ISRCTN43614355 https://doi.org/10.1186/ISRCTN43614355

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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?
Protocol article	protocol	29/11/2010		Yes	No