falls, swollen and tender lower limb joints (hip, knee or ankle), taking psychotropic medicines and VAS fatigue levels. Targeting interventions towards these risk factors could reduce the burden of falls and fall related fractures and injuries in patients with RA. Patients should
be prescribed psychotropic medicines with caution, with regular reviews and should take them no longer than necessary (Dickens et al., 2002). In older people, gradual withdrawal of psychotropic medication reduced the rate of falls (Gillespie et al., 2009) and this approach may also be effective in patients with RA. High fatigue levels are common in adults with RA and have been linked with pain and depression (Rupp et al., 2005; Pollard et al., 2006). However there is some evidence that fatigue levels fall with disease-modifying anti-rheumatic drugs (DMARDs) and anti-TNF therapy (Weinblatt et al., 2003; Strand et al., 2005). Swollen and tender lower limb joints may be improved through good multi-disciplinary management of the patient. Early intervention and consistent monitoring of the condition is needed to effectively manage recently diagnosed patients as well as those with established RA. Drug management of RA to reduce swollen and tender joints is complex and includes the use of DMARDs, steroids and biologic agents. From this study, the use of steroids was associated with an increased risk of falls and for these reasons and due to their long-term effects, it is recommended that they are used with caution.

Poor balance and lower limb strength were significantly associated with an increased risk of falling as observed by previous RA studies (Hayashibara et al., 2010; Armstrong et al., 2005; Jamison et al., 2003). Specific exercises adapted from research based falls prevention programmes could be used to improve muscle strength and balance in adults with RA and may reduce the risk of falls (Sherrington et al., 2008). Exercise has been shown to reduce fatigue in adults
with RA, and may also improve depression and sleeping problems (Neuberger et al., 1997).

Increasing HAQ disability score and high DAS28 scores were significantly associated with an increased risk of falling as found in other studies (Furuya et al., 2009; Oswald et al., 2006; Kaz Kaz et al., 2004; Fessel and Nevitt, 1997). Fear of falling was also associated with an increased risk of falls, as found in other studies (Jamison et al., 2003; Fessel and Nevitt, 1997) and may result in avoidance of activities and reduction of physical ability which could therefore increase the risk of future falls. Exercise may improve fear of falling, the functional status of the HAQ scores and disease activity scores such as the DAS28, however further studies are needed to investigate these hypotheses (Williams et al., 2010).

13.4 Strengths of the study

Strengths of the study include its prospective, longitudinal design, high response rate, low attrition rate and the use of validated measurement tools to collect data on fall risk factors.

The prospective design enabled assessment of the falls as they took place and further investigation of the self-reported reasons given for the falls and any functional changes, injuries and use of health services as a consequence of the fall. The one year follow-up takes into account any seasonal variations in the number of falls.
Another strength of the study was the amount of rich data that was gathered throughout the data collection period. The in-depth assessment enabled a wide collection of potential risk factor data as well as patient demographic and disease characteristics. Successfully recruiting the 559 patients was sufficient to calculate the true incidence of falls. Loss of participants during the one year follow-up could have affected the external validity of the study. However a 10% drop out rate was allowed in the recruitment of participants to minimise the affect of loss of participants to the follow-up. Fortunately there was a low attrition rate in the one year with only 24 participants withdrawing from the study. Regular contact with the participants through the use of follow-up telephone calls may have assisted with maintaining the interest of participants and the low attrition rate (McColl et al., 2001).

Quality checks were built into the study to validate the information collected, such as checking data with patient records (e.g. medication). All questionnaires were fully completed prior to leaving the outpatient clinic at the baseline assessment. Checks were also made immediately upon receipt of the postal Short FES-I questionnaire. To minimise missing data or errors a 10% double entry of the questionnaire and follow-up data was incorporated into the study to detect errors in data entry. The input error rate after comparing the double entry with the completed data inputting was 1.6% and further data cleaning and checking was carried out in order to minimise any errors. Missing values were inserted by referring back to primary sources i.e. participant or hospital database. The pilot
study on 10 participants ensured that the recruitment process was feasible and the questionnaires were suitable for participants to complete.

Careful selection and appraisal of the measurement tools was also undertaken to ensure that they were valid, reliable and responsive (Fitzpatrick et al., 1998), to enhance the internal validity of the study and the use of the ProFaNE consensus set for the use of outcome measures and to guide the analysis, also added to the validity of the study (Lamb et al., 2005).

The study also benefited from substantial peer review and having three patients with RA involved in the planning and management of the study.

13.5 **Limitations**

There are a number of biases that can affect the internal and external validity of the study. Internal validity refers to whether the results obtained are accurate and reflect the, “truth” in the study population (Silman and McFarlane, 2002). This can be compromised by areas such as confounding, selection bias and information bias. External validity refers to extent to which the results of the study can be generalised wider to other populations (Bhopal, 2008). These areas will be considered within the context of this study.

13.5.1 **Internal validity**

Participants with RA that fulfilled the eligibility criteria were consecutively sampled as they attended RA clinics. Attempts were made to recruit a
representative sample of patients and minimise potential selection bias by attending a variety of outpatient clinics that included nurse-led blood monitoring sessions, primary care out of hours clinics as well as rheumatology clinics. All patients diagnosed with RA and under the care of a hospital consultant or GP will at regular intervals attend for blood tests to monitor their inflammation levels or for therapeutic drug management. Therefore, patients who were in disease remission and continuing to work were in attendance at the clinics (albeit less regularly) as well as patients with more severe disease who required closer monitoring. In addition, the recruitment of participants from four different clinics enabled a larger cross-section of the population to be utilised in the sample. It is possible however, that patients in this study had more moderate to severe RA or more progressive disease than those generally found in primary care and some caution should be given in applying these results to other settings. Also, people who have previously fallen or who are fearful of falling may be more inclined to participate in the study and this could also cause a degree of selection bias.

The falls calendars were returned at the end of each month and participants recorded if they have fallen. It is possible that some poor recall may occur, particularly if the participants recorded a fall at the beginning of the month and are not telephoned until the beginning of the following month. Due to costs it was not possible to send the postcards more frequently and all attempts were made to follow-up fallers as soon as possible once the calendars were returned. Likewise, those participants who did not return their calendars were telephoned after a week to check their falling status and to remind them to post the
calendars. This technique is recommended by the ProFaNE consensus group (Lamb et al., 2005) who have carefully considered all available options and therefore was chosen as an effective method for this study.

Some caution should also be taken with the wider application of the fall consequences’ results. The fall events were self-reported and recall bias and difficulties in patients accurately describing their symptoms (e.g. syncope, hypotension or dizziness) may have led to some misclassification of the type or reason for the fall (O’Dwyer and Kenny, 2010). Ideally, all fractures that were reported by participants should be checked with the radiological evidence, to enable the calculation of the number of radiologically confirmed peripheral fracture events per person year (Lamb et al., 2005), however this was beyond the constraints of the resources in this study.

The DAS28 includes mainly upper limb joint measurement (hip and knee joints are also included) and excludes ankle and feet joints, which may have contributed to falls risk. Over 75% of patients report foot deformity within four years of developing RA (Silvester et al., 2010) and foot deformity has been associated with falls in the community dwelling population (Menz et al., 2006). An alternative approach may be to assess all joints, which may also assist with more accurate assessment of the joint damage and result in tighter disease management and follow-up of patients (Bakker et al., 2010). This was not possible in the current study due to time constraints but could be included in future studies.
The internal validity of the study may also be affected due to information bias. The HAQ, Short FES-I, Falls Risk Assessment Tool, VAS pain, VAS fatigue and data on eyesight were self-reported by the participants and may be subject to errors of recall, measurement error and interview bias (e.g. due to the presence of the interviewer a participant may give lower pain or fatigue scores due to wanting to appear better than their actual condition or vice versa). Pain, fatigue and fear are subjective and this may also result in variability between participants.

13.5.2 External validity

Non-response bias can affect the external validity of the study and the ability to which the results can be generalised to a wider population. There was a good response rate (85%) from participants and 96% completed the one year follow-up. There was a lower response rate to the second Short FES-I fear of falling questionnaire (47%) after one year and so information was presented on non-responders to determine the extent to which they differed from responders. The proportions were similar in the groups of participants who completed the baseline and follow-up Short FES-I survey revealing few differences between the groups.

Although the majority of participants in the study were of white British ethnicity (97%), there were also participants of Chinese, African, Indian, Pakistani and other ethnicities. The four outpatient clinics were all situated in the Northwest of
England where ethnic minority groups comprise almost 8% of the population (DH, 2010). RA affects all ethnic groups, races and age groups but mostly occurs in adults between the ages of 40 – 50 years and affects three times as many women as men (Symmons et al., 2002a). In our sample there were twice as many women recruited to the study which reflects this higher prevalence.

In hindsight, it would have been useful to have collected information on the amount of physical activity that participants undertook as this can also be a measure of functional status and affect fall rates. However, at the time of the study no measures of physical activity were recommended by the ProFaNE consensus group and further research was needed as all current measures were too long and complex (Lamb et al., 2005).

Despite these limitations, the study was designed to be as rigorous and robust as possible in the context of real world research that is subject to imperfections and practical constraints. Potential bias was minimised through the use of careful planning, high quality data collection incorporating quality checks and utilising validated measures.

13.6 **Relevance of findings to the health service**

This section of the thesis will discuss both falls and RA in the context of current UK health policy and the current government’s plan of reform for the health service. Although this section is written from the perspective of the UK health service it is equally relevant to other countries, however it is beyond the scope of
the thesis to report more widely on international policies. The health service is more than ever faced with the major challenges of using resources more efficiently and of meeting the needs of an ageing population in which long term conditions are increasingly prevalent. Despite the current government’s major reform programme of the NHS, it appears that the focus on long term conditions management has remained a key priority given the need to reduce unscheduled hospital admissions (DH, 2010).

Prior to the election of the coalition government in 2010, the management of people with a long term condition (including RA) was part of the core strategy for the NHS. The treatment of people with RA and people at risk of falls were both (albeit separately) at the forefront of current NHS policy due to the economic implications of chronic conditions, as eight of the top eleven causes of hospital admissions are due to long term conditions (DH, 2005a).

Lord Darzi’s report, “High Quality Care For All” emphasised the change in direction to an NHS that focuses on improving the quality, safety and access of care for those with long-term conditions (DH, 2008). The aims of the policies are to treat patients sooner, nearer to home and earlier in the course of disease, supporting a patient-led model of care.

To assist with the implementation of these goals, National Service Frameworks (NSFs) have been developed to establish national standards and to identify key interventions for particular care groups or diseases. The NSF for Long Term
Conditions largely focuses on neurological conditions but incorporates principles that can be applied to other chronic conditions such as RA (DH, 2005b). Key principles related to the management of chronic diseases have been highlighted as important:

- A person centred service
- Early recognition, prompt diagnosis and treatment
- Emergency and acute management
- Early and specialist rehabilitation
- Community rehabilitation and support
- Vocational rehabilitation
- Providing equipment and accommodation

(DH, 2005b, pg 4)

Although these key principles relate to the care of people with chronic diseases such as RA, they can clearly be applied to the management of fallers. A supporting document produced by the Department of Health regarding supporting people with long term conditions does highlight the importance of falls services but there is sparse information given (DH, 2005c).

The NHS strategies for reducing falls and to ensure effective treatment and rehabilitation for those who have fallen is mainly covered in the NSF for older people (DH, 2001). This has a standard dedicated to falls but is set in the context of older people and it only briefly covers RA as a risk factor for osteoporosis.
(and consequent fractures). As this study has demonstrated, falls are not exclusive to older people but can affect all age groups, however falls prevention services have been set up within the context of older people’s services.

More specifically related to the management of people with RA are the recently published National Institute for health and Clinical Excellence (NICE) guidelines (NICE, 2009). These focus mainly on the pharmacological and surgical management of people with RA and only briefly mention patient education and the role of members of the multi-disciplinary team to improve general health and prevent further deterioration.

More recently, as part of an 18-month inquiry into the quality of general practitioners (GP) practice, the King’s Fund published a report, “Managing people with Long-Term conditions” that includes RA. This describes the quality of care for RA overall as ‘highly variable and sub-optimal’, and found that many patients with RA do not receive the care they need because of huge variation in service quality and access to specialists in England. This is particularly concerning due to some patients receiving 'no support' from practitioners such as physiotherapists in multidisciplinary teams (Goodwin et al., 2010).

Currently, there are few health services available for patients with RA, at risk of falls, with limited therapy support. Yet RA appears as a condition in the widely used World Health Organisation’s FRAX fracture risk assessment tool (Kanis et al., 2010) and RA has been highlighted as a key risk factor for osteoporotic
fractures due to low bone mass (Huusko et al., 2001; Cooper et al., 1995). Indeed, the higher than expected fracture risk in this study may be due to an interaction between falls and low bone mass. Currently, there does not appear to be specialist service provision to which to refer RA patients at risk of falls and fractures. Although falls prevention services have grown rapidly since their recommendation in the National Service Framework for Older People (DH, 2001) and the consequent NICE guidelines (NICE, 2004), they have remained a service for older people who fall, not those of all ages with RA (Jamison et al., 2003).

Therefore this study into falls and RA is timely and relevant to current policy initiatives related to long-term care for people with chronic conditions as well as service providers and individuals affected by RA. It is also relevant as it fits within the current Department of health research priority areas that calls for research that explores specific disease areas and health promotion (DH, 2008b).

13.7 Conclusions

Adults with RA are at high risk of falls and fear of falling. Over a third of participants fell in the one year follow-up period during this study. Health professionals can identify patients of particular risk of falls by asking whether they have fallen in the past year. Patients with RA would benefit from a falls risk-screening tool that utilises the most clinically relevant and significant risk factors associated with falling. We recommend the following variables for an RA falls screening tool; a 12 month history of falls, an assessment of lower limb
swollen and tender joints, an assessment of psychotropic medicines, VAS fatigue and VAS pain score, the Four Test Balance Scale to measure postural stability, the Chair Stand Test to measure lower limb strength, the Short FES-I to measure fear of falling, and the HAQ to measure functional ability.

13.8 **Originality of the research study**

To date, this is the first prospective study with a sufficiently powered sample to determine the incidence of falls in adults with RA. It is also the first study to comprehensively investigate the risk factors associated with falls with both known falls risk factors and disease specific risk factors to enable a comprehensive picture of the multi-causal reasons for falls. No other study has intensively followed up participants with RA to capture the consequences of the falls and recorded all injuries, lie-times, use of health services and functional status. Previous studies have either used a cross-sectional design or have used a very small sample with women only to follow-up falls prospectively with limited risk factor measurements.

13.9 **Recommendations of research for health professionals**

As a result of this research, there are several recommendations for health professionals and policy makers associated with long term care and/or rheumatology:

- According to the literature, the problem of falls, fractures and their consequences do not appear to be routinely addressed by rheumatologist
doctors/nurses/allied health professionals or general practitioners through screening or preventative interventions for adults with RA. Changes need to be made both in current practice, service provision and within training in higher education institutes to ensure that appropriate assessment and intervention is carried out with patients in routine practice to reduce injury and disability.

- Future policy documents related to long term care and falls prevention should include references to the issues affecting adults with RA in terms of falls risk, fear of falling and the debilitating characteristics of the disease. There is currently an emphasis on falls prevention services for older people yet there are younger at risk groups such as adults with RA that would greatly benefit from intervention. This would help to raise awareness of the substantial obstacles that can impinge on the quality of life for individuals with RA. A reduction in falls may in turn reduce fractures (people with RA have double the risk of hip fractures, Cooper et al., 1995), improve bone density, reduce pressure on hospital admissions and health professionals and improve the health and quality of life for persons with RA.

- Adults with RA need to be screened for potentially modifiable risk factors for falls and treatments need to be targeted at each of the risk factors. Important identifiable risk factors include a 12 month history of falls, an assessment of lower limb swollen and tender joints, an
assessment of psychotropic medicines, VAS fatigue and VAS pain score, the Four Test Balance Scale to measure postural stability, the Chair Stand Test to measure lower limb strength, the Short FES-I to measure fear of falling, and the HAQ to measure functional ability.

13.10 Translating the research into practice

Figure 1 demonstrates how the findings of this research study could be applied alongside current falls screening and intervention recommendations (AGS, BGS, 2010) to enable adults of all ages with RA to receive falls prevention screening.

All adults with RA should be asked if they have fallen in the last year and if so, the frequency, injuries and circumstances of the fall(s). To target those at high risk of falls but who have not yet fallen a short assessment of the patients functional ability (using the HAQ) and physical ability (using the Four Test Balance Scale and Chair Stand Test) as well as their pain, fatigue and an assessment of lower limb swollen or tender joints. This would highlight those at particular risk of falls who would need to be referred to a falls clinic or for physiotherapy for an individualised falls prevention program. Recurrent fallers would benefit from a more detailed multifactorial assessment including a medication review (in particular the review of psychotropic medicines) and an individual falls prevention programme from a trained clinician or at a falls prevention clinic. It should be noted that further research is required to test if current successful falls intervention programmes for older people are also appropriate for adults with RA.
Figure 7. Algorithm of falls risk screening and intervention tool for patient with RA.

Patient with RA

Have you fallen in the past year?

NO

Short falls risk assessment:
- Functional ability – HAQ>1
- VAS fatigue and pain score >4
- Swollen or tender hips/knees/ankles
- Balance – Four test balance scale ≥level 5 (unable to do one leg stand)
- Lower limb strength – Chair Stand Test x5 <20 seconds

YES

Multifactorial falls risk assessment:
- Falls risk and bone health assessment
- Fear of falling Short FES-I assessment
- Functional ability – HAQ>1
- VAS fatigue and pain score >4
- Swollen/tender joint assessment
- Balance- Four Test Balance Scale
- Lower limb strength- Chair Stand Test

NO

YES

Multifactorial intervention:
- Medication review & modification/withdrawal
- Home hazard assessment and intervention
- Exercise intervention prescribed by fall clinic/physiotherapist x2 weekly for 25 weeks
- Reassess patient after 6 weeks

Education

Leaflets on:
- benefits of exercise
- home safety,
- foot health
13.11 Recommendations for future research

The findings from this study all relate to patients attending outpatient clinics in the Northwest of England. A future case-control study using random allocation and utilising a disease register (to ensure that patients of all disease severities living in the community are included) would be beneficial to further test the findings from this study and enable comparisons with an independent dataset.

A screening tool could be tested that incorporates the recommended independent risk factors from this study to assist practitioners to highlight patients at particular risk of falls.

In addition, using the results from this study and the wide available knowledge from trials on the prevention of falls for older adults (Gillespie et al., 2009), an RA falls prevention trial could be designed. There are currently no falls prevention trials in adults with RA. Therefore, using the findings from this study, future research should consider a trial of a falls prevention programme that incorporates exercises that specifically target lower limb muscle strength and challenge balance alongside a review of medication, in particular the use of psychotropic drugs. Exercise may also improve fatigue, functional status and have a positive effect on disease activity (Neuberger et al., 1997) however further research is needed to confirm these hypotheses. A recent Cochrane review (Hurkmans et al., 2009) that assessed the safety and effectiveness of short term and long term dynamic exercise therapy programs concluded that aerobic capacity training combined with muscle strength training should be
recommended as routine practice in patients with RA, however trials that target more of the modifiable risk factors would be beneficial. It is also important that a falls prevention program includes research based therapy to improve fear of falling in RA patients and incorporates an economic evaluation of the intervention.
14. References


Arthritis and Musculoskeletal Alliance (2004). Standards of Care for People with Inflammatory Arthritis. London: ARMA. Available at: www.arma.uk.net/


Clopper, C., Pearson, E. S. (1934). "The use of confidence or fiducial limits illustrated in the case of the binomial". Biometrika, 26: 404–413.


NHS Centre for Reviews and Dissemination (2001) Undertaking Systematic Reviews of Research on Effectiveness. CRD’s guidance for those carrying out or commissioning review. Report number 4(2), York, NHSCRD.


