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Football Fans in Training (FFIT): a randomized controlled trial of a gender-sensitive weight loss and healthy living programme delivered to men aged 35-65 by Scottish Premier League (SPL) football clubs

Chief investigator	Professor Sally Wyke
Sponsor	University of Glasgow
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Football Fans in Training (FFIT): a randomized controlled trial of a gender-sensitive weight loss and healthy living programme delivered to men aged 35-65 by Scottish Premier League (SPL) football clubs

1. Aims / Objectives:

To determine whether Football Fans in Training (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 BMI at least 28kg/m^2 achieve at least a 5% reduction in body weight 12 months after the start of their participation in FFIT.

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

Secondary outcomes: To investigate whether involvement with FFIT:

a) reduces body weight by 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 at 12 weeks and 12 months.

We will also examine the difference in area under the trend line of weight loss from baseline to 12 months, which gives a measure of the effect of the intervention across all time periods.

Cost effectiveness: To investigate whether 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.

2. Background:

2.1 The problem of male obesity

The UK prevalence of male obesity is amongst the highest in Europe (1) and is forecast to increase at a faster rate than female obesity in the next 40 years. On current trends, 60% of men will be obese in England by 2050 (2); figures for Scotland are likely to be similar. It is predicted that the link between obesity and socio-economic deprivation, already evident in women, will soon appear in men (2).

Excess weight is associated with undesirable health outcomes: obese men are 3 times as likely to have high blood pressure as men of normal weight (3); 90% of cases of type 2 diabetes can be attributed to excess weight; there is a more than twofold increase in the risk of coronary artery disease and stroke amongst obese

people (2); and, after smoking, obesity is the most important preventable cause of cancer (3). These conditions contribute to persisting gender and socioeconomic inequalities, and premature mortality. More deaths are attributable to excess weight in the UK than in the rest of Europe (4).

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

A 5-10% weight loss can produce significant health benefits (5;6) but few men use existing commercial and NHS weight loss programmes (7-9). Men's reluctance to enrol in these 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 (10) leading some men to be concerned about being too thin and less likely to diet than women (11-13). Indeed, men often view dieting as 'feminine' (14) and are more likely to use exercise to control their weight (12). In addition, men tend to have poorer nutrition knowledge than women, to be resistant to healthy-eating campaigns (15), and to be less aware of links between diet and ill health (12;16). Alcohol may pose an additional problem for weight management for many men (17;18); Scottish men drink around twice as much as Scottish women (19). However, evidence suggests that when gender issues are used to inform programme design, men *will* engage with weight management interventions and successfully lose weight (20).

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 (21). 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 (22). A scoping review identified a growing number of small scale, localised projects in professional rugby league and football clubs (FCs) that have been used to promote men's health (23-28). In 2009, drawing on the experiences of some of these collaborations between health professionals and sporting organisations, the English Premier League launched a £1.63 million programme to promote partnerships between Premiership football clubs and local health agencies to address a range of health issues experienced by young men from deprived areas (29;30).

Recent projects have also begun to explore the potential of professional sports club settings to engage men in weight loss programmes. Men at rugby league clubs in Leeds (n=7) and Wakefield (n=20) achieved an average 2.1kg weight loss in 6 and 10 weeks, respectively (26;31). In 12 months, 600 men (aged 40-65 years) attended Fit Fans, a 12-week weight loss and physical activity programme delivered by a commercial weight management organisation at football and rugby league clubs in Hull. 56% of men who completed the Fit Fans programme lost at least 5% of their bodyweight, and 75% of these maintained or increased their weight loss at 6 months (32). Pilot "Live Better, Live Healthier" programmes run by the Royal College of Physicians and Surgeons of Glasgow at Celtic and Rangers FCs (led by co-applicant, Adrian Brady), in which 40 men (aged 40-60 years) were given weight management and nutrition advice as part of a men's health education initiative, achieved an average 4% weight loss over 10 weeks, with participants continuing to lose weight in the 12 months after the programme ended. Participants, recruited using season ticket holder databases, reported the football clubs' involvement as their main motivator for joining the programme (33;34).

The **Football Fans in Training (FFIT)** intervention uses the traditionally male

environment of football clubs (35), existing loyalty to football teams and the opportunity to participate in men-only groups to maximise men's engagement with a successful evidence-based, gender-sensitised weight management programme (20) within the football clubs in the Scottish Premier League (SPL). The SPL has the highest match attendances per head of population in Europe; almost 4 million fans pass through club turnstiles each season. FFIT will be delivered at club stadia by coaches trained by the research team in diet, nutrition, physical activity and behaviour change techniques to a standard delivery protocol delivered over 12 sessions. Individually-tailored exercise programmes using club facilities form a component of the 90 minute within-stadia sessions. "Homework" between the sessions includes a pedometer-based walking programme allowing men to work at their own level: some will keep walking throughout the programme; others will be encouraged to progress to more vigorous regular activity, such as jogging, cycling or gym membership. 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.

2.3 Rationale for current study

Project team members have been collaborating with the SPL Trust (whose remit is to increase community engagement within the SPL) to design, implement and evaluate FFIT since June 2009. This collaboration has resulted in a deliverable, evidence-based programme that is low cost and has potential to be readily generalisable. FFIT is funded for delivery in 2011-13 by the SPL Trust, the Football Pools and the Scottish Government. It was piloted in SPL clubs in autumn 2010 and spring 2011. The full FFIT programme launch is scheduled for the start of the 2011-12 football season in August 2011.

3. News:

On the basis of our report to the SPL Trust and other publicity, Football Fans in Training won the Gold Award for Social Responsibility at the European Professional Football League (EPFL) Best Practice Awards Gala in Vienna on 7th July 2011. It also won The Herald Society Health Provider of the Year Award on November 17th 2011, and has been shortlisted for the Scottish Charity partnership award to be announced on 14th June 2012 www.scvo.org.uk/scvo-events/shortlist-2012/.

Paul Bradley, one of BBC Scotland's sports reporters, took part in FFIT in February / April 2011. He recorded a video diary about his own and other participants' experiences of FFIT. His posts can be viewed at: http://www.spl-ffit.co.uk/page/ffit-videos/. BBC Scotland broadcast a half hour documentary on the FFIT programme on 19th February 2012.

4. Methods:

4.1 Setting

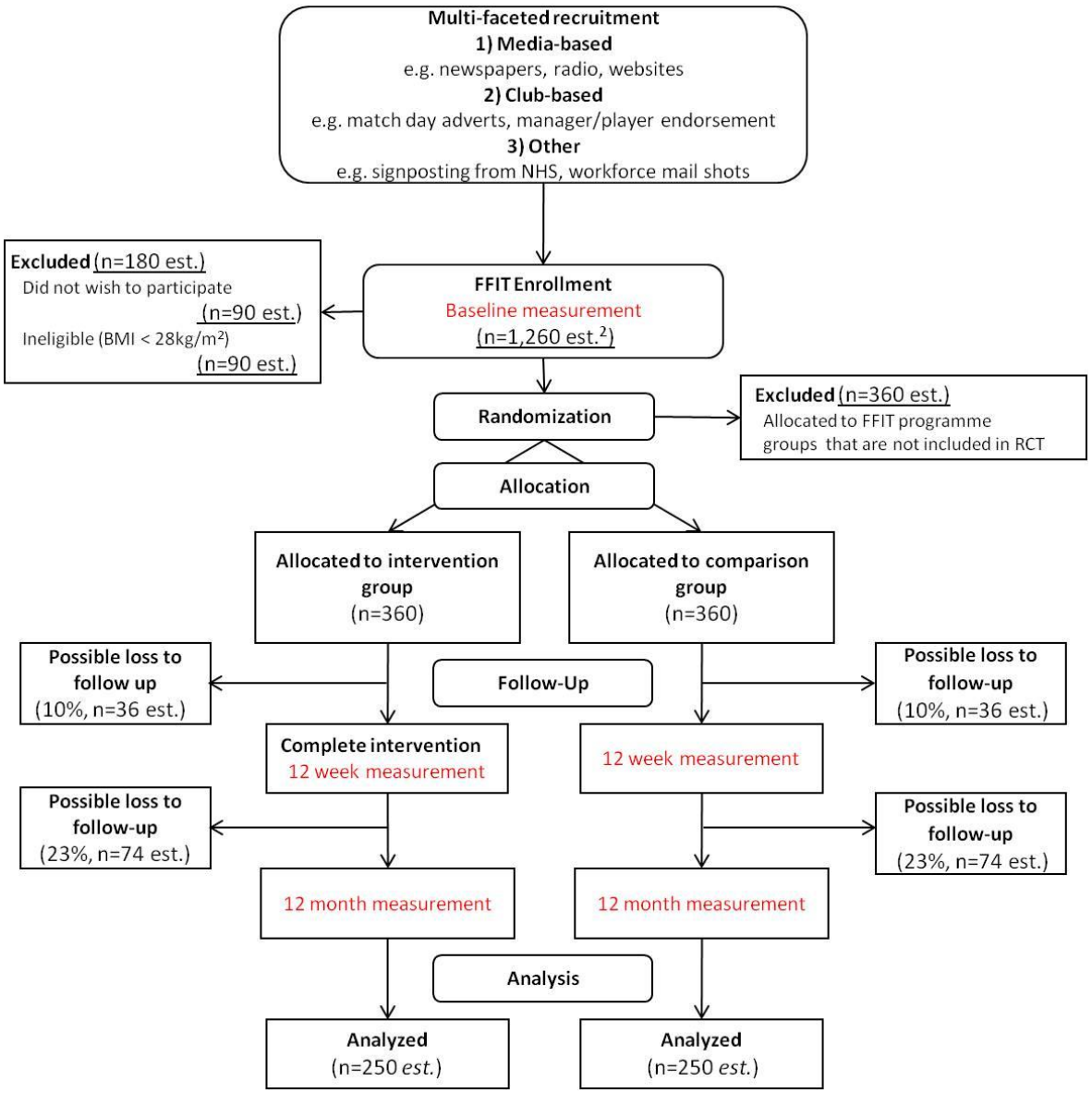
Twelve SPL football clubs and the club relegated to Division 1 at the end of the 2010-11 season (13 clubs in all).

4.2 Design

4.2.1 Overview

A two arm stratified individually Randomised Controlled Trial (RCT) to evaluate the FFIT programme. Figure 1 summarises the design of the study in a CONSORT diagram.

Figure 1. FFIT CONSORT Diagram



The design is pragmatic and influenced by a number of external constraints:

- The SPL is committed to delivering FFIT in *all* 12 SPL clubs and the club relegated to Division 1 at the *same time*;
- The NIHR Public Health Research Programme requires evidence that the FFIT programme is effective at maintaining weight loss over a **12 month period.** That is that men who undertake the programme record a weight loss of at least 5% of their baseline body weight 12 months after starting the programme;
- The programme funders (the Scottish Government and Football Pools) and the SPL Trust require the programme to be delivered at least twice in the 2011-12 football season.

Taken together these constraints mean that:

- Randomisation at a club level is not possible; randomisation will be at the

level of the individual participants, stratified by club;

- The comparison group is a 'waiting list' comparison: we will compare men randomly allocated to the FFIT programme in September 2011 with those randomly allocated to the comparison group who will start the FFIT programme in September 2012;
- The randomisation process must allocate men to fill the 'non-trial' delivery of FFIT (between the intervention and 'waiting list' comparison group programmes) to ensure that comparison group participants do not 'leak' into vacancies on the non-trial delivery programme. This programme will not be part of the trial, and **men allocated to this 'non-trial' delivery will have no further involvement in the RCT**.

4.2.2 Study population

Inclusion criteria

- Men aged 35-65 years.
- BMI at least 28kg/m^2.
- Have completed the Physical Activity Readiness Questionnaire.
- Willing to consent to weight, height and waist measurements.

Our age limits reflect evidence that overweight and obese men in their mid-to-late 30s may experience an attitudinal shift as they approach middle age (36) thus increasing the potential effectiveness of lifestyle interventions (2), and opinion that at older ages physical activity programmes may be more effective when targeted specifically at over-65s. Men who are obese, or at high risk of becoming obese, are more likely to want to lose weight than those who just exceed the normal weight range (20;36), hence our choice of 28kg/m^2.

The Physical Activity Readiness Questionnaire (37) will be used. It will not be possible for eligible men to access the FFIT programme unless they agree to be randomly allocated to the September 2011, February 2012, or September 2012 programmes. The SPL Trust requires participants to consent to weight, height and waist measurements, regardless of whether or not they take part in our RCT. RCT participants can opt out of additional measures / procedures relating to the trial's secondary and process outcomes.

Exclusion criteria

- Prior participation in FFIT. In addition, men whose measured blood pressure contraindicates vigorous exercise (systolic ≥ 160mmHg and/or diastolic ≥ 100mmHg) will be excluded from the more intense in-stadia training until they can provide evidence of its reduction.

Recruitment strategy

Our recruitment estimates are based on the "Live Better, Live Healthier" pilot programme at Rangers and Celtic FCs (34) and on our feasibility study. We are using a multifaceted strategy focussing on general media coverage supported by club-based and other recruitment. This strategy is summarised in Table 1 (below).

Information for participants

Publicity asks men to contact the FFIT team by freephone, email or text. All men contacting FFIT are told that they will be 'entered into a draw' to start the programme in September 2011, in February 2012 or in September 2012. All

interested men will be invited to a pre-programme 'weigh-in' in August / September 2011. At that point they will be sent a study information leaflet.

Table 1. Summary of recruitment strategies

Recruitment Strategy
Media campaign involving: local and national newspapers; BBC Scotland; local radio; websites
Publicity campaign at clubs including: • Endorsement from club personalities – e.g. Murdo McLeod (Celtic), John Robertson (Hearts), Derek Ferguson (Rangers), Peter Houston (Dundee United) have agreed to be involved • Match day advertising – posters, leafleting, programme advertising, tannoy announcements • Leafleting to people involved in other club community programmes – e.g. parents • Active involvement of local supporters' organisations
Online publicity including: SPL website; FFIT website; FFIT Facebook page; club websites; fan websites (e.g. http://www.pieandbovril.com/); club e-newsletters
Signposting of eligible men from: • NHS Local GPs; Keep Well [anticipatory care programme tackling health inequalities across Scotland (38)] • Local council / community health improvement projects
• Community-based advertising including: posters, flyers and workforce emails at local employers
Word of mouth: men participating in the pilot programmes recommend FFIT to their friends and family with incentives
Incentives to join programme: men meet club staff at enrolment in FFIT and receive club T-shirts

4.2.3 Randomisation

The Tayside Clinical Trials Unit (TCTU), a UKCRC registered trials unit, is responsible for randomisation. Randomised lists will be compiled using blocking (block size will be between 2 and 9, depending on how many participants are recruited at a club), and stratified by SPL football club. Individuals at each club will be randomised to intervention or comparison group in a 1:1 ratio. The TCTU statistician will send the allocation sequence in a password-protected file to a database manager at the MRC/CSO Social and Public Health Sciences Unit (MRC/CSO SPHSU) who is not part of the trial team. Phone calls and/or letters will be used to inform men of their allocation.

Cluster randomization will not be used because the risk of contamination is not considered to be sufficient to warrant it (39). For contamination to be an issue one would have to assume that discussion of the intervention between peers (i.e. those in the comparison group talking to those in the intervention group) is as effective as receiving the full intervention (i.e. receiving training according to a fixed schedule from club coaches over an extended period and then receiving ongoing support from club coaches for 9 months). Torgerson (39) highlighted that the effectiveness of an intervention delivered by an untrained member of the public will, if effective at all, be much less than if delivered by a trained professional. This means that contamination can be even higher before it outweighs the problem of the inflated sample size needed for cluster randomisation.

Since each participant will know which group they are in, randomisation cannot be blinded. However, allocation will not be known at the baseline measurement sessions and all efforts will be made to blind measurement of the primary outcome,

weight loss at 12 months.

4.2.4 The Intervention: Football Fans in Training (FFIT) programme

Overview: FFIT is a gender-sensitised, weight loss, physical activity and healthy living programme consisting of twelve 90-minute sessions of 'classroom-based' discussion and 'pitch-side' training that aim to achieve a 600kcal/day deficit. This weight loss phase is followed by a 9 month minimal contact weight maintenance phase with periodic post-programme e-mail prompts and a group reunion at the club 6 months after the end of the weight loss phase. FFIT is designed to be delivered to groups of up to 30 men, with a ratio of at least one coach to 15 men, and fully adheres to NICE 2006 and SIGN 2010 guidance. From September 2010, FFIT has been successfully delivered (but not rigorously evaluated) by community coaches to groups of men at 11 SPL clubs.

The coaches' existing skills in working with community groups (mainly running football programmes for youngsters) are augmented by training in the diet, nutrition, physical activity and behavioural change techniques incorporated into the FFIT delivery protocol. Training is led by research team members with expertise in delivering gender-sensitised weight management programmes and physical activity interventions for people who are largely inactive. It consists of two days of discussion of principles and role play based on the programme and the practical experience of coaches who have led programmes to date. Coaches also receive a detailed handbook containing a week-by-week explanation of the programme to support their delivery and advice to help them support men who may have mental health problems. The FFIT Programme delivery manual will be available online on completion of the trial (www.spl-ffit.co.uk).

Dietary change: The 'classroom-based' sessions have been developed from the Camelon programme (which was 100% classroom-based, although goals to increase physical activity were set). Over 75% of men who started the Camelon programme completed it, with 44% achieving at least 5% weight loss (20), which compares favourably with other NHS programmes (9;40). The health benefits of losing weight and increasing physical activity (41) are used to motivate initial change. A key feature of both Camelon and FFIT is that, although delivered in group sessions, all dietary advice is personalised to suit individual circumstances and preferences.

Physical activity: FFIT has two physical activity components: an incremental pedometer-based walking programme shown to increase physical activity and reduce sedentary behaviour (e.g. TV viewing) over 12 weeks (42) and 12 months (43); and pitch-side physical activity sessions led by club coaches. The men set individual daily brisk walking goals and report their progress each week; those who are able are encouraged to supplement walking with more vigorous activity (e.g. gym membership). However, the real value of the walking programme is that, regardless of their fitness level, all men learn how to incorporate walking into everyday activities thereby allowing them to achieve recommended physical activity levels (5;6) on days where they are unable to do any other form of exercise. The pitch-side physical activity sessions teach men how to increase fitness through structured activities and discuss how they can continue these activities in community settings using community resources. Men are encouraged to continue to meet to train together post-programme. Training is tailored to individual fitness levels and ability, and includes aerobic (e.g. walking, stair climbing, jogging), muscle strengthening (e.g. weight / circuit training) and flexibility (e.g. warm up /

cool down activities) exercises. Participants are encouraged to avoid the compensatory behaviours (e.g. increased snacking or television viewing) that may undermine weight loss following exercise (44;45).

Behavioural techniques: A wide range of evidence-based behaviour change techniques [e.g. self-monitoring of weight and physical activity (including pedometer steps)], intention formation, goal setting, 'if-then' plans, feedback and change reinforcement) (46) are used throughout FFIT.

Gender sensitivity: FITT contains many components that are specifically designed or adapted for a male audience including: the football setting and club-based incentives (e.g. club T-shirts; support from the manager / players); a focus on nutrition and education rather than dieting; the emphasis on physical activity; competition through quizzes; and sandbags as physical evidence of weight loss at 6 weeks. In addition, an entire classroom session is devoted to alcohol, its role in weight gain and advice on reducing consumption. Finally, men-only groups encourage use of 'banter', which can help men to discuss health issues (47;48).

Ongoing support: Having completed the initial 12 weight loss sessions, men will receive 6 email prompts at roughly 6 weekly intervals from their FFIT coach (those with limited internet access will receive letter prompts). These email prompts will include the same content across the clubs and will be developed by the research team. Men will also be invited to return to the club for a group reunion 6 months after the end of the weight loss phase. Men will be encouraged to: use the 'Ten Top Tips for a Healthy Weight' approach to maintaining weight loss (http://info.cancerresearchuk.org/healthyliving/obesityandweight/tentoptips/) and the Active Nation website (http://www.ouractivenation.co.uk/) for additional ongoing support with physical activity; and meet up regularly to exercise together (e.g. to play 5-a-side football) and provide mutual support. This 'Veterans' Club' approach was successful in helping participants in the "Live Better, Live Healthier" pilot programmes maintain positive weight and lifestyle changes (33), and has been adopted by participants from the pilot deliveries of FFIT at many clubs.

Fidelity: Whilst all coaches will be trained in delivery of FFIT to a standard protocol, differences in the facilities available (e.g. access to gyms), group dynamics, and the personalities of participants and coaches mean that some variation is inevitable. If FFIT is to be widely applicable, some degree of flexibility in its delivery is likely to be required; this is appropriate for a pragmatic trial (49).

Men allocated to the **intervention group** will start the FFIT programme within 3 weeks of their baseline measurement.

Comparator

Individuals randomised to the comparison group will receive the FFIT programme after a 12-month delay.

Intervention and comparator

All men attending the baseline measurement sessions will receive the British Heart Foundation's '*So you want to lose weight*?' manual (50).

Drop-out

Although it is unlikely that all men will attend all programme sessions, we expect drop out rates to be low. We will monitor drop-out from the FFIT programme in the intervention group. Additionally, we will use a range of measures to reduce loss to follow-up for the primary outcome – see *4.2.6 Retention strategies*.

4.2.5 Outcome assessment

Outcome measures: Outcome measures are set with reference to National Obesity Observatory guidance for the evaluation of weight management interventions (51).

Primary outcome: Percentage *weight loss* at 12 months.

Secondary outcomes:

a) Percentage *weight loss* at 12 weeks;
b) Percentage 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 measured by the International Physical Activity Questionnaire Short Form (52);
d) *Eating habits:* changes in self-reported intake of key contributors to weight gain [(53) e.g. fast foods, chocolate bars, chips, pies, sugary drinks] at 12 weeks and 12 months using questions adapted from the Dietary Instrument for Nutrition Education (54);
e) Changes in self-reported *alcohol consumption* over the last 7 days at 12 weeks and 12 months using an alcohol diary (55), and changes in football-associated alcohol consumption;
f) Reduction in *resting blood pressure* at 12 weeks and 12 months;
g) *Psychological outcomes:* a) changes in positive and negative affect as measured by the Positive and Negative Affect Schedule (56); b) changes in self esteem as measured by the Rosenberg Self Esteem Scale (57); c) changes in health-related quality of life as measured by the SF-12 (58), all at 12 weeks and 12 months;
h) Difference in area under the trend line of weight loss from baseline to 12 months.

Although objective measurement of physical activity is desirable, this has proven logistically impossible given the number of men involved in the trial and the fact that the SPL Trust requires the intervention to be delivered in all clubs at the same time. We will therefore collect before-and-after pedometer diaries from the intervention group to allow comparison with differences in self-reported PA at 12 weeks. We have also secured separate funding to obtain before-and-after objective measurements of activity and sedentary behaviour using activPAL monitors[1] with a sub-sample of men taking part in the February 2012 (non-trial) delivery of FFIT.

Cost-effectiveness:

a) Resource use: resources employed in providing the intervention, medication use and health care consultations;
b) Quality of life: the SF-12, as above.

Process outcomes:

a) *Programme reach* (59): because our recruitment methods are focussing on raising awareness through the media, advertising and networking, measuring reach accurately will be challenging. We will attempt an estimate

[1] http://www.paltech.plus.com/products.htm#activpal

by recording route of recruitment and asking for permission to interrogate club and programme databases to provide an estimate of eligible men with a registered interest in the football club.

b) Reasons for *continuation and drop out*:
   i. feedback questionnaires to all participants at the week 12 programme session;
   ii. thirteen focus group discussions with a subgroup of completers (n=6) from each programme;
   iii. brief individual structured interviews (face-to-face or telephone) with men who do not complete the FFIT programme.
c) Programme fidelity:
   i. observation of two sessions during each FFIT programme in the trial;
   ii. individual qualitative interviews with all coaches;
   iii. focus group discussions with subgroups of completers from each club.
d) Experiences of FFIT including satisfaction, acceptability, unexpected outcomes and experience of sustaining weight loss:
   i. individual qualitative interviews with coaches;
   ii. focus group discussions with a subgroups of completers from each club;
   iii. individual structured interviews with men who do not complete FFIT;
   iv. focus group discussions with intervention group participants after the 12 month measurements.

Timing of measurements: Outcomes will be measured at baseline, 12 weeks and 12 months according to the measurement schedule shown in Table 2:

Table 2. Outcome measurement schedule

Time	Height	Weight	Waist	BMI	Blood pressure	Modified DINE	IPAQ	Self Reported Alcohol	PANAS	Rosenberg self-esteem	SF12 &resource use
Baseline	x	x	x	x	x	x	x	x	x	x	x
12 weeks	x	x	x	x	x	x	x	x	x	x	x
12 months		x	x	x	x	x	x	x	x	x	x

In addition, we will 'future-proof' the study by asking men to give permission for the research team to re-contact them in the future (e.g. through postal questionnaires or for later measurement of weight) and / or access their NHS records. Any such long-term follow up that was deemed to be of interest would need to be funded by further grant applications.

Blinding:

It will not be possible to blind the intervention to the participants, and at 12 weeks, the in-stadia measurement sessions will be held on separate nights for the intervention and comparison groups to minimise contamination (beyond that which may happen naturally and which is discussed in *4.2.3 Randomisation*). However, all efforts will be made to ensure that measurement of the primary outcome, percentage weight loss at 12 months, is blinded. First, because contamination will no longer be an issue at 12 months (as the comparison group will start the intervention shortly afterwards), both groups will be invited to the same in-stadia

measurement sessions. Second, weight will be the first measure to be taken after consent, prior to any opportunity for the men to interact with each other or fieldworkers, which will inevitably reveal allocation. All data will be anonymised prior to analysis.

4.2.6 Retention strategies

Retention strategies are summarised in Table 3.

Table 3. Retention strategies

Timescale	Strategy
Baseline measures	Intervention group phoned to confirm their attendance at the 2011 programme delivery. Comparison group sent letter with programme allocation
12-week measures	Intervention group completers: 12 week measurements taken at or around final programme session (phone appointments and written reminders in advance) Intervention non-completers: phoned to arrange individual 12 week measurements and given short structured programme exit interviews; receive club shop gift vouchers in appreciation of their time Comparison group: 12 week measurements conducted at club stadia (phone appointments and written reminders in advance); receive travel expenses. Individual home visits arranged for any non-attenders; all receive club shop gift vouchers
12 month measures	Intervention and comparison group: 12 month measurements held at club stadia; with phone appointments and written reminders in advance; receive travel expenses; individual home visits arranged for non-attenders; all receive club-based tokens of thanks in appreciation of their time
Additional measures	If the Data Monitoring and Ethics Committee reports poor recruitment or retention, additional measures will be taken to reduce loss to follow up [e.g. door-stepping participants to obtain primary outcome measure (weight loss) at 12 months]

4.2.7 Risks and monitoring adverse events

The rapid increase in obesity in the UK represents a major public health challenge, particularly among men (2). FFIT aims to address this problem by encouraging men to lose weight, become more physically active and make sustainable changes to their diet and lifestyle. The intervention has the potential to reduce or prevent obesity in men, and thus to improve participants' health.

Risks from taking part in FFIT are minimal. Some men may be disappointed if they lose less weight than other group members; coaches will be trained to give individual support where needed.

Reducing risk

The following procedures will be used to ensure the potential for significant risk to participants and coaches is minimal:

1. As recommended in SIGN guidance (6), participants will be screened for contraindications to exercise using the Physical Activity Readiness Questionnaire (PAR-Q) (37) at baseline measurement sessions. Men who answer "yes" to any question on the PAR-Q will be encouraged to consult their GP. They will be given a letter providing information about their PAR-Q questions, and records will be kept of all letters issued.

2. Men found to have elevated blood pressure at baseline measurement sessions will also be encouraged to consult their GP. They will be given a letter providing information about their blood pressure readings, and records will be kept of all letters issued. Men whose measured blood pressure indicates that they should not undertake vigorous activity will be excluded from the in-stadia, coach-led physical activity component of the programme until they demonstrate to coaches that their GP approves of their participation or their blood pressure is lower (e.g. through a doctor's letter). They will be encouraged to undertake moderate intensity walking activities;
3. Coaches will be trained in tailoring physical activity programmes for men of varying levels of fitness and with the pre-existing health problems identified by the PAR-Q (e.g. high blood pressure, joint problems).
4. Coaches will also be trained to teach participants to use the Rate of Perceived Exertion (RPE) Scale to assist men in exercising at moderate intensity levels.

Monitoring adverse events

Adverse events will be monitored by:

1. Coaches will be trained to keep a weekly adverse events log during the intervention group FFIT programme delivery and will send a completed *serious* adverse events monitoring form to the project manager if a *serious* adverse event happens (e.g. they hear about or experience during the sessions a death, hospital admission, fall or injury requiring prolonged medical attention).
2. All men enrolling on FFIT in August / September 2011 will receive two prepaid postcards for reporting to the MRC/CSO SPHSU Survey Office any adverse events occurring during the 12-month research period (e.g. newly diagnosed medical condition, hospitalisation, injury requiring prolonged medical attention). Additional postcards will be provided at the 12 weeks measurements.
3. The Project Manager will report all adverse and serious events to the CI, the Study Steering Group and the Data Monitoring and Ethics Committee.

Structured interviews with men who do not complete the programme, conducted around the time of the 12 week measurements, will allow investigation of reasons for their withdrawal and any positive or negative changes they experienced from their involvement with FFIT. Focus groups with men who complete the programme will also explore any adverse outcomes. Any men who stopped attending the programme because of changes to their personal circumstances will be offered a priority place on a future FFIT programme.

Safety during home visits

Men who are unable to attend their club stadium for a measurement session will be given the opportunity to be visited by a fieldworker at their home or other convenient location. The following safeguards will be in place to protect both participants and fieldworkers:

i. In accordance with MRC policy, all fieldworkers will be Agenda checked[2];

[2] http://www.agenda-security.co.uk/

ii. All fieldworkers conducting out-of-stadia visits will use the Communicare Lone Worker Service[3].

4.3 Data collection

4.3.1 Data collection

Baseline data: All men registering interest in FFIT prior to the baseline measures in their club will be invited to attend measurement sessions either in-stadia or at another convenient location. Eligibility will be confirmed and men randomised to the intervention group (starting FFIT in September 2011), comparison group (starting FFIT in September 2012) or non-trial delivery programmes (starting FFIT in February 2012).

Outcome data: Intervention group 12-week measurements will be taken around the time of the final FFIT programme session, with phone appointments and written reminders in advance. Any men who do not attend the stadia for these measurements will be phoned to arrange individual measurements at home. Men who have dropped out of the FFIT programme will be invited to the measurement sessions and will also receive structured programme exit interviews and a £20 club shop gift voucher in appreciation of their time.

Comparison group 12 week measurements will be held at club stadia (on a different evening to the intervention group measurements), with phone appointments and written reminders in advance; the men will receive travel expenses and £20 club shop gift vouchers in appreciation of their time. Individual home visits will be arranged for non-attenders who will also receive £20 club shop gift vouchers.

Twelve month measurement sessions for both groups will be held at club stadia, with phone appointments and written reminders in advance; those who do not attend will be phoned to arrange individual home-based measurements. All men will receive club-based tokens of thanks in appreciation of their time.

Physical measures and questionnaire administration will be conducted by teams of fieldworker staff (including a designated team leader at every session and a fieldwork nurse at baseline measurements) trained to standard MRC measurement protocols by experienced MRC/CSO SPHSU survey staff. The training and strict adherence to protocol will minimise detection bias, and research standard weighing scales, stadiometers, tape measures, sphygmanometers and bioimpedance meters will ensure the high quality of captured data.

Secondary outcome measures and questions relating to postcode, ethnicity, disability, education, medical history, method of recruitment and a measure of adherence to stereotypical masculine norms will be gathered via a self-completion booklet, with sufficient staffing for a fieldworker to read out all questions and record verbal answers for men with low literacy. Fieldworkers will record all physical measures in the booklet.

Assessment of process outcomes: The method of recruitment to the programme (e.g. from newspaper article, advert, club website) will be recorded. Field notes will be written during observations of programme sessions, which will also be audio-recorded and part video-recorded. Coach interviews and focus group discussions will be audio- and video-recorded and transcribed verbatim to facilitate analysis.

[3] http://www.argyll-loneworker.co.uk/about/communicare/

Structured interviews with men who do not complete the programme and focus group discussions with programme completers will explore reasons for continuation and drop out, acceptability of FFIT to participants, satisfaction with FFIT and any unexpected outcomes. Interviews with coaches will also explore their views on these matters. Focus group discussions with intervention group representatives following the 12 month measurements will investigate experiences of sustaining weight loss.

4.3.2 Data management

Pages of the questionnaire booklet will be bar-coded to minimise assignation errors during data handling. Any personal details will be recorded in a different document which will be separated from the questionnaire before leaving either in-stadia or home-based measurement sessions and kept separate thereafter. Designated fieldwork staff will deliver both parts to the MRC/CSO SPHSU with a minimum delay. The personal details pages will be stored securely at the MRC/CSO SPHSU, the remainder will be transferred by secure courier to the Tayside Clinical Trials Unit (TCTU) at time points agreed between MRC/CSO SPHSU and TCTU staff. Following the period of active data handling, all data will be stored in the most appropriate secure storage.

The TCTU will provide data management support. It will use OpenClinica to generate a web based, GCP-compliant data management system. CRFs will be developed with the CI, trial management team, statistician and data manager to ensure that the data management system supports the research aims of the study. The data management system will be fully validated, including the provision of test data and supporting documentation. Data export will be in line with the statistical analysis plan which will be finalized prior to datalock.

Data entry will be handled by the TCTU using visual verification with correction to reduce transcription error. The TCTU Data Manager will coordinate handling of data queries.

All TCTU data management support will be in line with TCTU's Standard Operating Procedures for data management (http://www.tasc-research.org.uk/_page.php?id=266).

4.3.5 Progress reports

Progress reports will be written for the funders at 6-monthly intervals over the course of the project as follows:

1. 1 December 2011
2. 1 June 2012
3. 3 December 2012
4. 3 June 2013

4.3.6 Final report

The final report is to be received by PHR by 14 January 2014.

4.4 *Data analysis*

4.4.1 Sample size

To detect a difference in weight reduction of 5% between intervention and comparison groups at 12 months, with SD 19.9%, 80% power and a 2-sided significance level, 250 men are required in each arm of the trial. To allow for a 30% loss to follow up (based on feasibility work estimates), the sample size is inflated to 360 men in each arm (see Figure 1, above). As each FFIT programme can accommodate up to 30 participants, 13 programme deliveries are required to

recruit 360 men to the intervention and comparison groups.

4.4.2 Missing data

The patterns and extent of missing data will be examined and, if necessary, methods such as multiple imputation will be implemented to provide robust results, assuming data are missing at random (MAR). As this assumption is not testable in the data, a valid argument needs to be constructed. The assumption of MAR allows the use of mixed models in the repeated measures analysis which has the advantage of using all available data.

4.4.4 Quantitative analysis

All analyses will be based on intention-to-treat models in accordance with ICH E9 'Statistical Principles for Clinical Trials'.

The primary analysis will compare the difference in percentage change in weight at 12 months (60) between the intervention and comparison groups (using t-tests assuming a normal distribution, or a suitable transformation or non-parametric tests). The characteristics of baseline weight (61), age, compliance with the programme (as defined by attending at least 50% of sessions), socioeconomic status and masculinity norms will be adjusted for as covariates with 12 month weight as dependent variable in a multiple linear regression (62). All analyses will be stratified by SPL club.

As a secondary analysis of change over time, all the weight measurements from baseline to 12 months will be assessed in a mixed model by fitting polynomials to the trend lines and testing for differences between intervention and comparison groups and estimating the area between the trend lines (63). Random effects models will also be explored as a secondary analysis.

These analyses will be repeated for secondary outcomes. Pre-specified subgroup analyses (60) will test for interactions with group (intervention, comparison) by age, socioeconomic status and 'masculinity norms' scores. If significant interactions are found, differences in effect estimates for the intervention vs. comparison will be derived separately by levels of these factors. All quantitative analysis will be implemented in SPSS (v17.0) and SAS (v9.2).

No interim analyses are planned. A statistical analysis plan will be written with dummy tables of results prior to data lock at the end of the study to ensure hypotheses are *a priori*.

4.4.5 Qualitative and other process analyses

Transcripts of focus group discussions and interviews with club coaches will be analysed using thematic frameworks (64) to explore relevant research questions whilst allowing for unanticipated themes to be identified. Several researchers will read anonymised transcripts to support the development of a robust analytical framework and to ensure analytical rigour. Field notes from programme observations will be written up electronically as soon as is practical; ideally the following day, but always before a subsequent observation. Data from structured interviews with men who do not complete the programme will be presented as frequency tables. Data from focus group discussions, interviews, structured interviews and observations will be triangulated to construct a detailed description of the acceptability of FFIT to participants and coaches, their satisfaction with the programme, reasons for continuation / drop out, and the processes of, and any pitfalls in, delivery. The data from the process evaluation will be used alongside the

results of the cost-effectiveness analysis to assess the feasibility of implementing the intervention more widely. The organisation and analysis of qualitative data will be supported by the use of NVivo (v8) software. Frequency tables will be prepared using SPSS (v17.0).

4.5.6 Cost effectiveness analyses

The cost-effectiveness of the intervention will be assessed at two time points: an initial analysis based on the costs and outcomes measured within the trial period; and a second analysis modelling longer term cost-effectiveness. Both analyses will utilise the NHS and Personal Social Service perspective favoured by NICE (65).

The short-term within-trial analysis will compare the costs and outcomes associated with the intervention group to those of the comparison group at 12 months. Outcome measures for this analysis will be (a) number of men achieving and maintaining 5% weight reduction over the 12 month period; (b) a within-trial measure of QALYs determined from SF-12 scores using the algorithm described by Brazier and Roberts (65) and the area under the curve method (66).

Resource use will focus on the resources employed in providing the intervention, medication use (both prescription and over-the-counter) and health care consultations. The collection of resource use data will capture changes (either positive or negative) that occur as a result of the intervention; e.g. as men become more aware of health issues generally and seek advice about other issues that concern them, or reduce their reliance on these resources as they become fitter and healthier, or increase their requirement for these resources as a result of injuries or conditions that develop as a result of their increased physical activity or altered diet. Resource use will be collected at baseline, 12 weeks and 12 months directly from participants alongside the SF-12.

Unit costs will be obtained from appropriate sources (BNF, NHS reference costs, PSSRU costs of health and social care). Initial analysis will estimate cost-effectiveness of the intervention in terms of cost/person achieving and maintaining the 5% weight loss target and cost/QALY gained. The uncertainty surrounding estimates of cost and effects for the intervention and comparison group will be investigated through ‘bootstrapping’ (67), with resulting distributions of mean costs and effects presented graphically on the cost-effectiveness plane and using cost-effectiveness acceptability curves.

The longer term analysis will employ a decision model, populated with reference to the literature, to link the short term outcomes measured within the trial (in terms of physical activity, blood pressure, waist circumference and percentage body fat) to potential longer term impacts on health (e.g. in terms of impacts on the development of cardiovascular disease, diabetes, etc.). The model structure will be informed by a review of models previously undertaken in this area and in consultation with the project collaborators, and, where appropriate, outcomes from the process evaluation will be incorporated into the model structure. Data will be embodied in the model through the specification of probability distributions for each parameter, to reflect the uncertainty. The outputs reported from this analysis will be the same as those in the within trial analysis. Probabilistic sensitivity analysis will be employed, using Monte Carlo simulation techniques, to explore the uncertainty surrounding longer term estimates of costs, effects and cost-effectiveness for both groups. In addition, the results of the probabilistic analysis will be used within a Value of Information framework to identify the knowledge gaps and to determine

whether it would be potentially worthwhile undertaking further research in these specific areas to fill these gaps.

5. Contribution of existing research:

Although the potential of sporting organisations to deliver health initiatives to hard-to-reach populations is increasingly recognised, two Cochrane reviews (68;69) failed to find any controlled studies in this area. The 2011 launch of FFIT presents a unique opportunity to conduct an RCT evaluating the effect of a programme delivered through sporting organisations on weight loss outcomes at 12 weeks, and to examine whether these are maintained to 12 months. The SPL, the clubs, the Scottish Government and the Football Pools are all committed to FFIT and, if the intervention proves effective, the potential for widespread implementation is very high.

6. Plan of Investigation:

Project timetable and milestones

Date	***Milestones / tasks completed***
May 11	Ethics obtained
01 Jun 11	*Project starts*
Aug 11	Fieldworkers recruited and trained
Aug 11	Participant recruitment completed
Sept 11	***i.*** Baseline Measures in 13 clubs completed; ***ii.*** Preparation of protocol paper completed
Dec 11	***i.*** Observation of 2 programmes per club completed; ***ii.*** 12 Week Measures in 13 clubs completed
Jan 12	Participant chase up / structured exit interviews completed
Apr 12	Focus groups with participants and interviews with coaches completed
Jun 12	Quality assurance of initial transcripts completed
Sept 12	12 Month Measures in 13 clubs completed
Dec 12	Participant chase up for 12 Month Measures completed
Mar 13	Focus groups with participants focusing on sustaining outcomes long term completed
May 13	Database closed
Aug 13	***i.*** Quantitative outcome analyses completed; ***ii.*** Cost effective analyses completed
Sept 13	Quality assuring of transcripts and qualitative analysis completed
Dec 13	***i.*** Dissemination of findings at 13 clubs completed; ***ii.*** Preparation of papers on quantitative and qualitative results completed; ***iii.*** Preparation of project report completed
31 Dec 13	*Project ends*

7. Project Management:

7.1 Ethical review

The study complies with and is being conducted in accordance with the UK ESRC Framework for Research Ethics:
http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf

Ethical approval for the study has been obtained from the University of Glasgow College of Social Sciences Ethics Committee for non-clinical research involving Human Subjects (CSS/2011/029). The ethics approval and all relevant documentation are available on request.

There will be three management committees:

7.2 Study Steering Group

This will provide overall supervision of the trial. It will meet at once a year and its role will be to monitor and supervise the progress of the trial towards achieving its goals; to advise the investigors in general scientific and management issues; and to ensure that there are no major deviations from the protocol. Professor Frank Sullivan**,** School of Medicine, University of Dundee, has agreed to chair the SSG and may call additional meetings when there are matters arising from the conduct or management of the trial that might require their advice.

7.3 Data Monitoring and Ethics Committee

The DMEC will monitor data and inform the SSG whether there are any ethical or saftey reasons why the trial should not continue. It will meet twice during the 12 month fieldwork period. There are no formal stopping rules. Professor Alastair Leyland, MRC/CSO SPHSU has agreed to chair the DMEC.

7.4 The Trial Management Group

The trial management group consists of all applicants and will oversee the operational running and progress of the trial. The TMG will meet at least 4-monthly, convened by the CI. It will delegate day to day running to sub-groups responsible for: recruitment and retention; data collection and fieldwork; data management; and measurement.

8. Service users / public involvement:

Feasibility work (funded by the CSO and SPL Trust) following the September 2010 delivery of FFIT investigated participants' and coaches' views of the intervention and the research procedures. These views have been used to refine the FFIT intervention, the research protocol and research procedures prior to the start of the full trial. The SSG includes two past participants in FFIT who will act as independent advisors to ensure that men's opinions are represented throughout the project. The trial findings will be disseminated to all participants and coaches through a one-page lay summary and dissemination events at the end of the study.

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