

# Evaluation of the Palliative Care Needs Assessment Intervention

<b>Submission date</b> 13/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/12/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.newcastle.edu.au/research-centre/cherp/>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

Cancer Trials NSW PC-11-01

# Study information

## Scientific Title

Evaluation of the Palliative Care Needs Assessment Intervention: a multicentre interrupted time series design

## Study objectives

The systematic use of the Palliative Care Needs Assessment Guidelines and Needs Assessment Tool: Progressive Disease-Cancer (NAT: PD-C) will result in a better match between unmet needs and service utilisation of people with advanced cancer and their caregivers.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. University of Newcastle Human Research Ethics Committee approved on the 13th December 2006 (ref: H-355-1206)
2. Hunter New England Area Health Service Human Research Ethics Committee approved on the 19th October 2006 (ref: 06/09/27/4.01)
3. Sydney South West Area Health Service Human Research Ethics Committee approved on the 13th March 2007 (ref: 2007/05)
4. South Eastern Sydney and Illawarra Area Health Service Human Research Ethics Committee (Central Network) approved on the 13th December 2006 (ref: 06/113 Girgis)

## Study design

Multicentre interventional interrupted time series design

## Primary study design

Interventional

## Secondary study design

Multi-centre

## 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

Advanced cancer

## Interventions

Patient and caregiver participants will complete computer assisted telephone interviews (CATIs) every two months for a period of up to two years. Interviews will include questions about unmet needs, anxiety and depression, quality of life, satisfaction with care and service utilisation. The introduction of the intervention will begin approximately six months after the commencement of recruitment. The intervention will involve the introduction of the Guidelines and NAT: PD-C to medical, nursing and allied health professionals at each of the recruitment sites. Health professionals will be trained in the use of the Guidelines and NAT: PD-C and will be asked to complete the tool on each patient during their usual appointments (approximately monthly). Participants will continue completing CATIs every two months during the post-intervention phase of the study. Changes in outcomes will be compared pre- and post-intervention.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Each patient's unmet need as measured by the Supportive Care Needs Survey Short Form (SCNS-SF34). Each of the 34 items are mapped to five different domains: physical and daily living, psychological, patient care and support, health system and information and sexuality. Each domain is standardised to a score out of 100. Changes in domain scores will be measured at 2-monthly intervals from baseline for up to 15 months. Six spirituality items from the Needs Assessment for Advanced Cancer Patients (NA-ACP) will also be included to assess changes in spirituality needs. The sample size will give the study the power to detect a difference of between 4.2 and 6.7 units in each of the domains.
2. Each caregiver's unmet need as measured by the Supportive Care Needs Survey Partners and Caregivers (SCNS-PC). Changes in domain scores will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference of between 5.3 and 8.6 units in each of the SCNS domains for caregivers.
3. Patient self-report service utilisation, in particular the number of health professionals seen in the month preceding the patient's interview. Changes will be measured at 2-monthly intervals from baseline for up to 15 months.

## **Secondary outcome measures**

1. Patient anxiety and depression as measured by the Hospital and Anxiety Depression Scale (HADS). A score out of 21 is obtained for each subscale, classifying people as normal (score 0 - 7), borderline (score 8 - 10) or clinically anxious or depressed (score 11 - 21). Changes in subscale scores will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference of between 1 and 0.7 units in anxiety and depression scores.
2. Caregiver anxiety and depression as measured by the HADS. A score out of 21 is obtained for each subscale, classifying people as normal (score 0 - 7), borderline (score 8 - 10) or clinically anxious or depressed (score 11 - 21). Changes in subscale scores will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference between 1.2 and 1.5 in anxiety and depression scores.
3. Patient quality of life as measured by the two global questions from the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30). The scores for the two items will be added together and averaged and then scaled out of 100, with a higher score indicating a greater quality of life. Changes in score will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference of 4.7 units.

4. Caregiver quality of life as measured by the two global questions from the EORTC QLQ C30. The scores for the two items will be added together and averaged and then scaled out of 100, with a higher score indicating a greater quality of life. Changes in score will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference of 4.7 units.

5. Caregiver satisfaction with care as measured by the Family Satisfaction with Advanced Cancer Care Scale (FAMCARE). Changes in score will be measured at 2-monthly intervals from baseline for up to 15 months. The study will be able to detect a difference of 3.4 units.

**Overall study start date**

01/11/2006

**Completion date**

31/12/2009

## Eligibility

**Key inclusion criteria**

Patient criteria:

1. Person with a diagnosis of advanced cancer, i.e., no longer amenable to cure, with either extensive local or regional spread or metastatic disease
2. Aged 18 years or older, either sex
3. Able to understand English sufficiently to complete questionnaires and telephone interviews

Caregiver criteria:

1. The primary carer or the family member who provided, or may provide when needed, the most help to the patient, as nominated by the patient
2. Able to understand English sufficiently to complete questionnaires and telephone interviews

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

660 patients and 396 caregivers

**Key exclusion criteria**

Patients criteria:

1. Cognitively unable to give consent or unable to understand and respond to questions in English
2. Younger than 18 years of age

Caregiver criteria:

1. Cognitively unable to give consent or unable to understand and respond to questions in English

**Date of first enrolment**

01/11/2006

**Date of final enrolment**

31/12/2009

## **Locations**

**Countries of recruitment**

Aruba

Australia

**Study participating centre**

Centre for Health Research and Psycho-oncology (CHeRP)

Callaghan

Aruba

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## **Sponsor information**

**Organisation**

Australian Government Department of Health and Ageing (Australia)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.health.gov.au/>

**ROR**

<https://ror.org/0314h5y94>

# Funder(s)

## Funder type

Government

## Funder Name

Australian Government Department of Health and Ageing (Australia)

## Funder Name

National Health and Medical Research Council (NHMRC) (Australia) - PhD scholarship (ref: 455644)

# 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

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	Protocol	11/01/2010		Yes	No