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Football Fans and Betting (FFAB): a feasibility study and randomised pilot trial of a group-based intervention to reduce gambling involvement among male football fans

Study Protocol
V1.0
29-11-19

This protocol has regard for the HRA guidance

FULL/LONG TITLE OF THE STUDY

Football Fans and Betting (FFAB): a feasibility study and randomised pilot trial of a group-based intervention to reduce gambling involvement among male football fans

SHORT STUDY TITLE / ACRONYM

FFAB

PROTOCOL VERSION NUMBER AND DATE

Protocol Version: 1.0

Date: 29-11-19

RESEARCH REFERENCE NUMBERS

IRAS Number:	This project has not been approved through the IRAS system, as it does not involve NHS patients, staff or institutions, or any of the other organisations, agencies or categories covered by IRAS. The study has been registered with Research Registry and has been allocated reference number: researchregistry5256
SPONSORS Number:	N/A
FUNDERS Number:	PHR - NIHR127665

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor

Signature: **Date:** 30-11-19

Name (please print): Dr. Debra Stuart

Position: Research Governance Manager

Chief Investigator

Signature: **Date:** 29-11-19

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Committees	University of Glasgow, College of Social Science Research Ethics Committee.

STUDY SUMMARY

Study Title	Football Fans and Betting (FFAB): a feasibility study and randomised pilot trial of a group-based intervention to reduce gambling involvement among male football fans
Internal ref. no. (or short title)	Football Fans and Betting (FFAB): a feasibility study and pilot trial
Study Design	A mixed methods feasibility study and pilot randomised controlled parallel group trial
Study Participants	Male football fans who are heavily engaged in gambling who want to reduce their gambling involvement and improve their health and wellbeing.
Planned Size of Sample (if applicable)	Phase 1: 12 – 16 Phase 2: 30 Phase 3: 120
Follow up duration (if applicable)	12 months
Planned Study Period	24 months
Research Question/Aim(s)	***Overall Aims*** i) To develop and incorporate insights about UK sport bettors' behaviours into the current version of the FFAB programme and thus refine it for initial delivery (Phase 1: refinement); ii) To test the feasibility of delivering the FFAB programme within professional football clubs (Phase 2: feasibility); iii) To pilot the delivery of the FFAB programme under research conditions, assess research procedures for a future randomised controlled trial of an optimised FFAB programme, and refine our logic model (Phase 3: pilot). **Phase 1. *Refinement of FFAB for initial delivery*** RQ1. Is FFAB acceptable to the target population (men who are regular sports bettors who want to reduce their gambling involvement)? RQ2. What (if any) further adaptations are needed to enhance acceptability, usability and engagement with the FFAB programme and associated smartphone gambling diary in the professional football setting? RQ3. How can the football club setting be used to

	best effect in recruitment strategies to attract and recruit men to FFAB? ***Objective Phase 2. Feasibility of FFAB*** RQ4. To what extent does FFAB succeed in attracting and retaining the target population? RQ5. To what extent do football clubs, coaches and participants find FFAB and the associated smartphone app acceptable, and what changes (if any) are required? RQ6. How well is FFAB implemented by coaches and what changes are needed to optimise coach training to deliver the FFAB programme? RQ7. To what extent can the smartphone app be used to assess men's engagement with the programme, self-reported money and time spent gambling and physical activity? ***Phase 3. FFAB pilot and assessment of research procedures*** RQ8. Are the research procedures acceptable to FFAB participants (men, coaches and clubs)? RQ9. Is there evidence that delivery and acceptability of FFAB varies by features of the football club context, such as gambling sponsorship? RQ10. Does FFAB have the potential to encourage male sports bettors to reduce their gambling involvement and improve wellbeing? RQ11. What additional measures should be considered as primary and secondary outcomes to enable a robust evaluation of behaviour changes (e.g. gambling behaviours and attitudes), improvements in mental health and wellbeing (e.g. wellbeing, self-esteem, health-related quality of life), and changes in underlying theoretical constructs (social support, autonomy, competence)? RQ12. What are the optimum methods for follow-up data collection? RQ13. Are there other intended and unintended (positive or adverse) consequences? RQ14. Is it feasible to collect data on the relevant costs and consequences associated with gambling and potential pathways between gambling and its associated costs and outcomes over the short and long term? RQ15. Does the FFAB logic model need refinement? RQ16. Do the findings warrant a full scale randomised controlled trial of the FFAB programme?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
National Institute for Health Research	Research funding
Healthy Stadia European Healthy Stadia Network 151 Dale Street Liverpool L2 2JH UK 0151 237 2686	In-kind delivery support funding
BetKnowMore Betknowmore UK 9 St Mary's Path Estate Office Islington London, N1 2RU 0800 066 4827	In-kind delivery support funding
Beacon Counselling Trust Head Office: 263 Townsend Lane Liverpool L13 9DG 0151 226 0696	In-kind delivery support funding

ROLE OF STUDY SPONSOR AND FUNDER

The University of Glasgow will sponsor the study, providing the necessary insurance to indemnify the study. The sponsor will monitor the study commensurate with risk as required.

The NIHR will fund the study, providing the necessary resources to conduct the study. Beyond this function, the funder will exercise no influence or control over data analysis and interpretation, manuscript writing, or dissemination of results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Groups

Two groups are involved in the co-ordination and management of this study. Complying with best practice, this project will be managed by a Project Management Committee (PMC) and overseen by an independent Study Steering Committee (SSC).

The PMC will comprise of members of the study Investigators, including Gerda Reith, Kate Hunt, Cindy Gray, Heather Wardle, Sally Wyke, Chris Bunn, Robert Rogers and

Nicola Greenlaw. They will be responsible for overseeing all aspects of the project design and delivery and co-ordinating the work of other partners, such as Healthy Stadia, and the team at Northumbria responsible for designing and delivering the smartphone diary app. They will function as the executive committee responsible for all decisions to be made on the project. The PMC will meet face to face, on average, once every six weeks to review progress, make key decisions and agree any risk migration actions required. During Phases 1 and 2, they will supplement face to face meetings with video conference calls. There will also be a further core delivery team of Gerda Reith, Heather Wardle and the research associate who will meet on a weekly basis to plan actions and review progress, referring to the PMC where necessary. The full project team will meet at key milestones to agree actions. These include, but are not limited to, project inception to establish actions for the full project; end of Phase 1 to share learning and agree steps for Phase 2; end of Phase 2 to further share learning and agree steps for Phase 3; and after 12 month data collection in Phase 3 to agree outputs and dissemination activity, and review outcomes in relation to progression criteria. Detailed notes of all meetings with action points will be produced and agreed, and the CI will be responsible for ensuring that these actions are taken. A detailed project timetable will be produced, with dependencies clearly marked and shared with the whole team and used to track progress against key milestones.

The independent SSC will function as the executive committee overseeing the project, ensuring that the research is ethical and robust and providing advice to the PMC where needed. Membership of this independent group will be voluntary, with no remuneration or formal arrangements made (beyond the terms of reference, which will be drafted and agreed by the group). For this project, the SSC will be asked to operate as a critical friend to the PMC and this will be reflected in their terms of reference. Independent membership will include the following: Chair: Prof Sir Ian Gilmore, a specialist in public health and alcohol research; additional members: Shaun Treweek, an expert in trials; Darragh McGee, a sociologist with expertise in gambling and football; Sarah Tipping, a statistician; Tim Miller, Executive Director of the Gambling Commission; and Colin Bland, CEO of Sporting Chance (a charity providing treatment and education to professional sports people for mental health issues, including gambling); and representing public and patients, Andy Gray, a recovering problem gambler who has been assisting with the preparation of this proposal. Gerda Reith and Kate Hunt will represent the study team and Debra Stuart will represent the University of Glasgow's sponsorship team. The SSC will meet on average every 6-12 months throughout the duration of the project, or as required, with the timing of meetings to reflect key milestones and decisions, for example prior to Phase 3 implementation to discuss learning from Phase 2 and agree actions.

PROTOCOL CONTRIBUTORS

The University of Glasgow will sponsor the study, providing the necessary insurance to indemnify the study. Beyond this function, the sponsor will exercise no influence or control over data analysis and interpretation, manuscript writing, or dissemination of results. The sponsor exerted no control or influence over the final research design.

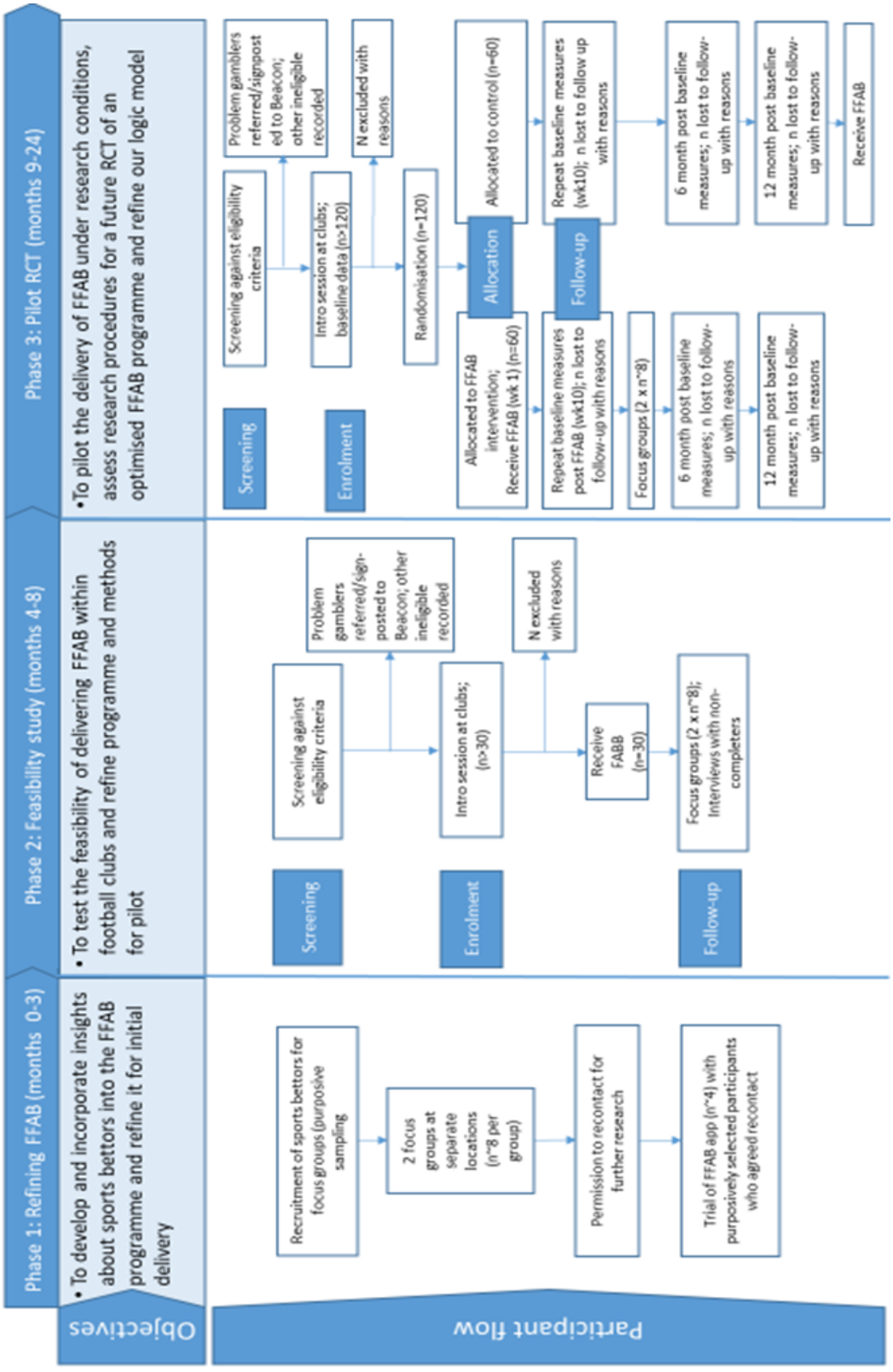
The NIHR will fund the study, providing the necessary resources to conduct the study. Beyond this function, the funder will exercise no influence or control over data analysis and interpretation, manuscript writing, or dissemination of results. The funder exerted no direct control or influence over the final research design, but did administer the peer review process through which the final design was arrived at.

Service providers and those with lived experience of gambling harm have been involved in, and contributed to, every stage of the development of this protocol. Members of two counselling organisations are included as Investigators on the project: Neil Platt, Clinical Director of Beacon Counselling Trust, and Frankie Graham, former problem gambler and founder of BetKnowMore, an organisation which specialises in peer-peer support. Another former problem gambler, Andy Gray, is also involved in the project and has been invited onto the Study Steering Committee. All three have provided input and feedback on every stage of the protocol development; from research design, recruitment strategies and target population, to co-development of the intervention with the research team. They have provided particular advice on programme content and delivery, and in the adaption of techniques for supporting problem gamblers for our specific population of heavily engaged male bettors.

KEY WORDS: Gambling harm, behaviour change, sports betting, football clubs, gender sensitisation.

STUDY FLOW CHART

Figure 1: Flow diagram of study design



University of Glasgow

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STUDY PROTOCOL

Football Fans and Betting (FFAB): a feasibility study and randomised pilot trial of a group-based intervention to reduce gambling involvement among male football fans

1 BACKGROUND

This study addresses an urgent and growing public health problem: gambling among the high-risk population of male sports bettors. Sports betting is a particularly male dominated form of gambling and is a major and highly visible area of growth for the gambling industry. Between 2014/15 and 2017/18 the online sports betting sector grew from £456m to £2.4bn, with online football betting increasing from £160m to £1bn, rising by £340m in the last year alone [1]. One in six men have placed sports bets in the past year [2]. Gambling companies are now the primary sponsor of half of the English Premier Football clubs, with in-play betting being heavily advertised and marketed to sports fans. Global trends in football-related sports betting indicate this trajectory will be sustained. It is likely that the gambling industry considers sports betting a large, untapped market. In the run up to the 2018 football World Cup, there was a notable increase in international operators launching sportsbooks aimed at the UK market, signalling the strategic importance of the UK market to businesses.

Gambling is associated with a range of adverse consequences and harms, affecting the health and wellbeing of individuals, families, communities and society. These can have enduring consequences that can exacerbate existing inequalities [3]. Gambling behaviour exists on a spectrum ranging from those who gamble and experience no adverse consequences, to those who experience some difficulties, to those whose gambling behaviour is defined as problematic against a range of validated criteria (e.g. health problems including stress, depression and anxiety) [4, 5]. The health harms from gambling can be severe, including self-harm, suicidal ideation and suicide attempts [6,7]. Longitudinal research has shown that stasis in gambling behaviour is not the norm, with people moving along the gambling-harms spectrum [8]. In Britain, a follow-up study of regular gamblers showed that nearly 1 in 3 (29%) of those who had previously reported no adverse consequences from gambling saw an increase in their experience of harms when re-interviewed one year later [9].

The experience of gambling-related harms is associated with higher levels of engagement in gambling activities [2]. Those who gamble 49+ times a year (i.e. ~weekly or more) are at greatest risk of experiencing harms, with around 1:10 estimated to experience adverse consequences as a result of their gambling, versus 1:100 of those who do not gamble/gamble under this threshold [10].

This study will first refine and then assess the feasibility of providing an independent, theoretically-informed and systematic intervention to regular male sports bettors who would like to reduce their involvement in gambling in the context of improving health and wellbeing. The intervention consists of a 9-week, face-to-face group based programme that aims to engage men in reducing their gambling involvement. It will be delivered by fully trained community coaches at professional football club home stadia. Each session lasts 90 minutes and includes 'classroom based' education round gambling behaviour,

motivations and impacts, followed by group-based physical activity sessions. Each session will be designed to be highly interactive, using whole group discussions, games and small group working to allow men to support each other to practice and build skills in order to monitor and reduce the amount of money and time spent gambling. A purpose built smartphone app will allow the men to record time and money spent gambling, as well as their daily step count, in a diary like format.

The study population will be male regular sports bettors aged 18 – 44 who feel their gambling may be affecting their health, wellbeing or relationships *and* who would like to make positive steps to change their gambling behaviour.

2 RATIONALE

The overall aim of the FFAB programme itself is to deliver an intervention to support men who are heavily involved in sports betting to reduce their involvement in gambling in the context of improving health and wellbeing. The research aims to refine and then test the feasibility of the intervention, before exploring a pilot randomised controlled trial (RCT) of the FFAB programme, compared with a control group, in order to prepare for a full-scale trial of effectiveness and cost effectiveness.

Our target population are at risk of going on to experience harms related to gambling, with attendant social and economic impacts and there are currently no interventions aimed at reducing these harms amongst this group. For this reason, it is important to test our ideas, in the feasibility stage, to find out if the intervention is acceptable to the target population of male sports bettors, to the coaches who will deliver it, and to the football clubs whose premises will be used.

Male sports bettors are an important population because sports betting, and online sports betting specifically, is one of the few gambling activities that has seen significant growth in levels of engagement. Between 2007 and 2016, the proportion of the British population betting online doubled (4% in 2007; 8% in 2016) [2]. Sports bettors are disproportionately male and younger, which are both well-established risk factors for the experience of harms [2]. It is therefore important to identify effective preventative interventions to limit the escalation and incidence of harms among this group.

Gambling not only strongly impacts on individuals' quality of life, but also represents a substantial economic burden to the NHS and wider society. In the UK, the excess fiscal cost associated with gambling has been estimated at around £1.6 billion per annum [11]. This is a conservative estimate as this figure includes only observable and measurable social costs (health; employment; housing; and criminal justice). Evidence has also shown that greater levels of harms (and so social costs) from gambling accrue to those who are at low or moderate risk of problems because of the greater population number [12]. Given the strong societal impact of gambling, finding effective and cost-effective interventions to reduce gambling involvement and, ultimately, incidence of regular and problem gambling, is a key policy issue. However, few studies have analysed the effectiveness of interventions directed towards reducing gambling involvement, and none for the target group of our proposed study, men who are regular sports bettors. Nor have any incorporated a formal economic evaluation [13-15].

Interventions targeting those with severe problems– cognitive-behavioural therapies and (brief) motivational interviewing – show some benefits in terms of clinical symptoms and sometimes decreased financial losses over relatively short follow-up times [16,17]. Only a very small number of studies have linked interventions to formal theories of change, most commonly trans-theoretical ('stages of change') models [18] and information-motivation-behavioural skills models (IMB) [19]. Very little is known about the characteristics that distinguish successful from unsuccessful interventions. A recent study developed a taxonomy of gambling interventions in an attempt to draw out components with potentially greater or lesser effectiveness [19]. This Gambling Intervention System of CharacTerization (GIST)] lists 35 characteristics of interventions but stresses the need for further research to identify their efficacy. Other recent evidence has suggested that interventions that involve certain behaviour change techniques (self-monitoring, goal setting, personalized feedback and reflection on behaviour) show promising results for sustained changes in gambling behaviour over time, particularly when targeted at high risk groups [20,21].

One of the major hurdles to reducing gambling harms is the potential to identify and attract those of higher risk of harms to a programme. There is strong evidence of using professional sports settings to attract men [22,23] including attracting men at high risk of other adverse health-related outcomes, to successful behavior change interventions, including, but not limited to, those developed by members of the current team [24]. The Football Fans in Training (FFIT) programme, for example, has been shown to be: effective in attracting and supporting obese/overweight men (a traditionally hard-to-reach group) from across the socio-economic spectrum to make sustained weight and behavioural changes, with benefits clearly evident to 3.5 years [25]. This model has also demonstrated sustainable post-research roll-out and ongoing public health impact. It works by attracting men who want to improve their health ('get fitter and lose weight'). Men are encouraged to make achievable and sustainable changes through the use of a 'toolkit' of behaviour change skills -such as self-monitoring and goal-setting- in a supportive group that enables mutual learning in an enjoyable and valued setting. It fosters sports-related socially supportive environments that enable men to incorporate new, healthier, behaviours into their identities and daily lives [26]. In the field of gambling, the PI's research has similarly highlighted the importance of social networks, environments and gender in reducing gambling involvement (in terms of time and money spent, frequency of gambling and range of activities undertaken) and in shaping non-gambling identities [8,27]. This evidence supports the potential for the careful adaptation of learning from FFIT to the FFAB (Football Fans and Betting) programme, specifically drawing on the power of professional sports clubs, and social support and interaction to encourage behaviour change (reductions in gambling behaviour and increases in other more positive behaviours e.g. physical activity) promoting better health and wellbeing outcomes in a context of symbolic value to participants, the football club.

This pilot study represents the first robust evaluation of an independent, theoretically-informed and systematic intervention for male sports bettors. Our approach is also distinct because it is independent of industry; most 'responsible gambling' initiatives are industry led or funded. By contrast, our independent team will draw on sports club

affiliation to encourage men to establish strategies to support behaviour change. In developing this proposal we have consulted with individuals who have been harmed by gambling; one recovered problem gambler who reviewed an early draft told us: 'I wish I had signed up to something like this a couple of years ago then perhaps my life would be a lot different to what it currently is'.

3 THEORETICAL FRAMEWORK

Theories of behaviour change around gambling interventions are very under-developed. Part of the process of this pilot study is to refine our understanding of how, and why, certain features of the intervention may be more or less effective for changing behaviour than others. As such, our conceptual approach is a pragmatic and multi-faceted one that draws on the best currently available evidence on what works for reducing involvement in gambling. This involves insights from a number of approaches.

In particular, FFAB draws on the principles of self-determination theory, to build autonomy, competency and relatedness, to motivate men who are heavily engaged in gambling and who want to regain control over their betting behaviour, to reduce time and money spent gambling, and thus improve self-esteem, health and wellbeing and social relationships. It also incorporates ideas from the information-motivation-behavioural skills (IMB) model, in which learning about gambling harms (e.g. impacts on social relationships) and benefits of reducing gambling (e.g. better financial wellbeing and, relatedly, better social and emotional wellbeing) is underpinned by motivational support and skills development [28].

The programme is also informed by theories of the influence of social contexts, social networks and gender on behaviour [29]. First, setting FFAB in professional football clubs is designed to attract men to the programme in ways that are congruent with their existing identities. Second, the men-only group setting of FFAB is designed to tap into the ways that positive behaviour change, i.e. reductions in gambling involvement, is fostered, encouraged and sustained through a supportive peer group. Third, the positive motivational climate created by coaches by the informal, interactive but structured style of the delivery is designed to support men to discuss and tackle potentially challenging and sensitive problems. These aspects were developed and shown to be successful in FFIT [24]. Although we recognise that gambling is a very different behaviour change to weight loss and associated behaviours, we are aware of the importance of social context in gambling behaviour [3,8], and believe that the specifically *social* element of the programme is something that gambling behaviour change can also be embedded in. In the social setting of the club, participants will be introduced to behaviour change techniques such as self-monitoring, information gathering, behavioural substitution, goal setting, feedback on behaviour, and relapse prevention [19] to help them better understand their gambling, and to develop strategies to change it. Following from findings of the process evaluation of FFIT, the *context, content and style of delivery* of the FFAB programme is designed to allow men to discuss potentially sensitive topics around their betting in a mutually supportive environment and apply strategies to

manage betting in ways that taps into important aspects of their sense of identity and so support change [8,27,30].

The FFAB intervention will also use engagement in group-based physical activities (PA) within the social setting of the football club to foster a socially supportive network of men. Unlike FFIT, where improvement in PA was an important secondary outcome, PA in the FFAB programme has a very different role. It is used primarily as a mechanism to strengthen social networks and peer support, and as a form of behavioural substitution by providing a displacement activity for gambling that men can focus on and bond around between sessions. To help to encourage this feature, the smartphone app is designed to allow participants to record and monitor their step counts, drawing on learning about the importance and enjoyment of this type of self-monitoring [31]. This feature will also encourage more general engagement with the app itself as a form of self-monitoring as well as goal setting, both of which are important in the generation of autonomy. It will allow participants to track the amounts of time and money they spend on gambling on a daily basis, which can be used in weekly group feedback sessions in which men set their own spending goals.

Our logic model incorporates core elements to test SDT as a provisional theory of change; but also includes other elements to explore complementary perspectives including maintenance processes, and IMB, which have also been used to understand gambling behaviour [32, 33] (see Figures 2&3). In this way, if successful, our feasibility study will afford the material required to develop a fully-specified model of change in a subsequent large-scale RCT of FFAB.

Figure 2: Logic Model for FFAB

Inputs	Activities				Outcomes	
	Attracting men	**Engaging men**	**Initiating change**	**Maintaining change**	**Short term**	**Long term**
Relational • Club and coach commitment to engage with programme training package, and preparation for each session **Physical** • Access to club facilities • Programme manuals • Self-monitoring app **Financial** • Resources to pay for materials and facilitator and coach time	Draw on multiple motivations: • desire to reduce gambling • desire to (re)gain control of time/finances • love of football club and behind-the-scenes access • desire to play football Appeal in ways that are congruent with existing identities (e.g. men only; at football club) Reassure men they will not stand out, they will be with other men 'like them'	Ensure men feel their decision to join the programme is valued Encourage a team spirit (relatedness) through: • promoting similar interests (e.g. football club, PA as part of the session) • demonstrating and sharing similar challenges in relation to gambling • use of social media Facilitate enjoyment in the sessions through interactions, fun and football	• Demonstrate and encourage practice of self-monitoring, goal setting (through the app), problem solving and feedback around gambling behaviours • Promote men's understanding of their own gambling behaviours and how gambling works in favour of industry • Appeal to men's sense of wanting to be in control of their (gambling) behaviours, and help them identify ways they can do this (autonomy) • Promote substitution of gambling for other (positive) behaviours (e.g. PA) • Promote stimulus control and financial restraint to limit access, time and money spent gambling • Promote competence in performances of new gambling behaviours including limiting gambling and abstinence • Promote development of a socially supportive network to support behaviour change A	• Build skills and competence through: i) Practice of behaviour change techniques ii) Optimal challenges in relation to gambling iii) Promoting self-referenced feedback • Encourage men to pursue a new interest (e.g. a form of PA they enjoy) that they can substitute for gambling • Encourage recognition of the personal benefits of changing gambling behaviour (e.g. more money, higher self-esteem, more connected to important people in their lives) • Encourage practice of strategies to avoid negative social influences • Encourage a deepening sense of positive social connectedness with peers (outside group session), family, friends • Help men to understand how to avoid and overcome setbacks	**Behaviours** • Men spend less time gambling • Men spend less money gambling • Men gamble less frequently • Men engage in a lesser range of gambling activities **Psycho-social** • Men improve their wellbeing • Men improve their self-esteem • Men feel more connected to important people in their lives • Men have more social support to facilitate behaviour change	**Behaviours** • Men continue to spend less time and money gambling • Men continue to gamble less frequently on fewer activities **Psycho-social** • Continued increased in wellbeing and self-esteem • Decreased relationship /problems breakdowns • Decreased levels of financial hardship • Men continue to feel well supported socially

4 RESEARCH QUESTION/AIM(S)

The primary aim of the research is to refine and then undertake a pilot RCT of the FFAB programme in order to prepare for a full-scale trial of effectiveness and cost effectiveness

4.1 Objectives

Specific objectives:

i) To develop and incorporate insights about UK sport bettors' behaviours into the current version of the FFAB programme and thus refine it for initial delivery (Phase 1: refinement);

ii) To test the feasibility of delivering the FFAB programme within professional football clubs (Phase 2: feasibility);

iii) To pilot the delivery of the FFAB programme under research conditions, assess research procedures for a future RCT of an optimised FFAB programme, and refine our logic model (Phase 3: pilot).

Specific research questions associated with these objectives are:

1. *Refinement of FFAB for initial delivery*

RQ1. Is FFAB acceptable to the target population (men who are regular sports bettors who want to reduce their gambling involvement)?
RQ2. What (if any) further adaptations are needed to enhance acceptability, usability and engagement with the FFAB programme and associated smartphone gambling diary in the professional football setting?
RQ3. How can the football club setting be used to best effect in recruitment strategies to attract men to FFAB?

2. *Feasibility of FFAB*

RQ4. To what extent does FFAB succeed in attracting and retaining the target population?
RQ5. To what extent do football clubs, coaches and participants find FFAB and the associated smartphone app acceptable, and what changes (if any) are required?
RQ6. How well is FFAB implemented by coaches and what changes are needed to optimise coach training to deliver the FFAB programme?
RQ7. To what extent can the smartphone app be used to assess men's engagement with the programme, self-reported money and time spent gambling and physical activity?

3. *FFAB pilot and assessment of research procedures*

RQ8. Are the research procedures acceptable to FFAB participants (men, coaches and clubs)?
RQ9. Is there evidence that delivery and acceptability of FFAB varies by features of the football club context, such as gambling sponsorship?

RQ10. Does FFAB have the potential to encourage male sports bettors to reduce their gambling involvement and improve wellbeing?
RQ11. What additional measures should be considered as primary and secondary outcomes to enable a robust evaluation of behaviour changes (e.g. gambling behaviours and attitudes), improvements in mental health and wellbeing (e.g. wellbeing, self-esteem, health-related quality of life), and changes in underlying theoretical constructs (social support, autonomy, competence)?
RQ12. What are the optimum methods for follow-up data collection?
RQ13. Are there other intended and unintended (positive or adverse) consequences?
RQ14. Is it feasible to collect data on the relevant costs and consequences associated with gambling and potential pathways between gambling and its associated costs and outcomes over the short and long term?
RQ15. Does the FFAB logic model need refinement?
RQ16. Do the findings warrant a full scale RCT of the FFAB programme?

4.2 Outcome

Our study outcomes include refinement of our recruitment and intervention approach (phase 1), feasibility of the FFAB intervention within clubs (phase 2) and an optimised pilot randomised control trial of FFAB (phase 3). Our outcome measures are commensurate with the objectives for each phase.

Phase 1: Our broad outcomes from Phase 1 include qualitative feedback from focus groups on:

- The acceptability of the FFAB programme to our target group
- Revision and refinement of the recruitment strategy

Thematic analysis will present data on: participant's views of target recruitment material; what works, what does not and why; which elements of the FFAB programme are most/least attractive to our target group and why; recommendations for changes to the recruitment strategy and suggestions for how to find, access and recruit our target group.

Other outcomes from this phase include:

- Production of the final FFAB intervention protocol and coach manual, based on feedback from the co-development group
- Qualitative feedback from a pilot test of the smartphone app diary data to include ease of use, frequency of use and quality of data entered.

Phase 2: Our outcomes for phase 2 focus on

- Data on the acceptability of the FFAB programme to participants by i) reviewing data on recruitment, retention, participation and drop-out rates. This will include monitoring: the number of enquiries made; number of hits to project website/social media pages; number of people screened; number of eligible candidates identified; co-operation rates among eligible candidates; attrition rates throughout the programme; number of sessions completed by each participant; ii)

qualitative feedback from focus groups among those completed the programme and in-depth interviews among those who did not (exit interviews) and iii) review of smartphone app data relating to use and quality of data recorded, including number of participants who used this, frequency of use per participant and quality of data (by reviewing reported data for extreme outliers and consistency).

- Data on the acceptability of FFAB delivery by coaches collected by i) focus groups with with feasibility coaches after the full delivery of FFAB to produce thematic insight into: the confidence of the coaches to deliver FFAB; what worked and what did not; challenges and how to over come these and revisions to coach training and the FFAB programme and ii) team observation of each session of FFAB in phase. Team observations will generate field notes identifying key themes for discussion by the full FFAB team in revising the programme.

Other outcomes from this phase will be further refinement of the FFAB intervention manual and coaches delivery manual, based on the feedback given above and finalisation of the recruitment and retention strategy.

Phase 3:

The broad outcome of the pilot trial is to assess the potential effectiveness of FFAB in improving wellbeing by reducing gambling involvement (RQ10). We propose to test the responsiveness of **potential primary outcomes** in the pilot trial: investigating both measures of improvements in health and wellbeing and of reductions in gambling involvement.

For health and wellbeing, the WEMWBS and ONS four item wellbeing questionnaire will be used. Data from the Health Survey for England and the British Gambling Prevalence Survey 2010 show that gambling behaviour is associated with both: problem gamblers are more likely to have lower WEMWBS and ONS scores [2,36]. WEMWBS has been shown to be sensitive to change in evaluations of diverse public health interventions and programmes including general lifestyle interventions and parenting programmes [37]. The ONS wellbeing questions cover personal wellbeing ranging from happiness to life satisfaction and have been developed to National Statistics standards. We will also include measures of health-related quality of life and capability suitable for use in economic evaluation, i.e. EQ-5DL and ICECAP-A [38,39].

Gambling involvement will be measured on two domains: breadth and depth [36, 40] and will be captured using validated measures of gambling involvement: number of different types of gambling activities undertaken (breadth) and self-reported gambling frequency (total number of bets placed, number of days spent gambling); total money spent on gambling; and total time spent on gambling (depth). All of these questions were developed and tested for the British Gambling Prevalence Survey 2010 [36]. Their validity and reliability have been assessed, showing good to excellent reliability and validity [41] when compared with diary methods.

Proposed **secondary outcome measures** include specific items from the DSM-5 problem gambling screening instrument pertinent to our intervention (such as betting more than one could afford to lose, trying and failing to cut back on gambling, gambling as escapism and being restless or irritable when trying to cut back on gambling) [42]; a measure of social support, (an adapted version of the Shortened Social Support Scale

made appropriate for gambling and perceived social support more generally) [43]; and Rosenberg's Self Esteem Scale [44].

We will collect information on attendance and logged data of app diary usage. If data quality permits, we will use data from the app to help inform progress towards reductions in gambling involvement (RQs7,12). Analysis of app data will be done post-intervention. We will conduct focus groups with intervention participants after they have completed the intervention to understand their experiences of FFAB, of making and sustaining reduction in their gambling behaviours, and of the research procedures (RQs8&10). Post intervention, we will conduct exit interviews with non-completers, and interviews with coaches and football club representatives to understand their views and experiences of delivering FFAB and of involvement in the pilot (RQs5,6,8,9).

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The research design is a mixed methods feasibility study and pilot multi-site parallel group RCT. It comprises three phases, corresponding to our three main research objectives.

Phase 1. Refinement of FFAB for initial delivery (months 0-6)

In Phase 1 we will *refine the FFAB intervention materials* and associated *smartphone diary* by working iteratively with a co-development group including representatives from Healthy Stadia, football clubs, Beacon Counselling Trust, BetKnowMore (who both provide specialist support services for problem gamblers), recovered problem gamblers and male sports bettors.

Members of the co-development group have already contributed to the development of the FFAB programme. In Phase 1 they will meet twice, in months 2 and 3. The first meeting will consider the results of the Focus Groups (described below) to assess whether/how the programme and app should be adapted, and develop recruitment strategies and branding of FFAB to maximise recruitment to and engagement with the programme (RQs 2&3). Between the first and second meetings, any necessary adaptations will be made to the programme and app to allow them to be reviewed again and any further changes made. The second meeting will also consider a draft of the coach training programme.

Data collection: Two focus groups with sports bettors in the target population (regular gamblers who want to reduce their gambling involvement) will be conducted in two football clubs (c.6-8 participants per club). Participants will be recruited through publicity campaigns at the clubs, online publicity and advertising and through local media. This will be facilitated by our co-development partners, Healthy Stadia, who have a close relationship with club management and clubs Community Trusts.

The focus groups will take place on club premises at a time that suits most participants and will be facilitated by two researchers from the FFAB team. They will be audio-recorded and transcribed verbatim. Participants will be offered a 'thank you' gift card of £20 for their participation and travel expenses. The discussions will be designed to better

understand the behaviours and motivations of sports bettors and explore views on the programme content and delivery (RQs 1&2). We will seek men's responses to different branding for FFAB, including the programme's proposed name, descriptions of key elements and tag-lines which describe FFAB's purpose. Our current ideas include: *'love the game, not the gamble'*, *'reclaim the game', 'play it safe'* as a way to express notions of rebalancing the relationship between sport and gambling (RQ3).

Analysis will be thematic and focussed on designing recruitment strategies and improving the FFAB programme for delivery in the professional sports setting. The findings will be used by the co-development group to refine the recruitment strategies and content of FFAB for Phases 2 & 3. This will include insight into how best to brand and 'sell' FFAB to the target audience.

Phase 1 will also include development of the *coach training programme* for FFAB. We will draw on our team's experience of training coaches to deliver related programmes, as well as our specialist expertise in counsellor training around gambling harms. As coaches employed by professional football clubs' community organisations are not likely to have practical experience and knowledge about supporting men to change their gambling behaviour, experts with in-depth knowledge of gambling behaviour and harms will be heavily involved in training and support. The 2-day training will include learning on the rationale for each part of the programme and practice in delivery of each essential element (e.g. teaching and practising BCTs, engendering a supportive motivational climate in which mutual learning can take place). Training will be experiential and led by research team members from University of Glasgow and Beacon Counselling Trust. Members of the research team will attend an early delivery of FFAB at each club to provide initial support and feedback, and will be available for further email/telephone support if required throughout feasibility and pilot trial deliveries.

Finally during Phase 1, a *personal tracking application* will be implemented and trialed with users (drawing on the app technology and experience developed for EuroFIT) (RQ2). The application will be cross-platform (available for use via web browsers and natively on Android and iOS devices). To suit the majority of participants, including those from low socio-economic groups, the app will be functional on low-end devices, and use of data will be minimised. The app will enable self-monitoring of time and money spent gambling, support goal setting, and produce weekly reports for discussion at sessions. The app will centre on self-report data so that users can track any gambling they do and can include the time they spend thinking about and researching bets as well as that spent in gambling applications. Engagement data will be logged. In Phase 1, the app will be tested by c.4 regular gamblers, recruited from those who took part in our focus groups and agreed to participate in future research. Feedback telephone interviews will be conducted to understand usability and use (RQ2). A beta version of the app will be available for Phase 2, with a fully developed version ready for Phase 3.

Phase 2: feasibility study (months 4-8)

Phase 2 will assess the feasibility of the FFAB intervention and inform whether further refinements to FFAB are needed prior to the Phase 3 pilot trial. This includes delivering the coach training and the FFAB intervention within two clubs to test: whether we can

recruit and retain the target population (RQ4); the acceptability of FFAB to clubs, coaches and participants (RQ5); the extent to which our training allows FFAB to be well implemented by coaches (including whether experts in gambling harms are needed) (RQ6); and whether the smartphone app can be used to assess men's engagement with the programme (RQ7).

Coach training: We will use the 2-day training programme developed in Phase 1 to train coaches at two feasibility pilot clubs in North West England to deliver the FFAB intervention to groups of male sports bettors (n~15). Specialist training will be provided in an intensive 2 day interactive workshop to upskill coaches in developing awareness of gambling related issues, explore the FFAB sessions (including the behaviour change goals of each), practice delivery of sessions and refresh skills on group facilitation. It will be led by team members from University of Glasgow and BCT, who respectively have experience in training coaches to deliver FFIT and EuroFIT and expertise in training for interventions to reduce gambling harms.

Recruitment to and delivery of FFAB: We will follow the recruitment procedures developed in Phase 1 to recruit ~15 men to attend the 9-week FFAB programme in the two clubs. The FFAB intervention is described more fully in the section on Phase 3 below.

Data collection: We will use data from five sources to assess feasibility.

i) Monitoring of recruitment and retention. We will: a) monitor how easy it is to recruit participants, assessing the most productive routes to recruitment and whether different routes differentially reach men from different socio-economic backgrounds; and b) train coaches to record weekly attendance at FFAB sessions, so we can assess the attraction of the programme and retention to it (RQ4).

ii) Observation of delivery sessions. Members of the FFAB research team will observe delivery of all sessions at both clubs to assess engagement with the programme, ease of delivery and acceptability of core elements. Observations will also give the team insight into whether community coaches can deliver FFAB without support from gambling experts (RQs 5&6).

iii) Exit interviews with non-completers. Brief telephone interviews will be conducted with men who miss two or more sessions in a row to ask why they did not attend and whether there are any changes needed to the programme to make it more attractive and engaging (RQs 4&5).

iv) Post-programme interviews with coaches from clubs and gambling behaviour experts. Interviews will elicit views on what went well and what less well, the adequacy of training, how the programme could be strengthened and whether community coaches could deliver the programme without weekly in-stadia support from gambling experts (RQs 5&6).

v) Post-programme focus group discussion with participants. The focus group discussions will elicit views on what attracted participants, why they kept coming, what they liked and did not like about the programme (including the associated smartphone app), what would have improved it, what helped them to make positive changes in their gambling

behaviours and their health, and any unanticipated beneficial or adverse outcomes (RQs 4,5,7).

vi) Logged data from the specifically-developed smartphone app. The app will capture self-report data on money and time spent gambling and daily step counts as part of men's self-monitoring. We will use these data to assess engagement with the app, whether and how it might need to change, and its potential as a data capture tool in a future trial (RQs 5&7).

Data analysis: Qualitative data will be transcribed and analysed thematically, to identify what helped or hindered the delivery of the programme and what needs changing. Descriptive analysis will be used to summarise recruitment and retention and (from app logged data) explore patterns of usage, any problems with use and the extent to which the smartphone app can be used as a data collection tool. Analyses will be triangulated to gain a detailed understanding of whether and how coach training, the app, programme materials and delivery format, and recruitment strategies need to be optimised prior for Phase 3 (RQs 6&7).

Phase 3. Pilot RCT and assessment of research procedures (months 9-24)

Design: Phase 3 is the pilot of a pragmatic, two-arm, RCT of FFAB conducted in four professional football clubs in North West England.

Randomisation: Following baseline data collection, study participants will be randomised either online or by telephone (IVRS). Randomisation will be stratified by football club, on a 1:1 basis to one of two arms: an **intervention arm** who will receive the FFAB intervention; or a **control arm** who will receive the intervention after the end of the project.

Intervention: FFAB is a 9-week, face-to-face group-based programme that aims to engage men in reducing their gambling involvement. FFAB is delivered by fully trained community coaches at professional football club home stadia. Each session lasts 90 minutes and includes 'classroom-based' education around gambling behaviour, motivations and impacts, followed by group-based physical activity sessions. The classroom sessions will support men to: understand the role, extent and influences on gambling in their life (including other people and environmental and psychological triggers); understand and reassess dysfunctional beliefs (e.g. around risk taking and chance); develop strategies to avoid triggers for gambling and relapse ('if-then' plans); identify the benefits to them and other people in their lives of reducing their gambling; and identify ways that they personally can (re)gain control (autonomy) over their gambling behaviours. Each session will be designed to be highly interactive, using whole group discussions, games and small group working, to allow men to support each other to practice and build skills (competence) in order to monitor and reduce the amount of money and time they spend gambling. Interaction between men will be encouraged to promote a team spirit and facilitate discussion of sensitive issues. In the group-based physical activity sessions that follow, men will be given the opportunity to take part in football-based activities (including training drills, walking football and small-sided matches) using club facilities. These are intended as a means to foster social

connectedness and male bonding around a substitution activity that is specifically non-gambling related. This is part of our goal to encourage a shift in shared values and attitudes around the idea of 'reclaiming the game'.

During sessions, men will learn to use the smartphone app to record time and money spent gambling, and to set SMART goals around these behaviours. Men will also be able to use the app to monitor and record their daily physical activity (step counts). It is anticipated that this functionality will encourage men's engagement with the app, and, by extension, with the gambling diary functionality. Discussion around app-based recording of PA is also intended to encourage bonding within the group as a subtle means of leading into potentially more sensitive discussions around recording of time and money spent gambling.

Control/Comparison group: Following baseline data collection, participants in the control arm will continue with their daily routines and usual activities.

Assessment and follow-up: We have four stages of assessment and follow-up for all participants: the first is baseline data collection, when information relating to all outcome measures (the outcome questionnaire) is collected prior to randomisation to the intervention and control groups. The second is immediately after the intervention group have completed FFAB (10 weeks post-baseline). This will allow us to explore any immediate effects of the intervention. The third is at six months post-baseline, to assess impact across a longer time frame. Finally, the outcome questionnaire will be repeated at 12 months post-baseline to give insight into the sustainability of potential impact (RQ10). This will be our primary data collection point for our RCT outcome measures and will be used to assess progression.

Methods for data collection: To maximise attendance at baseline and retention for follow-up, baseline data collection will take place in club stadia, a strategy successfully employed in the FFIT and EuroFIT RCTs. The baseline measurement session at the club, conducted prior to randomisation, will be used to explain more about the study, and its purpose and context, and a club coach will be on hand to answer questions about the programme.

An electronic case report form (eCRF) will be used to collect study data. This system will be developed by the Robertson Centre for Biostatistics (RCB – the Data Centre and Biostatistics arm of the UKCRC fully registered Glasgow Clinical Trials Unit) based within the University of Glasgow. Baseline and follow-up data will be collected using the eCRF and managed by the RCB. This will be a confidential, self-completion method, which is optimal for collecting data on sensitive behaviours. Individual participant user accounts will be provided to each participant for them to log in and enter their baseline and follow-up data.

FFAB's outcome data is completely self-reported, therefore it may not be necessary for participants to revisit the club for follow-up data collection, as they could do this confidentially from their own home. However, it may be the case that revisiting the club could be positive in terms of retention. Yet there is also a risk that asking participants to

revisit the setting of the intervention may bias responses. We will test this by conducting a methodological experiment, where half of the groups will be asked to complete follow-up data online in a place and time of their own choosing (within a data collection window set by the research team) and half are invited to revisit the club at a set time/date to complete follow-up data online then and there. For the former group, completion of measurements will be closely monitored, and reminders sent via email, text and follow-up phone calls, if necessary; for the latter group, non-attendees will be forwarded the online link and will again receive reminders (RQ12).

For all participants, if online accessibility is an issue, a paper version of the questionnaire will be sent/used, if necessary. For those receiving the intervention, and where they have agreed, push notifications to complete the follow-up data can be sent from the smartphone app. Given the age profile of participants (18-44) we anticipate that most will have internet access and will complete the surveys online. Where neither online nor paper-based responses are received, a member of the research team will call participants and attempt to collect the data over the phone.

Data and statistical analysis: Statistical analysis of the pilot RCT data will be undertaken by the RCB. In order to address RQ11 (best outcome measures) and RQ10 (the potential of FFAB to effect change), a full detailed statistical analysis plan will be developed and agreed prior to database lock and unblinding of the statistician. Descriptive summaries of the pilot RCT outcomes, including the numbers invited to participate, the numbers and proportions recruited, and retained during the study (six months post-baseline), and at the primary follow-up time-point (12 months post-baseline) will be provided along with 95% confidence intervals. The completeness of the proposed efficacy outcome measures at each of the four data collection time points during the study, will be provided. The distribution of the data will be explored and the variation, both between clubs and between participants, will be assessed. Baseline factors and their association with outcomes will also be examined. The intervention effect on outcome measures at our primary follow-up time point (12 months post-baseline) will be estimated in exploratory analyses and reported with corresponding 95% confidence intervals, as well as the intervention effect within each club. Changes in continuous outcome measures at each follow-up time point may be analysed using parametric or non-parametric models, depending on the nature of the data (eg. Normal regression, Poisson regression, Negative-Binomial regression, etc.). If required, appropriate transformations of the data will be made prior to analysis (eg. log transformation, square root, etc.). Categorical outcome measures at each follow-up time point (including dichotomised continuous outcome measures if required) will be analysed using appropriate regression techniques depending on the nature of the data (eg. binary logistic regression, ordinal regression, etc.). In each model, baseline values of the outcome measure will be adjusted for where available and the stratification variables will be accounted for accordingly. These models may then be extended to explore repeated measures analyses using data recorded during the study. We can also explore, recognizing the limits of power, whether it would be of benefit to adjust for other data collected at baseline. Based on these findings, and analyses of qualitative interviews and focus group data, we will refine our theory of change and logic model (RQ15).

Health economic evaluation: This pilot study is the first attempt to assess the feasibility of conducting the economic evaluation of an intervention directed towards reducing gambling behaviour. Furthermore, this is the first study of this type in the UK. In view of the novelty of the analysis, the economic evaluation alongside the FFAB feasibility trial represents a unique opportunity to explore the anticipated complexity associated to the identification, measurement and valuation of the plethora of inter-sectoral costs and outcomes associated to gambling.

Addressing RQ14, the economic evaluation alongside the FFAB feasibility trial will: identify the relevant costs and consequences associated to gambling; define and refine economic data collection methods; test the feasibility of data collection instruments in capturing participants' short term use of health and community services (RQ14); assess relevant short-term outcome measurement tools [45].

An economic conceptual model [8] will be developed to: systematically identify and represent all relevant multi-sectoral outcomes and costs (cost savings) associated to the intervention over the short and long term; highlighting the complex causal pathways and the multiple layers (i.e. individual; family; community; society) where cost and consequences of gambling arise; identify relevant pre-existing comorbidities/conditions which may led to spurious correlation between the intervention and its associated costs and outcomes. In line with current guidance [46], bespoke data collection instruments will capture the full range of inter-sectoral costs and consequences associated to gambling behaviour. adopting a wide public sector perspective. We will test the feasibility to capture use of health services (visits to the GP; usage of mental health services etc.); use of community services (e.g. community and social services, such as support groups); impacts on income and productivity (e.g. pre-absenteeism).

The feasibility of using resource use logs to capture the costs to deliver the intervention (i.e. cost of coaches and experts in gambling harm; participants' opportunity costs; cost of the venue) will also be assessed. Suitable reference costs (e.g. PSSRU [47]) will be identified. The preference-based instruments, ICECAP-A and EQ-5D-5L [38, 39], will be used to assess short-term health-related QoL and capability wellbeing, and validated against potential primary and secondary outcomes (e.g., self-reported gambling frequency; total money spent on gambling; self-esteem and mental health).

Descriptive statistics for each outcome and cost variable will be reported, for each data collection time point, alongside means, standard deviations and bootstrapped 95% confidence intervals by intervention/control group**.** An exploratory cost-consequences analysis (CCA), as recommended by the NICE public health economic evaluation guidance [48], will be conducted - reporting costs alongside consequences (such as QALYs, measures of gambling frequency; money spent on gambling; mental wellbeing) for intervention and control groups. Key sources of uncertainty in relation to the probability of the intervention being cost-effective will also be explored

6 STUDY SETTING

All of the phases of this project will each be multicentre, using 2, 2 and 4 professional football clubs respectively in North West England. The majority of the study activities will be carried out within these premises. These activities include:

Phase 1: 2 Focus groups in two different clubs

Phase 2: Delivery of intervention in two different clubs

Coach training in two different clubs

Post programme focus groups

Phase 3: Delivery of the intervention in four different clubs

For the pilot RCT, we will recruit four clubs with different characteristics to test our procedures in a range of settings. We require: a) at least one club with a primary betting partner and at least one with little/no gambling sponsorship; b) at least one urban/city-based club and at least one suburban club; e) at least one larger club (attendance at home games >20,000 people) and a smaller club (attendance at home games <20,000). To date we have secured support from two clubs: Everton FC, a large premier league club based in an urban area which currently has Sport Pesa (an online gambling company) as its primary sponsor; and Fleetwood Town FC, a small club in Football League 1 situated in a suburban/rural area of the North West which currently has no official gambling partnership.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Our target population is regular male sports bettors who feel their gambling may be affecting their health, wellbeing or relationships *and* who would like to make positive steps to change their gambling behaviour.

7.1.1 Inclusion criteria

1. Males aged 18-44.
2. Self-reported sports bettors (at least once a week).
3. Express an interest in reducing their involvement in gambling in the context of improving their health and wellbeing.
4. Can commit to attending sessions once a week for nine weeks.

7.1.2 Exclusion criteria

1. Females
2. Males < 18 or > 44 years old
3. Problem gambler, identified using the Problem Gambling Severity (PGSI) mini-screen (score of more than 4).
4. Cannot read/speak sufficient English to give informed consent

Men who are excluded from the study on the basis of being a problem gambler will be signposted to services for support and treatment.

7.2 Sampling

Phase 1: We will aim to recruit approx. 12- 16 men for the focus groups (n= 6-8 at each group)

Phase 2: We will aim to recruit approx. 30 male sports bettors for each of the feasibility deliveries in Phase 2 (n= 15 at each club).

Phase 3: We aim to recruit 120 male sports bettors (n=30 at each club) to the pilot RCT trial.

7.2.1 Size of sample

Guidance for pilot studies varies [18,19]. We will work with four football clubs in the North West of England, each recruiting 30 participants (60 per arm) to achieve a target sample size for the pilot RCT of 120. The retention rate in FFIT was high, exceeding 90% at 12 weeks and 12 months [16]. Allowing for slightly lower retention (80%), we would still have 96 participants with follow up data.

7.2.2 Sampling technique

For all phases, our sample will reflect our target population: men aged 18-44 who want to reduce their gambling. The sampling methodology will be a mix of convenience sampling with other methods like snowballing should recruitment prove more difficult than anticipated. For all phases, participants will be asked to opt-in to the study.

Convenience sampling is appropriate for all phases of the study as it allows easy access to a potentially hard to reach target audience, using the available mechanisms at the club to advertise and recruit participants.

The clubs themselves are purposively sampled based on the following criteria: a) at least one club with a primary betting partner and at least one with little/no gambling sponsorship; b) at least one urban/city-based club and at least one suburban club; e) at least one larger club (attendance at home games >20,000 people) and a smaller club (attendance at home games <20,000).

7.3 Recruitment

Approach: Building on insight gained in Phases 1 and 2, clubs (supported by Healthy Stadia) will use a range of recruitment strategies, including advertisements via the club's social media and at the club's ground, use of local fan networks and community groups, and advertising on local media to advertise and recruit to the study. Where data protection rules and club permissions permit, clubs will send direct recruitment material via email and post to potential participants.

- We intend to utilize the existing community and fan programmes that are run by football Clubs in both the Premier League and lower divisions as vehicles to refer men on to FFAB. Clubs have a wide range of these programmes, such as EuroFIT, Man V Fat, walking football, health checks and wider wellbeing programmes for men and family units and they have advised us that they are confident that these can be utilized effectively to attract participants. We anticipate that a minimum of 30% of men will be successfully recruited to FFAB through this method.
- In addition, most Clubs have strong links with local organizations who employ large numbers of men (e.g. bus or taxi companies, Royal Mail, warehousing), and these are an excellent way of recruiting participants to gender-sensitised programmes. Healthy Stadia will be able to work closely with each club foundation to ensure that these referral pathways are maximized to meet recruitment targets.
- We will also draw on the communications apparatus that Clubs have at their disposal. The infrastructure that Clubs have to engage and recruit men is extremely effective. For example, Everton FC (one of our pilot clubs) has a 'community database' of over 50,000 people. If we assume that 30% of those on the database are men aged 16-44 and that at least one third are regular gamblers, this gives an initial target population of c.5000 men from which to recruit 30 participants. Clubs will send direct recruitment material via email and post to potential participants
- We will use a range of materials and media to recruit men to the programme. We have budgeted for a professional design company to produce and print a range of FFAB branded recruitment materials. The FFAB 'brand' and logo will be specifically designed to appeal to our target group, and will be developed by the project co-development group, made up of team members, PPI Cis, as well as a football fan and a recovered problem gambler. The visual imagery will be used consistently across a range of media, including flyers and posters, and will be distributed widely to advertise and recruit to the programme. We intend to develop a project website and linked social media accounts, and will also target local community media networks and organisations, as well as Football Club grounds.

Process: The process of recruitment will be informed by learning from the Standard Operating Procedure (SOP) of the EuroFIT programme, which will be adapted for the specific context of FFAB.

- *Planning*: we will allow approximately 3 – 4 weeks to promote the programme before enrolment begins. We will work with Clubs to plan how best to promote FFAB through their community and fan programmes, as well as locally, focusing on where, how and when is best to do this, and what materials are needed.
- *Targeting* : we will discuss with Clubs which strategies to use and where to target. These will include:

    - Club-based venues, organisations and activities
        - Posters/flyers in Club
        - Posters/ flyers in community programmes
        - Advertisement on club/trust/fans website
        - Club/community trust twitter feed/ Facebook
        - Direct email to club fans with recruitment message
        - Announcement in fan newsletters
        - Match-day advertising, with a recruitment team in attendance to hand-out leaflets and collect contact details

  - Match-day programme advert and in-stadia announcements
- Local Media
  - Newspapers (local, regional, national), radio and TV coverage
- Other local organisations
  - Local employers (eg bus and taxi companies, warehousing, Royal Mail, community centres)

Recruitment text: a clear recruitment message, to be included on all recruitment materials, will be produced by the development group. It will explain the programme and outline the inclusion criteria. We will set up a single project contact email address and mobile phone number which will be included on all materials.

FFAB website: A project website will be established and linked to all participating organisations, including Clubs. Information about the programme and contact details for potential participants will be included.

7.3.1 Sample identification

For all phases, participants will self-identify and opt-in to the project by responding to recruitment advertising co-developed with clubs and the project teams.

A multimedia recruitment strategy will be developed and will include social media posts, posters and leaflets, all of which will provide instructions on how to join the study and necessary contact details. The football clubs and study partners will design and execute a co-developed recruitment strategy that makes use of these materials.

Interested participants who make contact with the study team will be asked a series of questions to screen for eligibility. This will aim to identify men who are: aged 18-44; self-report that they bet on sports at least once a week; express an interest in reducing their involvement in gambling and say they can commit to attending sessions once a week for nine weeks. At this point, men will also be screened to determine their gambling status, using the Problem Gambling Severity Index (PGSI) mini screening questionnaire. A score of 4 or more would indicate that they might have a gambling problem, and if this were the case, the potential participant would not be included in the study, but would be directed towards further information to self – refer to sources of advice and treatment offered by our expert partners.

Participants who take part in focus groups and/or in-depth interviews will be offered a £20 voucher to thank them for their time. Participants who take part in the full FFAB feasibility test or the pilot RCT will be offered £20 voucher to thank them for their time.

7.3.2 Consent

Informed consent will be obtained from all individuals before participation in the study. During recruitment, they will be provided with an information sheet, which outlines the purpose of the research, their potential role in it, and explains that participation is entirely voluntary, confidential, and can be stopped at any time. It will also have information about sources of further information, and of support and help. The information sheet will be

received at least 24 hours (either in person or via email) before the informed consent procedure.

The informed consent procedure will be conducted by a trained member of the research team, who will explain the the aims of the research, its benefits and potential risks, to ensure potential participants fully understand what participation in the study will involve . They will have the opportunity to ask questions, and to discuss any aspect of the research with the research team member.

Before signing consent forms, a trained member of the research team will ensure that they are satisfied all participants are fully informed and understand the nature and purpose of study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The research aims and methods are designed to develop an intervention that will help a population group at high risk of gambling related harm to reduce their involvement in gambling, and also to improve their overall wellbeing. The research process is guided by the principles of informed consent, participatory collaboration, and of doing no harm to participants. We have built in robust safeguards to uphold the wellbeing and dignity of participants at each stage of the research process.

We believe that the benefits to gamblers, their families and communities and society as a whole outweigh any possible inconvenience or discomfort to participants during the course of the study. Ultimately, the FFAB programme has the potential to reduce gambling-related harms and increase health and wellbeing among our target population. If successful, this will reduce the burden of gambling on the NHS and society. Our project will assess this potential and, should results look positive, then we will move to a full-scale trial to provide the most robust evidence of effectiveness and cost-effectiveness.

8.1 Assessment and management of risk

Risk/ Potential risks of the study. We are aware that gambling can be a sensitive topic, and that asking men to talk about their attitudes about it could involve bringing up issues of compulsive behaviour, mental health issues and financial problems, and could be distressing for some. Discussing gambling in a group context could encourage some participants to reflect on their own behaviour, and may generate feelings of shame or stigma, or prompt some to think they may have a gambling problem. Unanticipated outcomes could include participation in the study enabling a partner/family member to realize that the participant was involved in gambling, and precipitating rows/relationship breakup, or causing them to drink more to cope with the worry. For some, it could increase feelings of shame or guilt as the participant realizes the broader impact of their gambling on others, or the extent to which gambling has limited their range of engagement in other things. Non-gambling related outcomes could relate to sustaining an injury as a result of increased involvement in physical activity as a consequence of

taking part in FFAB. Throughout the project, we will explore the consequences of taking part in the study within all qualitative interviews with participants and coaches.

Risk management plan for risks of harm to participant./ others : The project team are aware of the potential for distress that could arise from discussing gambling. We have made use of the extensive experience within our team to mitigate it. Academic members of the team have experience in designing health-based interventions around sensitive topics (eg weight loss), while the gambling behaviour organisations have experience of dealing with issues related to gambling harms and mental health. We are confident that the co-development of the research, and its ongoing monitoring by these individuals and groups, will work to minimise risk and safeguard participants wellbeing.

To this end, we have built in safeguards at each step of participants' trajectory through the research.

- During recruitment, to ensure that participants understand the research and what it involves, participants will be provided with an information sheet and consent form which clearly explains the aims of the project, and their role in it. From the outset, this will include the details of project partners Betknowmore and Beacon Counselling Trust, as well as details of other organisations, including GamCare, a national treatment provider who have specialist online forums, chatrooms and a 24 hour helpline phone number. Discussion and questions about the research will be encouraged, to ensure that clear communication is established with the researcher, allowing for informed consent to be given.
- Before and during the sessions themselves, researchers will explain to participants that they do not have to participate in discussions/ respond to questions if they do not want to, and that if they become uncomfortable at any time, they are free to stop participating/ leave the group. Researchers will also be sensitive to the impacts of discussions during the focus groups and will monitor participants for signs of distress throughout. Being mindful of the group context of discussions, they will take steps to pause it if they feel that a participant needs a break, or if they wish to end the session. Researchers will be vigilant for signs of any psychological, emotional or other issues that may arise at any point during the study, and will be prepared to signpost/ refer an individual to sources of support if necessary. While coaches will be trained to ensure participants exercise within their limits, and how to respond when any injuries occur, any injuries that are sustained during the physical activity component of the project will be reported by coaches to the research team, as an adverse/serious adverse event.

- Throughout and at the end of discussions, details of organisations who provide support for a range of issues related to gambling, mental health and other problems, will be made available for participants who might wish to discuss anything further. These will be listed on the Participant Information Sheet. At the end of the session, participants will be thanked for their input and reminded of this list of organisations.

Risk management plan: We have identified a referral procedure for dealing with safeguarding issues. It has been guided by our CI partner, Neil Platt, Clinical Director of the Beacon Counselling Trust. As well as being a specialist gambling treatment provider,

the Trust is also one of the largest mental health support providers across the North West of England, engaging with over 3500 patients per year. Neil Platt has advised on adapting the Trust's protocol for referrals to the current study. As such, should any participant disclose to any team member as experiencing psychological, health or emotional issues during the study, or be identified by a team member as experiencing them, they will be offered an immediate referral for initial assessment at Beacon. There, they will be seen by a trained professional, who will make an assessment of their needs and identify the most appropriate next steps. This may involve continued care from Beacon therapeutic staff, or a referral into another, more appropriate service, which would be facilitated by Beacon. This process would be carried out following a standard care pathway, and in collaboration with the individual concerned.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before we begin the process of research, we will obtain ethical approval from The University of Glasgow's College of Social Sciences Research Ethics Committee, which is compliant with the ethics framework set out by the Economic and Social Research Council. This will be based on the protocol for the study, the informed consent document, plain English information leaflet and draft topic guide.

Regulatory Review & Compliance

No phase of the study will commence until the PI has received final approval letters from University of Glasgow, College of Social Sciences Ethics Committee. Each football club will only be permitted to commence the study on certified completion of coach training, which will include full guidance on how to implement the FFAB programme. Requests for amendments will be submitted to the same committee for approval before being implemented by the project management team.

Amendments

Amendments to the study design, will first be discussed with the legal team responsible for the University of Glasgow's sponsorship arrangements before being submitted to the ethics committee (University of Glasgow, College of Social Sciences Ethics Committee) for consideration.

