

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

<b>Submission date</b> 03/04/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/10/2020	<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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Geoffrey Mitchell

**Contact details**  
Discipline of General Practice  
School of Medicine  
University of Queensland  
Herston Road  
Herston  
Australia  
4006

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## 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

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 measure**

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.

#### **Secondary outcome measures**

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.

#### **Overall study start date**

01/01/2009

#### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

400, i.e. 200 per group

**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)

**Sponsor details**

GPO Box 1421  
Canberra ACT  
Australia  
2601

**Sponsor type**

Research council

**Website**

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

**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)**

NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

## **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	29/11/2010		Yes	No