

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

<b>Submission date</b> 13/06/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/09/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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**

**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 feasibility

**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  
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## **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?
<a href="#">Results article</a>	results	01/01/2020	12/05/2020	Yes	No
<a href="#">Results article</a>	results	17/08/2020	21/08/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No