8.3 Peer review

Before submission to the funding body, the study was peer reviewed internally by two academics with specialisms in public health and intervention research at the University of Glasgow. After submission, the study was reviewed twice (outline and full proposal) by a committee of independent experts convened by NIHR's Public Health Research stream. Recommendations made at the outline stage were addressed and incorporated into the full study proposal. Recommendations made at the full proposal stage were subsequently

agreed and incorporated into the design before the researchers signed a contract with the funder committing to deliver the study.

8.4 Patient & Public Involvement

We have a strong commitment to public involvement, and our PPI partners have been actively involved in the design and development of every stage of the development of the proposal. They will continue to be involved throughout the duration of the research. They include: Healthy Stadia (HS), who liaise with football clubs on a national scale; Beacon Counselling Trust (BCT), part of the nationwide GamCare treatment services network providing treatment and support for people dealing with gambling-related harms and Betknowmore (BKM), an organization which specialises in peer-peer support for gamblers. Development: Each partner was fully involved in developing the proposal for the research: presenting views at 2 full team meetings held in Glasgow, writing and contributing to sections of the proposal and reviewing final drafts. Healthy Stadia advised on the recruitment of clubs and of participants, and worked with the research team to write introduction letters for clubs. This has led to three clubs already committing to involvement in FFAB. Intervention development: BCT and BKN have been instrumental in the design of the FFAB programme itself, which was co-developed between them and the academic team members. BCT and BKM designed the template for the programme, adapting techniques and materials they had used with their clients, into an approach and format tailored to suit our particular study population and objectives. We drew on their working knowledge of gambling behaviour in our analysis of the most up to date research evidence on interventions for reducing gambling harms. This iterative process ensured that the lived experience of people who work with gamblers on a daily basis was incorporated into every aspect of the intervention, ranging from content and materials to timing of delivery.

Two 'experts by experience' (recovering problem gamblers) were also involved in intervention development. This led to the specific development of a session within the intervention on industry tactics, especially around advertising. Discussions with AG and AM also led to specific changes in our recruitment criteria; namely broadening the focus to include regular gamblers, and focusing on project tag-lines around the theme 'loving the game not the gamble' which they felt would be more acceptable to the target audience. AG and AM have both read and provided comments on multiple drafts of the proposal and intervention to ensure the views of those with lived experience of gambling are represented in the FFAB programme.

PPI underpins the design, delivery and implementation of our research. Together, HS, BCT and BKM form our co-development group. The group will be involved throughout the process of the research, from advising on ethical procedures to active involvement in coach training and programme delivery. We will also continue to seek the involvement of AG and AP and have invited AG to join our Study Steering Committee.

Undertaking and development of the research: PPI is key to the ongoing development of the project. At each stage, we will seek views, feedback and insight from football club coaches and male football fans. In particular, the views of sports fans will be sought on the recruitment strategy, on the form and content of the programme sessions, and on

the usability of the smartphone app, and their suggestions incorporated into refinements of the research. BCT and BKM, along with the academic team, will continue to have responsibility for the further development of the FFAB programme. Prior to the start of the project they will work together on developing a draft FFAB training manual to be refined and tested in Phase 1 of the study. Football clubs themselves will be key to the success of the project, and will be centrally involved with the research. Led by Healthy Stadia and supported by the academic team, we will seek the views of the clubs on the best methods for recruiting our target population and for promoting the study widely. This will aim to ensure that our strategies are tailored to local contexts, settings and demographics.

Dissemination Our PPI partners are also key to dissemination and impact activities. BCT are part of a nationwide network of gambling treatment providers, and HS are involved in national and international networks for the delivery of health interventions. Their networks will be important for ensuring that findings from the study are communicated to a wide audience in the fields of sport and gambling and to the public more generally, ensuring reach beyond our PPI partners themselves.

8.5 Protocol compliance

The study team are aware that accidental protocol deviations can happen at any time. Such deviations will be documented using forms tailored to each activity within the research study and reported to the Chief Investigator and Sponsor immediately. Any deviations found to be occurring on a regular basis will initiate an emergency meeting of between the PI, the sponsor, representatives of the TSC and SSCs to consider appropriate action, including termination of the research study. Decision making processes will be documented and shared with the funder and ethics committee

The research team will collect all data using electronic data capture methods, ensuring that data collection activities are logged in encrypted server logs. This will provide a reference point for monitoring deviations from data collection protocols. The research team will also conduct observations of FFAB, which will provide opportunities to identify, report on and, where possible, correct protocol deviations.

8.6 Data protection and patient confidentiality

We will protect participant confidentiality throughout the study, in line with the requirements of the General Data Protection Regulation 2018.

All *focus group and individual interviews* will be audio recorded, with permission, using an encrypted recorder. On completion, recordings will be transcribed and the transcripts and the notes of groups will be identified with a unique ID/group number, and the names corresponding with those numbers will be kept separately on a password protected list (destroyed on completion of the project). Data will be uploaded and held in a managed storage environment on the Glasgow University server, accessible only by the research team, through use of a secure password.

Data collected for the analysis will be via a secure web portal. Users will be given a unique username and password, participants will be identified by a study number and these data will be stored within the Robertson Centre for Biostatistics (RCB) in the University of Glasgow who are certified to ISO27001. RCB are audited every 6 months for their ISO27001 certification which ensures information security is upheld and compliant. In addition, RCB is part of a registered UKCRC Clinical Trials Unit and works to international standards for clinical trials. The data will be stored for a minimum of 5 years after the project finishes. Any approved data transfers will be done via the RCB's SFTP server in accordance with their standard operating procedures. Glasgow as Sponsor is controller and processor.

Data collected by the mobile diary designed for use by participants during the trial will be stored on a secure database hosted by a cloud computing provider (Google Firebase), which is necessary for the functioning of the application. Users will be given a unique username and password, and will also be able to set a pin-code for accessing the data on their own device. The data collected via the diary will include self-reported data about time and money spent gambling, goals set by the user, physical activity data including step counts, and free-text notes. In addition, we will collect engagement data concerning how often the diary is used, and how it is accessed (the type of web browser or mobile device used). We will also offer user-support via email. At the completion of the trial the username and password will be replaced with a study number, the free-text data anonymised, and the data securely transferred to the Robertson Centre for Biostatistics (RCB) at the University of Glasgow. Summary statistics about user support will be produced, and all original user support emails will be deleted. During the trial Northumbria University will be the controller and data processor, and in addition Google LLC will be a data processor (under the agreement "Firebase Data Processing and Security Terms").

No real names will be used in reports/publications and identifying details will be removed.

8.7 Indemnity

The University of Glasgow maintains research insurance which will cover the study design and protocol. Arrangement for insurance and any claim resulting from participation in the study will be detailed in the patient information sheet.

8.8 Access to the final study dataset

All investigators will have access to the full dataset, as will the research associate employed by the study. A publication proposal form will be developed and agreed by the research team, which investigators will have to complete before being granted permission by the PI to author papers derived from the dataset. All patient documentation – information sheet and consent form – will make clear that their

anonymised research data may be made available to other bona fide researchers for secondary analysis.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared and submitted to the NIHR PHR programme for publication in its *Public Health Research* series, which is open access an publicly available via the NIHR's website.

All research publications arising from the study will be submitted to peer reviewed journal. We anticipate that all publications will be completed within five years of the study's end date. The NIHR PHR programme will be acknowledged in these publications, but no NIHR staff or representatives will have influence or control over the content of these publications.

A lay report will be produced aimed at participants, football clubs, members of the third sector and other non-academic audiences. Participants and football clubs will be informed of results on request, but not until the main findings from the study have been published.

Quantitative datasets generated as part of this study will be deposited in the University of Glasgow's online data repository. Qualitative data will also deposited online, when doing so does is possible without significantly increasing the risk of compromising participant anonymity. After an embargo period to enable publication, requests for access to these data from bona fide researchers will be considered by the CI and an independent academic identified in conjunction with the SSC.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All individuals who have had input into the research design, production and analysis of the data will be granted authorship on the final study report. This will include all of the study Investigators and the RA and the lead statistician providing the analysis.

For manuscripts submitted to peer review journals, the International Committee of Medical Journal Editors criteria will be observed.

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11 Appendix 1- Required documentation

1. Patient Information Sheet which has been adapted to include the Club's logo
2. A copy of the consent form
3. A copy of a summarised version of the protocol suitable for reading by lay audiences, such as football club coaches and representatives.
4. A list of the coaches approved to deliver the FFAB programme and proof of training completion, signed off by one of: the training lead for the study (Dr Bunn); the PI (Prof Reith); or a designate from the research team authorised to do so by the PI.

12 Appendix 2 – Schedule of Procedures for phases 2 & 3

Procedures		**Visits (insert visit numbers as appropriate)**				
	Screening	**Baseline**	**Weeks 1-9**	**Week 10**	**6 months**	**12 months**
Phase 2						
Informed consent	x					
Observation of treatment			x			
Focus Group with completors/coaches				x		
Exit interviews with non-completors				x		
Phase 3						
Informed consent	x					
Demographics		x				
Medical history/outcome measures		x				
Observation of treatment			x			
Focus groups with completors				x		
Exit interview with non-completors				x		
Outcome measures data collected				x	x	x

13 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made