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Supported exercise training for men on androgen deprivation therapy (WP3)

Submission date
18/03/2019

Recruitment status
Suspended

Registration date
04/04/2019

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
STAMINA is a NIHR PGfAR funded 5-year programme of research aimed at determining whether an exercise intervention, embedded in NHS cancer care, can be cost-effective and improve cancer-specific quality of life (QoL) for men with prostate cancer (PCa) on androgen deprivation therapy (ADT) when compared with usual care. Finding cost-effective ways of getting men on ADT to take up and continue exercising is essential to reduce side-effects for sustained benefits. We propose embedding an evidence-based, behaviourally-informed exercise programme into routine NHS prostate cancer treatment for men with prostate cancer on ADT. This involves training cancer team members to endorse and support exercise, community-based gym professionals to deliver supervised exercise and communication between them to provide feedback and support. This model would offer an improved standard of care for men with prostate cancer and provide a blueprint for integration of exercise training into other cancer services.
This document describes the 3rd work package from STAMINA. These involve
1. Training of STH staff to act as a mentor site for the future STAMINA RCT.

Overall programme research questions:
1. Can a behaviour-change informed exercise intervention with extended support embedded in existing standard NHS-PCa care pathways (STAMINA) confer long-term benefits in cancer-specific QoL and fatigue, compared with usual care?
2. Can the 12-month STAMINA intervention be cost-effective and reduce healthcare resource utilisation compared with usual care?

WP3 - Pre-pilot
Timelines: Start –May 2019 and End – August 2020

RQ1: is it feasible to deliver STAMINA? RQ2: is STAMINA acceptable to patients and staff?

Purpose: To optimise our draft "in development" intervention with health care professionals (HCPs) and exercise professionals (EPs). We will train all members of the health care team

involved in delivering care to men with prostate cancer started on long-term ADT and to EPs in up to four sites. This intervention (STAMINA) will be delivered in to up to 32 men across these four sites.

Who can participate?
All men diagnosed with prostate cancer requiring ADT for 12 months or more will be eligible for recruitment, subject to the protocol defined exclusion criteria (please see attached protocol).

What does the study involve?
We will be using a non-randomised cohort study to test the core components of our 'in development' STAMINA intervention by delivering it to (upto) 32 men in 4 clinical sites. The aim is to generate rich qualitative feedback from participants (HCPS, patients and EPs) rather than test efficacy, so there is no control arm. This feedback will be used to optimise and refine the components of our intervention before we undertake a subsequent definitive trial of clinical and cost-effectiveness. This design was discussed and agreed with our dedicated STAMINA patient partnership panel and is supported by the most recent update of the CONSORT guidelines for pilot and feasibility studies.

What are the possible benefits and risks of participating?
NICE already recommends supervised exercise for men with PCa treated with ADT. All recruited men will continue to be under the care of their treating cancer clinician who will be aware of their participation in the trial and will follow current best practice standard of care. The risks of the supervised exercise programme in men on ADT are minimal, with no increase in the risk of serious adverse events reported in a systematic review of RCTs evaluating the delivery of such programmes in these men. The researchers involved have many years of experience of working with these men involved in such interventions.
NHS HCPs and Nuffield Health exercise professionals will be taught new skills around health behaviour change, motivational interviewing techniques and how to set, monitor and progress cancer-specific exercise programmes for men with prostate cancer. Men on ADT will have access to dedicated Nuffield Health exercise facilities and 1 to 1 personal trainers for free. These men will undertake an exercise programme which our previous studies have shown will provide clinically meaningful improvements in cancer-specific quality of life and reduce cancer-specific fatigue.

Where is the study run from?
Sheffield Teaching Hospitals trust is the study sponsor.

When is the study starting and how long is it expected to run for?
The study starts in May 2019 and is expected to run for approximately one year (current finish date 30th May 2020).

Who is funding the study?
The National Institute of Health Research

Who is the main contact?
Rebecca Turner, Rebecca.turner@sth.nhs.uk
Jemima Clarke (Research coordinator at Sheffield Teaching Hospitals), 0114 2265943, jemima.clarke@sth.nhs.uk
Prof Derek Rosario, derek.rosario@sth.nhs.uk

Study website
http://www.stamina.org.uk

Contact information

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Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41010

Study information

Scientific Title
Supported exercise TrAining for Men wIth prostate caNcer on Androgen deprivation therapy - the STAMINA programme: work package 3

Acronym
STAMINA

Study objectives
The hypothesis being tested in the STAMINA Programme is that an exercise intervention, embedded in NHS cancer care and supported by behaviour change, will confer long-term benefits in cancer-specific quality of life (QoL) and fatigue for men with prostate cancer (PCa) when compared with usual care.

The full scope of the 5 year programme is split into separate but interlinked projects called 'work packages':

Objectives
WORK PACKAGE 1: To understand variations in NHS PCa care pathways and exercise provision available to men on ADT
WORK PACKAGE 2: Develop our embedded STAMINA service-level intervention • WORK PACKAGE 3: To determine whether it is feasible and acceptable to deliver our 'in development' version of STAMINA intervention in a 'pre-pilot' study.

Work package 3 overview: Taking what we have learned from other previous work packages (i.e. work package 1 and 2) we will carry out a preliminary test in a non-randomised cohort study to determine whether it is feasible and acceptable to deliver our 'in development' STAMINA intervention. We call this preliminary testing phase a 'pre-pilot'. Qualitative evaluation only will be undertaken from participants including NHS staff, men with prostate cancer and exercise staff from our commercial partner, Nuffield Health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2019, North West - Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; HRA.approval@nhs.net; 0207 104 8001), ref: 19/NW/0025

Study design
Non-randomised cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate Cancer

Interventions
Patient intervention: Up to 32 men from 4 sites on long-term ADT will be referred for supervised exercise training for 12 weeks. The process can be broken down into distinct steps.
Step 1: HCP prescribing the ADT: All men on long-term ADT will be provided with a short, theoretically informed leaflet on potential adverse effects of ADT, benefits of exercise, lifestyle modification, dietary advice and fitting exercise into daily life etc. Exercise will be prescribed and endorsed as an essential part of PCa care for men on ADT by clinicians (see Step 2 below). Men on ADT will be provided with information on their nearest Nuffield Health gym and contact details provided for free access as part of STAMINA. Men who consent, will be contacted by the study team to arrange a visit to Nuffield to initiate a thorough assessment prior to exercise training (see Step 3).

Step 2: HCP responsible for exercise referral: will address any psychological barriers and facilitators for participating in exercise in individual participants. HCPs will be provided with training so as to: • directly endorse participation in supervised exercise training • address psychological capability and attitude e.g. ensure knowledge of the importance of exercise, • elicit and respond to illness and treatment (exercise) beliefs. • consider men's (and partners') worries and concerns regarding exercise. • address opportunity, (social and physical) including where may be best place to refer the participant to for exercise • consider motivation – prior experience, identity and exercise, using a motivational interviewing (MI) approach. At the end of this consultation HCPs will recommend exercise for suitable men and make a referral to the community exercise team at the local Nuffield Health site.

Step 3: Nuffield Health: the referral will be received at the partner Nuffield Health site by a specifically trained exercise professional (EP), trained to provide exercise to this clinical population. Session 1 The EP will assess the participant and write an exercise prescription tailored to account for participant's physical capability, psychological capability, opportunity (including social) and motivation. Twelve weeks of Nuffield Health gym membership with access to STAMINA-trained exercise professionals will be provided. Supervised exercise as per NICE CG175 will be delivered twice– weekly.

Step 4: HCP follow-up (prostate cancer treatment): following EP review at 12 weeks, patients will receive routine clinical review as part of standard follow-up. Consideration will be given to current exercise behaviour and application of behaviour change techniques such as goal setting, problem solving to facilitate exercise maintenance as far as possible.

Intervention Type
Other

Primary outcome measure
Primary outcome in this context is not applicable. Data generated will be purely descriptive and are required to inform the refinement and optimisation of our complex intervention which will be evaluated during our subsequent planned multi-centre RCT.

Secondary outcome measures
-

Overall study start date
13/05/2019

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Inclusion criteria for HCPs:
1.1 Involved in diagnosis and or treatment and or follow-up of men with prostate cancer on ADT
1.2 Able and willing to receive draft intervention training for HCPs as developed in STAMINA Work Package 2 (HRA approved: IRAS number 254343)
1.3 Based at a site with sufficient number of men started on long-term ADT to achieve recruitment target within timelines.

2. Inclusion criteria for men on ADT:
2.1 Prostate cancer within 12 months of starting ADT (at time of screening).
2.2 Receiving continuous ADT for a planned minimum of 12 months treatment
2.3 Willing and able to provide informed consent
2.4 Not due to receive chemotherapy within 3 months or those having completed chemotherapy

Participant type(s)
Mixed

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64

Total final enrolment
45

Key exclusion criteria
1. Exclusion criteria for HCPs:
1.1 Inability to read or speak English to an appropriate level

2. Exclusion criteria for participants:
2.1 Men with unstable angina
2.2 Uncontrolled hypertension and/ or diabetes mellitus
2.3 Recent myocardial infarction (within past 6 months)
2.4 Unable to provide informed consent (lack capacity)
2.5 Painful or unstable bony metastases
2.6 Fixed output pacemakers
2.7 Due to commence chemotherapy within 3 months

Date of first enrolment
19/05/2019

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Nuffield Health Gym Sheffield
Napier street
Sheffield
United Kingdom
S11 8HA

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Nuffield health gym Chesterfield
Alma Leisure Park
1 Derby Rd
Chesterfield
United Kingdom
S40 2EZ

Study participating centre
Nuffield Health Weston-super-Mare
168 Locking Rd
Weston-super-Mare
United Kingdom
BS23 3HG

Study participating centre
Weston General Hospital
Grange Rd
Weston-super-Mare
United Kingdom
BS23 4TQ

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Northern General Hospital
Herries Road
Sheffield
England
United Kingdom
S5 7AU
0114 2265943
jemima.clarke@sth.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed scientific journals, internal reports, conference presentations and publication on website

Intention to publish date
31/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the specific nature of the qualitative analysis. Aspects of the data analysis will be available in peer-reviewed publications and on request.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2021	10/09/2021	Yes	No
HRA research summary			28/06/2023	No	No