

Long-term weight loss following a randomised controlled trial of a weight management programme for men delivered through professional football clubs: the Football Fans in Training follow-up study

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

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Scientific summary

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Scientific summary

Background

Rising levels of obesity require interventions that support people to lose weight and to keep it off over the long term. Nevertheless, weight loss maintenance remains a challenge and is under-researched, particularly in men. The Football Fans in Training (FFIT) programme attracts men to weight management through an interest in football, and encourages them to lose weight by incorporating small incremental physical activity (PA) and dietary changes into daily life to support long-term maintenance. In 2011/12, a randomised controlled trial (RCT) in 13 Scottish professional football clubs found that the FFIT programme was effective in helping men lose weight and improve PA, dietary and psychological outcomes and in maintaining these changes up to 12 months.

Objectives

In 2015, we conducted a follow-up study of FFIT RCT participants 3.5 years after the intervention group started the FFIT programme, and 2.5 years after the comparison group did so. We aimed to investigate the primary long-term weight outcome and the physical, behavioural and psychological secondary outcomes; predictors, mediators and men's experiences of long-term weight control; medium- and long-term cost-effectiveness; and the potential for establishing very long-term follow-up of FFIT programme participants via linkage to NHS data sets.

Methods

Study design

We undertook a mixed-methods longitudinal study to investigate long-term weight loss and the experiences of participants in both RCT arms. The primary outcome was weight change from RCT baseline to 3.5 years. As both groups had an opportunity to take part in the FFIT programme, the follow-up study was a cohort study in the 13 football clubs that took part in the RCT.

Participants

The 665 out of 747 men (intervention group, $n = 316$; comparison group, $n = 349$) who consented to future contact at the 12-month RCT measurements were eligible to take part in the follow-up study. These men were aged 35–65 years and had a body mass index (BMI) of $\leq 28 \text{ kg/m}^2$ at RCT baseline. We used the same retention strategies that were found to be successful in minimising attrition in the RCT. These included personal invitations and football club coaches in attendance at football club stadia measurements, reminder e-mails and texts, home visits for men who did not attend stadia measurements, and travel expenses and shop vouchers for participation.

Data collection

A fieldwork team, who were trained to RCT protocols, assessed weight, BMI, waist circumference, percentage body fat and blood pressure (BP). Self-reported outcomes were PA and sedentary time; intake of fatty foods, sugary foods and fruit and vegetables; portion sizes; alcohol consumption; self-esteem; positive and negative affect; and mental and physical health-related quality of life (HRQoL).

Potential baseline predictors of changes in weight (age, education level, socioeconomic status, marital status, number of long-standing illnesses and orientation to masculine norms) were obtained from RCT baseline data. Potential mediators were self-regulation of PA and diet; perceived autonomy in PA and diet;

perceived competence in PA and diet; perceived relatedness; perceived satisfaction with PA and dietary behaviours; the use of behaviour change techniques (BCTs) likely to be associated with long-term weight loss (e.g. self-monitoring); contact with other FFIT programme participants, coaches and healthy lifestyle initiatives; major life events; post-programme weight loss; and injury and joint pain.

Health-care resource use, long-standing illnesses, general practitioner-prescribed medications and family history of coronary heart disease/stroke were self-reported for the economic and data linkage evaluations.

We conducted semistructured qualitative telephone interviews to investigate the experiences of men who were trying to sustain weight loss long term, with subsamples of participants grouped according to their long-term weight trajectories:

- group 1 – men in the FFIT follow-up intervention (FFIT-FU-I) group who achieved at least 5% weight loss at 12 months and 3.5 years ($n = 15$)
- group 2 – men in the FFIT-FU-I group who achieved at least 5% weight loss at 12 months but not at 3.5 years ($n = 15$)
- group 3 – men in the FFIT-FU-I group who achieved at least 5% weight loss at 3.5 years but not at 12 months ($n = 15$)
- group 4 – men in the FFIT follow-up comparison (FFIT-FU-C) group who achieved at least 5% weight loss at 3.5 years ($n = 15$)
- group 5 – men in the FFIT-FU-C group who achieved at least 5% weight loss at 12 months but not at 3.5 years ($n = 10$).

These interviews explored the practices and techniques that men had continued (or had stopped) using, the experiences of participants regarding motivation, including the role of emotions and relationships with other people, and how the men viewed their current and pre-FFIT programme identities.

We investigated the utility and feasibility of using data linkage to routine NHS data sets for long-term, low-cost, passive follow-up of FFIT participants by extracting records on hospital episodes, deaths, cancers and prescribing from 2009 for 648 men who had provided consent for data linkage to their NHS medical records at the RCT 12-month measures. We also visited football clubs that delivered the FFIT programme in spring 2015 to ask new participants for their permission to use their information for future data linkage. In addition, we visited trained coaches who were delivering the FFIT programme in autumn 2015 and spring 2016 to request data linkage permissions from participants (a total of $n = 511$ across all three delivery time points).

Sample size

The follow-up study was powered to detect a change in weight of 2.65% in the RCT intervention group, 2.52% in the RCT comparison group and 1.83% overall, with 80% power.

Statistical analyses

For weight and the secondary outcomes, non-response bias was investigated by comparing the baseline characteristics of participants who did and participants who did not take part in the 3.5-year measurements. All participants with available data were included in the outcomes analysis. We summarised outcomes separately by group and overall, and we used non-parametric tests to test change from baseline within and between groups. Adjusted mixed-effects linear regression models were used to estimate the mean change in outcomes for each group and to test for between-group differences in weight trajectories. Sensitivity analyses assessed the impact that weight changes up to 3.5 years had under various assumptions about the weight outcomes of men who did not attend the 3.5-year measures (return to baseline and the last value carried forward), and the fact that the groups had taken part in the FFIT programme at different times.

Predictors and mediators of change in weight were investigated by extending the repeated mixed-effects linear regression models to include each predictor separately and by backwards selection to identify any

independent predictors or mediators of change. All analyses were conducted using SAS® (version 5.1, SAS Institute Inc., Cary, NC, USA).

Qualitative interviews

We used a structured thematic framework approach to develop a broad coding frame. NVivo 10 software (QSR International, Warrington, UK) was used in the coding and organisation of data. Broad codes were read to identify subthemes, and matrices were developed to allow comparison across the five groups.

Cost-effectiveness

The costs associated with the FFIT programme were combined with self-reported health-care resource and prescription medication use to provide an estimate of the additional cost of providing the FFIT programme at 3.5 years. We compared the average utility change of the FFIT-FU-I group with six hypothetical 'no active intervention' control scenarios to estimate the quality-adjusted life-years (QALYs) gained from participation in the FFIT programme at 3.5 years. We used a model to predict the additional costs and effects of the FFIT programme over the individual's lifetime. A bivariate analysis examined heterogeneity in BMI subgroups.

Data linkage

Numbers of clinical health outcomes were summarised by RCT group and overall as frequencies of events and percentages of participants. Formal group and time period comparisons of the number of hospital admissions and the number of prescriptions were made using appropriate statistical tests. Mixed-effects regression models assessed the relationship between hospitalisations and prescriptions, and RCT baseline weight, 3.5-year change in weight and self-reported long-standing illnesses.

Results

Study population

We retained 488 men (73% of the cohort who consented to follow-up; 65% of the total RCT cohort). Compared with men who did not take part in the 3.5-year follow-up measures, those retained for follow-up weighed less, were older and were more likely to be home owners and in paid employment at the RCT baseline.

Long-term weight (primary) outcomes

Men who took part in the FFIT programme during the RCT (FFIT-FU-I group) sustained a mean weight loss from baseline of 2.90 kg [95% confidence interval (CI) 1.78 to 4.02 kg; $p < 0.0001$], with 32.2% (75/233) of men achieving $\geq 5\%$ weight loss. The FFIT-FU-C group (who took part in the FFIT programme under routine delivery conditions after the RCT 12-month measures) demonstrated similar results [a 3.5-year mean weight loss from baseline of 2.71 kg (95% CI 1.65 to 3.77 kg; $p < 0.0001$)], with 31.8% (81/255) of men achieving $\geq 5\%$ weight loss.

Between 12 months and 3.5 years, the FFIT-FU-I group regained 2.59 kg (95% CI 1.61 to 3.58 kg), although the FFIT-FU-C group lost 2.03 kg (95% CI 1.08 to 2.98 kg), which probably reflected their participation in the FFIT programme during this period.

Changes in randomised controlled trial secondary outcomes

The FFIT-FU-I group showed reductions from baseline to 3.5 years in other objectively measured physical outcomes (mean BMI of 0.96 kg/m², 95% CI 0.60 to 1.31 kg/m²), mean waist circumference of 2.90 cm (95% CI 1.91 to 3.89 cm), mean percentage body fat of 1.94% (95% CI 1.06% to 2.81%), and mean systolic and diastolic BP (3.13 mmHg, 95% CI 1.11 to 5.15 mmHg, and 1.56 mmHg, 95% CI 0.32 to 2.80 mmHg, respectively).

Self-reported PA was higher at 3.5 years than at baseline [e.g. total PA by a median of 800.0 metabolic equivalent of task (MET)-minutes per week, interquartile range (IQR) –120 to 2514 MET-minutes per week; walking by a median of 297.0 MET-minutes per week, IQR –66.0 to 1040 MET-minutes per week; and, on average, men sat less (median –30.0 minutes per day, IQR –180 to 120 minutes per day)]. In comparison with the RCT baseline measurements, men had lower fatty food and sugary food scores (mean –3.86, 95% CI –4.83 to –2.89, and mean –1.32, 95% CI –1.69 to –0.95, respectively) and a higher fruit and vegetables score (mean 0.50, 95% CI 0.23 to 0.76), ate smaller portion sizes of cheese (mean –1.22, 95% CI –1.51 to –0.93), meat (mean –1.03, 95% CI –1.24 to –0.81), pasta (mean –1.28, 95% CI –1.51 to –1.04) and chips (mean –1.23, 95% CI –1.47 to –0.98) and drank less alcohol (–2.68 units per week, 95% CI –4.52 to –0.83 units per week). They also demonstrated sustained improvements in self-esteem (mean Rosenberg Self-Esteem Scale score of 0.23, 95% CI 0.18 to 0.29), positive affect [mean Positive and Negative Affect Schedule (PANAS) score of 0.27, 95% CI 0.17 to 0.38], negative affect (mean PANAS score of –0.17, 95% CI –0.24 to –0.11), physical HRQoL [mean Short Form questionnaire-12 items (SF-12) score of 1.98, 95% CI 0.81 to 3.16] and mental HRQoL (SF-12 score of 1.12, 95% CI –0.19 to 2.43). The FFIT-FU-C group showed similar improvements across all outcomes.

The FFIT-FU-I group showed some regain of waist circumference and BMI, increases in systolic and diastolic BP and reductions in self-reported total and vigorous PA, fruit and vegetable consumption, and mental HRQoL between 12 months and 3.5 years. Nevertheless, improvements in walking, sugary foods and alcohol consumption, portion sizes of cheese and meat and all other psychological outcomes were sustained.

There were no significant baseline predictors of weight loss in either group. Increases in self-reported PA (walking at 3.5 years and total and vigorous PA at 12 months and 3.5 years) and reduced sitting time (at 3.5 years) were associated with improved long-term weight outcomes. Reduced consumption of fatty and sugary foods, smaller portions of cheese, meat, pasta and chips and increased consumption of fruit and vegetables at 3.5 years, improvements in positive affect and physical HRQoL at 12 months and 3.5 years and higher self-esteem at 3.5 years were also positively associated with long-term weight outcomes.

Autonomous regulation of PA and diet, an internal locus of control and perceived competence for PA and diet, relatedness to other men from the FFIT programme and family members, satisfaction with PA and diet, and end-of-programme weight loss were associated with lower weight at 3.5 years. Amotivation for PA and healthy eating were associated with poorer 3.5-year weight outcomes. Regular PA, regular meals, dietary restraint, self-monitoring of weight, reading food labels and ongoing contact with other FFIT participants and coaches were also associated with lower weight at 3.5 years. Injuries that limited activity (at 12 months and 3.5 years) and limiting joint pain (at 3.5 years) were both associated with higher long-term weight.

Men's experiences

Both men who were, and men who were not, successful in controlling their weight long term described continuing to monitor their weight and PA, often indirectly (through fit of clothes or by time or distance walked), and they talked about still using BCTs and information from the FFIT programme to control their weight. Some described having ongoing weight and PA goals. Many felt that PA was important for weight control, and walking remained a popular way to fit PA into regular routines. Common dietary strategies included awareness of portion sizes and eating fewer unhealthy snacks.

Men also reported that other people, the benefits associated with a healthier lifestyle, avoidance of guilt and embarrassment, personal pride, enjoyment of PA and eating practices, and being able to do things that were personally important motivated them to keep the changes going. Some men who had succeeded in long-term weight control distanced themselves from the person they had been before the FFIT programme or described specific changes in the way that they now viewed themselves.

Cost-effectiveness

At 3.5 years, the FFIT programme was associated an additional cost of £532–740 per individual, a gain of 0.046–0.051 QALYs and an incremental cost-effectiveness of £10,700–15,300 per QALY gained. In the

lifetime analysis, the FFIT programme was associated with an incremental cost-effectiveness of around £2000 per QALY gained. Cost-effectiveness acceptability curves show that, if a decision-maker is willing to pay more than around £2500 per QALY gained, there is no uncertainty at all that the FFIT programme is cost-effective. There was a greater effect in health outcomes for men with a baseline BMI of $> 35 \text{ kg/m}^2$, and the FFIT programme became cost saving for men with a BMI of $> 40 \text{ kg/m}^2$.

Linkage to NHS records

Data linkage was completed for 99.5% of consented men. Rates of hospital admissions and prescriptions were high, reflecting the fact that the FFIT programme succeeds in attracting men at a high risk of obesity. There were no differences in hospital admissions between the FFIT intervention group and the comparison group, or over time, but there was evidence of higher rates of prescribing in the comparison group, and increases in prescriptions of cardiovascular, urinary tract and musculoskeletal medications in both groups during the FFIT programme. There were no associations between hospitalisations, prescriptions and weight outcomes.

Coaches who delivered the FFIT programme appeared competent to inform participants about the rationale for and the process and implications of giving permission for data transfer and linkage, and to ask new participants for permission to link to their NHS records; large numbers (around 90%) of men agreed to future data linkage.

Conclusions

Men who take part in a weight management programme that is delivered through professional football clubs under both research and routine delivery conditions demonstrate significant long-term improvements in weight, waist circumference, percentage body fat, BMI, BP, self-reported PA, dietary intake, alcohol consumption and measures of psychological and physical well-being 3.5 years after baseline measurement, although some outcomes show a degree of attenuation over time. We found that the FFIT programme was cost-effective at standard UK NHS levels and that passive, long-term follow-up via linkage to NHS records is useful and feasible.

Further research priorities should include (1) investigation of how to design weight management programmes to improve long-term maintenance of weight and behavioural changes (e.g. through targeting sedentary behaviour and providing even greater support for internalised regulation), (2) further follow-up of the FFIT RCT cohort to assess longer-term outcomes and (3) establishment of very long-term follow-up of new participants in the FFIT programme via linkage to their NHS records.

Rising levels of obesity and associated health risks require interventions that can support sustained weight loss. We have provided evidence that the FFIT programme can deliver significant long-term improvements in weight, behavioural outcomes and psychological outcomes.

Trial registration

This trial is registered as ISRCTN32677491.

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