

# Rehabilitation evaluation in survivors of testicular cancer after radical treatment

<b>Submission date</b> 15/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/02/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-rehabilitation-programme-men-completed-treatment-testicular-cancer-restart>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jeff White

### Contact details

The Beatson West of Scotland Cancer Centre  
Level 3  
1053 Great Western Road  
Glasgow  
United Kingdom  
G11 6NT  
+44 (0)141 301 7060  
[jeffwhite@nhs.net](mailto:jeffwhite@nhs.net)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RESTART-2011

# Study information

## Scientific Title

RESTART: Rehabilitation Evaluation in Survivors of Testicular Cancer After Radical Treatment: a pilot study

## Acronym

RESTART

## Study objectives

The primary aim is to establish the components of a rehabilitation programme for testis cancer. In addition, we wish to measure the magnitude of effect using the change in Hospital Anxiety and Depression Scale (HADS) anxiety sub-score from pre to post the programme.

The median return to work/education time will also be estimated for the participants as background information for designing any subsequent phase III study.

The aim is to then set up a phase III trial to definitively investigate if such a programme may influence early reduction in treatment related anxiety and the time to return to employment following radical treatment of testis cancer compared to the current standard of care.

Secondary aims are assessment of the effect of the rehabilitation programme on Quality of Life (QOL), HAD depression sub-score, fatigue, exercise capacity and body mass index (BMI).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

West of Scotland REC 1, 18/08/2011, REC Ref: 11/WS/0007

## Study design

Phase II non-randomised feasibility study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## 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

## Testicular cancer

### **Interventions**

All patients who enter the study will take part in a six week rehabilitation programme in order to facilitate improvement in functional ability and psychological well being following treatment of testicular cancer. Specific components will be introduced to address the needs of this particular population group.

In addition to the exercise component, recreational and social elements to the programme, topics that will be included are:-

1. Healthy living advice (alcohol, diet, exercise, sun awareness)
2. Return to work
3. Role of Occupational Health Physician or Nurse
4. Financial issues
5. Insurance
6. Advice on recognising recurrence
7. Accessing more information and support service for testis cancer
8. Coping with life after a serious illness how to be positive
9. Fertility

As part of the exercise component, participants will wear a pedometer for the 6 weeks the rehabilitation programme takes place. They will record readings in an exercise diary each night. In addition they will record daily exercise activity.

Each of the components will be delivered by a specialist in that field. In addition, the course will be lead by co-ordinator with background experience in cancer rehabilitation.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Pilot study to establish the components of a rehabilitation programme for testis cancer and the effect of the programme by measuring change in the HADS anxiety sub score-from pre to post participation.

The aim is to then set up a phase III trial to definitively investigate if such a programme may influence early reduction in treatment related anxiety and the time to return to employment following radical treatment of testis cancer compared to the current standard of care.

### **Secondary outcome measures**

Assessment of the effect of the rehabilitation programme on:

1. Fatigue
2. Exercise capacity
3. HADS depression sub score
4. BMI

Measured pre and post rehabilitation programme.

### **Overall study start date**

19/01/2012

**Completion date**

01/01/2014

## Eligibility

**Key inclusion criteria**

1. Ability to commence rehabilitation programme within 8 weeks of confirmed completion of all radical treatment for testis cancer ((including all surgical procedures, such as retroperitoneal lymph node dissection) If surveillance, the date this is confirmed as their management / Date of recovery from last surgical procedure or chemotherapy).
2. No major cardio-respiratory problems, which would influence participation in an exercise programme.
3. Male aged 16 or over
4. Ability to provide written informed consent
5. Geographically close enough to site of rehabilitation programme or prepared to travel necessary distances involved

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

32

**Total final enrolment**

35

**Key exclusion criteria**

1. Alcohol/drug dependency
2. Cognitive dysfunction
3. Psychological distress that the referring clinician feels may make the individual not suitable for trial

**Date of first enrolment**

19/01/2012

**Date of final enrolment**

01/01/2014

## Locations

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**  
**The Beatson West of Scotland Cancer Centre**  
Glasgow  
United Kingdom  
G11 6NT

## **Sponsor information**

**Organisation**  
NHS Greater Glasgow and Clyde (UK)

**Sponsor details**  
c/o Dr Nathaniel Brittain  
Research and Development Central Office  
The Tennent Institute, 1st Floor  
Western Infirmary  
38 Church Street  
Glasgow  
Scotland  
United Kingdom  
G11 6NT

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.nhsggc.org.uk/r&d>

**ROR**  
<https://ror.org/05kdz4d87>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Macmillan Cancer Support (UK)

**Funder Name**

National Institute for Health Research Cancer Research Network (NCRN)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	20/05/2013		Yes	No
<a href="#">Abstract results</a>	results	04/11/2013		No	No