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Football Cooperative, a community-based health initiative for men: An evaluation when replicated across multiple sites

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Registration date 02/07/2025	**Overall study status** Ongoing	
Last Edited 02/07/2025	**Condition category** Other	

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. Football Cooperative (FC) is a not-for-profit social enterprise that was established to provide recreational football games for men in their communities to improve their overall health. Currently, FC games are available on two sites and have been shown to provide health benefits for men and are value for money. Therefore, it is planned to increase the number of FC game sites over three years (Year 1=12; Year 2 = 30; Year 3=60) so that more men can avail of these benefits. The objectives of the research are to 1) measure the health impact of playing by comparing men who play FC games with those who do not over 12 months, 2) calculate the economic and social value of FC games for men and their communities, 3) learn about what types of men play FC games and 4) understand what things help and hinder the delivery of and participation in the FC games so that the delivery of the games can be improved. The findings of this study will help expand the delivery of the games nationwide and abroad through European Football Associations to improve male health in Ireland and beyond.

Who can participate?

Adult men who participate in the FC games across the new sites, along with all service providers at a provider, organisational and funding level involved in the provision of games.

What does the study involve?

For men who play the games, participation involves a) being consulted to determine the outcomes from participation, b) being assessed for those outcomes at baseline, 3 months and 12 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, adapted from that used for Study 1 (https://www.isrctn.com /ISRCTN17438373), will be administered to Category 1 participants in the intervention group (IG) via the FC gatekeeper. As per Study 1, the link to the questionnaire will be sent to these participants via email and the FC App that is currently under construction. For Category 2-3 IG participants and control (CG) participants, the questionnaire will be administered via the data collection App, i.e. the research team can send participants a link to the questionnaire. As per Study 1, 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 Warwick-Edinburgh Mental Well-being Scale (WEMEBS). Structural and functional social relationships may be assessed via the Berkman-Syme social network index and the UCLA loneliness scale, respectively. 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. On two weekdays and 1 weekend day during data collection periods, participants in Categories 2-4 will receive a notification through the data collection App asking them a) how many fruit and veg portions they ate that day and b) how much alcohol they consumed that day.
3. Data will be collected on-site for Category 2 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). 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 NAME EQUIPMENT. 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.

4. A subset of participants (Category 3) in both the IG and the CG (n=200) will be given a wearable, e.g. Garmin watch, at B and asked to wear it for the 12M period. At data collection timepoints, data related to physical activity, sleep and stress will be synced with the data collection portal via an API. If we cannot provide wearables to participants, we will ask those who routinely wear one to sync with STRAVA, where we can access their data.
5. A subset of participants in the IG (Category 4) will wear a STAT Sport GPS vest and heart rate (HR) monitor during 3 games 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 FC initiative.
b) To investigate the implementation of the FC initiative 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 FC 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 FC social enterprise to continue to offer games and bring services to sites for their benefit. 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 playing and a data breach; there is evidence from Study 1 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?
February 2025 to January 2028

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

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

Study website
https://footballcooperative.ie/academic-partnership/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Paula Carroll

ORCID ID
https://orcid.org/0000-0001-8465-4535

Contact details
South East Technological University
Rm G06, Bianconi Building
Cork Road Campus
Waterford
Ireland
X91 K0EK
+353 051834141
paula.carroll@setu.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Health Research Board: APA-2024-004, SETU PhD Scholarship Programme Awards: SETU-2024-236; SETU-2024-213

Study information

Scientific Title
A hybrid, efficacy and translational formative evaluation of a community-based recreational football initiative for men to assess effectiveness and implementation at scale

Acronym
FC Study 3

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)
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

Study design
Parallel randomized controlled trial and implementation science

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention, Efficacy

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
Prevention of cardiovascular disease and overweight and obesity among general population men

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

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

Overall study start date
01/02/2025

Completion date
31/01/2028

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)
Healthy volunteer, Employee, Service user

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
1200

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
01/10/2025

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
Ireland

Study participating centre
Centre for Health Behaviour Research, South East Technological University
Cork Road Campus
Waterford
Ireland
X91 K0EK

Sponsor information

Organisation
Health Research Board

Sponsor details
Grattan House
67-72 Lower Mount Street
Dublin 2
Dublin
Ireland
DO2 H638
+353 1 234 5000
hrb@hrb.ie

Sponsor type
Government

Website
https://www.hrb.ie

ROR
https://ror.org/003hb2249

Organisation
South East Technological University

Sponsor details
Cork Road Campus, Cork Road
Waterford
Ireland

X91 K0EK
+353 051 830000
research@setu.ie

Sponsor type
University/education

Website
https://www.setu.ie/

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
Local government

Location
Ireland

Funder Name
South East Technological University

Results and Publications

Publication and dissemination plan
Planned publications in a peer-reviewed journal

Intention to publish date
31/12/2028

Individual participant data (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

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 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.

• 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. 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
No.. 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', this 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