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	Recruitment status No longer recruiting	Prospectively registered		
29/05/2003		[X] Protocol		
Registration date 23/07/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 23/06/2022	Condition category Other	[] Individual participant data		

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 $2 \times 2 \times 2$ 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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 measure

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)

Secondary outcome measures

Other outcome measures include control of other symptoms, health resource utilization, and quality of life.

Overall study start date

15/04/2002

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

Age group

Adult

Sex

Not Specified

Target number of participants

461

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)

Sponsor details

Southern Adelaide Palliative Services 700 Goodwood Road Daw Park Australia 5041

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/04b0n4406

Funder(s)

Funder type

Government

Funder Name

Commonwealth Department of Health and Ageing (Australia)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Other publications	Performance measure results	12/11/2005		Yes	No
<u>Protocol article</u>	protocol	01/02/2006		Yes	No
Results article		24/10/2012	23/06/2022	Yes	No