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Vocational rehabilitation services for patients with cancer: a feasibility study for a randomised controlled trial

Submission date 10/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/10/2010	**Overall study status** Completed	
Last Edited 21/06/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

A feasibility study for a single-blind, randomised controlled trial of vocational rehabilitation services for patients with cancer

Study objectives
This study aims to determine whether a single-blind randomised controlled trial of vocational rehabilitation services is feasible and the intervention acceptable among patients living with cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics A approved on the 26th March 2010 (ref: 10 /S1401/15)

Primary study design
Interventional

Study design
Interventional single-blind randomised controlled multicentre feasibility study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breast cancer

Interventions
The intervention is referral to a vocational rehabilitation service compared with usual care.

Intervention:
All participants allocated to the Intervention arm of the trial will be contacted by a vocational rehabilitation service by telephone within 10 days following recruitment to the study. The case manager will conduct a telephone assessment of supportive care needs to facilitate remaining in or returning to work. The case manager will signpost participants to support services including physiotherapy, occupational therapy, occupational health nurse, occupational health doctor, counsellor/psychological therapy, complementary therapy.

Usual Care:
Usual care following surgery involves no formal employment support.

Questionnaires will be administered to participants in both the Intervention and Usual Care arms on entry to the trial and again following 6 and 12 months of follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Self-reported sickness absence within the first six months post-surgery

Key secondary outcome(s)
1. Quality of life measured using the FACT-B questionnaire at baseline, 6 and 12 months of follow-up
2. Fatigue measured using the FACT-F questionnaire at baseline, 6 and 12 months of follow-up
3. Change in employment status measured at baseline, 6 and 12 months of follow-up

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Adults aged between 18 and 65 years old who are diagnosed with an invasive breast cancer tumour whose first treatment is surgery
2. In paid employment
3. Live or work in Lothian or Tayside, Scotland

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Anyone under the age of 18 years or over 65 years old
2. Anyone not in paid employment or self-employed
3. Does not live or work in Lothian or Tayside, Scotland

Date of first enrolment
01/03/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Cancer Care Research Centre
Stirling
United Kingdom
FK9 4NF

Sponsor information

Organisation
University of Stirling (UK)

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Charity

Funder Name
Macmillan Cancer Support (UK)

Funder Name
Scottish Centre for Healthy Working Lives (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?

Results article	results	14/06/2013	Yes	No
Protocol article	protocol	30/03/2011	Yes	No