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Evaluation of the Palliative Care Needs Assessment Intervention

Submission date	Recruitment status	[_] Prospectively registered
13/05/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2017	Cancer	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Multicentre interventional interrupted time series design

Study type(s)
Treatment

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(s)

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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)
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Sponsor information

Organisation
Australian Government Department of Health and Ageing (Australia)

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

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?
Protocol article	Protocol	11/01/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes