

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

Submission date 14/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/08/2021	Condition category 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

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

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

Primary study design

Interventional

Study design

Randomised; Interventional and Observational

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?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes