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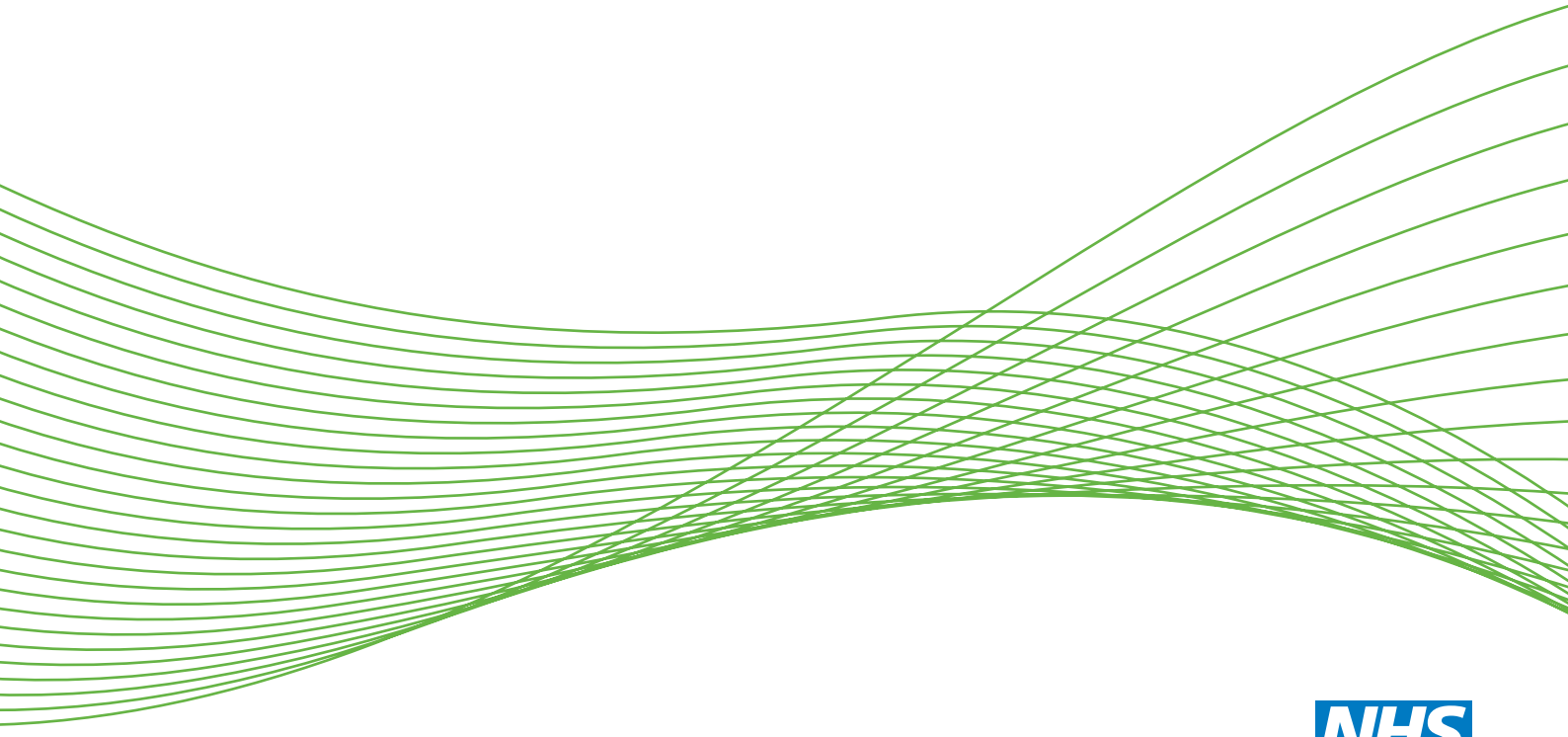

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Football Fans in Training (FFIT): a randomised controlled trial of a gender-sensitised weight loss and healthy living programme for men – end of study report

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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Abstract

Football Fans in Training (FFIT): a randomised controlled trial of a gender-sensitised weight loss and healthy living programme for men – end of study report

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Background: The prevalence of male obesity is increasing alongside low uptake of existing weight management programmes by men. Football Fans in Training (FFIT) is a group-based, weight management and healthy living programme delivered by community coaches.

Objectives: To assess (1) the effectiveness and cost-effectiveness of FFIT, (2) fidelity of delivery and (3) coach and participant experiences of FFIT.

Design: A two-arm, pragmatic, randomised controlled trial; associated cost-effectiveness [in terms of incremental cost per quality-adjusted life-year (QALY) within trial and over individuals' lifetimes]; and process evaluation. Participants were block randomised in a 1 : 1 ratio, stratified by club; the intervention group started FFIT within 3 weeks and the comparison group were put on a 12-month waiting list.

Setting: Thirteen professional football clubs in Scotland, UK.

Participants: A total of 747 men aged 35–65 years with an objectively measured body mass index (BMI) of ≥ 28 kg/m^2.

Interventions: FFIT was gender sensitised in context, content and style of delivery. A total of 12 weekly sessions delivered at club stadia combined effective behaviour change techniques with dietary information and physical activity sessions. Men carried out a pedometer-based walking programme. A light-touch maintenance programme included six e-mails and a reunion session at 9 months. At baseline, both groups received a weight management booklet, feedback on their BMI and advice to consult their general practitioner if blood pressure was high.

Primary outcome: Mean difference in weight loss between groups at 12 months expressed as absolute weight and a percentage. Intention-to-treat analyses used all available data.

Data sources: Objective measurements, questionnaires, observations, focus groups and coach interviews.

Results: A total of 374 men were allocated to the intervention and 333 (89%) completed 12-month assessments; a total of 374 were allocated to the comparator and 355 (95%) completed 12-month assessments. At 12 months, the mean difference in weight loss between groups, adjusted for baseline weight and club, was 4.94 kg [95% confidence interval (CI) 3.95 kg to 5.94 kg]; percentage weight loss, similarly adjusted, was 4.36% (95% CI 3.64% to 5.08%), in favour of the intervention ($p < 0.0001$). Sensitivity analyses gave similar results. Pre-specified subgroup analyses found no significant predictors of primary outcome. Highly significant differences in favour of the intervention were observed for objectively measured waist, percentage body fat, systolic and diastolic blood pressure, and self-reported physical activity, diet and indicators of well-being and physical aspects of quality of life. Eight serious adverse events were reported, of which two were reported as related to FFIT participation. From the within-trial analysis, FFIT was estimated to cost £862 per additional man maintaining a 5% weight reduction at 12 months and £13,847 per additional QALY, both compared with no intervention. For a cost-effectiveness threshold of £20,000/QALY, the probability that FFIT is cost-effective, compared with no active intervention, is 0.72. This probability rises to 0.89 for a cost-effectiveness threshold of £30,000/QALY. From the longer-term analysis, FFIT was estimated to cost £2535 per life-year gained and £2810 per QALY gained. FFIT was largely delivered as intended. The process evaluation demonstrated the powerful draw of football to attract men at high risk of ill health. FFIT was popular and analyses suggest that it enabled lifestyle change in ways that were congruent with participants' identities.

Conclusions: Participation in FFIT led to significant reductions in weight at 12 months. It was cost-effective at standard levels employed in the UK, attracted men at high risk of future ill health and was enjoyable. Further research should investigate whether or not participants retained weight loss in the long term, how the programme could be optimised in relation to effectiveness and intensity of delivery and how group-based programmes may operate to enhance weight loss in comparison with individualised approaches.

Study registration: Current Controlled Trials ISRCTN32677491.

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List of abbreviations

BBC	British Broadcasting Corporation
BCT	behaviour change technique
BMI	body mass index
CBVD	cerebrovascular disease
CHD	coronary heart disease
CI	confidence interval
COM-B	capabilities, opportunities, motivation and behaviour
CSO	Chief Scientist Office
CVD	cardiovascular disease
DINE	Dietary Instrument for Nutrition Education questionnaire
EQ-5D	European Quality of Life-5 Dimensions questionnaire
EVPI	expected value of perfect information
FFIT	Football Fans in Training
FGD	focus group discussion
GP	general practitioner
HDL	high-density lipoprotein
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
IPAQ	International Physical Activity Questionnaire
LSI	limiting long-standing illness
MET	metabolic equivalent
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
PANAS	Positive and Negative Affect Schedule
PAR-Q	Physical Activity Readiness Questionnaire
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
RGM	ratio of geometric means
RPE	rating of perceived exertion
RSE	Rosenberg Self-Esteem scale
SD	standard deviation
SDT	self-determination theory
SF-12	Short Form questionnaire-12 items
SHeS	Scottish Health Survey
SHHEC	Scottish Heart Health Extended Cohort
SIGN	Scottish Intercollegiate Guidelines Network
SIMD	Scottish Index of Multiple Deprivation
SMART	specific, measurable, achievable, realistic, time-limited
SMR	Scottish Morbidity Record
SMS	short message service
SPFL	Scottish Professional Football League
SPL	Scottish Premier League
TCTU	Tayside Clinical Trials Unit
VOI	value of information

Plain English summary

Obesity in men is rising but few men take part in existing weight management programmes. We developed a men-only weight management programme, Football Fans in Training (FFIT), which was specifically designed to be delivered in Scottish professional football clubs by club community coaches. In the 12 weekly sessions, men learnt about diet and healthy living for weight loss, how to set goals and monitor their eating and physical activity, and top tips for making long-term changes. The FFIT programme also included a pedometer-based walking programme, group physical activity sessions at the club and some minimal ongoing support including a reunion session at the club.

We evaluated whether or not FFIT was effective and good value for money, whether or not coaches delivered it as intended, what made men want to do FFIT and whether or not men and coaches enjoyed it. The study was the first randomised controlled trial of a health programme in a professional sports club setting. Out of 747 men who wanted to do FFIT, 374 were picked at random to do the programme immediately and 374 to be in a comparison group who did FFIT a year later.

Men who did the programme lost 4.94 kg more weight than men in the comparison group. They also had lower waist size, lower percentage body fat and blood pressure, reported higher levels of physical activity, better diets and felt better about themselves.

The programme was good value for money, was well-delivered by the coaches and attracted men at high risk of ill health. The club setting was a crucial factor in attracting men to FFIT.

Scientific summary

Background

The prevalence of obesity in men in the UK is among the highest in Europe, but men are less likely than women to use existing weight management programmes. Developing weight management programmes that are effective, appealing and acceptable to men is a public health priority.

We have worked with the Scottish Premier League (SPL) Trust (now the Scottish Professional Football League Trust) to develop Football Fans in Training (FFIT), a group-based, weight management and healthy living programme delivered by community coaches at 13 Scottish professional football clubs.

Methods

We conducted a two-arm, pragmatic, randomised controlled trial (RCT), cost-effectiveness analysis and process evaluation of the FFIT programme. The primary outcome was mean difference in weight loss between groups at 12 months, in terms of absolute weight loss (kg) and as a percentage.

Study design

The study was conducted in 2011–12 in the 12 SPL clubs that were in the premiere league that season and the club relegated the previous season. Following baseline measurement, eligible men were block randomised (block size 2–9) in a 1 : 1 ratio, stratified by club. The intervention group started the FFIT programme within 3 weeks, and the comparison group were put on a 12-month waiting list and invited to undertake the programme in autumn 2012. We measured participants at baseline, 12 weeks and 12 months in club stadia. To maximise retention we undertook home visits for those who were unable to attend in-stadia measurements.

Participants

We recruited through club-based activities, media coverage, workplace advertising and word of mouth. Those whose self-reported body mass index (BMI) and age suggested eligibility were invited to club stadia for assessment. Men were eligible if they were aged 35–65 years in 2011/12; had objectively measured BMI of at least 28 kg/m^2; completed the Physical Activity Readiness Questionnaire; and consented to randomisation, weight, height and waist measurements.

Interventions

The FFIT programme was 'gender sensitised' in relation to context (traditionally male environment of football clubs, men-only groups), content (information on the science of weight loss presented simply, discussion of alcohol and its role in weight management, branding with club insignia) and style of delivery (participative, peer-supported, learning which encouraged 'banter' to facilitate discussion of sensitive subjects). It was delivered free of charge by trained community coaching staff to groups of up to 30 men over 12 weekly sessions at the club's home stadium. Each session combined an educational 'classroom' discussion with a group-based physical activity session, both led by club community coaches. Participants were taught effective behaviour change techniques (self-monitoring, specific goal setting, implementation intentions, feedback on behaviour) and social support was promoted. The 12-week active phase was followed by a 'light-touch' weight maintenance phase with six post-programme e-mail prompts over 9 months and a group reunion at the club 6 months after the last weekly session.

At baseline, both groups received a weight management booklet; feedback on their objectively measured BMI; and advice to consult their general practitioner (GP) if blood pressure exceeded pre-specified thresholds.

Outcome measurement

Measurement of the primary outcome (weight at 12 months) was blinded. A trained fieldwork team assessed weight, height, waist circumference, percentage body fat and blood pressure objectively, following standard protocols. Other secondary outcomes were self-reported: physical activity and sedentary time using the International Physical Activity Questionnaire; eating habits using questions from the Dietary Instrument for Nutrition Education; alcohol consumption over the last 7 days using an alcohol diary; positive and negative affect using the Positive and Negative Affect Schedule; self-esteem using the Rosenberg Self-Esteem Scale; and health-related quality of life (HRQoL) using the Short Form questionnaire-12 items. Demographic characteristics were also self-reported at baseline. Health-care resource use and GP-prescribed medications were self-reported for the economic evaluation.

Process outcomes were investigated using nine data sources including questionnaires at registration, at baseline measurement, at the 12-month follow-up and to men who opted out; observations of delivery of the programme; weekly attendance sheets; focus group discussions (FGDs) at 12 weeks and 12 months; and interviews with club coaches.

Adverse events were self-reported by participants. Serious adverse events were also reported by coaches and researchers conducting programme observations and were recorded at follow-up sessions. When possible, reports of serious adverse events were followed up by a telephone call to the participant.

Sample size

The study was powered to detect a 5% mean difference in percentage weight loss between the intervention and comparison groups at 12 months, with standard deviation of 19.9%, 80% power and a two-sided significance level; 250 men were required in each trial arm. The sample size was inflated to 360 men in each arm to allow for 30% attrition.

Statistical analyses

All analyses were intention to treat on randomised participants with all available data in mixed models. We applied logarithmic transformations when distributions were not normal. We used multiple linear regression for all analyses; baseline measure, group allocation and club were included as fixed effects in adjusted models; and, for physical activity, outcomes analyses were conducted using repeated measures using results from 12 weeks and 12 months.

Pre-specified subgroup analyses for the primary outcome were investigated. Changes are presented as mean [95% confidence interval (CI)] unless log-transformed, in which case they are presented as median change from baseline and ratio of geometric means (RGM) (95% CI).

Sensitivity analyses for the primary outcome included (1) multiple imputation for missing data assuming data missing at random, (2) club as a random variable to account for possible clustering and (3) repeated measures analysis using results from both 12 weeks and 12 months. All analyses were conducted using SAS (v 9.3; SAS Institute Inc., Cary, NC, USA) and blinded to group allocation.

Cost-effectiveness analysis

The costs required to manage and run the intervention were combined with self-report data on health-care resource use and GP-prescribed medications to provide an estimate of the additional cost of providing FFIT. Following the approach specified and used by the UK National Institute for Health and Care Excellence to assess value for money, we conducted a within-trial analysis of differences in the average utility change between intervention and comparison groups to give an estimate of quality-adjusted life-years (QALYs) gained from the intervention, assuming no differences beyond the 12-month follow-up

period. Cost-effectiveness is presented as the incremental cost associated with FFIT per individual achieving and maintaining the 5% weight loss over 12 months and the incremental cost per QALY gained, both compared with no intervention. In addition, we used a model to predict the additional costs and effects of the intervention over the individual's lifetime. These estimates were combined with those from the within-trial analysis to produce an estimate of the longer-term impact of the intervention in terms of cost, effect and cost-effectiveness over the individuals lifetime compared with no intervention.

Analysis of process outcomes

The need to use multiple recruitment strategies meant that we could not provide a clear denominator to estimate reach. Instead, we describe routes to recruitment and compared participants' health risk and demographic characteristics with those of similarly aged men in the Scottish population. Reasons for participating were analysed thematically from FGDs and reasons for opting out were obtained from a telephone questionnaire. Fidelity was assessed using data from programme observations and thematic analysis of coach interviews. Experiences of the programme, and of maintaining changes to 12 months, were assessed through thematic analysis of FGDs at 12 weeks and 12 months.

Results

Study population

Of the 1231 men registering an interest, 483 were excluded, 374 were randomly allocated to the intervention group and 374 were allocated to the comparison group. One comparison group participant subsequently withdrew and requested that we destroy his data. Demographic and clinical characteristics of participants ($n = 747$) were well balanced across groups. Retention was high: measurements were obtained for 90.5% of participants at 12 weeks and for 92.0% at 12 months.

Changes in primary outcome

At 12 months, mean weight loss was 5.56 kg (95% CI 4.70 kg to 6.43 kg) among men in the intervention group and 0.58 kg (95% CI 0.04 kg to 1.12 kg) in the comparison group. The mean between-group difference at 12 months in weight loss adjusted for baseline weight and club was 4.94 kg (95% CI 3.95 kg to 5.94 kg) and in percentage weight loss was 4.36% (95% CI 3.64% to 5.08%), both in favour of the intervention ($p < 0.0001$). Sensitivity analyses gave similar results: (1) multiple imputation (94.93 kg, 95% CI 3.92 kg to 5.94 kg), (2) adding club as a random effect to account for possible clustering (4.94 kg, 95% CI 3.83 kg to 6.04 kg) and (3) repeated measures (5.28 kg, 95% CI 4.62 kg to 5.94 kg). Pre-specified subgroup analyses found no significant predictors of primary outcome.

Changes in objectively measured secondary outcomes

At 12 months, more men in the intervention group (39.04%, 130/333) than the comparison group (11.27%, 40/355) achieved at least 5% weight loss (relative risk 3.47, 95% CI 2.51 to 4.78) and more had a BMI below 30 kg/m^2 [intervention group 25.53%, 85/333; comparison group 13.52%, 48/355; RR 1.89 (95% CI 1.37 to 2.60)].

The differences between groups in waist circumference and BMI reduction at 12 months (adjusted for baseline measure and club) were 5.12 cm (95% CI 4.27 cm to 5.97 cm) and 1.56 kg/m^2 (95% CI 1.29 kg/m^2 to 1.82 kg/m^2), respectively, in favour of the intervention ($p < 0.0001$). Differences in all objectively measured secondary outcomes, including weight loss at 12 weeks, per cent body fat and systolic and diastolic blood pressure at 12 weeks and 12 months were also statistically significant and in favour of the intervention.

Changes in self-reported secondary outcomes

Increase in total metabolic equivalent (MET) minutes per week was greater in the intervention group than in the comparison group at both 12 weeks and 12 months with an adjusted RGM at 12 months of 1.49 (95% CI 1.09 to 2.05) for total MET minutes. Improvements were also reported for MET minutes per week

in vigorous, moderate and walking activities at both 12 weeks and 12 months but with considerable attenuation between these measurement time points.

A greater reduction in reported time spent sitting was seen in the intervention group at 12 weeks (RGM 0.85, 95% CI 0.78 to 0.93). However, by 12 months there was no statistically significant between-group difference in sitting time.

Intervention group participants also had improved scores for fatty and sugary food and for fruit and vegetable intake at both 12 weeks and 12 months [the difference between FFIT and comparison groups in fatty food score at 12 months = –2.74 (95% CI –3.52 to –1.96), sugary food score = –0.87 (95% CI –1.18 to –0.56) and fruit and vegetable score = 0.54 (95% CI 0.29 to 0.79)]. The intervention group also reported drinking fewer units of alcohol per week (–2.59, 95% CI –4.21 to –0.97) at 12 months.

Finally, intervention group participants reported greater improvements in self-esteem, positive and negative affect and scores on physical aspects of quality of life (QoL) at 12 weeks and 12 months than men in the comparison groups [difference between FFIT and comparison groups in self-esteem = 0.12 (95% CI 0.07 to 0.17), positive affect = 0.28 (95% CI 0.19 to 0.36), negative affect = –0.08 (95% CI –0.15 to –0.02), physical aspects of QoL = 1.89 (95% CI 0.89 to 2.90)]. However, the greater improvements in mental health aspects of QoL in the intervention group at 12 weeks were no longer significant by 12 months (0.50, 95% CI –0.62 to 1.62).

Serious adverse events

Eight serious adverse events were reported: five in the intervention group and three in the comparison group. Two appeared to be or were reported as related to participation in FFIT: one participant ruptured an Achilles tendon while playing football and the other was told by his doctor that intermittent abdominal pains from gall stones could have been aggravated or caused by weight or dietary changes.

Cost-effectiveness

From the within-trial analysis, FFIT was estimated to cost £862 per additional man achieving and maintaining a 5% weight reduction at 12 months and £13,847 per additional QALY gained, both compared with no intervention. For a cost-effectiveness threshold of £20,000/QALY, the probability that FFIT is cost-effective, compared with no active intervention, is 0.72. This probability rises to 0.89 for a cost-effectiveness threshold of £30,000/QALY. From the longer-term analysis, FFIT was estimated to cost £2535 per life-year gained and £2810 per QALY gained compared with no intervention.

Process outcomes

Football Fans in Training attracted men from across the socioeconomic spectrum although the proportion of FFIT trial participants who did not have paid work was lower than in the general population (17.2% vs. 22.4%) and fewer were non-white (white: 98.3% vs. 96.2%). FFIT trial participants were at higher risk of ill health (the proportion of FFIT trial participants at 'extremely high' risk was 21%, 16% and 12% at ages 35–44 years, 45–54 years and 55–65 years, respectively, compared with 2%, 2% and 1% of Scottish men of the same age). In addition, fewer than 5% had attended either a commercial or NHS weight management programme in the 3 months prior to undertaking FFIT.

Men reported being drawn to the programme through a combination of 'push' and 'pull' factors. Push factors included concerns about future health and 'being there' for their families, and pull factors included a powerful 'draw' of the football club and the opportunity to be with other 'men like them' to undertake weight management in circumstances that enhanced physical and symbolic proximity to the football club. The main reported reason for dropping out was changes to working patterns.

The FFIT programme was largely delivered as intended; community coaches delivered almost all key tasks and were able to be flexible with the timing of sessions to cover important points.

Participants expressed high levels of satisfaction with FFIT. They were motivated by the atmosphere fostered by coaches, taking part in the football club setting, feeling a part of and closer to the club (symbolised by T-shirts and other branded physical objects), enjoyment of the group interactions and feeling part of a team, and the satisfaction of learning tips and techniques for behaviour change from others. Together these factors built on one another to deliver tangible experiences of success which kept the vast majority of men engaged throughout the 12-week programme. Coaches enjoyed delivering FFIT, finding the course well structured. After brief training, they felt comfortable dealing with the questions asked by participants.

Men who were successful in maintaining changes reported making autonomous choices over which of the tools and techniques to continue using. They found it useful to retain continuing camaraderie and social support from their peers and families. Reported challenges to maintaining changes suggest the importance of preparing for set-backs, encouraging a flexible approach to being active and further emphasis on relapse prevention strategies.

Discussion

We conducted the first RCT of a healthy lifestyle programme in a professional sports club setting. We demonstrated that a 12-session, gender-sensitised, weight management and healthy living programme with subsequent light-touch weight loss support can help men achieve significant changes in weight, waist circumference, body fat, BMI, blood pressure, self-reported physical activity, dietary intake, alcohol consumption, and measures of psychological and physical well-being 12 months after baseline measurement. Mean weight loss in the intervention group fell only 0.04% short of 5% weight loss and is likely to be of clinical benefit. We also found that the programme was cost-effective at standard levels employed in the UK NHS, was well delivered and was highly acceptable to both participants and coaches.

Further research should investigate whether or not participants retained weight loss in the long term, how the programme could be optimised in relation to effectiveness and intensity of delivery and how group-based programmes may operate to enhance weight loss in comparison with individualised approaches.

Rising levels of obesity and lower participation in existing weight management programmes among men demands high-quality evaluation of innovative programmes in community settings to extend the evidence base for cost-effective strategies to support weight loss in men. We have provided evidence that FFIT offers one such strategy.

Trial registration

The trial is registered as ISRCTN32677491.

Funding

Scottish Government and The Football Pools funded the delivery of FFIT. National Institute for Health Research Public Health Research programme funded the evaluation.

Chapter 1 Introduction

The problem of obesity and male obesity

Rising levels of obesity are a major challenge to public health. There are expected to be 11 million more obese adults in the UK by 2030, accruing up to 668,000 additional cases of diabetes mellitus, 461,000 cases of heart disease and stroke, 130,000 cases of cancer, and up to 6.3 million lost quality-adjusted life-years (QALYs), with associated medical costs set to increase by £1.9–2.0B per year by 2030.[1]

In Scotland, more men (69%) than women (60%) are overweight or obese,[2] and the UK prevalence of male obesity is among the highest in Europe[1] and forecast to increase at a faster rate than female obesity in the next 40 years. It is likely that the link between obesity and socioeconomic deprivation, already evident in women, will soon appear in men.[2] Compared with women, men may be more vulnerable to adverse health consequences of obesity. At all ages, men are diagnosed with type 2 diabetes mellitus at lower body mass index (BMI) than women[3] and adult men are more insulin resistant than women, a finding that is associated with difference in fat distribution.[4]

Men, existing weight loss programmes and the potential of sporting organisations

Although 5–10% weight loss can produce significant health benefits,[5] men are under-represented in trials of weight loss interventions (only 27% of participants are men),[6] in referrals to commercial weight management programmes (between 11%[7] and 13%[8] of men) and in NHS weight management services (23% of men).[9] As a recent systematic review of approaches to the management of obesity in men concludes: 'That men are under-represented suggests that methods to engage men in services, and the services themselves, are currently not optimal'.[10]

Men's reluctance to enrol in weight management programmes in part reflects a failure to recognise gender differences in societal processes that contribute to becoming overweight or obese. For example, greater body size is often associated with masculinity,[11] leading some men to be concerned about being too thin and less likely to diet than women.[12–14] Indeed, men often view dieting as 'feminine'[15] and are more likely to use exercise to control their weight.[13] In addition, men tend to have poorer nutrition knowledge than women, to be resistant to healthy eating campaigns[16] and to be less aware of links between diet and ill health.[13,17] Alcohol may pose an additional problem for weight management for men;[18,19] Scottish men drink around twice as much as Scottish women.[20] However, evidence suggests that when gender issues are used to inform programme design, men *will* engage with appropriately gender-sensitised weight management interventions and lose weight.[10,21]

Another reason men may not enrol on weight loss programmes is the setting in which they are delivered. There is a common perception that commercial slimming groups are mainly for women.[22] However, recently the potential of professional sporting organisations to reduce health inequalities by providing access to hard-to-reach populations, including men, has been recognised.[23,24] Although some research has demonstrated the potential of professional sports clubs, particularly football clubs,[24–26] to engage men in lifestyle changes, there have been no published controlled studies.[10,26]

The Football Fans in Training (FFIT) intervention uses the traditionally male environment of football clubs,[27] existing loyalty to football teams and the opportunity to participate in men-only groups to maximise men's engagement with an evidence-based, gender-sensitised weight management programme.[28] FFIT is delivered under the auspices of the Scottish Premier League (SPL) Trust [which became the Scottish

Professional Football League (SPFL) Trust in June 2013].[29] During the 2011–12 season, nearly 2 million fans passed through SPL club turnstiles.[30]

The FFIT is delivered in 12 weekly sessions at club stadia by community coaches trained in diet, nutrition, physical activity and behaviour change techniques (BCTs) to a standard delivery protocol. This intensive weight loss phase is followed by a 9-month minimal contact weight maintenance phase including periodic post programme e-mail prompts and one face-to-face reunion session at the club. The programme's development is described in Gray *et al.*[28] and its components are detailed in *Chapter 2*, *Interventions*.

Rationale for current study

Project team members have collaborated with the SPL Trust (now the SPFL Trust) to design, implement and evaluate FFIT since June 2009. This partnership has complemented the Trust's remit to increase Scottish professional football clubs' community engagement and this is wholly supported by premier league clubs.[29] We developed the evidence-based programme,[28] conducted an initial evaluation of the delivery of the pedometer-based walking programme to ensure that it was appropriate for men[31] and conducted a feasibility study funded by the Chief Scientist Office (CSO) (CZG/2/504).[32] The feasibility study was conducted in one small and one large club in 2010/11 and demonstrated that men could be recruited to a randomised trial in this context, FFIT was successful in recruiting the target group (mean BMI 34.5 kg/m^2 ± 5.0 kg/m^2), retention through the trial was good (> 80% at 12 weeks and 6 months; > 75% at 12 months) and men would be likely to engage with the programme (76% attended at least 80% of available programme delivery sessions, and qualitative data examined their enthusiasm for the programme and the context).[31,32] We also found that the programme was likely to be successful; by 12 weeks, the intervention group had lost significantly more weight than the comparison group (4.6% vs. –0.6%; $p < 0.001$) and many maintained this to 12 months (intervention group baseline 12 month weight loss: 3.5%; $p < 0.001$).[32]

These results supported the decision to conduct the full randomised controlled trial (RCT) reported here.

Note: previous publication of some of the results

Some of the methods and results presented in this report have been previously reported. The design, methods and main results of the RCT were published in *The Lancet*.[33] The 'draw' of the football club setting to attract men to weight management who were at high risk of ill health and who would not otherwise have attended a weight management programme was published in *BMC Public Health*.[34]

Chapter 2 Methods

Setting

A total of 13 professional football clubs in Scotland, including the 12 football clubs constituting the SPL in the 2011–12 football season, and the club relegated to Division 1 at the end of the 2010–11 football season participated in the study.

Overview of study design

We undertook a two-arm, pragmatic, RCT to evaluate delivery of the FFIT programme in 13 Scottish professional football clubs in 2011–12. Men were randomised to intervention or comparator in a 1 : 1 ratio, stratified by club.

Randomisation of individuals within clubs (rather than randomisation of clubs) was chosen for two reasons. First, individual randomisation is more efficient unless contamination is a major risk[35] and, second, the SPL Trust was required to deliver the programme in all clubs at the same time.

Assessment of the primary outcome (mean difference in weight loss between groups at 12 months) was blinded.

A summary of the protocol is available at www.thelancet.com/protocol-reviews/11PRT8506.[36]

Recruitment strategies and contact with men

At the time of the trial, funding from the Scottish Government and The Football Pools had been secured for three deliveries of the FFIT programme (August to December 2011, February to April 2012 and August to December 2012) in 13 clubs, and the funders required the SPL Trust to provide two deliveries of FFIT in the 2011–12 season. We needed to recruit sufficient men to fill all available places in the three deliveries because the trial design compares men randomly allocated to the FFIT programme in September 2011 with those randomly allocated to a waiting list comparison group starting the FFIT programme 12 months later and we needed to ensure that comparison group participants could not 'leak' into vacancies on the non-trial delivery programme. This meant that our recruitment target was inflated from 720 to 1080 (see *Sample size* for the calculation).

Formal recruitment commenced on 2 June 2011 and continued until the week before the baseline measurements in each club, which took place between 11 August 2011 and 20 September 2011. Participants randomly allocated to the delivery in August to December 2011 formed the intervention group and those randomly allocated to the August to December 2012 delivery formed the waiting list comparison group and undertook the programme after the 12-month trial outcomes had been completed. Those allocated to the February to April 2012 delivery did not participate in the trial.

Our multifaceted recruitment strategy was informed by the feasibility study, which suggested that club-based strategies were likely to be most effective and that men may need multiple prompts before signing up.[32] *Box 1* lists the various strategies we adopted to recruit the numbers needed over a very limited time period. Club-based recruitment included advertisements on SPL, club and fans websites, in-stadia advertising (poster/flyers with endorsement from club personalities), active involvement of local supporters' organisations, advertisements in the club and Scottish Football Association e-newsletters.

BOX 1 Recruitment strategies and publicity for FFIT for recruitment

Club-based activities

Posters/flyers with endorsement from club personalities; end of season home match advertising (except at Hibernian); active involvement of local supporters' organisations (Kilmarnock, Motherwell, Hibernian, Hamilton and Aberdeen).

Online publicity including SPL website, club websites, fan websites, some club e-newsletters.

Publicity in media

Newspapers

Local papers: Evening Telegraph, 3 May 2011; *The Courier*, 6 May 2011; *Evening Times*, 31 May 2011; *Paisley Daily Express*, 18 May 2011; and *The Inverness Courier*, 9 September 2011.

National papers: The Sunday Times, 17 April 2011; *Daily Record*, 13 June 2011; *Sunday Post*, 10 July 2011; *Metro*, 11 July 2011; and *Daily Record*, 11 July 2011.

TV and radio coverage

BBC Radio Scotland: John Beattie show, lunchtime, 2 May 2011; Call Kay, morning, 17 June 2011; 'On the Ball', 18 June 2011; FFIT documentary, 18 June 2011 and 9 July 2011; STV: *The Hour*, teatime 17 May 2011.

Workplace advertising

Local councils: Perth and Kinross, Glasgow City, North, South and East Ayrshire, North Lanarkshire and Highland.

Other employers: Glasgow Benefits Office, Wiseman's dairies, HBOS, Clydesdale Bank, Scottish Qualifications Authority, Her Majesty's Inspectorate of Education, Thomas Cook, Mahle (Kilmarnock), Aviva, BP, Longannet Power Station, Dell Scotland, HP Scotland, Microsoft Scotland, Oracle, Scottish Business in the Community, Scottish Enterprise, all companies at City Park in Glasgow, Morris and Spottiswood and Adecco (Scotland).

Other

FFIT Facebook® (Facebook, Inc., Menlo Park, CA, USA) page, FFIT website (www.spl-ffit.co.uk), FFIT participant online diary February to June.

BBC, British Broadcasting Corporation; BP, British Petroleum; HBOS, Halifax Bank of Scotland; HP, Hewlett Packard; STV, Scottish Television.

We also employed fieldworkers to approach potentially eligible men on match days to ask if they would like to register an interest in FFIT. Between 16 July and 17 September 2011, our recruitment staff attended 25 pre-season 'friendlies', early-season home games and club open days.

We made a concerted effort to achieve media coverage. We were successful in attracting articles in local and national newspapers (see *Box 1*), a video blog filmed by a British Broadcasting Corporation (BBC) Scotland sports presenter who took part in one of the pilot deliveries of FFIT, a 1-hour-long documentary on BBC Radio Scotland and interviews with members of the research team and participants in the pilot FFIT programme on Radio Scotland and Scottish Television. As part of our recruitment drive, we ran a five-a-side tournament for 'graduates' of the pilot FFIT programme on 18 June 2011 at St Mirren's home

stadium, which formed an excellent focus for some of this publicity. We invited the BBC to contribute a team (made up of sports presenters and three former Scottish international football players) to participate and this event was the focus of live coverage on BBC Radio Scotland's 'On the Ball' football programme. It is possible that articles and events attracted other media coverage that we were not aware of during the recruitment period.

Other strategies included e-mails to staff through local employers (see *Box 1*) and word of mouth. Men who took part in the pilot FFIT programme told their family, friends and work colleagues about the programme and some also put up leaflets in their workplaces. An incentive (a £50 football club shop voucher) was offered to the FFIT graduate who generated the highest enrolment rate of eligible men in the FFIT study.

All publicity invited men to contact the research team by short message service (SMS) text, e-mail or telephone to register their interest in the study by providing their contact details and self-reported weight, height, trouser waist size and date of birth. They were also asked where they heard about the study. Men who gave their name to recruitment staff on match days were subsequently telephoned by the research team to confirm their interest in the study and to collect full contact and self-report information. All men whose self-reported BMI (calculated from self-reported weight and height) and age suggested they were eligible for the study were invited to participating club stadia for formal eligibility assessment.

Participants

Men were eligible if they:

- were aged 35–65 years in 2011/12
- had an objectively measured BMI of at least 28 kg/m^2
- completed the Physical Activity Readiness Questionnaire (PAR-Q)[37]
- consented to randomisation and
- consented to weight, height and waist measurements (this was a requirement for taking part in the FFIT programme imposed by Scottish Government, irrespective of the trial).

The age limits reflect recognition that overweight and obese men in their mid-to-late thirties may experience an attitudinal shift towards their health and weight,[38] and focusing on men in the middle years can maximise the potential effectiveness of lifestyle interventions.[39] The older age limit reflects opinions that for those over the age of 65 years, physical activity programmes may be more effective when targeted specifically.

The decision to include only men with a BMI of at least 28 kg/m^2 was made for three reasons. First, we had previously reported the power for men of being told that they were 'obese' as a motivator for them to want to lose weight[40] and that those labelled 'overweight' were more likely to challenge the validity of BMI categories.[41] We thought that 'approaching obese' would be similarly motivational. Second, men with a BMI of at least 28 kg/m^2 would also be more likely to benefit from weight loss. Third, in our feasibility study we had found that men liked being with others with similar weight loss goals.[28]

The PAR-Q is a self-screening tool to help identify those who should seek medical advice prior undertaking exercise. If any of the men had answered 'yes' to any of the seven questions, fieldwork staff were instructed to recommend that men consulted their general practitioner (GP) prior to commencing the FFIT programme. Although answering 'no' to all questions was not an inclusion criterion for FFIT, with participants' permission, copies of the PAR-Q forms were given to the community coaches so that they could check whether or not men had any pre-existing medical conditions and help the men exercise appropriately.

Because of the SPL Trust's whole-hearted commitment to collaborating in a rigorous evaluation of FFIT, it was not possible for eligible men to access the FFIT programme unless they agreed to be randomly allocated to any one of the three programmes starting in September 2011, February 2012 or September 2012.

The SPL Trust also required participants to consent to weight, height and waist measurements, but men were free to opt out of additional measures/procedures relating to the trial's secondary and process outcomes. Men were excluded if they had participated in FFIT previously.

If men's blood pressure, as measured at baseline, contraindicated vigorous exercise (systolic $\geq$ 160 mmHg and/or diastolic $\geq$ 100 mmHg), they were initially able to take part in the classroom sessions only and the incremental, pedometer-based walking programme; they were advised that they would be able to take part in more intense in-stadia training once they had provided coaches with evidence of a reduction in their blood pressure.

Interventions

All men measured at baseline were informed of their weight and BMI, given a British Heart Foundation booklet, *So You Want to Lose Weight?*, which offered detailed advice on weight management,[42] were advised to see their GP if baseline readings for blood pressure exceeded pre-specified levels, and met the coaches, who talked broadly about the FFIT programme and gave information of the timing of the programme at their club.

The FFIT programme was developed and optimised during our feasibility study and the content of the programme is described in detail elsewhere.[28] The programme adheres strictly to national guidance for weight management programmes.[5,43] The behavioural aspects of the programme were not based on any single theory of behaviour because, as Michie *et al.*[44] suggest, single theories contain so many overlapping constructs that there is no good basis for deciding which would be appropriate. Here we briefly describe the way in which the programme was gender sensitised, its dietary and physical activity components, the evidence-based BCTs[45] used, the format through which it was developed and the training delivered to coaches.

Gender sensitivity

The FFIT was designed to work with, rather than against, prevailing conceptions of masculinity[28,31,34] and gender sensitised in relation to the context, content and style of delivery.[31] The traditionally male environment of football clubs and men-only groups led by club community coaches provided a masculinised context for the *delivery* of key messages.

The programme *content* was developed to be attractive to men. It provided information on weight loss presented simply ('science but not rocket science'), included a separate session on alcohol reinforced by demonstration of the size of units and discussion of alcohol's potential role in weight management, and provided men with a physical representation of the amount of weight lost to date at week 7 for them to hold. In addition, materials 'branded' with club insignia were provided; for example, T-shirts in their club colours and with the FFIT logo were provided for men to wear when attending the programme and the programme notes were branded with club-specific insignia.

Finally, the *style* of delivery of the programme was participative, with coaches facilitating interactive learning through discussion of key points and encouraging camaraderie, 'team bonding' and 'banter' to facilitate discussion of sensitive subjects.

Dietary components

The dietary component of FFIT was designed to deliver a 600-kcal daily deficit (from estimated daily energy requirements)[5,46] through the gradual adoption of more nutrient-dense foods and reduction of portion size, particularly of energy-dense foods, as well as the reduction of snacks, sugary and alcoholic drinks. Classroom activities were aimed at encouraging participants to make dietary changes that suited their individual circumstances and eating preferences, to weigh themselves each week and to keep a personal record of their weekly weight loss. Men were encouraged to make changes to their diet informed by the recommended balance of food groups indicated in the 'Eatwell Plate'[47,48] and make small, gradual and achievable changes to their normal diet. Key messages for dietary habits indicated in Cancer Research UK's 'ten top tips'[49] were highlighted as the men moved towards a programme to maintain weight loss in the longer term.

Physical activity components

The FFIT had two physical activity components: an incremental pedometer-based walking programme shown to increase physical activity[50,51] and pitch-side physical activity sessions led by club community coaching staff.

The men set individual daily brisk walking goals and recorded their progress each week in step count diaries provided in programme notes and reported back to the group during the weekly classroom sessions. Our feasibility work had shown that the walking programme was highly acceptable to men; participants described the pedometers as a very useful technology for motivation, self-monitoring and goal setting. In addition, the men reported finding they (re)gained fitness quickly through walking, which in turn enabled them to participate in other forms of physical activity that they also enjoyed (such as playing football).[31] As the programme progressed, they were encouraged to supplement walking with more vigorous activity (e.g. gym membership).

The pitch-side physical activity sessions taught men how to increase fitness through structured activities. Training was tailored to individual fitness levels and ability and included aerobic (e.g. walking, stair climbing, jogging), muscle strengthening (e.g. weight/circuit training) and flexibility (e.g. warm-up/cool-down activities) exercises.[52] Participants were taught to use the rating of perceived exertion (RPE) scale to ensure their activity was appropriate for their own fitness level and was performed at moderate intensity. The men were encouraged to consider how they could continue these activities in community settings using community resources, to continue to meet to train together post programme and to avoid compensatory behaviours (e.g. increased snacking or television viewing) that can undermine weight loss following physical activity.[53,54]

Behaviour change techniques

Using the BCTs Taxonomy v1,[45] 37 specific BCTs are used in FFIT.[28] However, the programme draws most heavily on self-monitoring, implementation intentions, goal setting and review, and feedback on behaviour, all of which are associated with control theory[55] and have been shown to be effective in physical activity and healthy eating interventions.[56–58] The programme also encourages social support, which has been shown to be effective in weight loss interventions[57] and relapse prevention strategies. Further key techniques used in FFIT draw on other theoretical accounts of behaviour change (e.g. social cognitive theory and self-regulation)[59] and include information on consequences, identification of barriers to change, verbal persuasion about capability, instruction in performing new behaviours, graded tasks to encourage increases in self-efficacy and social comparison.

Format of the programme

The FFIT was delivered free of charge by community coaching staff, employed by individual clubs and trained to standard protocols, to groups of up to 30 overweight/obese men (participant to coach ratio of 15 : 1) over 12 weekly sessions at the club's home stadium. Each 90-minute session combined advice on

healthy diet with physical activity. The balance of classroom and physical activity sessions changed over the 12 weeks; later weeks focused more on physical activity as men became fitter and the classroom element was shorter and focused on revision.[28] A club-branded information booklet (including tables to record self-monitored weight loss and step counts) was given to each participant.

Based on evidence from previous group-based physical activity programmes,[60,61] we encouraged coaches to create a welcoming, supportive climate from the outset to encourage group cohesion. This included sharing some of their own experiences and allowing plenty of time for group interactions. Delivery notes reminded them which key tasks to deliver each week (summarised in *Table 1*). Nevertheless, the programme was cumulative in that each week built on what had been learnt in previous weeks and there was repeated practice of BCTs such as goal setting, self-monitoring and action planning with interactive problem-solving. Coaches were available at the end of each session if any man wanted to discuss issues individually.

TABLE 1 Key tasks for coaches to deliver in each session

Session	Number of key tasks per session
Session 1. Getting started	
KT1. Introduce men to aim of programme 'how to eat better, be more active and stay that way in the long term'	5
KT2. Getting to know one another and sharing ideas and experiences	
KT3. Influences on choosing what to eat and control over food and eating	
KT4. Energy balance (intake vs. output)	
KT5. Food diary homework	
Session 2. What are we eating?	
KT6. Explanation of food groups and eating a healthy diet using Eatwell Plate (less fatty and sugary foods, more fruit and vegetables, whole-wheat bread and pasta and brown rice)	3
KT7. Food diaries compared with healthy eating recommendations and smaller portions	
KT8. SMART goal setting introduced	
Session 3. Making changes	
KT9. Review of SMART goals	6
KT10. Avoiding compensation	
KT11. Example of individualised healthy eating plans	
KT12. Health benefits associated with 5–10% long-term weight loss	
KT13. Personal weight loss targets	
KT14. Importance of support from others	
Session 4. Thinking about physical activity	
KT15. Review of SMART goals	4
KT16. Health benefits of physical activity	
KT17. Overcoming barriers to physical activity	
KT18. Local amenities for physical activity	

TABLE 1 Key tasks for coaches to deliver in each session (*continued*)

Session	Number of key tasks per session
Session 5. Thinking about drinking	
KT19. SMART goal setting	5
KT20. Alcohol and weight gain	
KT21. Alcohol units	
KT22. Planning your drinking	
KT23. Cutting down on sugary drinks (fizzy and tea/coffee)	
Session 6. Halfway down	
KT24. Stages of change	3
KT25. Introduction to setbacks and strategies for dealing with them	
KT26. Measurements taken to review progress	
Session 7. How are we doing?	
KT27. Physical representation of individual weight loss to date (e.g. sandbag)	3
KT28. SMART goals and weight loss reviewed	
KT29. Reflection on how things are going so far	
Session 8. What to look out for	
KT30. Understanding food labels and choosing healthier foods	2
KT31. Importance of regular meals and breakfast	
Session 9. Practical stuff	
KT32. Making favourite meals healthier	3
KT33. Eating out sensibly	
KT34. Damage limitation for takeaways	
Session 10. Myths and moods	
KT35. Common ideas about healthy living	3
KT36. Triggers for setbacks and how to avoid them	
KT37. SMART goals reviewed	
Session 11. Making progress?	
KT38. Food diaries revisited	3
KT39. The energy balance and eating plans revisited	
KT40. Locus of control revisited	
Session 12. Looking forward	
KT41. Review of progress and next steps	2
KT42. Final measurements taken and recorded	
Total number of key tasks in the 12-week programme	**42**

KT, key task; SMART, specific, measurable, achievable, realistic, time-limited.

The 12-week active phase was followed by a 'light-touch', weight maintenance phase with six post-programme e-mail prompts over 9 months and a group reunion at the club 6 months after the end of the weekly sessions. E-mail prompts were designed to be easy to deliver and did not require coaches to interact with participants; however, this meant that they were largely passive and consisted of periodic reminders to enact some of the behavioural skills learnt on the programme. *Table 2* provides some more detail of their content.

TABLE 2 Content of the six e-mail prompts sent to participants by coaches after the 12-week programme

E-mail	Content	BCT reminded to use
1	***Football Fans in Training: how's it going?***	
	Restatement that coach enjoyed working with them and hopes they are keeping the weight they lost off and keeping up lifestyle changes Reminder to weigh themselves weekly or daily; to continue to monitor daily activity; to plan for set-backs and to remember to use SMART goals if going off-track	Self-monitoring of behaviour and outcome of behaviour; goal setting for behaviour and goal setting for outcome; problem-solving
2	***Football Fans in Training: still going well?***	
	Reminder to check current step count and consider whether or not it was as high as at the end of the programme Suggested ways to increase if not as high Recommend getting in touch with others who had done FFIT via Facebook® (Facebook, Inc., Menlo Park, CA, USA) site to help get active again	Discrepancy between current behaviour and goal; action planning; social support/encouragement
3	***Football Fans in Training: still on target?***	
	Reminder to check 5–10% weight loss target from baseline and current weight. Reminder of health benefits of losing weight Reminder to set some SMART goals for eating well if off-track and suggested ways to make small dietary changes Reminder that they will be meeting up again for 9-month reunion in club and will see other guys to discuss how will be doing	Goal setting for behaviour and outcome; discrepancy between current behaviour and goal; health consequences
4	***Football Fans in Training: looking forward***	
	Restatement that coach enjoyed seeing some people at 9-month reunion and reminder to keep in touch with other guys for support Reminder to check their progress, set some goals if not achieving them and check their confidence to achieve goals	Social support/encouragement; goal setting for behaviour and outcome
5	***Football Fans in Training: reflecting on progress***	
	Reminder to check whether eating and exercise routines are still healthy and make SMART goals if no longer on track, reminder that has been successful in past and that has skills to be so again. Suggestion that other men have used use if-then plans to plan for difficult situations	Focus on past success; verbal persuasion to boost self-efficacy; goal setting for behaviour and outcome; problem-solving
6	***Football Fans in Training: FFIT for life?***	
	Consider how many 'top tips for weight loss' still use. Reminder to use SMART goals to achieve them if not using. Information about some people has found FFIT to be life changing. Good luck for future	Goal setting for behaviour and outcome

SMART, specific, measurable, achievable, realistic, time-limited.

The 9-month reunion meeting was designed to allow men to share experiences of successes and difficulties in maintaining weight loss post FFIT, set new specific, measurable, achievable, realistic, time-limited (SMART) goals and take part in a group physical activity session.

Coach training

Coaches received group-based training over 2 days and detailed delivery notes. Within these notes, separate sections for each week of the programme described the 'key tasks' for the session (see *Table 1*), the equipment and preparation required, a suggested order of activities and the detailed content for that session. The coaches' delivery notes incorporated and cross-referenced to the participant notes.

The length of the training was limited by the availability of the coaches. It was delivered face to face in a central location (although some coaches still had to travel for up to 4 hours to attend) and took place over a period of 2 days, timed to fit in the training around a full programme of other activities.

The aim of the training was to foster full competence in delivering the programme *and* a sense of ownership of the delivery of the programme in their own club while adhering to the delivery of key tasks. Training was designed to build on coaches existing strengths, to teach them how to deliver each element of the programme and how to use their existing skills to create a positive, welcoming climate. Training was interactive to allow coaches to discuss their experience of delivering each component and exchange practical tips. It highlighted key elements of the programme (the use of pedometers, the Eatwell Plate, the alcohol session, the 'key tasks' for each week) and emphasised the importance of applying BCTs, in particular self-monitoring, goal setting and action planning and relapse prevention; personalisation of each element of the programme to suit individual men's abilities and circumstances; and encouraging mutually supportive interaction between participants.

The delivery of the programme, but not its core components, had to be flexible to allow coaches to adapt the programme to suit their club's facilities, their own skills set, the limitations and abilities of the specific men enrolled on their programme and external factors such as the weather, the rearrangement of club match fixtures or the timing of the recommended 'guest appearance' of a club celebrity (recommended for week 6) to suit the club celebrity's diary. Coaches were also encouraged to respond to group interactions and queries while ensuring that the key tasks in each session were covered.

In relation to physical activity, coaches were encouraged to use their own experience and the facilities available within their club to devise interesting and varied physical activity sessions. The training included a practical session in which coaches shared and demonstrated ideas about how to adapt flexibility, cardiac fitness and strength exercises for overweight, potentially very unfit men. Coaches were instructed that they should reinforce the use of the RPE scale in every session,[62] to ensure that men were exercising at a moderate intensity level.

The coach and participant notes have been made available for others' use. These can be requested from the FFIT research website, which can be accessed at www.ffit.org.uk.[63]

Aim and objectives

The aim of this study was to determine whether or not FFIT, a gender-sensitised, weight loss, physical activity and healthy living programme delivered in SPL football clubs, can help men aged 35–65 years with a BMI of at least 28 kg/m^2 achieve a reduction in body weight that is at least 5% more than any reduction seen in the comparison group 12 months after the start of their participation in FFIT.

Three further objectives related to the investigation of secondary, health economic and process outcomes:

Secondary outcomes to investigate whether or not involvement with FFIT:

(a) reduces body weight by at least 5% at 12 weeks
(b) reduces waist circumference and percentage body fat at 12 weeks and 12 months
(c) increases physical activity and reduces sedentary behaviour at 12 weeks and 12 months
(d) improves eating habits at 12 weeks and 12 months
(e) reduces alcohol consumption at 12 weeks and 12 months
(f) reduces blood pressure at 12 weeks and 12 months
(g) increases positive affect and self-esteem, and improves quality of life (QoL) at 12 weeks and 12 months.

We also examined the difference in area under the trend line of weight loss from baseline to 12 months as a measure of the effect of the intervention across all time periods.

Cost-effectiveness to investigate whether or not FFIT has the potential to provide a cost-effective use of resources.

Process outcomes to investigate:

(a) programme reach
(b) participants' reasons for continuing with or opting out of FFIT
(c) the extent to which coaches deliver FFIT as designed
(d) participants' views of FFIT: including satisfaction, acceptability and any unexpected outcomes
(e) coaches' experiences of delivering FFIT: including satisfaction, acceptability and any unexpected outcomes
(f) participants' experiences of maintaining weight loss and lifestyle changes in the longer term.

Under *Procedures* below, we report on the measures and processes of data collection for primary and secondary trial outcomes. *Chapter 3* reports the results of the trial, *Chapter 4* reports the economic analyses, including methods and results, and *Chapter 5* reports process outcomes.

Outcome assessment

Outcome measures are set with reference to National Obesity Observatory guidance for the evaluation of weight management interventions.[64]

Primary outcome

The primary outcome was mean difference in weight loss between groups at 12 months, expressed as absolute weight and as a percentage.

Secondary outcomes

(a) Weight loss at 12 weeks.
(b) Reduction in waist circumference and body fat at 12 weeks and 12 months.
(c) Physical activity: changes in self-reported frequency and duration of walking, moderate activity, vigorous activity and sedentary behaviour over the last 7 days at 12 weeks and 12 months as measured by the International Physical Activity Questionnaire (IPAQ) Short Form.[65]
(d) Eating habits: changes in self-reported intake of key contributors to weight gain (e.g. fast foods, chocolate bars, chips, pies, sugary drinks), expressed as estimated intake of fatty foods, sugary foods and fruit and vegetables at 12 weeks and 12 months.

(e) Changes in self-reported alcohol consumption over the last 7 days at 12 weeks and 12 months measured using an alcohol diary over a week[66] and expressed as units of alcohol per week.
(f) Reduction in resting blood pressure at 12 weeks and 12 months.
(g) Psychological outcomes: (1) changes in positive and negative affect as measured by the Positive and Negative Affect Schedule (PANAS),[67] (2) changes in self-esteem as measured by the Rosenberg Self-Esteem (RSE) scale[68] and (3) changes in health-related quality of life (HRQoL) as measured by the Short Form questionnaire-12 items (SF-12),[69] all at 12 weeks and 12 months.
(h) Difference in area under the trend line of weight loss from baseline to 12 months.

Procedures

Timing of measurements

Outcomes were measured at baseline, 12 weeks and 12 months according to the measurement schedule shown in *Table 3*. Demographic characteristics were measured at baseline. Copies of the questionnaires are available on request.

The fieldwork team

Data were collected by teams of fieldworkers, educated at least to degree level. Each team in each measurement session had a designated team leader and a fieldwork nurse responsible for blood pressure measurement. Staff were trained to standard measurement protocols by experienced research and survey staff in the Medical Research Council (MRC)/CSO Social and Public Health Sciences Unit. Training took place over 2 days and emphasised strict adherence to protocol to minimise detection bias. Field staff wore T-shirts branded with FFIT research logos at all measurement sessions. *Figure 1* illustrates the measurement team spirit that was encouraged.

Baseline data

All men who had registered an interest in FFIT prior to the baseline measures in their club (and whose self-reported BMI and date of birth suggested they were eligible to take part) were sent a letter of invitation to attend an appointment at an in-stadia measurement session at their club. They were asked to confirm or rearrange their appointment date and time by e-mail or telephone. Eligibility criteria were confirmed through objective measurement of height and weight.

Outcome measurement

The 12-week measures

The intervention group 12-week measurements were taken around the time of the final FFIT programme session. We telephoned participants to make appointments and sent written reminders in advance by e-mail or letter according to the individual's preference. Men who did not attend the stadia for these measurements were telephoned to arrange individual measurements at home.

TABLE 3 Measurement schedule

Time	Demographic characteristics	Height	Weight	Waist	BMI	Blood pressure	Modified DINE questionnaire	IPAQ	Self-reported alcohol	PANAS	RSE scale	SF-12 and resource use
Baseline	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
12 weeks		✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
12 months		✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗

DINE, Dietary Instrument for Nutrition Education.

FIGURE 1 Fieldwork team arriving at a 12-month in-stadia measurement session.

Men who had dropped out of the FFIT programme were invited to the measurement sessions by telephone and, if that was difficult for them, they were offered a home visit for measurement. Any men who had dropped out of the programme, and men in the comparison group, were offered travel expenses and a £20 club shop gift voucher in appreciation of their time. FFIT intervention group participants were not offered a club gift voucher because their 12-week measurements followed on immediately after the programme completed, but they were offered travel expenses if the made a special journey to take attend the 12-week measurements.

To avoid risk of contamination, 12-week in-stadia measurements for the comparison group were held on a different evening from the intervention group measurement sessions.

The 12-month measures

The 12-month measurement sessions for both groups were held at club stadia. To maximise retention at 12 months, the men were (1) sent an advanced reminder that follow-up measurements were imminent, using a personalised letter sent 4–5 weeks ahead of the measurement dates at their club; (2) telephoned within a fortnight of the reminder letter to arrange a personal appointment time; (3) sent an e-mail (or letter) around a week before their appointment and a SMS text reminder the day before; (4) offered a home visit if attending the stadium was difficult; and (5) offered a £40 club voucher to thank them for their time.

Measurement protocols: objectively measured outcomes

Weight (kg) was recorded using electronic scales (Tanita HD 352™, Middlesex, UK) with participants wearing light clothing, no shoes and with empty pockets. Height (cm) was measured without shoes using a portable stadiometer (Seca Leicester™, Chino, CA, USA). Waist circumference was measured twice (three times, if the first two measurements differed by 5 mm or more) and the mean of all recorded measurements calculated. Resting blood pressure was measured using a digital blood pressure monitor (Omron HEM-705CP™, Buckinghamshire, UK) by a fieldwork nurse. All equipment was calibrated prior to fieldwork.

Measurement protocols: outcomes based on self-report

Participants completed self-administered questionnaires. Fieldworkers assisted any participant who appeared to have literacy problems and, whenever possible, checked questionnaires before the participant left the measurement session to minimise missing data.

Measurement of adverse events

An adverse event was defined as any injury or newly diagnosed health condition (e.g. high blood pressure, diabetes mellitus) that occurred while a man was registered on the FFIT programme, whether or not it was related to his participation in FFIT. A serious adverse event was defined as an adverse event that included at least one of the following: an event requiring hospitalisation or prolonged medical attention, an event that is immediately life-threatening (such as a cardiac arrest), a fatal event. Any serious adverse events were reported immediately to the chairperson or the Trial Steering Committee. A report of all adverse events was provided at every meeting of the Data Monitoring and Ethics Committee.

At the baseline and 12-week measurements, men were given a pre-paid postcard and details about how to report any adverse events. In addition, coaches (and the researchers who conducted the observations of the programmes) were also asked to report any adverse events that came to their attention. At the 12-month measurements, all participants were asked whether or not they had experienced any adverse events since their last contact with the research team.

All adverse events were categorised by a member of the research team according to their severity and whether or not they were related to participation in FFIT. When possible, serious adverse events and any adverse events for which relatedness to participation in FFIT was not clear were followed up by a telephone call to the participant. Adverse events that occurred before the baseline measurement period or after the August to December 2012 delivery of FFIT had started were not recorded.

Preparation of self-reported variables for analysis

Physical activity

Following standard procedures described in the IPAQ scoring protocol,[70] we calculated and reported sedentary time, and metabolic equivalent (MET) minutes per week from self-reported walking, vigorous and moderate exercise and a measure of total MET minutes.

Diet

We used the adapted Dietary Instrument for Nutrition Education (DINE) questionnaire to collect data on self-reported frequency of intake of different food types and the dietary question referred to the last 7 days. The full DINE questionnaire can take a considerable time to complete and can be difficult for some participants. Recent evidence on dietary factors influencing weight gain highlights items not included in the tool (e.g. sugary drinks); therefore, we adapted the DINE questionnaire to reduce participant burden and capture information on additional relevant markers. From these data, we calculated a fatty food score, a fruit and vegetable score and a sugary food score.

Description of items included in the adopted Dietary Instrument for Nutrition Education questionnaire

Participants reported how many times (over the last 7 days) they had consumed a serving of cheese, beef burgers or sausages, beef, pork or lamb, fried food, chips, bacon or processed meat, pies, quiches or pastries, crisps and fast food. We also asked about the amount of milk used in a day (for drinking or in cereal, tea or coffee) and what kind of milk is usually used (full cream, semi-skimmed or skimmed). They also reported how many times a day they had consumed fruit and vegetables, chocolate or sweets, and biscuits and sugary drinks (fizzy drinks, diluting juice or fruit juice).

Scoring food frequencies

Food frequency categories differed for different food types and we converted the DINE questionnaire food frequency categories as described in *Table 4*.

Alcohol intake

Following Emslie *et al.*,[66] we converted responses to the 7-day recall diary for alcohol to standard units equivalent to 8 g of pure alcohol (half a pint of ordinary beer, lager or cider, one small glass of wine and one measure of spirits each contain 1 unit of alcohol). We calculated total number of units reported in the last week.

TABLE 4 Scoring of the DINE questionnaire food frequency categories

Food type	Scoring of frequencies
Cheese, beef burgers or sausages, beef, pork or lamb, chips and fried food	0 times = 1
	1–2 times = 2
	3–5 times = 6
	≥ 6 times = 9
Pies, quiches and pastries	0 times = 1
	1–2 times = 2
	3–5 times = 5
	≥ 6 times = 8
Bacon or processed meat and crisps	No times = 1
	1–2 times = 2
	3–5 times = 5
	≥ 6 times = 6
Milk amount	Less than one-quarter of a pint = 1
	About one-quarter of a pint = 2
	About half a pint = 3
	≥ 1 pint = 4
Sugary drinks	Less than once = 1
	1–2 times = 2
	3–5 times = 3
	≥ 6 times = 4
Biscuits, chocolate and sweets	Less than once = 1
	1–2 times = 2
	3–5 times = 4
	≥ 6 times = 6
Fruit and vegetables	Less than once = 0.5
	1–2 times = 1.5
	3–5 times = 4
	≥ 6 times = 6

Psychological outcomes

Scores for both the RSE scale and the short form of the PANAS were normalised so that values could be calculated for participants who had missed one or two items contributing to each scale. The PANAS-normalised scale scores range from 1 to 5, with higher scores indicating higher negative affect and higher positive affect. Similarly, higher scores on the RSE scale (normalised range 0–3) indicate better self-esteem.

Scores on QoL using the SF-12 were summarised scores for mental and physical health following standard algorithms.[69]

Changes to outcomes after trial commencement

The protocol stated that the secondary outcomes of weight loss at 12 weeks and reduction in waist circumference and body fat at 12 weeks and 12 months would be reported as percentages. To be consistent with best statistical practice[71] these were reported as absolute differences. All changes made, together with their rationale, are summarised in *Table 5*.

Sample size

The study was powered to detect a 5% mean difference in percentage weight loss between the intervention and comparison groups at 12 months, with standard deviation (SD) of 19.9%, 80% power and a two-sided significance level. A total of 250 men were required in each trial arm and based on our feasibility study,[32] the sample size was inflated to 360 men in each arm to allow for 30% attrition.

TABLE 5 Changes to outcomes after the trial commenced

Original outcome as expressed in the protocol	Changed outcome	Rationale for change
Percentage weight loss at 12 weeks	Weight loss at 12 weeks	To be consistent with best statistical practice, which recommends reporting absolute differences
Percentage reduction in waist circumference and body fat at 12 weeks and 12 months	Reduction in waist circumference and body fat at 12 weeks and 12 months	
Eating habits: changes in self-reported intake of key contributors to weight gain (e.g. fast foods, chocolate bars, chips, pies, sugary drinks) at 12 weeks and 12 months using questions adapted from the DINE questionnaire	Eating habits: we calculated dietary intake scores for fatty food, sugary food and fruit and vegetables	There were 17 separate variables included in our adapted DINE questionnaire; to reduce reporting burden we summarised these into three scores indicative of healthy changes that men could have made to their diets
Changes in self-reported alcohol consumption over the last 7 days at 12 weeks and 12 months measured using an alcohol diary over a week and expressed as units of alcohol per week, and changes in football-associated alcohol consumption	Changes in self-reported alcohol consumption over the last 7 days at 12 weeks and 12 months, measured using an alcohol diary over a week and expressed as units of alcohol per week	On reflection we realised that the questions we had developed to assess football-related alcohol intake lacked external validity and we focused our analysis only on total alcohol consumption

Randomisation

Following baseline measurement the randomisation sequence was generated by the Tayside Clinical Trials Unit (TCTU) statistician using SAS (v 9.2; SAS Institute Inc., Cary, NC, USA), blocked (block size between two and nine depending on how many participants were recruited at a club) and stratified by club. The allocation sequence was sent in a password-protected file to a database manager (not part of the research team) who assigned individuals to each group. All those allocated to the intervention group were telephoned within 3 weeks of baseline measurements at each club to notify them of their allocation and the date, time and place of the first FFIT session. This was confirmed in writing. Those allocated to the waiting list comparison group were informed of their allocation by letter and given information about when they should expect to hear from the research team over the following 12 months. They were reassured that they had a guaranteed place on the FFIT programme in their club commencing August/September 2012.

Blinding

To blind the measurement of the primary outcome at the 12-month measurement, session weight was the first measure taken and was taken by fieldworkers employed only for 12-month measures (and who, therefore, had not met the men before), who were trained to minimise interaction with men until weight had been recorded and was in a screened-off area to prevent interaction with others. Blinding for other measures was not possible.

Statistical methods

All analyses were conducted as intention to treat on randomised participants, with all available data in mixed models as recommended by White *et al.*[72] All outcome variables were continuous. If the distribution was not normal, we carried out a logarithmic transformation to achieve normality and results comparing intervention with comparators were subsequently expressed as the ratio of geometric means (RGM) with corresponding 95% confidence interval (CI). We used multiple linear regression for all analyses and baseline measure, group allocation and club (to allow for stratification by club) were included as fixed effects in adjusted models.

To assess whether or not the intervention effect on the primary outcome and four selected secondary outcomes differed between subgroups of the study population we conducted pre-specified subgroup analyses by adding allocation group by subgroup factor interaction terms to the models.[73] The four selected secondary outcomes were total MET minutes/week, fatty food score, sugary food score and positive affect. Potential moderating variables were age, marital status, Scottish Index of Multiple Deprivation (SIMD) from postcode of residence, location of measurement (stadium vs. home), orientation to masculine norms, affiliation to football, whether or not attended a formal weight management programme in the last 3 months, smoking, housing tenure, education, ethnicity, employment status, joint pain, injuries and limiting long-standing illness (LSI).

Changes are presented as mean (95% CI) unless otherwise specified.

We conducted sensitivity analyses for the primary outcome (1) multiple imputation for missing data assuming data missing at random,[72] (2) added club as a random variable to account for possible clustering[74] and (3) repeated measures analysis using results from both 12 weeks and 12 months.

All analyses were conducted using SAS (v 9.3; SAS Institute Inc., Cary, NC, USA) by the TCTU statistician who was blinded to group allocation.

Changes to protocol

There were no changes to protocol except those concerned with the way that outcomes were expressed. See *Table 5*.

Public involvement

Extensive public engagement was built into the development of the FFIT intervention and the evaluation design. This principally involved ongoing engagement during the programme development phase with key stakeholders (the SPL Trust, the football clubs and the programme delivery funders) and consultation with men who took part in the first pilot deliveries of FFIT at 11 clubs in the 2010–11 football season. Input from the coaches, the SPL Trust and the target group of men thus all fed directly into the final shaping of the intervention and the research design.

Representatives of the SPL Trust were actively involved throughout the development of the delivery protocol for the pilot FFIT programme. Following these initial meetings, we also met with community managers from the football clubs who would be involved in the pilot programme prior to the finalisation of the pilot delivery protocol. These meetings allowed the community managers to input into the programme design and to discuss the importance of undertaking a programme that was evidence based and generalisable, and of gathering gold standard evidence of its effectiveness by conducting an evaluation using a randomised design. We also met with the coaches who were delivering the autumn 2010 pilot programme at a training workshop in October 2010 to ask for feedback on the initial sessions. At the end of the autumn 2010 delivery, we held in-depth interviews with coaches at the two clubs which took part in our pilot trial to obtain their views about the programme and research design and received written feedback from coaches at the other clubs.[28] In addition, CMG visited all clubs during spring 2011 to observe delivery sessions of the second pilot programme and to speak informally to the coaches and in April 2011 we fed back the emerging the pilot findings at a plenary meeting organised by the SPL Trust at the National Football Stadium, Hampden Park. All comments were carefully considered in the development of the final version of the FFIT programme that was delivered in the intervention arm of the trial as reported by Gray *et al.*[28]

The views and experiences of the men who participated in the pilot deliveries also fed into the development of the intervention. All men taking part in the autumn 2010 pilot deliveries were asked to complete a programme evaluation form, which asked for their suggestions for changes. Men at the two clubs involved in the feasibility study also took part in focus groups following the autumn 2010 and spring 2011 pilot deliveries where they gave their views on the content of the programme and on the planned research procedures for the RCT.[28,32] In addition, when a reviewer of the grant application for this trial suggested that the evidence on men and health raised questions about whether or not men would engage with the pedometer-based walking programme, we undertook a series of semistructured telephone interviews ($n = 27$) with men from a number of clubs who had taken part in the autumn 2010 pilot deliveries, to ask them about their experience of this aspect of the programme. These interviews strongly reinforced our first hand experiences that men saw the pedometer-based walking programme as an appropriate way to begin to regain some fitness and (re-)engage with physical activity;[31] furthermore, it demonstrated that this was a part of the programme that was highly valued by our target group (men aged 35–65 years with a BMI ≥ 28 kg/m^2).

Participants in the pilot deliveries of FFIT in 2010/11 were also engaged in outreach work on FFIT prior to and during our intense period of recruitment to this trial. Many participated in various public engagement activities including the five-a-side football tournament held in June 2011 at St Mirren Football Club for ex-participants and a video diary made by a BBC journalist, Paul Bradley, who took part in the spring 2011 pilot FFIT programme, which illustrated week by week (each week being filmed at a different club) the atmosphere that the programme sought to foster in order to engage men. Throughout the summer of 2011 (July and August), participants from the pilot deliveries took part in TV, radio and newspaper

interviews about their experiences of FFIT (including a 1-hour-long BBC Radio Scotland documentary about the programme that was first broadcast on 18 June 2011). They also played an active role in recruitment by telling their friends and family about the programme, advertising it in their workplaces and local community venues (e.g. libraries) and supporting fieldworkers during match day visits to home fixtures. In February 2012, a half-hour TV documentary on FFIT, which involved interviews with several participants from the autumn 2011 deliveries of FFIT (the intervention group in the trial), was screened on BBC 2 Scotland. Finally, in September 2013, representatives from each of the groups of men who undertook the intervention in autumn 2011 readily agreed to come to a bespoke event at Hampden Park to talk about their experiences of FFIT for future dissemination purposes, including the FFIT research website (www.ffit.org.uk).[63]

Chapter 3 Results: the randomised controlled trial

Participant flow

Figure 2 shows participant flow through the trial. Of the 1231 men registering an interest during the recruitment period, 483 were excluded from the trial (101 decided against participation, 76 had a BMI < 28 kg/m^2, 306 were allocated to the non-trial delivery of FFIT). Three hundred and seventy-four were randomly allocated to the intervention group and 374 to the comparison group. One comparison group participant subsequently withdrew and requested we destroy his data.

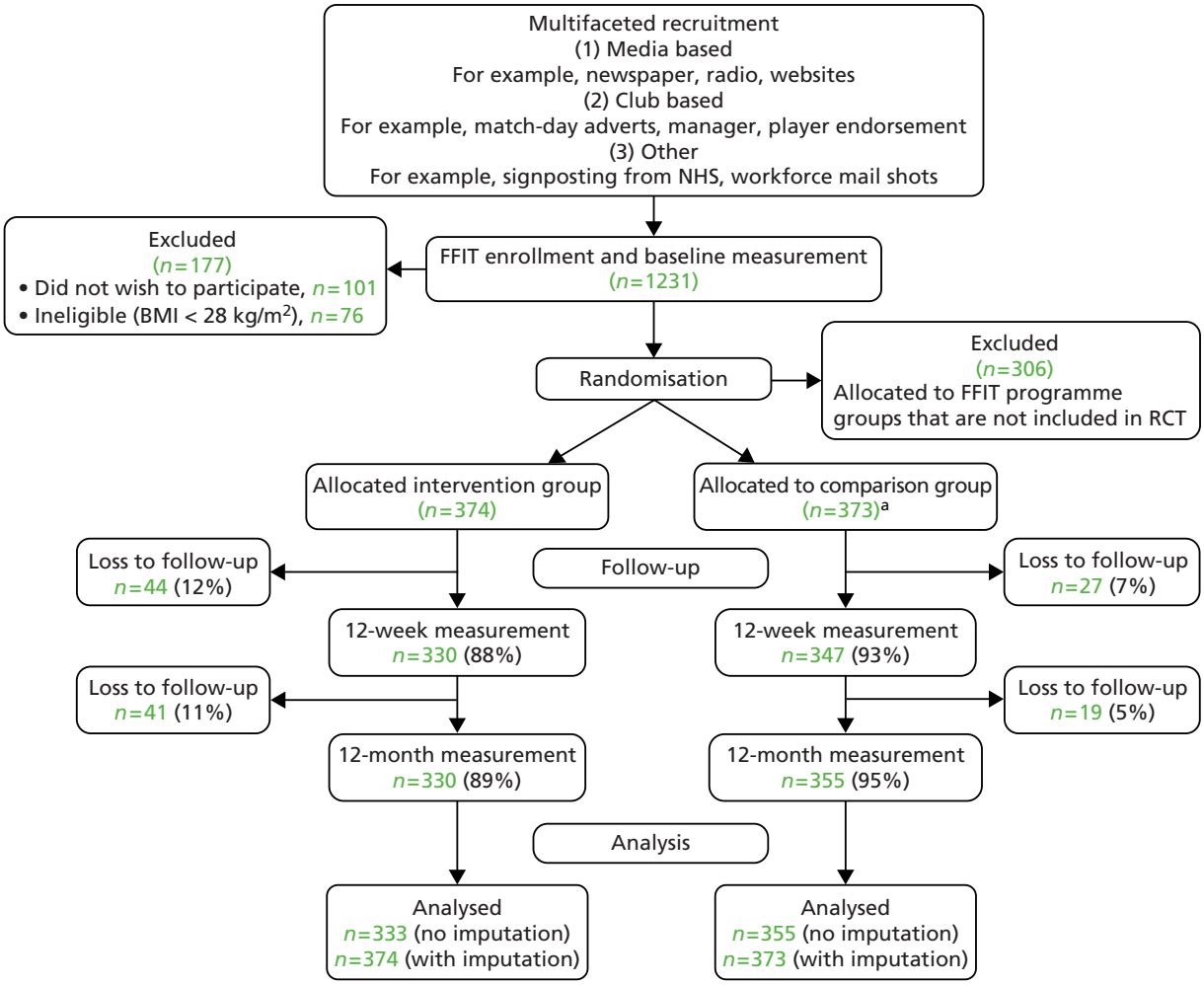

FIGURE 2 Flow of participants through the FFIT RCT. a, After randomisation, one participant requested to have all of his data destroyed. Reprinted with permission from Elsevier (*The Lancet*, 2014, **383**, 1211–21).[33]

Recruitment

As described below (see *Baseline data*), formal recruitment commenced on 2 June 2011 (although preparations for recruitment had begun in anticipation of receiving the grant award) and continued until the week before the baseline measurements in each club, between 11 August 2011 and 20 September 2011. *Figure 3* shows that recruitment started slowly, probably because in Scotland the 2010/11 season had closed and the 2011/12 season had yet to begin. As the clubs and media coverage geared up for the start of the season, and we were able to recruit men at games, recruitment speeded up so that we exceeded our target of 1110 men.

Baseline data

Table 6 shows baseline characteristics of participants ($n = 747$), including total self-reported MET-minutes per week. FFIT attracted men from across the socioeconomic spectrum, but few from ethnic minority groups.

Table 7 shows baseline levels of self-reported physical activity in relation to whether activity was vigorous, moderate or walking (reported in MET-minutes/week) or time spent sitting on a week day in the last 7 days.

Numbers analysed

After randomisation, one participant allocated to the comparison group withdrew and requested that all of his data be destroyed. This left 374 participants in the intervention group and 373 in the comparison group. Retention was high, although it varied between intervention and comparison groups (see *Figure 2*). At 12 weeks, measurements were obtained for 91% of participants: 330 out of 374 (88%) in the intervention group and 347 out of 373 (93%) in the comparison group. At 12 months, measurements were obtained for 92% of participants: 333 out of 373 (89%) in the intervention group and 355 out of 373 (95%) in the comparison group. All analyses were conducted as intention to treat on randomised participants with all available data.

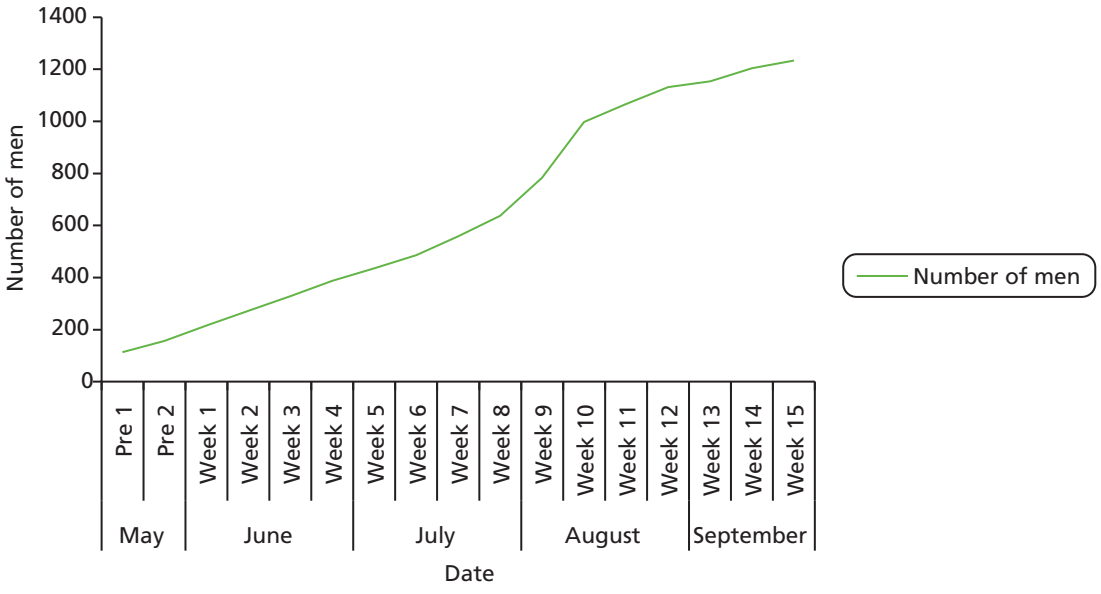

FIGURE 3 Recruitment to the FFIT study from May to September 2011.

TABLE 6 Baseline characteristics of participants allocated to the FFIT programme immediately (FFIT) or in 12 months (comparison). Data are number (%), mean (SD) or median (interquartile range)

Variable	FFIT ($n = 374$)	Comparison group ($n = 373$)	Total ($n = 747$)
Sociodemographic characteristics			
Age (years)	47.0 (8.07)	47.2 (7.89)	47.1 (8.0)
Ethnicity			
White – British/Scottish/Irish/other	367 (98.1)	368 (98.7)	735 (98.3)
Other	5 (1.4)	2 (0.5)	7 (1.0)
Missing	2 (0.5)	3 (0.8)	5 (0.7)
SIMD (% living in quintiles)			
1 (most deprived)	65 (17.4)	66 (17.6)	131 (17.5)
2	69 (18.4)	62 (16.6)	131 (17.5)
3	62 (16.6)	60 (16.0)	122 (16.3)
4	82 (21.9)	84 (22.5)	166 (22.2)
5	89 (23.8)	99 (26.5)	188 (25.1)
Missing	7 (1.9)	3 (0.8)	10 (1.3)
Employment status			
Paid work	322 (86.1)	304 (81.5)	626 (83.8)
Education or training	3 (0.8)	5 (1.4)	8 (1.1)
Unemployed	9 (2.4)	18 (4.8)	27 (3.6)
Not working due to long-term sickness or disability	8 (2.1)	8 (2.1)	16 (2.1)
Retired	14 (3.7)	18 (4.8)	32 (4.3)
Other	17 (4.6)	19 (5.0)	36 (4.8)
Missing	1 (0.3)	1 (0.3)	2 (0.3)
Education			
No qualifications	37 (9.9)	34 (9.1)	71 (9.5)
Standard Grades/Highers	115 (30.8)	126 (33.7)	241 (32.3)
Vocational or HNC/HND	133 (35.6)	107 (28.7)	240 (32.1)
University education	75 (20.1)	81 (21.7)	156 (20.9)
Other	14 (3.7)	25 (6.7)	39 (5.2)
Housing tenure			
Owner-occupied	280 (74.8)	283 (75.8)	563 (75.3)
Other	94 (25.2)	90 (24.2)	184 (24.7)
Marital status			
Married	249 (66.6)	269 (72.1)	518 (69.3)
Living with partner	55 (14.7)	40 (10.7)	95 (12.7)
Other	70	64	134

continued

TABLE 6 Baseline characteristics of participants allocated to the FFIT programme immediately (FFIT) or in 12 months (comparison). Data are number (%), mean (SD) or median (interquartile range) (*continued*)

Variable	FFIT ($n = 374$)	Comparison group ($n = 373$)	Total ($n = 747$)
Objectively measured outcomes			
Weight (kg)	110.3 (17.9)	108.7 (16.6)	109.5 (17.3)
Waist circumference (cm)	118.7 (12.3)	118.0 (11.1)	118.4 (11.7)
BMI (kg/m^2)	35.5 (5.1)	35.1 (4.8)	35.3 (4.9)
Body fat (% total weight)	31.8% (5.7)	31.5% (5.2)	31.7% (5.5)
Missing	7	3	10
Blood pressure (mm/Hg)			
Systolic blood pressure	139.4 (17.6)	141.2 (14.9)	140.3 (16.3)
Diastolic blood pressure	88.2 (10.3)	89.5 (10.1)	88.8 (10.2)
Missing	0	2	2
Participants with BMI < 30 kg/m^2	35 (9.4)	40 (10.7)	75 (10.0)
Self-reported outcomes			
Total MET-minutes/week	1188 (396–2559)	1173 (396–2559)	1188 (396–2559)
Missing	3	2	5
DINE-based measures			
Fatty food score (range 10–58)	23.3 (7.1)	23.4 (7.1)	23.3 (7.1)
Fruit and vegetable score (range 1–6)	2.3 (1.7)	2.3 (1.7)	2.3 (1.7)
Sugary food score (range 3-16)	6.0 (2.7)	6.2 (2.9)	6.1 (2.8)
Total alcohol consumption (units per week)	16.5 (17.4)	17.0 (17.4)	16.7 (17.4)
Self-esteem (normalised RSE score, range 0–3)	1.1 (0.5)	1.1 (0.5)	1.1 (0.5)
Positive affect (normalised PANAS score, range 1–5)	3.2 (0.7)	3.2 (0.7)	3.2 (0.7)
Missing	1	0	1
Negative affect (normalised PANAS score, range 1–5)	1.7 (0.6)	1.7 (0.6)	1.7 (0.6)
HRQoL (SF-12)			
Mental aspects	48.9 (10.1)	48.3 (9.2)	48.6 (9.7)
Missing	1	0	1
Physical aspects	47.0 (7.9)	47.7 (7.5)	47.4 (7.7)
Missing	1	0	1

HNC, Higher National Certificate; HND, Higher National Diploma.

TABLE 7 Baseline self-reported physical activity from the IPAQ at baseline. Data are median (interquartile range)

Variable	FFIT ($n = 374$)	Comparison group ($n = 373$)	Total ($n = 747$)
Vigorous MET-minutes/week	0 (0–720)	0 (0–720)	0 (0–720)
Missing	*4*	*3*	*7*
Moderate MET-minutes/week	0 (0–360)	0 (0–360)	0 (0–360)
Missing	*3*	*2*	*5*
Walking MET-minutes/week	462 (132–1188)	396 (99–1039)	445 (99–1188)
Missing	*4*	*2*	*6*
Time spent sitting on a week day in last 7 days	480 (300–600)	420 (300–600)	450 (300–600)
Missing	*75*	*72*	*147*

Outcomes

Primary outcome: weight at 12 months

At 12 months, mean weight loss among men in the intervention group was 5.56 kg (95% CI 4.70 kg to 6.43 kg) and 0.58 kg (95% CI 0.04 kg to 1.12 kg) in the comparison group (*Table 8*).

The mean difference in weight loss between groups, adjusted for baseline weight and club, was 4.94 kg (95% CI 3.95 kg to 5.94 kg) and the mean difference in percentage weight loss at 12 months, similarly adjusted, was 4.36% (*Table 9*).

Sensitivity analyses on primary outcome: change in weight at 12 months

The sensitivity analyses gave similar results to the main analysis (*Table 10*). Using multiple imputation, assuming data were missing at random, to account for missing data the mean difference in weight loss between groups adjusted for baseline weight and club was 4.93 kg (95% CI 3.92 kg to 5.94 kg). Adding club as a random effect to account for possible clustering, the mean difference in weight loss between groups adjusted for baseline weight was 4.94 kg (95% CI 3.83 kg to 6.04 kg). Using repeated measures to

TABLE 8 Change in weight at 12 months complete case analysis (mean, 95% CI)

	FFIT ($n = 374$)		Comparison group ($n = 373$)	
Variable	*n*	Mean (95% CI)	*n*	Mean (95% CI)
Change in weight from baseline (kg)	333	–5.56 (–6.43 to –4.70)	355	–0.58 (–1.12 to –0.04)
% change in weight from baseline	333	–4.96 (–5.71 to –4.20)	355	–0.52 (–1.00 to –0.03)

TABLE 9 Difference between groups in change in weight at 12 months (linear regression models) (mean, 95% CI)

Variable	Difference between groups	*p*-value
Change in weight from baseline (unadjusted) (kg)	–4.11 (–6.75 to –1.47)	0.0023
Change in weight from baseline (adjusted for baseline weight and club) (kg)	–4.94 (–5.94 to –3.95)	< 0.0001
% change in weight from baseline (unadjusted)	–4.36 (–5.09 to –3.64)	< 0.0001
% change in weight from baseline (adjusted for baseline weight and club)	–4.36 (–5.08 to –3.64)	< 0.0001

TABLE 10 Sensitivity analyses: difference between groups in change in weight (kg) at 12 months (linear regression models) (mean, 95% CI)

Model	Difference between groups	*p*-value
Multiple imputation model (adjusted for weight at baseline and club)	–4.93 (–5.94 to –3.92)	< 0.0001
Club as a random effect (adjusted for baseline weight)	–4.94 (–6.04 to –3.83)	< 0.0001
Repeated measures model (adjusted for weight at baseline and club)	–5.28 (–5.94 to –4.62)	< 0.0001

make use of weight loss data from both 12 weeks and 12 months found that the mean difference in weight loss between groups at 12 months, adjusted for baseline weight and club, was 5.28 kg (95% CI 4.62 kg to 5.94 kg) (see *Table 10*).

As shown in *Figure 4*, participants lost most weight over the period that coincided with the 12 weekly sessions delivered in the clubs.

Subgroup analyses on primary outcome

In order to investigate potential differential effects on the primary outcome by subgroup, we investigated associations between pre-specified subgroups (see *Chapter 2*, *Statistical methods*) and weight loss at 12 months. *Table 11* shows which variables were significantly associated with weight loss in univariate analyses.

Table 12 demonstrates that in multiple regression analyses including only those variables which had shown significant association with weight loss in univariate analysis together with weight at baseline and treatment group, the only significant associations were weight at baseline and treatment group. That is, the pre-specified subgroup analyses found no significant additional predictors of primary outcome and the

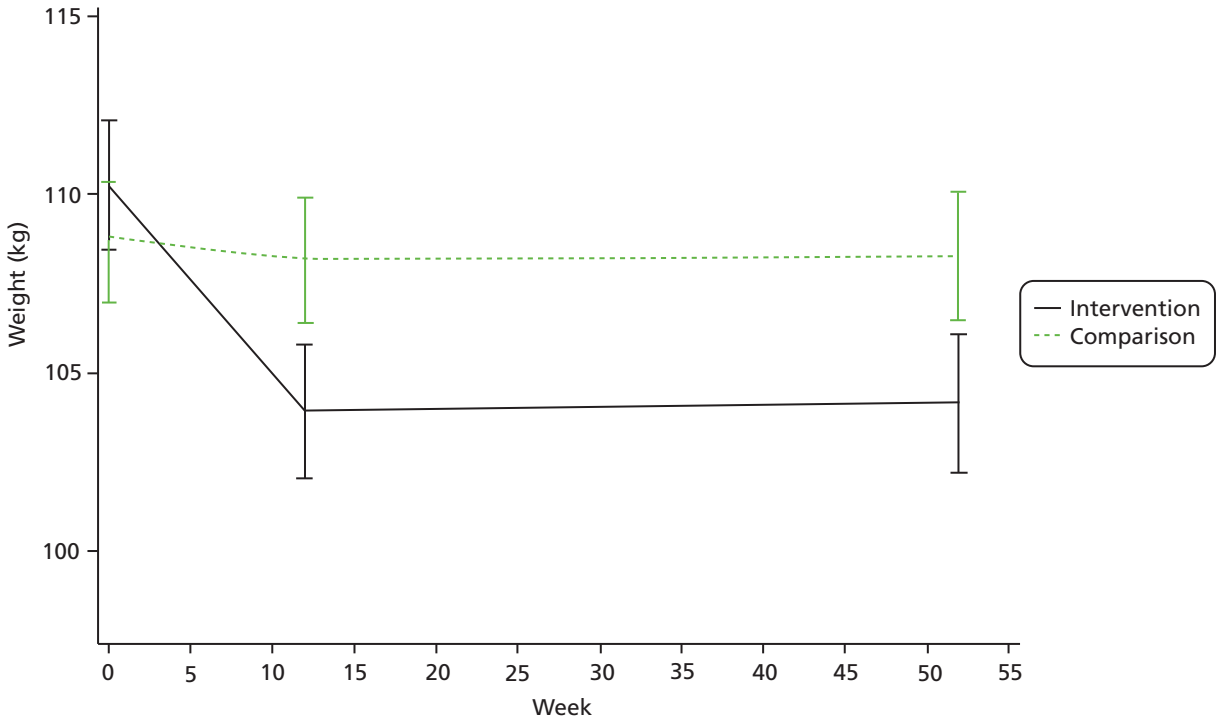

FIGURE 4 Mean weight (kg, 95% CI) in participants allocated to the FFIT weight loss programme or waiting list comparison group 12 weeks and 12 months after baseline measurement. Note that the *y*-axis (weight) does not start at zero. Reprinted with permission from Elsevier (*The Lancet*, 2014, **383**, 1211–21).[33]

TABLE 11 Univariate associations between various characteristics of FFIT participants and weight loss at 12 months

Variable	ANOVA *F*-value	*p*-value
Age (years)	26.02	< 0.0001
Number of long-standing illnesses	9.88	0.002
Fatty food score	10.06	0.002
Conformity to masculine norms	5.81	0.016
Employment status	2.08	0.024
Fruit and vegetable score	4.63	0.032
Joint pain	4.82	0.029
Housing tenure	2.20	0.053
SIMD (quintile)	2.08	0.080
Affiliation to football	0.98	0.47
Any attempts to lose weight in last 3 months	0.26	0.61
Ethnicity	0.69	0.63
Ever smoked	0.24	0.79
Highest educational status	0.86	0.53
Number of injuries	1.78	0.18
Marital status	0.75	0.61
SIMD (decile)	1.32	0.22
Sugary food score	0.49	0.48
Trained at club they supported	0.21	0.64

ANOVA, analysis of variance.

TABLE 12 Multivariate analyses: effect of various characteristics of FFIT participants, treatment group and weight at baseline on weight loss at 12 months

Variable	Estimate (95% CI)	*p*-value
Treatment group (FFIT vs. comparison)	0.94 (0.92 to –0.97)	< 0.0001
Weight at baseline	–4.94 (–3.95 to –5.94)	< 0.0001
Club		0.637
Age (years)		0.051
Fatty food score		0.999
Fruit and vegetable score		0.652
Number of long-standing illnesses		0.182
Joint pain		0.713
Conformity to masculine norms		0.600
Employment status		0.428
SIMD (quintile)		0.311

intervention effect did not vary significantly by age, marital status, deprivation of area participants' residence, location of measurement (stadium vs. home), orientation to masculine norms, affiliation to football, whether or not attended a formal weight management programme in last 3 months, smoking, housing tenure, education, ethnicity, employment status, joint pain, injuries and number of long-standing illnesses.

Secondary outcomes

More men in the intervention group (39.04%, 130/333) than the comparison group (11.27%, 40/355) achieved at least 5% weight loss at 12 months (RR 3.47, 95% CI 2.51 to 4.78) and more had a BMI below 30 kg/m^2 (*Table 13*).

Table 14 shows changes in other secondary outcomes at 12 weeks and 12 months, before and after adjusting for baseline measure and clubs. These analyses show similarly positive results.

In relation to objectively measured secondary outcomes, adjusting for baseline measure and club, the mean difference in reduction at 12 months in waist circumference was 5.12 cm (95% CI 4.27 to 5.97 cm) and in BMI was 1.56 kg/m^2 (95% CI 1.29 to 1.82 kg/m^2). Differences in changes in all other objectively measured secondary outcomes, including weight loss at 12 weeks, % body fat at 12 weeks and 12 months, and systolic and diastolic blood pressure at 12 weeks and 12 months were also all in favour of the intervention and highly statistically significant ($p < 0.0001$, except for systolic BP at 12 months where $p = 0.017$) (see *Table 14*). There was clear attenuation of effect between the end of 12-week programme and 12-month measurements.

In relation to eating and drinking alcohol, *Table 14* demonstrates that reductions in the fatty food and sugary food scores were greater for participants in the FFIT programme than in the comparison group at 12 weeks, and these differences remained highly significant at 12 months ($p < 0.0001$) although, again, there was considerable attenuation of the effects between 12 weeks and 12 months. Similarly, positive changes in reported eating patterns were seen for the fruit and vegetable score; the differences in the increase seen in fruit and vegetable consumption were highly significant ($p < 0.0001$) at 12 weeks and 12 months, in favour of the intervention (see *Table 14*). They also reported drinking less units of alcohol per week; the mean difference in units of alcohol reported being drunk between groups, adjusted for baseline units and club, was 4.47 (95% CI –6.09 to –2.86) at 12 weeks and 2.59 (95% CI –4.21 to –0.97) at 12 months (see *Table 14*).

In relation to changes in self-reported QoL and mental health, *Table 14* illustrates that FFIT also resulted in greater improvements in self-esteem and positive affect at 12 weeks and 12 months in the intervention than the comparison groups, and greater reductions in negative affect at 12 weeks and 12 months. Similarly, there were greater improvements in scores on physical aspects of QoL as measured by the SF-12

TABLE 13 Changes from baseline in objectively measured categorical outcomes at 12 weeks and 12 months in FFIT participants and waiting list comparison group and relative risks of achieving target weight loss and being classified as not obese[a]

		FFIT ($N = 374$)		Comparison group ($N = 373$)		
Variable		*n*	*n* (%)	*n*	*n* (%)	Relative risk (95% CI)
Percentage who achieve at least 5% weight loss	12 weeks	329	154 (46.81)	347	24 (6.92)	6.77 (4.52 to 10.13)
	12 months	333	130 (39.04)	355	40 (11.27)	3.47 (2.51 to 4.78)
Percentage with a BMI < 30 kg/m^2	12 weeks	329	85 (25.84)	347	44 (12.68)	2.04 (1.46 to 2.84)
	12 months	333	85 (25.53)	355	48 (13.52)	1.89 (1.37 to 2.60)

a Reprinted with permission from Elsevier (*The Lancet*, 2014, **383**, 1211–21).[33]

TABLE 14 Changes in objectively measured continuous outcomes, self-reported outcomes and self-reported psychological health outcomes

	FFIT ($n = 374$)		Comparison group (n = 373)		Mixed models, difference between groups, mean (95% CI)		Mixed models, difference between groups, mean (95% CI)	
Variable	*N*	Mean (95% CI) or median (interquartile range)	*N*	Mean (95% CI) or median (interquartile range)	Unadjusted	*p*-value	Adjusted[a]	*p*-value
Objectively measure outcomes								
Change in weight (kg)								
12 weeks	329	−5.80 (−6.33 to −5.27)	347	−0.42 (−0.76 to −0.09)	−3.93 (−6.47 to −1.38)	0.0026	−5.18 (−6.00 to −4.35)	< 0.0001
12 months	329	−5.23 (−5.69 to −4.78)	347	−0.37 (−0.67 to −0.07)	−4.72 (−5.45 to −3.99)	< 0.0001	−4.71 (−5.44 to −3.98)	< 0.0001
Change in waist circumference (cm)								
12 weeks	329	−6.70 (−7.28 to −6.13)	345	−1.00 (−1.43 to −0.56)	−4.88 (−6.72 to −3.04)	< 0.0001	−5.57 (−6.41 to −4.72)	< 0.0001
12 months	318	−7.34 (−8.18 to −6.49)	353	−2.04 (−2.63 to −1.46)	−4.47 (−6.31 to −2.63)	< 0.0001	−5.12 (−5.97 to −4.27)	< 0.0001
Change in BMI (kg/m^2)								
12 weeks	329	−1.87 (−2.04 to −1.70)	347	−0.14 (−0.25 to −0.03)	−1.36 (−2.09 to −0.63)	0.0003	−1.66 (−1.93 to −1.40)	< 0.0001
12 months	333	−1.79 (−2.07 to −1.51)	355	−0.20 (−0.38 to −0.02)	−1.27 (−2.00 to −0.54)	0.0007	−1.56 (−1.82 to −1.29)	< 0.0001
Change in % body fat								
12 weeks	276	−2.70 (−3.21 to −2.23)	260	−0.30 (−0.62 to 0.09)	−1.77 (−2.70 to −0.84)	0.0002	−2.16 (−2.81 to −1.51)	< 0.0001
12 months	271	−2.20 (−2.88 to −1.60)	312	0.00 (−0.40 to 0.43)	−1.92 (−2.83 to −1.00)	< 0.0001	−2.15 (−2.78 to −1.52)	< 0.0001
Change in systolic blood pressure (mmHg)								
12 weeks	295	−7.50 (−9.14 to −5.89)	280	−3.50 (−4.97 to −2.00)	−5.41 (−7.70 to −3.12)	< 0.0001	−4.51 (−6.36 to −2.67)	< 0.0001
12 months	318	−7.90 (−9.54 to −6.25)	351	−6.60 (−7.98 to −5.31)	−3.58 (−5.76 to −1.39)	0.0025	−2.27 (−4.01 to −0.54)	0.0171
Change in diastolic blood pressure (mmHg)								
12 weeks	295	−3.70 (−4.77 to −2.70)	280	−1.50 (−2.53 to −0.54)	−3.10 (−4.56 to −1.64)	< 0.0001	−2.51 (−3.71 to −1.32)	< 0.0001
12 months	318	−4.60 (−5.63 to −3.60)	351	−3.80 (−4.74 to −2.96)	−2.16 (−3.55 to −0.76)	0.0014	−1.36 (−2.48 to −0.24)	0.0102

continued

TABLE 14 Changes in objectively measured continuous outcomes, self-reported outcomes and self-reported psychological health outcomes (*continued*)

Variable	FFIT (*n* = 374)		Comparison group (n = 373)		Mixed models, difference between groups, mean (95% CI)		Mixed models, difference between groups, mean (95% CI)	
	N	Mean (95% CI) or median (interquartile range)	*N*	Mean (95% CI) or median (interquartile range)	Unadjusted	*p*-value	Adjusted[a]	*p*-value
Self-reported physical activity								
Changes in total MET–minute/week (walking, vigorous and moderate exercise)								
12 weeks	325	1485 (IQR 339–3435)	341	0 (IQR −840–747)	2.43 (IQR 1.92–3.07)	< 0.0001	2.38 (IQR 1.90–2 .98)	< 0.0001
12 months	310	1219 (IQR 54–3111)	347	375 (IQR −414–1800)	1.51 (IQR 1.12–2.04)	0.0.007	1.49 (IQR 1.11–1.99)	0.008
Self-reported eating and alcohol intake								
Change in DINE-based measures								
Fatty food score								
12 weeks	330	−5.60 (−6.39 to −4.86)	345	−1.40 (−2.03, −0.77)	−4.45 (−5.35 to −3.55)	< 0.0001	−4.39 (−5.16 to −3.61)	< 0.0001
12 months	318	−4.50 (−5.32 to −3.74)	353	−1.70 (−2.32 to −1.13)	−2.72 (−3.62 to −1.82)	< 0.0001	−2.74 (−3.52 to −1.96)	< 0.0001
Fruit and vegetable score								
12 weeks	330	1.60 (1.39 to 1.81)	347	0.20 (0.03 to 0.41)	1.26 (1.03 to 1.57)	< 0.0001	1.32 (1.07 to 1.57)	< 0.0001
12 months	333	0.80 (0.60 to 1.07)	355	0.30 (0.11 to 0.49)	0.53 (0.26 to 0.80)	0.0001	0.54 (0.29 to 0.79)	< 0.0001
Sugary food score								
12 weeks	330	−2.10 (−2.43 to −1.84)	345	−0.70 (−0.95 to −0.39)	−1.57 (−1.91 to −1.22)	< 0.0001	−1.52 (−1.83 to 1.21)	< 0.0001
12 months	318	−1.30 (−1.62 to −0.97)	353	−0.50 (−0.81 to −0.25)	−0.93 (−1.28 to −0.59)	< 0.0001	−0.87 (−1.18 to −0.56)	< 0.0001
Change in alcohol consumed (units per week)								
12 weeks	329	−6.20 (−7.58 to −4.79)	345	−2.10 (−3.43 to −0.68)	−5.14 (−7.43 to −2.86)	< 0.0001	−4.47 (−6.09 to −2.86)	< 0.0001
12 months	318	−4.20 (−5.55 to −2.87)	353	−2.20 (−3.39 to −0.96)	−3.40 (−5.69 to −1.11)	0.0037	−2.59 (−4.21 to −0.97)	0.0017

Variable	FFIT ($n = 374$)		Comparison group (n = 373)		Mixed models, difference between groups, mean (95% CI)		Mixed models, difference between groups, mean (95% CI)	
	N	Mean (95% CI) or median (interquartile range)	*N*	Mean (95% CI) or median (interquartile range)	Unadjusted	*p*-value	Adjusted[a]	*p*-value
Self-reported psychological health and QoL outcomes								
Change in self-esteem (Rosenberg score)								
12 weeks	330	0.30 (0.24 to 0.32)	344	0.10 (0.05 to 0.12)	0.17 (0.10 to 0.25)	< 0.0001	0.19 (0.14 to –0.24)	< 0.0001
12 months	317	0.30 (0.22 to 0.30)	350	0.10 (0.10 to 0.17)	0.11 (0.03 to 0.18)	0.0052	0.12 (0.07 to 0.17)	< 0.0001
Change in positive affect (PANAS score)								
12 weeks	328	0.50 (0.45 to 0.59)	344	0.10 (0.01 to 0.14)	0.45 (0.34 to 0.55)	< 0.0001	0.44 (0.36 to 0.53)	< 0.0001
12 months	317	0.30 (0.27 to 0.41)	350	0.10 (0.01 to 0.14)	0.29 (0.18 to 0.39)	< 0.0001	0.28 (0.19 to 0.36)	< 0.0001
Change in negative affect (PANAS score)								
12 weeks	329	–0.20 (–0.21 to –0.11)	344	–0.10 (–0.11 to –0.01)	–0.08 (–0.16 to 0.00)	0.0591	–0.09 (–0.15 to –0.03)	0.0039
12 months	317	–0.20 (–0.24 to –0.13)	350	–0.10 (–0.14 to –0.05)	–0.07 –(0.15 to –0.01)	0.0998	–0.08 (–0.15 to –0.02)	0.0079
Change in mental HRQoL (SF-12 score)								
12 weeks	328	3.20 (2.33 to 4.12)	345	1.50 (0.66 to 2.39)	2.56 (1.12 to 4.00)	0.0005	2.01 (0.89 to 3.12)	0.0004
12 months	316	1.90 (0.93 to 2.83)	351	1.60 (0.82 to 2.42)	0.97 (0.47 to 2.42)	0.1861	0.50 (–0.62 to 1.62)	0.3822
Change in physical HRQoL (SF-12 score)								
12 weeks	328	3.30 (2.53 to 4.00)	345	0.40 (–0.33 to 1.12)	2.00 (0.77 to 3.24)	0.0015	2.60 (1.60 to 3.60)	< 0.0001
12 months	316	2.30 (1.48 to 3.21)	351	0.20 (–0.62 to 0.93)	1.30 (0.06 to 2.54)	0.0400	1.89 (0.89 to 2.90)	0.0002

PANAS, positive and negative affect scale.
a Adjusted for baseline, stratified by club.
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at 12 weeks and 12 months, but the greater improvements in mental HRQoL in the intervention group at 12 weeks were no longer significantly different from the comparison group at 12 months (see *Table 14*). As with all other outcomes, there was attenuation of the differences between the two groups between 12 weeks and 12 months.

In relation to self-reported physical activity, as the changes in MET-minutes were highly positively skewed, the standard linear-mixed models were not valid and so linear modelling on natural log-transformed was implemented for total MET-minutes/week. *Table 14* illustrates that the increase in total MET-minutes per week was greater in the intervention group than the comparison group with an adjusted RGM at 12 months of 1.49 (IQR 1.11–1.99) for total MET-minutes, in other words roughly 50% higher in the intervention.

To further investigate changes in self-reported physical activity in addition to log-transformations, we applied a repeated measures analysis using data from 12 weeks and 12 months in relation to total activity but also whether activity was vigorous, moderate or walking (reported in MET-minutes/week) and time spent sitting on a week day in the last 7 days.

Table 15 illustrates that the repeated measures analysis gave very similar results to the standard analysis in relation to increase in total MET-minutes per week. The results also indicated that when total activity is subdivided into the constituent elements, the improvement in physical activity was greatest for vigorous (RGM 4.63, 95% CI 2.64 to 8.12), followed by moderate (RGM 2.10, 95% CI 1.22 to 3.62) and then walking (RGM 1.31, 95% CI 0.91 to 1.89) (see *Table 15*). It is also clear that there was considerable attenuation in the effects between 12 weeks and 12 months, although there were still highly significant differences between the groups at 12 months for vigorous and moderate physical activity at 12 months, though not in walking.

There was some evidence of a reduction in time spent sitting in the intervention group, especially at 12 weeks (RGM 0.85, 95% CI 0.78 to 0.93) but these effects were modest; at 12 weeks self-reported sitting time was 15% lower in the intervention group relative to the comparison group ($p = 0.0005$). However, at 12 months there was no statistically significant difference in sitting time (see *Table 15* between groups).

Adverse events

Eight serious adverse events were reported: five in the intervention and three in the comparison group. Two appeared to be, or were reported as, related to participation in FFIT: one participant ruptured an Achilles tendon while playing football and the other was told by his doctor that intermittent abdominal pains from gall stones could have been aggravated or caused by weight or dietary changes.

A total of 211 adverse events were reported: 107 events reported by 96 men in the intervention and 104 events in the comparison group reported by 92 men. Ten appeared to be, or were reported as, related to participation in FFIT: five occurred at FFIT sessions, three elsewhere (two when running; one playing football) and it was unclear where the other two occurred. Seven of the men reported leg injuries (often ligament damage), one a dislocated shoulder, one leg and shoulder injuries and one a head collision (with another participant at a FFIT session). Another 11 adverse events could have been related to participation in FFIT, but the research team were unable to contact the men to confirm this. Of these, five occurred playing football and two when running; it was not clear where the remainder had happened. Six involved leg injuries and the others were reported as neck, leg, groin, hand and collar bone injuries.

TABLE 15 Changes from baseline in physical activity measured by the self-reported IPAQ at 12 weeks and 12 months and differences between participants allocated to the FFIT weight loss programme or waiting list comparison group

Variable		FFIT ($n = 374$)		Comparison group ($n = 373$)		Mixed models (repeated measures): difference between groups (FFIT comparison) mean (95% CI)			
		n	Median (interquartile range)	*n*	Median (interquartile range)	Unadjusted ratio RGM (95% CI)		Adjusted[a] ratio RGM (95% CI)	
Changes in total MET minutes/week (walking, vigorous and moderate physical activity)	12 weeks	325	1485 (339–3435)	341	0 (–840–747)	3.94 (2.84 to 5.47)	< 0.0001	3.79 (2.77 to 5.20)	< 0.0001
	12 months	310	1219 (54–3111)	347	375 (–414–1800)	1.53 (1.10 to 2.12)	0.011	1.49 (1.09 to 2.05)	0.013
Changes in vigorous MET minutes/week	12 weeks	324	360 (0–1640)	340	0 (0–240)	10.64 (5.92 to 19.12)	< 0.0001	9.21 (5.26 to 16.10)	< 0.0001
	12 months	309	440 (0–1680)	346	0 (0–720)	5.23 (2.90 to 9.44)	< 0.0001	4.63 (2.64 to 8.12)	< 0.0001
Changes in moderate MET minutes/week	12 weeks	325	160 (0–840)	339	0 (–120–240)	9.29 (5.34 to 16.14)	< 0.0001	9.48 (5.53 to 16.26)	< 0.0001
	12 months	310	0.0 (0–720)	346	0.0 (0–360)	2.03 (1.16 to 3.53)	0.013	2.10 (1.22 to 3.62)	0.007
Changes in walking MET minutes/week	12 weeks	324	528 (0–1353)	340	0 (–280.5–396)	3.20 (1.22 to 5.37)	< 0.0001	3.39 (2.35 to 4.88)	< 0.0001
	12 months	311	222.8 (–99–956.3)	348	99 (–198–693)	1.41 (0.96 to 2.07)	0.080	1.31 (0.91 to 1.89)	0.151
Changes in time spent sitting on a week day in last 7 days (minutes)	12 weeks	236	–60 (–180–0)	248	–30 (–120–60)	0.86 (0.79 to 0.94)	0.001	0.85 (0.78 to 0.93)	0.0005
	12 months	235	–60 (–180–0)	260	–15 (–120–60)	1.00 (0.92 to 1.09)	0.99	0.96 (0.88 to 1.04)	0.314

a Adjusted for club and baseline measure.

Chapter 4 Economic evaluation: methods and results

Introduction

The aim of the economic evaluation was to determine the cost-effectiveness of the FFIT programme compared with no active intervention. No intervention was used as the comparator as, in the absence of the FFIT intervention, this was the most likely alternative for this population. Throughout the analyses, the waiting list comparison group was used as the source of data for the 'no active intervention' group. The evaluation was undertaken from the NHS and Personal Social Service perspective favoured by the National Institute for Health and Care Excellence (NICE).

An initial, short-term analysis estimates the cost-effectiveness of FFIT compared with no active intervention over the period of the trial. This analysis requires the assumption that there are no differences in costs or effects between the intervention and comparison groups beyond the 12-month trial follow-up period. A second, longer-term analysis employs a model to estimate additional costs and benefits over the participants' lifetime in order to provide an estimate of the lifetime cost-effectiveness of FFIT compared with no active intervention. Further details of each analysis are provided in the sections below.

Within-trial analysis

Introduction

The aim of the within-trial analysis was to estimate the immediate impacts (in terms of costs and effects) associated with the FFIT intervention in order to establish the cost-effectiveness of the intervention compared with no active intervention. The within-trial analysis compared the FFIT intervention group with the waiting list comparison group in terms of (1) costs incurred over the 12-month period, (2) number of men achieving and maintaining a 5% weight reduction over 12 months and (3) QALYs gained over the 12-month period.

Methods

Resource use and costs

The cost calculation included the resources required to manage and run the programme (*Table 16*), as well as self-reported health-care resource use and GP-prescribed medications.

The principal part of the intervention cost is the £3544 cost of running the intervention in each club. This covers all the clubs costs involved in providing the intervention, including club-level management, staff time and venue hire and club-based recruitment activities. In addition, the SPL Trust management cost of £5000 per season covers the cost of training the coaches, the SPL-level management and co-ordination of the intervention across the clubs and marketing and additional recruitment. In addition to these costs, there are a number of resources required to provide the intervention. These include equipment to measure the height, weight, blood pressure and waist circumference of the participants, plus a display plate (Eatwell Plate)[47] to illustrate the appropriate proportion of food stuffs to each from the five main food groups and portion sizes, and materials to deliver the intervention (including a pedometer and booklet for each participant and booklets for coaches). Each club was assumed to receive one complete set of equipment per year (with the exception of the waist measures of which each club was assumed to be provided with four sets per year), with the assumption that each club provided the intervention twice in each year. The materials were assumed to be provided per participant/coach, with the addition of a few

TABLE 16 Intervention costs

Item	Unit cost (£)	Units	Total cost of intervention (£)
SPL/club costs			
Club running costs	3544.00	Per club	46,072.00
SPL Trust management cost	10,000.00	Per season	5000.00
Equipment costs (per unit)			
Scales	131.00	Per club	1703.00
Height measure	30.50	Per club	396.50
Waist measures	8.80	Per club	114.40
Blood pressure monitor	65.00	Per club	845.00
Food plate and plastic food display	144.00	Per club	1872.00
Material costs (per unit)			
Pedometer	6.60	Per participant + spare	2917.20
Participant guide	7.00	Per participant	2639.00
Coaches guide	3.50	Per coach	182.00
Roll out costs			**61,741.10**

spares. All resources required to deliver the intervention were costed according to the price paid to purchase them at the start of the trial (September 2011). Overall, the cost of providing the intervention in all SPL clubs was estimated to be £61,741, equivalent to £165 per FFIT participant.

In addition to the intervention costs, data were collected at each time point (baseline, 12 weeks and 12 months) from each participant relating to the number and type of any NHS resources used in the preceding 12-week period. This included visits to the GP, practice nurse or physiotherapist and any attendances at accident and emergency. Unit costs for each of these visits were taken from Personal Social Services Research Unit (PSSRU) 2011/12 (*Table 17*).[75]

Data were also collected at each time point relating to any inpatient stays and outpatient appointments in the preceding 12-week period. Unit costs were taken from Information and Statistics Division Scotland tariffs for 2012 and, when necessary, NHS reference costs for 2011/12.[76–78]

Finally, self-reported data were collected at each time point regarding GP prescriptions of antidepressants, painkillers, asthma, pain gels/creams, anti-inflammatories and sleeping tablets in the preceding 12 weeks. These medications were identified as the most likely to be affected by the intervention and were pre-specified on the advice of our clinical advisor; diabetes mellitus medication was not included in this list

TABLE 17 Unit costs of NHS resources (all taken from PSSRU 2011/12)

Type of health professional visit	Unit cost (£)	Notes
GP visit	43.00	Per patient contact in surgery (assumed 11.7 minutes). Includes direct care staff costs
Practice nurse visit	13.25	Per patient contact in surgery (assumed 15 minutes)
Physiotherapist	16.50	Per patient contact in community (assumed 30 minutes)
A&E	41.00	Walk-in service, not admitted

A&E, accident and emergency.

it was not expected to be affected by the intervention over the within-trial period. Other prescribed medications were also excluded from the analysis. In addition, because the analysis used an NHS and Personal Social Service perspective, we excluded over-the-counter medications. Medications were costed using unit costs for a typical prescription from the *British National Formulary*[76] (*Table 18*).

In the economic evaluation, as in the main analyses, we did not take account of missing resource use data. For NHS resource use, the proportion of missing responses across all time points ranged from 1.3% to 2.3% across the different categories. The proportion of missing responses for medications was less than 2% across the different categories.

We used 12 weeks as the time frame over which participants were asked to recall their resource use, as longer periods have potentially been found to be subject to greater recall bias.[79]

Table 19 shows that at baseline comparison group participants had higher inpatient costs.

TABLE 18 Unit costs of prescribed medications (all taken from the *British National Formulary*)[76]

Kind of medication	Unit cost (£)	Drug costed
Asthma	2.19	Beconase
Antidepressants	0.96	Citalopram: 20 mg, 28-tablet pack
Painkillers	4.70	Cocodamol: 8 mg, 100-tablet pack
Anti-inflammatories	3.23	Diclofenac: 25 mg, 28-tablet pack
Sleeping tablets	0.86	Diazepam: 5 mg, 28-tablet pack
Gels/creams	3.89	Ibuprofen: maximum strength 10% w/w, 50-g pack

w/w, weight for weight.

TABLE 19 Baseline costs for use of primary care, secondary care and NHS-prescribed medications

Type of cost	Intervention (£)	Comparison (£)
GP	48,074.00	52,732.33
Nurse	5913.92	6545.50
A&E	3020.33	5507.67
Physiotherapy	1930.50	2860.00
Concomitant medications	3941.99	3757.61
Inpatient	24,277.98	54,171.00
Outpatient	35,213.23	33,495.89
Total baseline costs	22,371.95	159,069.99

A&E, accident and emergency.

Outcome measurement

The initial outcome measure for the within-trial analysis is the number of men achieving and maintaining the 5% weight reduction over 12 months, as measured at the 12-month follow-up.

In addition, self-report SF-12 data were collected at baseline, 12 weeks and 12 months. These values were converted into utility weights using the Short Form questionnaire-6 Dimensions algorithm.[75,80,81] *Table 20* details the mean utility score associated with FFIT and no active intervention at each time point (baseline, 12 weeks and 12 months) with and without adjustment for missing data.

The area under the curve method was used to determine the overall utility for each participant over the trial period.[82] This provides a utility weighting, similar to a QALY, but measured over a 12-month period. Change from baseline has been used to account for differences in the average baseline values between the intervention and comparison groups, to give an estimate of the utility change over the year for each participant.

Analysis

The within-trial effectiveness is presented both in terms of the number of men achieving and maintaining a 5% weight reduction over 12 months, and QALYs gained over 12 months. The individual-level data on achieving and maintaining a 5% weight reduction are summed to provide the number attaining this outcome in each group, while the individual-level QALY data are averaged within each group (intervention, comparison). Differences in the average utility change between the intervention and comparison groups give an estimate of the QALYs gained from the intervention, assuming no differences beyond the 12-month follow-up period. Effect results are presented as mean values with CIs.

The cost associated with each individual is determined as the sum of the per participant intervention cost (for the FFIT intervention group), plus the cost of NHS resource use, plus any medication cost. The individual costs are averaged within each group to give an estimate of the average cost associated with the FFIT intervention and the comparison groups. The incremental cost associated with the FFIT intervention is the difference between the average cost of the FFIT intervention group and the average cost of the comparison group. Cost results are presented as mean values with CIs.

The incremental cost-effectiveness associated with the FFIT intervention is then presented in terms of incremental cost per additional individual achieving and maintaining the 5% weight reduction over 12 months and the incremental cost per QALY gained. Discounting of costs and outcomes is not required owing to the 12-month time frame of the within-trial analysis.

The uncertainty surrounding the estimates of incremental costs, incremental effects and cost-effectiveness was investigated through the use of bootstrapping with 10,000 iterations. The uncertainty surrounding the cost-effectiveness results are presented on the cost-effectiveness plane and summarised on a cost-effectiveness acceptability curve.

TABLE 20 Mean utility scores at baseline, 12 weeks and 12 months

Analysis	Baseline utilities	12-week utilities	12-month utilities
Intervention			
With missing data	0.78	0.83	0.80
Adjusted for missing values	0.78	0.82	0.80
No active intervention			
With missing data	0.77	0.79	0.79
Adjusted for missing values	0.77	0.79	0.78

Results

The total costs associated with the FFIT intervention group were estimated to be £254,579 (£680 per participant), compared with total costs for the 'no active intervention group' of £177,025 (£475 per participant), giving an incremental cost of £77,554 (£205 per participant) (*Table 21*).

At the 12-month follow-up, 130 men in the FFIT intervention group and 40 men in the comparison group had achieved and maintained a 5% weight reduction. The incremental cost of FFIT was estimated as £862 per additional man achieving and maintaining a 5% weight reduction at 12 months.

The results illustrate that FFIT is more expensive than no active intervention, with an additional cost of £205 per individual (95% CI £27 to £386). This is driven mostly by the additional cost of the intervention. The results also indicate that FFIT is more effective in terms of QALYs, with a gain in QALYs of 0.015 (95% CI 0.003 to 0.027) (see *Table 21*). As a result, the FFIT intervention is associated with an incremental cost-effectiveness of £13,847 per QALY gained.

Figure 5 shows the uncertainty surrounding the estimates of the costs and effects on the incremental cost-effectiveness plane. The figure shows that there is no uncertainty surrounding the existence of a cost difference – FFIT is more expensive than no active intervention (i.e. all the incremental costs are positive),

TABLE 21 Average costs and utility changes per participant in each group with a breakdown of total resource use by category

				Breakdown of costs			
Analysis	Cost per person (£)	Utility change over 12 months	Total costs (£)	Primary care (£)	Secondary care (£)	Medication (£)	FFIT costs (£)
FFIT	680	0.029	254,579	72,281	116,156	4892	61,250
No active intervention (comparison)	475	0.014	177,025	73,634	95,874	7517	0
Incremental	205	0.015	77,554	–1353	20,282	–2625	61,250

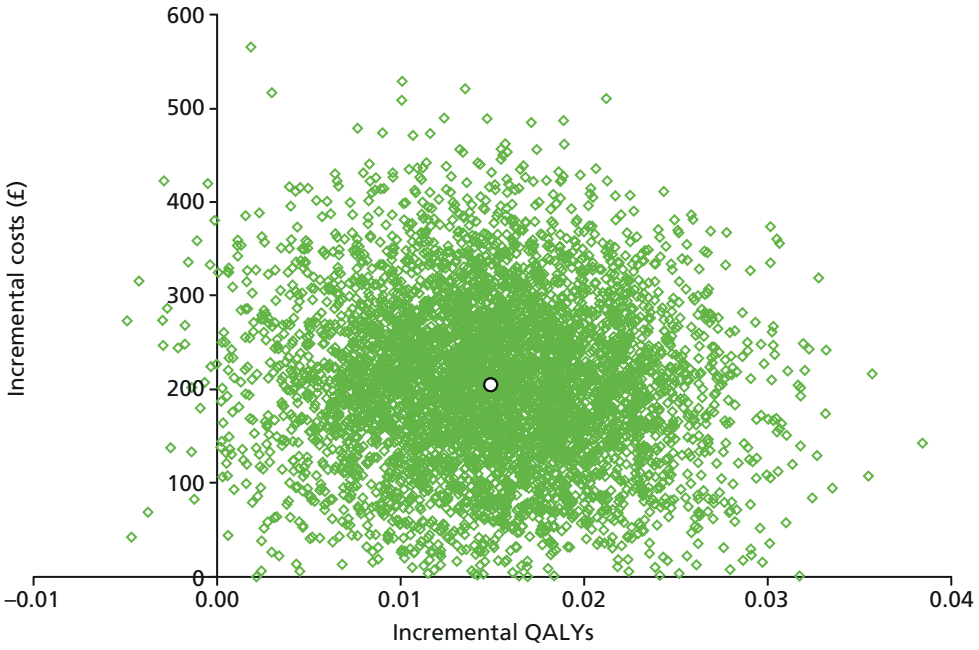

FIGURE 5 Incremental cost-effectiveness plane for FFIT intervention compared with no active intervention (within-trial analysis).

although there is some uncertainty about the extent of the cost difference. In addition, the figure shows that there is some uncertainty about whether or not FFIT is more effective than no active intervention (i.e. a few of the incremental QALYs are negative) and there is considerable uncertainty about the extent of the effect difference.

The cost-effectiveness acceptability curve (*Figure 6*) illustrates the probability that the FFIT intervention is cost-effective for any given value of the cost-effectiveness threshold. For a cost-effectiveness threshold of £20,000/QALY, the probability that FFIT is cost-effective, compared with no active intervention, is 0.72. This probability rises to 0.89 for a cost-effectiveness threshold of £30,000/QALY.

Lifetime analysis

Introduction

The within-trial cost-effectiveness analysis assumes that there are no differences in QALYs between the intervention and comparison groups beyond the 12-month trial follow-up period. The aim of the lifetime analysis was to estimate the longer-term implications (in terms of cost or effect) of the FFIT intervention in order to establish the long-term cost-effectiveness of the intervention compared with no active intervention. The analysis involved linking the short-term impacts identified within the trial period to longer-term impacts through the use of a model. As such, the initial step involved a review of published models undertaken in this area. Following this review a model structure was selected and this is presented below followed by the results of the lifetime analysis.

Review of existing models

We reviewed a variety of models in the area of weight management and physical activity. These models were generally one of two types:

1. Risk factor models: these link risk scores to impacts on health outcomes and are driven by changes in the risk factors that compose the risk score. These models have been presented both in terms of population-level changes and as individual-level models.

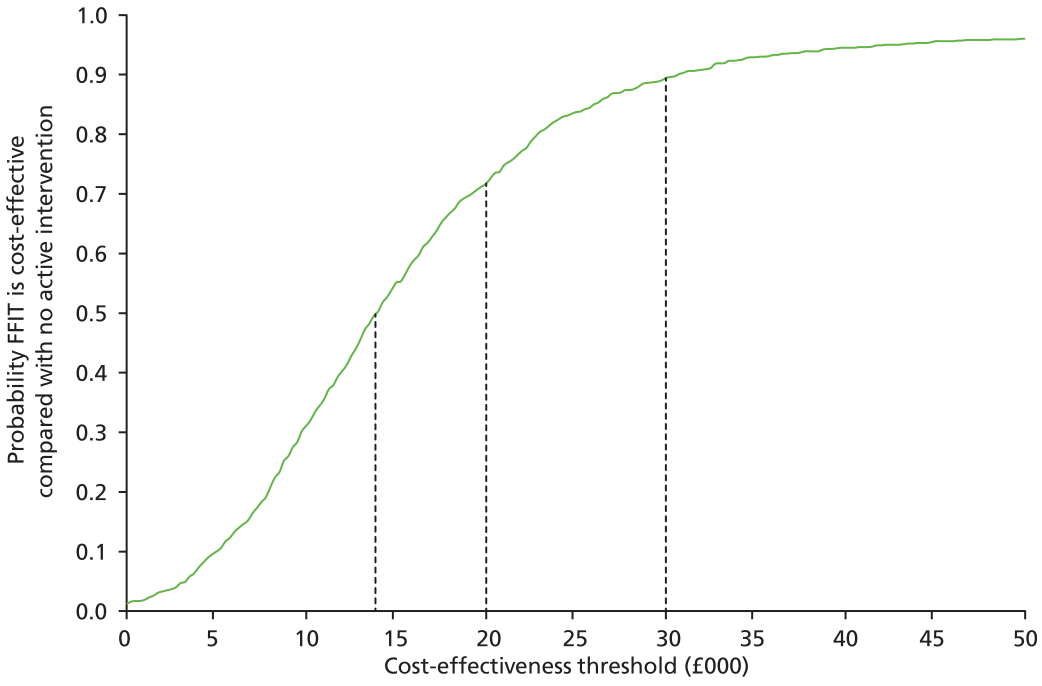

FIGURE 6 Cost-effectiveness acceptability curve for FFIT intervention (within-trial analysis). Reprinted with permission from Elsevier (*The Lancet*, 2014, **383**, 1211–21).[33]

2. Behaviour change models: these link health/risk behaviours (e.g. smoking, physical activity) with health outcomes and are driven by changes in these health behaviours. These behaviour change models are typically individual-level models projecting the impact of individual behaviour change on individual health outcomes.

Bending *et al.*[83] adapted and developed a model to estimate cost-effectiveness for interventions that promote physical activity for a NICE report on physical activity interventions in the workplace.[83] This risk factor model employed the Framingham risk profiles[84] and Lindström *et al.*[85] risk equations to estimate the probabilities of developing coronary heart disease (CHD), stroke and type 2 diabetes mellitus within a 10-year period based on age, gender, cholesterol, blood pressure, BMI, smoking and diabetes mellitus status. These probabilities were combined with published evidence of effectiveness to estimate the number of cases of disease that would be averted by a proportion of the sedentary population taking up certain levels of physical activity. Estimates, from the literature, of the utility and cost impact of these diseases were applied to generate lifetime health and cost estimates.[83]

Brennan *et al.*[86] used a behavioural model to establish the likely cost-effectiveness of various walking and cycling interventions for a NICE report.[86] The model estimated the statistical relationships between levels of walking and cycling and overall physical activity using data from the Health Survey for England. This allowed direct evidence of intervention effects on walking and cycling to be converted into overall changes in physical activity levels. These changes in physical activity were then transformed into changes in life expectancy using the relationship observed between physical activity and relative risk of mortality from a long-term prospective study.[87] Finally, the model employed national life tables and evidence on average HRQoL to estimate discounted QALYs, costs of the interventions if rolled out across the country and lifetime cost per QALY gained.[86]

The Prevent model, developed by Gunning-Schepers,[88] converts changes in behaviour into changes in exposure to risk factors. Various studies have been published[89–91] using this model to estimate the effect of behaviour changes such as smoking, alcohol consumption and physical activity on incidence of disease and mortality. Recently, Dallat *et al.*[91] used the Prevent model to assess the cost-effectiveness of an urban regeneration project by modelling the impact of the intervention on ischaemic heart disease, type 2 diabetes mellitus, stroke, colon and breast cancer to the year 2050.

Haby *et al.*[92] assessed the impacts of behaviour changes in diet, physical activity or both, brought about by preventative childhood obesity interventions, on energy imbalance. A model then determined the impact of these energy deficits on changes in weight. Published data were used to translate mean changes in weight to mean changes in BMI, assuming no change in height.[92] Potential impact fractions were used to assess the impact of the changes in BMI on the prevalence of risk factors for heart disease, stroke, type 2 diabetes mellitus, osteoarthritis and obesity-related cancers. This, in turn, was used to estimate the impact on mortality, morbidity and changes in lifetime disability-adjusted life-years saved.[92]

The Foresight Programme developed a two-part modelling process to predict future levels of obesity in England.[93] The first part utilised a cross-sectional analysis of data from the Health Survey for England and implemented a non-linear regression analysis to derive BMI projections for the English population in 2050. The second part generated a longitudinal analysis using microsimulation to simulate successful obesity interventions and consequent changes in obesity-related diseases and NHS expenditure.[93] Foresight modelling estimates for 2050 indicate that 60% of adult men, 50% of adult women and 25% of children could be obese.[93] Costs attributable to overweight and obesity are estimated at £10B to the NHS in 2050, with wider costs to society estimated to reach £49.9B.[93] Two further studies[1,94] have employed the Foresight model to evaluate interventions in childhood obesity and to project future trends in obesity prevalence, diseases and costs. However, the Foresight model is not published in a peer-reviewed journal and was not available to us.

Methods

Following the review of the existing models and in consultation with project collaborators the decision was taken to employ a risk factor model, developed by colleagues at the University of Glasgow, Glasgow, UK, with funding from Scotland's CSO (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014), to project the longer-term impacts of FFIT.

The cardiovascular disease (CVD) model for Scotland (also known as the 'HELP' model; two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014) was chosen because it is an established model employing a risk score developed for the Scottish population, supplemented with Scottish data on costs and health outcomes, to examine long-term health outcomes. The model uses ASSIGN risk factors published in Tunstall-Pedoe *et al.*[95] to predict both CVD events and death from all non-CVD causes, including, for example cancers and respiratory diseases. The model utilises data from the Scottish Heart Health Extended Cohort (SHHEC),[96] which measured the ASSIGN risk factors, linked through Scottish Morbidity Records (SMRs) and General Register Office for Scotland, to identify all hospital events and death records. As such, the model provides a prediction of life expectancy, long-term costs and outcomes for individuals based on their risk score. For more details on ASSIGN please see http://assign-score.com.[96]

HELP model

The objective in developing HELP was to build a model capable of undertaking economic evaluation to inform Scotland's approach to primary prevention (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014). Predictions of life expectancy from the model closely match those published in national life tables (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014). The structure of the state transition model is shown in *Figure 7*. Using the nine ASSIGN[97] risk factors as parameter inputs, the HELP model predicts life-years gained, QALYs and lifetime costs.

The numbers in brackets in *Figure 7* refer to the following equations:

Function [age, systolic blood pressure, total cholesterol, high-density lipoprotein (HDL) cholesterol, cigarettes per day, diabetes mellitus, family history, SIMD] (1)

Function (age at event, family history, SIMD) (2)

Background morbidity = function (age, deprivation) (3)

Morbidity impact of non − fatal CVD events = function (age, family history, SIMD) (4)

Risk of subsequent CVD events = function (age, family history, SIMD) (5)

Costs prior to first event = function (age, family history, SIMD) (6)

Costs post first event = function (age, family history, SIMD) (7)

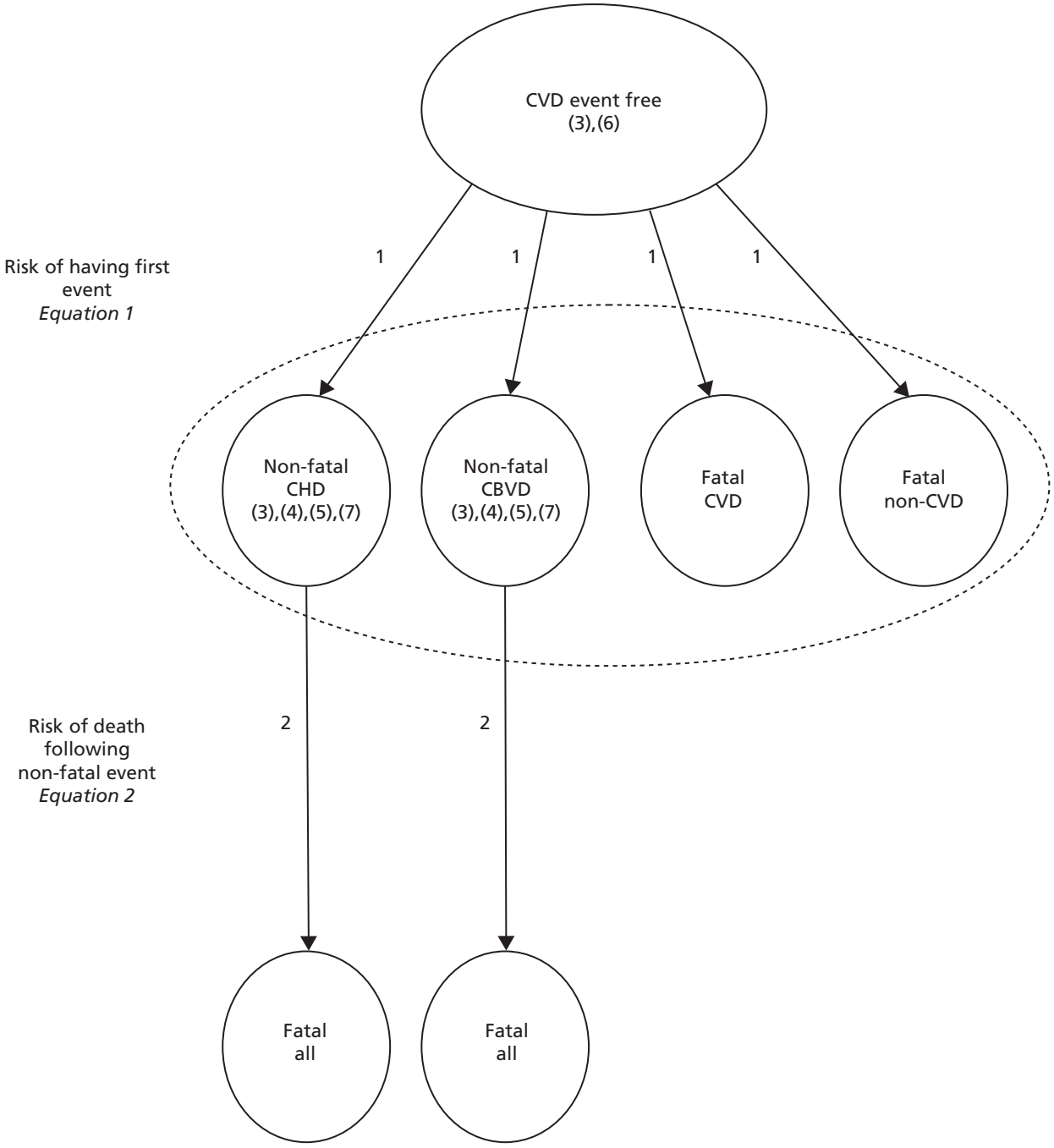

FIGURE 7 Structure of the state transition model. The numbers in brackets refer to *Equations 1–7*. CBVD, cerebrovascular disease.

Life expectancy

Individuals are assumed to be free from CVD at the point that they enter the model. Each individual is allocated a risk score based on their ASSIGN[97] risk variables. These variables include age, gender, family history of CHD and stroke, postcode (linked to SIMD), diabetes mellitus, systolic blood pressure, number of cigarettes smoked per day, total and HDL cholesterol. It is this individual risk score that determines the risk of experiencing an initial event [non-fatal CHD, non-fatal cerebrovascular disease (CBVD), fatal CVD and fatal non-CVD] (see *Equation 1*). Individuals subsequently transit into one of four 'competing' events, non-fatal CHD hospitalisation, non-fatal CBVD hospitalisation, death from CVD and death from non-CVD causes. Survival analysis was used to model the cause-specific hazards of these competing first events. As not all SHHEC participants had experienced a first event by the end of follow-up, a parametric approach was used to extrapolate and provide estimates of the total remaining life expectancy. The predicted

cumulative incidence of events was calculated from the cause-specific hazards and the probability of surviving from any of the competing events at a given time. Those individuals for whom the initial event is non-fatal will experience a fatal event at some point in the future, the risk of which is a determined by a combination of their age at initial event, family history and SIMD (see *Equation 2*; two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014). Each individual's life expectancy is determined as the sum of the time to the initial event plus the time to the fatal event (for those whose initial event is not fatal).

Quality-of-life adjustment

Quality-of-life adjustment is made in three ways as an individual transits through the model to account for background morbidity (see *Equation 3*), impact of experiencing a first non-fatal CVD event (see *Equation 4*) and impact of experiencing subsequent non-fatal CVD events (see *Equations 4* and *5*). These are then combined to generate overall quality-adjusted life expectancy (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014).

For background morbidity, Scottish Health Survey (SHeS) 2003[98] cross-sectional survey data were used to generate a preference-based weighted HRQoL score for each age group (*Table 22*).[75] These scores were used to weight survival probabilities in all arms of the model (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014).

These utility scores were then adjusted to account for the experience of non-fatal events using utility decrements (*Table 23*) also estimated using data from SHeS 2003 (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014).

TABLE 22 Age-related utility scores estimated from SHeS 2003

Age (years)	Utility
25–34	0.8310
35–44	0.8200
45–54	0.8060
55–64	0.8010
65–74	0.7880
> 74	0.7740

TABLE 23 Utility decrements attributed to non-fatal events

Event	Utility decrement
Angina	0.0891
Myocardial infarction	0.0403
Irregular heartbeat	0.0499
Stroke	0.0938
Intermittent claudication	0.0199
Other cardiac	0.0336

Lifetime health service costs

Individuals accumulate health service costs as they transit through the model. These costs are a mixture of age-related costs (associated with increasing comorbidities) and costs associated with the experience of specific events. The linked SHHEC and SMRs data set provides information on all hospital episodes (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014). These episodes were costed using method 1 in Geue *et al.*[99] to generate annual age-related health-care costs. Costs accumulate in the period prior to the initial event (see *Equation 6*) and following a non-fatal CVD event (see *Equation 7*).

More details on the HELP model are available on request.

Employing the HELP model for the longer-term analysis of Football Fans in Training

Within the longer-term analysis, the HELP model is used simply as a means to extrapolate the trial results. The model utilises individual sampling that enables us to generate estimates of long-term cost and outcomes for each individual within the trial population with which to supplement the trial data. This allows us to estimate the longer-term costs and outcomes associated with the FFIT intervention compared with no active intervention. As such, the model is populated with the 12-month data concerning the individual participants' risk factors. These data are used to generate a post-intervention risk score from which the model generates a post-intervention estimate of life expectancy, a post-intervention estimate of QALYs as well as an estimate of cumulative lifetime hospital costs for each participant. The impact of the FFIT intervention is based on the differences between these estimates for the participants who received the FFIT intervention and those who were part of the waiting list comparison group.

It was necessary to make a number of assumptions and adjustments in order to use the HELP model within the longer-term FFIT analysis. All but three of the nine ASSIGN[97] risk factors were collected for participants at baseline, 12 weeks and 12 months. The remaining three risk factors (family history of CHD/stroke, total cholesterol and HDL cholesterol) were not available for the participants. In order to generate an ASSIGN score these risk factors were imputed for each participant using information from other Scottish sources.

Family history of CHD/stroke is defined as an immediate family member (mother, father or sibling) being diagnosed with heart disease or stroke before the age of 60 years.[100] A participant may also be classed as having a family history if two or more of their aunts, uncles or cousins suffered CHD/stroke before age 60 years, despite not having a mother, father or sibling affected. The Midspan Family study[101] is a cardiorespiratory investigation of two generations of a population based in the west of Scotland. The original Renfrew/Paisley study[102] contained a cohort of 4064 married couples from 1972–6. In 1996, their offspring were traced and 2338 attended the cardiorespiratory examination and completed the survey questionnaire. From this data set we were able to find a proportion estimate of family history to apply to our study population (Professor Michaela Benzeval, University of Essex, 2013, personal communication). The proportion was based on men with at least one parent who experienced or died of CHD/stroke in our population of interest: men with a BMI $\geq 28\,kg/m^2$, aged 35–65 years. This proportion (121/313) was then applied randomly to our study population, resulting in 38% of both intervention and comparison groups having a family history CHD/stroke.

Using this approach to estimate family history has limitations. Generalisability is questionable as the Midspan population is specific to the offspring of a west of Scotland general population, whereas our sample is from all over Scotland. In addition, the definition of family history varied slightly from the ASSIGN risk score definition as information from the Midspan Family Study was only available on parents. Finally, the proportion with a family history is likely to be an underestimate, as it was based on self-reported data rather than hospital admissions data. However, as family history is not influenced by the intervention, these limitations should not impact the incremental analysis.

Data on total and HDL cholesterol for men aged 35–65 years with a BMI ≥ 28 kg/m^2 were available from the west of Scotland Twenty-07 study.[103] From these data, multivariate regression equations were estimated through discussion with clinical colleagues to relate total and HDL cholesterol to age, BMI, SIMD, education, diabetes mellitus and smoking status (*Tables 24* and *25*). The approach to estimate total and HDL cholesterol for each participant in this way was discussed and agreed with clinical colleagues, who suggested that activity, weight loss and diabetes mellitus would all effect HDL cholesterol more than total cholesterol. Note that we are not attempting to estimate the impact of behaviour change on cholesterol change, an approach which was deemed inappropriate by our clinical colleagues.

The equation for total cholesterol was based on a sample of 337 men, while the equation for HDL cholesterol was based on a sample of 317 men. Note that those with higher BMI were more likely to be on statins, lowering their cholesterol and, thus, explaining the negative coefficient in the results in *Tables 24* and *25*.

TABLE 24 Multivariable coefficients for regression of total cholesterol on age, BMI, SIMD, education, smoking and diabetes mellitus in 337 men with a BMI ≥ 28 kg/m^2

Variable	Regression coefficient	95% CI
Age (1-year increase)	–0.0068598	–0.192659 to 0.0055462
BMI (unit increase)	–0.0450094	–0.0781239 to –0.0118948
SIMD (unit increase)	–0.0066748	–0.013775 to 0.0004254
Intermediate vs. higher education	0.0676622	–0.2250695 to 0.3603939
Basic vs. higher education	0.2754775	–0.0712515 to 0.6222065
Diabetes mellitus vs. none	–0.883468	–1.431325 to –0.3356115
Ex-smoker vs. non-smoker	–0.1088097	–0.3963641 to 0.1787446
Current smoker vs. non-smoker	0.2003869	–0.1046881 to 0.0505462
Constant term	7.601214	6.345408 to 8.857019

TABLE 25 Multivariable coefficients for regression of HDL cholesterol on age, BMI, SIMD, education, smoking and diabetes mellitus in 286 men with BMI ≥ 28 kg/m^2

Variable	Regression coefficient	95% CI
Age (1-year increase)	–0.0035155	–0.0088002 to 0.0017692
BMI (unit increase)	0.0020153	–0.0031141 to 0.0030424
SIMD (unit increase)	–0.0000358	–0.0031141 to 0.0030424
Intermediate vs. higher education	–0.0872548	–0.2098335 to 0.0353239
Basic vs. higher education	–0.083006	–0.2273535 to 0.0613415
Diabetes mellitus vs. none	–0.01753	–0.2294473 to 0.1943874
Ex-smoker vs. non-smoker	0.1154253	–0.0057461 to 0.2365966
Current smoker vs. non-smoker	0.1083991	–0.0237426 to 9.2405409
Constant term	1.577714	1.053263 to 2.1022164

Analysis

The long-term effectiveness is presented in terms of both life-years gained and QALYs. These estimates are generated for each individual as the sum of the individual's within-trial outcome (in terms of life-years or QALYs) and the individual's estimate of life expectancy generated from the HELP model (in terms of life-years or QALYs).

The long-term cost associated with each individual is determined by the sum of the individual's within-trial cost and the individual's estimate from the HELP model.

The longer-term estimates of life expectancy, QALYs and costs were all discounted at a rate of 3.5% following guidance from the UK NICE.[104]

The cost and effects of the FFIT intervention are calculated by averaging the costs and effects of the individual participants who received the FFIT intervention; the same process is undertaken for members of the waiting list comparison group to determine the costs and effects associated with no active intervention. The incremental cost associated with the FFIT intervention is the difference between the average cost of the FFIT intervention group and the average cost of the comparison group. The incremental effects associated with the FFIT intervention are taken as the difference in the average effects (in terms of life-years or QALYs) between the FFIT intervention group and the comparison group. The incremental cost-effectiveness associated with the FFIT intervention is then presented in terms of incremental cost per life-year gained and incremental cost per QALY gained.

Probabilistic analysis

In order to estimate the uncertainty in the model estimates, we undertook a probabilistic sensitivity analysis allowing for uncertainty in the estimation of all of the parameters within the model. Running this analysis required simulating 1000 draws from the probability distributions for each of the parameters and using each of these 1000 draws to estimate the life expectancy, QALYs and lifetime costs for each of the participants, generating an estimate of the average costs, life-years and QALYs for each group for each draw.

The resulting uncertainty in the incremental costs and effects associated with the intervention is plotted on the incremental cost-effectiveness plane. The cost-effectiveness acceptability curve presents the uncertainty surrounding the cost-effectiveness of the FFIT intervention compared with no active intervention.

Finally, the uncertainty surrounding the decision to implement the FFIT intervention was formally assessed, in terms of the associated costs and consequences, within a value of information (VOI) analysis. The expected value of perfect information (EVPI) provides a monetary valuation of the impact of the uncertainty surrounding the decision between FFIT and no active intervention every time that a decision is made. This per-decision amount is scaled up according to the frequency of the decision in order to provide a population-level value of the uncertainty. This valuation provides an estimate of the maximum return achievable, for the population, from reducing uncertainty through further research and can be used to determine whether or not it is potentially worthwhile undertaking further research around the effectiveness or cost-effectiveness of FFIT compared with no active intervention.

Within the VOI analysis of the FFIT intervention, the eligible population was specified as Scottish men aged 35–65 years identified over the next 3 years with a BMI ≥ 30 kg/m^2; that is a population of 365,000 men.

Scenario analysis

Uncertainty about the long-term sustainability of behavioural change (structural uncertainty) is examined through a scenario analysis that limits the time frame for the risk reduction impact of the intervention. This was achieved by changing the hazard ratios utilised within the model 5 years after the intervention.

Results

Table 26 presents the results of the probabilistic analysis in terms of the average lifetime costs and QALYs per participant in each group.

The results illustrate that FFIT is more expensive than no active intervention, with an average additional cost of £1074 per individual (95% CI £780 to £1298). The results also indicate that the FFIT intervention is also marginally more effective with an average increase of 0.43 life-years (95% CI 0.32 to 0.56 life-years) and 0.38 QALYs (95% CI 0.25 to 0.55 QALYs). As a result, the FFIT intervention is associated with an incremental cost-effectiveness of £2810 per QALY gained (£2535 per life-year gained).

Figure 8 shows the uncertainty surrounding the estimates of the lifetime incremental costs and effects. The figure shows that there is no uncertainty surrounding the existence of a cost difference – FFIT is more expensive than no active intervention (i.e. all the incremental costs are positive), although there is some uncertainty about the extent of the cost difference. In addition, the figure shows that there is no uncertainty surrounding the existence of a difference in effect (i.e. all the incremental QALYs are positive), although there is uncertainty about the extent of the effect difference.

Figure 9 presents the cost-effectiveness acceptability curve for the lifetime analysis. This demonstrates that when the decision-maker is willing to pay £20,000 or £30,000 per QALY, there is no uncertainty that FFIT is cost-effective compared with a no active intervention alternative, with a probability of 1. In fact, this is the case for any value of the cost-effectiveness threshold beyond £5000 per QALY, as such if the decision-maker is willing to pay more than this value there is no uncertainty that FFIT is cost-effective.

Figure 10 presents the EVPI associated with the decision between FFIT and no active intervention for each instance of the decision (individual eligible man). This illustrates that for any value of the cost-effectiveness threshold above £5000 per QALY (i.e. when the decision-maker is willing to pay > £5000 per QALY) there is little value associated with further research and data collection.

TABLE 26 Average lifetime costs and QALYs (lifetime analysis: base case)

Costs variable	Cost (£)	Life-years	QALYs
FFIT	19,452	66.94	65.59
No active intervention	18,378	66.51	65.21
Incremental	1074	0.43	0.38

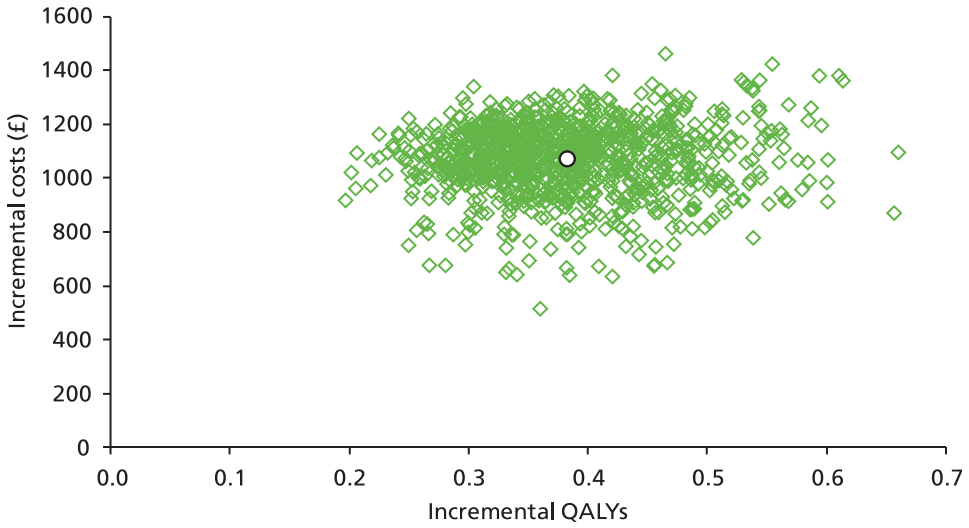

FIGURE 8 Incremental cost-effectiveness plane (lifetime analysis).

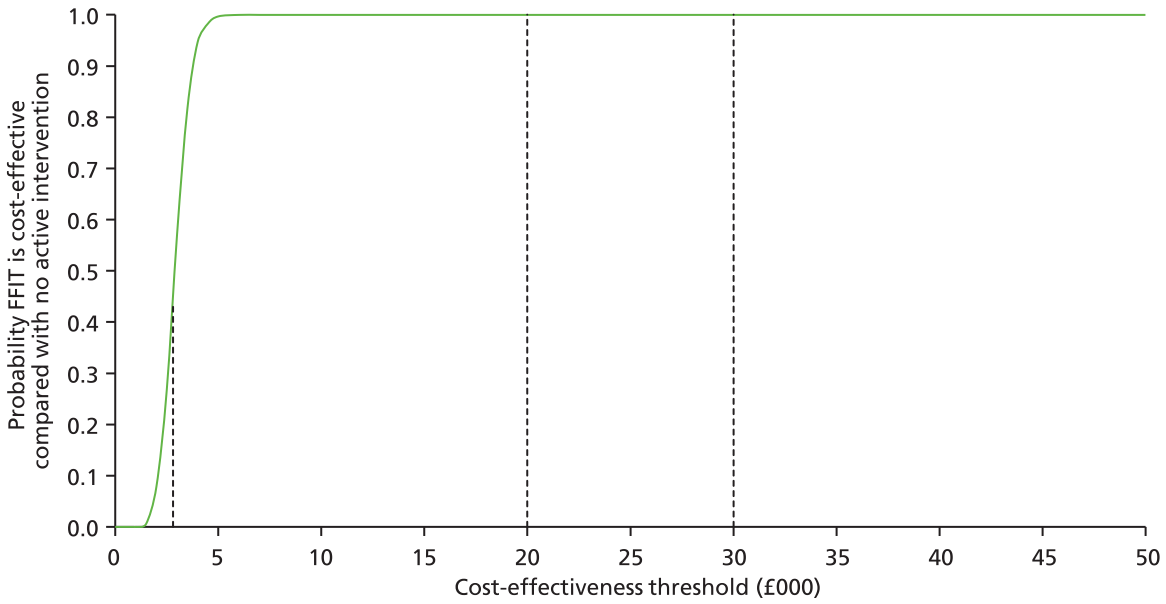

FIGURE 9 Cost-effectiveness acceptability curve for FFIT intervention (lifetime analysis).

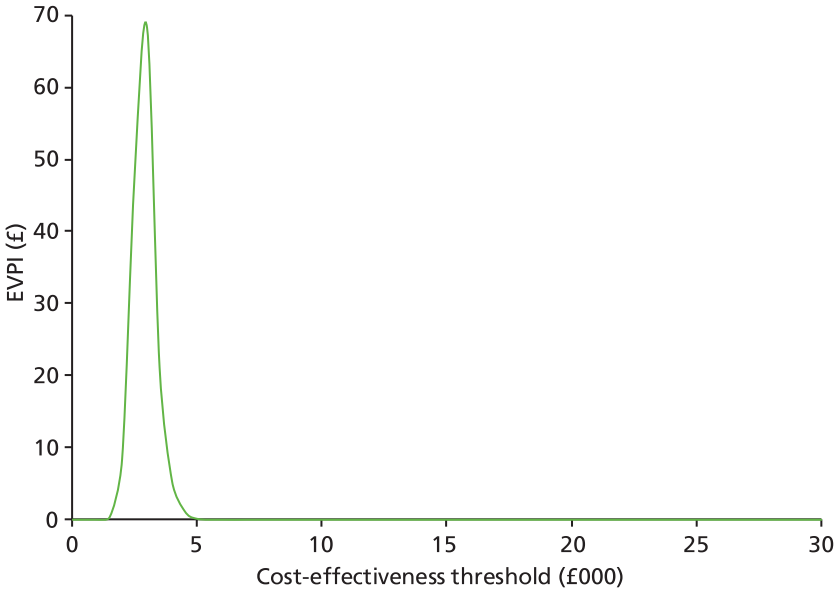

FIGURE 10 The EVPI for each eligible man aged 35–65 years.

Figure 11 presents the EVPI associated with the decision to implement FFIT (compared with no active intervention) for a Scottish population of men aged 35–65 years identified with a BMI ≥ 30 kg/m^2 over the next 3 years. Again, the figure shows that there is very little value associated with further research and data collection if the decision-maker is willing to pay > £5000 per QALY. For cost-effectiveness thresholds below this level, there is considerable value in undertaking further research: up to £25M for a willingness to pay of £3000 per QALY. This reflects the increasing level of certainty concerning the cost-effectiveness of the FFIT intervention as cost-effectiveness thresholds rise from £2810 per QALY (the level at which FFIT becomes cost-effective) to £5000 per QALY (for which there is no uncertainty). For the range of thresholds generally employed within the UK (£20,000–30,000 per QALY) there is no uncertainty about implementing FFIT and, consequently, no potential value in undertaking further research.

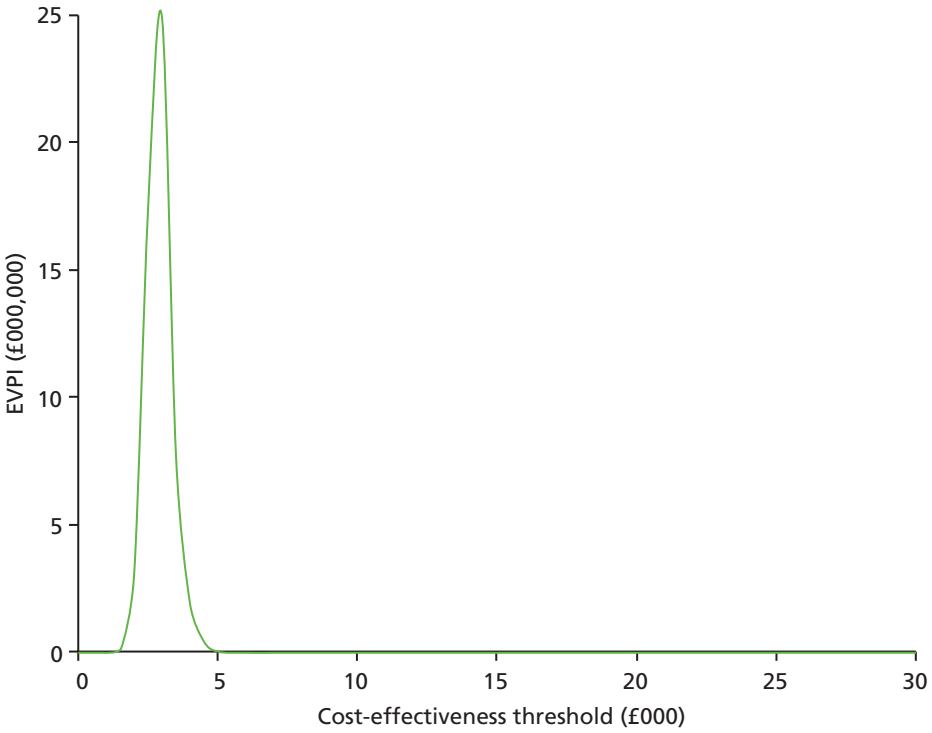

FIGURE 11 The EVPI for a population of men aged 35–65 years with a BMI ≥ 30 kg/m^2.

The results of a scenario analyses (*Table 27*) is limiting the beneficial behaviour change impact of the intervention to 5 years indicates that FFIT remains more expensive than no active intervention, although the average additional cost is reduced to £289.00 per individual (95% CI £0.12 to £503.00). The results also indicate that the FFIT intervention remains marginally more effective, with an average increase of 0.21 life-years (95% CI 0.12 to 0.31 life-years) and 0.25 QALYs (95% CI 0.12 to 0.38 QALYs). The overall result is to improve the cost-effectiveness of the FFIT intervention; incremental cost-effectiveness ratio (ICER) £1174 per QALY gained (£1384 per life-year gained). This counterintuitive result is because restricting the behaviour change has a greater impact on the life-years and QALYs associated with FFIT intervention than the no active intervention group (reducing the incremental outcomes associated with FFIT). In addition, the reduction in life-years and QALYs has a greater impact on the lifetime costs associated with the FFIT intervention than the no active intervention (reducing the incremental costs associated with FFIT). These two effects, when combined in a ratio, lead to a fall in the additional cost per QALY associated with FFIT.

If altering the behaviour change assumption were assumed to only impact outcomes with costs (and incremental costs) remaining at their original levels, the impact would be to increase the ICER associated with FFIT to £4475 per QALY compared with no active intervention.

TABLE 27 Average lifetime costs and QALYs (lifetime analysis: scenario 1)

Cost variable	Cost (£)	Life-years	QALYs
FFIT	17,924	65.68	64.36
No active intervention	17,635	65.47	64.12
Incremental	289	0.21	0.24

Chapter 5 Process evaluation: methods and results

Introduction

The process evaluation investigated six process outcomes:

(a) process outcome 1: programme reach
(b) process outcome 2: participants' reasons for continuing with or opting out of FFIT
(c) process outcome 3: the extent to which coaches deliver FFIT as designed (fidelity)
(d) process outcome 4: participants' views of FFIT including satisfaction, acceptability and any unexpected outcomes (participants' experiences of taking part)
(e) process outcome 5: coaches' experiences of delivering FFIT including satisfaction, acceptability and any unexpected outcomes (coaches' experiences of taking part)
(f) process outcome 6: participants' experiences of maintaining weight loss and lifestyle changes in the longer term.

In this chapter we describe the methods of data collection (data sources) and analysis used to address each process outcome. We then present results in relation to each outcome in turn and, finally, present our conclusions from the process evaluation.

Methods

Data sources and data collection

We used mixed methods and nine data sources to address the process outcomes. *Figure 12* shows which sources of data (1–9) were used to address each process outcome (1–6).

Data source 1: self-reports on online registration form and registration telephone calls

On registration, men were asked to provide their name, contact details, date of birth, the club they wished to attend and their self-reported trouser waist size, height and weight. When the research team telephoned men who had registered an initial interest in FFIT (either online or when approached at football games), 98% (1206/1231) were asked how they had heard about FFIT and a single response was recorded.

Data source 2: baseline questionnaire

The methods of data collection for the baseline questionnaire and measurements are reported in *Chapter 2*, *Procedures* and baseline characteristics of trial participants are reported in *Chapter 3*, *Baseline data*.
In this chapter, we use age and objectively measured BMI and waist circumference to compare FFIT trial participants with men in the general population. Categories of waist circumference ('low' < 94 cm; 'high' ≥ 94 cm and < 102 cm; 'very high' ≥ 102 cm) and BMI ('overweight' BMI 28–29.99 kg/m^2; 'mild obesity' BMI 30–34.99 kg/m^2; 'moderate obesity' BMI 35–39.99 kg/m^2 and 'extreme obesity' BMI > 40 kg/m^2) were used to assess risk of future ill health following Scottish Intercollegiate Guidelines Network (SIGN) guidelines.[43] Comparison figures for similarly aged men in the Scottish population were obtained from the SHeS 2011.[2]

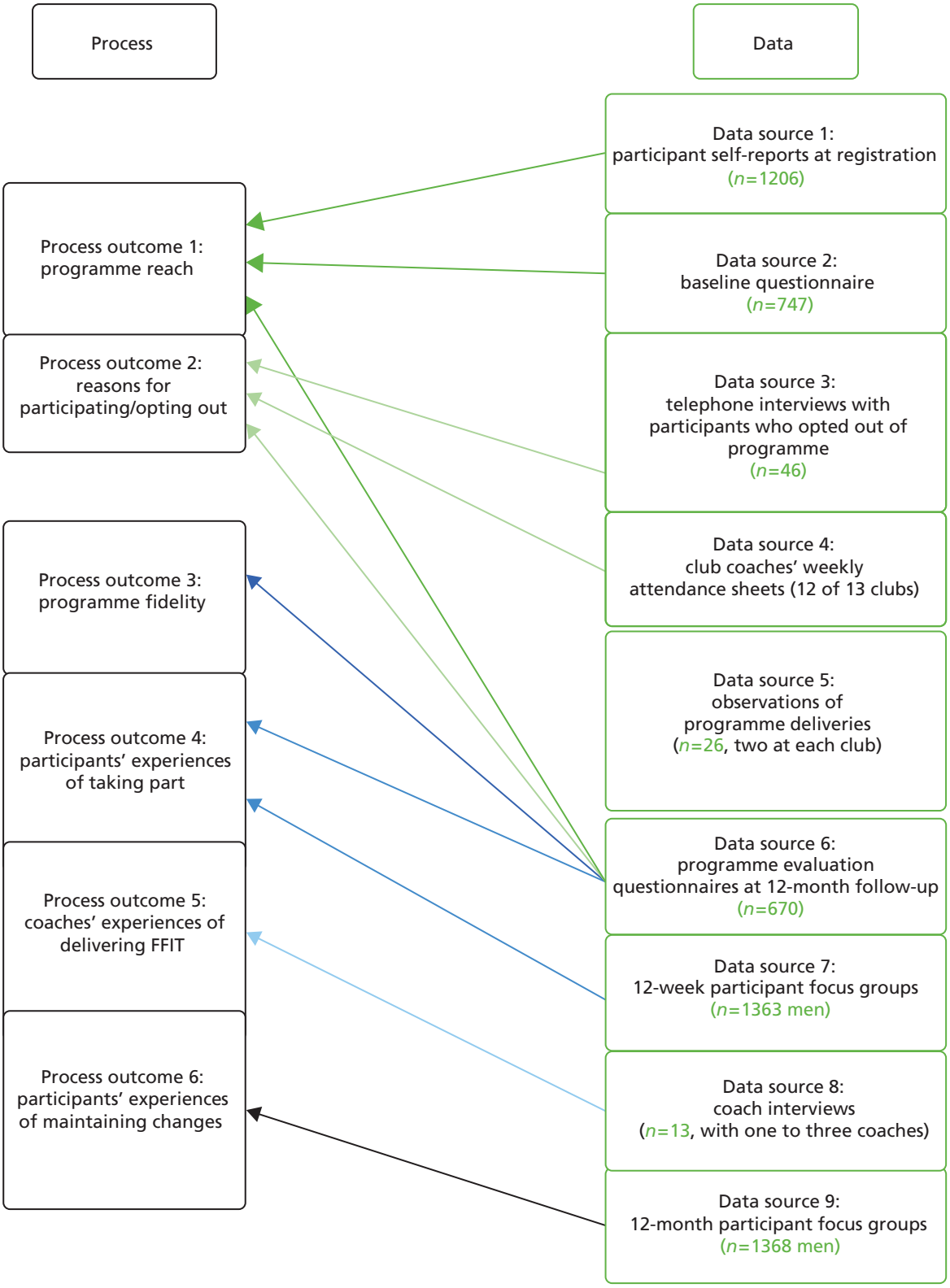

FIGURE 12 Sources of data used to address process outcomes.

Data source 3: telephone interviews with men who opted out of Football Fans in Training

At 12 weeks, participants were contacted by the research team to arrange post-intervention measurements. At this point, 46 participants (12% of the original intervention group) informed the research team that they had left the intervention while it was still being delivered. During this telephone call, a brief structured exit survey was undertaken by telephone with any men who had opted out of FFIT (see *Appendix 1*). This asked about their reasons for joining, why they stopped attending, whether or not their attendance had changed them in any way and any suggestions for improvements to the programme (and whether or not this would have encouraged them to stay on the programme). It also invited them to make any additional comments not covered by these questions.

Data source 4: club coaches' weekly attendance sheets

Club coaches were asked to keep a record of attendance at each of the 12 weekly sessions. Coaches for 12 of the 13 clubs (covering 356 of the 374 men allocated to the intervention arm) were able to provide these; one club (Club09) suffered a computer failure that resulted in the loss of their attendance record.

Data source 5: observations of programme deliveries

Three researchers were trained to conduct observations of the intervention delivery. Across the 13 clubs, 26 sessions were observed (observations were distributed so that each of the 12 sessions was observed at least twice and every club was observed twice). *Table 28* details which sessions were observed in each of the clubs.

Researchers were introduced to the men by the coach at the beginning of each session. The researcher explained their role as observer, gave the men an opportunity to ask questions and asked for their consent to observe, take notes, audio-record the classroom session and video-record the physical activity session. They reassured participants that the researcher would leave the session if anyone did not wish to give their consent. Men in all sessions consented to be observed.

TABLE 28 The FFIT session deliveries observed in each club

Club	First session observed	Second session observed
Club01	4	11 and 12[a]
Club02	2	6
Club03	5	10
Club04	4	12
Club05	6	9
Club06	1	10
Club07	3	12
Club08	2	8
Club09	3	11
Club10	3	8
Club11	2	7
Club12	1	9
Club13	5	7

a The session was a double session, as the previous session had to be cancelled because of operational reasons.

As soon as possible after observing the session, researchers wrote detailed notes using a proforma that focused on the extent to which coaches delivered key tasks for the session as specified in the programme delivery guide and identification of particularly good practice and/or any problems/issues with the delivery (see *Appendix 2*). Researchers listened to the audio-recording of the classroom session and watched the video of the physical activity session and supplemented their proforma notes with any relevant observations which had not already been captured. The key tasks for each session were designed to deliver core educational messages (see *Table 1*). In total, there were 42 key tasks to be delivered in 12 classroom sessions, as shown in *Table 1*. Observers rated whether or not key tasks had been 'delivered' or 'not delivered' and recorded reasons for their rating.

Data source 6: programme evaluation questionnaire

We asked men in the intervention group to complete a questionnaire to evaluate their experiences of the FFIT programme (the exit questionnaire is available from the authors on request). This was administered at 12-month measurement sessions after completion of all other measures. It was completed by 316 out of 333 men (95%) who attended the 12-month measurement sessions and 316 out of 374 men (84%) who were randomised to the intervention group. The questionnaire asked how useful they found key aspects of the programme including physical activity, diet, goal setting, weight loss, group interactions and support.

Data sources 7 and 8: participant focus group discussions

We conducted two sets of focus group discussions (FGDs), the first soon after the delivery of the intervention programme was completed (data source 7: 12-week FGDs) and the second after the 12-month follow-up measurements had been completed at each club (data source 8: 12-month FGDs). At each time point, one FGD was conducted at each of the 13 clubs.

For the 12-week FGDs, men who had consented to additional research-related contact and who had attended the programme for at least 6 weeks were approached to ask if they would be willing to take part in a group discussion on their views of the programme. Of 295 men contacted, 133 (45%) indicated interest in taking part. Up to six men per club were invited to take part in a 60-minute focus group. If men were not available or did not wish to attend at the chosen time, additional men were contacted from the list (if numbers permitted) until five or six men per club had confirmed they could take part. The 12-week FGDs covered how they had heard about FFIT and their reasons for taking part; perceptions of any impacts the programme had; which, if any, aspects of the programme had enabled them to make changes; any negative experiences; and any suggestions for changes that could be made to improve the programme (see *Appendix 3*). In total, 63 men participated in the 12-week FGDs across the 13 clubs (*Table 29*).

We wanted to ensure that the 12-month FGDs (which were conducted following final 12-month measurements) included a mix of men who had been variously successful in achieving and maintaining weight loss to 12 months. We e-mailed 280 men who had consented to additional research-related contact and 143 (51%) indicated that they were willing to take part. Again, up to six men per club were invited and if they were not available or did not wish to attend at the chosen time, additional men were contacted from the list (if numbers permitted) until five or six men per club had confirmed they could take part. In total, 68 men participated in the 12-month FGDs across the 13 clubs (see *Table 29*). The topic guide focused on what had helped and hindered men's attempts to maintain weight loss, increased physical activity and a healthier diet (see *Appendix 3*).

With participants' consent we audio- and video-recorded all FGDs. They were transcribed verbatim and checked for accuracy. As part of the consent procedure, men were assured that they could withdraw from the discussion at any time, they could choose not to answer any questions and their participation/lack of participation would not affect future participation in FFIT-related or other activities at their club. Participants were given a £20 club shop voucher to thank them for participation and offered reimbursement for any travel expenses incurred.

TABLE 29 Number of men participating in 12-week and 12-month FGDs by club

Club	12-week FGDs	12-month FGDs
Club01	2	4
Club02	5	6
Club03	6	6
Club04	4	6
Club05	6	5
Club06	5	5
Club07	5	5
Club08	5	4
Club09	4	6
Club10	6	4
Club11	4	5
Club12	5	6
Club13	6	6
Total	63	68

Data source 9: coach interviews

We conducted semistructured interviews with coaches who had delivered the programme at each club as soon as possible after the 2011 delivery was completed. At one club, all three coaches involved were interviewed together, at eight clubs two coaches were interviewed together, at one club both coaches were interviewed individually and at the remaining three clubs the main coach was interviewed individually.

As part of the consent procedure, coaches were assured that they could terminate the interview at any time or choose not to answer any question and that their participation/lack of participation would not affect future participation in FFIT.

The topic guide included questions about coaches' experiences of delivering the programme, elements they thought were effective/less effective, aspects that were difficult to deliver and any changes they would like to suggest for future versions of the FFIT programme. Interviews were conducted at the clubs, lasted up to 1 hour, were audio-recorded, transcribed verbatim and checked for accuracy.

Analysis

Qualitative data from focus group discussions, coach interviews and observational data

We used a structured, thematic, approach to analyse transcripts from FGDs, coach interviews and qualitative data from observations.[105–107] First, transcripts were repeatedly read and coded to broad themes reflecting the research questions covered in the process evaluation. For the 12-week focus group data, these broad themes were reasons for participating in FFIT, reasons for continuing with FFIT and satisfaction with/acceptability of FFIT. For the 12-month FGDs, themes relating to participant experiences of maintaining weight loss and lifestyle change were identified. For coach interview data, broad themes were experiences of delivering FFIT, satisfaction and acceptability of FFIT and any adaptations made during the delivery of FFIT.

Second, all data coded to these 'broad themes' were read independently by two researchers who noted all subthemes that were present, including both anticipated subthemes that related to the main research questions and any unanticipated themes or topics.[106] This mixed approach ensured that the full range of participants' views was captured.[107] Third, the two researchers compared the themes they had identified and collectively agreed a coding framework based on these.

Fourth, each broad theme was recoded by one researcher to the agreed coding framework to ensure that all material of relevance to these analytical categories was captured. Finally, the same researcher produced an extended descriptive summary of each analytical category using data extracts to illustrate each point. This summary was read by the second researcher to double-check that all views were covered and then used to write this report.

In conducting our analysis we were particularly mindful of the capabilities, opportunities, motivation and behaviour (COM-B) model of behaviour change[108] and the ROMEO logic model by Robertson *et al.*[10] The COM-B model argues that for behaviour change people need the right combination of capabilities, opportunities and motivation. The opportunity and motivation aspects of the COM-B model were especially useful for explaining data relating to reasons for participation. The ROMEO logic model describes the important influence of wider environments and culture and of family, friends and workplace interactions on individuals' 'weight loss journeys'; this was particularly useful in interpreting extrapersonal factors that drew men to the programme, why they engaged with FFIT and influenced the weight loss trajectories men followed after the programme finished. In conducting the analysis of men's experiences of maintenance, we also drew on self-determination theory (SDT), which argues that maintenance of weight loss-related behaviours is associated with the satisfaction of three universal psychological needs: autonomy (volition), relatedness and competence.[109] Thus, men may be more likely to succeed in maintaining their weight loss, increased physical activity and healthier diet if they have developed internalised self-regulation and have integrated their new behaviours with other aspects of their personal identity; feel optimally challenged to perform the new behaviours; and feel meaningfully connected to others.

Quantitative data from the baseline questionnaire, the programme evaluation questionnaire and exit survey

Categories of waist circumference ('low', < 94 cm; 'high', ≥ 94 cm and < 102 cm; 'very high', ≥ 102 cm) and BMI ('overweight', 28–29.99 kg/m^2; 'mild obesity', 30–34.99 kg/m^2; 'moderate obesity', 35–39.99 kg/m^2; and 'extreme obesity', > 40 kg/m^2) were used to assess risk of future ill health. Descriptive statistics were used to examine men's satisfaction with the programme, as reported in the programme questionnaire at 12 months, and men's reasons for dropping out of the programme, as recorded in the exit survey.

Results

Process outcome 1: programme reach

In this section we report the start of men's 'weight loss journeys'[10] by considering *who* the FFIT programme managed to reach and *how* these men were engaged.

Reach

In order to attract sufficient numbers to the FFIT trial within a very constrained recruitment period, we needed multiple recruitment strategies (see *Chapter 2*, *Recruitment strategies and contact with men* and/or *Chapter 3*, *Recruitment*). Potential participants could therefore have been exposed to information on the upcoming FFIT programmes from multiple sources (e.g. leafleting at football matches, workplace fliers/e-mails, word of mouth) and we are unable to provide a clear denominator for any estimation of reach. Here then, we consider 'reach' in relation to the kinds of men who chose to participate in FFIT.

The baseline demographic characteristics of trial participants (see *Table 6*) demonstrate that FFIT was successful in reaching men from across the socioeconomic spectrum. However, in comparison with the general population, fewer participants were not in paid work (17.2% in FFIT compared with 22.4% of men aged 35–64 years in the Scottish population)[110] and fewer were from non-white ethnic backgrounds (98.3% of FFIT participants described themselves as 'white' compared with 96.2% in the total Scottish population).[111]

The FFIT succeeded in attracting men who were at high risk of ill health on the basis of their BMI, waist circumference and blood pressure.[34] As reported in *Chapter 3*, mean BMI was 35.3 kg/m^2 (SD 4.9 kg/m^2). Over 90% of participants had a BMI $\geq$ 30 kg/m^2; 44% were classed as mildly obese, 31% as moderately obese and 17% as extremely obese. Mean weight was 109.5 kg (SD 17.3 kg) and mean waist circumference was 118.4 cm (SD 11.7 cm); all but two men had a high (4%) or very high waist circumference (96%). Mean systolic and diastolic blood pressure readings were 140 mmHg and 89 mmHg, respectively. *Table 30* compares FFIT RCT participants with male SHeS respondents of similar ages[2] according to health risk category.[34] On the basis of their BMI and waist circumference, FFIT trial participants were at much higher risk of future ill health (type 2 diabetes mellitus, hypertension and CVD); around 10 times more men were classed as being at 'extremely high' risk (21%, 16% and 12% of FFIT participants aged 35–44 years, 45–54 years and 55–65 years, respectively, as compared with 2%, 2% and 1% of Scottish men of the same age). A further 223 out of 311 men (72%) aged 35–44 years, 212 out of 290 men (73%) aged 45–54 years and 116 out of 146 men (80%) aged 55–65 years were at 'very high' risk, compared with 25%, 25% and 32% of Scottish men, respectively.

Furthermore, despite being sufficiently concerned about their weight to register for the FFIT programme, only 3.6% had attended a commercial weight management programme and only 1.7% a primary care-based programme in the 3 months prior to undertaking FFIT.[34]

Routes to recruitment

Men expressing an interest in FFIT reported hearing about the programme from a range of different sources. The most widely reported sources of information about the programme were match-day recruitment (reported by 327 men, 27% of the 1206 who were asked to identify what led them to join the programme). At least 13% (154/1206) of potential participants also reported hearing about the programme through club websites, articles or news pieces in the media (newspaper, radio and TV) and through word of mouth. Several other sources were mentioned by a small minority of men (< 10% of participants) including work-based advertisement (6%, 77/1206), posters at the clubs (5%, 55/1206), other club associations (4%, 45/1206), fans' websites (3%, 40/1206) and GPs (1%, 9/1206).

Accounts from participants in the 12-week FGDs confirm findings from our feasibility study.[32] The most common account was of having heard or read about the programme from multiple sources. For example:

> *I'd actually, I had heard, coming to one of the home games, there was, like, folk out sort of talking to people periodically. We just happened to be walking past somebody when I heard – that was probably the first I heard of it, and then I'd picked it up in the work through someone in the work, who was actually sort of involved wi' [with] the measuring side of it. So she'd kind of highlighted the fact that, you know, did I know fans [who would be interested]? I don't know if it was a subtle hint!*
>
> *Participant 1, Club12, 12-week FGD*

This extract also points to the importance for some men of interactions with others in their decision-making about whether or not to engage with the programme. Other examples suggest some men were strongly encouraged to sign up by family members and some needed prompts from multiple sources before a final decision to sign up. Collectively, the data suggest that it is important to use multiple media outlets when advertising for recruitment and that each source can reinforce another and that making it as easy as possible for men to make the decision to participate is important.

TABLE 30 Comparison of health risk category of men recruited to FFIT RCT with men in Scottish general population by age group from 2011 SHeS[a]

Waist circumference and BMI classification	Health risk category according to SIGN guidelines[43]	All FFIT	Age categories (years)								
			FFIT 35–44		SHeS 35–44	FFIT 45–54		SHeS 45–54	FFIT 55–65		SheS 55–64
		n	*n*	%	%	*n*	%	%	*n*	%	%
Overweight											
Low waist circumference	No increased risk	2	1	0.3	19.4	1	0.3	14.6	0	0.0	9.3
High waist circumference	Increased	18	4	1.3	17.7	10	3.4	19.7	4	2.7	21.3
Very high waist circumference	High	37	13	4.2	6.2	17	5.9	8.2	7	4.8	16.4
All		57	18	5.8	43.2	28	9.6	42.5	11	7.5	47.0
Obesity I											
Low waist circumference	Increased	0	0	1.9	0.4	0	0.0	1.2	0	0.0	–
High waist circumference	High	11	6	0.0	2.8	3	1.0	5.8	2	1.4	0.9
Very high waist circumference	Very high	318	114	36.7	22.4	131	45.2	18.3	73	50.0	25.5
All		329	120	38.6	25.7	134	46.2	25.3	75	51.4	26.5
Obesity II											
Low waist circumference	Very high	0	0	0.0	–	0	0.0	–	0	0.0	–
High waist circumference	Very high	1	0	0.0	–	1	0.3	–	0	0.0	–
Very high waist circumference	Very high	232	109	35.1	2.8	80	27.6	6.3	43	29.5	6.9
All		233	109	35.1	2.8	81	27.9	6.3	43	29.5	6.9
Obesity III											
Low waist circumference	Extremely high	0	0	0.0	–	0	0.0	–	0	0.0	–
High waist circumference	Extremely high	0	0	0.0	–	0	0.0	–	0	0.0	–
Very high waist circumference	Extremely high	128	64	20.6	1.7	47	16.2	2.0	17	11.6	1.1
All		128	64	20.6	1.7	47	16.2	2.0	17	11.6	1.1
Total		747	311	–	–	290	–	–	146	–	–

a Reprinted with permission from Hunt K, Gray C, Maclean A, Smillie S, Bunn C, Wyke S. Do weight management programmes delivered at professional football clubs attract and engage high risk men? A mixed-methods study. *BMC Public Health* 2014;**14**:50.[34]

Process outcome 2: reasons for participating/opting out

Reasons for participation: personal motivations and the 'draw' of the football club

During the 12-week FGDs, participants were asked about their motivations for signing up for the FFIT programme. They offered multiple and overlapping explanations. This included a range of personal or family 'push' factors, such as wanting to regain a more youthful, better functioning or less compromised body. For example:

> *Well, I used to play football, [. . .] and when I had to chuck it, I kept playing fives [five-a-side], but I was kidding mysel' on, and you're no' doing the same training but you continue to eat the same way you always did, and you continue to drink on the Saturday wi' [with] your mates, the same way you did. And year on year, it [weight] just crept up to the point where I think I hit about sixteen stone, and I thought I need to dae [do] something aboot [about] it. And I did try to do something aboot [about] it, and it worked for a wee while, and then lapsed again, and then this came up through the work [advert about FFIT] and I thought, 'I'm going to [Club12 ground],' so my motivation was to lose the weight and get back fit again . . .*
>
> *Participant 3, Club12, 12-week FGD*

The opportunity to stave off or fight back health problems was frequently raised. One participant explained how when he was approached by a member of the recruitment team at a home game he connected his weight to his musculoskeletal health:

> *He said they were looking for fat bastards, and I'd had trouble wi' [with] my knees because of the additional weight I'd been putting on. I knew I had to do something, so it just sort of fitted in.*
>
> *Participant 5, Club13, 12-week FGD*

Similarly, another participant noted that concerns about his high blood pressure prompted him to think about joining FFIT to lose weight.

> *I just wanted to lose weight. I mean, I've been on blood pressure tablets for, I dunno [don't know] – three or four years. That's something I've never particularly taken seriously, but you should take it seriously, obviously. It's not a good thing. My doctor's often said to me, 'Lose that weight, you never know, you might come off that medication!' Well, there's a goal in itself, I suppose.*
>
> *Participant 2, Club08, 12-week FGD*

Another very commonly mentioned 'push' factor was a desire to 'be there' for family. This referred both to the present, what they wanted to be able to do *now* with or for family members, and to the future, through an expressed desire to survive long enough to support their families over coming decades and to see their children grow up. As one man put it, when describing why he took part in FFIT:

> *And plus the fact I've got a nine-year-old daughter, and she was beginning, it was beginning to tell when, if she was even swimming, I was swimming with her and I couldnae [couldn't] keep up with her. She's only nine, and that was the real, you know, sort of slap in the face, if you like, for me to say to myself, 'well, I've really got to do something,' because she's getting fitter and fitter. She's only nine, but what happens when she's twelve and I can hardly run a hundred yards without [without], you know, breathing really heavy?*
>
> *Participant 6, Club10, 12-week FGD*

These push factors correspond to what the ROMEO model[10] describes as history and personal motivations for weight loss.

At the same time, they were powerful 'pull' factors that drew the men to the programme. The most important of these were the programme's delivery within the football club; being with people like them (men who were perceived to be like-minded and like-bodied); and the group format with opportunities to interact with other men. The football club setting was very important for most of the focus group participants and was frequently discussed as a very important 'pull' factor.

> *I think the big pull was you're actually going to [Club12] to do it. So you're going to a club where you're spending a lot of time, anyway, coming to watch games and following the team. And, a bit like saying, well, like-minded [Club12] fans, and that's really, I think that was the big pull in for me.*
>
> *Participant 1, Club12, 12-week FGD*

Equally important in many discussions was knowing that the programme would be for people like them: men who liked football and were of similar ages, sizes and levels of fitness. The following exchange is a good example:

> Participant 1: *I think the thing, also, about what we went through, as well, was, I mean, the common denominator is football. We all like football, you know? And that gets us all going.*
>
> Participant 4: *Of course it does.*
>
> Participant 3: *That was it.*
>
> Participant 2: *The good thing, to me, is I didnae [didn't] like going to a gym. I would prefer to go to a class, or have somebody telling you what to dae [do] and what not to dae [do]. It was kinda like, I don't want to go to a gym and see all the younger ones, the fitter ones – and you got a kinda, you look roon [around] and you think they're looking at ye [yourself]. 'He's that fat he cannae [can't] even dae [do] that.' And that was the kinda thing I liked. You come here, everybody was in the same boat – everybody was between a certain age and overweight, coz that's how I got into it.*
>
> *Club10, 12-week FGD*

Linked to the importance of being in a group of like-minded (and like-bodied) men was the feeling that pursuing weight loss in a group setting would make the task easier:

> *Yeah, that was part of it as well, and as you says aboot being at [Club09 stadium] – that was another draw, being at your local club, being about the place. I just agree with what everybody's saying – coz you're doing it in a group, it's so much easier. You're encouraging each other and you're happy to see other people getting on and losing weight – no' just the losing weight.*
>
> *Participant 3, Club09, 12-week FGD*

These 'pull' factors correspond to what the ROMEO model[10] describes as engagement. Men saw the programme as being in the *right* setting and circumstances to support them in losing weight and commonly articulated that the FFIT programme was an 'ideal' opportunity to translate an emerging or conscious desire to lose weight into action:

> *I've struggled with my weight since, maybe, early twenties and I've tried various diets, various things, and you seem to get to a stage where you're successful, then you fall back out the way again. So, when I seen this advertised in the paper . . . the main thing that drew us to it was because it's [Club07]. You're going to be involved at [Club07], whether it just be at the ground, stadium . . . That was what really attracted me to it.*
>
> *Participant 1, Club07, 12-week FGD*

There were many similar examples of men discussing the synergy between their (developing or long-standing) *motivation* to lose weight or get fit ('push' factors) and the *opportunity* to take part in a programme in their club ('pull factors') and the ways in which this encouraged their initial engagement.

Figure 13 illustrates how the combination of 'push' and 'pull' factors, together with the increasing awareness of the opportunity to enrol for FFIT provided by the multifaceted recruitment strategy, were sufficient to encourage men to register their interest in the programme. Thus, in line with the COM-B model, the focus group data repeatedly provided accounts of men who *wanted*, and were *motivated*, to lose weight for whatever reason and for whom the FFIT programme was an appealing *opportunity* to engage.

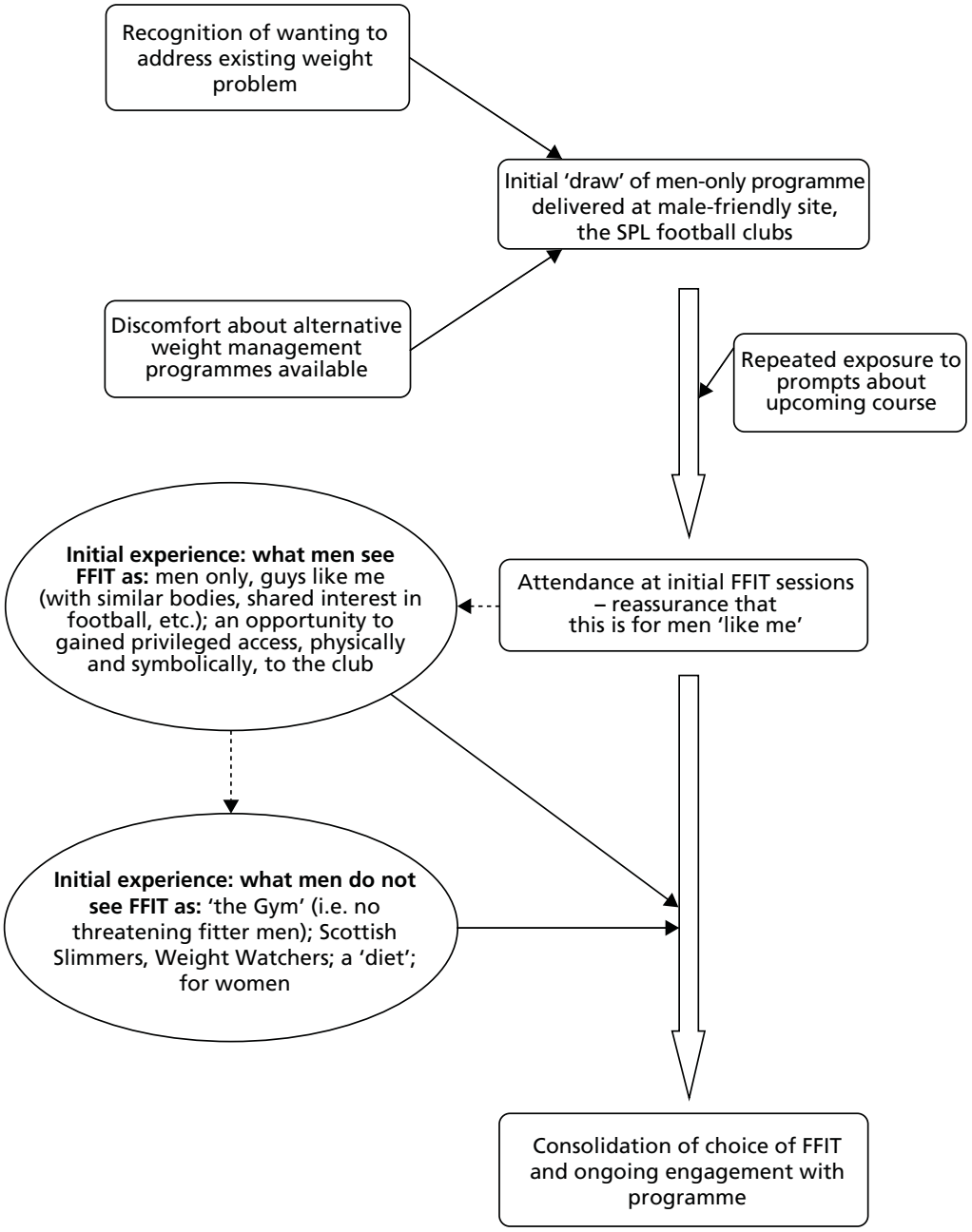

FIGURE 13 Factors attracting men to take part in FFIT: the power of the 'draw' of the football club for themselves and other like-minded/like-bodied men. Reprinted with permission from Hunt K, Gray C, Maclean A, Smillie S, Bunn C, Wyke S. Do weight management programmes delivered at professional football clubs attract and engage high risk men? A mixed-methods study. *BMC Public Health* 2014;**14**:50.[34]

The powerful combination of 'push' and 'pull' factors is illustrated in some men's accounts of overcoming deep-seated barriers to taking part in a weight management programme. For example, one man described how his experience of attending baseline measurement in his club's grounds and discussion with the club coach afterwards had helped him to overcome long-held anxieties about tackling his weight problems:

> *I remember the first time . . . when you got weighed and all that sort of stuff [. . .] and I genuinely, I just didnae [don't] want to be here. I felt very nervous aboot [about] the whole thing, . . . It was very embarrassing. It's not now, but at the time, it was. At the time, I was like, 'Oh, this is terrible,' and aye, measuring my waist, and I came in here . . . That was the first time I met [Club07 Coach 1], and I genuinely thought, 'After I get out [of] here, I'm just going in the car, ignore the phone calls, ignore the e-mails, I'm not daen [doing] that. That's ridiculous.' And I sat in here with [Coach 1], and he was telling us, 'Right, you know, of course we train here, at [Club07's stadium].' And I thought, 'That's good. I wouldn't mind training here at [Club07's stadium] . . .' And after that, he said, 'Aye, ken [you know] what we'll do, we'll get you some training gear . . . you'll be running aboot [about] in the training gear.' And honestly, I couldnae [couldn't] get the grin off my face. I was like a bairn [child]. I thought, 'I want to be training at [Club07's stadium],' with the, you know, aye, with the kit.*
>
> *Participant 4, Club07, 12-week FGD*

Others expressed their worries about weight management in different ways, such as a fear of being so overweight, unwell or unfit that they might be rejected when they applied for FFIT.

Men's very early experience of the programme reinforced their view that FFIT was the right programme for them and increased early engagement (see *Figure 13*). Men articulated this in relation to gaining privileged access to club facilities (e.g. home/away changing rooms, the tunnel, pitch side), as noted in the two examples below:

> Participant 1: *I'm a fan, and I think that helped a lot . . . the fact that I was coming to [Club05 stadium] and going into the changing room and stuff like that . . . I mean, it was just nice. And you felt kinda part of it . . .*
>
> Participant 3: *The fact, walking about the stadium, up and doon [down] the stairs.*
>
> *Club05, 12-week FGD*

> *Just the enjoyment of coming along and being involved in the club . . . even walking round [Club04 stadium], to me, was an exciting part of the Monday night . . . walking up and down the terraces. You might only be restricted to one area when you come to a game, but, you know, the fact that you've got carte blanche, you can go wherever you like, other than the pitch.*
>
> *Participant 1, Club04, 12-week FGD*

Thus, FFIT was able to harness men's initial desire to 'do something' about their weight, fitness and health with the deep symbolic and cultural attachments to the football clubs that many participants held. Many had supported their club since they were boys and the chance to take part in a weight management programme which gave them enhanced physical and symbolic access to that club, its coaches and like-minded fans was sufficiently powerful to overcome any reservations they may have felt about signing up for the programme (see *Figure 13*).

As discussed later, this powerful attachment to the club was also important in retaining men's engagement with FFIT once they had started on the programme (see *Process outcome 2: reasons for participating/opting out*).

Attendance and opting out of Football Fans in Training

Across the 12 clubs for which we have data, attendance was high. Participants attended a mean of 8.7 (SD 3.7) sessions during the 12-week programme; 78.9% of men (281/356) attended at least six sessions; and 61.8% attended at least 10 sessions (*Table 31*).

However, although attendance at the main 12-week programme was high, attendance at the 9-month 'reunion' was quite poor; 72% (261/365) did not attend. This may have been because the sessions coincided with the Euro 2012 football championship or because they were held in the 'closed' season when we know men often switch off from football. However, it may also indicate less interest in the programme 6 months after the main sessions had been completed.

Some men did drop out of the programme. Examination of participant attendance week by week over the 12-week programme (*Figure 14*) demonstrated that there was an initial drop-in attendance between sessions 1 and 5, after which attendance remained relatively stable until the final two sessions, when a further small drop-off was observed.

Table 32 shows the results from exit telephone interviews with the 46 'drop-outs' whom we were able to contact. The most common reason cited for dropping out was changes to work patterns that meant they could no longer attend (19/46, 41% of 'drop-outs'). Much less common were course-related issues, although seven men (15% of 'drop-outs') reported not being able to continue because of injury. Only one man said that he left FFIT because he did not like the classroom sessions and only two cited dislike of the physical activity sessions as their reason for dropping out. Of the 16 'other reasons' cited, four men said that the course did not meet their expectations and one felt he was not making sufficient progress. Not only were programme-related reasons for leaving the course uncommon, but some men stressed in the exit survey that they felt that FFIT had had a positive effect on their lives or health: 20% (9/46) reported that they had lost weight; 43% (20/46) said they had improved their eating habits and 24% said they were doing more exercise (11/46).

TABLE 31 Number of FFIT sessions attended

Number of FFIT sessions attended	Number of participants	Row % (base $n = 356$)	Cumulative %
12	74	20.8	20.8
11	87	24.4	45.2
10	59	16.6	61.8
9	29	8.1	69.9
8	15	4.2	74.1
7	10	2.8	76.9
6	7	2.0	78.9
5	13	3.7	
4	6	1.7	
3	11	3.1	
2	18	5.1	
1	11	3.1	
0	16	4.5	
Total	356	100	

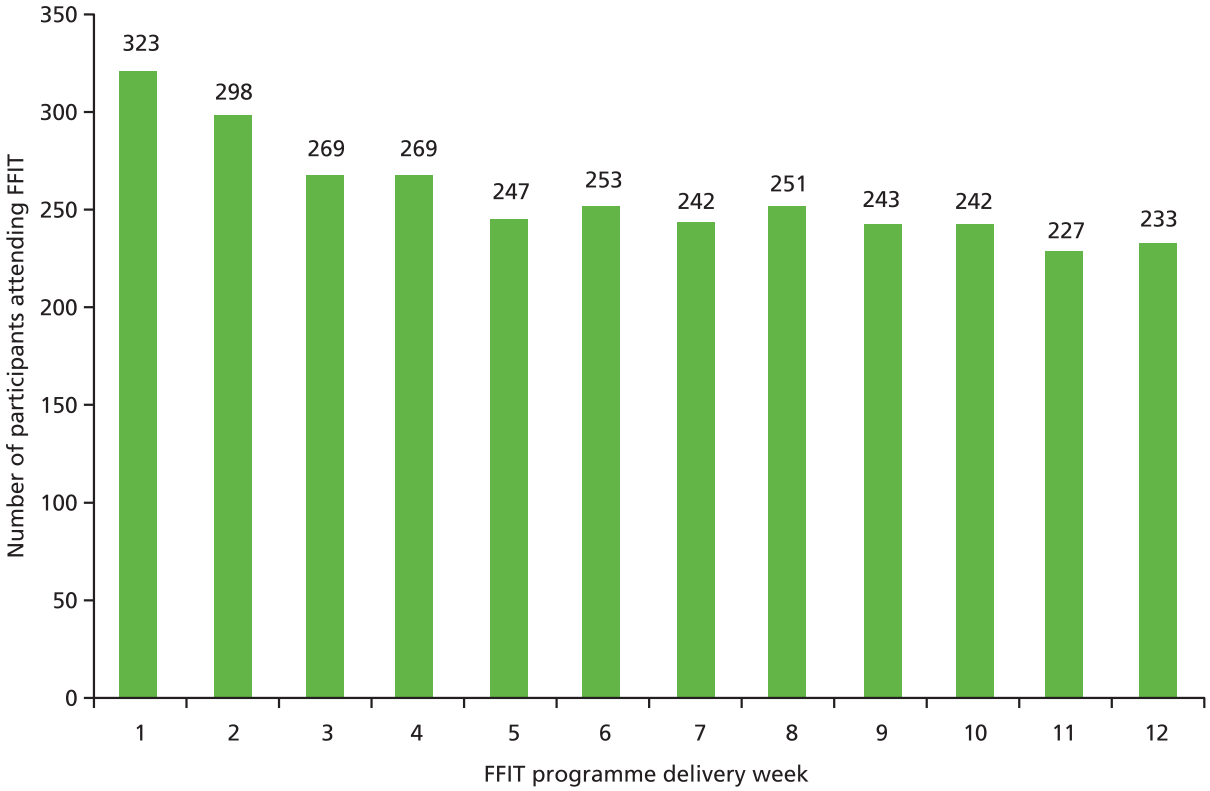

FIGURE 14 Number of participants attending FFIT by delivery session (of 356 for whom we have attendance data).

TABLE 32 Reasons for opting out of FFIT ($n = 46$; multiple responses allowed)

Reason	Number of times cited (% of all 46 responders to exit survey)
Changes to work commitments	19 (41)
Injury	7 (15)
Health reasons	5 (11)
Changes to family commitments	3 (7)
Could not devote the time needed	3 (7)
Did not like exercise sessions	2 (4)
Did not like classroom sessions	1 (2)
Other	16 (35)

Process outcome 3: the extent to which coaches deliver Football Fans in Training as designed (fidelity)

To address objective process outcome 3 we draw on data from the observations, the coach interviews after the initial 12 weekly sessions at the club and the weekly attendance sheets to consider whether or not the coaches delivered the programme as intended, the extent to which the coaches were judged to have delivered the key tasks in observed sessions and any problems or challenges with delivery identified in coach interviews and the researchers' observation field notes.

In the 12 clubs for which we have attendance records, all but two delivered 12 sessions over a 12-week delivery period as intended: one club (Club01) had to combine sessions 11 and 12 because of operational problems and another (Club04) had to cancel session 11 because of snow.

As we described under *Data source 5: observations of programme deliveries*, we observed two sessions in each club (26 in all) and each session of the 12-week programme was observed in at least two clubs. Therefore, we were able to calculate the number (%) of key tasks that could be delivered in each observed session and the number (%) of key tasks that observers judged to have been delivered as intended (*Table 33*).

Of 93 key tasks that should have been delivered in observed sessions, the observers judged that 81 (87%) tasks were delivered. *Table 33* shows that in weeks 3 and 12, fewer key tasks were judged complete by observers. Session 3 contained the most key tasks ($n = 6$), meaning that it was extremely challenging to deliver in a single week. Coaches were trained to ensure that delivery was highly interactive and to exercise flexibility in terms of the content and timings of each session to allow full discussion of the key points. The coaches were encouraged to reflect after each session, noting any key tasks they had not managed to deliver and to ensure these were delivered in future sessions. In session 12, two clubs did not record the final measurements because these had already been done by the research fieldwork team.

All coaches interviewed reported that the programme was enjoyable and easy to deliver. However, when pressed they identified some challenges, including the enthusiasm of the men during discussion of some of the key points. For example:

> *I think the notes are very comprehensive. If you've read through them beforehand and you've got them in front of you, it's quite an easy programme to follow, and most of the talking points, if not all of them, that you're asked to invite the men to talk about are very relevant, and they work really well in getting them discussing the issues and topics that are required. And it's, again, just looking at being flexible – so it might say ten minutes in the book, but it might take twenty minutes if you get a good discussion going about it. And just fitting the rest of the programme around that, whether you curtail something else in the programme. But everything in it is relevant. And it's just individual preference of how much time you want to spend on each thing.*
>
> *Coach 1*

TABLE 33 Key tasks delivered as intended in observed delivery sessions

Delivery week	Number of key tasks in delivery session	Number of sessions observed	Total key tasks that should have been delivered in the sessions observed	Number (%) key tasks judged to have been delivered as intended
1	5	2	10	9 (90)
2	3	3	9	8 (89)
3	6	3	18	11 (61)
4	4	2	8	8 (100)
5	5	2	10	10 (100)
6	3	2	6	6 (100)
7	3	2	6	6 (100)
8	2	1[a]	2	2 (100)
9	3	2	6	6 (100)
10	3	2	6	5 (83)
11	3	2	6	6 (100)
12	2	3	6	4 (67)
Total	42	26	93	81 (87)

a Availability of a club personality to attend during week 8 of the programme meant the key tasks for this session were moved to other sessions. This flexibility in delivery is in line with guidance provided during training.

Interviewer: *Spend on each thing, yeah.*

So some things you want to spend a bit longer, sometimes, not quite, or just the time, more.

Club06, 12-week coach interview, coach 1

Although the coaches welcomed the interactive nature of the sessions, there was evidence that on occasion this did cause some problems. For example:

> *I tend to find you just get caught up in questions from the guys which is, obviously they're needing that information so you try and give them that but you then become side-tracked. So you might very well miss stuff and I kinda feel that I did miss things like just simple things like explaining, I don't know, I can't remember off the top of my head right now but eh like wholemeal bread instead of white bread and things like that. Brown rice instead of white rice.*
>
> *Club11, 12-week coach interview, coach 2*

The observation notes provided some detail about ways in which coaches modified programme delivery when time was short. For example, on occasion very little time was allowed for a warm-down period after the physical activity session. Similarly, in later sessions the coaches did not always remind the men about their step count targets. Sometimes, when small-sided football games were used as part of a physical activity session, observers noted that these made it difficult for individuals to regulate their level of exertion: participants tended to push themselves further than they should have done. This emphasises the importance of including the RPE to help structure appropriate physical activity, particularly for those who are less fit.

Taken together, these data suggest that the frequency and coverage of the key tasks of the FFIT intervention were delivered largely as intended in the sessions observed. Coaches delivered almost all of the key tasks and largely succeeded in incorporating flexibility with regard to the recommended timings to allow the men to discuss relevant issues, while ensuring all of the important messages were delivered. Nevertheless, a weakness of our approach is that we were unable to observe all FFIT sessions in each club and we recognise that the observation and coach interview data may not capture any issues or departures from the delivery protocol that arose at other times. For example, during the 12-month FGDs, it emerged that operational problems had led to a delay in men receiving their pedometers in one club:

Participant 5: *Aye, and one of the things that helped me a lot was the pedometer. Because once we got it, and we were a while getting it, because it was about just how little you actually moved about and then you were making a bid tae try and get a bit better for the next week . . .*

Participant 1: *That's right, yeah.*

Participant 5: *And next week. So . . .*

Participant 3: *It was week 6 that we actually got that.*

Participant 5: *Aye, that was it and you're supposed to get it in week two.*

Club12, 12-month FGD

Process outcome 4: participants' views of Football Fans in Training, including satisfaction, acceptability and any unexpected outcomes (participants' experiences)

We now consider men's satisfaction with the programme, the extent to which different elements proved acceptable to them and any suggestions they made for potential improvements. This section focuses on the intervention stage of participants' weight loss journeys, in relation to the interactions between participants and with coaches during the programme, the content of the programme, the context in which it was delivered and the relationships that emerged with and between these factors.[10]

Satisfaction and acceptability

Overall, both men expressed very high levels of satisfaction with the programme and found its content highly acceptable, as succinctly illustrated in one interchange at the end of a FGD when participants were asked for their final reflections on the programme as a whole:

> Participant 1: *I would just have said it was one of the best 12 weeks.*
>
> Participant 5: *Aye, it was brilliant.*
>
> Participant 2: *That's one of the best things I've ever done in my life.*
>
> Participant 4: *To me, it's life changing. It was life changing, you know? Hopefully, you know, that you know, it will keep it up. I know I'm determined, I will keep it up.*
>
> *Club02, 12-week FGD*

Such spontaneous and enthusiastic praise was common, as one participant said:

> *I honestly can't praise it enough. I thought it was great.*
>
> *Club03, 12-week FGD, participant 6*

A number of factors, which are considered in turn below, are particularly salient in explaining these high levels of satisfaction: (1) the football club setting, (2) the delivery of the programme by club coaches, (3) men's enjoyment of interactions in the group and of being with men like themselves, (4) the content of the course and, (5) their experience of bodily changes over the 12-week programme.

The football club: branding and setting

We describe above how participants cited the location of the programme in the stadium and its close association with the football club as powerful 'draws' to the programme in the first place (see *Reasons for participation: personal motivations and the 'draw' of the football club*). These factors appeared to be equally important in men's continued engagement with the programme and were elements that men consistently said they liked about FFIT. For example:

> Participant 4: *One of the things that I found, and it's such a simple thing, [. . .] the booklet you got, first of all, from the club, with all the information on it – and I'm sure it's identical in all the other clubs had it – but the fact that they did the [Club03] crest on it, then, you kind of felt as if, yeah, you were part of a bigger thing, doing it. I know it seems like a really small, stupid thing, but that really did kinda hook me.*
>
> Participant 5: *You actually thought, at the end of the day, once you leave your group, you had your [Club03] jersey. You were actually doing it for [Club03], as well, not just yourself.*
>
> Participant 4: *Aye, that's right.*
>
> *Club03, 12-week FGD*

This exchange highlights the importance participants placed on symbolic representations of FFIT's proximity to the club – the crests on the booklets and the team shirts – that were harnessed in the intervention (see *Chapter 2, Gender sensitivity*). Another group conceptualised the connection engendered with club in terms of being part of the 'fans' team':

> Participant 5: *There's an ownership wi' [with] the club, or I suppose 'ownership' is probably not the right word, but you definitely feel a connection to the club that you maybe didn't have before. Even just the T-shirts we all got.*

Participant 2: *Aye.*

Participant 1: *Aye, it's like an identity. It's almost as if it's you become, I know this sounds crazy, but I had this in my head that it's all like, you know, I'm part of the team, the fans' team, you know? And it's nothing to do with that, but there is a kind of psychological part of that, as well – but I think that was one of the things that kept me going, as well.*

Club12, 12-week FGD

Thus, participation in the programme seemed to engage a new, enhanced, relationship to the club, symbolised through tangible markers or symbols. This enhanced closeness was also apparent in the way the men spoke of their enjoyment of being in the club grounds. For example:

Participant 1: *I think the other good thing was it's actually held here, in [Club08 stadium]. I remember, I think it was week 1 or week 2 and it was [FFIT participant] said, 'You know, it's unbelievable! We're here and we're in the stadium and, you know, we can go out to the park and things like that!' And that was encouraging a lot more than anything else.*

Interviewer: *Yeah.*

Participant 4: *A couple of people said, in our group that, 'Why did you not have it at [Club08 training ground]?' And they says, 'Well, we thought yous would all want to come here [stadium], rather than go to [training ground].' He says, 'Well, we could have went up to [training ground] one or two weeks of the course, like.' And then most people said, 'No, this is what we come for, to see this place [Club08 stadium].'*

Club08, 12-week FGD

Other men expressed pleasure at getting access to parts of the stadium they would otherwise not see, such as the changing rooms or warm-up facilities. Thus, the physical setting of the stadium provided a direct, ongoing motivation for continuing with the programme. This shows that the physical, not just the cultural, connection to their clubs was important for galvanising participant attendance, that the setting was as important as the branding.

Taken together, the data on the importance of the football club as *both* setting *and* brand suggest that another angle of analysis could usefully be added to the micro level of the ROMEO model by Robertson *et al.*:[10] the importance of objects. This resonates with Latour's suggestion that inanimate objects play an active role in the social, acting as mediators of social relationships that are far more durable than transient interactions.[112] The fact that men cited the club-crested T-shirts and books that they received and the stadia in which the intervention took place as significant reasons for continuation and satisfaction suggests that this analytical approach holds value and should be carefully considered in the development and delivery of interventions; other health interventions might increase engagement if they are able to integrate objects that are symbolically valued by participants.

The delivery of the programme by club coaches

When talking about their experiences of FFIT, participants often spontaneously attributed their high level of commitment to FFIT to the positive interactions they had had with the coaches that led the sessions. For example,

Participant 1: *And I think the two people that were running it were, you know, could have a laugh and, you know, there was wee jibes and jokes, so it was . . .*

Participant 2: *Yeah, it wasnae [wasn't] somebody just up there rattling change in their pocket and talking at you.*

Participant 1: *Aye.*

Club01, 12-week FGD

The importance of the genuine interest in the men that the coaches had shown was felt to set the tone for a sociable, enjoyable and motivational environment for participants; they had succeeded in promoting a very positive motivational climate in which the group could operate. Another aspect of the sessions that participants valued highly was the positive group interactions between participants on the programme and this too was something that was attributed to the coaches' style of facilitation:

> *And I think the club coach was a big part of that, bonding everybody together and I think we're lucky we got such a – he's a good guy. He knows what, he's very good at what he, at doing it and presenting it. So everybody felt quite comfortable as soon as he started on you.*
>
> *Participant 5, Club07, 12-week FGD*

Thus, coaches played a central role in the formation of the group and the fostering of group cultures. This was seen to be down to the engaging, knowledgeable and sociable approach they adopted while delivering the intervention, which really encouraged the building of relationships and to a genuine interest that they had in the participants.

Enjoyment of group interactions

Men's active enjoyment of group interactions and the relationships they developed with each other while on the programme was also an important contributor to the very high levels of reported satisfaction with FFIT. There were three features to this: team spirit, the sociability of the group and a sense of solidarity deriving from being with men very much like themselves.

All groups made reference to the *team spirit* engendered among those that participated in FFIT. For example:

> *I think self-encouragement is, we're there, because we're part of a group, we were all encouraging each other. It's not, you were no longer an individual. You were part of a team, and [. . .] I think it helped, and even although you had the book to start with, you could have flicked through the whole book yourself and worked it out yourself – I think you wanted the encouragement, as well, by going on to the next stage and having a wee bit of explanation. You can learn a lot from books, but the practical side, you learn a heck of a lot more from the practical side than you do from just the written word.*
>
> *Participant 1, Club08, 12-week FGD*

For this participant, the importance of working with others in maintaining commitment to and attendance at the programme was vital. As another participant put it:

> *There was a team spirit and you didnae [didn't] want to let the team down, you know?*
>
> *Participant 1, Club03, 12-week FGD*

This was also reflected in responses to the programme evaluation questionnaire; 277/316 (88%) of respondents reported that it was 'quite' or 'very' useful to hear how other men were getting on during the course of the 12 weekly session highlighting the vicarious learning that is a feature of group-based interventions.[113,114]

Related to team spirit was discussion of the *sociable atmosphere* in which the programme was delivered. The men joked, teased and supported one another and laughed together about incidents they related to each other, as illustrated by the next extract:

> Participant 1: *And the craic.*
>
> Participant 4: *And the craic was great.*

Participant 1: *The biggest thing, I think, in life, is laughing because, you know, aw [all] the chemicals go off and you know . . .*

[. . . discussion about a particular night].

Participant 1: *But things like that was just, and like, wee bits of banter when we're in the gym, or playing fitba [football] or that – you'd have a wee craic with somebody. And the laughter, when I played football – no' at a great level, like – but I used to prefer the training bit to the actually going oot [out] and somebody trying to kick lumps out of you. And that was the environment we were working in. It was almost, coz we had training every week, you know?*

Participant 2: *And it was completely non-threatening.*

Participant 1: *Yeah.*

Club02, 12-week FGD

Thus, within the football club setting, coaches and participants between them created a supportive, cohesive, non-threatening environment in which humour was experienced. This appeared to give meaning to the experience of taking part in FFIT that was said to be an important reason for continuing with the programme. For many, this was likened to other forms of sociality that they enjoyed in their day-to-day lives:

Participant 5: *It was [like] going to the pub for the banter withoot [without] the drink.*

Participant 1: *Aye.*

[Laughing.]

Participant 5: *You know? That's what it was.*

Participant 2: *Right enough, it just aboot [about] was.*

Club13, 12-week FGD

The comparison of the atmosphere within the sessions to the geniality, comfort and sense of belonging that men might experience with their friends in the pub, points not just to men's enjoyment of the sociality of the programme, but also to the ability of the programme to support group cohesion and demonstrates that its design successfully tapped into cultural frames that appeal to men.

Alongside enjoyment of the sociality and team spirit, participants often commented on the importance of the programme being aimed at people like themselves, in relation to age, love of football, love of their club and being aimed specifically at men only. For example:

I think it was quite good because your peers were people of possibly similar age, or within a reasonable age bracket of yourself. You were no gonna [going to], aye, you werenae [weren't] gonna have your twenty-year-old who could, maybe is slightly overweight, who'll find it easy to lose where, when you're a wee bit older, it's a lot harder.

Participant 1, Club08, 12-week FGD

The fact that the intervention was aimed at older men was often reported to be extremely important. Another perspective on commonality, a shared interest in the club, was frequently brought up:

> Participant 1: *The good thing was, straight from the start, we all had something in common with each other. Rather than being sixteen strangers, we'd all something in common, and that was the club and a love for it.*
>
> Participant 5: *Two things in common. We were fat and we supported [Club03].*
>
> Participant 1: *Sorry, we were cuddly and supported [Club03], and that was the big factor. So no matter, you met up the first few weeks, you didn't know each other's names, we immediately were able to converse with each other easily.*
>
> *Club03, 12-week FGD*

Thus, the combination of a shared passion and a shared problem allowed for the rapid consolidation of a group that they wanted to remain a part of and to high levels of cohesion. Others commented on another commonality, the fact that the programme was targeted at men, and contrasted FFIT to commercially available weight management programmes:

> Participant 5: *I think we were quite happy it was just men, to be honest. We spoke about going to Weight Watchers or that . . . but we were saying that, a lot of things are set up and it is mainly female – so it was good to see something that was just for male.*
>
> Participant 1: *For guys.*
>
> *[. . .]*
>
> Participant 1: *That's right. I think the majority felt that Weight Watchers was not for us. That was very much a women's thing.*
>
> Participant 2: *That's a ladies' thing.*
>
> *Club08, 12-week FGD*

Another group expressed these commonalities (and a humour typical of the groups) between participants very succinctly:

> Participant 1: *We're all similar, old, fat gits.*
>
> Participant 6: *Yeah, exactly.*
>
> Participant 1: *You know? And that was it.*
>
> P5: *You could count five points we all have in common, right? One – age. One – weight, yeah? [Club03] supporters, yeah? I've ran oot [out] of ideas on that.*
>
> Participant 6: *All want to lose weight, all want to get fit.*
>
> Participant 4: *Uh huh.*
>
> Participant 1: *Male.*
>
> Participant 2: *Hair falling out.*

Participant 5: *Yeah.*

Participant 1: *No, mine's fell out.*

Participant 5: *Every single one of us [over talking] has sort of, OK, I'll say three, four, five things in common, and that's the pulling thing for the whole lot.*

Club03, 12-week FGD

The humour, facilitated through group interactions and the tone set early on by the coaches, not only contributed to men's enjoyment of FFIT, but was seen as an important factor in enhancing participants' engagement with the course content:

Participant 5: *You know, outside what we did [i.e. activities to lose weight before FFIT], we're doing it because we feel we have to do it, whereas, what we did here [on FFIT programme], we wanted to do it. It was a pleasure, it was enjoyable, and it was great meeting the guys.*

Participant 1: *No, they were. I think they were, there's eh, you get a bit of a laugh with it, as well. It wasnae [wasn't] all, you know – it was a kind of learning, a wee bit of fun and exercise with a bit of fun, as well. So, although there was a serious side to it, there was also the, there was a wee bit of [pause] I mean, [pause] at some points, it was laugh a minute.*

Club12, 12-week FGD

For participants, behavioural changes encouraged by FFIT were transformed from an obligation – 'we feel we have to do it', to a desire – ' we wanted to do it'. Yet, this enjoyment enhanced, rather than detracted from, the 'serious side' of the programme: humour and fun were seen to facilitate learning and exercise, not impede them. It suggests that the high levels of group identity, which formed over the course of the programme, actually helped men to be even more committed to the changes they were making to their lifestyles. We turn now to men's views of the course content.

The course content

The men (and coaches, see *Process outcome 6: participants' experiences of maintaining weight loss and lifestyle changes in the longer term*) discussed how much they enjoyed and appreciated the actual *content* of the programme, in terms of classroom activities, physical activity sessions and 'homework' and skills they learnt on how to make behavioural changes. The content was seen as one of the reasons the programme '*was so good*'. Men commented on the style of delivery of the programme, which was non-didactic and based on adult learning techniques and on the value of graduated learning and the practicality of the skills learnt. They also valued the walking programme, the pedometers as tools for self-monitoring their progress with the walking programme, the self-monitoring of weight more generally and, to a lesser extent, the SMART goal setting. We discuss each of these in turn.

Men appeared to value the way in which the programme materials, supported by the style of delivery of these materials, encouraged them to build autonomy and take personal responsibility for their own behaviours. For example:

Participant 5: *They're giving us the tools – aye, but they're not telling us what to do. They're saying, 'You can do this. This would be beneficial to you.' They gave us that booklet and all the other tools and let us take them away.*

Participant 1: *It's up to you.*

> Participant 5: *And we've done what we've done with the basic information – and that's what's changed us all. It's, you know what I mean? Yes, the course has helped, and all the work that they've done and everything else. They've given us the tools and the opportunity, and we've taken it away, and everybody's nurtured it in a different way.*
>
> *Club10, 12-week FGD*

For participant 5 (Club10), then, the information was delivered in an empowering way as 'tools' to be used, not orders to be followed. The tools could be adapted and used in ways relevant and meaningful in the context of their own lives.

The modular, graduated, nature of the programme was also discussed in relation to building knowledge and skills over time. When one group was asked what it was about the programme that helped them make the positive changes they had just been discussing, a participant said:

> *I think coz it was in bite-sized chunks, you know? It was just like a week, every week was something different, so you could get stuck into it for a week, type thing. It wasnae [wasn't] like overloading, trying to maybe do different things, coz that would probably switch me off, trying to change diet portion control, going shopping, trying to, you know, look at the labels, etc. It was bite-sized chunks with an education. It was like going through modules, for want of a better word, which was quite good for me.*
>
> *Participant 5, Club08, 12-week FGD*

By breaking down the programme's educational content into 'bite-sized chunks', which were 'like going through modules', participant 5 (Club08) felt that the course facilitated positive change, a view endorsed by the coaches (*see Process outcome 6: participants' experiences of maintaining weight loss and lifestyle changes in the longer term*). He appreciated being able to focus on one new aspect of lifestyle change at a time.

Responses to the programme evaluation questionnaire also suggested that the course's educational content was important. The vast majority judged that the information about diet (302/316, 96%), food portion sizes (300/316, 95%), regular eating (291/316, 92%), daily calories and personal eating plans (296/316, 94%) was either 'quite' or 'very' useful. These judgements were supported by comments in the focus groups. The information on portion sizes and nutrition was particularly memorable for participants, as the following illustrates:

> *I got most of . . . the thing out the course I liked was the fact that I didnae [didn't] know much aboot [about] food labels and nutrition and what to eat and portion sizes – so the whole start of the course, rather than the exercise – the whole nutrition and aw [all] that, getting aw that in was good, because then I could sit doon [down] and say, 'Well, haud [hold] on. Looking at these Weight Watchers boxes and that, they arenae [aren't] good for you because there's still a lot of fat in them through cheese and aw [all] that,' which I never knew about. And then it's going home and educating my family to say, 'Well, we need to, instead of having this, we need to have that because, even though it does say it's good for you, it's no'.' So it was good to go back and educate my family, plus, then, empty oot [out] the cupboards and start again, and mair [more] fruit, and if I didn't like certain fruit, put it in a smoothie, and then you could have it, rather than just say, 'I cannae [can't] eat that coz I don't like it.' Bung it in a smoothie. You can have it then, because you're drinking it all in the one. So it was an education in food.*
>
> *Participant 2, Club12, 12-week FGD*

Thus, the information relating to portion sizes, nutritional values and food choice was a highly valued part of FFIT for many participants. They learnt to renegotiate their understanding of what an appropriate portion was for different foodstuffs and the course provided them with skills to scrutinise the content of the foods and to think about ways to include more nutritious foodstuffs into their daily diet.

More generally, participants commented on how useful they found the basic information and the very practical tips they discussed in the sessions, as illustrated in the following exchange:

Participant 4: *It's good stuff, aye. It's good.*

Participant 5: *It is really basic stuff. Nobody ever really has told me that before.*

Participant 4: *It's good quality information, wasn't it? It was good quality information.*

Participant 1: *Aye. People think it's going to be rocket science when you tell them what it is. You point to your pedometer, and then you say, 'By the way, you watch your portion controls and, you know, naan breads, this. . .'. Remember the naan bread?*

Participant 5: *Aye. 'Stop eating half the stuff that comes with curry!'. It's, like you say, no' rocket science at all.*

Participant 1: *Aye, and folk get surprised when you tell them.*

Club02, 12-week FGD

Many participants expressed enthusiasm about the new information and understandings they had gained about diet and physical activity. They appreciated the way in which the programme was set out to explain the importance of balancing calorific input and output while also providing skills to make easy, practical, changes to achieve this. One participant suggested that this 'scientific' or 'technical' focus was one of the reasons the programme was so appealing to many men:

And the other, the part of the programme that helped, I think, again, for guys, there was a technical aspect to it, as well, you know? There was a scientific, technical background, and I think guys, especially, will react to stuff like that, when it's put factual[ly] – it's not airy-fairy and there it is.

Participant 2, Club01, 12-week FGD

This resonates with culturally prevalent perceptions of gender roles and interests, which tend to cast men as practical, device loving and scientific. While these norms have and should be questioned, it is noteworthy that men perceived the FFIT intervention to be sufficiently 'scientific' and 'technical', but yet accessible and credible, expressed by some men through references to 'science' but not 'rocket science'.

We have previously demonstrated that men who took part in the pilot deliveries of FFIT responded extremely well to the walking programme as a first step towards regaining increased physical fitness and were enthusiastic about being able to monitor their progress with the pedometers provided.[31] In the FGDs presented here, men also repeatedly reinforced the views expressed by men on the earlier deliveries of FFIT and discussed how the walking programme supported them to build up their physical activity, typically from low levels of fitness, in a slow and graduated manner they felt suited them well. For example:

I think the pace of the course was good . . . if they put us in the gym the first week, most of us wouldn't have came back in week two. I'd have been out.

Participant 4, Club13, 12-week FG

Participant 6: *Walking is all I could have coped with, when I started out you know.*

Interviewer: *Yeah.*

Participant 6: *There's no way I could have done anything else. I couldn't have gone into a gym.*

Interviewer: *Yeah.*

Participant 6: *I certainly couldn't have gone out running, jogging or anything.*

Participant 6, Club05, 12-week FGD

The suggestion that the walking programme was a well-received component of FFIT was supported by responses to the programme evaluation questionnaire: 298 out of 316 (94%) of participants rated advice on walking either 'quite' or 'very' useful. In the FGDs, the pedometer was again seen as a key tool for monitoring and, thus, supporting achievement of their physical activity goals. It was seen as 'the best thing':

I think for me, personally, I started to think about what I'm putting in my mouth, now, and I started to think about an increase in exercise. The pedometer, for me, was brilliant because it made me go out and, I work in an office job, now – when I was a kid, I was very healthy, very active, played a lot of football, was super fit – but going into an office, you get out of the way of it. I was doing zilch exercise, and it [pedometer] gave you that incentive to go for a fifteen minute walk on my lunch break, and I started doing that, just to get my steps up – but it was for me. It made me change a lifestyle thing, change a habit into a good habit and then start doing more exercise.

Participant 3, Club13, 12-week FG

Thus, the pedometers provided participants with a tangible way of engaging with and adjusting their levels of physical activity. These data are again supported by the results from the programme evaluation questionnaire, which showed that 91% (288/316) found the pedometer either 'very' or 'quite' useful. The pedometer thus appeared to provide men with a concrete externalisation of their levels of activity that rendered an otherwise abstract and unmeasured aspect of their life visible and easy to manipulate.

One of the key BCTs known to be effective in weight management is goal setting and this is a key component of FFIT, in relation to both eating and physical activity. In response to direct questioning on how useful SMART goals were, some men discussed the difficulties they first had with setting SMART goals as well as how they used them effectively, at least in early parts of the course:

Participant 2: *The first one [goal-setting exercise], when you first got to it, you didnae [didn't] really ken [know] – then he sort of told you to change your goals to sort of exercise and try something different.*

Participant 1: *It was difficult. I mean, we had the first set of goals – and I can't even remember what my first one was. Lose three pounds in one week or something. Don't eat chocolate, I think, or something. And then, as the weeks went by, it was difficult to set yourself different goals – coz it was really the same thing you were doing every week, you know? The goals were the same goals, sort of thing.*

Participant 5: *Aye, you changed yoursel' [yourself] right from the start, didn't you? Coz everybody sort of said, well, I think it was after the portion size, I sort of looked at myself and thought, 'Right, well, I'm really going to have to drastically change the way I'm going,' you know what I mean? So from there it was like, well, what are my goals? Well, I'll put another fifteen hundred steps on. Right, no problem. I'll eat more veg. Well, I have been doing that. I'll cut out another thing and I'll cut out another – you know what I mean?*

Club10, 12-week FGD

Although the SMART goals proved to be 'difficult', as participant 1 (Club10) notes, participant 5 was able to recount the processes that this technique led him through, demonstrating the impact it had on his thinking, from the initial realisation that he needed to change his lifestyle through to the tangible and incremental actions he identified to help him achieve this change.

However, success in identifying and implementing SMART goals was not uniform and not all men found them useful:

> *To be honest wi' [with] you, I didnae [didn't] buy into that part of it at all, because I knew what, I knew, myself, what I was wanting to achieve, and I didn't – you know, I wrote them down, then thought, 'Right, ok, we'll try and do so many of these extra steps this week,' you know? But eventually, I did, I ended up just chucking it, because I thought to myself, 'If I keep to the step thing,' you know, the increasing the steps, 'and if I keep to the eating bit, I should be ok', you know? I mean, for some, maybe some people found it helpful – I don't know.*
>
> *Participant 1, Club01, 12-week FGD*

Thus, although the principle of goal setting is clearly important in the early stages of the programme, only some participants reported making use of SMART goal setting as the programme progressed, at least for eating goals. As Dombrowski *et al.*[58] suggest, different techniques may be more useful in the initiation rather than the maintenance phases of weight management.

Despite these mixed views of SMART goals, most participants found understanding their weight loss target to be useful, as reinforced by data from the programme evaluation questionnaire [in which 280 out of 316 (89%) participants reported it was 'quite' or 'very' useful to know their 5–10% weight loss target].

Experiencing successes

The experience of success, of progress, both individually and as a 'team', was reported to be highly motivating for participants. As one commented, when asked why the men kept coming back to the FFIT sessions:

> *It's the success. Success, because it breeds success, doesn't it, you know? If you're doing well and you get off to a good start, you want to improve and to go on and lose weight, and then you're, the sort of team thing comes in, where you're part of a team and you want to go forward as part of the team, and to make sure that we all do the same things and we're trying to encourage each other, as well.*
>
> *Participant 3, Club08, 12-week FGD*

Thus, the programme was seen to work, not just theoretically, but through, embodied, experiences:

> Participant 5: *I think also it works, or it certainly worked for the majority of people who went on it. I mean, I've done diets, etc. and not lost a jot, and the fact that, you know, you're going on the scales every week and I was losing weight was incentive. I think, probably, halfway through, if I hadn't been losing weight, I probably would have dropped out – but the fact that I was losing it, it was working, and it's continued to do so very easily, you know? Obviously reducing your calorie intake slightly – I mean, I haven't changed my life, eating-wise, hugely. Me breakfast, I certainly have, but other than that, I haven't changed it. It's actually the walking, and the walking has made the huge difference to me [. . .].*
>
> Interviewer: *And what kept you coming back, week after week?*
>
> Participant 5: *The fact it was working.*
>
> Participant 3: *Aye.*
>
> Participant 6: *Yeah.*
>
> *Club05, 12-week FGD*

For many, then, the achievements they realised each week led them to continue to attend the programme and fuelled their high levels of satisfaction with the programme overall. Many expressed a sense of

personal achievement, particularly when they had tangible evidence (such as looser clothes) or external verification (such as others commenting on how they looked) of their successes:

> Participant 3: *I think one of the nicest things, when you lose your weight, if you've been successful, to put on a pair of trousers you've no' had on for three or four years, and you know, just that nice feeling to think, 'Oh my goodness me' you know? Your notches on your belt and all the different signs that you track.*
>
> *[. . .]*
>
> Participant 2: *I think you get, I mean, when people, when somebody notices you get a wee bit, you feel a wee bit pleased, you know? If somebody hasn't seen you for a wee while and they say to you, 'Have you lost weight?' And you think, 'Well,' you know, you know you have, coz you've got the letter telling you – I think you do get a wee bit, aye, you feel quite pleased and quite, and a wee bit proud, you know? Coz it's not, nobody can do it for you. It's all very much been your own efforts. I mean, it is a very personal achievement, and you do feel, you get a wee bit, aye, you feel quite proud and quite pleased when people are noticing. [. . .] And I think when people are telling you you're looking better, it's a circular thing, you know? Just self-perpetuates, that's really what I'd say.*
>
> *Club08, 12-week FGD*

Further discussion of the importance of tangible markers of success emerged when participants and coaches commented on the use of physical representations of weight loss in session 7 of the programme:

> Participant 1: *Yeah, I couldnae [couldn't] believe it, when you were handed the [sand]bag and [coach 2] said, 'Feel that weight!' Because we didn't know [at first] what it was all about. 'That's what you've lost in the last . . .' what was it, 6 weeks, about week 6 or something, wasn't it?*
>
> Participant 3: *I'd lost eight bags of it [physical representation of actual weight loss], yeah, which was quite incredible, yeah.*
>
> Participant 1: *Yeah, could not believe it!*
>
> Participant 4: *That was the thing, when you seen the bags lying, you thought one was for every person that was there, but they gave you four. You're saying, 'No, no, that's not for me!'*
>
> Participant 1: *The other thing that amazed me was that lump of rubber which represented the fat.*
>
> *Club08, 12-week FGD*

Thus, the sandbags and other physical objects (e.g. replica lumps of fat in week 11), which were used to render weight loss visible and tangible, were another successful component of the programme. Men's recollections of seeing and handling these objects convey some of the excitement they felt at the time – 'I couldnae believe it' (participant1, Club08,12-week FGD) and 'it was amazing' (participant 3 Club08_12-week FGD).

When we explicitly asked about unexpected outcomes, the only ones mentioned, usually partly in jest, were the need to buy new clothes:

> Participant 5: *Do you know the only thing, it's costing me a fortune!*
>
> Participant 1: *On clothes.*
>
> Participant 5: *In clothes.*
>
> *Club10, 12-week FGD*

In summary, men recounted a strong experience of enjoyment while taking part in the programme and expressed very high levels of satisfaction with, and acceptability of, the programme. Several factors were repeatedly raised in discussions about what motivated them to keep coming along to the programme: the positive atmosphere fostered by coaches, the physical environment of the football club setting, feeling a part of and closer to the club (symbolised by the T-shirts and other branded physical objects), the enjoyment of the group interactions and feeling part of a 'team' indicating high levels of group cohesion and the satisfaction of learning tips and techniques for behaviour change for themselves and for others. Together these built to deliver tangible experiences of success in reaching their weight and physical activity goals, which kept the vast majority of men engaged throughout the 12-week programme.

Process outcome 5: coaches' experiences of delivering the Football Fans in Training intervention

In many ways the coaches' experiences of delivering FFIT mirrored the positive aspects of the programme that had been valued by men. They had observed, and enjoyed, the excitement and engagement that men felt in coming to the club each week. They also noted the largely positive interactions between the men that allowed them to learn from each other's experiences as well as from the formal course materials. And they also felt that the structure of the programme worked well:

> *I think it all kind of linked well with each other, like in terms of the weeks. Obviously we started off in terms of obviously the diet and then adding, having a little bit of physical activity and then obviously increasing the physical activity as you went along obviously helped with that. And then I think obviously having the weeks where you then obviously have the alcohol and things like that. Just giving them that sort of weeks where they do have sort of different things. So, it's not always just about the food, not always just about the physical activity. So, there are sort of weeks that sort of break up that sort of stuff, but then there are things that do. So, I do feel it kind of all linked in well together.*
>
> *Club13, 12-week coach interview, coach 2*

Like the participants, the coaches also recognised the usefulness of the pedometers in helping men get into routines of increasing physical activity and of self-monitoring. When the coaches in Club10 were asked what they thought about the use of pedometers within the programme, they said:

> Coach 1: *Massive.*
>
> Coach 2: *Aye cause it [pedometer] keeps them going, eh? Cause, they keep going, like they get into that sorta addictive sort of mode ae [of] checking every, like every day going 'Right, I still need to go and dae [do] another thousand'. So they go out and they'll like, they'll drag their dog out who's already been for aboot [about] five walks that day and they take him roon [round] the block just to get like those extra steps up. So they're constantly monitoring themself on this pedometer.*
>
> *Club10, 12-week coach interview*

Another aspect of the programme that the coaches felt was very powerful was men's reactions to seeing each other receive the tangible feedback on their actual weight loss halfway through the programme:

> Coach 1: *I think, going back to the difference that the, the sessions that made the difference, I don't know what week it was, but it was when they got to see, I think it was the halfway point, when we gave them bags of sands to show them what they'd lost.*
>
> Coach 2: *Week 6.*
>
> Coach 1: *. . . and you could see it, they were like 'Whoa!'.*
>
> Interviewer: *[Week] six or seven, yeah.*

> Coach 1: *. . . that's, and I mean the guys were taking the bags of sand home with them to show their wives.*
>
> Coach 2: *To show their missus.*
>
> Coach 1: *How much they'd lost because you could say to them well you've lost four kilograms or whatever and they'd be like 'Oh all right' but when you actually give them it, they're like 'Whoa!'. One guy, [FFIT participant], he had these bags in his hand, loads of bags eh? And it almost weighed the same as his kid. I think his kid was like three years old or something eh? And he was like 'I can't believe it!'.*
>
> *Club10 12-week coach interview*

Thus, here we see how the halfway session could be one of 'the sessions that made the difference' because it allowed men to make real life comparisons between the weight they had lost and an object they could hold, equating this to something meaningful in their lives, such the weight of a small child.

However, there were three areas that coaches felt could sometimes present difficulties. The first was the pressure of time. This was spoken about in relation to the actual delivery of the session and related to a tension they sometimes felt between allowing men to have a discussion that appeared important for a particular issue and needing to leave enough time to deliver all the key tasks for that week of the programme. A further time-related issue emerged from the coach interviews and this was a concern that other demands and pressures of their job as community coaches within the club could place on the time needed to attend fully to the paperwork that accompanied FFIT deliveries:

> *I think, wae [with] the overall programme, is that most of the guys [coaches at other clubs] that are responsible for delivering this . . . are football development officers, so they've already got a real hectic programme in place, anyway. So they're out doing development squads and loads of other stuff, and they've got lots of other stuff that they're involved in, lots of different programmes. We're the same, here at [Club08] – we've got education programme and social programmes, but we've all got small staff, in that predominantly, it's one person or two people if you're really, really lucky. So if something comes through that requires a lot of admin, the guys are like 'Oopf!', you know? [. . .] So I think, when there's a lot ae [of] admin there, the guys are like 'Phew, I'm gonna have to give more time to doing this.'*
>
> *Club08, 12-week coach interview, coach 1*

Despite considerable enthusiasm for the programme and what it can deliver for men and for society, coaches could feel under considerable time pressure while trying to get through this addition to their workload with few club resources. These pressures could influence the fidelity of intervention delivery if adequate support is not provided.

The second area that the coaches sometimes found difficulties with was overcoming differential engagement with SMART goal setting. They described this as something that suited some men but not others:

> *SMART goals tends to be something that's kinda come from business, I think, and it's a bit touchy-feely, airy-fairy. I think the guys come in with the same SMART Goal every week, and it's trying to kinda progress them there on from it. It'll work for some. Some people think differently. Some people like to list things and categorise things and how they work it out in their head and how I'm going to get from A to B. Some just do it a different way. So it'll fit for some people. It won't fit for all of them, though. Yeah.*
>
> *Club01, 12-week coach interview, coach 1*

Given that coaches and men (see *The course content*) noted such a range of reactions to SMART goals, it might be suggested that future interventions consider deploying a range of approaches to goal setting. This could help increase engagement by ensuring that approaches that have negative associations (e.g. SMART goals and work/business), can be replaced where necessary with an approach that is more acceptable.

The final aspect of the programme coaches sometimes found challenging, related to a medical responsibility they often felt towards participants. Although participants were screened for their readiness to take part in physical activity (see *Chapter 2*, *Physical activity components*) and strict blood pressure cut-offs were put in place for those at the highest risk of an over exertion-induced health event (see *Chapter 2*, *Participants*), coaches were aware that these precautionary measures were by no means fail-safe.

> Interviewer: *Mm hmm, and I suppose there's things like guys who maybe have high blood pressure and that sort of thing, that has to be . . .*
>
> Coach 2: *Things you maybe don't – obviously, we don't deal with that in a football centre, or one of the coaches wouldn't have to deal with this. You're working with a wider range of age as well.*
>
> Coach 1: *That's certainly an issue. That is certainly an issue from our perspective, the fact that we do first aid courses for sports injury or emergency first aid. The client group that we have, Football Fans in Training, are completely different and probably, I think, the benefit of having someone with more medical background and medical knowledge would be, I think it would be important. I think it would be important because we're dealing with guys, here, who, as I say, at the start of each course, someone at one of the clubs will die during this course – not because of the course, but just because of the condition that that type, that person is in. Now, fingers crossed, that's never happened so far, on site or on course, but who's to say it wouldn't happen? And that added responsibility for a coach, I think's extremely demanding.*
>
> *Club05, 12-week coach interview*

Thus, some coaches expressed concern about the amount of responsibility they felt they carried in relation to men's health risks. Accounts such as these suggest that the FFIT programme could include more detailed first aid, medical emergency and medical risk training for coaches, with a particular focus on the kinds of issues that men eligible for FFIT are more at risk of experiencing. They also point to the importance of coaches adhering to the guidance to make sure men work at a level of exertion that is appropriate to their own level of fitness. Alternatively, coaches could be relieved of some of the sense of responsibility by a waiver signed by men themselves that they are happy to bear any responsibility.

From the interview data presented here, we are able to conclude that the programme was highly acceptable to the coaches who delivered the FFIT programme. They reported enjoying the delivery experience, finding the course well structured and resourced, and felt comfortable dealing with the questions asked by participants. Coaches also judged the pedometers, self-monitoring and tangible weight loss feedback (in the form of sandbags or a lump of fat) to be central to the success of the programme and stressed that the group context in which these BCTs were practised strengthened their efficacy. Alongside these positive judgements, coaches pointed to the challenge of fitting FFIT into their busy coaching schedules, the need for a more diversified approach to goal setting and the benefit they feel they would receive from more detailed training in how to respond to exercise-related medical emergencies in the overweight and obese men that FFIT targets.

Process outcome 6: participants' experiences of maintaining weight loss and lifestyle changes in the longer term

We now consider men's experiences of maintaining the weight loss, physical activity and dietary changes they had made during the initial 12 weekly sessions at their club once these had finished. During the 9 months following the active phase of FFIT (i.e. until 12 months after they had started the programme), participants received 'light-touch' weight loss maintenance support incorporating six passive e-mail prompts (see *Chapter 2, Format of the programme*) and a poorly attended reunion 9 months after they started [see *Process outcome 3: the extent to which coaches deliver FFIT as designed (fidelity)*]. The results below draw on the 12-month FGDs to describe men's experiences of trying to maintain weight loss post programme, and include perspectives from men who had been successful and less successful in maintaining weight loss. We describe factors that facilitated and hindered attempts at maintaining weight loss in turn. As described under *Qualitative data from focus group discussions, coach interviews and observational data*, our analysis was guided by SDT,[109] which describes processes essential for behavioural persistence and psychological well-being, including feelings of autonomy through the internalisation of motivations, increasing feelings of relatedness and of competence in performing behaviours.

Factors that facilitated weight loss maintenance

During the FFIT programme, the coaches had provided clear, easy-to-follow advice about how to lose weight by adopting healthier eating habits. The men were shown practical examples of how to reduce portion sizes and how to make better food choices (by swapping energy-dense foods for nutrition-dense foods) and learned about the benefits of regular mealtimes. This learning was reinforced through group discussion about adapting this information for their personal situations and the use of goal setting and action planning. At 12 months, members of the FGDs who had successfully maintained weight loss described following the lessons learnt on eating in ways that best suited their own lifestyle:

> *We stick to the Eatwell Plate, we've got that up in the kitchen which is good, it's a good reminder, you know, when you're doing the shopping we check out all the, you know, the various fat content, sugar, salt, things like that.*
>
> *Participant 5, Club02, 12-month FGD*

> *Instead of eating at 11, 12 o'clock at night when I come home from work (having a big plate of food), stopping suppertime, 5, 6 o'clock, no matter what I'm doing, and having a meal. I've managed to do that. I've had breakfast in the morning, dinner and I have a supper at night. And it's just maintaining that, and then that stops all form of binge eating, grabbing what you can sorta stuff, you know? It's just certainly giving you a structure for eating like that.*
>
> *Participant 1, Club06, 12-month FGD*

> *My eating habits have totally changed and that's since I've started the programme to now, and I don't think I'll ever go back to where I was. I mean, even things like, it's just a small thing, but I got a tub of Mackie's ice-cream, you know, the two litre, and before, I was sitting with that and eat it, maybe not eat it all obviously, but you know, I'd eat part of it. And now what I've learnt is, because what [coach 1] was saying . . . I put it into a bowl, I put the ice cream away, so that I'm only eating that specific amount, rather than eating a whole lot.*
>
> *Participant 6, Club07, 12-month FGD*

These extracts illustrate how being able to make autonomous choices about how to change their eating habits had helped the men sustain the improvements in the longer term.

Another way that FFIT had tried to support weight loss maintenance was by promoting the ongoing use of self-monitoring, which has been shown to be associated with weight loss maintenance.[58] Towards the end of the active phase, the men were encouraged to continue to weigh themselves regularly and to use their pedometers to monitor and record their physical activity levels as part of their weight loss maintenance strategy. Many (but not all) men had found this advice helpful:

> *I find that the pedometer, even now it's my conscience. If I can look back 7 days and say, 'Phew, I'm only averaging about 7000. I usually should be doing eight or nine', it'll make me go for a longer walk some time later in the week.*
>
> *Participant 2, Club10, 12-month FGD*

> *[Weighing myself] it's my motivation. It's the fact 'Shit I've put on four pounds here in a fortnight!' So it motivates me to do a bit more, eat a bit better so that's my own self-monitoring motivator and that's what I've always stuck to myself. 'Cause if I didn't do it then I just would not bother my shirt, you know.*
>
> *Participant 3, Club09, 12-month FGD*

Once again, the FGDs provided evidence of how men had made their own choices over how to apply advice around ongoing self-monitoring: some continued to use their pedometer, others to weigh themselves regularly, while one man described using internalised somatic and psychological cues to regulate his eating and physical activity. For some participants, maintaining weight loss remained effortful and while there was little evidence that men had continued to use SMART goal setting and review, some had found the action planning they had learned to use during FFIT was helpful in maintaining behavioural change:

> Participant 3: *I think the thing for me is actually the planning of stuff because you tend to need to plan a bit more about your activity. You know about how, if you want tae walk you're gonna have to plan about 'When am I gonna walk?' An' also I quite often end up staying at hotels or whatever for work, an' you have to know, 'What am I gonna eat? Where am I gonna eat?' So you have to do a bit more planning about how you do that. [. . .] You have to sort of try an' work something out there so you don't end up goin' to [a bakery] or whatever.*
>
> Participant 1: *You have to plan your [food] shop as well.*
>
> Participant 3: *Yeah (nodding).*
>
> *Club05, 12-month FGD*

A clear message that was emphasised during FFIT was the importance of men feeling comfortable with the changes they made to their eating habits and not feeling they had to totally deprive themselves of foods they really enjoyed. Many of the men who had been successful in maintaining their weight loss had adopted a flexible approach (e.g. allowing themselves to eat unhealthy foods on occasion). Men who had tried to follow a more rigid eating regimen during the active phase had found this more difficult to sustain afterwards:

> *My diet changed a wee bit because I wasn't sorta eating healthily or as much as I was when I was involved in the twelve-week programme. I don't know if that was me, just, I don't know, it's, just found it quite difficult to stick to the eating plan because, you know, you had, for that twelve-week period, I done so well losing so much weight and I don't know if I found it, did I find it boring or some of the things that? I know I've gotta try and eat five bits of fruit every single day, and I just found or, you know, your veg as well, sometime I just couldn't do it.*
>
> *Participant 1, Club08, 12-month FGD*

Finally, following the active phase of FFIT, the coaches sent participants e-mail prompts every 6–8 weeks that were designed to support the maintenance of weight loss, physical activity and healthy eating and the men were invited back to attend the 9-month reunion meeting at their club. There was some confusion in the FGDs over the 9-month meeting. Some men appeared unclear whether they had attended it or not and, as we saw under *Attendance and opting out of Football Fans in Training*, very few had attended the sessions. The utility of the e-mail prompts was also the subject of some debate:

> *The prompts have been good from [Club02 coach] and some of his prompts about getting through yourselves as well, just to say, 'Look, you know, how are you doing?' and that type of thing. You felt, still feel part of it even though [. . .] no I found them, you know, they're very good, you know, 'cause it gets you thinking again, you know, right okay, you know. And there's this, you know, we're doing this and we're doing that. That type of thing.*
>
> *Participant 5, Club02, 12-month FGD*

> *I just got the impression these were e-mails that had been sent by the people at [Club01] so they can fulfil the criteria required to get to do this Football Fans in Training. 'We did what we had to do, we had to send out an e-mail periodically.' It didn't seem that it was anything really in it. It was just a case of, 'Right we've now met every criteria we've to complete the thing.' That's all I felt it was. I didn't get anything from that, to be honest wi' [with] you.*
>
> *Participant 1, Club01, 12-month FGD*

It therefore appears that few of the men had found the 'light-touch' components of the weight maintenance phase of FFIT particularly useful. They preferred to select the tools and BCTs that were most salient to them and which best suited their lifestyles as they tried to maintain their weight loss, physical activity and healthy eating.

Self-determination theory also argues that people who feel *intrinsically* motivated (e.g. who do something because they find it interesting or beneficial) are more likely to sustain a behaviour than those who are *extrinsically* motivated[109] (e.g. who do something because someone else has told them to, such as eating smaller portions because the FFIT coach has suggested you do it). The contributions within the FGDs of men who had successfully maintained weight loss were certainly congruent with SDT as we show below.

Deci and Ryan[109] describe three stages in the internalisation of regulation. The first stage is 'introjection', when a person manages to regulate his or her own behaviours, but this is driven by external values. The result is that positive (e.g. pride in personal achievement) and negative emotions and external factors become important sources of motivation. There was evidence of this in the FGDs:

> *I think the information you got has increased the guilt conscience more. There's a bit o' [of] that in there to be honest. There's a bit o'[of] that that said 'Jeez, I suppose I better do something!' Not the driving factor, but certainly in there.*
>
> *Participant 1, Club09, 12-month FGD*

> *Something that was never mentioned when we did all this course was we were talking, we don't buy crisps now, we don't buy chocolate things. I reckon I probably spend ten quid a week less 'cos I'm not buying the rubbish that I was eating before in the evening.*
>
> *Participant 2, Club02, 12-month FGD*

Although introjected regulation of behaviour is more likely to persist than external regulation, it remains relatively unstable. Recognition that a healthier lifestyle can save money may be an example of introjected behaviour, but it also shows some elements of the second stage of internalisation, 'identification', when people recognise and accept the value of a behaviour for them. Deci and Ryan[109] argue that as

identification is associated with greater regulatory stability, it should be more effective than introjection in supporting behavioural persistence. Many of the FGD participants described their appreciation of how much better their positive lifestyle had made feel in themselves:

> *I would start to eat more greens, more – what I call wet food, you know. The vegetables, you know, the stuff that's carrying more water and towards the end of it, it clears out my system, it allows you to breathe, you feel fitter [. . .] you feel healthier, you feel more able to function.*
>
> *Participant 3, Club01, 12-month FGD*

> *We all know once you've done the exercise how you get a buzz out of it – endocrines is it or . . .?*
>
> *Participant 2, Club10, 12-month FGD*

> Interviewer: *Endorphins?*

> *Endorphins, aye. But, you start to – I wouldnae [wouldn't] say you start to be a junkie on them, but your day does feel different if you've done that, and I now have that discipline.*
>
> *Participant 2, Club10, 12-month FGD*

The third stage of the internalisation process, 'integration', occurs when people fully assimilate their new behaviours with other aspects of their personal values and identity. The result is complete self-regulation, which is the most stable form of regulation and is most likely to support long-term maintenance of weight loss-related behaviours. A few of the men who had been successful in maintaining their weight loss appeared to have achieved a new, coherent sense of self:

> *I used to, when I was out in the car look at people runnin' out in the street thinkin', 'God, they're really keen, they're [pause] look at that idiot!' But that's now me [points thumb at self]. So it's . . . I dunno, it's just a perception, I couldn't have done it before. An' even things like runnin' across the road to the shop when it's rainin' an' runnin' back to the office. I'm not outta [out of] breath when I come back in an'. . . you realise that and you remind yourself how much better you've become because of it.*
>
> *Participant 3, Club03, 12-month FGD*

However, a FGD among men who had experienced mixed success in weight loss at 12 months suggested they had been less successful in internalising their new behaviours:

> Participant 3: *I don't feel that, I don't feel I've changed at all but I feel that, you know, that my habits have changed and, you know, eating habits.*

> Participant 5: *As I was saying, I'm wi' [with] you on that, it's like I think I'm the same person, but I know a lot of my habits have changed. I mean, is changing your habits changing the person? I don't really think so.*
>
> *Club07, 12-month FGD*

Taking part in FFIT therefore helped some men internalise extrinsic motivation and develop different degrees of self-regulation of their new weight loss-related behaviours. Many appeared to have moved beyond 'introjection' to 'identification' and a few appeared to have developed the highly stable 'integrated' self-regulation that SDT suggests is most likely to be associated with long-term maintenance of behaviour change.

Self-determination theory suggests that for fully integrated motivation (regulation), two other universal needs are necessary – feelings of *relatedness* and of *competence*. Again, there is evidence of increasing experiences of each of these as facilitators of maintenance of weight loss.

We have seen how much men enjoyed interacting with one another in the 12-week programme (see *Enjoyment of group interactions*). In some clubs, men had continued to meet up to exercise together regularly after the 12 weekly active phase of FFIT had ended suggesting very high levels of group cohesion and social identification. Some of these ongoing groups were organised by the FFIT coaches and a couple were held at the clubs; others were organised by the men themselves and took place at local community venues. FGD participants appreciated these opportunities to keep meeting up, irrespective of how well they were doing in maintaining their weight loss:

> *I was still struggling, but the coach organising the Monday night thing was a Godsend to me 'cause I coulda [could have] easily have just slipped into bad habits again.*
>
> *Participant 4, Club13, 12-month FGD*

> *Aye, it's really like . . . I mean, the physical activities, I wouldn't say almost are a by-product of it, but, you know, we go round there and everybody's sorta common goals or aims; and, like I say, we've got common setbacks a lot of us, you know, and things like that. And you, and like you say, it's like a support group, as such, 'cause we're all in there, everybody's there for the same reason sorta thing, so it's a good sorta almost like a, what's the word I'm looking for? . . . Safety valve almost, you know?*
>
> *Participant 5, Club07, 12-month FGD*

Some men were not able to make these meetings; others had taken part in FFIT at a club where ongoing groups had not been set up. They described experiencing a real sense of loss when the active phase of FFIT had ended:

> *I would like tae have seen it [the active phase] just a wee bit longer . . . Even if it had went doon [down] from every week to know, maybe once a month or something like that? I think it would still have gave everybody the wee incentive to go along, share their experiences an' things like that. Pass on like the good habits, the bad habits – the good an' bad times an' things like that . . .*
>
> *Participant 1, Club05, 12-month FGD*

For other men, leading a healthier, more active lifestyle had helped them to become more involved in family life. For them, this was a really positive benefit that helped them maintain the changes they had made:

> *I must admit my kids have kept me goin' an' a lot of the—an' they're now startin' to drag their mother out as well when they're wantin' to go oot [out] for runs on their bikes an' things, an' that's made a big difference [touches nose] to keepin' you goin' when you get . . . If you're havin' a – you want tae [to] have . . . or feel like being lazy or tired, I've got one [child] at five an' one at ten an' they just want to be goin' all the time. So it does give you a good feelin' when they'll come tae [to] me if they want to go an' do somethin' that involves either runnin' aboot [about] or cyclin' aboot [about] an' the mum gets left, so . . .*
>
> *Participant 6, Club03, 12-month FGD*

For many men, feeling meaningfully connected to other people, both their peers from the programme and family members, was a valued outcome from taking part in FFIT and this continued to be an important factor for many in the period after the active phase. However, as the extracts demonstrate, satisfaction of relatedness was not necessarily associated with autonomy and increased well-being and, for some men, it was particularly important when things were not going well.

People are more likely to engage in healthy lifestyle behaviours when they have the necessary skills to perform them, and find them interesting and optimally challenging.[108] FFIT provided the men with a range of skills and knowledge about how to lose weight by improving their eating habits and becoming more active and the coaches were trained to further support the development of a feeling of competence

through providing positive feedback about the men's efforts and achievements. Men who had done well in maintaining their weight loss spoke with confidence about applying what that had learnt from participation in FFIT:

> *I feel I'm more knowledgeable about things as well. I mean obviously those were the main things, but I mean for instance food advertising and what they put on the labelling is a disgrace. It wouldn't be allowed in other fields, and yet you know they can get away with it. They're misleading, it's pretty bad actually, it's pretty bad and I'm aware of that now . . . it's changed the way I look at things.*
>
> *Participant 2, Club13, 12-month FGD*

> *So, I mean, I went out and bought a slow cooker and started cooking things like that, just using fresh vegetables putting things like that in it, meat joi— getting proper big meat joints and actually cooking them off and doing things like that.*
>
> *Participant 3, Club11, 12-month FGD*

Practice theory describes how 'novices' learn experientially and assimilate new behaviours into their routinised practice to become 'full practitioners'.[115,116] The FGD participants' narratives revealed a trajectory of increasing competence, confidence and habit formation.

> *I think now right the exercise . . . is a part of your way of life . . . used to be your work, sleep, up again, work, sleep . . . Now you make time, either once a day or at least a couple of times a week, to go and do that wee bit [of] exercise. Now it's, it just pushes you right on.*
>
> *Participant 2, Club10, 12-month FGD*

As their feeling of competence and expertise increased, men described how they and others viewed themselves differently. Some changed from 'novice learner' to fully practising 'carriers of practice' who took pleasure in sharing their new knowledge with their family and friends:

> *Everything about my life – and my children – even my children, you know what I mean . . . We'll walk to the shops, you know what I mean? Or they'll take their bikes. Any chance they've got to come out wi' [with] me they'll do it, so they've started tae [to] get more exercise, they've started to watch what they're eating, they'll not have chocolate cereal in the morning, they'll have normal cereal or they'll have porridge or that so . . . It's not just my aspect on life, it's theirs as well that's sorta benefited from twelve weeks.*
>
> *Participant 1, Club10, 12-month FGD*

> *The racquetball has been a revelation . . . Absolutely love it [participant 1 agrees]. And, you know, I've got to the point where I'm trying to sort of get of some of my workmates involved in playing as well now and I'm back down south next week and I phoned up my brother-in-law and said 'Do you fancy a game of racquetball?', sort of thing, so he's gonna give it a go.*
>
> *Practice theory 4, Club08, 12-month FGD*

The preceding sections have shown that men made autonomous choices over which tools and techniques they continued to use to maintain their weight loss and positive lifestyle changes after the active phase of FFIT. Many succeeded in developing some degree of internalised self-regulation and those who were successful in maintaining their weight loss and lifestyle changes spoke with confidence about applying their new knowledge both in their own lives and to influence other people. However, although continuing to meet up with other men they perceived as being 'like them' was important for many FGD participants, this was not always associated with weight loss maintenance nor the development of self-regulation; men who found it difficult to maintain their weight loss and lifestyle changes also valued the continuing camaraderie and social support from their peers. Many of the men reported facing a number of challenges in maintaining the changes they had made after the active phase of FFIT ended. The next section examines these problems.

Factors that hindered weight loss maintenance

As we have seen in *Chapter 3*, although there was a large difference in outcomes between the intervention and control group, less than half of the intervention group maintained at least a 5% weight loss at 12 months. Participants in the 12-month focus groups described a range of difficulties and issues they had encountered in trying to maintain their weight loss and positive lifestyle changes in the longer term, including specific events and more generalised barriers.

Most men reported some degree of success in maintaining increased physical activity levels after the end of the 12 weekly sessions. However, the most commonly reported barrier to remaining physically active was injury, which often occurred as a result of men's increased activity levels:

> *Couple of times wi' [with] me, I reckon I picked up [. . .] injury after injury at five-a-sides, and it was really frustrating 'cos I really enjoy it . . . I can hardly do anything for . . . I mean, I can hardly get oot [out] o' bed. So that's the thing that kinda puts me, sort of puts me back a bit. But that's . . . I maybe go back down tae [to] just doing walking and cycling and just doing stuff that's no' gonna have much impact in terms of your muscles and your bones so, and I could probably get by with that.*
>
> *Practice theory 4, Club12, 12-month FGD*

A number of men reported that changes at work had played a major role on their ability to maintain their physical activity levels after the active phase of FFIT. Sometimes these changes had a positive effect (e.g. starting new job and standing up all day), but more often the impact was negative:

> *I'm less active now 'cos I've moved offices. I used to park my car in near the [Local Bridge] and walk to my office. But, my office moved to the other side of the city centre, and it's now half an hour walk instead of fifteen minute walk. But I can't really afford an hour of my day walking to and from my car, and plus trying to get home and everything. So, I now get the underground, so that's less walking.*
>
> *Practice theory 1, Club01, 12-month FGD*

Three reported how health problems had limited the amount of physical activity they were able to do, as illustrated here:

> *Sadly after the course finished, I put on a couple of pounds over Christmas and New Year, which I wasn't too concerned about – got back on track in January – and I suffered much more serious haemorrhaging in my right eye, which I was very, very disappointed with because I'd got my blood sugar down and I'd lost a couple of stone in weight, and that really put me on the back foot. For six months I couldn't exercise, or I probably could have if I'd gone to a gym, but I had been doing all my work outside, walking and running in the streets. I couldn't drive at night, so that restricted me as well.*
>
> *Practice theory 3, Club12, 12-month FGD*

Taken together, these extracts suggest that adopting a flexible approach (finding different activities to suit different circumstances) is important for overcoming specific barriers to remaining physically active in the long term.

Most of the men had also experienced challenges to maintaining healthy eating presented by holidays and other special occasions (e.g. Christmas, weddings). A common response (as had been emphasised in the course material) was to view these events as temporary lapses that could be overcome by using the techniques and strategies they had learnt on FFIT:

> *Everything noo [now] is great. I was on holiday for the last fortnight there, I was in Florida, and I did put two or three pound on. But I came back on Monday there, and this is now Friday, and I've lost a pound again. Just because eating salads and stuff and goin' tae [to] the gym again.*
>
> *Practice theory 2, Club12, 12-month FGD*

However, occasionally, major events in men's personal lives had totally undermined their efforts to maintain change:

> *My brother passed away, which is one o' the difficult things. My dad became unwell, and so that was, that, a lot o' [of] that's kinda impinged in, you know . . . when my brother died, basically he died in his early fifties, so it's young. But it was his heart that caused problems, so you think that well that kinda would inspire you. But to a certain extent that was probably one of the worst times where, you know, things were going wrong, and it was just, you know, feeling bad and eating.*
>
> *Practice theory 5, Club09, 12-month FGD*

In addition to the challenges posed by specific events, the men reported a number of other, more generalised, problems they had encountered in trying to maintain their weight loss and positive lifestyle changes. These included not being able to find enough time to be physically active:

> Participant 5: *But I think this last year for me has been kinda busy, and the bits that you don't need tae [to] do get kinda left behind. So it will, so I think when you're that busy, sometimes when you get in at night and you think, 'Right, I need tae go for a walk', and you're thinking, 'Do you know, just no' got the energy'.*
>
> Participant 4: *Well, it's winter time isn't it . . .*
>
> Participant 5: *And it's just, there's no' enough time in the day. Then tae just, you know, sit back and gather your thoughts and things.*
>
> *Club09, 12-month FGD*

Despite discussion of strategies to overcome the negative influence Scotland's weather could have on people's motivation to be physically active during the active phase of FFIT, a number of participants still reported they struggled to keep active when the weather was bad:

> *Weather's the worst one, absolutely by a mile, because you would go, I would be, I'd be out playing golf and I'd gone for a walk. See when I'm on holiday, guaranteed, absolutely guaranteed, when I'm on holiday, other when I was on a cruise to be fair, but normally after dinner her [wife] and I'll go, and we can walk for Britain – literally hours on end, walk. And it's great, pleasure walking at night, cool breeze, all that – lovely. Come hame [home] that's . . . it's pissing from the heavens, an' I think, 'Nah, we'll no' bother' [participant 2 nods], just sit in.*
>
> *Practice theory 1, Club09, 12-month FGD*

For some men, the cost of healthy food and access to exercise facilities were significant obstacles to maintaining a healthy lifestyle:

> *Well, I find it's price of the stuff, prices you oot [out] o' [of] the market. See, I'm the oldest here. Now I'm a pensioner now, so it's difficult when you, when you're on the State Pension, especially when you're trying to pay for electricity, gas and stuff like that. And I've got my, gotta keep my car running.*
>
> *P6, Club08, 12-month FGD*
>
> *I find it's quite disappointing that sort of like [local public leisure facilities] are probably one of the most expensive ones in, you know, sort of, in Scotland. If you look at the prices of, you know, municipal leisure centres and all that around the rest of the country, [local public leisure facility]'s really quite poor in terms of what they charge.*
>
> *P4, Club08, 12-month FGD*

Finally, while other people were an important source of support for many men, their influence was not always positive or helpful:

> *My brother split up wi' [with] his missus, come doon [down], 'Would you like a glass o' water?' 'No! I've just spilt up wi' [with] my missus!' 'Right, have a beer then.' (Laughter.) I don't want a beer, you know? So there is a sorta wee daft things that go on. I can't believe his missus has left – that's really inconsiderate of her! Now I've got tae [to] drink one beer . . . (laughter). 'Have you any crisps?' Oh, he's only wantin' crisps as well! (laughter). I'm on a diet here!*
>
> *Participant 1, Club05, 12-month FGD*

In summary, although many of the men who took part in the 12-month FGDs appeared to be doing well in maintaining their weight loss and lifestyle changes, most had faced some challenges in the period since the active phase of FFIT ended. These included specific events such as injuries, changes at work, holidays, ill health and bereavement, and more generalised issues such as time and financial pressures, the weather and negative social influences. However, some of the men also reported how they had overcome these challenges through taking a flexible approach to being active and using the relapse prevention strategies (regular self-monitoring and recording of weight and/or physical activity, SMART goal setting) they had learnt on FFIT.

Chapter 6 Discussion

Introduction

Rising levels of obesity, particularly in men, and men's lower participation in existing weight management programmes[6] mean that there is a clear need for innovation in the design and delivery of programmes to attract overweight/obese men.[117,118] Professional sports clubs, and specifically professional football clubs in the UK, are increasingly seen as settings that can attract men to health promoting activities.[24,25] Pringle *et al.*[24] suggest that 'the product [i.e. football/EPL (English Premier League)] . . . the place (club stadia and facilities), people (players and management) and processes (including communication, marketing and the product delivery infrastructure)' all contribute to their appeal.[24] Our developmental[28] and pilot work on FFIT[31,32] and the process evaluation for this trial[34] attest to the power and cultural currency of this 'draw' for many men.

However, if the 'draw' of the football club is to be used to maximum public health benefit (and for maximum benefit for individual men), it is important that programmes delivered in these popular locations are based on best evidence about what works and reach those men most likely to benefit.

Our team have collaborated with the SPL Trust (now SPFL Trust) to design, implement and evaluate the FFIT programme. We have reported the development of the evidence-based programme[28] and on the conduct of a feasibility study.[32] In this report we build on existing peer-reviewed papers[33,34] to present the full findings of a RCT, health economic and process evaluation of the FFIT Programme.

Interpretation

This trial has shown that a 12-session, gender-sensitised, weight management and healthy living programme with subsequent light-touch weight loss support (including six e-mail prompts and a reunion session at 9 months) can help men achieve significant changes in objectively measured weight, waist circumference, body fat, BMI, blood pressure and self-reported physical activity, dietary intake, alcohol consumption and measures of psychological and physical well-being 12 months after baseline measurement. Mean weight loss in the intervention group fell only 0.04% short of 5% weight loss and is likely to be of clinical benefit. The only predictors of weight loss at 12 months were participation in the programme and baseline weight (with relationship with age of borderline significance); all other potential mediators and moderators that were pre-specified in our protocol were unrelated to weight loss.

Although the difference in weight loss in favour of the intervention group was highly statistically significant, as in other weight management research[119] we found small improvements in the comparison group in terms of mean weight loss, and 11% of these men (compared with 39% in the intervention group) had also lost at least 5% of their baseline body weight. We suggest a number of potentially interacting explanations. First, it could be argued that all of the men who attended the baseline measures recognised that they wished to lose weight and were motivated, to some extent at least, to lose weight. Second, the experience of undergoing the baseline measurements prior to randomisation (including measures of mental and physical well-being and self-esteem, etc.) may have had the effect of heightening their awareness of the need to lose weight as all men were shown where their current objectively measured height and weight placed them on the 'BMI Wheel' and were told that the evidence suggested benefits to weight loss among those who were classified as obese. Any men with blood pressure readings over pre-specified thresholds were also advised to consult their GP for advice. These measurements were successfully repeated in a high percentage (93%) of the comparison group 12 weeks later and this may have provided a second prompt or 'wake-up call' about their weight and overall health. Third, following

the baseline measurements, all men were given an advice booklet (British Heart Foundation's *So You Want to Lose Weight?*[42]) and had the chance to speak briefly to the coach about the impending FFIT programmes. Together, these factors may have been sufficient to help a minority of men in the 'waiting list' comparison group to lose weight independently, or to motivate them to find alternative resources to do so (although we know that a very small proportion had used existing NHS or commercial weight management programmes in the 3 months prior to any of the measurement sessions). Fourth, it is possible that some men allocated to the comparison group may have known men in the intervention group, or men who participated in the pilot deliveries of FFIT, and gleaned some details about the approach taken to weight loss in FFIT. Finally, our recruitment activities within clubs may also have changed men's views about the acceptability of weight loss in men in general, or among their football-supporting peers in particular. Taken together, these factors suggest that the difference in weight loss between the groups is a conservative estimate of what FFIT can deliver. It also raises the possibility that there may be some men who can be motivated to achieve weight loss independently if primed or motivated in the right settings and manner.

A recent systematic review reported only 11 other RCTs investigating interventions to reduce male obesity,[10] of which only three were of interventions combining dietary and physical activity advice with support for behavioural change (the approach shown to be most effective).[10] Only two of these three trials, both internet-based programmes with some one-to-one support, reported outcomes for both intervention and comparison groups to 12 months.[118,120] The weight loss reported in FFIT was substantially greater than the mean differences in weight loss of 2.20 kg (95% CI 1.25 kg to 5.65 kg)[118] and 0.60 kg (95% CI 0.14 kg to 1.52 kg)[120] reported at 12 months in these trials. FFIT is a more intense, although relatively inexpensive, group-based programme and is gender sensitised not only in content (as others also are[118,120,121]), but also context (the football club) and style of delivery (participative, peer-supported learning). This gave the men opportunities for direct group interactions in a valued environment, which were seen clearly to enhance the cohesion of the group and formation of a group identity, and the chance to build networks of social support during, and in some cases after, the programme. These differences may explain why weight loss was greater in FFIT than in earlier trials.

The weight loss that the FFIT intervention group achieved at 12 weeks was comparable to that reported in a UK study of primary care referral to a 12-week commercial weight management programme.[7] Stubbs *et al.*[7] report greater weight loss and percentage weight loss in men [weight loss at around 12 weeks: mean (SD) 5.8 kg (4.9 kg) in men and 3.8 kg (3.5 kg) in women; per cent weight loss at around 12 weeks –4.9% (4.0%) in men and –3.9% (3.5%) in women]. However, only 11% of the 34,271 participants were men and outcome data were available only up to the last session attended (with outcome measures collected as part of routine data collection within the referral programme) so there are no comparable data at 12 months.

The increase in self-reported physical activity suggests that men in the intervention group had taken the physical activity message 'on board' and changed their habits to include vigorous activity (such as attending the gym or playing five-a-side football) as well as more moderate activities including walking. Greatest differences in self-reported physical activity were seen at 12 weeks, but many were maintained to 12 months. The difference in total activity reported between the two groups at 12 months (844 MET minutes/week) equates to approximately 3–4 hours of walking, although the greatest difference between the groups was in MET minutes/week spent in vigorous activity. Qualitative data from the process evaluation supported our earlier findings about the popularity and utility of the pedometer-based walking programme as a means of helping men regain some fitness.[31] These data taken together suggest that the combination of regaining fitness through a walking programme, combined with the experience of undertaking physical 'training' activities guided by the coach each week, may have enhanced men's confidence and motivation to take up new forms of physical activity or restart more vigorous activities that they had enjoyed earlier in their lives.

The intervention appears to have had an immediate effect on reducing self-reported sitting time at 12 weeks. However, this difference was not maintained to 12 months. This suggests that, if the reduction of sedentary time is an important primary or secondary outcome of this type of intervention, this element of the programme needs further development to give greater emphasis and support to reducing sedentary time.

The reduced frequency of reported consumption of fatty foods, sugary foods (including drinks) and alcohol suggests that weight loss was in part due to decreased caloric intake. It is not possible to assess whether or not the total decrease amounted to the 600 kcal deficit recommended. However, the reduction in all food categories, and in reported portion sizes, indicate that a range of strategies were utilised, including reduced frequency of intake of main meal items, snacks and drinks. The range of high-fat foods included in the modified DINE questionnaire matched those targeted in the intervention (cheese, processed meats, fried foods and whole milk). Reduction in the consumption of these foods indicates a reduction in saturated fats as well as total calories, which is desirable for reduced cardiovascular risk, and it seems likely from qualitative data about reductions in portion size that changes in quantities eaten will also have contributed to lower energy intake.

The reported increase in fruit and vegetable consumption indicates that men took on board the strong messages that this was an area of consumption that they should strive to increase, at the expense of foods from less healthy food groups. Hence, the data suggest that the overall balance of the men's diet changed and the overall diet quality improved. Consumption of a greater proportion of plant-based items is associated with reduction of cancer and cardiovascular risk (especially combined with weight loss).[122] The increased consumption score for fruits and vegetables of 1.6 indicates an increase of one to two portions per day. Even modest increases in fruits and vegetables (e.g. increases by one portion per day) are associated with a significant reduction in CVD risk. In addition, increasing fruit and vegetable consumption by as little as an extra apple a day could cut the risk of dying early from any cause by 20% (irrespective of age, blood pressure or smoking status).[123] Current intakes of fruit and vegetables in Scottish men are estimated at three portions per day and trend data show no increase in intake in men in the general population despite significant public health efforts.[2]

The short-term within-trial cost-effectiveness analysis demonstrated that the FFIT intervention was inexpensive to deliver, with an additional cost of just £205 per participant. This analysis also indicated that FFIT is more effective than no active intervention, both in terms of numbers of men achieving and maintaining a 5% weight loss at 12 months (130 compared with 40) and in terms of QALYs (with a utility change of 0.029 over 12 months compared with a change of 0.014). As such, the within-trial analysis demonstrated that the FFIT intervention was cost-effective, with an additional cost per man achieving and maintaining the 5% weight loss at 12 months of £862 and an incremental cost of £13,847 per QALY gained.

A within-trial analysis assumes that there are no differences in costs and QALYs between the groups beyond the trial follow-up period. Our second analysis employed an established Cardiovascular Disease Model for Scotland (two unpublished articles by Lewsey JD, Lawson KD, Ford I, Fox K, Ritchie LD, Tunstall-Pedoe H, *et al.*, University of Glasgow, 2014) in order to investigate the additional costs and benefits which accrue over the participants' lifetimes so that we could provide an estimate of the lifetime cost-effectiveness of FFIT compared with no active intervention.

The model we used projects life expectancy, utility-adjusted life expectancy and lifetime costs based on the risk factors of individual participants' as measured at 12 months. The lifetime analysis demonstrates that FFIT remains more expensive than no active intervention, with an average additional cost of £1074 per individual (95% CI £780 to £1298). Nevertheless, the results also suggest that FFIT remains more cost-effective, with an average increase of 0.43 life-years (95% CI –0.32 to 0.56 life-years) and 0.38 QALYs (95% CI –0.25 to 0.55 QALYs). As a result, the FFIT intervention is associated with an incremental cost-effectiveness of £2810 per QALY gained (£2535 per life-year gained). A scenario analysis, limiting the

longer-term impact of the FFIT intervention to 5 years, demonstrated that FFIT remains more expensive and more effective, with a cost-effectiveness estimated between £1174 to £4475 per QALY gained (compared with no active intervention) depending on the assumptions made about the impact on longer-term costs.

All of these estimates are well below the threshold range of £20,000 to £30,000 per QALY used by NICE and comparable to the cost-effectiveness of community-based physical activity interventions (US$14,000–69,000 per QALY) found in a review by Roux *et al.*[124] in 2008 and the estimates of cost-effectiveness of behavioural interventions (US$235–30,419 per QALY) found in the review by Griffiths *et al.*[125] in 2012.

The data from the process evaluation on what attracted men to the FFIT programme demonstrated the complex interplay between 'push' and 'pull' factors to the programme, but also the over-riding power of the football club to help men overcome cultural barriers to group-based weight management. Push factors included concerns about their future health and wanting to 'being there' for their families, in the present and the future, able to actively fulfil roles they valued as fathers, sons, husbands and so on. This suggests that strong and positive masculine ideals of men as 'providers', which have been shown to motivate South Asian men to seek prompt health care for coronary symptoms,[126] can also be relevant as motivations for weight loss. Pull factors included the football club setting, the potential to get an 'insider' view of the club and the opportunity to be with other people like them.

Our findings are consistent with the COM-B model of behaviour change by Michie *et al.*,[108] which suggests that both motivation and opportunity are necessary for behaviour change (as well as capability which we discuss below). The multiple invitations from different sources to take part in the programme made it relatively easy for men who had already considered weight loss to take part.

They are also consistent with the ROMEO model by Robertson *et al.*,[10] which emphasises the importance of extrapersonal factors that drew men to the programme; we found that FFIT was able to harness an initial desire to 'do something' about their weight, fitness and health through the deep symbolic and cultural attachments to the football clubs that many, though not all, participants held.

The process evaluation clearly demonstrated high levels of satisfaction with and acceptability of the FFIT programme, based on a combination of factors. Coaches were encouraged in both face-to-face pre-delivery training and in training manuals to value the participants, to share experiences and to create a positive environment. Participant reports suggest that this was very successful and that the supportive, participative, atmosphere fostered by coaches in which laughter and enjoyment was fostered alongside the 'serious' business of behaviour change was important in the success of the programme. These findings are congruent with the creation of the positive motivational climate known to be important for behaviour change in sport and exercise science.[127]

Equally important in participant discussions was the physical environment of the football club setting which enhanced participants' sense of being a part of and closer to the club (symbolised by the club T-shirts and other branded programme materials they were given). Participants also discussed their real enjoyment of group interactions during the course and feelings of being part of a 'team' and the satisfaction of learning 'tips' and techniques for behaviour change for themselves and for others. Together, these factors suggest that at least part of the reason that group interventions work is through the promotion of high levels of group cohesion, the creation of a 'social identity' as a group or team and the opportunities for vicarious learning. All of these factors have previously been proposed as mechanisms through which group-based therapies and group-based motivational interviewing could operate.[113,114] Together the factors men reported enjoying built to deliver tangible experiences of success in reaching their weight and physical activity goals which kept the vast majority of men engaged throughout the 12-week programme.

Coaches also enjoyed delivering the programme and thought the course was well structured. They felt comfortable dealing with the questions asked by participants. They also delivered the programme largely as intended. However, they highlighted the ongoing challenge of fitting FFIT into their busy coaching schedules, often in resource-poor environments, suggesting that a clear business model and support from public health organisations may be needed for long-term implementation of the programme in these settings.

Findings from FGDs at 12 months suggest that those men who were successful in maintaining longer-term changes had used the lessons they had learnt flexibly in the context of their own lives, using self-monitoring of both weight and step counts and adapting what they ate according to their personal circumstances. They also suggest, consistent with SDT,[109] that self-regulation of behaviours had become integrated for some; what had once been new behaviours had become everyday and almost unremarkable so that they represented a new sense of identity, as the kind of person who eats well and is physically active. These qualitative findings support other research that suggest that physical activity programmes based on SDT may be effective in supporting behaviour change in the long-term.[128]

Nevertheless, some men had found it extremely difficult to maintain the changes they had made during the 12-week programme, reporting a combination of stressful life events, social commitments as well as the high cost of some activities as barriers. This suggest that further developments to the programme may be needed to enhance the maintenance of longer-term changes in some men.

Strengths and limitations

The FFIT programme has a number of strengths and some limitations. One of the major strengths of the programme, relevant to the generalisability of the programme, was that it was conceived in partnership between the SPL Trust and Scottish universities. This partnership was possible because the support for public health the programme offered was congruent with SPL and clubs commitment to community engagement, discussed in *Chapter 1*, *Rationale for current study*.

In addition, it was specifically designed with few exclusion criteria so as to increase generalisability. It attracted men from across the socioeconomic spectrum, reflecting the reach of football across social groups.[129] We report elsewhere that FFIT succeeded in attracting men at high risk of future disease, among whom only 3.6% had attended a commercial weight management programme and only 1.7% a primary care-based programme in the 3 months prior to undertaking FFIT.[34] Thus, FFIT succeeded in reaching high-risk men who were not attracted to other weight management programmes. However, unlike health-related initiatives within the English Premier League,[26] FFIT attracted few men from ethnic minority groups. In part, this reflects the lesser degree of ethnic diversity in many parts of Scotland, but this is something that should be further addressed in other research and development projects.

The programme was evidence based and the qualitative process evaluation suggests it succeeded in creating a positive motivational climate which fostered behaviour change through providing information and teaching the use of BCTs in a group-based context that participants could enjoy while dealing with serious and potentially sensitive issues. However, there is some evidence from the process evaluation that SMART goal setting did not suit everyone. There is increasing evidence that although goal setting is an effective technique to initiate behaviour change it may be less important in the maintenance of those changes.[58]

Coach training was interactive, built on coaches' existing experience and skills, and took place over 2 days. It was supported with written coaching materials that included prompts for coaches on which tasks were essential to deliver in each week. Coaches reported finding FFIT easy to deliver and they were able to deliver the programme's content largely as intended. We also found that any variation in the delivery of FFIT between coaches in clubs was not sufficient to effect the main outcomes; club was not significantly

associated with outcomes in any of the analyses undertaken. Nevertheless, in line with best practice,[130] it might have been even better to have trained coaches for longer with some observed practice and feedback and to have provided some 'top-up' training in the middle of the programme deliveries. Neither of these options was feasible because of resource constraints and coach workload; we had limited resource to train them and coaches had no more time in which to attend training.

Although the between-group differences clearly demonstrate FFIT's effectiveness, around 60% of participants, who we know were motivated enough to join the programme in the first place, did not achieve 5% weight loss at 12 months. This suggests that there are many improvements that could be made and we return to this when we consider further research.

Finally, the data from process evaluation suggest that the 'light-touch' maintenance programme of passive e-mail prompts and the relatively poorly attended 9-month reunion session in each club is unlikely to have contributed to the overall programme's effectiveness.

The evaluation also had key strengths and weaknesses. It was pragmatic and we were able to blind measurement of the primary outcome through careful fieldwork procedures. Although the objective measurement of physical activity would have been desirable, it was logistically impossible given the number of men involved in the trial and the fact that the SPL Trust required the intervention to be delivered in all clubs at the same time.

We exceeded our recruitment and retention targets and participating men fully reflected the socioeconomic mix of football supporters in general. Nevertheless, we are aware that those attracted to the programme were already at least partly motivated to make changes to the lifestyles given the right opportunity. FFIT is an innovative and successful programme, but it may not attract those who have not already, even at some subconscious level, considered weight loss. In addition, FFIT is unlikely to attract those who are actively disinterested in football or other sports and other approaches will be necessary. FFIT is thus only one part of, but not the whole, solution to the public health problem of rising levels of obesity in men. Nonetheless, it provides evidence of men's enthusiasm for making positive changes in their life and health when presented with the tools and the opportunity packaged in ways that are congruent with dominant cultural constructions of masculinity.

Our approach to assessing fidelity was pragmatic in the context of the resources available to us and limited coach time for research. Best practice in the measurement of fidelity would have included assessment of coach competencies and an assessment of the fidelity of delivery in each week.[130,131] Constraints on coach and researcher time and resources, already discussed, meant that these data were impractical to collect.

The cost-effectiveness analyses have a number of strengths and limitations. The HELP model underlying the lifetime analysis is based on the ASSIGN score, which is the preferred screening tool for CVD risk in Scotland.[96] HELP uses risk factors that were measured during the trial within a patient-level simulation to predict the long-term health consequences in terms of survival, comorbidities, QoL and costs for each individual. These estimates are combined with those from the within-trial analysis in what Griffiths *et al*.[125] describe as a mixed-methods approach and which is accepted as best practice for economic evaluation.

The main strengths of the HELP model relate to the data sources, modelling methods used, and the fact that validation and calibration of the model is more advanced than is usually undertaken for other models of this type. It uses data from the Scottish population in the estimation of the risk, projections of life expectancy, comorbidity and as the source of cost and utility inputs. The SHHEC survey[96] linked to all national hospital discharge and death records allows individuals to be followed up for a long time (median survival time to first event was almost 21 years). These linked data allow a competing risk analysis to be undertaken to estimate the association between risk factors and CVD and non-CVD outcomes using a single cohort of individuals. Estimates between risk variables and events were made continuously when possible. This enhances the discriminatory ability of the model so that no averaging across groups is

required (common in cohort state transition models). HELP also has the ability to assess cost-effectiveness over the lifetime of individuals. This is in contrast to many other models which project potential impacts over shorter periods (e.g. the NICE Programme Development Group projected potential impacts of changes in legislation, for example salt reduction, over a period of only 10 years).[132] HELP model predictions accurately reproduced observed events in a randomised trial (West of Scotland Coronary Prevention Study) and life expectancy predictions have been calibrated to contemporary Scottish life tables. In addition, the analysis involves a probabilistic sensitivity analysis to estimate the uncertainty as recommended by Griffiths *et al*.[125]

However, there are limitations associated with the HELP model used for the longer-term extrapolation. It does not take into account other risk factors and outcome measurement used in the FFIT trial and not all of the risk factors required by for the ASSIGN score were measured within the trial population. Cholesterol and family history had to be imputed from external sources. This limits the ability of the ASSIGN score to produce an accurate prediction of risk for each individual. Although family history is an important element in the ASSIGN score, it is not affected by the intervention and, as such, will not impact the incremental analysis. Weight loss is, in contrast, not a risk factor in the model but it is the main outcome of the trial reported here. Despite not being a risk factor within the ASSIGN risk score, the impact of weight loss is included in the long-term model, and thus projections of future events, indirectly through its influence on the other risk factors that are used within the model presented here.

In addition, the HELP model predicts hospitalisations so less serious events that could be treated in a primary care setting are not explicitly modelled. The result is that the projection of lifetime costs in the model is limited to hospital costs; primary care costs are not included. These costs may be considerable especially following a non-fatal event (e.g. stroke). Nevertheless, although this impacts on the estimate of the individual's total cost, it should not impact on the incremental cost unless there is a large disparity in the number of events between the intervention and waiting list comparison groups.

The within-trial analysis also has a number of limitations. The costing of medications is limited to GP prescriptions of antidepressants, painkillers, asthma, pain gels/creams, anti-inflammatories and sleeping tablets. Other prescribed medications and over-the-counter medications are excluded from the analysis. The exclusion of over-the-counter medications, and nearly all the medications included here are available over the counter, is a limitation of utilising the NHS perspective preferred by NICE as opposed to taking a wider societal perspective. These exclusions will affect the estimate of the total cost for each individual but will only affect the incremental cost if the use of other prescribed or over-the-counter medications differs markedly between the intervention and waiting list comparison groups over time.

Finally, we acknowledge that NICE prefers the use of European Quality of Life-5 Dimensions (EQ-5D) questionnaire, rather than the SF-12 to generate health utilities. At the time that the trial was planned there was uncertainty about whether or not the EQ-5D would be responsive to change in such a 'healthy' population. As a result, a decision was made to use the SF-12 as it served to provide both physical and mental summary component scores as well as health utility scores for the economic analysis.

Further research

We have shown the FFIT programme to be effective in supporting men to achieve weight loss 12 months after starting the programme. For lasting public health benefit it is necessary for this weight loss to be retained over the long-term. Follow-up of the cohort and further data linkage to NHS resource use data sets would enable investigation of whether or not the programme was able to support weight loss in the very long term.

Although the programme was effective at a group level, just over 60% of participants were not successful in achieving or maintaining 5% weigh loss from baseline and the programme can clearly be improved. This suggests that further research is necessary to optimise the programme and we agree with other commentators that further research is necessary to improve maintenance to weight loss into the long term.[58,133] The processes involved in maintaining weight loss may be quite different to those involved in initiating weight loss.

In future programme development we will place even greater emphasis on BCTs known to be effective in maintenance of behaviours (especially self-monitoring of both behaviour and outcome)[58] and on approaches that provide even greater support for the development of intrinsic motivations[128] so that it is possible for the practical and emotional barriers to weight loss maintenance reported by participants to be overcome.

Our qualitative analyses suggest that group interaction between the participants and the coaches, and between participants themselves, created high levels of group cohesion and a social identity which themselves supported change. However, many men who did not succeed in maintaining weigh loss also reported the importance of the group support. It would be useful to understand exactly how, in the context of a warm, positive, atmosphere promoted by coaches, peer group interaction operates and to harness this learning for further group programme development. In addition, although the FFIT programme was clearly successful, we are not sure what is the optimal length for a programme; we would certainly advocate experimentation with different approaches to a 'light-touch' ongoing programme.

Our finding that men in the comparison group also lost weight and that by 12 months 11% of them had lost up to 5% of their baseline body weight is not unusual. Comparison group participants in the recently published BeWEL trial to evaluate the impact of a diet and physical activity intervention on weight change in people at increased risk of colorectal cancer and other obesity-related comorbidities also lost 0.78 kg (95% CI 0.19 kg to 1.38 kg) compared with weight loss of 3.50 kg (95% CI 2.70 kg to 4.30 kg) in the comparison group.[119] Taken together, these findings suggest that much more research is necessary to understand the minimum requirements for weight loss support.

We are confident that our results have excellent generalisability to other football-based settings. Indeed, we believe that the results have relevance for lifestyle improvement programmes delivered through other types of sports club. We see no reason why FFIT, or something very like it, could not achieve similar results if adapted for delivery through, for example, rugby or cricket clubs. We also think that the model could be adapted to attract some women or families to weight management of physical activity programmes and would like to see the model extended to lower league or non-professional sports club settings. Nevertheless, the organisational barriers and resource constraints are considerable and it would be useful to investigate how resourcing and other organisational barriers can be overcome to implement the FFIT model effectively on a wide scale.

Chapter 7 Conclusions

Rising levels of obesity and lower participation in existing weight management programmes among men demand high-quality evaluation of innovative programmes in community settings to extend the evidence base for cost-effective strategies to support weight loss in men.

The evidence presented in this report demonstrates that the football setting proved highly effective in attracting and engaging overweight and obese men from a wide range of social backgrounds and that the programme engaged them in health behavioural changes in ways that were congruent with keys aspects of their identities. The degree of men's engagement with the programme challenges a predominant view of 'masculinity' as somehow intrinsically linked to negative behaviours in relation to health;[134] our results suggest that there is greater potential for engaging men in positive health behaviours, through linking more healthful behaviours to prevalent constructions of masculinity.

The report has also clearly demonstrated that FFIT, an evidence-based programme, gender sensitised in context, content and style of delivery, was effective in helping a significant proportion of men to achieve clinically important weight loss sustained to 12 months. A cost-effectiveness analysis suggested that the approach was cost-effective with QoL gains well below the threshold range of £20,000 to £30,000 per QALY used by NICE. The evidence we present suggests that public health commissioners and other organisations committed to public health improvement should consider whether or not the FFIT programme could be delivered in their jurisdiction.

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Contributions of authors

Sally Wyke (Deputy Director, Institute of Health and Wellbeing, health social sciences), in close collaboration particularly with Kate Hunt and Cindy Gray and others as specified below, wrote the original grant application, developed the intervention, designed the trial, measurement schedules and qualitative topic guides, contributed to the design and delivery of the training of the community coaches and interpreted the findings. She was coprincipal investigator with Kate Hunt of the project reported here, and coprincipal investigator on the earlier feasibility pilot study with Kate Hunt and Cindy Gray. She and Kate Hunt jointly drafted this report (with input from other authors as specified below).

Kate Hunt (Associate Director, health social sciences), in close collaboration particularly with Sally Wyke and Cindy Gray and others as specified below, wrote the original grant application, developed the intervention, designed the trial, measurement schedules and qualitative topic guides, contributed to the design and delivery of the training of the community coaches, and interpreted the findings. She was coprincipal investigator with Sally Wyke of the project reported here and coprincipal investigator on the

earlier feasibility pilot study with Sally Wyke and Cindy Gray. She oversaw the fieldwork training and conduct with Cindy Gray and contributed expertise in gender and health in the gender-sensitisation of the programme. She and Sally Wyke jointly drafted this report (with input from other authors as specified below).

Cindy M Gray (Lord Kelvin Adam Smith Fellow, health psychology), in close collaboration particularly with Sally Wyke and Kate Hunt and others as specified below, wrote the original grant application, developed the intervention, designed the trial, measurement schedules and qualitative topic guides and interpreted the findings. She co-ordinated recruitment to the trial, developed the training materials and manuals for participants and coaches, oversaw the training of the coaches, liaised with the clubs at all stages of the development and delivery of the intervention and the fieldwork and oversaw the fieldwork training and conduct with Kate Hunt. She drafted part of the process evaluation chapter (see *Chapter 5*) and provided detailed critical comments on the full report. Cindy was a grant holder on project and the project manager until December 2012.

Elisabeth Fenwick (Professor of Health Economics) was a grant holder and contributed to the original grant application. She designed and oversaw the economic evaluation and wrote the economic evaluation sections of the report.

Christopher Bunn (research fellow, sociology) was the project manager from January to December 2013. He led analysis, drafted most of the process evaluation chapter (see *Chapter 5*) and provided detailed critical comments on the full report.

Peter T Donnan (Professor of Statistics) was a grant holder on this project and contributed to the design of the trial and the original grant application. He oversaw and interpreted the statistical analysis and provided critical comments on chapters reporting the trial methods and results.

Petra Rauchhaus (research fellow, statistics) undertook the statistical analyses and oversaw the quantitative data management at the University of Dundee, Dundee, UK. She provided comments on chapters reporting the trial methods and results (see *Chapters 2* and *3*).

Nanette Mutrie (Professor, Sports Psychology) contributed to the design of the intervention (in particular providing expertise on physical activity) and the trial, the original grant application, the design and delivery of the training of the community coaches, provided critical additions and comments on the trial results, particularly in relation to physical activity, and made critical comments on the report. She was a grant holder on this project and on the earlier feasibility pilot study.

Annie S Anderson (Professor of Public Health Nutrition) contributed to the design of the intervention (in particular providing expertise on diet and dietary behaviour change) and the trial, the original grant application, provided critical comments on the trial results, particularly in relation to diet, and made critical comments and additions to the Report. She was a grant holder on this project and on the earlier feasibility pilot study.

Nicole Boyer (research assistant, health economics) undertook the economic analysis with Eleanor Grieve and Elisabeth Fenwick and provided critical comments on the economic evaluation chapter (see *Chapter 4*).

Adrian Brady (Associate Professor, University of Glasgow and Consultant Cardiologist, Glasgow Royal Infirmary) was a grant holder on the project. He provided clinical oversight of the programme and contributed to the analyses of adverse events. He commented on the health economics chapter and provided critical feedback throughout the project.

Eleanor Grieve (research fellow, health economics) undertook the economic analysis with Nicole Boyer and Elisabeth Fenwick and provided critical comments on the economic evaluation chapter (see *Chapter 4*).

Alan White (Professor of Men's Health) was a grant holder on the project. He provided comments on the grant application and the final report.

Catherine Ferrell (survey manager) wrote the fieldwork protocols, designed the databases and contributed to the Standard Operating Procedures. She developed training protocols and oversaw quality assurance of fieldwork and measurements. She gave critical comment on the plain English summary.

Elaine Hindle (survey support officer) developed questionnaires, oversaw database management and delivery of fieldwork timetables. She gave critical comment on the plain English summary.

Shaun Treweek (Professor of Health Services Research) contributed to the design of the intervention and the trial, the original grant application, provided critical comments on the trial results and the cost-effectiveness analysis and gave detailed critical comments on the report. He was a grant holder on this project and on the earlier feasibility pilot study.

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Hunt K, Wyke S, Gray CM, Anderson AS, Brady A, Bunn C, *et al.* A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial. *Lancet* 2014;**383**:1211–21.

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Appendix 1 Exit questionnaire

Date administered:_____ Participant IDNO _____

1) Why did you join the FFIT Programme? (interviewer - please tick all that apply)

To get fitter	☐	
To lose weight	☐	
To get fitter for a specific reason	☐	What reason? (e.g. to do more with children) _____
To lose weight for a specific reason	☐	What reason? (e.g. family wedding) _____
To improve lifestyle	☐	
Health reasons	☐	What health reasons? (personal or family history) _____
Someone recommended it to me	☐	Who? (e.g. former participant) _____
Someone told me I needed to go on it	☐	Who? (e.g. wife) _____
Because it was at the club	☐	
Because it was with men like me	☐	
Other	Please specify_____	

2) Why did you stop attending FFIT? (interviewer - please tick all that apply)

Changes to work commitments	☐	What work commitments? _____
Changes to family commitments	☐	What family commitments? _____
Health reasons	☐	What health reasons? _____
Injury	☐	What happened? _____
Didn't like classroom sessions	☐	Please say why _____
Didn't like exercise sessions	☐	Please say why _____
Couldn't devote the time needed	☐	
Other	Please specify_____	

3) Has your involvement with FFIT changed you in any way? (interviewer - please tick all that apply)

No	☐

Lost weight	☐	
Better eating habits	☐	What in particular? _____
Taking more exercise	☐	What sort of exercise? _____
Drink less alcohol	☐	_____
Have more energy	☐	_____
Feel better in myself	☐	Please say how (e.g. more confident, not depressed) _____
Injury	☐	
Other not covered here	Please specify_____	

_____

_____

_____

_____

4) How could the programme have been done differently?

_____

_____

_____

_____

_____

5) Would this have encouraged you to stay?

Yes	☐
No	☐
Don't know	☐

6) Is there anything else you would like to add?

_____

_____

_____

_____

_____

Thank the man very much for answering the questions

and say we really value his feedback

Appendix 2 Example programme observation proforma

Session: *SPL FFIT SESSION 1 Getting Started*	**Notes**
Date, time, venue and club	*(e.g. 21/02/11; 18.00-19.30; Learning Centre in South Stand at Easter Road, Hibernian FC, then a tour of dressing rooms). Please describe the venue and layout*
Coaches	*Please give names and roles of coaches, with notes of delivery style and relationship with each other and the men.*
Participants	*Please give the number of participants attending (and the number of absentees). Note when the men started to arrive and what happens before the programme starts (if they arrive early).*

Session content - coaches notes

Classroom	***Physical activity***	***Delivered Classroom?***	***Delivered PA?***
• Introduce men to aim of programme *'how to eat better, be more active* ***and stay that way in the long term'*** • Getting to know one another and sharing ideas and experiences • Influences on choosing what to eat and control over that • Energy balance (intake vs output) • Food diary homework	• Introduction to pedometers and how to use them • Short stadium tour wearing pedometer • Ensure everyone understands how to do baseline step count homework		

RESOURCES	*SPECIFIC PREPARATION*	*Done?*
Participant programme notes Club FFIT top for each participants Flip chart and pen (Exercise 6)	Prepare flip chart sheet with **'I HAVE COMPLETE CONTROL OVER WHAT I EAT'** at top, **'I HAVE NO CONTROL AT ALL OVER WHAT** I EAT' at bottom, and a line linking them Plan stadium tour and 'insider' stories	
1. Introduction 5min		
Background Group members need to know something about you, your link to the club, why you are running the group and that they can feel comfortable with you. You also need to allay any anxieties they have about the programme and help them get to know each other.		
Content, Style & Method of Delivery • Warmly welcome all the men and congratulate them for making the effort to attend • Introduce yourself and tell them a bit about you		
Comments		
Key Lessons		
2. Overview of the 12 weeks 5min		
Resources 1. Programme notes for each participant 2. Club FFIT top for each participant		
Content, Style & Method of Delivery • Give out the participant programme notes and ask men to bring them (and a pen) every week • Give a brief tour of the 12 sessions of the; programme referring to the		

"SPL Football Fans in Training Core Components" (page 8) • Describe how the "fitness sessions" will be introduced gradually during the 12 weeks, with the first 2 weeks concentrating on the importance of eating and drinking more healthily and on using pedometers to increase daily walking • Ask the men how the programme compares to their expectations. **Emphasise that the key message of FFIT is to encourage them to eat more healthily, be more active, and to keep those changes going in the long term.** Stress that FFIT is **not a diet** • Give out the club FFIT tops and ask the men to wear these every week	
Comments	
Key Lessons	
3. Ground rules and commitment **10min**	
Background Setting ground rules early can help to avoid difficult situations arising.	
Resources Flip chart and pen	
Content, Style & Method of Delivery • Ask the men to suggest ground rules for the group and write ideas up on the flip chart • Make sure the following rules are covered: TIME-KEEPING CONFIDENTIALITY INVOLVING EVERYONE INTERRUPTING RESPECTING OTHERS • Stress that you need commitment to the programme from **everyone. Nobody should have more than 2 absences**. Ask if anyone can foresee any difficulties with that? • Check the men understand that their regular attendance is important	

for the group.	
Comments	
Key Lessons	
4. An ice-breaker for personal introductions 10min	
Background The men may feel anxious about speaking in a group of strangers and an ice-breaker helps to introduce and involve them from the outset	
Content, Style & Method of Delivery • Get the men to introduce themselves and to state their most memorable football game and favourite food • Start off by describing your own most memorable game and favourite food • Ask the men about their choices to encourage them to interact	
Comments	
Key Lessons	
5. Influences on food choice **5min**	
Background The next two exercises start to bring out some of **the barriers** people face in trying to eat more healthily and being more active. They can also give them **inspiration and ideas** for how to stop things getting in the way of eating healthily and being more active.	
Resources 1. Flip chart and pen	
Content, Style & Method of Delivery • Ask men to call out things that influence what they eat and write them on the flip chart • Ask men to call out things that influence how active they are and write them on the chart • Discuss how long the lists are and how difficult it can be to eat	

healthily and have an active life amidst all these other factors	
Comments	
Key Lessons	
6. Locus of control 10min	
Background The men must accept the choices they make about their eating and physical activity are their own responsibility if they are to make effective long term changes.	
Resources 1. Prepared "Locus of Control" flip chart sheet (see Specific Preparation)	
Content, Style & Method of Delivery • Tell the men it is their decision to attend the programme and whether or not it works for them is in their own hands. They can't 'blame' anyone else for any failure. Equally, they should congratulate themselves when things go well • On the "Locus of Control" flip chart sheet put your initials on the line between the two statements and give reasons for doing so (e.g. I just eat what's put down for me) • Then ask each man to come and add their initials on the line and ask some men for their reasons once they have all added their names	
Comments	
Key Lessons	
7. Food diary homework 5min	
Background Before trying to make changes it is important to establish current eating and activity patterns to provide a baseline from which to start to make changes.	

Content, Style & Method of Delivery • Ask each man to complete **"Food Diary 1"** (page **Error! Bookmark not defined.**) for two days (one work day and one non-work day) before the next session • Urge them to choose days that are typical of what they normally eat and not to make any changes yet • Stress the importance of being truthful to make this exercise meaningful	
Comments	
Key Lessons	
8. Pedometers **20min**	
Background For many people, walking more can be an effective and achievable way of increasing activity. Measuring their baseline levels will allow the men to plan future activity.	
Resources 1. Pedometers: one for each man and one for you to demonstrate	
Content, Style & Method of Delivery • Link the importance of eating more healthily *and* being more active by telling the men that getting the balance between energy intake (through food and drink) and energy output (through being active) is crucial to staying in shape • Anything that we eat that is not used for energy is stored as fat by our bodies. To lose weight they need to "tip the balance" towards eating less and being more active • Give out the pedometers, explain how they work and demonstrate the correct positioning of them on the body • Ask the men to start wearing the pedometers immediately and to record their daily steps in the **"Measuring your Current Step Count"** table (page **Error! Bookmark not defined.Error! Bookmark not defined.**)	

• Urge them to not to increase their normal activity yet so they can get a realistic baseline
• Key points:
  ○ Make sure the pedometer is upright, men with a large belly may have to wear it round the back of their trousers for it to work properly
  ○ Make sure the men know how to zero the pedometer
  ○ Encourage the men to be honest
  ○ It is important to register a full day, encourage the men to get into the habit of putting their pedometer on as soon as they get up (even if they don't get dressed immediately) and taking it off last thing at night
  ○ Make sure the men understand the importance of recording their step count accurately at the end of each day
• Suggest that walking is a social activity and they might like to meet up as the weeks go on to walk together – say some other groups have really enjoyed doing this	

Comments	
Key Lessons	
9. Tour of the stadium and ending 20min	
Background Feeling part of the club is a **vital** component of the programme. Finishing on time is also important as the men may have other commitments.	
Resources 1. Pre-plan the tour of the club's facilities, checking which areas are accessible to the group. 2. Have some "behind the scenes" stories so the men feel they are getting a special insight	
Content, Style & Method of Delivery	

• Halfway round the tour get the men to check their pedometers (all should have roughly the same amount of steps). Get the men to reposition any that are not working well to ensure they are upright (e.g. ask the men to try the pedometer round the back) • At the end of the tour do another pedometer check and replace any that are not working • Remind the men to weigh themselves and note their weight on their **"Personal Weekly Progress Record"** at the start of their notes (page **Error! Bookmark not defined.** in yours), but not to worry about the percentages at the top for now • Genuinely thank everyone for coming along, summarize the session and look forward to next week and the rest of the programme.	
Comments	
Key Lessons	

Appendix 3 Participant focus group and coach interview topic guides

Football Fans in Training 12-week focus group topic guide

Introduction

- Aims of group – first, I want to find out what you thought of the FFIT programme, how being involved with it has changed your life, and any changes you would like to see made to it.
- I am simply here as a sort of chairperson to make sure that everyone gets a chance to speak. What you have to say is important to me and the other researchers so please don't be afraid of speaking your mind.
- I will audio- and video-tape the discussion, and the recordings will kept for 10 years after the project finishes, but everything you say will be in strictest confidence.
- Questions and consent forms.
- Start by getting the men to introduce themselves and say what was their most memorable football game (for voice identification).

Discussion

1. Why did you join the FFIT Programme?
2. What did you want to achieve when you came along?
3. What are the main differences being on the programme has made to you? Positive and negative (Prompts: weight-loss, following better eating habits, taking more exercise, drinking less, having more energy, feeling better, injury)?
4. What was it about the programme that helped you make these changes? Why?
5. Was there anything about the programme that was not so helpful? Why?
6. What did you think about using club coaches to deliver the programme? What did you feel about external staff being brought into help?
7. Did you know that we had selection criteria for joining? What did you think about that? (Prompt age range/BMI/waist) How did these affect group dynamics?
8. Was there anything else you would have liked to have been included in the programme? (Prompt: continuing support) How would this have changed the programme, do you think?
9. Was there anything you don't think should have been included in the programme?
10. Why did you keep coming to the programme?
11. Did your being on the programme have any effect on your family? If so, how and why?
12. Would you like to see the club offering any other kinds of programmes to supporters?

Summary

At end of discussion, summarise what has been said and ask men if there is anything else they would like to add.

Football Fans in Training 12-month focus group

Introduction

- Aims of group – I want to find out how you have been getting on with your weight management and exercise in the 12 months since you joined the FFIT programme at [Club Name]. We particularly want to know what information or 'tricks' that you learned from FFIT have been useful in helping you maintain the changes over the last 9 months or so. I would also like you to be honest about the difficulties and problems you have faced too.
- I am simply here as a sort of chairperson to make sure that everyone gets a chance to speak. What you have to say is important to me and the other researchers so please don't be afraid of speaking your mind.
- I will audio- and video-tape the discussion, and the recordings will kept for 10 years after the project finishes, but everything you say will be in strictest confidence.
- Questions and consent forms.
- Start by getting the men to introduce themselves and say what was their most memorable football game (for voice identification).

General

1. Looking back at taking part in the FFIT programme and the time since, would you say that it has affected any aspect of your day-to-day life or your health?

Eating

2. Thinking about your eating habits, what were the main changes you managed to make, if any, while on the FFIT programme at [Club Name].
3. Which of those changes have you managed to maintain over the nine months since the programme ended?
4. What difficulties have you faced in trying to maintain the changes to your eating habits?
5. What have you found helpful in maintaining the changes to your eating habits?

Physical activity

6. Thinking about physical activity now, what were the main changes you managed to make, if any, while on the FFIT programme at [Club Name].
7. Which of those changes have you managed to maintain over the nine months since the programme ended?
8. What difficulties have you faced in trying to maintain the changes to your physical activity level?
9. What have you found helpful in maintaining the changes to your physical activity level?

Anything else?

10. Are there any other changes you have made to your lifestyle as a result of being on the FFIT programme? If yes, how have you found maintaining these since the programme ended?

Overall impact

11. Finally, 12 months on, what would you say are the main impacts being on the FFIT programme has made on your life/or the lives of those around you?

Summary

At end of discussion, summarise what has been said and ask men if there is anything else they would like to add.

Football Fans in Training face-to-face interview with coaches

1. Can you tell me about your programme? (Prompts: no. of men, date and time and why these were chosen.)
2. How do you feel it went?
3. How did you find it to deliver? Any specific problems?
4. How did you find the training sessions (helpful/not helpful)? What could have been done differently?
5. How did you find the support you were given to deliver the programme (Prompts: from the SPL, from the programme trainers?)
6. What did you think was good about the programme?
7. What did you think was not so good about the programme?
8. Which parts of the programme did you think were effective in helping the men to lose weight? Why?
9. Which elements did you think were effective in helping the men to increase physical activity? Why?
10. Were there any elements that you thought weren't useful for helping the men to lose weight? Why?
11. Were there any elements that you thought weren't useful for helping the men to increase physical activity? Why?
12. Did you find anything particularly helpful in allowing you to deliver the programme? If so, what?
13. Was there anything that made delivery of the programme more difficult? (Prompt age range; different physical activity abilities.)
14. How did you feel about dealing with questions the men asked?
15. Are there any changes you would like to see made to any aspect of the programme? (Prompt: more information; targeting different men) Why?
16. Would you like to see the club offering any other kinds of programmes to supporters?

Summary

At end of interview, summarise what has been said and ask the trainers if there is anything else they would like to add.

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