European Fans in Training (EuroFIT): A multicentre randomised controlled trial of a gender-sensitised programme to increase physcal activity and reduce sedentary time delivered to men aged 30-65 in elite European football clubs

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The main aim of the EuroFIT trial is to assess the effectiveness and cost-effectiveness of the EuroFIT programme in supporting men to achieve an increase of at least 1000 steps per day (about 10 minutes on average per day, or 70 minutes per week)...

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43569

Source
ToetsingOnline

Brief title
EuroFIT

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Synonym
blood pressure, cardiovascular disease, diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: obesity, physical activity, Sedentary behaviour

Outcome measures

Primary outcome

Primary outcome measures are changes to total sedentary time (i.e. minutes per day) and total physical activity (i.e. steps per day) at 12 months objectively measured with ActivPAL.

Secondary outcome

Secondary outcomes are changes in self-reported physical activity and sedentary time, food intake, body weight, BMI, waist circumference, diastolic and systolic blood pressure, cardio-metabolic disease risk biomarkers related to glucose, insulin, HbA1c, lipids and liver function, self-reported general physical health, wellbeing, self-esteem, vitality and quality of life. Cost effectiveness will be assessed and a process evaluation will be conducted.

Outcomes for the replication measures (comparison group only) are changes to total sedentary time (i.e. minutes per day) and total physical activity (i.e. steps per day) objectively measured with ActivPAL after participation in the program by the comparison group since 12 month measures. Additional outcomes

are weight, BMI, waist, self reported wellbeing, food intake and injuries.

Study description

Background summary

Low levels of physical activity are associated with increased risk of a number of chronic diseases including heart disease and diabetes. More recently, it has become clear that time spent sedentary (i.e. sitting down) is a risk factor for these diseases independent of time spent in physical activity. Thus, interventions to increase physical activity and reduce sitting are likely to reduce cardio-metabolic disease risk. Current *lifestyle* intervention programmes aimed at reducing cardio-metabolic disease risk attract relatively few men (<30% of participants) and generally attract participants with relatively high socio-economic status (SES). Thus, men, particularly those from lower SES groups, are an under-represented and *hard-to-reach* group with respect to lifestyle interventions to improve cardio-metabolic health. The European Commission-funded EuroFIT aims to address this important public health concern by leveraging the allegiance that many men across the SES spectrum have for their football teams, to develop and trial a sustainable lifestyle-intervention programme in adult male fans of top-level football clubs in England, the Netherlands, Norway and Portugal.

EuroFIT builds on recent experience with the evidence-based Football Fans in Training (FFIT) programme in Scotland. The Scottish FFIT programme was specifically designed as a gender-sensitised programme to attract men with BMI>=28, aged 35-65, to lose weight, become more active and adopt healthy lifestyles, and to maintain these changes to at least 12 months. FFIT was successful in recruiting men from across the socio-economic spectrum who were at high risk of future ill health, and who reported the football club setting as the key draw of the programme for them. The Scottish FFIT programme helped men lose weight and maintain their weight loss over 12 months; the mean difference in weight loss at 12 months between the intervention and control group, adjusted for baseline weight and club, was 4.94 kg (95% CI 3.95-5.94) and mean percentage weight loss, similarly adjusted, was 4.36% (3.64-5.08), both in favour of the intervention group (p<0•0001). (Hunt et al, 2014 Lancet)

Following the successes of the Scottish FFIT programme, the programme was adpated to other European countries, amonst others the Netherlands.

Study objective

The main aim of the EuroFIT trial is to assess the effectiveness and cost-effectiveness of the EuroFIT programme in supporting men to achieve an

increase of at least 1000 steps per day (about 10 minutes on average per day, or 70 minutes per week) and a decrease of at least 25 minutes per day spent sitting, at least 12 months after their participation in EuroFIT.

Study design

A two arm, stratified, individually randomized within clubs, pragmatic, controlled trial to assess the effect of the EuroFIT programme with an embedded process evaluation across 4 European countries.

Intervention

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 programme is gender-sensitised in relation to context, content and style of delivery. In relation to context, deliverydelivery 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 content, 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/sitting in their daily lives. 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 vicarious learning and mutual support. Clubs will also organise a re-union session, which will take place at a time of the clubs* choosing after the programme has finished.

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.

Study burden and risks

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

• As recommended in SIGN guidance, participants will be screened for

contraindications to exercise using the Physical Activity Readiness Questionnaire (PAR-Q+). Men who answer *yes* on one of the section 2 questions of the PAR-Q+ will be excluded.

• Men found to have elevated blood pressure at baseline measurement sessions (systolic >= 140mmHg and/or diastolic >= 90mmHg) will be encouraged to consult their GP. They will be given a letter providing information about their blood pressure readings, and records will be kept of all letters issued.
• Men found to have elevated blood pressure at baseline measurement sessions (systolic >= 160mmHg and/or diastolic >= 100mmHg) will be encouraged to consult their GP. They will be given a letter providing information about their blood pressure readings, and records will be kept of all letters issued. They will be allowed to participate in the EuroFIT programme, however, coaches will not allow them to undertake vigorous activity as part of the coach-led physical activity component of the programme, until they have provided evidence to their coach that their blood pressure is released. They will be encouraged to undertake moderate intensity walking activities.

• Coaches will be trained in tailoring physical activity programmes for men of varying levels of fitness.

• Coaches will also be trained to teach participants to use the Rate of Perceived Exertion (RPE) Scale to assist men in exercising at moderate intensity levels.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- men;
- aged 30 to 65 (based on self-report data at initial screening);
- who have a self-reported BMI >=27 kg/m2 at initial screening;
- who consent to randomisation.

Exclusion criteria

- 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;
- who answer *yes* on one of the section 2 questions of the self-reported PAR-Q+ screening instrument;
- who already participate in some sort of health promotion programme at their club, when the trial starts.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-09-2015
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN81935608
CCMO	NL53236.029.15