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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	[_] Prospectively registered [_] Protocol
Registration date 15/01/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/08/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English Summary
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 hypothesis
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

Condition
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

Overall study end date
31/08/2016

Eligibility

Participant 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.

Participant exclusion criteria
Patients:
1. Aged less than 18 years
2. With a history of severe psychiatric disorder

Recruitment start date
02/07/2014

Recruitment end date
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
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United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

Sponsor details
Warwick Medical School
Coventry
England
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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