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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

Scotland

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

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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

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?
Results article	results	20/05/2013		Yes	No
Abstract results	results	04/11/2013		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes