

SUBGROUPS DEFINED BY HOEHN AND YAHR GROUPS: INTENTION-TO-TREAT ANALYSES OF FALLING OUTCOMES

	H&Y	Period (months)	PDSafe	Control	PDSafe/control**	P**	Interaction P**
Repeat falling* restricted to ≥50% diaries			Number (%)		OR (95% CI)		
	1	pre	5/26 (19%)	8/30 (27%)			0.267
		0-6	8/35 (35%)	10/28 (36%)	0.78 (0.21, 2.80)	0.320	
	2	pre	34/76 (45%)	17/55 (31%)			
		0-6	31/71 (44%)	23/53 (43%)	0.78 (0.33, 1.84)	0.571	
	3	pre	65/86 (76%)	59/98 (60%)			
		0-6	71/90 (79%)	58/67 (87%)	1.71 (0.80, 3.66)	0.163	
	4	pre	21/29 (72%)	23/35 (66%)			
		0-6	21/23 (91%)	24/32 (75%)	4.01 (0.62, 25.92)	0.145	
Fall rates			Falls/person/6 months***		FRR (95% CI)		
	1	pre	2.0 (n=26)	2.1 (n=30)			0.828
		0-6	1.3 (n=25)	1.3 (n=30)	0.85 (0.41, 1.73)	0.648	
	2	pre	3.1 (n=78)	2.5 (n=56)			
		0-6	1.8 (n=77)	1.8 (n=56)	0.87 (0.58, 1.30)	0.493	
	3	pre	6.2 (n=102)	3.4 (n=112)			
		0-6	5.4 (n=98)	3.4 (n=109)	1.01 (0.77, 1.32)	0.957	
	4	pre	8.7 (n=31)	6.3 (n=38)			
		0-6	7.6 (n=31)	5.4 (n=35)	1.11 (0.73, 1.71)	0.623	

* For participants with incomplete diaries and < 2 falls during 0-6 or 6-12 months, PDSAFE records checked.

** Controlled for site, age, gender, repeat falling or not in the year prior to screening, log number of falls in the year prior to falling, log rate of falling in the pre randomisation falls collection period, and Hoehn and Yahr.

*** Geometric mean of individual fall rates with 0.5 added to all numerators