

# PRO-REHAB - The development and pilot trial of two programmes of rehabilitation for cancer patients

<b>Submission date</b> 14/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/08/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-at-two-rehabilitation-programmes-for-people-with-cancer-pro-rehab>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Joanne Fisher

### Contact details

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## Additional identifiers

### Protocol serial number

15361

## Study information

Scientific Title

PRO-REHAB - The development and pilot trial of two programmes of rehabilitation for cancer patients: a pilot randomised controlled trial

## **Acronym**

PRO-REHAB

## **Study objectives**

What effect on participants' quality of life, well-being, physical and psychological functioning and perception of distress does: (i) an individualised home-based rehabilitation programme, facilitated by allied health professionals or (ii) a group-based rehabilitation programme, facilitated by a multidisciplinary team of allied health professionals have, compared to usual care?

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15361>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee West Midlands, Solihull, ref: 13/WM/0340

## **Study design**

Randomised; Interventional and Observational

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Rehabilitation for cancer patients following the end of their treatment

## **Interventions**

The two intervention arms of this three-arm randomised control trial are home-based rehabilitation and group-based rehabilitation programmes.

The home-based programme is an individualised holistic rehabilitation programme, developed jointly by the participant and a personal allied health professional and delivered over 10 weeks. Participants can choose from a wide range of areas, activities and topics that they would like to improve or change in their lives. Participants who would like to improve activity will receive an individualised exercise programme, developed by specialist exercise physiologists. The programme will be supported by a workbook with a goal diary and CD-based relaxation.

The group-based programme is an holistic rehabilitation programme, developed jointly by the group (maximum 10 people) and a multi-disciplinary team of allied health professionals and delivered over 10 weeks. Participants can choose from a wide range of areas, activities and topics that they would like to improve or change in their lives. Participants who would like to

improve activity will receive an individualised exercise programme, developed by specialist exercise physiologists. The programme will be supported by a workbook with a goal diary and CD-based relaxation.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Identification and recruitment of participants, and recruitment strategies
2. Sample size calculations for a future multi-centre trial

## **Key secondary outcome(s)**

1. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-EORTC QLQ-C30 (version 3)
2. Generalised Anxiety Disorder Assessment (GAD-7)
3. Euroqol quality of life questionnaire (5 item) - EQ5D-5L
4. Patient Health Questionnaire (PHQ-9)
5. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
6. The Distress Thermometer
7. Incremental Shuttle Walk Test (ISWT) score
8. Joint British Societies recommendations on the prevention of Cardiovascular Disease (JBS3) score
9. Malnutrition Universal Screening Tools score (MUST)

## **Completion date**

31/08/2016

## **Eligibility**

### **Key inclusion criteria**

Patients:

1. With cancer (breast, colorectal, head and neck, lung and prostate) of any stage, will be invited to participate along with their carers
2. Who have completed the initial phase of intensive intervention (surgery, chemotherapy and /or radiotherapy)
3. Are able to read written and comprehend spoken English
4. Are aged 18 years and over
5. Are able and willing to give informed consent; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients:

1. Aged less than 18 years
2. With a history of severe psychiatric disorder

**Date of first enrolment**

02/07/2014

**Date of final enrolment**

31/08/2016

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University of Warwick**

Clinical Trials Unit  
Warwick Medical School  
Gibbet Hill Road  
Coventry  
United Kingdom  
CV4 7AL

**Sponsor information**

**Organisation**

University of Warwick

**ROR**

<https://ror.org/01a77tt86>

**Funder(s)**

**Funder type**

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes