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Exercise training for men with prostate cancer on hormone therapy

Submission date
06/07/2020

Recruitment status
No longer recruiting

Registration date
30/07/2020

Overall study status
Ongoing

Last Edited
24/07/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The STAMINA study is looking at how men diagnosed with prostate cancer on hormone therapy (Androgen Deprivation Therapy [ADT]) can be supported to exercise, to improve and maintain their quality of life. Whilst ADT has proven anti-cancer benefits, it often causes deterioration in quality of life with side-effects of hot flushes, severe tiredness and sexual problems. ADT also increases the risks of dementia, diabetes and heart disease. Some ADT side-effects, including fatigue, can feel like recurrent cancer and cause understandable concern, leading to extra consultations/tests. Many treatments are suggested for these side-effects, but supervised exercise is the only supportive treatment proven to improve disease-specific quality of life in men with prostate cancer on ADT. Exercise, therefore, is an important part of prostate cancer care and is recommended by the National Institute for Health and Clinical Excellence (NICE). Working in partnership with NHS Healthcare Professionals, a team of Exercise Professionals at Nuffield Health will deliver the STAMINA exercise programme over a 12-month period. The STAMINA exercise programme is based on the scientific evidence behind the NICE guidelines and this study will explore how to get the maximal benefit from these recommendations in men with prostate cancer on ADT. Also, men currently on ADT inform us they would welcome exercise with support embedded in their standard prostate cancer care rather than as an add-on. This study is part of a 5-year programme of work, which means we have developed and tested the STAMINA exercise programme in smaller packages of work before we started this larger study.

Who can participate?
Men with prostate cancer can take part if the hospital where they receive treatment takes part in STAMINA, and if their clinical team feels they are eligible to take part.

What does the study involve?
This study will randomly allocate participating men to one of two groups:
1. Optimised usual care (OUC): men will continue to receive care in the same way as usual, optimised to promote exercise in accordance with NICE guidance.
2. STAMINA Lifestyle Intervention (SLI): this involves receiving exercise sessions supervised by an exercise professional employed by Nuffield Health.
The group that people are allocated to will be decided by chance (randomly). This means that

neither the hospital nor the researchers who run the study can influence who goes into each group. All participants will be asked to complete a questionnaire booklet at five timepoints over a maximum of 2 years.

What are the possible benefits and risks of participating?
It is hoped that this study could improve the quality of life for men with prostate cancer on ADT, but we cannot say that men who take part will definitely experience an improvement. The researchers do not expect there will be any direct risks or disadvantages to taking part.

Where is the study run from?
The study is being organised and supervised by Sheffield Teaching Hospitals NHS Foundation Trust (UK). The study is coordinated by the Clinical Trials Research Unit at the University of Leeds (UK).

When is the study starting and how long is it expected to run for?
September 2018 to December 2026

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Prof Derek J Rosario, d.j.rosario@sheffield.ac.uk
2. STAMINA Senior Trial Manager, stamina@leeds.ac.uk
3. STAMINA team (SHU), sth.stamina@nhs.net

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-supported-exercise-programme-for-men-with-prostate-cancer-stamina

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
259674

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45624, IRAS 259674

Study information

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

Acronym
STAMINA

Study objectives
The STAMINA programme is a 5 year programme grant for applied research funded by the NIHR. The aim is to determine whether an exercise intervention, embedded in routine 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) on Androgen Deprivation Therapy (ADT), and be cost effective when compared with optimised usual care. The STAMINA programme has a number of work packages.

Please note. This registration only pertains to work packages 4/5. All approvals for other work packages i.e. 1-3 have been sought elsewhere.

Work package 4 overview: Building on outputs from preceding work packages as part of the programme grant, and drawing on the MRC framework for complex interventions, Work Package 4 (WP4) will conduct a definitive, pragmatic cluster randomised controlled trial, evaluating the clinical and cost-effectiveness of the STAMINA intervention compared to optimised usual cancer care, in men with prostate cancer, incorporating an internal pilot phase to ensure acceptable recruitment, follow-up and intervention adherence rates.

Work Package 5 overview: A parallel, mixed methods process evaluation will be conducted based on the framework of Linnan and Steckler and informed by the Medical Research Council (MRC) guidance for process evaluation of complex interventions. The acceptability of the intervention is a key aspect for the process evaluation to explore but it is not an explicit element of the Linnan and Steckler framework. We will therefore include an assessment of acceptability following Sekhons framework.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2020, West of Scotland Research Ethics Service (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WosRec1@ggc.scot.nhs.uk), ref: 20/WS/0069

Study design
Individually randomized controlled trial and qualitative assessment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Interventions
Current interventions as of 06/10/2021:
STAMINA WP4 & WP5 is a definitive, multi-centre, two-arm, individually randomised controlled trial with an internal pilot, including a cost-effectiveness analysis (WP4) and an embedded process evaluation (WP5).

The study aims to recruit 697 participants from approximately. 22 NHS sites considered to be within a reasonable distance of travel for the patient of a participating community-based exercise facility (i.e Nuffield Health (NH)).

Healthcare Professionals (HCPs) involved in the Prostate Cancer (PCa) care pathway will receive specialised training to provide patient-facing behavioural support for initiating and maintaining exercise, and undertake a clinical review upon completion of the exercise prescription. The intervention will be delivered in NH exercise facilities by STAMINA-trained Exercise Professionals (EP).

Participants randomised to the optimised usual care arm will receive unrestricted usual care as provided by cancer care services, including cancer-specific information leaflets that promote exercise in accordance with NICE guidelines.

Patients will be approached at their routine clinic visit by a trained STAMINA member of their health care team who will introduce the STAMINA trial and determine if the patient is interested in participating. Verbal consent will be sought from the patient for their contact details to be forwarded to a member of the central research team. The central research team member will further discuss the trial and agree and obtain consent (over the telephone) from the participant to collect data for trial purposes. Eligibility to enter the trial will be assessed at this point. Following consent and confirmation of eligibility, participants will be registered and randomised into the trial. Participants will be randomised on a 5:4 basis to receive either the STAMINA Lifestyle Intervention or Optimised Usual Care. A computer-generated minimisation programme that incorporates a random element will be used to ensure arms are well-balanced for the following participant characteristics (stratification factors), details of which will be required for randomisation:
1. Age (<70 years OR ≥70 years)
2. Duration on ADT: ≤12 weeks (including yet to start treatment) OR >12 weeks
3. Receiving chemotherapy and/or novel androgen receptor inhibitors (ARI) (yes OR no)
4. Receiving radiotherapy (yes OR no)

The primary outcomes for the trial are whether the STAMINA lifestyle intervention improves participant cancer-specific quality of life for men with PCa (measured using FACT-P at 12 months post-registration) and whether there is a reduction in cancer-specific fatigue (measured using FACT-F at 12 months post-registration). The trial outcome data will be collected using self-report postal/online questionnaires based on participant preference at 3, 6, and 12 months (with additional collection at 24 months for those recruited early to the trial). Additional supplementary support will be available via postal/telephone/online/text reminders as required. Intervention data will be collected by the care providers (NH and NHS – EP/HCP) on those patients in the intervention arm to assess adherence. Recordings of the intervention

participants' reviews with the community clinical exercise professionals will be made at induction, 3, 6, and 12 months. Safety data will be collected by care providers in accordance with the protocol.

Participants and personnel delivering the intervention will not be blind to the treatment allocation. Outcome assessment using self-report methods is planned to reduce the risk of assessment bias. Supplementary follow-up support (i.e. via telephone) will be performed blinded to treatment allocation, whenever practicable to reduce the risk of assessment bias, for study participants requiring these methods.

A process evaluation is embedded into this trial to describe the intervention implementation, uptake, experience by providers and recipients, and fidelity in delivery. The researchers will conduct one-to-one interviews (telephone or face-to-face) and focus groups (choice depending on interviewee preference and feasibility) with a purposive sample of up to: 15 intervention study participants, 10 control arm participants; 10 exercise professionals, and 10 health care professionals. A topic guide will be used to guide the interviews. Audio recordings of review sessions between participants and exercise professionals will be rated against a checklist for delivery of behaviour change techniques and a general patient-centred approach. Theoretical Domains Framework questionnaires will be given to Health Care Professionals and Exercise Professionals to complete.

Previous interventions:
STAMINA WP4&WP5 is a definitive, multi-centre, two-arm, cluster randomised controlled trial with an internal pilot, including a cost-effectiveness analysis (WP4)and an embedded process evaluation (WP5).

The study aims to recruit 1100 participants (550 optimised usual care and 550 STAMINA lifestyle intervention), from approximately. 44 NHS sites considered to be within a reasonable distance of travel for the patient of a participating community-based exercise facility (i.e., Nuffield Health [NH]).
In intervention sites, Healthcare Professionals (HCPs) involved in the Prostate Cancer (PCa) care pathway will receive specialised training to provide patient-facing behavioural support for initiating and maintaining exercise, and undertake a clinical review upon completion of the exercise prescription. The intervention will be predominantly delivered in NH exercise facilities by STAMINA-trained Exercise Professionals (EP).
Participants in the optimised usual care arm will receive unrestricted usual care as provided by cancer care services, including cancer-specific information leaflets that promote exercise in accordance with NICE guidelines.

Eligible NHS sites (clusters) will be randomly allocated on a 1:1 basis to either the STAMINA lifestyle intervention or optimised Usual Care by the statistician at the Clinical Trial Research Unit (CTRU). Stratification will ensure the treatment groups are well balanced for the following characteristics: regional cancer centre vs District General Hospital and the number of men started on ADT per year (<50 vs. >=50). Cluster randomisation is appropriate as the intervention is delivered at a service level, involving training of clinical and exercise teams and with the aim of minimising contamination between the groups.

Following randomisation, sites will open to participant recruitment, with individual participants consenting to trial data collection ahead of registration. Wherever practicable, recruiting researchers will not be aware of site allocation, with HCPs supporting NHS intervention activity following participant registration. We will regularly monitor for selection bias by i) reviewing monthly numbers and proportions of eligible men screened, consented and recruited by

treatment arm and by site, checking for imbalance; ii) monitoring recruited participant characteristics (e.g. disease status, age, etc) by treatment arm.

Patients will be approached at their routine clinic visit by a trained STAMINA member of their health care team who will introduce the STAMINA trial and determine if the patient is interested in participating. Verbal consent will be sought from the patient for their contact details to be forwarded to a member of the central research team. The central research team member will further discuss the trial and agree and obtain consent (over the telephone) from the participant to collect data for trial purposes. Eligibility to enter the trial will be assessed at this point. Following consent and confirmation of eligibility, participants will be registered into the trial. Participants in the optimised usual care arm will be followed up as part of their routine clinic visits (no extra visits for research purposes). Participants who attend a hospital which is in the 'intervention group' will be contacted to discuss what the STAMINA-supported exercise programme involves for them.

The primary outcomes for the trial are whether the STAMINA lifestyle intervention improves participant cancer-specific quality of life for men with PCa (measured using FACT-P at twelve months post registration) and whether there is a reduction in cancer-specific fatigue (measured using FACT-F at twelve months post registration). The trial outcome data will be collected using self-report postal/online questionnaires based on participant preference at three, six, and twelve months (with additional collection at twenty-four months for those recruited early to the trial). Additional supplementary support will be available via postal/telephone/online/text reminders as required. Intervention data will be collected by the care providers (NH and NHS – EP /HCP) on those patients in the intervention arm to assess adherence. Recordings of the intervention participants' reviews with the community clinical exercise professionals will be made at induction, 3, 6, and 12 months. Safety data will be collected by care providers in accordance with the protocol.

Participants and personnel delivering the intervention will not be blind to the treatment allocation. Outcome assessment using self-report methods is planned to reduce the risk of assessment bias. Supplementary follow-up support (i.e. via telephone) will be performed blinded to treatment allocation, whenever practicable to reduce the risk of assessment bias, for study participants requiring these methods.

A process evaluation is embedded into this trial to describe the intervention implementation, uptake, experience by providers and recipients, and fidelity in delivery. We will conduct one-to-one interviews (telephone or face-to-face) and focus groups (choice depending on interviewee preference and feasibility) with a purposive sample of up to: 20 intervention study participants, 6 control arm participants; 10 carers; 20 exercise professionals, 10 health care professionals, and 10 other stakeholders. A topic guide will be used to guide the interviews. Audio recordings of review sessions between participants and exercise professionals will be rated against a checklist for the delivery of behaviour change techniques and a general patient-centred approach. Theoretical Domains Framework questionnaires will be given to Health Care Professionals and Exercise Professionals to complete.

Intervention Type
Behavioural

Primary outcome measure
1. Disease-specific quality of life at 12 months post registration measured by the Functional Assessment of Cancer Therapy – Prostate (FACT-P)

2. Fatigue at 12 months post registration measured by the Functional Assessment of Cancer Therapy - Fatigue (FACT-F)

Secondary outcome measures
1. Physical, social, emotional and function wellbeing is measured using FACT-P at 3, 6 and 12 months post-registration
2. Cancer specific fatigue is measured using FACT-F at 3, 6 and 12 months post-registration
3. Leisure time physical activity measured using Godin Questionnaire at 3, 6 and 12 months
4. Fear of Cancer Recurrence is measured using FCR4 and FCR7 at 3, 6 and 12 months
5. Functional capacity and body composition is measured using blood pressure, chair sit-to-stand, waist and hip circumference and body mass at 3, 6 and 12 months
6. Adverse event rates and their severity are measured using a Safety Case Report Form
7. Cost-effectiveness is assessed using incremental cost-effectiveness ratios (ICERs)
8. Quality-adjusted life year (QALYs) is derived from the EQ-5D-5L at 3, 6, 12 and 24 months

Overall study start date
01/09/2018

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Men with prostate cancer on ADT or due to start ADT within the next 12 weeks
2. Willing and able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 697; UK Sample Size: 697

Key exclusion criteria
Current exclusion criteria as of 06/10/2021:
1. Absolute contraindication to exercise as defined by clinical guidance e.g. ACPICR standards
2. Uncontrolled hypertension
3. Uncontrolled diabetes mellitus
4. Recent myocardial infarction (within past 6 months)
5. Unable to provide informed consent (e.g. lack of capacity)
6. Unstable bony metastases unresponsive to treatment
7. Unable to complete study assessments

8. Participation in other lifestyle intervention trial for PCa
9. Estimated life expectancy of less than 12 months for reasons unrelated to PCa diagnosis
10. Involvement in previous STAMINA work packages or PPI panel

Previous exclusion criteria:
1. Proven metastatic castrate-resistant prostate cancer (mCRPC) on imaging
2. Unstable angina
3. Uncontrolled hypertension and/or diabetes mellitus
4. Recent myocardial infarction (within past 6 months)
5. Unable to provide informed consent (e.g. lacking capacity)
6. Painful or unstable bony metastases
7. Inability to read or speak English to an appropriate level is an exclusion criteria, to ensure safe compliance with the exercise programme
8. Fixed output pacemakers
9. Any other absolute contraindication to exercise as defined by clinical guidance, e.g. ACPICR standards
10. Unable to complete study assessments
11. Participation in other lifestyle intervention trials for PCa
12. Estimated life expectancy of less than 12 months for reasons unrelated to PCa diagnosis

Date of first enrolment
01/12/2021

Date of final enrolment
12/06/2023

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
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Herries road
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United Kingdom
S5 7AU
+44 (0)1142 265945
sth.researchadministration@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20007

Funder Name
National Institute for Health Research (NIHR) (UK)

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 high-impact peer-reviewed journal.

Intention to publish date
21/01/2026

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 01/07/2022:
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.
CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.
The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.
The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from CTRU-DataAccess@leeds.ac.uk Data will be shared according to a controlled access approach. Data will only be shared for participants who have given consent to use of their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		01/04/2024	15/04/2024	Yes	No
Other publications	Process evaluation workshop data	02/09/2024	03/09/2024	Yes	No

Protocol article	Process evaluation protocol	14/07/2025	16/07/2025	Yes	No