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European Fans in Training (EuroFIT): working with professional football clubs to help men become more active and less sedentary

Submission date 05/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/06/2015	**Overall study status** Completed	
Last Edited 24/03/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Inactive and sedentary lifestyles are pandemic. In Europe, lack of physical activity accounts for around a million deaths per year (about 10% of the total). It is also a major contributor to a number of diseases, including coronary heart disease, type 2 diabetes, breast cancer and colon cancer. Sedentary behaviour and low physical activity are both associated with other risk factors for ill health such as poor diet and obesity. In 2006, physical inactivity costs the EU €150-300 per citizen each year, accounting for around 1.5-3.0% for the health care budget; in 2010, obesity was responsible for up to 8% of EU health care costs. A critical issue is that existing health promotion programmes, even when they work well, reach only a small proportion of the population. There are large gender imbalances in recruitment (only between 10% and 30% of participants are men), and participants tend to be well-educated. Programmes tailored specifically to attract men and to less educated population groups are urgently needed. EuroFIT' s key innovation is to harness the personal connection, loyalty and attachment many men feel to football and their club to attract them to health-promoting lifestyle change programmes delivered in top-flight European football clubs. Here, the EuroFIT (European Fans in Training) study will look at how a 12-week programme (the EuroFIT programme) held at football clubs can help men improve their lifestyle. The study aims to attract men to lifestyle change through the personal connection and loyalty to the team they support.

Who can participate?
Men aged 30-65 with a BMI of 27 kg/m2.

What does the study involve?
All potential participants are initially invited to an information evening where what is involved in taking part is explained. If they then decide to take part, they are given a small activity monitor, the ActivPAL, to wear for 7 days. The ActivePAL is worn on the thigh and records physical activity throughout the day, as well as how much time spent sitting, standing or lying down. The ActivPAL device is collected one week later and each participants height, weight, waist size and blood pressure is measured. They are also asked to complete a questionnaire about their physical activity, eating habits, general physical health and wellbeing. The participants are then

randomly assigned to one of two groups. Those in group 1 (intervention group) enter the EuroFit programme. The programme consists of 12, weekly group sessions at football clubs and led by club coaches. It includes a combination of classroom-based learning and physical activity training to help men become more active, fitter, eat better and reduce the time they spend sitting down. Those in group 2 (control) are not enrolled in the EuroFit programme. All participants from both groups are followed up 3 months and again 12 months later whereby they are asked to wear the ActivPAL device for 7 days, their weight, height, waist size and blood pressure are measured and the questionnaire is completed again. They are also asked to provide a small blood sample (this is optional). Participants may also be asked to attend focus group discussions during these follow ups. Once the study is complete, participants in the control group are invited to take part in the EuroFIT programme.

What are the possible benefits and risks of participating?
Although we can't promise that taking part in the study will directly benefit the participants, we hope that EuroFIT programme will help them become more active and lead a healthier lifestyle. It is very unlikely that participants will come to any harm from taking part. If they agree to have their blood taken, minor bruising or an inflammation of the vein may occur. We minimize this risk by using well trained staff and good practice. Some people may feel faint when they give blood. There is a small possibility that taking part in this study will reveal a health problem that a participant already has such as high blood pressure. If we find this, we will let them know and ask them to take the information to their GP who can assess the issue and discuss the appropriate care options.

Where is the study run from?
The research is being conducted at 15 football clubs in England, Netherlands, Norway and Portugal

When is the study starting and how long is it expected to run for?
November 2013 to June 2017

Who is funding the study?
European Commission's FP7 program

Who is the main contact?
Dr Chris Bunn (public)
Professor Sally Wyke (scientific)

Study website
http://eurofitfp7.eu

Contact information

Type(s)
Public

Contact name
Dr Chris Bunn

ORCID ID
http://orcid.org/0000-0001-6604-1305

Contact details
27 Bute Gardens, University of Glasgow, Glasgow
Glasgow
United Kingdom
G12 8RS

Type(s)
Scientific

Contact name
Prof Sally Wyke

ORCID ID
http://orcid.org/0000-0002-7509-8247

Contact details
27 Bute Gardens, University of Glasgow, Glasgow
Glasgow
United Kingdom
G12 8RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7.0

Study information

Scientific Title
Social innovation to improve physical activity and sedentary behaviour through elite European football clubs: European Fans in Training

Acronym
EuroFIT

Study objectives
Can a 12-week gender-sensitised behavioural change programme based in elite European football clubs enable men aged 30-65 with a BMI of 27 or more to increase their physical activity levels and reduce the time they spend in sedentary states?

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethics committee of the VU University Medical Center (Netherlands), 09/06/2015, ref: 2015.184
2. Ethics Council of the Faculty of Human Kinetics, University of Lisbon (Portugal), 03/08/2015, ref: 36/2015
3. Ethics Committee at the University of Glasgow College of Medical Veterinary and Life Sciences (UK), 15/07/2015 ,ref: 200140174
4. Regional committees for medical and health research ethics (Norway), 19/11/2015, ref: 2015 /1862

Study design
Interventional multi centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Physical activity and sedentary behaviour

Interventions
The study design is a two arm, stratified, individually randomised within clubs, pragmatic, controlled trial to assess the effect of the EuroFIT programme with an embedded process evaluation across four European countries.

Participants will be randomly allocated to receive the EuroFIT programme or comparator. Both intervention and control group participants will receive a healthy advice leaflet. The comparison group is a ‘waiting list’ group. This means that the comparison group will be placed on a ‘waiting list’ to receive the EuroFIT intervention after the 12 months measurement.

The intervention group will then receive the EuroFIT programme. The EuroFIT programme is designed to support men to become more active, less sedentary, improve their diet, and maintain these changes long term. It is delivered through twelve, weekly, 90-minute group sessions delivered by club community coaching staff. They include classroom-based learning activities and physical activity training using club facilities. The men receive scientific information delivered simply (“science but not rocket science”) and a “toolbox” of skills and behaviour change techniques they can apply to make changes and maintain them long-term. The men also receive a state-of-the-art self-monitoring device (the SitFIT) that allows them to self-monitor increases in physical activity (through walking) and time spent standing in their daily lives. In addition to the SitFIT, the MatchFIT application, will stimulate social support. Coaches

are trained to provide a positive social environment that supports men to make changes that suit them in the context of their own lives.

The programme is gender-sensitised in relation to context, content and style of delivery. In relation to context, delivery through top professional football clubs aims to attract men by tapping into the powerful loyalty and affiliation they feel towards the club they support and to engage them by appealing to their existing identities as football fans.

In relation to style of delivery, the programme is designed to maximise the time spent in interaction with peers and coaches on specific topics to encourage learning and mutual support. Coaches, who receive two days of training to deliver EuroFIT, help the men feel comfortable and receptive to change from the outset by demonstrating that they are with other 'men-like-me' and that their efforts are valued by the coach and the club. Engagement is promoted by ensuring the sessions are enjoyable, fun, experiential and interactive. Banter is used to create a mutually supportive 'team' environment which encourages the men to learn from each other by sharing tips and advice.

EuroFIT draws on psychological theory (i.e. Achievement Goal Theory and Self-Determination Theory) and on sociological theories of identity management and masculinity to provide a 'toolbox' of evidence-based behaviour change techniques (e.g. self-monitoring, goal setting, implementation intentions) that have been shown to increase physical activity and improve diet . Simple, practical, relevant messages allow participants to understand what they personally can do to improve their physical activity, sedentary behaviour and diet, and how to use behaviour change techniques and strategies in ways that are consistent with their current lifestyles. This is designed to promote sustained behaviour change through the formation of new healthy habits that become part of everyday routine in their normal lives.

Positive feedback and celebration of individual progress (not just achievement) towards small, short-term goals helps the men to feel competent and confident that they can succeed in their long term physical activity, sedentary behaviour, healthy eating and weight loss (if appropriate) targets. Men are also encouraged to recognise the personal benefits to them (e.g. feeling fitter, having more energy) of the changes that they are making and to develop individual relapse prevention strategies. Interaction with others through the programme and beyond is designed to support long-term changes through the co-construction of changes to identities and the ways they are performed and expressed. Long-term social support is promoted throughout the programme both within the group (e.g. through social media, through a web-based app that promotes social interaction around physical activity, and by meeting up between sessions to exercise together) and among their wider social networks (e.g. family, friends).

Intervention Type
Behavioural

Primary outcome measure
1. Changes to total physical activity (i.e. steps per day) at 3 and 12 months after baseline, objectively measured with the ActivPAL device (an instrument worn on the thigh for one week at a time to capture the pattern and intensity of the participant's activities)
2. Changes to total sedentary time (i.e. minutes per day spent sitting) at 3 and 12 months after baseline, objectively measured with the ActivPAL device

Secondary outcome measures

1. Body weight at 3 and 12 months after baseline, objectively measured with weight scales,
2. Body Mass Index (BMI) at 3 and 12 months after baseline objectively measured with weight scales and height measuring stadiometer
3. Waist circumference at 3 and 12 months after baseline objectively measured using a measuring tape
4. Resting diastolic and systolic blood pressure at 3 and 12 months after baseline objectively measured with a blood pressure monitor
5. Metabolic measurements: cardio-metabolic disease risk biomarkers related to glucose, insulin, HbA1c, lipids and liver function, objectively measured at 12 months after baseline by taking and analysing a venous blood sample
6. Self-reported total physical activity and sedentary time, activity choice index (capturing non-sedentary behaviours), food intake, wellbeing, self-esteem, vitality, long-standing illnesses, joint pain, and injuries. This will be measured using self-completed questionnaires at 3 and 12 months after baseline.
7. Mediation and Moderation: To investigate whether the effect of EuroFIT is:
7.1. Moderated by age and ethnicity, marital status, education, current employment and income,
7.2. Mediated by indicators of motivation for physical activity, ego/task involvement, need support/thwarting by coaches, mastery/performance climate, relatedness to group, need satisfaction from physical activity, club identification, previous weight management strategies and weight loss activities.
8. Cost effectiveness: To investigate the cost-effectiveness of the EuroFIT programme in comparison with receipt of an advice leaflet only. Direct costs will be measured at 12 months after baseline. Indirect costs will be measured at 3 months, 6 months and 12 months after baseline. This will be measured using quality of life and cost-effectiveness questionnaires.
9. Process Evaluation: this will be conducted at 3 months (post-programme) and 12 months after baseline (intervention group only), involving questionnaires, interviews and focus groups with coaches and participants. The aims of the process evaluation are:
9.1. To investigate recruitment, reach and delivery of the EuroFIT programme, and both participants' and coaches' experiences of taking part in EuroFIT at 15 clubs implementing EuroFIT to explain programme outcomes, including unintended outcomes
9.2. To investigate the facilitating factors and barriers to the adoption, implementation and continuation of EuroFIT in clubs
9.3. To investigate participants' experience of maintaining lifestyle changes between completing the programme and 12 months

Overall study start date
01/11/2013

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Men
2. Aged 30 to 65
3. Self-reported BMI 27 kg/m2
4. Consent to randomisation
5. Willing to consent to the measurements conducted as part of the trial (ActivPAL, body weight and height, resting blood pressure, waist circumference, questionnaires).

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
1200

Key exclusion criteria
1. Men who do not provide at least 4 out of 7 days of usable data from objective measurement of physical activity/sedentary time (activPAL) at baseline. This will be checked by researchers preceding further baseline measurement, men will be provided with an extra possibility to wear the activPAL when providing not enough data is due to malfunctioning of the device, if time permits
2. Men who answer 'yes' on one of the section 2 questions of the adapted self-reported PAR-Q+ screening instrument

Date of first enrolment
22/06/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Netherlands

Norway

Portugal

Scotland

United Kingdom

Study participating centre
University of Glasgow
27 Bute Gardens
Glasgow
United Kingdom
G12 8RS

Study participating centre
VUmc Amsterdam
De Boelelaan 1118
Amsterdam
Netherlands
1081 HZ

Study participating centre
University of Lisbon
Lisbon
Portugal
1649-004

Study participating centre
Norwegian School of Sports Sciences
Oslo
Norway
0863

Sponsor information

Organisation
University of Glasgow

Sponsor details
University Avenue
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type
University/education

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/07/2016		Yes	No
Results article	results	05/02/2019		Yes	No
Results article	qualitative data implementation secondary outcomes	20/03/2023	24/03/2023	Yes	No