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An evaluation of a community-based football programme for inactive men: protocol paper for a pragmatic feasibility trial

Submission date 27/06/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 02/07/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 09/04/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
A significant health concern is that too many men die too young, and that men are more likely to die of all causes of death and at all ages than women. This is largely as a result of their health-related behaviours. To address this, in 2008, Ireland became the first country in the world to publish a national men's health policy. This policy calls for health service providers to offer services to men in places and in ways that are not 'traditional' and are more appealing to them. Recreational football is successful in both engaging men and improving their health. The FFP was developed in Denmark in 2010 and has been delivered there and elsewhere to different population groups with great health effects. The objectives of the research are to 1) measure the health impact of participating in the FFP to men who do not by taking measures at before, after and 3 months after the FFP ends, 2) calculate the economic and social value of the FFP for men and their communities, 3) learn about what types of men participate in the FFP and 4) understand what things help and hinder the delivery of and participation in the the FFP so that the delivery of the games can be improved. The findings of this study will help expand the delivery of the FFP nationwide and abroad through European Football Associations to improve male health in Ireland and beyond.

Who can participate?
Adult men who participate in the FFP, along with all service providers at a provider, organisational and funding level involved in the provision of the FFP.

What does the study involve?
For men who participate, participation involves a) being consulted to determine the outcomes from participation, b) being assessed for those outcomes at baseline, 3 months and 6 months and c) completing a survey to determine the relative importance and value of those outcomes. Specifically, the outcomes to be measured will be assessed via several mechanisms:

1. A self-reported questionnaire will be administered to participants in the intervention group (IG) at registration. Thereafter, it will be administered via the data collection App which will also be used to record all other data collected. This questionnaire will probably assess reach (date of

birth, ethnic origin, educational attainment, relationship, housing and employment status), how participants had heard about FC, smoking status, use of primary care services and prescription medicine, perception of health and workplace capacity. Mental well-being may be assessed at all time points via the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS), while the Patient Health Questionnaire - 4 (PHQ-4) will be used to assess players' depression and anxiety at all data collection time points. Structural and functional social relationships will be assessed via the Optimism–Pessimism Short Scale–2 (SOP2), which will assess the individual's general disposition toward optimism and pessimism. Generic health status may be assessed using the EQ-5D instrument. Only validated questionnaires will be adopted to assess outcomes reported in Step 3.

2. Data will be collected on-site for participants to assess physical health outcomes at all time points. Specifically, these are:
Blood pressure (BP, mmHg) will be measured using an automated sphygmomanometer (Heine Ltd., Munich, Germany). Participants will have the BP cuff placed above their elbow in a seated position. The sphygmomanometer will automatically provide blood pressure figures that are generally displayed as Systole/Diastole mmHg. Every participant will be informed of their BP result. Where high BP is recorded outside safe ranges as outlined by the Irish Heart Foundation (IHF: 140/90 or higher), the participant will be asked to remain seated so that it can be assessed up to three times to confirm the result. Once the result has been confirmed, as per best practice, they will be referred to their GP. They will also be excluded from participating in the remaining tests.

Waist circumference (cm) will be measured over light clothing using a standard tape measure. Weight (kg) will be measured using a Seca 813 electronic weighing scale (Seca Corporation, Hamburg, Germany) with participants wearing light clothing, no shoes and with empty pockets. Height (m) will be measured using a portable stadiometer (Seca 220; Seca Corporation, Hamburg, Germany), and measurements will be taken to the nearest centimetre.

Body composition will be assessed via a total body scan. These will be conducted using a multifrequency bioelectrical impedance analyser (InBody 720; Biospace Co. Ltd, Seoul, Korea) at frequencies of 1, 5, 50, 250, 500, and 1000 kHz. This instrument uses a tetrapolar eight-point tactile electrode system (four in contact with the palm and thumb and the other four in contact with the feet) that separately measures impedance of the arms, trunk, and legs. Participants will place their bare feet on the metal plates of the scale and grab the hand electrodes as instructed by the manufacturer. The InBody 720 automatically measures total body mass, fat mass, muscle mass, and lean (muscle and bone) mass in absolute terms to the nearest 0.05 kg and relative terms (%).

Aerobic fitness (VO2max) will be measured by asking participants to complete a distance of 1 mile at their own pace and recording their time to completion, OR by the YoYo Intermittent Recovery test (YYIR) OR the 12-min Cooper run. The YYIR is a reliable and valid field measure of aerobic endurance. Participants will perform the YoYo Intermittent Endurance test (level 1), which involves the participants running 2 × 20 m at progressively increasing speeds controlled by audio bleeps interspersed with 10-second recovery (ibid). The test ends when all runs are completed or if the distance is not reached in the allocated time upon the second occasion for each participant (ibid).

Lower body strength will be measured via the counter movement jump (CMJ) test. Maximal vertical jump height will be assessed to the nearest 0.1 cm during a counter movement jump (CMJ) using a Chronojump Plate (Chronojump Inc., Barcelona, Spain), which measures flight time taken as the duration between take-off and landing. Participants will be instructed to jump as

high as possible, with a rapid, preparatory downward eccentric action while their arms are freely able to be moved. All participants will complete three jumps separated by 1 minute of passive recovery, with the highest jump taken as the outcome measure. The CMJ arm swing test is a valid and reliable field test for the assessment of muscular fitness.

Cholesterol (mmol) will be measured by analysis of a finger-prick blood sample using an Accutrend Plus. Fingers will be cleaned using sterile swabs before being pierced using a lancet. Blood samples will be collected on an Accutrend Plus cholesterol strip and inserted into the analyser. All waste will be disposed of in a sharps bin. Participants will be encouraged to apply pressure to their finger until bleeding stops. Given the small puncture, excessive bleeding is not predicted.

3. Participants in the IG will wear a STAT Sport GPS vest and heart rate (HR) monitor during 3 programme sessions at each data collection time point to assess game-play demands and playing efficiency over time. Again, this data will be synced with the data collection portal via an API.

All other stakeholders will be consulted via interview or focus group and cross-sectional survey to determine:
a) The outcomes they experience from being involved in or supporting the FFP.
b) To investigate the implementation of the FFP with respect to reach, adoption, fidelity, acceptability, provisions and implementation barriers and facilitators.

What are the possible benefits and risks of participating?
The potential benefits of participation for participants are that they get a suite of information about their physical, mental and social health, along with contributing to generating evidence that may support the FAI to continue to offer programmes for the benefit of men's health. All other stakeholders may benefit from participation by ultimately being equipped with study findings to support them in their work with respect to getting funding and other supports for the FC initiative in the future.

Risks to the stakeholder group are experiencing an injury from participating and a data breach; there is evidence from previous studies that men do experience predominantly minor injuries from playing; stringent safeguards have been put in place to mitigate against any data breach. Risks to other stakeholder groups include a data breach, and as stated above, stringent safeguards have been put in place to mitigate against any data breach.

Where is the study run from?
The Centre of Health Behaviour Research at the South East Technological University, Ireland.

When is the study starting and how long is it expected to run for?
June 2026 to March 2027.

Who is funding the study?
1. The Health Research Board, Ireland.
2. The South East Technological University, Ireland, PhD Scholarship Programme Awards.

Who is the main contact?
Dr Paula Carroll (Principal Investigator), Paula.Carroll@setu.ie.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Health Research Board number
APA-2024-004

SETU PhD Scholarship Programme Award numbers
SETU-2024-236, SETU-2024-213

Study information

Scientific Title
To evaluate the feasibility and preliminary efficacy of translating the Football Fitness Programme (FFP), a recreational football health intervention for inactive, adult men to Ireland, using a hybrid methodological approach

Acronym
FFP Feasibility

Study objectives
Current study objectives as of 07/04/2026:
The aim of this study is to evaluate the feasibility of the translation of the 12-week Danish Football Fitness Programme (FFP) health intervention to 2 FAI Clubs for inactive adult men using a hybrid methodological approach.

Previous study objectives:
The social return on investment (SROI) ratio for FC will demonstrate equivalent social value and cost effectiveness as per the 10-site scenario [€1:€9.37] and will be favourable for national scale-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 12/05/2025, University Ethics Committee, South East Technological University (South East Technological University, Waterford, X91 K0EK, Ireland; +353 051 302609; ethics@setu.ie), ref: SETU/REC/24/25/081

2. approved 26/03/2026, University Ethics Committee, South East Technological University (South East Technological University, Waterford, X91 K0EK, Ireland; +353 051 302609; ethics@setu.ie), ref: SETU/REC/25/26/080

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Supportive care

Study type(s)
Efficacy, Prevention

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease and overweight and obesity among general population men

Interventions

Current interventions as of 07/04/2026:
Parallel pragmatically controlled trial and implementation science. Adopting a hybrid model, the objectives of the study are as follows:
1. An experimental repeated measures pragmatically controlled trial within a social return on investment (SROI) framework to a) determine the social value of the FFP in 2 FAI clubs, b) the biopsychosocial health impact of the FFP, c) the reach of the FFP and d) the health economic impact of the FFP.
2. An implementation science approach to investigate the processes of implementing the FFP, i. e. identifying implementation barriers and facilitators, and addressing potential barriers to implementation, thereby ensuring fidelity and equitable benefit for participants across sites.