15. Appendices

Appendix 1: Details of websites used in the literature review

Appendix 2: Table of key studies on falls or fear of falling in rheumatoid arthritis

Appendix 3: Invitation letter to patients

Appendix 4: Consent form and information sheet

Appendix 5: Questionnaire

Appendix 6: Rheumatoid arthritis and medication assessment form

Appendix 7: Fall event form

Appendix 8: Falls calendar artwork

Appendix 9: Pilot study in muscle strength and postural balance in 26 adults with RA

Appendix 10: Levene's Test for Equality of Variances and One way analysis of variance (ANOVA) summary table of results for mean differences in continuous variables by groups of non-fallers, single fallers and multiple fallers.
APPENDIX 1

Internet sites:

Arthritis Care - http://www.arthritiscare.org.uk/Home

Arthritis Research UK - http://www.arthritisresearchuk.org/

British Society of Rheumatology - http://www.rheumatology.org.uk/

The European League Against Rheumatism (EULAR) - http://www.eular.org/

The National Rheumatoid Arthritis Society (NRAS) - http://www.nras.org.uk/

Health management Information Service (HELMIS) –

http://www.ovid.com/site/products/fieldguide/hmni/Copyright.jsp

Health Management Information Consortium (HIMC) –


EQUATOR network for research reporting guidelines - http://www.equator-network.org/

STROBE guidelines for reporting observational studies – http://www.strobe-statement.org/
Appendix 2: Studies that investigate falls or fear of falling in adults with rheumatoid arthritis

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<thead>
<tr>
<th>Authors and location</th>
<th>Design/aim</th>
<th>Participants</th>
<th>Interventions/tools used</th>
<th>Outcome measures/risk factors</th>
<th>Results</th>
<th>Quality weighting and validity issues</th>
<th>Reviewer Comments</th>
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<tr>
<td>Hayashibara et al., (2010)</td>
<td>Prospective cohort design used to determine the one year incidence and fall risk factors in community based women with RA attending outpatient clinics in 1 hospital.</td>
<td>84 community dwelling women with RA aged 50 – 84 (mean age 64 years). Consecutive sampling.</td>
<td>Modified Health Assessment Questionnaire (mHAQ) used to measure functional ability, Steinblocker criteria used to measure RA stage and impact on well-being, DAS28, current medication, vitamin D, foot deformity, 5 physical performance tests including: functional reach; maximum step length; 5 metre walk time; step-up-and-down test; one-leg standing test; grip strength. Physical activity, standing balance, bone mineral density and muscle and fat volume measured.</td>
<td>Number of falls, disease activity, postural stability, physical performance related to falls, muscle volume and bone density.</td>
<td>n=84 women (mean age 64.1 yrs) 50% reported fall. No age differences in fallers. Swollen joints. &gt;pain. Low levels of outdoor activity, impaired vision.</td>
<td>Detailed methods, good repeatability. 95% Confidence intervals NOT reported. Small consecutive sample, women only. Comparisons made with community dwelling adults. Standard definition of fall included. Limited generalisability.</td>
<td>N.B. Fall incidence is lower in Japan (approx. 20% of older adults fall annually).</td>
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<td>Yamagiwa et al., (2011) Japan</td>
<td>Retrospective cohort design used to determine the 6 month year prevalence of falls and fear of falling in RA aged 18 – 75+.</td>
<td>N = 5,326 (765 men and 4,231 women)</td>
<td>Japanese Health Assessment Questionnaire (J-HAQ) used to measure functional ability, VAS – pain (0-10), VAS – general health (0-10), VAS – physician (0-10), Disease activity score (DAS28)</td>
<td>Functional ability, Body Mass Index, Rheumatoid factor, pain, general health, disease activity, tender and swollen joint counts, prednisolone (steroid) dose.</td>
<td>Among 765 men with Ra 8% reported 1 fall and 1.3% reported multiple falls in the previous 6 months. Among 4,231 women 10.5% fell once &amp; 2.4% had multiple falls. More women reported multiple falls than men &amp; the incidence of 1 or more falls increased with age for both genders. Those &gt;65 yrs old had a sig. higher risk of falls than those under the age of 65 yrs old. More women reported fear of falling compared to men.</td>
<td>Cross-sectional, only previous 6 months falls data measured. Methods not detailed (given in Furuya et al., 2009). Large cohort study, 95% Confidence intervals reported. No definition of fall included. Limited generalisability as only 1 site included in recruitment.</td>
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& influence of age on fear of falling differed between men and women
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<tr>
<td>Furuya et al. (2009) (NB – same study as Yamagiwa et al., 2011, reporting risk factors and incidence) Japan</td>
<td>Cross-sectional, retrospective, cohort design used to determine the one year prevalence and factors associated with falls in community based women with inflammatory arthritis. Study was part of larger cohort study.</td>
<td>4,996 (male 765, female 4231) community dwelling adults (median age 60 yrs, range 18-75+)</td>
<td>No intervention, Japanese Health Assessment Questionnaire (J-HAQ) used to measure functional ability BMI, Rheumatoid factor, CRP, VAS – pain (0-10), VAS – general health (0-10), VAS – physician (0-10), full DAS, tender and swollen joint counts, prednisolone (steroid) dose.</td>
<td>Swollen/ tender joints using 45 joints to include feet (DAS) and neck,</td>
<td>10.1% fell once, 2.2% fell twice and 19.2% reported fear of falling. J-HAQ, tender joint counts, VAS – general health were associated with at least 1 fall, multiple falls and fear of falling respectively.</td>
<td>Limited detail given on methods. Large cohort study, 95% Confidence intervals reported. No definition of fall included. Limited generalisability as only 1 site included in recruitment. Possible poor recall of falls due to retrospective design. Unable to determine association between risk factors and falls</td>
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<td>Smulders et al., (2009) The Netherlands</td>
<td>Small prospective cohort study of 84 adults with RA, follow-up one year using monthly fall registration cards.</td>
<td>84 adults (59 women, 25 men, aged 24-86 years).</td>
<td>Arthritis Impact Measurement Scale, Health Assessment Questionnaire scale, Visual analogue scale for pain.</td>
<td>Demographics, disease duration, medication, co-morbidity, visual impairment, fear of falling, 1 year history of falls, health status, function, balance confidence, pain.</td>
<td>43% reported a fall in 1 year (n=35) a fall rate of 0.82 falls/person year. Fall history and pain were predictors of falls.</td>
<td>Small sample, not powered to detect true incidence. No monitoring of reasons for falls, causal relationship unknown. Mail recruitment, fallers may have been more likely to take part.</td>
<td>Brief article with limited information. No definition of fall given.</td>
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<td>Çakıt et al., (2011) Turkey</td>
<td>Case-control, retrospective, cohort design used to evaluate fall frequency, fear of falling and fall risk in patients with RA.</td>
<td>84 patients with RA and 44 healthy controls.</td>
<td>Falls efficacy scale, Tinetti balance and gait tests, Health Assessment questionnaire (HAQ), Chronic Arthritis Systematic Index, Beck Depression Inventory, Steinbrocker functional classification.</td>
<td>Demographics, disease duration, duration of morning stiffness, numbness, dizziness, headache, upper and lower limb weakness, disease activity, previous year fall history, fear of falling, hand grip strength, depression, walking time, function, balance and gait speed.</td>
<td>14.3% RA group fell in 1 year (n=12), 67% described fear of falling, balance and disability level were independently linked to falls and fear of falling.</td>
<td>Small sample, no definition of falls, retrospective data collection, recruitment details lacking, limited generalisability.</td>
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<td>Oswald et al., (2006)</td>
<td>Cross-sectional, retrospective, cohort design, one year prevalence and factors associated with falls in community based women with inflammatory arthritis.</td>
<td>316 community dwelling women ≥16yrs with inflammatory polyarthritis, registered in the Norfolk Arthritis Register (NOAR). Consecutive sampling.</td>
<td>No intervention, Health Assessment Questionnaire (HAQ) used to measure functional ability, VAS pain.</td>
<td>Swollen/tender/deformed joints, height, weight, pain, functional ability, history of falls, vision, general health status, current exercise level, age at menarche, menopause &amp; use of hormone replacement therapy. Fallers asked about injuries &amp; fractures.</td>
<td>Out of 316 women (mean age 59 yrs) 34% reported fall in previous year. Falls more common in ≥75yrs. Swollen joints, &gt;pain, low levels of outdoor activity, impaired vision &amp; impaired general health were associated with higher level of falls.</td>
<td>Detailed methods, good repeatability. 95% Confidence intervals reported. Comparisons made with community dwelling adults. Did not include a standard definition of a fall. Only included women in Norfolk, limited generalisability. Possible poor recall of falls due to retrospective design. Unable to determine association between risk</td>
<td>Analysis only included subjects who at their 5th year review fulfilled the 1987 ACR criteria (Arnett et al., 1988) for diagnosis of RA or been given a Consultant diagnosis of RA.</td>
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Factors and falls. Selection bias - only 47% of sample completed questionnaire.
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<td>Armstrong et al., (2005) UK</td>
<td>Retrospective cross-sectional cohort study of RA patients. Survey methods used to investigate falls in previous year and the associations with concurrent medical treatment and disability.</td>
<td>253 men and women with RA aged 35 years and over, recruited consecutively from one outpatient clinic in the Northwest of England.</td>
<td>Structured, interview assisted questionnaire. occurrence and number of falls in previous year, and HAQ.</td>
<td>Falls, previous hip/knee surgery, functional ability (using HAQ), use of anti-hypertensives, diuretics, sedatives or hypnotics.</td>
<td>84 patients (33%) reported falling in the previous year (36% women and 26% men). 52% fallen on more once Fallers were associated with taking antidepressants and impairment in walking. HAQ score was higher in fallers than no fallers but not statistically significant.</td>
<td>No formal definition of falls used, falls caused by road accidents or violence excluded. Data based on self-report over previous 12 months, poor recall may have occurred. Sample recruited from hospital clinic therefore selection bias may result in participants with more severe condition than those managed in primary care. Small sample (n=253).</td>
<td>Authors recommend prospective studies to be conducted to confirm results and to further investigate falls risk factors. Unable to determine how patients with RA were selected and diagnosed i.e. did they fulfil the 1987 ACR criteria (Arnett et al., 1988) for diagnosis of RA or been given a Consultant diagnosis of</td>
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Unable to determine associations with falls and risk factors due to cross-sectional design.

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<tr>
<td>Kaz Kaz et al., (2004) UK</td>
<td>Case control study of older women (aged 65≥) with RA compared with women without RA. The study aim was to see if fall risk is increased with women with RA, to define high risk subgroups and determine what proportion of women have increased risk of hip fracture due to osteoporosis and due to increased fall risk.</td>
<td>103 women with RA and 203 women without RA, aged 65 years and over. Case group recruited from rheumatology in 1 hospital, control group were community dwelling women referred by GPs for open access bone density measurement, matched by age and body mass index. Control group excluded if RA or diseases causing bone abnormalities</td>
<td>DAS28, HAQ, standing and walking time for 7 days, Bone density, binocular corrected visual acuity, balance using heel-toe walking and lower limb strength.</td>
<td>Disease activity and duration of RA, functional status, bone density, swollen/tender joints, steroids, hip, knee or ankle disease, vision, physical activity (hours on feet per day), lower limb strength, balance.</td>
<td>54 % of women with RA reported fall in previous year compared to 44% of controls, but short of being statistically significant (CI –2 to 22). Women with RA had poorer heel-toe walking (balance) and inability to perform stand-ups (strength) compared to controls (P&lt;0.001). Femoral neck osteoporosis found in 31% of RA group. Visual acuity</td>
<td>Women only included, limiting generalisability. Cross-sectional design and use of fall risk factors as surrogates of falling, acknowledged as a limitation. Selection bias present as in control group women were referred for bone densitometry. Similar characteristics reported between 2 groups. Confidence intervals and P-values reported. No fall definition</td>
<td>RA participants fulfilled ACR 1987 criteria for diagnosis of RA (Arnett et al., 1988)</td>
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<td>present.</td>
<td>similar between case and control group.</td>
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<td>Jamison et al., 2003 USA</td>
<td>Cross-sectional cohort study of RA patients attending rheumatology outpatient clinics. Objective of research was to identify predictors of fear of falling, prevalence of falls over previous year, and to examine how fear of falling affects activities.</td>
<td>128 adults with RA recruited from an RA clinic, through contact with rheumatologists/physicians or via adverts in local press. Subjects were participants in a larger study and excluded if they had severe respiratory problems, fibromyalgia, systemic lupus erythematosus, major depression, mental impairment or if taking beta-blockers.</td>
<td>Structured questions related to falls, fear of falling, and activities modified. Profile of Mood States Short Form, the McGill Pain Questionnaire Short Form.</td>
<td>Falls, fear of falling, fall injuries, modified activities, emotional status and pain were measured through questions. Walk time, grip strength, physical fitness and total joint count also assessed.</td>
<td>35% participants fell during previous year. Subjects who fell had more co-morbid conditions than those who did not fall. Almost 60% were fearful of falling. Fearful subjects reported longer walk times, more co-morbid conditions and more intense pain.</td>
<td>Retrospective. Detailed methods given but unclear whether questions were questionnaire or interview based. A definition of falls was given but not substantiated. Small convenience sample used limits statistical significance of study. Authors did not use validated falls efficacy scale for fear of falling. Selection bias due to exclusion criteria (suitable for larger study but not this sub-study). Methods</td>
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A sub-study within a larger study that examined the effects of psychosocial factors on exercise participation and the effects of exercise participation on fatigue, pain and depression. Results are consistent with Fessel & Nevitt’s (1997) study into falls and fear of falling. Authors state need for prospective studies into falls and fear of falling. All fall
of RA diagnosis not given. P-values given but confidence intervals not used. Retrospective, cross sectional design prohibits causality definitions prior to 2005 have since been superseded by ProFaNE definition (Lamb et al., 2005).
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<tr>
<td>Fessel &amp; Nevitt, (1997) USA</td>
<td>Cross-sectional sub-sample of RA patients using telephone interviews and data previously gained using questionnaires from a larger study into depression and RA. The aim was to examine factors associated with fear of falling, activity limitation due to fear of falling and how persons modified their activities due to fear of</td>
<td>Participants in a panel study of RA ≥50 years (n = 570). Subjects randomly referred by rheumatologists.</td>
<td>Falls in previous year and fear of falling, HAQ, VAS pain in 18 joints, duration of disease, Geriatric Depression scale.</td>
<td>Falls, fall related injuries, fear of falling, physical and functional status, emotional health, pain, joint pain (in 18 joints).</td>
<td>Fifty per cent reported fear of falling and 38% modified activities due to fear of falling. Correlates of fear of falling included female gender, depressive symptoms, poor physical functioning, minor fall related injuries and greater number of painful joints. Nearly 87% of those who fell experienced some kind of Fall definition given, P-values but no confidence intervals reported. Cross-sectional design unable to assess changes in behaviour, attribute causality or determine whether significant risk factors preceded. Insensitive measure of fear of falling, use of a 4-point scale rather than the falls efficacy scale. Recall</td>
<td>A sub-study within a larger study that investigated prevalence and correlates of depression among persons with RA</td>
<td></td>
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<tr>
<td>falling in older persons with RA.</td>
<td>injury.</td>
<td>bias may affect results due to retrospective nature of study.</td>
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</table>
Dear Sir/ Madam

An invitation to participate in a research project

Our department is supporting a research study being undertaken by the University of Manchester. We have been asked to pass on details of this study to men and women with rheumatoid arthritis attending the hospital for treatment to see if you would be willing to take part.

This research is concerned with falls in rheumatoid arthritis patients. The study aims to find out how common falls are and what causes them. The study is being supported by all of the rheumatologists at the hospital.
The enclosed information leaflet explains the study in detail. If you wish to take part, please complete the acceptance form enclosed, place in the envelope provided and bring it with you at your next routine appointment.

Your participation in this study is voluntary. Even if you decide not to take part, we would be very grateful if you could please complete the decline form and return it in the prepaid envelope. Not taking part in this study will in no way affect the standard of care you receive.

If you have any queries, please contact Emma Stanmore at the University of Manchester on 0161 306 7645. If there is no-one available, please leave a message and someone will contact you as soon as possible.

Thank you for your time and co-operation.

Yours sincerely

Terence O’Neill
Consultant Rheumatologist
APPENDIX 4
(Form printed on Trust headed paper)

Centre Number:
Study Number:
Patient Identification Number for this study:

CONSENT FORM

Title of Project: Falls and fear of falling in people with rheumatoid arthritis

Name of Researcher: Emma Stanmore

Please initial box

1. I confirm that I have read and understand the information sheet dated 1/4/08 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from The University of Manchester, from regulatory authorities or from the NHS
Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my Consultant being informed of my participation in the study and for my Consultant to be informed if it is found that I am falling repeatedly.

5. I agree to take part in the above study.

_________________                ________________
Name of Patient                        Date                                            Signature

taking consent

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes
Patient Information Sheet
Study of Adults with Rheumatoid Arthritis

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

What is the purpose of the study?
Findings from research studies suggest that rheumatoid arthritis sufferers may be more prone to falling. Little is known though about how common falls are in people with rheumatoid arthritis and what causes them. This study will attempt to address this lack of information by looking at falls in a group of men and women with rheumatoid arthritis over a 12 month period.

Why have I been invited?
You have been asked to take part in this study because you have rheumatoid arthritis and are attending/ have attended Hope Hospital for treatment of the disease.

Who is funding this study?
The Arthritis Research campaign is funding the study.

Who is conducting the study?
The study co-ordinator is Mrs Emma Stanmore who is based at the University of Manchester and is conducting the study as part of an educational qualification. This study is also being directed by researchers...
at the University of Manchester and Doctors at both Hope Hospital and Manchester Royal Infirmary (MRI). The study is being supported by all of the rheumatologists at Hope and MRI including Dr O’Neill, Dr Herrick, Dr Benita, Dr Cooper, Professor Jones, Professor Silman, Dr Ho, Dr Hyrich, Dr Gorodkin.

**Do I have to take part in the study?**
No, you do not have to take part. It’s OK if you don’t want to give a reason. Also, if you do decide to take part, you do not have to answer any questions if you don’t want to. You are free to withdraw at any time, without giving a reason. Not taking part will not affect the standard of care you receive now or in the future.

**What will happen to me if I take part?**
If you agree to take part what will be involved is that one of the researchers in the study will arrange to see you. Where possible this will be at your next clinic appointment though if not possible we would arrange to see you at a mutually convenient time at the hospital outpatients. You will be asked to fill in a short questionnaire. You will also have your joints examined by a trained nurse or clinical support worker and you will be asked to undertake 2 simple physical checks. The first check will involve you standing in different positions to check your balance. The second check will involve standing up and down 5 times in a chair to check your strength. You will be assisted at all times. The procedure will take about 25 minutes to complete.

You will also be asked to complete, over the next year, a monthly calendar, to be filled in daily to monitor whether you fall. This involves writing the letter “F” for a fall or “N” for no fall. The calendar should take less than a minute to complete each day. We ask that you return this to us by post (postage will be prepaid). If you report a fall, you will be telephoned by the research nurse to find out more details.
What does the questionnaire ask?
The questionnaire asks you about details of your arthritis, your general health, whether or not you have suffered from a recent fall and also questions about any fears / concerns you have about falls.

What will I have to do for the calendars?
After you have completed the baseline questionnaire we will give you 12 prepaid postcards each of which incorporates a monthly calendar. We would ask that you indicate on the calendar for each day whether or not you have fallen. This should take in total less than 30 minutes per month. At the end of each month we ask that you post the calendar to us. By completing the calendar we will be better able to determine how frequent falls are in rheumatoid arthritis. If you do report that you experienced a fall we will telephone you to ask about more information about your fall.

What are the disadvantages or risks of taking part?
We do not foresee any risks in taking part in this study as all of the checks have been tested before with large groups of people, many with severe arthritis. Completing the questionnaires and calendar should not cause you any harm or distress. In the unlikely event that you find any aspects of the checks, questionnaires or falls calendar uncomfortable or distressing, then you will be able to discontinue your participation in the study. The researcher, Emma Stanmore will be happy to discuss possible options in dealing with this. You are free to withdraw from the study at any time.

