# Can the needs of caregivers of patients with advanced cancer be met using a general practitioner (GP) caregiver needs toolkit?

Submission date Recruitment status [X] Prospectively registered 03/04/2008 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 01/05/2008 Completed [ ] Results Individual participant data Last Edited Condition category Record updated in last year 23/10/2020 Cancer

**Plain English summary of protocol**Not provided at time of registration

### Contact information

Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

**Protocol serial number** 511168

# Study information

Scientific Title

Can the needs of caregivers of patients with advanced cancer be met using a general practitioner (GP) caregiver needs toolkit?

#### **Study objectives**

The number and levels of unmet needs of caregivers of patients with advanced cancer will be significantly lower in caregivers whose needs are systematically assessed using a needs assessment tool and then addressed by their general practitioner (GP), compared with caregivers receiving usual care.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the University of Queensland Behavioural and Social Sciences Ethical Review Committee on the 26th February 2008 (ref: 2008000206).

#### Study design

Multi-centre randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Advanced cancer

#### **Interventions**

On recruitment, caregivers will be randomised off-site into the intervention or control group using computer-generated random number tables.

#### Intervention group:

The caregiver needs assessment tool (C-NAT) will be developed in the next six months. It will assess caregivers' unmet needs across a number of domains including their physical and psychological wellbeing, spiritual, existential, social, financial and legal needs, and bereavement grief. To evaluate caregivers' needs and the effectiveness of the C-NAT, participants will be surveyed using computer-assisted telephone interviews at four time-points over a six-month period: as soon as possible after recruitment, then at one month, three months and six months. We anticipate that each interview will take approximately 40 minutes. Prior to the first interview, intervention group caregivers will receive a copy of the C-NAT and the interview questions, for reference during each telephone interview. At the end of the first interview, caregivers will be asked to rate their levels of needs and to attend their GP to discuss these, preferably between one and two weeks from the interview, so that the GP can be briefed regarding the study materials. Caregivers will complete the C-NAT again after the three-month interview and visit their GP to discuss. The identified needs of intervention caregivers will be assessed and managed through a specifically developed general practice-based strategy.

#### Control group:

Caregivers in the control group will receive usual care, i.e. they will be surveyed regarding their

needs via phone interviews only; they will have no awareness or involvement with the C-NAT nor will they be asked to visit their GP.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

- 1. Reduced number and levels of unmet needs reported by caregivers
- 2. Demonstrated acceptability of the intervention for GPs

The primary outcome will be a difference of 0.9 to 1.4 units in intervention group carers' anxiety and depression scores over six months.

#### Key secondary outcome(s))

- 1. Reduced number and levels of unmet needs reported by caregivers
- 2. Demonstrated acceptability of the intervention for GPs

The secondary outcomes will be the results for these measures at one month and three months.

#### Completion date

01/10/2010

# **Eligibility**

#### Key inclusion criteria

- 1. Nominated caregiver of a patient 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

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### Key exclusion criteria

- 1. Caregivers of cancer patients with a prognosis of greater than 12 months
- 2. Cognitively unable to give consent or unable to understand and respond to questions in English
- 3. Younger than 18 years of age

# Date of first enrolment 01/01/2009

Date of final enrolment 01/10/2010

#### Locations

#### Countries of recruitment

Australia

Study participating centre
Discipline of General Practice
Herston
Australia
4006

# **Sponsor information**

#### Organisation

National Health and Medical Research Council (NHMRC) (Australia)

#### ROR

https://ror.org/011kf5r70

# Funder(s)

#### Funder type

Research council

#### Funder Name

National Health and Medical Research Council (NHMRC) (Australia) (ref: 51168)

#### Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

National government

#### Location

Australia

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

#### **Study outputs**

Output type	Details	Date created Date adde	d Peer reviewed	? Patient-facing?
Protocol article	protocol	29/11/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes