Comparison and impact of prospective and retrospective falls data completion methods in the PreFIT trial: Results of a randomised methodology Study Within A Trial (SWAT)

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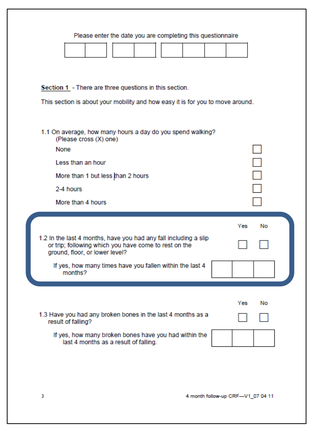

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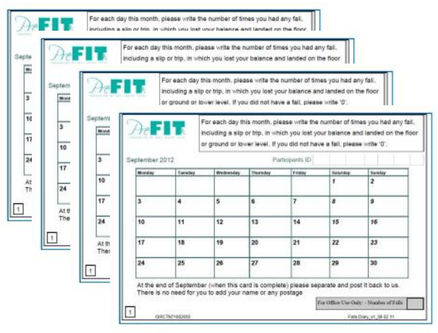

Background

- Falls are the leading cause of accident-related mortality in older adults. Injurious falls, including fractures, are associated with functional decline, loss of independence, disability and significant health and social care costs.
- **PreFIT** is a three-arm, cluster randomised controlled trial (RCT), conducted within primary care across England. We recruit 9821 participants, aged 70 and above, from 63 general practices.
- The collection of accurate falls data is problematic within clinical trials. In particular there are issues with reporting falls when these events are associated with recall bias. Different data collection methods have been proposed to minimise bias.
- In the **PreFIT** trial we performed a study within a trial (SWAT) to compare two common methods of data collection – (i) daily falls diaries collected via a calendar format and (ii) retrospective reporting within questionnaires every four-months.

Methods

- Participants were asked to complete prospective fall diaries across a four month period; participants were randomly allocated to one of the periods (baseline to 4 months, 5 months to 8 months or 9 months to 12 months). Falls diaries were produced in a calendar format, posted to participants in a pack of four, with a covering instruction letter. Participants also completed follow-up questionnaires, containing a retrospective question on the number of falls in the preceding months at 4, 8, 12 and 18 months post randomisation.

Key objectives:

- To compare the two reporting methods and assess the impact on prevalence and pattern of missing values. **(Table 1)**
- To assess the impact of allocation to complete diary cards on withdrawal rates from the main study. **(Table 2)**
- To assess agreement between both data sources, where both data sources were available and complete. **(Table 3)**
- To model differences in rates using a mixed effects negative binomial model to estimate adjusted incidence rate ratios (IRR) of fall rate by method of data collection. **(Table 4)**
- To compare baseline participant characteristics by diary completion status to identify the characteristics of completers and non completers.

Results

Table 1: How well completed were prospective diary cards compared to retrospective questionnaires?

- A total of 9375 participants were asked to complete diary cards over one of the three time periods.
- Diaries were fairly well completed with 69% of participants completing all four monthly diaries.
- Patterns of completion were similar across all timepoints, with monotonic completion most common.
- Participants who returned no diaries were older and had poorer levels of physical and mental health than those who completed at least one diary card.

	Timepoints			
Number completed diaries	**0-4 mth**	**4-8 mth**	**8-12 mth**	**Totals**
4	2315 (71%)	2065 (67%)	2128 (70%)	6508 (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%)	1613 (17%)
Total	**3256**	**3093**	**3026**	**9375**

