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A pilot study to assess whether delivery of a health and well-being programme set within a community based football club is feasible and acceptable to hard to reach men

Submission date 05/08/2019	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/08/2019	**Overall study status** Stopped	
Last Edited 28/05/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims

This study is designed to assess whether men who wouldn't usually access health programmes through the NHS or other health services find a programme that targets physical health and mental health and wellbeing acceptable. The 12-week health and wellbeing programme (called the 12th Man) is delivered through a community-based football club, Newcastle United Foundation. Previously published research and recently collected data from our research group suggest that community-based football clubs are a successful means of recruiting hard to reach groups of men. Hard to reach groups of men are those who do not usually engage with traditional health programmes provided by the NHS or other healthcare providers. In addition, these groups of men generally do not consider themselves unhealthy despite living unhealthy lives. Using the pride and passion for football in regions like the North East of England can help to improve the health of men from this population. That is what has inspired Newcastle United Foundations '12th Man' programme. The 12th Man programme has been developed taking in to account views and feedback from study participants who received this programme during a previous small scale study. Findings from our previous research have enabled researchers to develop a 12-week programme that targets physical, mental and social health elements designed specifically for men aged between 30 and 65 years. During the 12-week programme, participants will take part in behaviour change workshops that cover common health issues that men experience and lifestyle behaviours. These issues include: exercise, diet, stress, sleep, anger, happiness, social support and will teach self-help strategies. Participants will also take part in a variety of physical activity and exercise sessions that will provide an introduction to activities that they can access beyond the end of the programme. The activities are located around the region. The aim of this study is to assess whether participants like and are willing to complete the 12th Man programme.

Who can participate?

Men aged 30 – 65 from the North East of England

What does the study involve?
Participants are randomly allocated to one of two groups. The first group is the intervention (the12th Man programme delivered face to face by a coach), and the second is a comparator group (the 12th man programme delivered online). Measurements are taken at four timepoints: at the start of the study, immediately after, 6 months after, and 12 months after the end of the programme. The researchers monitor their ability to recruit the number of participants required and whether participants remain in the study until the end. They also seek the views of participants to find out their thoughts about the programme including reasons why they did or did not find it useful and beneficial. They also assess changes to physical, mental and social health outcomes at the start and end of the programme. These changes include body mass index, blood pressure, hip to waist ratio and markers of health outcomes within blood samples. Mental health measures include self-efficacy, self-esteem and quality of life.

What are the possible benefits and risks of participating?
Benefits of taking part in this research for the participants may include improvements to physical and mental health and improvements in social connectedness. The results of this study will inform a larger trial investigating the long term implications of participating in the 12th Man intervention on hard to reach groups of men. This may in turn demonstrate a need for this intervention to be extended throughout other football clubs around the country which may ultimately impact the health of a large number of individuals. Risks may include: discomfort during blood sampling; musculoskeletal injury; cardiorespiratory complications; trips, slips and falls; and the potential for psychological damage. These have all been addressed in the attached risk assessment for this study and has been reviewed by the ethics panel.

Where is the study run from?
Newcastle United Football Club (UK)

When is the study starting and how long is it expected to run for?
January 2018 to July 2021

Who is funding the study?
1. Newcastle University (UK)
2. Newcastle United Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
12thManpRCT

Study information

Scientific Title
A pilot randomised controlled trial to assess feasibility and acceptability of a behavioural intervention targeting physical and mental health of hard to reach men via a football club - the 12th Man

Acronym
12th Man Pilot RCT

Study objectives
A pilot randomised controlled trial to assess the feasibility and acceptability of the 12th Man intervention with hard to reach men. The intervention has been developed and delivered via a football club to reach and engage with men who would not ordinarily contact NHS services or health providers to address physical and mental health support needs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/08/2019, Faculty of Medical Science Research Ethics Committee, part of Newcastle University's Research Ethics Committee (Medical Sciences Faculty Office, Faculty of Medical Sciences, Newcastle University, Newcastle Upon Tyne, NE2 4HH, UK; Tel: +44 (0)191 208 5301; Email: marjorie.holbrough@ncl.ac.uk), ref: 1713/13707

Study design
Single-centre two-armed randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Physical and mental health

Interventions
The proposed study is not disease-specific. Men aged between 30 and 65 years who are free from any condition that would prevent or restrict them from participating in physical activity are the focus of this intervention. The purpose of the intervention is to improve physical and mental health.

Participants will be randomly allocated 1:1 to the intervention or comparator group using statistical software with random block sizes of 2, 4 and 6. Randomisation will be completed by an individual from outside of the research team.

Intervention arm: The 12th Man intervention is a 12-week behavioural programme that targets physical and mental health and wellbeing in hard to reach men. The 12 weekly sessions will each last 2 hours in duration and will be delivered face-to-face in a group setting. They will each involve a one hour workshop and a one-hour physical activity session utilising local facilities and clubs. In addition, there will be a 6-month reunion meeting held post completion of the programme.

During week one, each participant will be given a copy of the intervention workbook that provides a brief overview of each weekly session. The workbook also includes interactive tasks to complete during and/or outside of sessions. Participants are advised that the aim is to complete the workbook by the end of the intervention.

Participants are also invited to join the Facebook Group for their individual 12th Man cohort and the group for all 12th Man participants.

Comparator arm: The 12th Man intervention delivered online
The comparator group will receive the 12th Man intervention delivered online without face-to-face weekly contact with the coach or other participants. Participants will be invited to the same study visits as the intervention group to allow the collection of outcome data and these data collections will take place in various NUFC buildings including the football stadium and the training ground. These locations are intended to increase adherence to outcome measurement sessions.

The comparator group will receive 12 weekly videos emailed to them (one per week). The sessions will be recorded prior to the beginning of the 12th Man intervention and will be generic – i.e. they will not be tailored in the same way as the 12th Man intervention delivered face-to-face, however, participants will be able to use the content in a tailored fashion supported by their workbooks that will be given during week one of the intervention. The videos will cover all topics delivered to the participants in the intervention group.

In addition to the 12 weekly videos, comparator group participants will also be added to WhatsApp and Facebook groups (subject to consent). Here they will be updated with all the physical activity opportunities available to them in their local community, similar to the intervention group. They will be encouraged to access these but will not be guided by a weekly coach.

Fasted (> 6 hours) venous blood samples will be taken by a trained phlebotomist using a 2 x 10ml vacutainer tubes treated with di-potassium ethylene diamine tetra-acetic acid (EDTA) and serum using standard operating procedure. Samples will be stored at 4 C (either refrigerator or cool bag with ice) until processing at a laboratory within 24 hours. All blood samples will be centrifuged at 3000 rpm for 20 minutes at 4 C with the corresponding plasma and serum supernatant transferred to aliquots and stored at -80ºC until later analysis.

12-month post-intervention follow-up (i.e. a 15-month study period).

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility and acceptability:
1.1. Feasibility assessed by recording recruitment, retention and adherence rates of study participants including willingness to be randomised
1.2. Acceptability assessed qualitatively via focus group discussions upon completion of the study
Outcomes measured at baseline, immediately post intervention, and 6 and 12 months post intervention

Secondary outcome measures
Measured at baseline, immediately post intervention, and 6 and 12 months post intervention:
1. Fasting measures of plasma, serum or whole blood insulin, glucose, non-esterfied fatty acids, interleukin-6, tumour necrosis factor alpha, C-reactive protein, haemoglobin A1c, triglycerides and cholesterol
2. Body height (cm) and body weight (kg) collected to analyse body mass index (BMI)
3. Diastolic and systolic blood pressure (mmHg) measured with an automated blood pressure monitor. A body tape measure will be used to measure hip to waist ratio
4. Self-reported physical activity measured using IPAQ-short form (Ingledew and Markland., 2008)
5. Planning and coping planning of behaviour change measured using self-reported questionnaire adapted from Sniehotta, Scholz and Schwarzer., 2003
6. Behaviour regulations in exercise measured using BREQ-2 (Markland and Tobin 2004)
7. Quality of life measured using EQ-5D-5L (Herdman et al., 2011)
8. General self-efficacy measured using self-reported questionnaire from Jerusalem and Schwarzer 1979
9. Self-esteem measured using self-reported questionnaire from Rosenberg, 1986

10. Perceived and received social support assessed through questionnaires adapted from previous research (Freeman and Rees., 2008)

Overall study start date
01/01/2018

Completion date
01/07/2021

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Men
2. Aged 30 – 65 years
3. Consent to randomisation

Participant type(s)
Other

Age group
Adult

Sex
Male

Target number of participants
92

Key exclusion criteria
1. Failure to return pre-screening questionnaire
2. Condition or disability which would prevent participation in physical activity or exercise

Date of first enrolment
01/03/2021

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle United Football Club
St James Park
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Sponsor information

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Newcastle University

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Sponsor type
University/education

Website
http://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Organisation
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St James Park
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Sponsor type
Charity

Website
https://nufoundation.org.uk/

Funder(s)

Funder type
University/education

Funder Name
Newcastle University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Newcastle United Foundation

Results and Publications

Publication and dissemination plan
Findings from the Pilot RCT will be communicated to local, regional and national groups and via social media.
Throughout the trial period findings will be disseminated at academic and professional conferences.

Intention to publish date
01/11/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date