

# Lifestyle intervention in men with advanced prostate cancer receiving androgen suppression therapy

<b>Submission date</b> 23/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/12/2014	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

STH 14639

# Study information

## Scientific Title

Lifestyle intervention in men with advanced prostate cancer receiving androgen suppression therapy: a randomised control trial

## Study objectives

1. Patients undergoing androgen suppression therapy (AST) randomised to a lifestyle intervention increase their total physical activity levels in comparison to a usual care control group over the period of the intervention and at six months of follow up.
2. Patients undergoing AST randomised to a pragmatic lifestyle intervention experience improvements in health-related outcomes in comparison to a usual care control group over the period of the intervention and at six months of follow up.
3. Patients undergoing AST randomised to a lifestyle intervention demonstrate improvements in biomarkers associated with disease progression in comparison to a usual care control group.

As of 03/05/2012, the following changes were made on the record.  
Anticipated end date has been updated from 01/09/2009 to 01/01/2013.  
Target number of participants has been updated from 50 to 100.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical approval and research governance approval for this study was granted by South Sheffield Research Ethics Committee and the Sheffield Teaching Hospitals research department on the 22nd of June 2007 (ref: 07/Q2305/3)

## Study design

Prospective randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Men with advanced prostate cancer receiving androgen suppression therapy

## Interventions

A 12 week pragmatic, combined exercise and diet advice intervention (a "lifestyle" intervention) compared with usual clinical care controls.

## Intervention Type

Other

## Phase

Not Applicable

## **Primary outcome(s)**

Current primary outcome measures as of 12/07/2013:

To be measured at baseline, 12 and 26 weeks:

1. Quality of life measured using the FACTP questionnaire
2. Diastolic blood pressure measured using an automated sphygmomanometer

Previous primary outcome measures:

1. Exercise behaviour measured using the Godin Leisure Score Index questionnaire at baseline, 12 weeks and 6 months of follow-up
2. Dietary intake measured using three day diet diaries over the intervention period

## **Key secondary outcome(s)**

Current secondary outcome measures as of 12/07/2013:

To be measured at baseline, 12 and 26 weeks:

1. Fatigue measured using the FACT-F questionnaire
2. Aerobic exercise tolerance measured using the Bruce treadmill protocol
3. Body mass measured using balance beam scales
4. Systolic blood pressure measured using an automated sphygmomanometer
5. Exercise behaviour measured using the Godin leisure score index questionnaire and heart rate monitoring

To be measured at baseline and 12 weeks:

1. Dietary macro- and micro-nutrients measured using three-day diet diaries and Netwisp software
2. PSA measured using an immunoenzymatic assay
3. Serum lipid profile measured using an enzymatic colorimetric assay
4. Serum androgen profile measured using an electrochemiluminescence assay
5. Arterial health measured using flow-mediated dilatation

Previous secondary outcome measures:

1. Quality of life measured using the FACT-P questionnaire
2. Fatigue measured using the FACT-F questionnaire
3. Body Mass Index (BMI) and waist-to-hip ratio
4. Aerobic exercise tolerance measured using the Bruce treadmill protocol
5. Lower limb strength measured using isokinetic dynamometry
6. Functional capacity measured using the chair sit-to-stand test

Above outcomes measured at baseline, 12 weeks and at six months of follow-up.

7. Biomarkers associated with disease progression were assessed at baseline and after the intervention period.

## **Completion date**

01/01/2013

## **Eligibility**

### **Key inclusion criteria**

1. Histologically confirmed, non-localised prostate cancer (PCa)
2. Stable disease (stable prostate specific antigen [PSA])
3. Receiving Androgen suppression therapy (AST) for a minimum period of six months

4. A willingness to comply with the randomised allocation to intervention and willing to undertake the requirements of the allocated intervention. If allocated to the exercise intervention, willing to aim to achieve 80% compliance to the exercise intervention.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

Male

**Key exclusion criteria**

1. Participation in regular physical activity (defined as purposeful physical activity of a moderate intensity for 30 minutes three or more times per week in the previous six months)
2. Unstable angina, uncontrolled hypertension, recent myocardial infarction, pacemakers
3. Uncontrolled painful or unstable bone lesions
4. Less than two months post surgical treatment
5. Any physical, neurological or psychiatric impairment or disease such as dementia, multiple sclerosis, severe arthritis or other condition that would limit the ability to understand and complete the study exercises and complete the required questionnaires, recall and record of dietary information

**Date of first enrolment**

22/06/2007

**Date of final enrolment**

01/01/2013

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**STH Teaching Hospitals**

Sheffield

United Kingdom

S11 7FE

**Sponsor information**

## Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

## ROR

<https://ror.org/018hjpz25>

## Funder(s)

### Funder type

University/education

### Funder Name

Sheffield Hallam University (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	feasibility study results	01/04/2011		Yes	No
<a href="#">Results article</a>	results	14/11/2012		Yes	No
<a href="#">Results article</a>	results	01/05/2014		Yes	No