ISRCTN10276684 https://doi.org/10.1186/ISRCTN10276684

Peer support to maintain psychological wellbeing in people with advanced cancer: A feasibility study

Submission date 13/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/06/2016	**Overall study status** Completed	
Last Edited 14/09/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

Contact name
Dr Diane Roberts

ORCID ID
http://orcid.org/0000-0003-0264-921X

Contact details
University of Manchester
Room 5.305
Jean McFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PL

Type(s)
Scientific

Contact name
Prof Catherine Walshe

Contact details

C052, C - Floor
Furness College
Lancaster University
Bailrigg
Lancaster
United Kingdom
LA1 4YW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30442

Study information

Scientific Title
PACT: Peer support to maintain psychological wellbeing in people with advanced cancer. A feasibili

Acronym
PACT

Study objectives
The aim of this study is to determine the feasibility of delivering and investigating a novel peer mentor intervention to promote and maintain psychological wellbeing in people with advanced cancer using a randomised controlled trial design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 5 Bangor, 03/02/2016, ref: 16/WA/0032

Study design
Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Palliative and supportive care; UKCRC code/ Disease: Cancer/ Malignant neoplasms of ill-defined, secondary and unspecified sites

Interventions
Patients completing baseline assessment (T=0) will be allocated to either intervention or control group using a telephone system provided by Manchester Academic Health Science Centre Clinical Trials Unit (MAHSC-CTU). Carers will NOT be randomised independently but will be considered as belonging to intervention or control group according to the allocation of the associated patient.

Intervention Group: Patients will be preference matched with a trained volunteer mentor for a period of 12 weeks during which time they will meet/communicate in various ways according to personal preference to facilitate peer learning of coping strategies. Patients will continue to receive 'usual care' i.e. all those therapies and clinical interventions/services which would be offered in the absence of the study intervention. Carers will not be actively involved in receipt of the intervention but will be assessed for indirect effects.

Control group: Patients allocated to the control group will solely receive usual care for the 12 weeks of the study.

Participants in both groups are followed up after 4 and 12 weeks. Additionally, a sub-group of participants from each category (patient, carer, mentor or health professional) will be interviewed at baseline and 12 weeks (or earlier exit from the study).

Intervention Type
Behavioural

Primary outcome measure
Patient and carer psychological wellbeing is measured using the WHO Quality of Life-BREF questionnaire (WHOQOL-BREF) at baseline, 4 and 12 weeks.

Secondary outcome measures
1. Patient and carer psychological wellbeing (WHOQOL-BREF) at T = 12 weeks (or completion of intervention if before 12 weeks).
2. Patient health related quality of life is measured using the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (EORTC QLQ C 15 PAL) at baseline, 4 and 12 weeks (or completion of intervention if before 12 weeks)
3. Patient and carer coping strategies is measured using the Brief Coping Orientation for Problems Experienced (Brief COPE) questionnaire at baseline, 4 and 12 weeks (or completion of intervention if before 12 weeks)
4. Patient depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline, 4 and 12 weeks (or completion of intervention if before 12 weeks)

5. Social Support is measured using the modified Medical Outcomes Study Social Support Survey (mMOS-SS) in patient participants, and the Carer Support Needs Assessment Tool (CSNAT) questionnaire in carer participants) at baseline, 4 and 12 weeks (or completion of intervention if before 12 weeks)

Overall study start date
11/12/2015

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Patient inclusion criteria:
1. Aged 16 years and over
2. With advanced cancer (any type), defined as metastatic disease at diagnosis, and/or with local or metastatic spread following treatment and/or where prognosis is estimated as less than a year. Those whom their health care professionals judge to have a prognosis > 3 months to facilitate study completion.
3. Those whom their health care professionals judge have capacity to give informed consent to research participation.
4. Assessed by their health care professional as understanding their diagnosis of advanced cancer.
5. Able to adequately understand and respond to verbal and written material in English.

Peer Mentor inclusion criteria:
1. Experience of living with cancer
2. At least six months post diagnosis
3. Aged 18 years and over
4. Able to commit to six months of volunteering
5. Have at least two hours per week available for volunteering
6. Live in the geographic area selected for the project
7. Fluency in written and spoken English
8. Qualitative demonstration of empathy, compassion, and open and non-didactic communication skills
9. Satisfactory completion of project-specific training (assessed by research team)
10. DBS clearance for working with vulnerable people.

Carer and Professional Participants:
Recruited patients will be asked to nominate one “person they get most support from”, and an invitation to participate sent to this identified carer. In addition, patient participants will nominate one healthcare professional providing cancer and/or palliative care to them on a regular basis, and an invitation to participate will be sent to this identified healthcare professional.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
30

Key exclusion criteria
Patient criteria:
1. Aged under 16 years
2. With advanced cancer prognosis < 3 months
3. Those whom their health care professionals judge not to have capacity to give informed consent to research participation
4. Assessed by their health care professional as not understanding their diagnosis of advanced cancer

Peer Mentor criteria:
1. No experience of living with cancer
2. Less than months post diagnosis
3. Aged under 18 years
4. Unable to commit to six months of volunteering
5. ave less than two hours per week available for volunteering
6. Live outside the geographic area selected for the project
7. No qualitative demonstration of empathy, compassion, and open and non-didactic communication skills
8. Unable to be granted DBS clearance for working with vulnerable people

Carer Participants:
1. Aged under 18 years
2. Caring for someone with an advanced cancer prognosis < 3 months
3. Those whom patient's health care professionals judge not to have capacity to give informed consent to research participation
4. Assessed by the patient's health care professional as not understanding the associated patient's diagnosis of advanced cancer

Professional Participants:
No exclusion criteria

Date of first enrolment
01/08/2016

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Christie NHS Foundation Trust
Oncology Unit
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Health Park
Clatterbridge Road
Wirral
United Kingdom
CH63 4JY

Sponsor information

Organisation
Lancaster University

Sponsor details
Research Support Office
B58
Bowland Main
Lancaster
England
United Kingdom
LA1 4YW

Sponsor type
University/education

ROR
https://ror.org/04f2nsd36

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
1. Planned publication of articles covering several aspects of the study including mentor training and design
2. Planned dissemination of results through professional and academic conferences or similar routes

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	12/05/2020	Yes	No
Results article	results	17/08/2020	21/08/2020	Yes	No
HRA research summary			28/06/2023	No	No