	0-4 mth		4-8 mth		8-12 mth	
	Allocated	Not Allocated	Allocated	Not Allocated	Allocated	Not Allocated
(a) Total number	3273	6548	3278	6543	3270	6551
(b) Number who withdrew or died in previous timepoint (%=b/a)	n/a	n/a	125 (3.8%)	256 (3.9%)	192 (5.9%)	604 (9.2%)
(c) Number who died (%=c/a)	23 (0.7%)	35 (0.5%)	28 (0.9%)	27 (0.4%)	16 (0.5%)	48 (0.7%)
(d) Number able to withdraw (%=d/a)	3250 (99.3%)	6513 (99.5%)	3125 (95.3%	6260 (95.7%)	3062 (93.6%)	5899 (90.1%)
(e) Number who withdrew	164	159	165	195	163	173
% withdrawal (e/d)	5.04%	2.44%	5.28%	3.12%	5.32%	2.93%
p-value (difference between proportions)	p<0.001		p<0.001		p<0.001	

Table 2: Did being allocated to complete diaries affect withdrawal from the trial?

- In order to complete the diary cards during their allocated period a participant needs to have not died or withdrawn in any preceding timepoint.
- During each time period those who allocated to complete diary cards withdrew from the study at a higher rate than those who were not completing diary cards.
- There is a difference in withdrawal rates of at least 2% between those allocated to complete diary cards, and those not; which was consistent at all timepoints.

Table 3: How comparable were the number of falls reported when participants completed both data sources?

- A total of 6418 participants completed a full set of four diary cards and a corresponding questionnaire covering the same period – these are the population most appropriate to compare falls rate between data collection methods.
- 87% of participants reported the same number of falls on both data sources, 13% had discrepancies in number of falls.
- Of the participants who had a different number of falls, the majority (65%, n=546/845) reported a higher number of falls on the diary cards compared to the corresponding report in the questionnaire – indicating more falls are reported on diary cards than retrospective questionnaires.

		No of falls on equivalent questionnaire					
		0	1	2	>2	.	Total
No of falls on diary cards	**0**	4616	144	34	11	35	**4840**
	1	308	548	55	24	47	**982**
	2	48	57	98	31	12	**246**
	>2	56	28	49	199	18	**350**
	Total	**5028**	**777**	**236**	**265**	**112**	**6418**

		Timepoints			
		4mth	8mth	12mth	Total
	Number of participants	2231	2005	2070	6306
QUESTIONNAIRE	Number of falls	1257	1047	769	3073
	Rate pppm	0.14	0.13	0.09	0.12
DIARY	Number of falls	1496	1476	1107	4079
	Rate pppm	0.17	0.18	0.13	0.16
	Difference (Diary rate – questionnaire rate)	0.03	0.05	0.04	0.04
	Unadjusted RR (Diary rate/questionnaire rate)	1.18	1.41	1.44	1.33
	Adjusted iRR (95% CI)	1.17 (1.05,1.31)	1.43 (1.30,1.57)	1.40 (1.27,1.54)	1.32 (1.25, 1.41)

Table 4: How different were falls rates when participants completed two data sources simultaneously?

- The rate of falls reported on diary cards was consistently higher than questionnaire reporting, the mean unadjusted difference being 0.04 per person per month (pppm) across all timepoints
- The unadjusted rate ratio was 1.33 implying the rate of falls reported in diary cards was 33% higher than the equivalent rate from questionnaires.
- In a mixed effects negative binomial model adjusting for baseline falls rate, GP practice, deprivation score, age and gender the incidence RR for data collection method was 1.32 (95% confidence interval 1.25, 1.41).

Conclusions

- This SWAT provides evidence that participants in a large multicentre RCT are willing to complete and return postal diary cards alongside four-monthly retrospective postal questionnaires.
- However allocation to complete prospective diary cards has a small but significant effect on withdrawal from the main trial. In **PreFIT** this was a considerable increase in the withdrawal rate of around 2%, consistent at each timepoint.
- Retrospective and prospective falls data are not consistently reported when collected simultaneously, with the rate of falls reporting approximately 32% higher when collecting data using diary cards compared to retrospective questionnaires.
- SWATs are an efficient additional component of RCT design and should be considered to improve the design of future trials.

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PreFIT PREVENTION OF FALL INJURY TRIAL

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