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

Asked for: women aged 65 or over with a history of three or more falls in the last year, living independently and willing to enter a research trial which may or may not include Recruitment a weekly exercise class using Posters (Emergency Depts, Fracture Clinics, Day Centres, Voluntary Organisations); Local and National Newspapers (articles and interviews); Local Radio Stations (interviews) - Over 2000 letters of interest or telephone calls received (including men, women who mentioned diagnosed osteoporosis or who lived further than 50 miles from the laboratory) Assessed for eligibility (n=482) (Trial information sent and a pre-trial health questionnaire included) Excluded (n=159) Not meeting inclusion criteria (including 106 less than 3 falls/last year, diagnosed **Enrolment** osteoporosis, recent stroke) Refused to participate (n=223) (distance/time to travel; primary carer; duration too long, did not reply) Randomised (n=100) pre-baseline period 60 Exercisers; 40 Controls (see Study Design) "Exercisers" "Controls" Allocated to Control (n=40) Allocated to Intervention (n=60) Received allocated intervention (n=50) Remained as Control (n=31) Did not receive allocated intervention Did not remain as control (n=9) Allocation (n=10) (dropped out of trial as did not (wanted to join exercise sessions outside of the trial) want to exercise) **Drop-outs** (n=4) **Drop-outs** (n=7) (ill health (n=4), nursing home admission (n=2), death) (ill health (n=2), nursing home **Drop-outs Discontinued Intervention** (n=5) admission, death) (disliked travel to class (n=3), orthopaedic surgeon advised Analysed (n=50) Analysed (n=31) Excluded from analysis of falls after Excluded from analysis of falls after **Analysis** baseline period (n=0) the baseline period (n=0) i.e. Analysis was done on an intention to treat basis

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:

	1 I <i>A</i>		0 -	NIA	fall	1	_	Eal	ı
Γ	\rightarrow LL	-	$\cup =$	IMO	1711	- 1	=	Fai	ı

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) IF FALL:

TIME OF FALL:			
LOCATION OF FALL:	Indoors	Outdoo	ors
(Specify)			
REASON FOR FALL:	Trip (object/paveme	nt)	Knocked Over
	Footwear problem		Unknown
	Other (specify)		
ANY LOSS OF CONSCIOUSNES	SS: Yes/No		
Attendance at GP surgery/hospita	al because of fall:	Yes/No)
If yes, specify:			
Were you able to get up off the flo	oor without help?:	Yes/No)

Appendix 3:

Negative Binomial Regression Analysis on Total Falls

nbreg falls group, irr exposure (fup) nolog

Negative binomial regress Log likelihood = -208.332	Number of obs = 81 LR chi2(1) = 4.68 Prob > chi2 = 0.0305 Pseudo R2 = 0.0111		
falls IRR S		P> z [95% Con	f. Interval]
group .6963198 .1 fup (exposure)	1153906 -2.18	0.029 .503213	.9635308
/Inalpha -1.109774	2523605	-1.604392	6151568
alpha .3296333 .0			.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 Log likelihood = -102.06932			Number of obs = 81 LR chi2(1) = 2.91 Prob > chi2 = 0.0880 Pseudo R2 = 0.0141			
, ,		Std. Err.			[95% Conf.	-
group fup (e	.6042621 exposure)	.1781425	-1.71	0.088	.3390647	
/Inalpha	7521381	.6626206				.5465744
	.4713577				.1286254	

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	3	7		
	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.