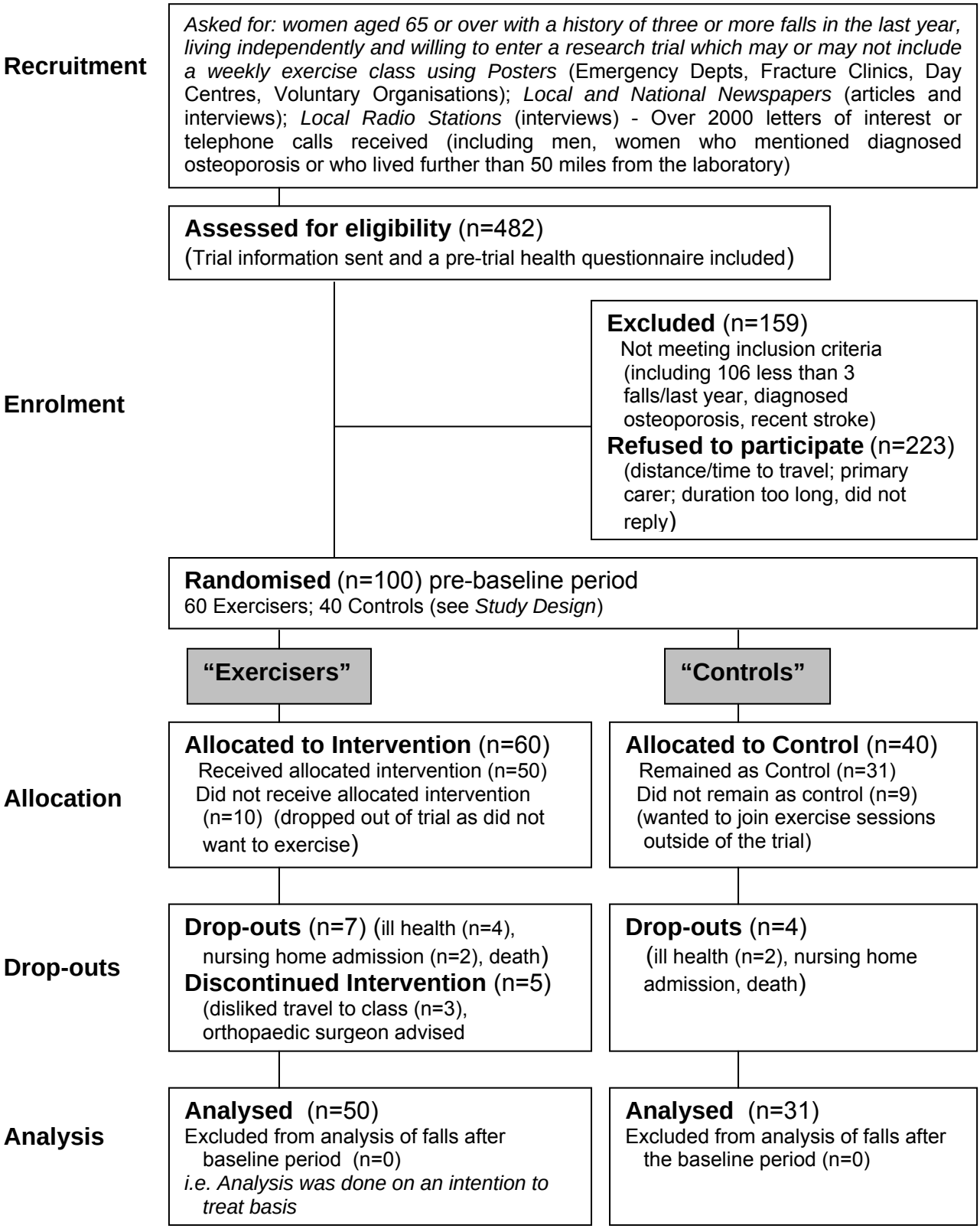
SUPPLEMENTARY DATA TO "Tailored Group Exercise (FaME) reduces falls in community dwelling older frequent fallers (an RCT)"

Appendix 1: Recruitment and Compliance of the subjects – Flow Chart



Study Design

A sample size of 50 completing in each group would provide a power of 80-85% at α=0.05 to detect a difference in the fall rate of mean 3 falls per year in the control group to a mean of 1 per year in the intervention groups. Recruitment for this trial was difficult mainly because frequent falls are generally associated with frailty and poorer health (Figure 1). It was expected that there would be a greater dropout rate in the exercise group so random allocation (blind) was weighted [1] 3:2 for exercise:control. Randomisation was performed by random numbers tables by an observer unconnected to the trial.

Group allocations were made before the baseline reporting fall period started. The Exercise sessions were run in four venues across London. The trial ran from March 1998-March 2001.

1. Torgerson D, Campbell M. Unequal randomisation can improve the economic efficiency of clinical trials. J Health Service Res Policy 1997: 2: 81-85.

Exclusion criteria were: acute rheumatoid arthritis, uncontrolled heart failure or hypertension, significant cognitive impairment, significant neurological disease or impairment, or previously diagnosed osteoporosis.

Fall data collection

The minimum trial period for the baseline and follow-up was 36 weeks, however, some people could not join classes at the end of the 36 week baseline and so completed diaries until they could, and others continued to complete diaries for longer than the 36 week follow-up period. Each fall was followed up by questionnaire and telephone for reason/cause, timing, injury and medical attention.

Appendix 2: Fall Diary Card

WEEK:	**Start Date:**		**WEEK:**	**Start Date:**	
	FALL (see below for code)	IF FALL (see below for code)		FALL (see below for code)	IF FALL (see below for code)
MONDAY			MONDAY		
TUESDAY			TUESDAY		
WEDNESDAY			WEDNESDAY		
THURSDAY			THURSDAY		
FRIDAY			FRIDAY		
SATURDAY			SATURDAY		
SUNDAY			SUNDAY		

CODES:

FALL: 0 = No fall, 1 = Fall

IF FALL: 0 = No injury, 1 = Bruise and/or cut, 2 = Bruise and/or cut and immobilization, 3 = Soft tissue injury, 4 = Broken bone, 5 = Other (please specify)

TIME OF FALL:

LOCATION OF FALL: Indoors Outdoors

(Specify).....

REASON FOR FALL: Trip (object/pavement) Knocked Over

Footwear problem Unknown

Other (specify).....

ANY LOSS OF CONSCIOUSNESS: Yes/No

Attendance at GP surgery/hospital because of fall: Yes/No

If yes, specify:.....

Were you able to get up off the floor without help?: Yes/No

Appendix 3:

Negative Binomial Regression Analysis on Total Falls

nbreg falls group, irr exposure (fup) nolog

Negative binomial regression — Number of obs = 81
LR chi2(1) = 4.68
Prob > chi2 = 0.0305
Log likelihood = -208.3327 — Pseudo R2 = 0.0111

falls	IRR	Std. Err.	z	P>|z|	[95% Conf.	Interval]
group	.6963198	.1153906	-2.18	0.029	.503213	.9635308
fup | (exposure)						
/lnalpha	-1.109774	.2523605			-1.604392	-.6151568
alpha	.3296333	.0831864			.2010118	.5405561

Likelihood ratio test of alpha=0: chibar2(01) = 64.35 Prob>=chibar2 = 0.000

Negative Binomial Regression Analysis on Total Injurious Falls

nbreg injfalls group, irr exposure (fup) nolog

Negative binomial regression — Number of obs = 81
LR chi2(1) = 2.91
Prob > chi2 = 0.0880
Log likelihood = -102.06932 — Pseudo R2 = 0.0141

injfalls	IRR	Std. Err.	z	P>|z|	[95% Conf.	Interval]
group	.6042621	.1781425	-1.71	0.088	.3390647	1.076882
fup | (exposure)						
/lnalpha	-.7521381	.6626206			-2.050851	.5465744
alpha	.4713577	.3123313			.1286254	1.727326

Likelihood ratio test of alpha=0: chibar2(01) = 4.15 Prob>=chibar2 = 0.021

Calculation for Numbers needed to Treat to prevent falls.

This was calculated as the proportion of exercisers who did not fall during the follow-up period (15/50) and the proportion of controls who did not fall (3/31) during the follow-up period.

http://www.jr2.ox.ac.uk/bandolier/band59/NNT1.html

Numbers of fallers and falls during Baseline, Intervention and Follow-up periods by group in the 60 women who completed the full 36 week follow-up period for falls data collection (not including drop outs, see Appendix 1)

	Exercisers		Controls	
Number of women	43		27	
	All falls	**Injurious falls**	**All falls**	**Injurious falls**
Baseline period				
Number of fallers	40	21	25	10
Total number of falls	139	28	83	11
Mean (SD) falls per group member	3.2 (2.3)	0.7 (0.8)	3.1 (2.4)	0.4 (0.6)
Intervention period				
Number of fallers	35	9	23	11
Total number of falls	100	9	54	11
Mean (SD) falls per group member	2.3 (2.7)	0.2 (0.4)	2.0 (2.1)	0.4 (0.5)
Follow-up period				
Number of fallers	28	6	24	12
Total number of falls	81	8	89	13
Mean (SD) falls per group member	1.9 (2.4)	0.2 (0.6)	3.3 (2.8)	0.5 (0.6)

Appendix 4: Limitations of the Trial

However, there are a number of limitations in the evidence from this trial. The number of subjects enrolled in the trial was low (30%) compared with those invited but this may be expected as frequent fallers are more likely to be frail and have more complex medical conditions. Inevitably, the women in this trial were not blind to their groups and the Exercisers had considerably more contact with members of the trial team (exercise instructors) and 68% chose to continue in other exercise opportunities after the trial finished. The benefits of group exercise extends into peer support and social contact that may have an effect on falls. A final, important point is that although a range of strategies were employed to standardise the exercise delivery and progression, some variation is inevitable.