

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

<b>Submission date</b> 18/03/2019	<b>Recruitment status</b> Suspended	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/09/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

## Type(s)

Public

## Contact name

Ms Rebecca Turner

## Contact details

J104, J Floor  
Royal Hallamshire Hospital  
Sheffield  
United Kingdom  
S10 2JF  
0114 2252410  
Rebecca.turner@sth.nhs.uk

## Type(s)

Scientific

## Contact name

Prof Derek Rosario

## ORCID ID

<http://orcid.org/0000-0002-9086-3592>

## Contact details

Directorate of Urology  
Royal Hallamshire Hospital  
H Floor  
Sheffield  
United Kingdom  
S10 2JF  
0114 2254404  
derek.rosario@sth.nhs.uk

# 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?
<a href="#">Results article</a>		14/06/2021	10/09/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No