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Improving the provision of palliative services: A randomised controlled trial of the use of enhanced primary care items and educational interventions - the Palliative Care Trial

Submission date
29/05/2003

Recruitment status
No longer recruiting

Registration date
23/07/2003

Overall study status
Completed

Last Edited
23/06/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title
Improving the provision of palliative services: A randomised controlled trial of the use of enhanced primary care items and educational interventions - the Palliative Care Trial

Acronym
PCT

Study objectives
The Palliative Care Trial (PCT) is a pragmatic 2 x 2 x 2 factorial cluster randomized controlled trial that tests the ability of educational outreach visiting and case conferencing to improve patient-based outcomes such as performance status and pain intensity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
All 13 relevant independent human research ethics committees and institutional review boards approved the PCT.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Palliative Care

Interventions
461 consenting patients and their GPs were enrolled into a randomised controlled trial set up in a 2x2x2 factorial clustered design of:

- A coordinated palliative care model centred on case conferencing versus the standard model of palliative care in Adelaide (3:1 randomisation).

- Educational outreach visiting for the patient's GP, versus the routine teaching currently offered by the service (1:1 randomisation).

- Educational outreach visiting for the patient, versus the routine teaching currently offered by the service (1:1 randomisation).

An interaction term from the 2x2 analysis of GP education and patient education allows evaluation of the interaction between these two interventions.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Randomisation 1: performance status on the Australian-modified Karnofsky Performance Status Scale
Randomisations 2 & 3: pain intensity on a 0-10 visual analogue scale (VAS)

Key secondary outcome(s))
Other outcome measures include control of other symptoms, health resource utilization, and quality of life.

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Because an aim of this study was to improve specialized palliative healthcare delivery, the eligibility criteria were broad. All adult patients referred to the Southern Adelaide Palliative Services with any form of pain in the preceding 3 months were eligible after providing written informed consent. Participants were mentally competent at enrollment (Folstein Mini-Mental State Examination Score ≥24).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Total final enrolment
461

Key exclusion criteria
Patients who were expected to die within 48 hours of referral and who lived out of the geographic region served by the team were excluded.

Date of first enrolment
15/04/2002

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
Australia

Study participating centre
Southern Adelaide Palliative Services
Daw Park
Australia
5041

Sponsor information

Organisation
Repatriation General Hospital (Australia)

ROR
https://ror.org/04b0n4406

Funder(s)

Funder type
Government

Funder Name
Commonwealth Department of Health and Ageing (Australia)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/10/2012	23/06/2022	Yes	No
Protocol article	protocol	01/02/2006		Yes	No
Other publications	Performance measure results	12/11/2005		Yes	No