

ORIGINAL ARTICLE

Comparison of alternative falls data collection methods in the Prevention of Falls Injury Trial (PreFIT)

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Abstract

Background and Objectives: Prospective, monthly diaries are recommended for collecting falls data but are burdensome and expensive. The aim of the article was to compare characteristics of fallers and estimates of fall rates by method of data collection.

Study Design and Setting: A methodology study nested within a large cluster randomized controlled trial. We randomized 9,803 older adults from 63 general practices across England to receive one of three fall prevention interventions. Participants provided a retrospective report of falls in postal questionnaires mailed every 4 months. A separate randomization allocated participants to receive prospective monthly falls diaries for one simultaneous 4-month period.

Results: Falls diaries were returned by 7,762 of 9,375 (83%); of which 6,306 (67%) participants reported the same number of falls on both data sources. Diary nonresponders were older and had poorer levels of physical and mental health. Analysis of time points where both data sources were available showed the falls rate on diaries was consistently higher than on the questionnaire (mean rate: 0.16 vs. 0.12 falls per person-month observation). Diary allocation was associated with a higher rate of withdrawal from the main trial.

Conclusion: Diary completion was associated with sample attrition. We found on average a 32% difference in falls rates between the two data sources. Retrospective and prospective falls data are not consistently reported when collected simultaneously. © 2018 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Keywords: Falls; Older adults; SWAT; Clinical trials; Data quality; Statistical analysis

1. Introduction

Falls are a common problem for older adults, with one-third of community-dwelling adults aged older than 65 years falling at least once per year. Epidemiologic studies and clinical trials often use postal questionnaires to capture falls data by including questions about previous falls over a specific period. These postal surveys rely upon memory recall of past events, and inaccuracies in reporting of falls have been attributed to general forgetfulness, and

even denial, as a reason for underreporting, particularly for those falls not resulting in injury [1,2]. Other factors that may contribute to either an overestimation or underestimation of self-reported falls include cognitive impairment or the use of psychotropic medication [3]. Higher levels of pride have recently been found to be associated with underreporting of self-reported falls in a longitudinal analysis of older English adults [4]. Interestingly, recall of falls over 1 year has been found to have better sensitivity (80–89%) and specificity (91–95%) than over shorter recall periods, such as the previous 3–6 months [2,3].

Prospective data collection, using monthly calendars, postcards, or diaries, is considered the gold standard for collecting data on falls, as these allow participants to record events in real time and minimize recall bias [3,5]. The Prevention of Falls Network Europe (ProFaNE) expert group recommended that falls should be recorded using prospective daily recording and a notification system with a minimum of monthly reporting [6]. Telephone or face-to-face

Trial Registration: Trial registered as ISRCTN under trial registration number 71002650. The study protocol has approval from the National Research Ethics Service (REC reference 10/H0401/36; Protocol V.3.1, 21/May/2013).

Conflicts of interest: none.

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What is new?**Key findings**

- Older adults reported more falls in prospective monthly diaries compared with postal questionnaires asking them to recall falls frequency.
- Allocation to prospective falls diary completion over 4 months resulted in increased likelihood of withdrawal from the clinical trial.

What this adds to what was known?

- Previous studies have compared falls data collection methods, but this is the first large-scale population study of older adults to demonstrate the impact of short-term diary completion on overall study retention.

What is the implication and what should change now?

- Postal questionnaires to older adults asking them to recall number of falls is likely to be an underestimate.
- Researchers should consider both the positive and negative implications of using falls diaries as a means of data capture in epidemiologic studies and clinical trials. Prolonged or long-term use of falls diaries leads to attrition.

interview should be used to capture missing data wherever possible. However, intensive monitoring is burdensome and expensive to administer in a research environment.

Previous studies have compared the use of prospective monitoring among specific patient groups or clinical settings. Kunkel et al. compared falls data captured from retrospective interviews and prospective falls diaries over a 12-month period in stroke patients discharged from hospital [7]. Although there was good agreement (83%) in the classification of fallers between the two methods, more participants yielded information during face-to-face interviews than from diaries (92% vs. 62% completion). Importantly, those with very frequent falls were less likely to complete diaries [7]. A systematic review investigating recurrent falls in people diagnosed with Parkinson's Disease (PD) [8] found that although almost all of the included studies used prospective monitoring methods, studies using retrospective methods over longer time points (e.g., 6 months) generally reported lower rates of falling. Given the frequency of repeat falling in this population, whereby recurrent falls can occur in up to 70% of those with PD, prospective monitoring methods were strongly encouraged. A community-based study of women with low bone density found that annual retrospective questioning resulted in one-

third fewer falls being reported compared with monthly telephone calls [9].

These studies have investigated falls in specific clinical populations; however, less is known about the impact of using more intensive falls recording methodology in community-dwelling older adults. A systematic review by Ganz et al. [3] identified only six studies (2,212 participants contributing falls data) and revealed conflicting evidence for ability to recall falls over different time intervals.

To date, no studies of community-dwelling adults have assessed the impact of regular falls monitoring on participant retention to a clinical trial. Participant retention to a clinical trial is essential to avoid impact upon or reduction in statistical power. Losses to follow-up over time will introduce attrition bias, particularly if there is an association between likelihood of falling and nonresponse. We used an efficient framework to undertake an embedded methodological study within a clinical trial (SWAT) [10]. We incorporated the SWAT within a large UK cluster randomized controlled trial testing three alternative falls prevention interventions on outcomes of falls and fractures in older adults (the Prevention of Falls Injury Trial [PreFIT]) [11]. The primary aim of the SWAT was to compare falls data using two methods of data collection, namely diary card and retrospective postal questionnaires. This was achieved by the following objectives: (1) to assess the rate of return of falls diary cards and falls questionnaires; (2) to compare the patient characteristics for three groups: those who had a full return of diary cards, those who had a partial return (at least one card), and finally, those who did not return any diary cards; (3) to estimate differences in falls rates and agreement between reporting in falls diaries and postal questionnaires; (4) to estimate the impact of requests to complete monthly falls diaries over 4 months on overall retention to the main clinical trial; and finally, (5) to explore statistical methods of dealing with partial completion of falls diaries, that is, missing at least one monthly diary within a 4-month period.

2. Methods

2.1. Study design and participants

The full trial protocol is reported in full elsewhere [11]. In brief, the trial used a cluster-randomized pragmatic design to test alternative falls prevention interventions of advice, exercise, and multifactorial assessment, on outcomes of falls and fractures in community-dwelling adults aged 70 years and older. The unit of randomization was the general practice (GP); a total of 9,803 older adults were randomized from 63 practices across England. The SWAT design used a separate randomization strategy to allocate trial participants to prospective data collection over a period of 4 months in the first year of follow-up. Participants were randomized to receive falls diaries during one period only (either from randomization to 4 months

follow-up; 5–8 months; or between 9 and 12 months). Falls were collected using two data collection methods described in the following.

2.2. Retrospective falls reporting: postal questionnaires

Postal questionnaires were administered to all trial participants at baseline and at 4, 8, 12, and 18 months postrandomization, but only data collected up to 12 months were used in this SWAT, as diary card data were only collected for the first 12 months of follow-up. Two questions were asked in relation to falls: (1) “In the last 4 months, have you had any fall including a slip or trip; following which you have come to rest on the ground, floor, or lower level?” (yes/no) and (b) “If yes, how many times have you fallen within the last 4 months?” The definition for falls was consistent with recommendations from ProFaNE [6]. Postal questionnaire data received up to 12 months were used for the SWAT substudy, and the falls recall period was 4 months. Explanatory cover letters were included with follow-up questionnaires, along with a prepaid stamped addressed envelope.

2.3. Prospective falls reporting: monthly falls diaries

In addition to postal questionnaires, all trial participants were invited to self-complete four monthly falls diaries. Falls diaries were produced in a small calendar format, printed in color on firm card, with the reverse side being the prepaid return address for the study office. The diaries were posted to participants in a pack of four, with a covering instruction letter. Each diary instructed: “for each day this month, please write the number of times you had any fall, including a slip or trip, in which you lost your balance and landed on the floor or ground or lower level. If you did not have a fall, please write ‘0’.”

2.4. Data entry and quality assurance

Questionnaire survey data were scanned using the Formic Fusion software (Formic Solutions). Data from falls diaries were manually entered by an independent data clerk onto a bespoke database designed for the trial. For each period, a validation check was undertaken on a random sample of questionnaires and diaries to assess accuracy of data entry. Where an error rate of more than 5% was identified, another random sample was drawn for accuracy checks. Additional checks for missingness and range values were conducted by the trial statisticians.

2.5. Statistical analysis

2.5.1. Baseline

Falls were reported at baseline, 4, 8, and 12 months using self-reported falls in questionnaires. Diary return rates were summarized for each of the periods: baseline to 4 months; 5–8 months; and 9–12 months. The pattern of

return was examined to explore whether there was a systematic monotonic return (all four diaries returned or three-, two-, or one-consecutive returned) or random return (any period with at least one monthly diary not returned). Baseline demographic characteristics were assessed by diary complier status (full = completed all diaries; partial = returned at least one, nonresponder = none completed). Overall comparison of the three categories was made for (1) categorical outcomes using chi-square tests and (2) for the continuous data using nonparametric tests for trend. The baseline outcomes consisted of quality of life, measured using the SF-12 V2 [12], cognitive function using the Clock Drawing Test [13], and frailty through the Strawbridge Frailty questionnaire [14]. Frailty was categorized as frail for any problem in two or more domains vs. nonfrail for those with no problems or problem in one domain only [15]. Other characteristics assessed were sex, age at randomization, marital status, age on leaving full-time education, body mass index (BMI), and falls history in preceding 12 months.

2.5.2. Retention

Analysis of the impact of diary allocation against no diary card allocation on overall retention to the trial was examined by comparing withdrawal rates between the two groups as appropriate for each time point. The number of participants who provided falls data on a full set of diaries and on the questionnaire for the corresponding period was summarized. Level of agreement between the numbers of falls reported by method was assessed using Cohen’s unweighted Kappa test statistics [16] (where the null hypothesis is no agreement) and Bland and Altman plots [17]. Withdrawal rates were calculated using appropriate denominators, where those who had withdrawn or died in a previous period were excluded. Numerators for withdrawal rate calculations were defined as those who had submitted a formal request to withdraw from participation in the trial.

2.5.3. Analysis of falls data

Number of falls were categorized as none (nonfaller), one (single faller), and two or more falls (repeat faller) during the specified period. Falls rate was calculated as falls per person per month (pppm) of data collection. The rate was computed for those who returned four diaries and a completed questionnaire for a particular time interval and presented as unadjusted estimates of rate ratios (RR). A mixed-effect negative binomial model was used to compare the rate of falls by method of data collection because of the potential for overdispersion, which is often found for count data such as monthly falls. The model structure mirrored the planned statistical analysis of falls data for the main PreFIT study. Thus, covariate adjustment was undertaken with prespecified baseline variables (age at randomization, sex, prerandomization falls history (faller/nonfaller based on falls reported in 12 months before randomization), and GP deprivation score.

2.5.4. Analysis of missing falls diaries

Three analytical approaches were used to account for missing diaries to allow comparisons with the number of falls from the corresponding questionnaire. These included (1) an assumption of zero falls for the missing monthly diary; (2) dropping the missing months from the denominator of rate calculations; and (3) multiple imputations using chained equations to impute missing monthly diary values. Under an assumption that data were missing at random, an imputation model was specified for each month, using participant age, sex, and deprivation score of GP as prediction variables. The imputation strategy was consistent with recommendations from the Cochrane review on principles of missing data and other guidance [18].

All response rates, falls rates, and other statistical estimates are presented with 95% confidence intervals (CIs) where appropriate. Statistical testing was conducted at the 5% significance level. All statistical analyses were conducted using STATA version 15 (StataCorp) [19].

3. Results

3.1. Diary completion and participant characteristics

A total of 9,803 participants were randomized to PreFIT interventions, all of whom were also randomly allocated to one of the three periods for the SWAT. Of those randomized, 9,375 participants (95.6%) were sent falls diaries, whereas the remaining 428 participants (4.4%) had either withdrawn from the trial or had died before the allocated period for posting diary cards. Table 1 shows the completion of falls diaries by period. Most participants ($n = 6,508$ of 9,375, 69%) returned all four diaries for the allocated period, with 14% ($n = 1,254$ of 9,375) returning one, two, or three diaries and 17% (1,613 of 9,375) failing to return any diary. The pattern of diary returns was monotonic for 74% ($n = 6,955$ of 9,375), with 5% ($n = 507$ of 9,375) returning diaries in a nonmonotonic fashion, thus skipping a monthly diary but then returning a subsequent monthly diary (Appendix A: Table 1). Those who failed to return any diaries were older, had poorer levels of physical and mental health, and had poorer cognitive function compared with those who returned one or more diaries (Table 2).

Table 1. Falls diary completion by period of follow-up

No. of diaries returned	Period of follow-up			Total
	0–4 mo, n (%)	5–8 months, n (%)	9–12 m, n (%)	
4	2,315 (71)	2,065 (67)	2,128 (70)	6,508 (69)
3	284 (9)	319 (10)	224 (7)	827 (9)
2	97 (3)	91 (3)	64 (2)	252 (3)
1	62 (2)	64 (2)	49 (2)	175 (2)
0	498 (15)	554 (18)	561 (19)	1,613 (17)
Total	3,256	3,093	3,026	9,375

Across each of the three allocated periods, there was a statistically significant difference in the proportion of withdrawals from the main trial between those participants allocated to complete diaries and those not (Table 3). The difference in proportions was at least 2% across each period. The mean difference in withdrawal rates across all three periods between those allocated to complete diaries ($n = 493$ of 9,437, 5.2%) or not ($n = 527$ of 18,672, 2.8%) was 2.4%.

3.2. Comparison of falls reporting methods

There were a higher number of falls reported on prospective diaries than reported on the retrospective questionnaires for each period (Table 4). Of the 6,418 participants who fully completed both data collection methods during their allocated period, there was exact agreement for 85% ($n = 5,459$) when falls were classified by nonfaller, single faller, and repeated faller [20]. There was substantial agreement between the two data collection methods [21]; Cohen's unweighted kappa test statistic 0.638 ($P < 0.001$).

Where there was lack of agreement in number of falls between both data sources, 65% ($n = 546$ of 845) of participants reported a higher number of falls on prospective diaries, compared with 35% ($n = 299$ of 852) who reported a higher number of falls on the questionnaires. Figure 1 displays the Bland and Altman plot of the prospective minus the retrospective difference in number of falls plotted against the mean of the two measurements [22]. The mean difference in falls reported in prospective diaries compared with questionnaires was 0.056 falls pppm. The limits of agreement of -0.98 to 1.09 indicate we would expect 95% of differences to be different by only one fall in either direction.

3.3. Falls rate calculation: full compliers

Among the full compliers with diaries, the reported rate of falling was consistently higher compared with falls reported in questionnaires. Tables 4 and 5 shows the fall rates by complier status using both data collection methods by period. Among full compliers, a total of 3,073 falls were reported in postal questionnaires, and 4,079 falls reported in diaries. The unadjusted difference in falls rate is 0.04 pppm, with the unadjusted RR being 1.33; thus, the rate of falls was 33% higher on prospective diaries compared with retrospective questionnaires. After adjustment for age, sex, GP deprivation score, and falls history, the adjusted RR from the negative binomial model was 1.32 (95% CI 1.25–1.40).

3.4. Falls rate calculation: partial compliers

Table 5 presents the corresponding falls rates using the three analytical approaches to replace missing diary data. When making the assumption of zero falls where a diary

Table 2. Comparison of participant characteristics by status of falls diary completion

Characteristic	Diary responder		Nonresponder	P value ^a
	All four completed (N = 6,508)	At least one missing (N = 1,254)	None completed (N = 2,057)	
Sex, n (%)				0.003
Male	3,084 (66)	639 (14)	921 (20)	
Female	3,382 (66)	603 (12)	1,109 (22)	
Age at baseline				<0.001
n	6,508	1,254	2,043	
Mean (SD)	77.7 (5.6)	78.0 (6.1)	78.7 (6.1)	
Marital status, n (%)				0.001
Married	4,115 (63)	765 (13)	1,140 (24)	
Not married	2,371 (68)	484 (13)	906 (19)	
Age when left education				<0.001
n	6,440	1,234	1,988	
Mean (SD)	16.9 (4.6)	16.9 (4.5)	16.6 (6.4)	
BMI, n (%)				<0.001
<30	5,531 (68)	1,042 (13)	1,584 (19)	
≥30	816 (61)	183 (14)	333 (25)	
SF-12 physical				<0.001
n	6,000	1,100	1,729	
Mean (SD)	44.3 (11.3)	42.6 (11.9)	39.9 (12.5)	
SF-12 mental				<0.001
n	6,000	1,100	1,729	
Mean (SD)	55.1 (8.0)	53.4 (8.5)	51.7 (10.1)	
Clock drawing test, n (%) ^a				<0.001
Low (0–4)	391 (45)	133 (15)	350 (40)	
High (5–6)	6,027 (69)	1,096 (12)	1,636 (19)	
Strawbridge frailty score, n (%)				<0.001
Not frail	5,251 (70)	905 (12)	1,317 (18)	
Frail	1,081 (55)	288 (15)	603 (30)	
Fallen in previous, n (%)				<0.001
Non faller	4,530 (69)	810 (12)	1,273 (19)	
Faller	1,889 (63)	414 (14)	700 (23)	
Falls history (previous year, ppm)	4.167	3.333	9.167	<0.001

Abbreviations: BMI, body mass index; SD, standard deviation.

^a Categorical variables: P-value for a chi-square test of association; continuous variables: P-value for a nonparametric test for trend across ordered groups.

was not returned (Method 1), the fall rates for both methods were similar (adjusted RR 1.04, 95% CI 0.89–1.21). For Method 2, missing months were dropped from the rate calculation, resulting in the same number of falls as the first approach but with a lower denominator. This resulted in a larger adjusted RR of 1.52 (95% CI 1.30–1.79), indicating the rate of falls was over 50% higher than the rate reported in questionnaires. Using Method 3, the full data set, imputed values were generated for each missing month using a multiple imputation model using age, sex, baseline fall count, and GP surgery deprivation score to generate an imputed total for the 4-month period. The adjusted RR of 1.21 (95% CI 1.05–1.41) indicated a consistent effect of higher reporting in diaries, even after imputation of missing values for months where no diary was returned.

4. Discussion

This is the first large-scale clinical trial to investigate the impact of multiple methods of falls data collection on falls rates, participant retention, and attrition over time. Among our community-dwelling population of adults aged 70 years and older, the overall completed diary return rate was excellent, with 83% of participants returning one or more falls diary. The return rate for all four diaries remained consistent over each period (71%, 67%, and 70%). However, the rate of nonresponse increased over each 4-month period (15%, 18%, and 19%).

There were systematic differences in the characteristics of trial participants by whether they returned all, some, or none of the diaries. Older age, poorer physical and mental

Table 3. Impact of time period of allocation to diary completion on main trial withdrawal rates

Time of allocation	0–4 mo		5–8 mo		9–12 mo	
	Allocated	Not allocated	Allocated	Not allocated	Allocated	Not allocated
(a) Total number	3,273	6,548	3,278	6,543	3,270	6,551
(b) Number who withdrew or died during previous time period (% = b/a)	N/A	N/A	125 (3.8%)	256 (3.9%)	192 (5.9%)	604 (9.2%)
(c) Number who died during the time period, (% = c/a)	23 (0.7%)	35 (0.5%)	28 (0.9%)	27 (0.4%)	16 (0.5%)	48 (0.7%)
(d) Number eligible to withdraw at the period, (a-b-c) (% = d/a)	3,250 (99.3%)	6,513 (99.5%)	3,125 (95.3%)	6,260 (95.7%)	3,062 (93.6%)	5,899 (90.1%)
(e) Number who withdrew during the period	164	159	165	195	163	173
% withdrawal, (e/d)	5.05	2.44	5.28	3.11	5.32	2.93
Difference in proportions (95% CI)	2.60% (1.76–3.45)		2.16% (1.27–3.06)		2.39% (1.49–3.29)	
Rate ratio (RR) (95% CI)	2.07 (1.65–2.59)		1.70 (1.37–2.10)		1.82 (1.46–2.26)	
P-value (difference between proportions)	<0.001		<0.001		<0.001	

Abbreviations: CI, confidence interval; N/A, not available; SD, standard deviation.

health, poor cognitive function, a history of falling in the previous year, and frailty were associated with a decreased probability of diary return. Other factors associated with nonresponse included female sex, higher BMI, and lower age when left full-time education. Most of these factors are risk factors for falling; thus, it is likely that selection bias occurred, whereby rate and risk of falling were likely to be higher among the 2,000 participants failing to return a single diary.

We found a consistent and meaningful impact of allocation to complete falls diaries on overall withdrawal from the main PreFIT trial. The absolute difference in proportions was approximately 2.4% for each period, which is a small but consistent effect over the entire year of follow-up. This translates into almost a doubling of risk of withdrawal over time (RR from 1.70 to 2.07 across each period). If this increase in withdrawal rate of 2.4% among

those allocated to complete diaries was extrapolated across the wider PreFIT trial population of 9,375 participants, then we would expect an additional 225 participants to withdraw from the trial as a result of diary allocation. Older people asked to complete only a short period of 4 months' worth of falls diaries were more likely to withdraw from the trial, both during their allocated period of diary completion and in the future.

In terms of differences in data capture by method, the rate of falls captured by diaries was higher than for questionnaire completion. Adjusted analyses summarized for the whole year of follow-up suggested a 32% difference in falls rate between prospective and retrospective data collection method. This is a clinically important difference.

These results bring in to question whether falls diaries should be the recommended default choice of data collection for trialists who are designing trials for populations similar to the PreFIT study. There is a balance between

Table 4. Falls reporting by diary and questionnaire reporting, over 4 months of simultaneous data collection for full and partial compliers

	No. of falls on equivalent questionnaire				
Status	0	1	≥2	Missing	Total
Full compliers (N = 6,418)					
No. of falls on diaries					
0	4,616	144	45	35	4,840
1	308	548	79	47	982
≥2	104	85	377	30	596
Total	5,028	777	501	112	6,418
Partial compliers (N = 1,112)					
No. of falls on diaries					
0	735	78	21	1	835
1	67	49	21	0	137
≥2	46	29	63	2	140
Total	848	156	105	3	1,112

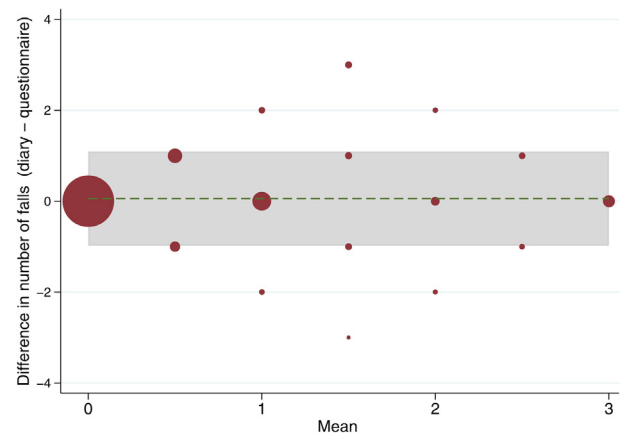
**Fig. 1.** Bland and Altman plot comparing number of falls between two data collection methods for full compliers.

Table 5. Number and rate of falls among full and partial compliers

Status	Allocated period (months of follow-up)			
	0–4	5–8	9–12	Total
Full compliers (<i>N</i> = 6,306)				
No. of participants	2,231	2,005	2,070	6,306
No. of months	8,924	8,020	8,280	25,224
Questionnaire falls	No. of falls	1,257	1,047	769
	Rate pppm	0.14	0.13	0.09
Diary falls	No. of falls	1,496	1,476	1,107
	Rate pppm	0.17	0.18	0.13
Rate difference (Questionnaire-diary)	–0.03	–0.05	–0.04	–0.04
Unadjusted RR	1.21	1.38	1.44	1.33
Adjusted RR ^a (95% CI)	1.17 (1.05–1.31)	1.43 (1.30–1.58)	1.40 (1.27–1.55)	1.32 (1.25–1.40)
Partial compliers (<i>N</i> = 1,112)				
Method 1	Adjusted RR ^a (95% CI)			1.04 (0.89–1.21)
Assume zero falls				
Method 2	Adjusted RR ^a (95% CI)			1.52 (1.30–1.79)
Drop month from denominator				
Method 3	Adjusted RR ^a (95% CI)			1.21 (1.05–1.41)
Imputation				

Abbreviations: CI, confidence interval; pppm, per person per month; RR, rate ratio.

^a Covariates in mixed effect negative binomial model include age, sex, practice, deprivation score and baseline number of falls.

the impact on study withdrawal against the higher rate of falls recorded using diaries, and trialists should consider the impact of asking participants to complete diaries. A recent clinical trial [23] used diary cards to collect falls but had to reduce the frequency of diary cards because of problems with participant burden.

Ganz [3] argued that the sensitivity of 12-month fall recall was not high enough to recommend it as a substitute for weekly or monthly follow-up, particularly where false negatives are a problem. Previous studies have shown that those most likely to have recall biases include people with poorer cognitive function. Importantly, those who fall but fail to recall falling, thus false negatives, are those most likely to require referral to falls prevention treatment. In our community sample, less than 10% of our cohort had a low score (<5) on the clock drawing test although our sample is based on adults consenting to participate in a clinical trial. For very large prospective studies aiming for longer term falls monitoring, one potentially efficient approach would be to target more intensive monitoring in those screened as having poorer cognitive function, with longer recall intervals for those of high functioning.

We also explored the impact of alternative analytic methods for dealing with missing falls data. The multiple imputation approach yielded the adjusted RR closest to RR observed among full compliers. Assuming zeroes and dropping missing monthly diary cards provided consistently lower and higher rates of falls reported respectively, when compared with falls reported on questionnaires.

The strengths of this study include the large sample of older adults recruited from primary care across England.

Participants were recruited from geographically and ethnically diverse regions, ensuring both urban and rural representation. The novel SWAT design incorporating additional randomization ensured that every trial participant was prospectively monitored for a standard period, but this approach also reduced overall participant burden of data collection. Given the scale of the trial whereby the aim was to recruit almost 10,000 older adults, this also reduced cost and researcher burden. Following recommended international guidance [24] and extending this to 12 months of prospective monitoring across all participants would have required postal administration and data entry of 117,648 falls diaries.

Previous studies have argued that seasonal variation may explain fluctuations in falls data captured using diary completion [25,26]. We did not account for seasonal effects as each participant was randomized to a period of diaries (or not) as GPs were recruited consecutively between 2011 and 2014; thus, all seasons were captured within our period of data collection.

A weakness of our analyses is the assumption that the request to complete monthly falls diaries was independent of other external factors potentially contributing to withdrawal from the trial. We did not analyze by treatment arm, and it may be that withdrawal was confounded by ongoing falls prevention treatment. Qualitative interviews with a subsample of nonrespondents would allow finer level exploration of reasons for withdrawal, and assuming nonresponders would be willing to be interviewed. The act of requesting participants to complete diaries and the retrospective questionnaire concurrently may have influenced the response to the retrospective questionnaire had the diaries not been completed.

In summary, our study confirms the risk of systematic bias in falls monitoring, whereby, those likely to be at greatest risk of falling are less likely to complete and return falls diaries. Falls diaries can be burdensome for people to complete, particularly for those who are frequent fallers, and they can be expensive to administer. We found a small but consistent effect of decreasing compliance with diary completion over time. Trialists should consider the impact of falls diaries before incorporating this data collection method in clinical trials with long follow-up. Although we found clear differences in falls rates by method of data completion whereby the falls rate was consistently higher on monthly diaries compared with questionnaire completion, the costs and benefits of these approaches should be weighed up. A 2% increase in withdrawal rate every few months, extrapolated over several years of follow-up, will seriously reduce the statistical power of a clinical study to detect differences in study outcomes.

5. Conclusion

We collected falls data both prospectively and retrospectively from 9,803 older adults recruited to the PreFIT trial. An efficient SWAT design provided the opportunity to compare the completeness and accuracy of alternative data collection methods and consider the impact of methods on study withdrawal. We found a consistent and meaningful impact of allocation to falls diaries on overall withdrawal from the main trial; those asked to complete diaries were more likely to drop out. People who failed to return a single diary were older, frailer, had a poorer quality of life, and had a history of falling, compared with those who returned diaries. Trialists should consider the impact of requesting additional data collection or at least should consider sample size inflation to account for potential losses to follow-up. The recognized gold standard for accurate falls monitoring is prospective data collection over 12 months. Although considered gold standard in terms of data accuracy, we argue that for studies where sample retention over time is paramount, a trade-off between data accuracy and overall retention should be carefully considered as intensive and persistent falls monitoring increases attrition.

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Supplementary data

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