

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

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

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Scientific summary

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Scientific summary

Background

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

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

Methods

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

Study design

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

Participants

We recruited through club-based activities, media coverage, workplace advertising and word of mouth. Those whose self-reported body mass index (BMI) and age suggested eligibility were invited to club stadia for assessment. Men were eligible if they were aged 35–65 years in 2011/12; had objectively measured BMI of at least 28 kg/m²; completed the Physical Activity Readiness Questionnaire; and consented to randomisation, weight, height and waist measurements.

Interventions

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

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

Outcome measurement

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

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

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

Sample size

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

Statistical analyses

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

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

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

Cost-effectiveness analysis

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

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

Analysis of process outcomes

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

Results

Study population

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

Changes in primary outcome

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

Changes in objectively measured secondary outcomes

At 12 months, more men in the intervention group (39.04%, 130/333) than the comparison group (11.27%, 40/355) achieved at least 5% weight loss (relative risk 3.47, 95% CI 2.51 to 4.78) and more had a BMI below 30 kg/m² [intervention group 25.53%, 85/333; comparison group 13.52%, 48/355; RR 1.89 (95% CI 1.37 to 2.60)].

The differences between groups in waist circumference and BMI reduction at 12 months (adjusted for baseline measure and club) were 5.12 cm (95% CI 4.27 cm to 5.97 cm) and 1.56 kg/m² (95% CI 1.29 kg/m² to 1.82 kg/m²), respectively, in favour of the intervention ($p < 0.0001$). Differences in all objectively measured secondary outcomes, including weight loss at 12 weeks, per cent body fat and systolic and diastolic blood pressure at 12 weeks and 12 months were also statistically significant and in favour of the intervention.

Changes in self-reported secondary outcomes

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

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

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

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

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

Serious adverse events

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

Cost-effectiveness

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

Process outcomes

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

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

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

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

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

Discussion

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

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

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

Trial registration

The trial is registered as ISRCTN32677491.

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This report

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