Title: Rheumatoid arthritis, fall incidence and consequences: A prospective, cohort study of 559 adults.

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Abstract

Objectives

To determine the incidence of falls and to investigate the consequences of falls in adults with rheumatoid arthritis.

Methods

559 community dwelling adults with RA, aged 18 to 88 years (mean age 62; 69% female) participated in this prospective cohort study. Patients were followed for 1 year after a detailed clinical assessment, using monthly falls calendars and follow up telephone calls. Follow-up took place in participants' usual place of residence in the Northwest of England. 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.

Results

535 participants followed for 1 year had a total of 598 falls. 36.4% participants (95% CI 32% to 41%) reported falling during 1 year follow-up with an incidence rate of 1313/1000 person-years at risk or 1.11 falls per person. Age and gender were not associated with falls. 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). Treatment by general practitioners or other health professionals was required for 15.0% of falls and emergency services were required after 8.8% of falls.

Conclusions

These results indicate that adults with RA are at high risk of falls and fall-related injuries, fractures and head injuries. Strategies to prevent falls in adults with RA must be prioritised to reduce falls and fall-related injuries, and fractures.

Word count: 241 words

Keywords: accidental falls, falling, rheumatoid arthritis, fractures, incidence.

Falls in adults and older people are a global public health challenge and are associated with substantial health, social and economic costs. Falls are not just restricted to older persons, but can have severe consequences for other at risk groups such as people with arthritis. Rheumatoid arthritis (RA) affects approximately 0.8% of the UK population and 1% worldwide. [1] Previous small scale research suggests that people with rheumatoid arthritis may be at greater risk of falls and osteoporotic fractures due to altered gait, poor mobility and balance, muscle weakness, bone fragility, pain, and fatigue. [2 3 4 5 6] To date, 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 12 months. [4 7 8] These studies report similar results with 31-35% of people with RA reporting falls. A small prospective study of 84 women with RA reported an incidence of falls of 50% in a 12 month period. [2] However these results cannot be generalised due to the age range (50 – 82 year old) and exclusion of men. Another small prospective study of 25 men and 59 women reported an incidence of 42% [9] but did not use a definition of a fall, which may lead to different interpretations of falls by participants and researchers.[10] To date, there are no prospective data reporting fall incidence in younger subjects.

Many epidemiological studies and fall prevention trials have been conducted in older community dwelling adults .[11] In comparison, there is scant epidemiological research relating to the occurrence and consequences of falls in adults with RA. The aim of this study was to determine the one year incidence of falls in adult men and women with RA and to characterise the mechanisms and outcomes related to falls which occurred.

Methods

Participant recruitment

Participants were recruited from four rheumatology outpatients' clinics in three National Health Service (NHS) Hospital Trusts and one Primary Care Trust (PCT) in Northwest England. Patients were included if they had RA based on the 2010 American College of Rheumatology classification criteria for RA[12] and were over 18 years of age. Participants were excluded from the study if they were without the mental or physical capacity to give informed consent.

Three patients with rheumatoid arthritis were involved in the planning of the study and assisted with data collection decisions such as the language used in the questionnaire and information sheets. Patients gave written informed consent before taking part. Ethical approval was gained from the National Research Ethics Committee, reference 08/H1009/41and the University of Manchester Committee on Ethics of Research on Human Beings.

Baseline assessments

Measurements taken at the baseline clinical assessment included: demographic data (age, gender, ethnicity, socioeconomic status); Rheumatoid Arthritis Disease Activity Score (DAS28) including number of swollen and tender joints; Stanford Arthritis Centre Health Assessment Questionnaire (HAQ); 12 month history of falling; fear of falling questionnaire (Short Falls Efficacy Scale-International), and falls risk using the Assessment of Falls Risk Tool (FRAT). Fall history was recorded 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". Data on medication, pain, fatigue, vision, co-morbidities, and history of surgery, fractures, and joint replacements were also recorded. The results and further details on these measurements are reported elsewhere. [13]

Follow-up

Falls and injuries were recorded during the follow-up period using the ProFaNE fall definition of, "an unexpected event in which participants come to rest on the ground, floor, or other lower level".[14]Falls and injuries were monitored using monthly, prepaid, preaddressed calendar postcards that were filled in daily by participants. Those reporting a fall were followed up by telephone to gather information about the fall and any injuries. This information included; date of fall, participant description of how the fall occurred, consequences and injuries (injuries coded by researcher as 0 = no injury, 1 = moderate injury, 2 = severe injury), and length of time before able to get up or help arrived (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?", "As a result of this fall, did you have any difficulty walking around 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). Participants who failed to complete the calendars were followed up by telephone.

Sample

Based on an estimated frequency of falls over 12 month period of 30% it was estimated that a sample of 550 people with RA (495 people after an assumed 10% drop-out rate) was needed to achieve an exact 95% confidence interval (Clopper-Pearson[15]) for the rate of (0.26, 0.35), as given by StatsDirect[16] version 2.6.5. (StatsDirect Ltd).

Data analysis

Fall data were summarised as recommended by ProFaNE[13] using number of falls, number of non fallers/single fallers/multiple fallers and fall rate per person year. Confidence intervals were reported for the incidence rate of falls. Injuries were classified according to the International Classification of Diseases, (10^{th} Revision) classification system[17]. Injury data were summarised as type of injury, fracture rate per person year, number of fractures, number of persons sustaining fractures and number of persons sustaining multiple injury events. Statistical analysis was performed using SPSS[18] (version 16.0; SPSS Inc., Chicago, IL, USA).

Results

845 letters were sent to participants prior to their clinic appointment (figure 1). 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 1 year follow – up. Sixty per cent of participants completed all of the 12 calendar returns within the 1 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).

(Figure 1 here)

Table 1 presents the demographic and descriptive characteristics of the sample. More women (n=386, 69%) were recruited to the study than men. 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 majority of participants were married or living with a partner (n=378, 69.7%) and were of white British ethnicity and born in the UK (n=544, 97.3%). Over half of the participants were retired (n=327, 58.5%), and 15% were unable to work due to their disabilities (n=82). Twenty-four percent of the participants continued to be employed (n=134).

(Table 1 here)

Incidence of falls

From the initial sample of 559 participants, 535 (95.7%) completed 1 year follow-up. 598 falls were reported in 5467 months of observation with a crude incidence rate of 1313/1000 person-years at risk or 1.11 falls per person. Over a third of the participants experienced 1 or more falls (36.4%, 95% CI 32% to 41%). Ninety – four people fell once, and one hundred and one people fell twice or more.

Age/sex–specific incidence rates in 12 months

Table 2 presents the age-specific incidence rates in 12 months for the participants. A small number of younger participants (n=7) fell frequently which gave the 0-34 age-band a high incidence rate of falls. However, due to the small number in this group confidence intervals are wide. There was also an increase in the incidence rate of falls in the 65-74 age-band but this drops again in the >75 age group.

There were no significant differences in the percentage of men and women who fell in the 1 year. 70.2% of the fallers were women but the sex-specific incidence rates (table 3) 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 2 and 3 here)

Self-reported fall event descriptions and locations

The self-reported fall descriptions were recorded and later categorised into types of falls and reasons for falls. Seventeen participants could not remember the full details of the fall.

The commonly reported types of falls were hips or knees or ankles, "giving way" (n=187, 31.0%), with the knee joints most frequently affected 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 4 summarises the self-reported underlying reasons for the falls(s), described by participants. Sixty-three per cent of the participants (n=356) affected by falls blamed their RA for the underlying cause of the fall (described as joint pain, muscle weakness, joints giving way or a flare- up of the condition). Tripping over hazards was the next most commonly described fall (n=105, 18.7%) and the majority of the tripping over hazard falls resulted in moderate or serious injuries (n=61, 58.1%). Sixty-five per cent 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=363), whilst 31.5% participants fell outside their home or outside going up or down steps (n=177).

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).

(Table 4 here)

Injuries and consequences of falls

Over half of the falls (n=291, 51.5%) resulted in bruising, stiffness and exacerbated joint pains, sprains, bangs to head (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%). Lower body injuries were most common (table 5) 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 high (n=27, 5.1%) compared to other studies[8]. Injuries involving multiple body regions (n=81, 14.3%) were also high. There were 26 fractures in total as a result of falls (n = 20, 4%) which resulted in a fracture rate of 57.1 fractures per 1000 person-years at risk. Of these 15 were single fractures, 3 falls resulted in 2 fractures, and 2 falls resulted in 3 fractures (bilateral hip fractures and a fractured pelvis for one participant, and 3 fractured toes in another participant).

(Table 5 here)

Over half of the falls that participants related to their RA resulted in moderate injuries (n=182, 51.1%) and 7.0% (n=25) resulted in serious injuries (e.g. fractures or hospitalisation). Significantly more outdoor falls resulted in moderate or severe injury (n=124, 70.1%) in comparison to indoor falls (n=210, 54.6%, χ^2 =14.1, df=2, p=<0.01).

As a consequence of a fall, 31.9% of participants' experienced more difficulty in being able to walk around their home (n=183), whilst 8.2% of the falls resulted in the participants being unable to walk independently around their home (n=47). Nearly 40% of the falls resulted in participants having difficulty or being unable to walk outside or away from their home (n=217). Thirteen per cent of participants could not walk outside before the fall occurred. 36.5% of the falls led to participants being unable or having difficulties in being able to continue with activities around the home such as cooking and cleaning (n=209).

Use of health services

Fifteen percent of falls (n=86) resulted in visits to the GP or required physiotherapy or nursing assistance for treatment or rehabilitation. Furthermore, emergency services such as an ambulance or visit to the accident and emergency department were necessary for treatment of 8.8% (n=50) of the falls and 2.4% (n=14) of the falls resulted in hospital admissions. Hospital stays ranged from 5 -140 days (median=6 days).

Discussion

In the largest prospective study of falls in rheumatoid arthritis 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 12 months follow up 36.4% (95% CI 32% to 41%) participants reported one or more falls.

Increasing age was not associated with increased falls. Hayashibara et al.[2] and Smulders et al.[9] 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.[10] [19 20] Older people in general have decreased activity leading to muscle weakness, poor 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 and this may lead to the similar fall rates.

No relationship was found between frequency of falls and gender in adults in this study and by Smulders et al.[9] which is also different to studies of community dwelling people where women are more likely to fall than men.[21] [10] 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.[22] 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.[23] 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,[8] possibly due to hand joint involvement causing difficulties in breaking the impact of falls. Injuries involving multiple body regions were also high.

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.[23] The functional ability of participants was decreased after more than a third of the falls which could affect levels of independence and requirements from caregivers.

There are few health services available for patients with RA, at risk of falls, other than mainstream physiotherapy and occupational therapy. 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.[24] Yet RA appears as a condition in the widely used World Health Organisation's FRAX fracture risk assessment tool[25] and RA has been highlighted as a key risk factor for osteoporotic fractures due to low bone mass.[6 26] 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[27] and the consequent NICE guidelines,[28] they have remained a service for older people who fall, not those of all ages with RA.[7]

The strengths of this study are its prospective design, high response rate and low attrition rate. The 12-month follow up allowed for any seasonal variations in the number of falls. The study has a number of limitations. Attempts were made to attend a variety of clinics so that people with varying levels of severity of RA were recruited from the four outpatient clinics. However, it is likely that people with more severe RA may be included in the sample due to the recruitment from the clinics. Also, people who have previously fallen may have been more inclined to participate in the study and this could cause a degree of selection bias.

Conclusions

Falls are common and an important cause of injury and fracture in adults of all ages with RA. Head injuries and fractures appear to be particularly high in this group of patients. Due to the lack of patients reporting falls and minor injuries to clinicians, it is important that falls are assessed regularly in medical consultations.

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Ethical approval

This study was conducted with the approval of the National Research Ethics Committee, reference 08/H1009/41.

Declaration of competing interests.

The authors have declared no conflict of interest.

Contributors: ES conceived the study with support from CT and JO. ES, CT (study guarantor), JO, DS and TO were responsible for the design of the study and obtaining funding, analysis and interpretation of the data and preparation of the manuscript. ES and MP conducted data analyses. All authors reviewed the manuscript.

Figure 1: Flow diagram of the research process

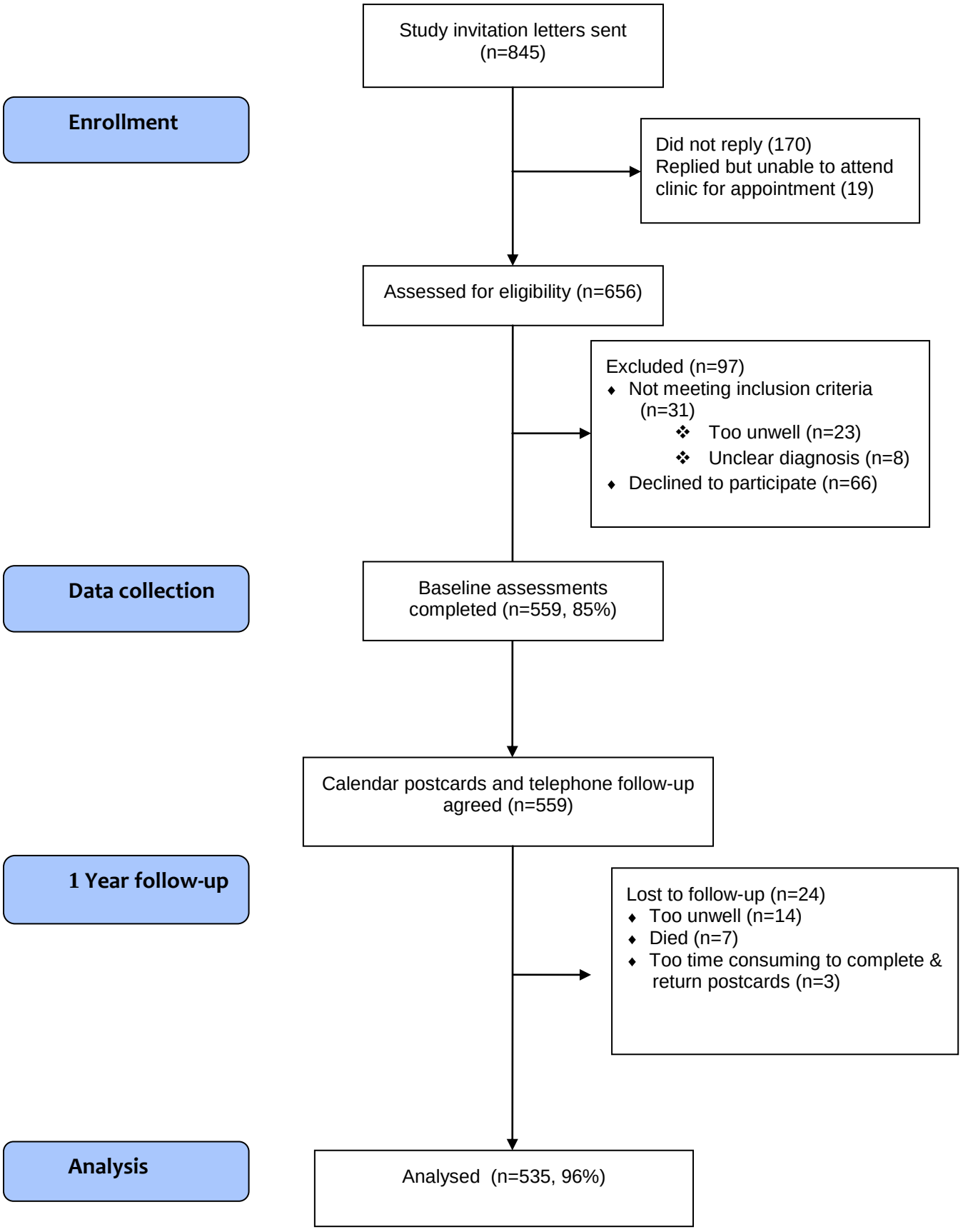

Table 1. Baseline demographics and characteristics of study participants (n=559)

Characteristics	**Number (%)**
Sex	
Male	173 (30.9)
Female	386 (69.1)
Ethnic origin	
African/Caribbean	3 (0.5)
White British/white Irish/other white background	544 (97.3)
Asian/British Indian/British Pakistani	8 (1.4)
Mixed ethnicity	2 (0.4)
Other ethnicity	2 (0.4)
Employment status	
Employed	134 (24.0)
Retired	327 (58.5)
Full time student/voluntary work/unemployed	3 (0.5)
At home doing housework/caring for family	13 (2.3)
Unemployed due to sickness/disability	82 (14.7)
Marital status	
Single, never married	49 (9.0)
Married/living with partner	378 (69.7)
Divorced/separated	43 (7.9)
Widowed	72 (13.3)
	(not recorded = 17)
Socio-economic classification (NS SEC, ONS, 2005)	
Higher managerial and professional occupations	13 (2.3)

Lower managerial and professional	87 (15.6)
Intermediate	85 (15.2)
Small employers and own-account workers	120 (21.5)
Lower supervisory and technical	166 (29.7)
Semi-routine/routine	57 (10.8)
Never worked and long-term unemployed	1 (0.2)
	(not recorded = 30 (5.4))

Table 2. Age–specific incidence rates in 1 year

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

Table 3. Sex-specific fall incidence rates in 1 year follow-up

Gender	Fallers (n)	Fall event s (n)	% Fallers per year	Person-years at risk	Incidence rate of falls per 1000 person years	95% Confidence intervals
Male (n=162)	57	240	35%	136.6	1756.9	1541.7, 1993.9
Female (n=373)	138	358	37%	318.9	1122.6	1009.3, 1245.1

Table 4.Self-reported reason for fall in 1 year follow-up

Reason for fall	**Number of falls (%)**	**95% Confidence Intervals**
RA	356 (63.3)	55.5 to 63.4
Tripped over hazard	105 (18.7)	14.7 to 20.8
Dizziness	21 (3.7)	2.3 to 5.3
Slipped on ice	17 (3.0)	1.9 to 4.7
Feeling generally unwell	14 (2.5)	1.4 to 3.8
Recent surgery	9 (1.6)	0.8 to 2.9
Momentary lapse of concentration	8 (1.4)	0.7 to 2.6
Epilepsy	7 (1.2)	0.6 to 2.4
Rushing	7 (1.2)	0.6 to 2.4
Difficulty with visibility at night	6 (1.1)	0.5 to 2.2
Fatigue	5 (0.9)	0.3 to 2.0
Transcient ischaemic attack/Stroke	5 (0.9)	0.3 to 2.0
Fainted	1 (0.2)	0.0 to 0.95
Hypotension	1 (0.2)	0.0 to 0.95
Total	562 (100.0)	
Missing	36	
Total	598	

Table 5. Type of fall-related injury in 1 year follow-up according to International Classification of Diseases (10^{th} edition)

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