What are the possible benefits of taking part in the study?
There will be no direct benefits for you. It is hoped that the findings of the study will help in understanding how frequent falls are and what causes them in rheumatoid arthritis sufferers and we hope will help in the
development of interventions to reduce the risk of falls and fall related injuries.

**What will happen to the results of the research study?**
The information you provide will be analysed and the results of the research will be published in project reports and made widely available to clinicians involved in the care of rheumatoid arthritis.

**Will my taking part in the research be confidential?**
Yes, all information which is collected about you during the course of the research will be kept strictly confidential. Information stored on computer will not include your name or address.

**What if there are any problems?**
If at any time you are unhappy about how this study is being conducted or have any complaints then please contact The University of Manchester’s Research Office on 0161 275 7583 or email research-governance@manchester.ac.uk

**What if I have further questions or worries?**
If you have any questions about the study then please contact Emma Stanmore who is the researcher working on this project (contact details below)

**What do I do next?**
If you would like to take part please indicate this on the attached sheet and return in the stamped addressed envelope. We will arrange to see you at your next clinic visit or at a convenient time for you. If you decide you do not wish to take part please indicate this on the attached sheet and return to us.

Thank you very much for considering taking part in this research project
Emma Stanmore
School of Nursing, Midwifery & Social Work
The University of Manchester
Oxford Road
Manchester
M13 9PL

Telephone: 0161 306 7645
Email: Emma.K.Stanmore@manchester.ac.uk
APPENDIX 5

A survey on falls and fear of falling in people with rheumatoid arthritis
General Instructions

Thank you for agreeing to help us in our research. Before continuing with this questionnaire please make sure that you have read the information sheet that was provided. We assume that you have no further questions about the study. If you do, then please ask the research nurse who gave you the questionnaire.

Your participation is entirely voluntary and you are free to withdraw at any time without giving any reason. If you do not wish to take part then please return the unanswered questionnaire.

All the information that you give us will be COMPLETELY CONFIDENTIAL and will not be seen by your doctor. Please answer ALL the questions.

For most questions you simply need to tick a box or put a circle around a number.

Here are some questions which have already been filled in as an example:

Some questions will start with a statement and you will be asked to tick the appropriate box
For example, if you would probably not visit your general practitioner by car then you would answer the following question like this:

*Do you use your car to visit your general practitioner?*

<table>
<thead>
<tr>
<th>Definitely</th>
<th>Probably</th>
<th>Probably</th>
<th>Definitely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Some questions will require you to write a response on a line

For example, if your age is 73 years then you would complete the following question as follows:

How old are you? 73 (years)
**Information about yourself**

1. Do you take four or more types of medicine each day? □ Yes □ No

2. Do you take medicine for sleeping difficulties, anxiety or depression? □ Yes □ No

3. Do you sometimes feel dizzy or unsteady? □ Yes □ No

4. Have you ever had a Stroke or Parkinson’s disease? □ Yes □ No

5. Using this pain scale (at one end, no pain and at the other end extreme pain) how would you rate your current level of pain?

(Please mark on the line below)

No pain _____________________________ Extreme pain _____________________________

6. Using this fatigue scale (at one end, no fatigue and at the other end extreme fatigue) how would you rate your current level of fatigue?

(Please mark on the line below)

No fatigue _____________________________ Extreme fatigue _____________________________
Questions about past falls

A fall is an unexpected event in which you come to rest on the floor, ground or lower level.

7. During the past year, how often have you had any fall including a slip or trip in which you lost your balance and landed on the floor, ground or lower level?

☐ Never    ☐ Once    ☐ Twice or more

If you have ticked NEVER then please jump to question 11

If you have had a fall, please answer the questions below for your most severe fall in the past year:

8. Which of the following types of injury did you suffer? (tick all that apply)

☐ Broken bone  ☐ Dislocated joint

☐ Losing consciousness  ☐ Straining or twisting a part of the body

☐ Cutting, piercing or grazing a part  ☐ Bruising, pinching or crushing a
9. As a result of the fall did you have to give up or change any of your normal daily activities?  
   □ Yes  □ No

10. Are you back to normal now?  
    □ Yes  □ No
**Concerns about falling**

Now we would like to ask some questions about how concerned you are about the possibility of falling. For each of the following activities, please tick the option closest to your own to show how concerned you are that you might fall if you did this activity. Even if you currently don’t do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Not at all Concerned</th>
<th>Somewhat Concerned</th>
<th>Fairly Concerned</th>
<th>Very Concerned</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Getting dressed or undressed</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
</tr>
<tr>
<td>12. Taking a bath or shower</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
</tr>
<tr>
<td>13. Getting in or out of a chair</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
</tr>
<tr>
<td>14. Going up or down stairs</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
</tr>
<tr>
<td>15. Reaching for something above your head or on the ground</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
</tr>
</tbody>
</table>
16. Walking up or down a slope

17. Going out to a social event (e.g. religious service, family gathering or club meeting)

Questions about your usual abilities

Now we would like to ask some questions about your usual abilities.

For each of the following activities, please tick the one response which best describes your usual abilities over the past week.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Without ANY difficulty</th>
<th>With SOME difficulty</th>
<th>With MUCH difficulty</th>
<th>UNABLE to do so</th>
</tr>
</thead>
</table>

Dressing and grooming

Are you able to

Dress yourself, including tying shoelaces and doing buttons?

Shampoo your hair?
Rising

Are you able to

18. Stand up from an armless straight chair?

19. Get in and out of bed?

Eating

Are you able to

20. Cut up meat?
21. Lift a full cup or glass to your mouth?

☐ 1    ☐ 2    ☐ 3    ☐ 4

22. Open a new milk carton or soap powder?

☐ 1    ☐ 2    ☐ 3    ☐ 4

Walking

Are you able to

23. Walk outdoors on flat ground?

☐ 1    ☐ 2    ☐ 3    ☐ 4

24. Climb up five steps?

☐ 1    ☐ 2    ☐ 3    ☐ 4
25. Please tick any AIDS or DEVICES that you usually use for any of the above activities

- Devices used for dressing (button hook, zipper pull, etc)
- Built up or special utensils
- Crutches
- Special or built up chair
- Stick
- Wheelchair
- Other ______________
- Walking frame

26. Please tick any categories for which you usually need HELP FROM ANOTHER PERSON

- Dressing and grooming
- Rising
- Eating
- Walking
Please tick the one response which best describes your usual abilities over the past week.

<table>
<thead>
<tr>
<th></th>
<th>Without ANY difficulty</th>
<th>With SOME difficulty</th>
<th>With MUCH difficulty</th>
<th>UNABLE to do so</th>
</tr>
</thead>
</table>

**Hygiene**

Are you able to

- **27. Wash and dry your entire body?**
  - [ ] 1
  - [ ] 2
  - [ ] 3
  - [ ] 4

- **28. Take a bath?**
  - [ ] 1
  - [ ] 2
  - [ ] 3
  - [ ] 4

- **29. Get on and off the toilet?**
  - [ ] 1
  - [ ] 2
  - [ ] 3
  - [ ] 4

**Grip**

Are you able to

- **30. Open car doors?**
  - [ ] 1
  - [ ] 2
  - [ ] 3
  - [ ] 4

- **31. Open previously opened jars?**
  - [ ] 1
  - [ ] 2
  - [ ] 3
  - [ ] 4
32. Turn taps on and off?  

Activities

Are you able to

33. Run errands and shop?

34. Get in and out of a car?

35. Do chores such as vacuuming or housework or light gardening?
36. Please tick any AIDS or DEVICES that you usually use for any of the above activities

☐ Raised toilet seat  ☐ Bath rail  ☐ Long-handled appliances

☐ Bath seat  ☐ Long-handled appliances in the bathroom

☐ Other________

37. Please tick any categories for which you usually need HELP FROM ANOTHER PERSON

☐ Hygiene  ☐ Gripping and opening things

☐ Reach  ☐ Errands and housework
Further background information

38. Are you? □ Male □ Female

39. Date of birth: □ □ □ (day) / □ □ □ (month) / □ □ □ (year)

40. Please tick the appropriate box which best describes your ethnic origin.

  a) Black or Black British □ Caribbean □ African
     □ Any other Black background within (a)

  b) White □ British □ Irish
     □ Any other White background

  c) Asian or Asian British □

  d) Mixed
1. Ethnicity:

- [ ] Indian
- [ ] Pakistani
- [ ] Bangladeshi
- [ ] Any other Asian background within (c)
- [ ] White & Black Caribbean
- [ ] White & Black African
- [ ] White & Asian
- [ ] Any other mixed background
- [ ] Other ethnic groups
- [ ] Chinese
- [ ] Any other ethnic group
- [ ] Not stated

41. Where were you born?

- [ ] 1 UK
- [ ] 7 Middle East
- [ ] 45 USA
- [ ] 46 Canada
- [ ] 47 Ireland
- [ ] 48 Australia
- [ ] 49 New Zealand
- [ ] 50 Other

266
- Ireland
- Caribbean
- East Africa
- West Africa
- South Africa
- India
- Pakistan
- Bangladesh
- Far East
- Other *

* If other please specify:

________________________________________
Finally, we would like to know about what you do or did for a living. This is important as certain jobs can affect your chance of getting ill and may influence your decision about going to see a doctor. We realise that these questions are quite difficult to answer, and we would be grateful for as much information as you can give us.

42. Are you currently:

- [ ] Employed
- [ ] At home doing housework / caring for family
- [ ] Retired
- [ ] Unemployed seeking work
- [ ] Full-time student
- [ ] Unemployed through sickness/disability
- [ ] Doing voluntary work

43. Have you ever had a paid job?

- [ ] No (go to question 54)
- [ ] Yes
Please complete Box A for the main job you have done for most of your life.

**Box A: YOURSELF**

44. Your job title (Avoid general titles like clerk, engineer, supervisor):

45. Please describe the main tasks of your job:

46. Which **one** of the following best describes your position at work? (tick one box only)

- [ ] Self employed (25 or more employees)*
- [ ] Manager (less than 25 employees)*
- [ ] Self employed (less than 25 employees)*
- [ ] Supervisor
- [ ] Self employed (no employees)
- [ ] Employee
☐ Manager (more than 25 employees)*

* total number in company, not just those of whom your partner is in charge

47. Are you currently (tick one box):

☐ Single, never married (go to end of questionnaire)

☐ Married/living with partner

☐ Divorced

☐ Separated

☐ Widowed

48. Has your partner ever had a paid job?

☐ No (go to question 119)

☐ Yes

Please complete Box B for the main job your partner has done for most of their life.
49. Your PARTNER’S job title (Avoid general titles like clerk, engineer, supervisor):

50. Please describe the main tasks of your partner’s job:

58. Which one of the following best describes your partner’s position at work?
   
   (tick one box only)
   
   - Self employed (25 or more employees)
   - Manager (less than 25 employees)
   - Self employed (less than 25 employees)
   - Supervisor
☐ Self employed (no employees)  ☐ Employee

☐ Manager (more than 25 employees)*

* total number in company, not just those of whom your partner is in charge

We may wish to contact you in the future either to clarify your responses to this questionnaire or to invite you to attend a clinic for further checks to find out about your balance and strength. If you leave this blank we will assume you do not wish to be contacted.

I agree to be contacted by the researchers in the future

NAME (CAPITALS): ________________________________

Signature: ________________________________ Date: ___/___/_____

Home or mobile telephone number: ________________________________

Thank you for filling in this questionnaire
APPENDIX 6

**Rheumatoid Arthritis & Medication Assessment**

**DAS28**

Number of swollen/tender joints =

Most recent ESR =

Global Health Score =

DAS28 score =

**Medication** (Please circle)

Psychotropic drugs (antidepressants, antipsychotics, benzodiazepines)

yes/no

Cardiovascular drugs (diuretics, digoxin, IA antiarrythmics)

yes/no

**List of medication** (duration and type and history of steroid use)

**Co-morbidities** (Past medical history)
History of steroid use

Yes/No

Less than 6 months steroid use

Yes/No

6-12 months steroid use

Yes/No

More than 12 months steroid use

Yes/No

Type of steroid(s)______________________________

Eyesight

Ask-“At the present time, would you say your eyesight using both eyes (with glasses or contact glasses if you wear them) is”

Excellent/Good/Fair/Poor/Very Poor/Registered Blind

(Circle response)

History

Fractures  Yes/No Location___________

Surgery  Yes/No Location___________

Joint replacement(s) Yes/No Location(s) _________

Painful feet  Yes/No
Chair stand test

- Use a straight-backed firm chair with no armrests.
- Place the chair with a wall behind for safety.
- Instruct the person to stand up and sit down as quickly as possible five times with the arms folded.
- Using a stopwatch, record in seconds the time taken to stand up and sit down five times.
- Allow a maximum of two minutes to complete the test.

Scoring unsuccessful/successful; time taken in seconds.


Four-test balance scale

- Includes four timed static balance tasks of increasing difficulty that are completed without assistive devices (see figure opposite for position of feet).
- No practices are allowed before each task.
- The test is carried out in bare feet.
- The assessor can help the person to assume each foot position, then the person should indicate when ready to begin unaided.
- If the person cannot assume the position, do not continue (failed task).
- The person must hold each position for 10 seconds before progressing to the next task.
- Timing is stopped if:
– The person moves their feet from the proper position
– The assessor provides support to prevent a fall
– The person touches the wall or external object for support.

Scoring feet together stand unsuccessful/highest level task successful

APPENDIX 7
FALL EVENT FORM

Telephone .............................

1. Date of the fall
2. Fall circumstances
   “Please describe how the fall occurred and what happened as a result of the fall”
   …………………………………………………………………………
   …………………………………………………………………………
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3. How long did you lie before being able to get up, or help arrived?

4. Please describe all injuries
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..
   …………………………………………………………………………..

Did this fall result in:
5. Death 1=Yes 2=No
6. An ambulance attending? 1=Yes 2=No
7. A visit to the emergency department? 1=Yes 2=No
8. A stay overnight or longer in a public hospital? 1=Yes 2=No
Name of hospital
........................................................................................................................................

Number of nights ...........☐☐☐

9. A stay overnight or longer in a private hospital or rest home?
   1=Yes  2=No
   ☐

   Name of institution ................................. Number of nights  ☐☐☐

10. Permanently shifting to a rest home?
    1=Yes  2=No
    ☐

11. A visit to the doctor or other health professional?
    1=Yes  2=No
    ☐

12. An injury that required stitches?
    1=Yes  2=No
    ☐

13. The dislocation of a joint?
    1=Yes  2=No
    ☐

14. An injury resulting in haemarthrosis?
    1=Yes  2=No
    ☐

15. Head injury?
    1=Yes  2=No
    ☐

16. Fracture of a bone?
    1=Yes  2=No
    ☐

    If yes, which bone(s)?
    1 = Head/skull  7 = Upper arm  13 = Upper leg/femur
    Fracture 1: ☐
    2 = Face/teeth  8 = Lower arm  14 = Knee
    Fracture 2: ☐
    3 = Neck  9 = Wrist  15 = Lower leg
    Fracture 3: ☐
    4 = Ribs  10 = Hand  16 = Ankle
    5 = Back/vertebrae  11 = Pelvis  17 = Foot
    6 = Shoulder/clavicle  12 = Hip  18 = Toe(s)
As a result of this fall, which of the following activities could you not do, or did you have difficulty doing, for at least 3 days after the fall?

a. As a result of this fall, did you have any difficulty walking around your home?
   1 = Could not do before the fall
   2 = Could not do because of the fall
   3 = Able to do but had more difficulty than before the fall
   4 = Could do after the fall without difficulty

b. As a result of this fall, did you have any difficulty walking around outside or away from your home?
   1 = Could not do before the fall
   2 = Could not do because of the fall
   3 = Able to do but had more difficulty than before the fall
   4 = Could do after the fall without difficulty

c. As a result of this fall, did you have any difficulty doing things around your home like cooking or cleaning?
   1 = Could not do before the fall
   2 = Could not do because of the fall
   3 = Able to do but had more difficulty than before the fall
   4 = Could do after the fall without difficulty
APPENDIX 8

Falls and rheumatoid arthritis study

1. At the end of each day, please place the letter “N” in the box if you did not fall, or the letter “F” in the box if you did fall.
2. At the end of each month, please detach the calendar for that month and post it. No stamp is necessary.

THANK YOU!

Any questions, please contact
Emma Stanmore on Tel. 0161 306 7645

A0012 MAY 2009

<table>
<thead>
<tr>
<th></th>
<th>SUN</th>
<th>MON</th>
<th>TUES</th>
<th>WED</th>
<th>THURS</th>
<th>FRI</th>
<th>SAT</th>
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<td>24</td>
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<tr>
<td>25</td>
<td>26</td>
<td>27</td>
<td>28</td>
<td>29</td>
<td>30</td>
<td>31</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 9

A pilot study to assess muscle strength and balance in 30 patients with rheumatoid arthritis

Recruitment and response rates
During the recruitment of the 559 participants, a sample of 30 participants (15 fallers and 15 non-fallers, who agreed to be contacted during the assessments) were selected from the participants who lived in Greater Manchester (n = 311), for a pilot study investigating lower limb strength and postural stability in adults with RA. These tests were conducted at the Wellcome Trust Clinical Research Facility, Manchester (WTCRF). At the end of the recruitment phase, a total of 33 participants attended the WTCRF for the postural stability and lower limb strength tests; however seven participants were unable to perform the tests and consequently withdrew due to feeling too unwell. A total of 26 participants remained in the study, of which 13 had a 12 month history of falls and 13 had a 12 month history of no falls.

Eligibility criteria
Interested participants were screened for eligibility by an assessment phone call. The screening phone call was used to check for any contraindications associated with undertaking strength or balance assessments including:

- Current flare up of rheumatoid arthritis or any other acute illness
- A history of epilepsy
- Cardiac insufficiency, severe peripheral vascular disease or known aneurysms
- Current use of anticoagulants e.g. warfarin
- Use of steroids for longer than 3 months
- Malignancies, injuries, skin problems, severe limitations of movement or severe effusions on lower limbs
- Pregnancy
- Diagnosis of severe osteoporosis
- Use of steroids for longer than 3 months
- Recent (<3 months previous) radiotherapy or chemotherapy
- Severe pain

**Sampling methods**

In the original proposal, a computer generated random sampling sequence was planned in order to choose which patients to approach. However, due to the large number of participants who had taken steroids for periods of more than 3 months (n = 203), or had been diagnosed with osteoporosis (n = 17), it was very difficult to randomly recruit eligible participants and so all Manchester residents that took part in the full study were eventually screened. Of the 311 participants, only 91 were eligible to take part in the muscle strength and balance tests. The eligible participants were given further written and verbal information about the muscle strength and balance tests. Of these, a further 28 did not wish to take part and thirty were not able to attend due to feeling too unwell. Thirty three interested participants were given an appointment date/time to attend the WTCRF and an information sheet regarding the tests.

The participants were invited to attend the Wellcome Trust Clinical Research facility on two occasions. The first visit was to obtain their written consent, to familiarise themselves to the facility and to see what was entailed in the tests. Previous research has demonstrated that this trial attempt is also required to ensure the validity of the tests undertaken (Callaghan, et al., 2000). On arrival at the second visit participants undertook the muscle strength and balance tests and the results were recorded.

**Dynamic balance instrumentation**

A Biodex Stability Platform (BSS; Biodex Medical Systems, Shirley, NY, USA) was used to measure dynamic postural stability. Ability to control variable platform angles of tilt is quantified as variance from a centre point on a visual circular grid by a biofeedback screen. The BSS consists of a moveable balance platform that provides up to 20° of surface tilt in a 360° range of motion. The
BSS is interfaced with computer software that objectively assesses the overall postural stability (OA), the anterior/posterior (AP) and the medial/lateral (ML) postural stability scores. A high OA score indicates poor balance and is the best indicator of the overall ability of the participant to maintain balance on the platform (Aydoğ, et al., 2006; Testerman & Griend, 1999)

Lower limb muscle strength instrumentation
Lower limb muscle strength was measured isometrically using an ISOCOM dynamometer (ISOCOM, Isokinetic Technology, Bingham Industrial Estate, Nottingham, UK). Participants were positioned on the ISOCOM chair with 90° hip flexion with the knee angle set at 90° flexion. Participants were secured with pelvic and torso seat belts to minimise body movements. The participants’ lower leg was strapped to the dynamometer lever arm resistance using a calf pad at 5cm proximal to the lateral malleolus. All tests were conducted unilaterally, with the dominant limb. The settings of the chair for each participant were recorded to ensure standardisation on each visit. The ISOCOM software programme automatically adjusts for the effects of gravity during the setup procedure.

Isokinetic exercises
Participants were given standardised instructions:
“When you are ready we will perform the exercise. First you will be asked to raise and lower your leg 5 times. We will have a practice run, 1 minute rest and then I will ask you to do it again as hard and fast as you can. If at any point you are in pain and wish to stop please let me know. Do you understand? Are you ready?”
The participants performed 5 test repetitions with 1 minute rest and then repeated the exercise with maximum effort. The maximum effort results were recorded and the maximum of the five repeats was used for the data analyses.

Isometric exercise
The participants were positioned as for the isokinetic exercises. The following standardised instructions were used:
“We are now going to perform a different set of exercise. This time the arm and pad will not move. You will push against them. When I say go, push against the pad for 5 seconds. We will do 2 practice ones with a short break in between and then I will ask you to do this as hard as you can. If at any point it becomes painful and you wish to stop let me know. Do you understand? Are you ready?”

There is a short countdown and the exercises start. The participant is encouraged to push for the full 5 seconds. Once the exercise is complete there is a 30 second rest period and the participants’ comfort is checked. Following the countdown, the participant repeats the exercises for another 5 seconds to complete the practice contractions then rests for 120 seconds. The process is repeated 3 more times until the participant completes a total of 5 isometric exercises with 30 seconds rest periods in between. The maximum value of the 3 extension peak torques was used for subsequent analysis.

Data analysis

Data were collected for the maximum single peak torque for extension and flexion for the isokinetic tests. The peak torque for extension was recorded for the maximum isometric contraction. The mean values for the isokinetic extension and flexion, isometric contraction and the balance scores were analysed by independent sample t tests to ascertain any differences in gender and fallers and non-fallers. A one way analysis of variance (ANOVA) was used to test for any differences between the age groups of participants and the mean values of the isokinetic, isometric and balance results.

As this study is exploratory and not statistically powered to detect significance, 95% confidence intervals were also reported for differences between males and females and fallers and non-fallers. Independent samples t-tests were applied in SPSS to estimate the confidence interval and the test results are reported but interpreted cautiously due to the small sample size.
Descriptive and analytical results

The demographics and characteristics of the 26 participants are initially presented (table 1) and descriptive statistics are used to summarise the basic features of the data.

Demographic results

There were nearly twice the number of female participants recruited for the pilot study (table 1) which was similar to the proportion of female participants in the full study. Participants were largely retired (77%) and of white British ethnicity (89%).

Table 1. Demographics and characteristics of pilot study participants (n=26)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (34.6)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (65.4)</td>
</tr>
<tr>
<td>Ethic origin</td>
<td></td>
</tr>
<tr>
<td>1. White British</td>
<td>23 (88.5)</td>
</tr>
<tr>
<td>2. White Irish</td>
<td>3 (11.5)</td>
</tr>
<tr>
<td>Country of origin</td>
<td></td>
</tr>
<tr>
<td>1. UK</td>
<td>24</td>
</tr>
<tr>
<td>2. Ireland</td>
<td>2</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>1. Employed</td>
<td>4 (15.4)</td>
</tr>
<tr>
<td>2. Retired</td>
<td>20 (76.9)</td>
</tr>
<tr>
<td>3. Full time student</td>
<td>0</td>
</tr>
<tr>
<td>4. Doing voluntary work</td>
<td>0</td>
</tr>
<tr>
<td>5. At home doing housework/caring for family</td>
<td>0</td>
</tr>
<tr>
<td>6. Unemployed seeking work</td>
<td>1 (3.8)</td>
</tr>
<tr>
<td>7. Unemployed due to sickness/disability</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>1 (3.8)</td>
</tr>
</tbody>
</table>
Marital status
1. Single, never married 2 (7.7)
2. Married/living with partner 20 (76.9)
3. Divorced 1 (3.8)
4. Separated 0
5. Widowed 3 (4.5)

Socio-economic classification (NS SEC, ONS, 2005)
1. Higher managerial and professional occupations 1 (3.8)
2. Lower managerial and professional 6 (23.1)
3. Intermediate 6 (23.1)
4. Small employers and own-account workers 3 (11.5)
5. Lower supervisory and technical 7 (26.9)
6. Semi-routine 1 (3.8)
7. Routine 1 (3.8)
8. Never worked and long-term unemployed (Missing =1) 0

The mean age of the participants was 65 (Median = 66, Std. Dev. 8.9) which was slightly higher than the mean of the full sample (62 years of age). Most of the participants were aged between 55 and 74, the youngest participant was 42 years old and the oldest participant was 79 years old. Table 2 summarises the age ranges of the participants. Using Fisher’s exact test, there were no significant differences in age between participants with a 12 month history of falls and those without a 12 month history of falls ($\chi^2 =4.36$, df = 8, p=0.76).
Table 2 Age groups of participants at baseline assessment

<table>
<thead>
<tr>
<th>Age group</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>35 - 54</td>
<td>2 (7.6)</td>
</tr>
<tr>
<td>55 - 64</td>
<td>10 (38.5)</td>
</tr>
<tr>
<td>65 - 74</td>
<td>11 (42.3)</td>
</tr>
<tr>
<td>Over 75</td>
<td>3 (11.5)</td>
</tr>
<tr>
<td>Total</td>
<td>26 (100.0)</td>
</tr>
</tbody>
</table>

Table 3. Characteristics of participants using continuous data

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean ±standard deviation (minimum to maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (cm)</td>
<td>166 ± 8.6 (142.7-179.3)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>71.1 ± 14.6 (43.6-98.7)</td>
</tr>
<tr>
<td>Number of swollen joints (0 – 28)</td>
<td>3.1 ± 5.6 (0-22)</td>
</tr>
<tr>
<td>Number of tender joints (0 – 28)</td>
<td>5.3 ± 7.6 (0-24)</td>
</tr>
<tr>
<td>DAS28 score (0 – 8)</td>
<td>3.7 ± 1.5 (1.2-6.8)</td>
</tr>
<tr>
<td>Global health score (0 – 100)</td>
<td>32.6 ± 20.0 (0-83)</td>
</tr>
<tr>
<td>Number of medicines</td>
<td>6.8 ± 4.1 (2-19)</td>
</tr>
<tr>
<td>Number of co-morbidities</td>
<td>1± 1.6 (0-7)</td>
</tr>
<tr>
<td>VAS pain score (0 -10)</td>
<td>3.7 ± 2.4 (0-9)</td>
</tr>
<tr>
<td>VAS fatigue score (0 – 10)</td>
<td>4.9 ± 2.5 (0-9)</td>
</tr>
<tr>
<td>FES-I score (7 – 28)</td>
<td>11.6 ± 4.9 (7-23)</td>
</tr>
<tr>
<td>HAQ score (1.0 – 4.0)</td>
<td>1.8 ± 0.8 (1.0-3.9)</td>
</tr>
<tr>
<td>Time taken for Chair stand test (seconds)</td>
<td>18.5 ± 9.8 (4 – 49)</td>
</tr>
</tbody>
</table>

There appears to be wide variation in the physical characteristics of the 26 participants as seen in table 3. On the whole however, the participants had low numbers of tender and swollen joints, disease activity scores (DAS28) and numbers of co-morbidities. Fatigue, pain and fear of falling were moderate with mean scores of 4.9, 3.7 and 11.6 respectively. Functional ability was also fair.
with a mean HAQ score of 1.8 and the median time taken for the Chair stand test was 15.0 seconds (mean =18.1 seconds)

Table 4. Characteristics of participants using categorical data

<table>
<thead>
<tr>
<th>Measure</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking steroids at baseline (Y/N)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>History of fractures (Y/N)</td>
<td>12 (46.2)</td>
</tr>
<tr>
<td>History of previous surgery (Y/N)</td>
<td>21 (80.8)</td>
</tr>
<tr>
<td>Painful feet (Y/N)</td>
<td>17 (65.4)</td>
</tr>
<tr>
<td>Four or more types of medicines (Y/N)</td>
<td>17 (65.4)</td>
</tr>
<tr>
<td>Medicines for sleeping difficulties, anxiety or depression (Y/N)</td>
<td>4 (15.4)</td>
</tr>
<tr>
<td>Complaints of feeling dizzy or unsteady (Y/N)</td>
<td>10 (38.5)</td>
</tr>
<tr>
<td>History of stroke or Parkinson’s disease (Y/N)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>History of previous fall(s) (Y/N)</td>
<td>13 (50.0)</td>
</tr>
<tr>
<td>Injuries from previous fall(s) (Y/N)</td>
<td>12 (70.6)</td>
</tr>
<tr>
<td>DAS28 score range</td>
<td></td>
</tr>
<tr>
<td>&lt; 2.6 (disease remission)</td>
<td>6 (23.1)</td>
</tr>
<tr>
<td>2.6 to &lt;3.2 (low disease activity)</td>
<td>5 (19.2)</td>
</tr>
<tr>
<td>3.3 to &lt;5.1 (moderate disease activity)</td>
<td>9 (34.6)</td>
</tr>
<tr>
<td>&gt; 5.1 (severe disease activity)</td>
<td>6 (23.1)</td>
</tr>
<tr>
<td>Eyesight:</td>
<td></td>
</tr>
<tr>
<td>Registered blind</td>
<td>1 (3.8)</td>
</tr>
<tr>
<td>Poor</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>Fair</td>
<td>8 (30.8)</td>
</tr>
<tr>
<td>Good</td>
<td>13 (50.0)</td>
</tr>
<tr>
<td>Excellent</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>Chair stand test:</td>
<td></td>
</tr>
<tr>
<td>Unsuccessful</td>
<td>1 (3.8)</td>
</tr>
<tr>
<td>Successful</td>
<td>25 (96.2)</td>
</tr>
</tbody>
</table>
The categorical participant characteristics are shown in table 4. The purposive sampling resulted in the recruitment of 50% of the participants with a 12 month history of a fall. It is notable that nearly half of the participants had a history of fracture(s) and the majority had also had previous surgery, painful feet and took more than four or more types of medicines. After transforming the continuous disease activity score (DAS28) data into categorical bands, it can be seen that overall the participants’ scores varied fairly evenly from remission through to severe disease activity. Over a third of the participants felt dizzy or unsteady at the baseline assessment, although over half managed to complete the Four Test Balance scale and stand on one leg for ten seconds. Only one participant could not complete the Chair Stand Test due to tender and swollen lower arm joints.

Table 5. Summary of overall balance and lower limb strength results

<table>
<thead>
<tr>
<th>Balance and strength measures</th>
<th>Mean ± standard deviation (minimum to maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall postural stability</td>
<td>1.5 ±0.8 (0.6-3.6)</td>
</tr>
<tr>
<td>Anterior/Posterior Index</td>
<td>1.1 ±0.6 (0.2-2.2)</td>
</tr>
<tr>
<td>Medial Lateral Index</td>
<td>0.9 ±0.6 (0.0-2.8)</td>
</tr>
<tr>
<td>Isometric extension peak torque (Nm)</td>
<td>89.9 ±67.8 (-241)</td>
</tr>
<tr>
<td>Isokinetic extension peak torque (Nm)</td>
<td>60.7 ±42.3 (-141)</td>
</tr>
<tr>
<td>Isokinetic flexion peak torque (Nm)</td>
<td>26.6 ±36.1 (-180)</td>
</tr>
</tbody>
</table>
The balance and strength measures (table 5) were analysed by gender of study participants using an independent samples t-tests. There were no significant gender differences found in the balance measures of overall postural stability ($t= -0.35$, $p = 0.73$, 95% C.I. $-0.8$, 0.6) anterior/posterior index ($t= -0.54$, $p = 0.6$, 95% C.I. $-0.7$, 0.4) or medial lateral index ($t= -0.17$, $p = 0.87$, 95% C.I. $-0.7$, 0.4). However, males had significantly greater isometric extension peak torque than female participants ($t= -3.12$, $p = <0.01$, 95% C.I. 25.4, 124.8). Males also had borderline significantly greater isokinetic extension peak torque measurements ($t=2.05$, $p = 0.05$, 95% C.I. -0.31, 67.4) and isokinetic flexion peak torque ($t=2.04$, $p = 0.05$, -0.28, 57.6).

Table 6. Balance and lower limb strength measures by gender

<table>
<thead>
<tr>
<th>Balance and strength measures</th>
<th>Gender</th>
<th>Mean (± standard deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall postural stability</td>
<td>Male (n = 9)</td>
<td>1.46 ± 0.54</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>1.57 ± 0.91</td>
</tr>
<tr>
<td>Anterior/Posterior Index</td>
<td>Male (n = 9)</td>
<td>1.01 ± 0.56</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>1.15 ± 0.68</td>
</tr>
<tr>
<td>Medial Lateral Index</td>
<td>Male (n = 9)</td>
<td>0.84 ± 0.29</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>0.89 ± 0.73</td>
</tr>
<tr>
<td>Isometric extension peak torque (Nm)</td>
<td>Male (n = 9)</td>
<td>139.02 ± 71.62</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>63.94 ± 50.51</td>
</tr>
<tr>
<td>Isokinetic extension peak torque (Nm)</td>
<td>Male (n = 9)</td>
<td>82.62 ± 45.94</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>49.07 ± 36.35</td>
</tr>
<tr>
<td>Isokinetic flexion peak torque (Nm)</td>
<td>Male (n = 9)</td>
<td>45.31 ± 53.66</td>
</tr>
<tr>
<td></td>
<td>Female (n = 17)</td>
<td>16.64 ± 17.23</td>
</tr>
</tbody>
</table>

Table 6 displays the differences in mean measures of balance and lower limb strength between fallers and non-fallers. Overall postural stability, anterior/posterior index and medial lateral index scores were higher in fallers than non-fallers which indicate poorer balance in the fallers and this is clinically
relevant. However, when an independent samples t-test was applied these differences did not appear to be statistically significant. However these results should be interpreted cautiously due to the small sample size and with a larger sample size the differences may also be statistically significant.

Table 7. Balance and lower limb strength measures by fallers and non-fallers

<table>
<thead>
<tr>
<th>Balance and strength measures</th>
<th>Ever fallen in 12 months</th>
<th>Mean (± standard deviation)</th>
<th>P – values (95% confidence intervals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall postural stability</td>
<td>No (n = 15)</td>
<td>1.34 ± 0.86</td>
<td>p = 0.22 (-1.0, 0.25)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>1.76 ± 0.65</td>
<td></td>
</tr>
<tr>
<td>Anterior/Posterior Index</td>
<td>No (n = 15)</td>
<td>0.93 ± 0.61</td>
<td>p = 0.11 (-0.9, 0.1)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>1.34 ± 0.61</td>
<td></td>
</tr>
<tr>
<td>Medial Lateral Index</td>
<td>No (n = 15)</td>
<td>0.83 ± 0.67</td>
<td>p = 0.71 (-0.6, 0.4)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>0.93 ± 0.53</td>
<td></td>
</tr>
<tr>
<td>Isometric extension peak torque (Nm)</td>
<td>No (n = 15)</td>
<td>101.74 ± 70.18</td>
<td>p = 0.31 (-27.6, 83.4)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>73.83 ± 64.13</td>
<td></td>
</tr>
<tr>
<td>Isokinetic extension peak torque (Nm)</td>
<td>No (n = 15)</td>
<td>65.22 ± 42.68</td>
<td>p = 0.53 (-24.3, 45.8)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>54.49 ± 42.92</td>
<td></td>
</tr>
<tr>
<td>Isokinetic flexion peak torque (Nm)</td>
<td>No (n = 15)</td>
<td>34.37 ± 44.26</td>
<td>p = 0.20 (-10.7, 47.6)</td>
</tr>
<tr>
<td></td>
<td>Yes (n = 11)</td>
<td>15.92 ± 17.44</td>
<td></td>
</tr>
</tbody>
</table>

Summary
There appear to be differences in the balance and lower limb strength of adults with RA with and without a 12 month history of falls. Fallers appear to have poorer balance, indicated by the mean overall postural stability, anterior/posterior index and medial lateral index measurements. Fallers also had lower mean peak torque measurements for the isometric extensions and isokinetic extensions and flexions for the lower limb tests. Due to the small sample sizes, these results were not statistically significant but do have some clinical relevance. This research is worthy of more detailed study with a larger sample to test whether these
differences are statistically significant between fallers and non-fallers in adults with RA.

References


**APPENDIX 10:** Levene’s Test for Equality of Variances and One way analysis of variance (ANOVA) summary table of results for mean differences in continuous variables by groups of non-fallers, single fallers and multiple fallers.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Levene’s test of homogeneity met yes/no (p-value)</th>
<th>ANOVA Test F value</th>
<th>Welch Test Statistic</th>
<th>Significant Tukey/ Dunnetts T3 post hoc results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Yes (0.6)</td>
<td>2.6</td>
<td>N/A</td>
<td>No sig. differences</td>
</tr>
<tr>
<td>Baseline Short FES-I</td>
<td>Yes (0.39)</td>
<td>12.37</td>
<td>N/A</td>
<td>MF&gt;SF, MF&gt;NF</td>
</tr>
<tr>
<td>Change in Short FES-I</td>
<td>Yes (0.43)</td>
<td>0.69</td>
<td>N/A</td>
<td>No sig. differences</td>
</tr>
<tr>
<td>One year Follow-up</td>
<td>Yes (0.2)</td>
<td>12.8</td>
<td>N/A</td>
<td>MF&gt;SF, MF&gt;NF</td>
</tr>
<tr>
<td>Number of medicines</td>
<td>No (&lt;0.001)</td>
<td>N/A</td>
<td>7.9</td>
<td>MF&gt;NF</td>
</tr>
<tr>
<td>Time taken for Chair Stand Test</td>
<td>No (0.04)</td>
<td>N/A</td>
<td>4.3</td>
<td>NF&lt;MF</td>
</tr>
<tr>
<td>Number of swollen joints</td>
<td>No (0.008)</td>
<td>N/A</td>
<td>0.09</td>
<td>No sig. differences</td>
</tr>
<tr>
<td>Number of tender joints</td>
<td>No</td>
<td>N/A</td>
<td>4.2</td>
<td>MF&gt;NF</td>
</tr>
<tr>
<td>Pain</td>
<td>Yes (0.07)</td>
<td>N/A</td>
<td></td>
<td>MF&gt;NF</td>
</tr>
<tr>
<td>Fatigue</td>
<td>No (&lt;0.001)</td>
<td>N/A</td>
<td>20.4</td>
<td>MF&gt;NF, MF&gt;SF</td>
</tr>
<tr>
<td>DAS28</td>
<td>Yes (0.006)</td>
<td>N/A</td>
<td>6.4</td>
<td>MF&gt;NF</td>
</tr>
<tr>
<td>Global Health</td>
<td>No (0.22)</td>
<td>16.3</td>
<td>N/A</td>
<td>MF&gt;SF</td>
</tr>
<tr>
<td>Co-morbidities</td>
<td>Yes (0.4)</td>
<td>1.2</td>
<td>N/A</td>
<td>No sig. differences</td>
</tr>
<tr>
<td>HAQ score</td>
<td>Yes (0.8)</td>
<td>15.3</td>
<td>N/A</td>
<td>MF&gt;SF, MF&gt;NF</td>
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</tbody>
</table>