

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/06/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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)

Study design

Interventional single-blind randomised controlled multicentre feasibility study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

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 measure

Self-reported sickness absence within the first six months post-surgery

Secondary outcome measures

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

Overall study start date

01/03/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

66

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**

Scotland

United Kingdom

Study participating centre**Cancer Care Research Centre**

Stirling

United Kingdom

FK9 4NF

Sponsor information**Organisation**

University of Stirling (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.stir.ac.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

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