ISRCTN14861313 https://doi.org/10.1186/ISRCTN14861313

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

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| **Submission date**<br>14/01/2015 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>15/01/2015 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>09/08/2021 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] 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

**Study website**
http://www2.warwick.ac.uk/fac/med/research/hscience/sssh/research/pro-rehab/

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

**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 contact details to request a patient information sheet

**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 rehabilitaion programme, developed jointly by the participant and a personal allied health professional and delivered over 10 weeks. Particpants 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 recieive 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 rehabilitaion prgramme, 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 recieive 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 measure
1. Identification and recruitment of participants, and recruitment strategies
2. Sample size calculations for a future multi-centre trial

### Secondary outcome measures
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)

### Overall study start date
02/07/2014

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 170; UK Sample Size: 170; Description: A sample size of 150 patients (50 patients on each arm) in the pilot trial will be sufficient to give an indication of the feasibility of the full trial. This sample size will allow the mean difference in pre and post intervention scores on the global quality of life scale from the EORTC QLQ-C30 questionnaire to be estimated to within 6% with 95% confidence, i.e. 95% confidence interval (CI) width of 12%, for each arm, assuming a standard deviation of 20.

### 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
England

United Kingdom

### 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

**Sponsor details**
Warwick Medical School
Coventry
England
United Kingdom
CV4 7AL

**Sponsor type**
Hospital/treatment centre

**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

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |