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# 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

## Contact information

**Type(s)**
Scientific

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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 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(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
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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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |