1. Project title: Long term weight loss trajectories in participants in a randomised controlled trial of a weight management and healthy lifestyle programme for men delivered through professional football clubs: the Football Fans in Training follow up

2. Background: Obesity is a major public health problem (1). There are expected to be 11 million more obese adults in the UK by 2030, accruing up to 668,000 additional cases of diabetes, 461,000 cases of heart disease and stroke, and 130,000 cases of cancer: with associated medical costs set to increase by £1.9-2 billion/year (2). Although the behavioural change techniques that are effective in helping people achieve clinically significant [at least 5% (3)] *short term weight loss* (i.e., during and immediately post-intervention) by increasing physical activity and improving diet are now well described (4-6), *longer term weight loss* is less well researched and remains a challenge. A systematic review suggested that mean weight loss two years following participation in behavioural interventions is under 2kg (7); other research has demonstrated that most people return to their initial body weight within 5 years (8).

A conceptual review suggested that short term weight loss, sustained positive health behaviours (being physically active, eating regular meals (including breakfast) and a flexible approach to dietary control), stability in life and ongoing self-monitoring are associated with successful long term weight loss (9). Theoretical accounts of maintenance of change suggest that satisfaction with behaviour and habit formation may be important (10), and also that satisfaction of three basic psychological needs – autonomy (associated with the internalisation of regulation), competence to perform behaviours and relatedness to others may predict successful long term weight control (11, 12). However, evidence on long term weight loss remains limited, particularly in men (13). More research is required to improve understandings of the determinants of long term weight loss following behavioural interventions (specifically who is successful in achieving weight loss long term, how and why) in order to inform the development of future interventions to improve long term outcomes.

Men and weight management: The UK prevalence of male obesity is amongst the highest in Europe (2) and is forecast to increase at a faster rate than female obesity in the next 40 years. Compared to women, men may be more vulnerable to the adverse health consequences of obesity: men's tendency to carry excess fat abdominally puts them at greater cardiometabolic risk (14) and they are diagnosed with type 2 diabetes at a lower body mass index (BMI) than women (15). In Scotland, obesity-related health risk is socially-patterned, with men who are less affluent and less well educated at increased risk (16). However, men are under-represented in referrals to commercial weight management programmes (between 11% (17) and 13% (18) of referrals are men) and in NHS weight management services (23% men) (19). A recent systematic review concluded: "That men are under-represented suggests that methods to engage men in services, and the services themselves, are currently not optimal." (20)

Men's reluctance to enrol in weight management programmes may in part reflect the way men perceive weight management – as a 'diet' or a 'women's' issue (21-23). It may also be influenced by the setting in which such programmes are delivered: for example, a Slimming World initiative to target men (by offering men-only groups) failed to increase their engagement beyond 5% (24). However, the potential of professional sporting organisations to attract men to health promotion activities is now being recognised (25-30), and their success in engaging men in weight loss has recently been demonstrated by the NIHR PHR-funded (09/3010/06) randomised controlled trial (RCT) of the **Football Fans in Training (FFIT)** weight management programme at 13 of the top professional football clubs in Scotland (ISRCTN32677491) (31).

Football Fans in Training: weight loss, physical activity and healthy eating for men: FFIT is designed to work with, rather than against, prevailing conceptions of masculinity (32-34). It is 'gender-sensitised' in relation to context (the traditionally male environment of football clubs, men-only groups), content (information on the science of weight loss

presented simply ('science but not rocket science')), discussion of alcohol, 'branding' (e.g., use of club insignia on programme materials) and style of delivery (participative, peer-supported learning which encourages male 'banter' to facilitate discussion of sensitive subjects). The programme is delivered free of charge by community coaching staff at professional football clubs in Scotland to groups of up to 30 overweight/obese men (participant:coach ratio 15:1) over 12, weekly sessions at club home stadia. Each week combines advice on healthy eating and/or behaviour change techniques ('classroom component') with group physical activity sessions led by the coaches. The behaviour change techniques are those known to be effective in physical activity and dietary interventions (self-monitoring, goal setting, implementation intentions, feedback on behaviour) (4), and social support (5) is also promoted. Throughout FFIT men are encouraged to make behavioural changes they can sustain long term, and to incorporate physical activity and healthy eating into their daily lives. The 12-week active phase is followed by a light-touch weight maintenance phase (six e-mail prompts from coaches until 12 months after the start of FFIT and a group reunion at the club at 9 months) (34).

Our RCT baseline measures demonstrated that FFIT successfully engaged men aged 35-65 years from across the socio-economic spectrum (35) whose excess bodyweight put them at high risk of ill-health (33). After baseline measurements, 747[1] men were randomised to either the intervention group (N=374) or comparison group (N=373). All men were given an information book on weight loss at enrolment. Men in the intervention group took part in FFIT immediately (in autumn 2011); men in the comparison group were asked to wait 12 months (until autumn 2012) before attending the programme (see Figure 1). We conducted follow up measurements at 12 weeks and 12 months in both groups (with 92% retention overall at 12 months). The waitlist design means that all men in our RCT (i.e., the comparison group as well as the intervention group) have now had an opportunity to take part in FFIT. Because the comparison group took part in FFIT after the end of the RCT, we did no further data collection (i.e., post-invention measurements) with them. In spring 2015, it will be 3.5 years since the intervention group started FFIT and 2.5 years since the comparison group began.

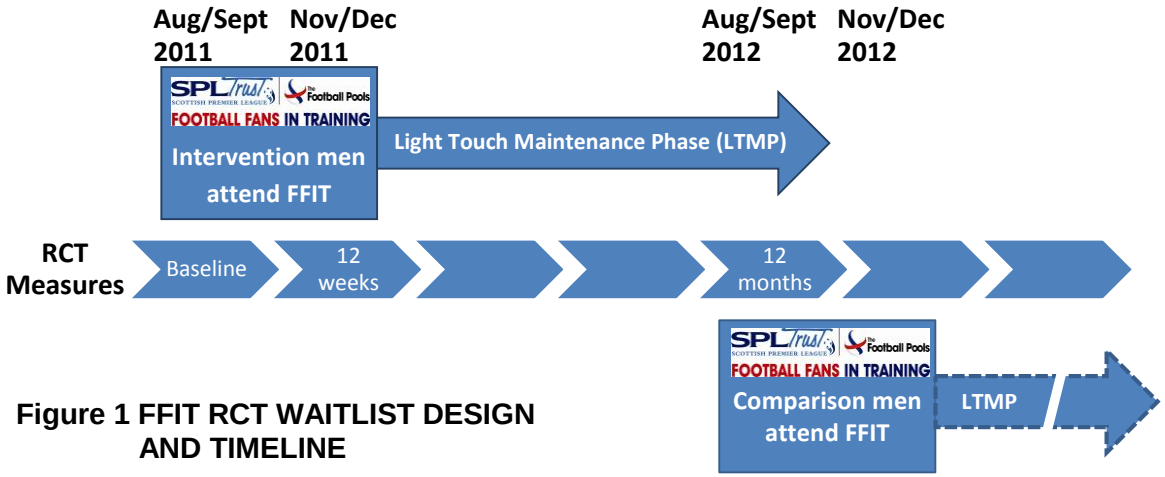

Figure 1 FFIT RCT WAITLIST DESIGN AND TIMELINE

During the RCT, the coaches delivering FFIT reported the intervention group's weekly attendance at programme sessions to the research team; four out of five men attended at least six of the 12 sessions during the active phase (35). By 12 weeks (i.e., immediately post-programme), the intervention group had lost on average 5.18 kg (95% CI 4.35, 6.00, p<.0001) more than men in the comparison group, and 46.8% (154/329) had achieved a weight loss of at least 5% of their initial bodyweight. This compares to 6.9% (24/347) of men in the comparison group (35). At 12 months, many, but not all, intervention group men had

[1] Originally 748 men were randomised, but one man from the comparison group withdrew from the RCT and asked to have his data destroyed after the 12 week measures.

succeeded in maintaining their weight loss. An objectively-measured weight reduction of at least 5% was recorded in 39.0% (130/333) of intervention group men, compared to 11.3% (40/355) of the comparison group, and the mean between-group weight loss difference was 4.94 kg (95% CI 3.95, 5.94, p<.0001) in favour of the intervention group. Significant between-group differences were also observed at 12 weeks *and* 12 months in a range of secondary outcomes, including waist circumference, percentage body fat, resting blood pressure, self-reported physical activity, dietary intake, alcohol consumption, and psychological outcomes (self-esteem, affect and physical health-related quality of life) (35).

The RCT demonstrated that FFIT was inexpensive to deliver and was cost effective, with an incremental cost of £13,387 per QALY gained (35). This was calculated over the 12 month within-trial period. For a cost-effectiveness threshold of £20,000/QALY, the probability that FFIT was cost-effective, compared to no active intervention, was 0.72. This probability rose to 0.89 for a cost-effectiveness threshold of £30,000/QALY. The longer term modelling also showed favourable results; limiting the longer term impact of the FFIT intervention to 5 years, our analysis demonstrated that FFIT has a cost-effectiveness estimated between £1,174 per QALY gained and £4,475 per QALY gained (compared with no active intervention) depending on the assumptions made about the impact on longer term costs (36).

Focus group discussions with a sub-sample (N=68) of intervention group men (with a range of experiences of weight loss to 12 months) from each of the 13 football clubs in the RCT were conducted as part of the process evaluation. Analyses of these data suggested that men had exercised autonomy in their choice of strategies to control their weight post-programme. Some had found focusing on a healthy, balanced diet with structured, organised eating patterns helpful. Many described how they had succeeded in incorporating new physical activity and healthy eating habits into their daily routine, and how they were continuing to self-monitor their weight and/or physical activity. Most had, to some extent, developed internalised behavioural regulation. Many spoke about the importance of ongoing social support, either from their partners and children or from fellow FFIT participants (in some clubs men had continued to meet up following the 12, weekly club sessions), and some felt they had changed aspects of their identity through participation in the programme. Nevertheless, men also reported a number of barriers to ongoing weight control post-programme; these included injury, illness and stressful life events (e.g., bereavement) (36).

The RCT findings have clearly demonstrated the effectiveness of FFIT in helping many men aged 35-65 with BMI≥28kg/m^2 achieve a clinically-significant weight loss in the short (immediately post-intervention) and medium term (to 12 months), and the qualitative process evaluation has provided further insight into the barriers and facilitators of maintaining weight loss and improvements in physical activity, diet and alcohol intake to 12 months. The 12 month measurements also demonstrated that 1:10 men in the waitlist comparison group had succeeded in losing weight before starting the programme. This change in the comparison group, which is contrary to the usual pattern of weight gain, has been shown in other RCTs (37), and has important implications for research and practice (38). In the case of FFIT, the ≥5% pre-intervention weight loss in 11.3% of the comparison group may reflect an effect of being measured and receiving feedback on weight and/or completing questionnaires on diet and physical activity in a setting which has high cultural value for participants (the football club).

Around 3000 men have now taken part in FFIT, and the Scottish Government is currently funding further deliveries in over 20 Scottish Professional Football League clubs (the SPFL now includes 42 football clubs) overseen by the SPFL Trust. The core FFIT research team is committed to supporting the widespread implementation of FFIT. In partnership with the SPFL Trust, we are currently developing a FFIT training package (including online as well as face-to-face materials) to train new coaches to deliver FFIT, and we have made the delivery materials available using online registration and a free-of-charge licence to allow ongoing monitoring of the wider impact of the FFIT programme.

However, the RCT leaves a number of crucial questions unanswered:

(i) *to what extent* and *who* is successful in *achieving long term weight loss* following participation in FFIT, and to what extent are weight loss trajectories similar or different in the intervention and waitlist comparison groups?
(ii) *to what extent* are *changes in health behaviours and psychological outcomes sustained* over the long term following participation in FFIT?
(iii) *which factors* are associated with successful long term weight loss following participation in FFIT?
(iv) *how* do men who achieve long term weight loss account for their success, and what obstacles or barriers explain why others are not successful?
(v) what is the cost-effectiveness of FFIT over the medium and longer term?
(vi) what are the *wider long term health outcomes* of men who participate in FFIT and what is the potential for very long-term cost-effectiveness?

