ISRCTN77608320 https://doi.org/10.1186/ISRCTN77608320

Rehabilitation evaluation in survivors of testicular cancer after radical treatment

Submission date	Recruitment status	[_] Prospectively registered
15/01/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/01/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/02/2020	Cancer	

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

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?
Plain English results				No	Yes
Results article	results	20/05/2013		Yes	No
Abstract results	results	04/11/2013		No	No