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Supported resistance training for prostate cancer patients

Submission date 24/10/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2016	**Overall study status** Completed	
Last Edited 16/12/2021	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-exercise-to-help-with-the-side-effects-of-prostate-cancer-treatment

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Additional identifiers

Protocol serial number
31496

Study information

Scientific Title
Supported progressive resistance exercise for countering the adverse side effects of prostate cancer treatment

Study objectives
The aim of this study is to develop and/or assess the effects of home-based progressive resistance exercise programmes following radical prostatectomy and androgen deprivation therapy in prostate cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland REC 02, 08/09/2016, ref: 16/SS/0143

Study design
Randomised; Both; Design type: Treatment, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Cancer/ Malignant neoplasms of urinary tract

Interventions
Phase 1:
Patients, treated via radical prostatectomy or androgen-deprivation therapy, will be recruited

for a 2 month window. The will be asked to complete a questionnaire booklet every day for a 2 week period. The questionnaire booklet will contain validated questionnaires, including the Scottish Physical Activity Questionnaire (SPAQ), Brief Fatigue Inventory and the Stage of Change questionnaire as well as asking about current health issues. A stamped addressed return envelope will also accompany the questionnaire booklet. Phase 1 will help to inform the subsequent phases of the project.

Phase 2:
Phase 2 will involve small groups of ~6 men at a time invited to The Freeman Hospital for exercise programme development sessions. All patients will have been treated for prostate cancer via radical prostatectomy or androgen-deprivation therapy. These sessions will be broken down into three sections
1. Patient discussion: This involves asking both radical prostatectomy and androgen-deprivation therapy patients about their physical activity levels and their opinions on a proposed exercise study.
2. Pilot work: Initially patients will be able to look at the equipment and try some exercises. Patients will then be shown 2 exercises per major muscle group and they will have the opportunity to try these exercises whilst having measures of heart rate, blood pressure and perceived exertion taken.
3. Patient feedback: Patients will be asked about the feasibility of the exercises and equipment in the home setting and which exercises they prefer. The researcher will use this information to develop a resistance training programme that can be transferred to the home environment.
The researcher aims to complete at least 3 initial sessions to establish a programme and 3 follow-up sessions to provide feedback on the programme therefore approximately 40 patients will be recruited. The programme developed will be trialled in phase 3.

Phase 3:
Phase 3 will involve sixty patients, who have previously undergone radical prostatectomy, being randomised into one of two groups (control vs intervention). The control group will be instructed to continue with usual care but will be offered some supervised exercise sessions after completion of the study. The intervention group will also continue with usual care alongside a supported progressive resistance exercise programme. Blocked randomisation, stratified for age, will be used to ensure that the overall order of testing is balanced (ratio 1:1). Randomisation will be undertaken by an independent person not directly involved with the trial after completion of the baseline assessments.

All outcome measures will be assessed in all participants (control and intervention) at baseline (0 weeks), mid-way (13 weeks) and on completion of the trial (25 weeks). The intervention group will be asked to complete 3 resistance exercise sessions each week for 24 weeks. During the first week all 3 sessions will be supervised. In week 2, 2 of the sessions will be supervised and 1 will be home-based (i.e., unsupervised). During weeks 3 and 4, 1 session will be supervised and 2 completed at home. All supervised session will take place in a designated room at The Freeman Hospital. During weeks 5 to 12, aIl sessions will be unsupervised, but participants (intervention only) will receive regular telephone/email/text message (via Florence) contact from a member of the research team from week 2. During weeks 13-24, all sessions will be unsupervised and there will be no contact from the research team. The control group will be asked to continue with their usual activity levels. Both groups will use an exercise diary to record their activity levels.

Usual care will not be affected by this trial.

Intervention Type

Other

Primary outcome(s)
Phase 1 and 2 are purely developmental work and no specific outcome measures are collected.

Phase 3:
Endothlial function will be assessed through flow-mediated dilation. This will be measured at baseline (0 weeks), mid-way (13 weeks) and on completion of the trial (25 weeks).

Key secondary outcome(s))
Phase 3:
All secondary outcomes will be measured at baseline (0 weeks), mid-way (13 weeks) and on completion of the trial (25 weeks).
1. Aerobic exercise tolerance will be assessed using the BSU/Bruce ramp protocol
2. Upper and lower-limb strength will be assessed using the senior fitness test: arm curl and the sit-to-stand test performed using a chair with a seat 45 cm above the ground
3. Glucose and insulin levels and blood lipid profile are measured using venous blood samples and are analysed by the hospital laboratory
4. Body composition is assessed by calculating body mass index (BMI) from height and weight measurements, skinfolds using skinfold calipers and waist measurements using a body composition tape measure.
5. Blood pressure and heart rate are measured using a stethoscope, sphygmomanometer and heart rate monitor.
6. Generic and specific quality of life will be assessed using the EQ5D and FACT-P with fatigue assessed using the Brief Fatigue Inventory
7. Risk of suffering from a heart attack or stroke in the next 10 years will be analysed using the Q-Risk assessment

Completion date
25/09/2018

Eligibility

Key inclusion criteria
Phase 1
1. Prostate cancer patients treated with radical prostatectomy or androgen-deprivation therapy
2. Able to provide consent
3. Able to read and speak English to a level allowing satisfactory completion of written questionnaires unless an interpreter is available

Phase 2 and 3
1. Prostate cancer patients treated with radical prostatectomy or androgen-deprivation therapy
2. Able to provide consent
3. Able to read and speak English to a level allowing satisfactory completion of written questionnaires unless an interpreter is available
4. All men will have been previously cardiac assessed and undergone a cardio-pulmonary exercise test (CPET) for major surgery (within 4 months)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
40

Key exclusion criteria
Phase 1
Receiving other treatments for prostate cancer.

Phase 2
1. Receiving other treatments for prostate cancer
2. Participation in another clinical trial where concurrent participation is deemed inappropriate.

Phase 3
1. Participation in another clinical trial where concurrent participation is deemed inappropriate
2. Receiving any other treatment for cancer
3. Planned further surgery within the first 3 months after being randomly assigned to a group
4. Unsuitable for resistance exercise training based on opinion of the clinical investigator

Date of first enrolment
19/10/2016

Date of final enrolment
28/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle Upon Tyne
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Sponsor information

Organisation
Northumbria University Newcastle

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Charity

Funder Name
Urology Foundation

Alternative Name(s)
The Urology Foundation (TUF), TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from r.ashton@derby.ac.uk

Previous:
All data will be written up as part of a PhD thesis and publications may arise from this. All data to be published from this research will be done so by January 2019

IPD sharing plan:
The datasets generated during and/or analysed during the current study are/will be available upon request from john.saxton@northumbria.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/01/2021	25/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results		15/12/2021	16/12/2021	No	Yes