2.1. Risks and benefits: The RCT demonstrated that the potential health benefit (through weight loss) of taking part in FFIT far outweighed the risk. Our health economic models suggested that participation in FFIT was associated with an average increase of 0.43 life years (95% CI 0.32, 0.56) and 0.38 QALYs (95% CI 0.25, 0.55) (36). During the RCT, eight serious adverse events (SAEs) were reported, five in the intervention group and three in the waitlist comparison group. Although becoming more physically active may increase opportunity for injury, only two of these SAEs were reported as, or appeared to be, related to participation in FFIT (an Achilles tendon rupture and aggravated gallstones) (35). However, despite instruction from the FFIT coaches on how to exercise safely (e.g., by warming up, cooling down and using the Rate of Perceived Exertion Scale (39)), some participants said in the 12 month focus groups that their efforts to maintain weight loss and remain more active had been hampered by minor injuries sustained post-programme (36). The proposed long term follow up presents an opportunity to collect further detailed information about injuries, joint problems and newly-diagnosed medical conditions that they perceive as being related to their involvement in FFIT, and major life events.

2.2. Rationale for the current study: The 12 month results from the FFIT RCT compare favourably with RCTs of other men-only weight management programmes. A review of interventions to reduce obesity in men identified two randomised controlled trials that: 1) targeted men; 2) combined dietary and physical activity advice with support for behavioural change; and 3) reported outcomes for intervention and comparison groups at 12 months (20). These trials, which were of internet-based programmes with some one-to-one support, recorded mean between-group weight loss differences of 2·2 kg (95% CI 1·25, 5·65) (40) and 0·6 kg (95% CI 0·14, 1·52) (41) in favour of the intervention groups at 12 months – whereas FFIT achieved a mean between-group 12 month weight loss difference of 4·9 kg (95% CI 3·95, 5·94) (35).

To fully understand the potential public health benefit of FFIT, it is important to conduct longer term follow up of the promising RCT 12 month outcomes to understand: the extent to which long term weight loss and positive behavioural and psychological changes are achieved following participation in FFIT; whether participants in FFIT programmes delivered under 'non-research' conditions (as was the case for the comparison group) are as successful as participants in programmes delivered under 'research' conditions (as was the case for the intervention group where some deliveries were observed by the research team); who does best in achieving positive long term outcomes; the factors associated with successful/less successful long term weight control; and whether the programme remains cost-effective in the medium and long term. Such evidence remains extremely limited, particularly in men (13). In spring 2015, participants in the FFIT RCT will be 3.5 years (intervention group) and 2.5 years (comparison group) post-intervention. We intend to revisit both groups to assess and investigate explanations for any differences in weight loss trajectories between and within the RCT intervention and comparison groups. The project

also provides an opportunity to investigate the feasibility and potential utility of low cost, passive, long term follow up of men taking part in the FFIT RCT through routinely-collected NHS medical records, which could be extended to men taking part in future 'routine implementation' (non-research) deliveries of FFIT. If this feasibility work suggests that data linkage is acceptable to non-research FFIT participants, it could enable low-cost investigation of the wider long-term health outcomes and cost-effectiveness of FFIT in a much bigger cohort of men. Findings from the proposed research will inform the development of future interventions to support long term weight loss and health behaviour change delivered in professional sports club and other settings.

3. Research objectives: Our main aims are:

1) To investigate long term weight loss trajectories from baseline to 3.5 years (i.e., 3.5 years after the intervention group commenced participation in FFIT and 2.5 years after the comparison group did so) in men who were aged 35-65 with BMI at least 28kg/m^2 at the start of the FFIT RCT.
2) To establish the cost-effectiveness of FFIT over the medium and longer term.
3) To investigate the feasibility and utility of establishing low cost, long-term, passive follow up of current and future participants in FFIT via routinely-collected NHS records.

There are six objectives that relate to: long term weight outcomes; long term changes in the FFIT RCT secondary outcomes; the predictors of long term weight loss; men's experiences of successful/unsuccessful long term weight control; cost-effectiveness; and future follow up via linkage to medical records:

Objective 1 Long term weight outcomes: To investigate the extent to which:

(i) participants in the *FFIT intervention group* achieve objectively-measured long term weight loss (3.5 years after baseline measurements and 3.5 years after commencing participation in FFIT);
(ii) participants in the *FFIT comparison group* achieve objectively-measured long term weight loss (3.5 years after baseline measurements and 2.5 years after commencing participation in FFIT);
(iii) weight loss trajectories and weight loss 3.5 years after baseline measurements differ between the intervention group and the comparison group.

Objective 2 RCT Secondary outcomes: To investigate the extent to which there are long term changes in the intervention and comparison groups in the RCT secondary outcomes, and how these differ between groups:

(i) other objective physical measurements: BMI, waist circumference, percentage body fat and resting blood pressure;
(ii) health behaviours: self-reported physical activity (PA), sitting time, diet and alcohol intake;
(iii) psychological outcomes: self-esteem, positive and negative affect, and health-related quality of life (HRQoL).

Objective 3 Predictors of long term weight loss: To investigate:

(i) the baseline predictors (age, BMI, education, socioeconomic and marital status, and orientation to masculine norms) of successful long term weight loss in the two groups and how these may differ;
(ii) how the following variables predict long term weight loss after controlling for the baseline predictors in both groups and how these may differ between the groups:
    a) change (from RCT baseline, 12 weeks and 12 months) in health behaviours (self-reported PA, sitting time, diet and alcohol intake);
    b) change (from RCT baseline,12 weeks and 12 months) in psychological status (self-esteem, positive and negative affect, and HRQoL);
    c) perceived autonomy, competence, relatedness and satisfaction with physical activity and dietary behaviours, as assessed at 3.5 years;
    d) the extent to which physical activity and healthy eating routines are established, ongoing use of behavioural change techniques, ongoing contact with other

FFIT participants, and major life events, as assessed by self-report at 3.5 years;

e) end-of-intervention weight change (intervention group – from objective RCT measurements; waitlist comparison group – self-reported) and pre-intervention weight change (comparison group only – from objective RCT measurements);
f) self-reported injury and joint pain as assessed at 12 months and 3.5 years.

Objective 4 Men's experiences: To describe men's experiences (including their motivations, emotions and relations with others) of attempting to control their weight over the long term, their reasons for achieving/failing to achieve long term weight loss, and the strategies they have continued to use/stopped using.

Objective 5 Cost-effectiveness: to investigate medium and long term cost-effectiveness of FFIT by:

a) establishing the extent to which weight loss and positive behavioural changes are sustained beyond the first 12 months, and the subsequent impact on the cost-effectiveness of FFIT at 3.5 years;
b) updating the modelling of the longer term health outcomes and resource use of men who participate in FFIT, and assessing the potential for cost-effectiveness;
c) exploring heterogeneity of the cost-effectiveness of FFIT.

Objective 6 Long term follow up via medical records: To explore the utility and feasibility of using linkage to routinely-collected NHS datasets to allow long term, low cost, passive follow up of FFIT participants through investigation of:

(i) utility: long term health outcomes (through linkage data on hospitalisations, mortality, prescribing, cancers, diabetes and, where possible, blood test results) of RCT participants, and the extent to which these are associated with long term weight loss and behaviour change;
(ii) feasibility: the extent to which men enrolling in routine implementation deliveries of FFIT (in spring and autumn 2015) are prepared to give permission for transfer of their baseline, post-programme and 9 month weight and BMI (as measured by coaches in participating clubs) to the research team, and to agree to linkage of these data to their NHS records.

4. Research design: A mixed methods, longitudinal, follow up study to investigate long-term weight loss trajectories in participants in a randomised controlled trial of a weight management and healthy lifestyle programme for men delivered through professional football clubs: Football Fans in Training. As both groups in the FFIT RCT (the comparison group as well as the intervention group) have now taken part in the intervention (the comparison group in autumn 2012; the intervention group in autumn 2011), the follow up is essentially designed as a cohort study.

To investigate our first research aim (weight loss trajectories), intervention group and comparison group participants will provide before-and-after measurements (baseline to 3.5 years) of the RCT primary and secondary outcomes using the same assessment protocols as in the RCT. The 3.5 year follow up assessments therefore take place 3.5 years after the intervention group started the FFIT programme in 2011, and 2.5 years after the comparison group started the FFIT programme in 2012. Additional measures of perceived autonomy, competence, relatedness, and satisfaction with, and the extent of establishment of routines of, physical activity and dietary behaviours, ongoing use of behaviour change techniques, ongoing contact with other FFIT participants, and self-reported major life events will be included at the 3.5 year measurements. Semi-structured qualitative telephone interviews will explore men's accounts of attempting to control their weight over the long term.

To investigate our second research aim (cost effectiveness), we will use the 3.5 year measurement and assessment data (described above) to revise estimates of the impact of FFIT at 3.5 years. We will also use these data and the additional NHS linked data from the FFIT RCT cohort (intervention and comparison groups) to model the longer term impact of

FFIT, and to explore heterogeneity to identify sub groups for whom FFIT is or is not cost-effective.

To investigate our third research aim (utility and feasibility of long term, low cost follow up through NHS records), we will: undertake record linkage to NHS data on hospitalisations, deaths, prescribing, cancers, diabetes and, if possible, blood test results for RCT participants who have already given their permission for data linkage; and visit clubs to seek written permission from participants in new deliveries of FFIT for transfer of key pre, post-programme and 9 month measures to the research team, and for data linkage.

5. Study population: Men who were aged 35-65 with BMI ≥28kg/m^2 at the time of the FFIT RCT baseline measurements in August/September 2011, who were randomly assigned to either the FFIT intervention group (started FFIT within three weeks of baseline measures in August/September 2011) or the waitlist comparison group (started FFIT soon after the 12 months measurements in August/September 2012) and who consented to being contacted for follow up research at the RCT 12 month measurements. Over 89% of men who took part in the RCT baseline measurements have consented to being contacted for follow up (N=665/747); almost 87% have already consented to data linkage (N=648/747).

We will also approach men taking part in deliveries of FFIT in spring and autumn 2015 to investigate the feasibility of establishing low cost, long-term, passive follow up of future participants in FFIT via routine NHS records.

6. Socioeconomic position and inequalities: The FFIT RCT attracted men from across the socioeconomic spectrum: baseline measures showed that despite no attempts being made to specifically target low SES groups, 35% of RCT participants were from more deprived areas (quintiles 1 and 2 of the Scottish Index of Multiple Deprivation[2]) (35). This reflects the traditional 'working class' appeal of football (42) and the fact that many SPFL clubs are located within, and have strong links to, disadvantaged communities. Compared with men of the same age in the general population, around ten times more FFIT participants were classed as being at 'extremely high' risk of ill health on the basis of their BMI and waist circumference; and less than 4% had attended a commercial or NHS weight management programme or clinic in the previous 3 months (33).

FFIT therefore demonstrated good potential to reduce health inequalities, and there were no differences in 12 month weight loss outcomes across the SIMD quintiles. This follow up study aims to assess the longer term impact of FFIT on weight and other objective physical measures (BMI, waist circumference, percentage body fat, resting blood pressure), health behaviours (self-reported physical activity, sitting time, diet and alcohol intake) and psychological outcomes (self-esteem, positive and negative affect, HRQoL). It will also examine whether long term weight loss following participation in FFIT is associated with socioeconomic status.

7. Planned interventions: The proposed research is a longitudinal follow up of participants in the FFIT RCT. We do not plan to conduct any further interventions as part of this study. A detailed description of the intervention is available elsewhere (34).

8. Retention strategies: The personalised approach to recruitment and retention during the FFIT RCT resulted in excellent retention: over 88% (330/374) of the intervention group and almost 93% (347/374) of the comparison group took part in the 12 week measures; 89% (333/374) of the intervention group and almost 95% (355/374) of the comparison group took part in the 12 month measures. We therefore have a 'study-loyal' population, of whom 316 men in the intervention group and 349 men in the comparison group have consented to further follow up.

[2] http://www.scotland.gov.uk/Topics/Statistics/SIMD/

We intend to maximise attendance at long term follow up measures by adopting the RCT retention protocols:

i. Measurement sessions will be held at club stadia, with club FFIT community coaching staff present to incentivise men to attend;
ii. At least two measurement sessions will be held at each club (n=13) to maximise men's opportunity to attend;
iii. One month before the club measurement sessions, men will receive a personalised letter and information sheet about the follow up study;
iv. Three weeks before the club measurement sessions, men will be contacted individually by telephone to make an appointment, and appointments confirmed by email/post (according to men's preferences);
v. Appointment reminder texts will be sent up to 48 hours in advance of the club sessions;
vi. Men who fail to attend their appointment will be phoned during the club measurement session to rearrange their appointment;
vii. Men unable to attend club measurements will be offered a fieldworker visit at their home (or another convenient location, if they prefer);
viii. All men will be offered club shop vouchers (£20) and any travel expenses for taking part in the follow up measurements.

A sub-sample of men purposively selected to take part in qualitative telephone interviews (see rationale for the purposive sampling strategy below) about their experiences of long term weight control will be offered an additional £20 voucher in recognition of their time.

9. Proposed outcome measures: The main outcome measures are the same as those assessed at baseline, 12 weeks and 12 months during the FFIT RCT. They were set with reference to National Obesity Observatory guidance for the evaluation of weight management interventions (43).

Primary outcome: Objectively-measured *weight change* from baseline measures to 3.5 years expressed as a mean and as a percentage.

Secondary outcomes:

i. Change from baseline to 3.5 years in objectively-measured *BMI*, *waist circumference*, *percentage body fat* and resting *blood pressure*;
ii. *Physical activity:* change from baseline to 3.5 years in self-reported frequency and duration of walking, moderate and vigorous activity, and duration of sitting time over the last 7 days measured using the International Physical Activity Questionnaire (44);
iii. *Diet:* change from baseline to 3.5 years in self-reported frequency of intake of key contributors to weight gain [(45) e.g., fast foods, chocolate bars, chips, pies, sugary drinks] and breakfast using questions adapted from the Dietary Instrument for Nutrition Education (46) and changes in portion size (47);
iv. *Alcohol intake:* change from baseline to 3.5 years in self-reported consumption over the last 7 days (48);
v. *Psychological outcomes:* a) change from baseline to 3.5 years in positive and negative affect as measured by the Positive and Negative Affect Schedule (49); b) self-esteem as measured by the Rosenberg Self Esteem Scale (50); c) health-related quality of life (HRQoL) as measured by the SF-12 (51).

Baseline predictors: Baseline age, BMI, education, socioeconomic and marital status, and orientation to masculine norms from the RCT.

Other predictors: Change from baseline in health behaviours (self-reported physical activity, sitting time, diet and alcohol intake) and psychological outcomes (self-esteem, positive and negative affect, HRQoL) outcomes. In addition:

a) Self-determination theory constructs (11): Reported self-regulation of physical activity and dietary behaviours (52); Perceived autonomy in physical activity and dietary

behaviours (53); Perceived competence in physical activity and dietary behaviours (54); Perceived relatedness (55), all as reported at 3.5 years;

b) Perceived satisfaction with current physical activity and dietary behaviours (56), as reported at 3.5 years;
c) Self-reported use of behavioural techniques likely to be associated with long-term weight loss including on-going self-monitoring of weight/physical activity, and the extent of establishment of dietary and physical activity daily routines, as reported at 3.5 years;
d) Self-reported frequency of contact with other FFIT participants, coaches and club-based and other health promotion/weight management initiatives since the end of the 12 week active phase of FFIT, as reported at 3.5 years;
e) Self-reported major life events (e.g., bereavement, family illness, separation, divorce, redundancy) since the end of the 12 week active phase of FFIT, as reported at 3.5 years;
f) End-of-intervention weight change (for the intervention group – from objective RCT baseline and 12 week measurements; for the comparison group – self-reported at 3.5 years) or pre-intervention weight change (for the comparison group – from objective RCT baseline and 12 month measurements);
g) Self-reported injury and joint pain, as reported at 12 months and at 3.5 years.

Qualitative outcomes: Past experience with participants in non-RCT deliveries of FFIT (34, 57) and in an adapted version of FFIT being piloted in a Rugby Union club setting (RuFIT) (58, 59) show that telephone interviews are a cost-effective way of collecting high quality qualitative data from men with whom we have already established rapport during stadia measurement sessions. In the proposed study, experiences of succeeding/not succeeding in achieving long term weight loss will be investigated through individual in-depth telephone interviews with men (n~55) sampled purposively from both intervention and waitlist comparison groups to include:

a) **Group 1 - 'long term maintainers':** *~15 men in the intervention group* who achieved ≥5% weight loss at 12 months *and* at 3.5 years. This group is of interest because they have succeeded in maintaining weight loss long term;
b) **Group 2 - 'long term regainers':** *~15 men in the intervention group* who achieved ≥5% weight loss at 12 months but did not maintain this to 3.5 years. This group is of interest because despite initial success, they did not succeed in maintaining weight loss long term;
c) **Group 3 - 'delayed responders':** *men in the intervention group* who did not achieve ≥5% weight loss at 12 months but went on to achieve ≥5% weight loss at 3.5 years. We do not expect there to be many men in this group, but will aim to interview them all, as these 'deviant' cases will add an important perspective;
d) **Group 4 - 'long-term achievers':** *~15 men in the comparison group* who achieved ≥5% weight loss at 3.5 years. This group is of interest because they provide the experience of succeeding in controlling their weight for 2.5 years post-FFIT.

We will use a semi-structured topic guide with these groups to explore:

a. The practices and techniques (e.g., incorporation of new physical activity and dietary behaviours into daily routine, self-monitoring, structured meal times) that men have continued to use in attempting to control their weight long term and those they adopted but have since stopped using;
b. Men's experiences of: motivation (including the extent to which regulation of physical activity and dietary behaviours are internalised, part of a transformed everyday life); the role of emotions in changes made or not; the extent to which men's relations with others have supported their changed behaviours; and/or the extent to which men's relations with others have changed as a result of their new behaviours/practices;
c. The extent to which (if at all) men view their identities differently in relation to performances of masculinity and health-related practices around diet, physical

activity and other behaviours (e.g., health care utilisation, sleep) following participation in FFIT.

We will also interview *~10 men in the waitlist comparison group* who achieved ≥5% weight loss before taking part in FFIT (**Group 5 - 'pre-FFIT achievers'**), to investigate their motivation and approach to losing weight prior to taking part in FFIT, what they learned or adapted as a result of taking part in FFIT, their experience of FFIT as men who had achieved recent weight loss, as well as their experiences of long term weight control (as above).

Wider health outcomes: through linkage to routinely-collected NHS data on hospitalisations (SMR01 and SMR04 records), deaths and recorded cause of death (GRO records), cancers (SMR06), diabetes (SCI-DC) and prescribing (PIS) from 2009 onwards; and, where possible, blood test results (SCI-Store, due to become available in 2014).

Cost-effectiveness:
a) Resource use: resources employed in providing the intervention (from the FFIT RCT), and NHS linked data and self-reported over-the-counter medication and health care consultations (both as described above);
b) Quality of life: SF-12 (as described above).

10. Assessment and follow up: This protocol relates to follow up of men 3.5 years after the FFIT RCT baseline measurements (i.e., 3.5 years after participation in the FFIT programme for the intervention group, and 2.5 years after participation in FFIT for the comparison group). As both groups have undergone the same intervention, they will essentially be treated as a single cohort for physical measurement, questionnaire administration and data linkage. Subsequent analysis will explore whether there are any between-group differences.

10.1. Assessment of efficacy/effectiveness:
Assessment of effectiveness: Teams of fieldworkers will visit each club (N=13) on at least 2 occasions (to maximise the likelihood that men will be able to attend) to conduct outcome measurements. Physical measures and questionnaire administration will be conducted by teams of 6-12 fieldworkers, with a team leader to oversee and quality assure procedures (the size of the team will depend on the number of men with appointments at each session). All field staff will receive 1.5 days training to standard measurement protocols. Team leaders will receive an additional day's training in leadership and quality assurance. The training, adherence to fieldwork protocols and quality assurance procedures will minimise detection bias, and research standard weighing scales, tape measures, sphygmanometers and bioimpedance meters will ensure the high quality of captured data. Other outcome measures will be gathered via a self-completion booklet. Fieldworkers will record all physical measures in the booklet.

Men who are not able to attend the club measurement sessions will be offered a home visit at a time that is suitable to them. Home visits will be conducted by an experienced member of the fieldwork team. To minimize risk during home visits, all fieldworkers will use the Communicare Loneworker System[3]. As in the main RCT, all men will receive club shop vouchers (£20) to thank them for their ongoing commitment to the study. In addition, we will 'future-proof' the study by informing the men that we may want to follow them up again, and gaining their consent to do so.

Assessment of health status: Full contact details of all FFIT participants who have consented to their RCT information being linked to routinely-collected medical records (N=648) will be submitted to the Electronic Data Research and Innovation Service (eDRIS[4]). The community health index number (CHI) for all participants will be used to link to data on hospitalisations and death certificates from 2009 onwards. We will also request information

[3] http://www.argylltelecom.com/lg/services/communicare/communicare.html
[4] http://www.isdscotland.org/Products-and-Services/EDRIS/

to be extracted from community prescribing, cancer registry and national diabetes datasets, and (if available) blood test result datasets.

The data extracted by eDRIS will be combined with the RCT data within a secure network before being anonymised prior to analysis using standard procedures which remove all possible identifiers to protect individual privacy and confidentiality. Reasons for hospitalisation and cause of death will be interpreted using the International Classification of Disease codes (V10) for the main reason for admission, and for the primary and underlying cause of death. All prescriptions will be examined and classed by British National Formulary category (e.g., 2.5.1 Vasodilator antihypertensive drugs), with the total number of different drugs and categories calculated. We will also report on incidence of cancer and diabetes and (if available) blood test results.

Assessment of men's experiences of long term weight loss: Men attending the measurement sessions will be asked if they would also be willing to take part in an individual telephone interview about their experiences of attempting to control their weight over the long term. As soon as the club visits are completed at each club, the entry of data on objectively-measured weight will be prioritised to allow purposive sampling of men for the telephone interviews as described in 'Qualitative outcomes' above.

All telephone interviews will be tape-recorded, transcribed verbatim, anonymised and checked against the original recordings prior to analysis. A semi-structured format will be used to guide men to provide a narrative account of their experiences of attempting to control their weight long term. Interviewees will be asked whether (and, if so, why), the strategies they have used (e.g., self-monitoring of weight and/or physical activity, and the use of health and fitness technologies to do so; regular eating patterns; flexible vs. rigid approach to dietary control) have changed over time, and about the challenges, barriers (e.g., injury, illness) and facilitators (e.g., social support from family members) they have encountered. The interviews will explore the extent to which behaviours have become internalised and/or part of daily routine, the extent to which men continue to use the behaviour change techniques learnt in the early days of the programme, and the emotional aspects of changes they made or did not make in relation to long term weight management. We will also explore whether there are any ways in which men see themselves differently having taken part in FFIT. For example, one man who took part in the RCT 12 month focus groups described how his self-perception had changed:

> **P3:** *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 – 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.*
> **[Club03_12moFGD]**

Finally, men in the comparison group who had lost ≥5% weight by the time of the 12 month RCT measurements will also be asked about their experiences before and during participation in the FFIT programme in autumn 2012.

Assessment of the feasibility of long term passive follow up of future FFIT participants: We will visit at least 20 clubs delivering FFIT at the start of the spring and autumn 2015 programmes to ascertain how many men are willing to provide written permission to having their baseline, post-programme and 9 month weight, date of birth and contact details transferred to the research team, and for this to be linked to their NHS records for long-term monitoring of health outcomes.

10.2. Assessment of harms: All men taking part in the 3.5 year measurements will be asked to provide detailed information about any injuries, joint problems and other adverse events they have experienced since the 12 month RCT measures (when they were asked to recall the same information for the previous 12 months) that they perceive as being related to their involvement in FFIT. This will provide a complete record of men's self-reported injuries, joint pain and other potential adverse events since the start of their participation in the RCT.

10.3 Future work: If the results of the current study suggest that longer term follow up is warranted (i.e., if RCT participants have succeeded in achieving long term weight loss, if linkage to health service records in these men shows good utility, and if men in new deliveries of FFIT are happy to give permission for linkage of minimal pre- and post-FFIT measures to health service records), we plan to refine the FFIT programme delivery protocol to include a request for permission for data transfer and data linkage, and to submit a proposal for funding for future long term follow up. We will also consent the RCT participants to be contacted for future active follow up and will administer a short survey during the current measurement sessions about the acceptability of online questionnaire administration (to reduce future fieldwork and data entry costs).

Because the comparison group in the FFIT RCT undertook the intervention immediately after the 12 month measurements, an unavoidable consequence of the original trial design is that we no longer have a comparator group who have not had the opportunity to do FFIT for long-term follow up (i.e., the proposed project is essentially a cohort study). However, the development of data linkage capabilities in Scotland over the next few years to include more complete general practice information, which could include BMI measurements, could present other novel and low cost opportunities for assessing and modelling long-term outcomes (e.g., creating a synthetic comparator cohort by identifying BMI-, age- and practice-matched controls, or another suitable synthetic comparator group, e.g., from the Scottish Health Survey).

11. Proposed sample size: 665 men (intervention group N=316; comparison group N=349) who have consented to follow up will be invited to attend outcome measurements at 13 club stadia. Assuming an attrition rate of 20% (we have conservatively assumed a worse attrition rate than that observed during the RCT due to the length of time from the last contact with the research team), we will have outcome measures for 532 men (intervention group N=253; comparison group N=279). The standard deviation for the percentage change in weight loss during the study was approximately 10% in the intervention group. Assuming that this will be higher in the longer term (e.g., 15%) but similar in both groups, we will have 80% power to detect a change in weight of 2.65% in the intervention group, 2.52% in the comparison group and 1.83% overall.

Linkage to routine NHS data will allow us to explore the utility of using data linkage for long term, low cost, passive follow up of FFIT participants. Given the current cohort of 648 RCT participants who have provided prior consent to data linkage, we will be able to estimate a 5% population incidence of a particular health outcome (e.g., hospital admission, death, cancer) with a 95% CI of +/- 1.7%, and a 10% population incidence with a 95% CI of +/- 2.3%.

In addition, for a health outcome (e.g., cancer diagnosis) that occurs in 5% of the sample (32 men), there will be 80% power (at a 5% significance level) to detect a hazard ratio (HR) of 2.66 between two equally-sized subgroups (e.g., men who achieved 5% weight loss at 3.5 years, and those that did not), or for a continuous predictor of the health outcome (e.g., weight loss at 3.5 years), there will be 80% power to detect a HR of 1.63 per standard deviation increase in the predictor. For a health outcome (e.g., hospital admission) with a 10% incidence (65 events), there will be 80% power to detect HRs of 2.00 for a binary predictor, and 1.41 for a continuous predictor (60).

12. Analysis:

Quantitative analyses:

All participants with available data will be included in the analysis.

To investigate the primary and RCT secondary outcomes (Objectives 1 and 2), each group (intervention, comparison) will be analysed separately. Mixed effects linear regression models will be used in the analyses of continuous outcomes (e.g., change from baseline outcomes), with adjustments for baseline value as a fixed effect where appropriate and club

as a random effect. The mean value (change from baseline), 95% confidence interval and p-value will be estimated from these models. Repeated measures models will also be considered.

Differences in weight loss trajectories between the intervention and waitlist comparison groups will be investigated by considering both groups together and including a fixed effect term for group. The group effect, 95% confidence interval and p-value will be estimated from this model.

For each group, the predictors of change in weight (Objective 3) will be investigated by extending the linear regression models described above to include each predictor separately to assess their impact individually. All predictors will then be added to the model and a backwards selection method applied to identify the independent predictors of change in weight. To determine whether there are significantly different predictors for each group, the combined data will be considered together and interactions between the predictors and group investigated.

We will, where possible, implement additional analyses, including comparison of the backward selection data-driven model with a theoretically-driven model which includes the following hypothesised predictors of long-term weight loss: end-of-intervention weight change; sustained behaviour change (physical activity and diet); continued use of self-monitoring; major life events, injury and joint pain; social support; the extent to which behaviour has become routinized; satisfaction with behaviour change; self-regulation, perceived autonomy, competence and relatedness. We will also examine whether there are plausible interactions between factors (e.g., socioeconomic status and social support) to identify the presence of any multiplicative effects in relation to long term weight loss to ensure that the final model represents the best evidence from both statistical and theoretical analyses.

Health outcomes (Objective 6) (e.g., number of hospital admissions, deaths, cancer incidence) will be summarised by group (intervention, comparison) and individually as frequencies and percentages. Relationships between health outcomes (e.g., number and type of admissions) and intervention outcomes (e.g., change in weight, change in health behaviours) will be investigated using mixed effects linear regression models. We will also investigate the relationship between intermediate health outcomes and change in weight (i.e., how specific health events (e.g., stroke, myocardial infarction) impact on weight loss over the follow up period).

A number of sensitivity analyses will be carried out. Non-response bias will be investigated by assessing the characteristics of those participants who have agreed to follow up and took part in the 3.5 year measurements (responders) and those who did not (non-responders). The sensitivity of the overall results to a variety of assumptions about the outcomes of the non-responders will be assessed by imputing missing outcome data under various assumptions (e.g., return to baseline, last value carried forward). Missing data for the predictors of outcome will also be imputed using multiple imputation methods, and the analyses described above repeated for the imputed data.

Qualitative analyses: Interview transcripts will be analysed using thematic frameworks (61) to explore our research questions and any emerging themes. Several members of the research team will read anonymised transcripts to support the development of a robust analytical framework and to ensure analytical rigour. The analysis will draw on psychological and sociological theories in constructing a detailed description of men's accounts of the practices and techniques they use/have stopped using to control their weight (and why), of their motivation(s) for controlling their weight and the locus of regulation of their health behaviours, of their emotional response to achievements and setbacks, and of the role and responses of others to their attempts to exercise ongoing control of their weight post-FFIT. Our analysis will also investigate the extent to which men describe their behaviours in the context of performances of masculinised identities and how they account for succeeding/not succeeding in controlling their weight long term.

Responses will be compared between the groups outlined above ('long-term maintainers', 'long term regainers', 'delayed responders', 'long term achievers' and 'pre-FFIT achievers'). The organisation and analysis of qualitative data will be supported by the use of NVivo (v10) software.

Cost effectiveness analysis: The cost-effectiveness of the intervention will be estimated at two time points: medium term (3.5 years) based on the costs and outcomes measured in the follow up study; and longer term cost-effectiveness using health economics models. Both analyses will utilise the NHS and Personal Social Service perspective favoured by NICE (62). Outcome measures for the medium term analysis will be (a) number of men achieving a 5% weight reduction at 3.5 years; (b) a measure of QALYs determined from SF-12 scores using the algorithm described by Brazier and Roberts (62). Resource use will focus on the resources employed in providing the intervention (from the FFIT RCT), and self-reported medication use (prescribed and over-the-counter) and health care consultations (collected during the 3.5-year follow up). NHS linked data (e.g., on hospitalisations) will also be incorporated into the model. Unit costs will be obtained from appropriate sources (e.g., BNF, NHS reference costs, PSSRU costs of health and social care). Data obtained from the original comparison group at the RCT 12 month time point (and hospitalisation data from this period) will be extrapolated and used as a control group. We will also consider a general population cohort comparator using suitable data to inform BMI projections. We will consider the usefulness of updating the original within-trial analysis using data linkage. The uncertainty surrounding estimates of cost and effects will be investigated through 'bootstrapping', with the resulting distributions of mean costs and effects presented graphically on the cost-effectiveness plane and using cost-effectiveness acceptability curves (63).

The follow up data will also be used to update the long term CVD risk factor model from the FFIT RCT (36), with the 12 month data on risk factors being replaced by 3.5 year data on risk factors. Data on long term maintenance of behaviour change from the follow up study will also be used to inform the rate of relapse back to the original risk factors that is incorporated in the modelling. In order to estimate the uncertainty in the model estimates, we propose a probabilistic sensitivity analysis using Monte Carlo simulation techniques, allowing for uncertainty in the estimation of all of the parameters within the model.

In addition, we will use the data collected on BMI/weight changes at 3.5 years in modelling the longer term outcomes as part of the economic analysis. We will also have self-reported data on physical activity and diet at 3.5 years which could potentially be included in a model as independent risk factors. This would facilitate a cross-validation exercise with the original long term CVD risk factor model. The aim will be to build on existing work that has already been done in modelling BMI (and physical activity and diet) as a risk factor, as well as the impact of weight gain on medical service use and quality of life. Again, parameter uncertainty in the decision model will be handled using probabilistic methods supplemented by standard sensitivity analysis to explore structural uncertainties in the model. Finally, we will also model heterogeneity using regression-based techniques to identify sub-groups for whom FFIT is or is not cost-effective, using for example, the baseline predictors of age and BMI.

13. Ethical arrangements: Men who took part in the FFIT RCT will only be approached to take part in this 3.5 year follow up study if they gave consent to follow up at the 12 month RCT measurements. All will receive an initial letter of invitation to the 3.5 year follow up measurements with an information sheet which clearly states their right to withdraw their ongoing consent at this stage. This will be followed up by individual telephone calls to provide men with an opportunity to have any questions about the new research answered. Informed consent will be taken by a trained fieldworker prior to the follow up measurements. Based on our previous contacts with the men, we anticipate that all will be able to give informed consent. We are aware that some men may need additional assistance with questionnaire completion, and we will ensure that additional fieldworkers are available for

one-to-one support where needed. Men will also be asked to give opt-in consent to the additional individual telephone interviews in the current study, and to future follow up.

At the RCT 12 month measurements, men were also asked to consent to linkage to their NHS records. Data linkage will be carried out for men who gave their permission at that time.

Ethical approval for the follow up measurements, qualitative interviews and for asking men taking part in future deliveries of FFIT for permission for data transfer and data linkage has been obtained from the College of Social Sciences Ethics Committee at the University of Glasgow (CSS/400140075), which complies with the Economic and Social Research Council's research ethics framework. Following advice from the NHS West of Scotland Research Ethics Service, we will submit a separate application to the West of Scotland NHS REC for linkage to NHS records for the FFIT RCT cohort.

14. Research Governance: The project will be sponsored by the University of Glasgow.

Study Steering Committee: The SSC will meet at least twice during the project and will operate in an advisory capacity to the CI. Minutes of SSC meetings will be available to those connected to the trial.

Data Monitoring and Ethics Committee: This is project is a 3.5 year follow up of participants in an RCT of a weight management and healthy lifestyle intervention, with measurements only conducted on one occasion. Therefore we do not propose to have a DMEC.

Project Management Group: The PMG consists of all applicants and will oversee the operational running and progress of the trial. The PMG will meet at least quarterly, convened by the CI. It will delegate day-to-day running to sub-groups responsible for: quantitative data collection, quantitative analysis, qualitative data collection and analysis, data linkage, and cost-effectiveness.

Data management and monitoring information: Quantitative data will be managed by the Robertson Centre for Biostatistics (RCB), which is part of the Glasgow Clinical Trials Unit. RCB has an ISO 9001/2008 quality management system, ISO 27001 certification for information security and TickIT certification for software development. RCB has its own secure computer network ensuring that data are handled in a secure environment. Computer systems for data capture comply with regulatory requirements for Computer Systems Validation. Studies are conducted in compliance with RCB standard operating procedures, which in turn comply with national and international regulatory and legal requirements.

15. Project timetable and milestones:

Date	***Milestones***
Pre Jan 15	Local Glasgow University ethics obtained
1st Jan 15	*Project starts*
Jan-Mar 15	Visits to participating clubs in spring 2015 deliveries of FFIT to ask for data transfer and linkage permissions
Feb 15	Fieldworkers recruited and trained; NHS REC ethics for data linkage obtained
Feb-Apr 15	Participants contacted and appointments for follow up measurements made
Mar-May 15	Measures in 13 clubs (at least 2 visits per club) completed
Mar-Jul 15	Home visits completed
May-Oct 15	Telephone interviews and interview transcript quality assurance completed
Sept 15	Data linkage completed
Sept-Nov 15	Visits to participating clubs in autumn 2015 deliveries of FFIT to ask for data transfer and linkage permissions
May-Sept 15	Data entered, cleaned and database closed

Nov 15	Quantitative analyses completed
Dec 15	Qualitative analyses completed; cost-effectiveness analyses completed
29h Feb 16	*Project ends; outcomes paper submitted for publication*
Mid-Mar 16	Project report submitted to NIHR PHR

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