The FFP involves twice-weekly recreational football sessions for 12 weeks. The 60 min sessions consist of a 20 min warm-up based on the FIFA11+ concept modified for inactive players; 20 min of football-specific drills, and 20 min of 5–7-a-side football. The sessions will be delivered by experienced Football Fitness Instructors upskilled on the delivery of the Football Fitness programme and its Education Manual.

Groups will be pragmatically chosen to be involved in this study as the FFP is happening under 'real-world' conditions. Intervention Group [IG]: 2 FAI clubs will host the FFP.
Comparison in the waiting Group [CG]: 2 FAI clubs will host the CG. Criteria for Site Selection: To be selected for the study, it is desirable that the FAI Clubs;
- Be a Club Mark Club
- Have a full-size AstroTurf pitch with flood lighting
- Have toilet facilities on site
- Be accessible by public Transport
- Have a Local Sports Partnership (LSP) engaged.
- Have the HSE Community Health Organization (CHO) partner engaged.
- The county must have hosted other community health initiatives such as Men on the Move, Parkrun, Men's Shed, Cadbury FAI Kick Fit Programme and Lions Club

The IG and CG clubs that meet these criteria and are willing to be part of the study will be chosen.

The FFP will be delivered at clubs by local club coordinators and volunteers with the support of local stakeholders. Club coordinators have experience in managing the club and organising a range of club activities. They will have also undergone Garda vetting, safeguarding and first aid courses. Those who volunteer to be involved in delivering the FFP, along with the Club Coordinators, will attend FFP-specific training before the initiative starts at their club.

Previous interventions:
Adopting a hybrid model, this study aims to conduct, in parallel:
1. An experimental repeated measures randomised controlled trial within a social return on investment (SROI) framework to a) determine the social value of the FC games at scale, b) the biopsychosocial health impact the FC games at scale, c) the reach of FC games at scale and d) the health economic impact of FC games at scale.
2. An implementation science approach to investigate the processes of replicating the FC initiative at scale, i.e. identifying implementation barriers and facilitators, and addressing potential barriers to implementation, thereby ensuring fidelity and equitable benefit for participants across sites.

The intervention involves twice weekly (50 weeks/year), 60 mins, 9v9 - 11v11, recreational 'pick up' football games delivered under 'real world' conditions.

Groups will be pragmatically randomised in this study as the FC initiative is happening under 'real-world' conditions. Intervention Group [IG]: 7 FAI clubs will host the FC initiative. Comparison in waiting Group [CG]: 4 FAI clubs will host the CG. Criteria for Site Selection: To be selected for the study, FAI Clubs must
- Be a Club Mark Club
- Have a full-size AstroTurf pitch with flood lighting
- Have toilet facilities on site
- Have an area to place Marquees
- Be accessible by public Transport
- Have a Local Sports Partnership (LSP) engaged.
- Have HSE Community Health Organization (CHO) partner engaged.
- The county must have hosted other community health initiatives such as Men on the Move, Parkrun, Men's Shed, Cadbury FAI Kick Fit Programme and Lions Club

The CG clubs will be preparing to build their Astroturf facility and/or have it floodlit. The IG and CG clubs that meet these criteria and are willing to be part of the study will be chosen. Notably, we are also adopting a 2:1 ratio for IG and CG participants, again a feature of this pragmatically controlled trial.

The FC initiative will be delivered at clubs by local club coordinators and volunteers with the support of the FC operational lead. The latter has experience of developing and delivering FC games and managing all aspects of the game cycle across two sites since 2017. Club coordinators have experience of managing the club and organising a range of club activities. They will have also undergone garda vetting, safeguarding and first aid courses. Those who volunteer to be involved in delivering the FC games, along with the Club Coordinators, will attend FC-specific training before the initiative starting at their club. The FC operational lead will deliver this training and will: a) Relate the story of the FC initiative, b) Ensure Volunteers and Club Coordinators are clear on their role, c) Articulate why (why it's important to be part of the FC initiative), who and what of the role, d) Focus on policies, checklists and guides for managing the game cycle, community events, health and safety and disciplinary issues, e) Generate a positive 'value' culture for Volunteers and Club Coordinators, and f) Generate a network or support and learning (community of practice) for Volunteers and Club Coordinators.

The FC initiative is a weekly recreational 'pick up' football initiative targeting busy men with competing demands who want to play recreational football in their community in accordance with FC values (fair play, respect, integrity, inclusivity and community). Games are played from 8 pm on astroturf pitches 50 weeks of the year on either one or two nights a week (depending upon the site). Games are typically 9v9 – 11v11 and are played for 60 mins.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome as of 09/04/2026:
Systolic blood pressure will be measured using an automated sphygmomanometer (Heine Ltd., Munich, Germany) at Baseline (B), 3 months (3M) and 6 months (6M)

Previous primary outcome:
Systolic blood pressure will be measured using an automated sphygmomanometer (Heine Ltd., Munich, Germany) at Baseline (B), 3 months (3M) and 12 months (12M)

Key secondary outcome(s))
Current secondary outcome as of 09/04/2026:
Waist circumference will be measured over light clothing using a SECA 201 tape measure at B, 3M and 6M.

Previous secondary outcome:
Waist circumference will be measured over light clothing using a SECA 201 tape measure at B, 3M and 12M.

Completion date
07/03/2027

Eligibility

Key inclusion criteria
All stakeholder groups are eligible for inclusion in the study if they are:
1. ≥ 18 years
2. A member of the stakeholder group
3. Provided written consent
4. Are proficient in written and oral English

Participant type(s)
Employee, Healthy volunteer, Service user

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
85 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. < 18 years
2. Not a member of the stakeholder group
3. Do not provide written consent
4. Are not proficient in written and oral English

Date of first enrolment
24/08/2026

Date of final enrolment
14/09/2026

Locations

Countries of recruitment
Ireland

Study participating centre
Centre for Health Behaviour Research, South East Technological University
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Sponsor information

Organisation
Health Research Board

ROR
https://ror.org/003hb2249

Organisation
South East Technological University

ROR
https://ror.org/03fgx6868

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
South East Technological University

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 09/04/2026:
The datasets generated during and/or analysed during the current study will be available upon request from Dr Paula Carroll (Principal Investigator), Paula.Carroll@setu.ie

• The type of data that will be shared

Kind of Data:
Qualitative Data: Qualitative methodologies will be used to develop Theories of Change for each stakeholder group that will focus on a) profiling the stakeholder group, b) the environment that supported their involvement, c) the impact of their involvement and d) the outcomes experienced as a result of their involvement. Throughout implementation, qualitative data will also be collected to assess implementation (adoption, fidelity etc.). Only audio files will be saved and uploaded to OneDrive for transcription (only relevant for data collection on Zoom). Audio files will be transcribed verbatim for analysis and once checked for accuracy, they will be deleted from OneDrive. This will occur within 7-10 days post data collection. Anonymised transcripts will be shared.
Quantitative Data: Quantitative data will be downloaded from Qualtrics and the Kitman Labs data collection portal in Excel spreadsheet format. Once saved, they will be uploaded to OneDrive. All 'Individual Data Event' (IDE) Excel spreadsheets from Kitman Labs will be merged to create a 'Masterfile' for analysis. All Qualtrics survey Excel spreads for participants will be merged with the Masterfile. The Masterfile will then be exported to SPSS to be analysed. The Masterfile will be shared in Excel format.

• Timing for availability
The study will commence in June 2026 and it is expected that data collection will not be complete until March 2027. Given data processing and dissemination of findings, it is expected that data will not be made available for re-use until June 2028. Exclusive use of the data will be claimed by the research team until then to allow for the publication of findings. The data will be made available on the secure Zenodo data repository for a period of 10 years, after which time it will be destroyed. All data will be freely available to anyone with access to the Zenodo repository.

• Whether consent from participants was required and obtained
No, this will not be required as only anonymised data will be shared and participants will not be identifiable.

• Comments on data anonymization
Steps 1-3: In relation to qualitative data gathered in the early steps of this study, data from the interviews/focus groups will be transcribed verbatim and all stakeholders' names will be replaced by codes/pseudonyms. All identifying information will be removed as far as possible. Participants will be asked to provide their date of birth (DoB) and mothers' maiden name (MMN) for identification purposes and link this information to their UID.

Step 4:
Participants in both the IG and CG will be given a UID. Members of the research team will ascertain their DoB and MMN for identification purposes and link this information to their UID. Only their UID, DoB and MMN will be recorded on the data collection portal.

All other stakeholder groups: At 6M, these groups will be sent a questionnaire that they will be asked to complete anonymously i.e. no identifying information will be collected.

• Any ethical or legal restrictions
No.. Ethical approval has been granted for this study by SETUs' Research Ethics Committee [Ref: SETU/REC/25/26/080]. The Ethics Application included a detailed 'Data Protection Impact Assessment', which includes issues such as confidentiality, informed consent, anonymity, data access and storage and data destruction. As per SETUs' policy, all data will be destroyed after 10 years. Notably, SETU's Data Protection and Data Retention policies are in keeping with international best practice.

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study will be available upon request from Dr Paula Carroll (Principal Investigator), Paula.Carroll@setu.ie

• The type of data that will be shared

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Qualitative Data: Qualitative methodologies will be used to develop Theories of Change for each stakeholder group that will focus on a) profiling the stakeholder group, b) the environment that supported their involvement, c) the impact of their involvement and d) the outcomes experienced as a result of their involvement. Throughout implementation, qualitative data will also be a collected to assess implementation (adoption, fidelity etc.). Only audiofiles will be saved and uploaded to OneDrive for transcription (only relevant for data collection on Zoom). Audio files will be transcribed verbatim for analysis and once checked for accuracy, they will be deleted from OneDrive. This will occur within 7-10 days posts data collection. Anonymised transcripts will be shared.
Quantitative Data: Quantitative data will be downloaded from Qualtrics and the Kitman Labs data collection portal in Excel spreadsheet format. Once saved, they will be uploaded to OneDrive. All 'Individual Data Event' (IDE) Excel spreadsheets from Kitman Labs will be merged to create a 'Masterfile' for analysis. All Qualtrics survey Excel spreads for C1 participants will be merged with the Masterfile. The Masterfile will then be exported to SPSS to be analysed. The Masterfile will be shared in Excel format.

• Timing for availability
The study will commence in January 2026; it may be necessary to collected data in 2027 as well

as 2026 if numbers are low in 2026. Therefore, it is expected that data collection will not be complete until December 2027. Given data processing and dissemination of findings, it is expected that data will not be made available for re-use until June 2028. Exclusive use of the data will be claimed by the research team until then to allow for the publication of findings. The data will be made available on the secure Zenodo data repository for a period of 10 years after which time it will be destroyed. All data will be freely available to anyone with access to the Zenodo repository.

• Whether consent from participants was required and obtained
No this will not be required as only anonymised data will be shared and participants will not be identifiable.

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Steps 1-3: In relation to qualitative data gathered in the early steps of this study, data from the interviews/focus groups will be transcribed verbatim and all stakeholders' names will be replaced by codes/pseudonyms. All identifying information will be removed as far as possible. Participants will be asked to provide their date of birth (DoB) and mothers' maiden name (MMN) for identification purposes and link this information to their UID. This will then be used for the selection process for Categories 2-4.

Step 4:
Participants in both the IG and CG will be given a UID. Members of the research team will ascertain their DoB and MMN for identification purposes and link this information to their UID. Only their UID, DoB and MMN will be recorded on the data collection portal i.e. the research team will not know the name or contact details of participants and will only contact them through the FC gatekeeper (Category 1 participants) or the data collection App on their phone (Categories 2-4 participants). To access their participation data from the FC App, the FC initiative will also collect their DoB and MMN at registration so that the research team can share their UID with the FC initiative. The FC initiative will not have access to any of the data on the data collection portal. Sharing of the UID is only so that the FC initiative can identify the participants at each site who are participating in the study so that they can share participation data with the research team.
All other stakeholder groups: At 12M these groups will be sent a questionnaire that they will be asked to complete anonymously i.e. no identifying information will be collected.

• Any ethical or legal restrictions
Ethical approval has been granted for this study by SETUs' Research Ethics Committee [Ref: SETU/REC/24/25/081]. The Ethics Application included a detailed 'Data Protection Impact Assessment', which includes issues such as confidentiality, informed consent, anonymity, data access and storage and data destruction. As per SETUs' policy, all data will be destroyed after 10 years. Notably, SETU's Data Protection and Data Retention policies are in keeping with international best practice.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			02/07/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes