

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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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+44 (0)1786 466690

carol.johnstone@stir.ac.uk

**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?
<a href="#">Protocol article</a>	protocol	30/03/2011		Yes	No
<a href="#">Results article</a>	results	14/06/2013		Yes	No