Sensitivity analyses for the primary outcome (weight at 3.5 years) for the FFIT Follow up study

Two types of sensitivity analyses were conducted on the primary outcome (change in weight at 3.5 years). The first assessed the sensitivity of the main analyses to assumptions about the long-term weight outcomes of the men who had not taken part in follow up measures at 12 months and 3.5 years. The second took into account the fact that both groups had had the opportunity to take part in the FFIT intervention, but at different times.

1.1 Imputing 3.5-year weight values for the 'Not Followed Up' Cohort

Sensitivity of the main analyses to a variety of assumptions about the long-term weight outcomes of men who did not take part in the follow up measures at 12 months and 3.5 years was assessed by imputing missing primary outcome data using: 1) the return to baseline method (which is reported in Chapter 3, Section 3.4.1.2); and 2) the last observation carried forward method (LOCF, which is reported here).

Table i shows that the LOFC sensitivity analysis favours the intervention group, as most men who were lost to follow up at 3.5 years had their 12-month measures carried forward as their 3.5-year measures. Consequently, the intervention group is lighter at 3.5 years compared to the main analyses. The between-group difference at 3.5 years is also significant with the intervention group losing significantly more weight than the comparison group (p=0.0008).

Table i. Baseline sensitivity analysis (LOCF): change in weight at 3.5 years in all men in the RCT intervention and comparison groups

	RCT intervention group (n=374)		RCT comparison group (n=373)		Difference between groups Comparison-Intervention	
	Mean (95% CI)	p	Mean (95% CI)	p	Mean Change (95% CI)	p
Absolute change (kg)	-3.59 (-4.43, -2.75)	<0.0001	-1.97 (-2.76, -1.19)	<0.0001	1.61 (0.47, 2.76)	0.0008
Percentage change	-3.11 (-3.82, -2.41)	<0.0001	-1.75 (-2.45, -1.05)	<0.0001	1.36 (0.37, 2.35)	0.0013

Table ii shows that the change in weight between 12 months and 3.5 years in the intervention group is slightly lower using the LOCF method than in the main analyses, and slightly higher in the comparison group (this is because many of the missing 3.5-year values are imputed using 12-week or 12-month values). However, the between-groups difference in weight loss trajectories remains significant at 3.00 kg (2.10, 3.91), p<0.001.

Table ii. Baseline sensitivity analysis (LOCF): Change in weight in all men in the RCT intervention and comparison groups between 12 months and 3.5 years

	RCT intervention group (n=374)		RCT comparison group (n=373)		Difference between groups[¶] Comparison-Intervention	
	Mean (95% CI)	p	Mean (95% CI)	p	Mean (95% CI)	p
Absolute change (kg)	1.62 (0.99, 2.24)	<0.0001	-1.39 (-2.04, -0.73)	<0.0001	-3.00 (-3.91, -2.10)	<0.0001
Percentage change (as % of baseline)	1.52 (0.99, 2.05)	<0.0001	-1.22 (-1.82, -0.62)	<0.0001	-2.74 (-3.54, -1.94)	<0.0001

[¶] Adjusted for baseline measure, group, visit (baseline, 12 months and 3.5 years) and group*visit interaction as fixed effects, and for participant and club as random, effects

1.2 Using different baseline time points

The FFIT-FU-C group had the opportunity to take part in the FFIT programme a year after the FFIT-FU-I group. Sensitivity analyses were therefore performed to take into account the fact that it was 3.5 years since the FFIT-FU-I group started FFIT, and 2.5 years since the FFIT-FU-C group had the opportunity to do so. These analyses used RCT baseline weight for the FFIT-FU-I group and 12-month weight for the FFIT-FU-C group. These time points occurred immediately before participants in each group were given the opportunity to take part in the FFIT programme.

- Baseline time points sensitivity analysis 1 (BTPSA 1): baseline was defined as month 0 for the FFIT-FU-I group and as month 12 for the FFIT-FU-C group.
- Baseline time points sensitivity analysis 2 (BTPSA 2): the same baselines were used as in BTPSA1, but men in the FFIT-FU-C group who had lost at least 5% of their baseline weight by month 12 were excluded. The rationale was that these men had already managed to lose weight with no access to the FFIT programme, and could have been the most highly motivated to lose weight.

Table iii shows that the baseline time points sensitivity analyses gave similar results to the main analyses. In BTPSA 1, mean 3.5-year weight loss was 2.90kg (95% CI 1.78, 4.02) in the FFIT-FU-I group, and 2.03kg (1.08, 2.98) in the FFIT-FU-C group. The corresponding figures in BTPSA 2 were, 2.90kg (95% CI 1.78, 4.02) and 2.65kg (1.67, 3.64), respectively. The mean adjusted (non-significant) difference in 3.5-year weight loss between groups was 0.72 kg (-0.72, 2.15) in BSA 1, and 0.19kg (-1.28, 1.66) in BSA 2.

Table iii. Baseline time points sensitivity analyses: Change in weight at 3.5 years in FFIT-FU-I and FFIT-FU-C groups

	FFIT-FU-I group (n=233)		FFIT-FU-C group (n=255)		Difference between groups FFIT-FU-C – FFIT-FU-I	
	Mean (95% CI)	**p**	**Mean (95% CI)**	**p**	**Mean (95% CI)**	**p**
BTPSA1 Absolute change (kg)	-2.90 (-4.02, -1.78)	<0.0001	-2.03 (-2.98, -1.08)	<0.0001	0.87 (-0.59, 2.33)	0.2435
BTPSA2 Absolute change (kg)	-2.90 (-4.02, -1.78)	<0.0001	-2.65 (-3.64, -1.67)	<0.0001	0.24 (-1.25, 1.73)	0.7493