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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

**Public** 

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# Type(s)

Scientific

#### Contact name

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s))

- 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)

# 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

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

16 years

#### Sex

ΔII

## 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

United Kingdom

England

Study participating centre
The Christie NHS Foundation Trust

Oncology Unit Wilmslow Road Manchester United Kingdom M20 4BX

## Clatterbridge Cancer Centre NHS Foundation Trust

Clatterbridge Health Park Clatterbridge Road Wirral United Kingdom CH63 4JY

# Sponsor information

### Organisation

Lancaster University

#### **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**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes