

Recruitment of 461 patients into a longitudinal randomised controlled trial (RCT) in the palliative care setting. How can it be done?

A Abernethy^{1,2,3} T Shelby-James^{1,2}, C Lillie², D Currow^{1,2}



¹Dept of Palliative & Supportive Services, Flinders University, Adelaide, SA; ²Southern Adelaide Palliative Services, Repatriation General Hospital, Daw Park, SA; ³Duke University Medical Center, Durham, North Carolina, USA

Background

Authors argue that recruitment in large RCTs in palliative care is not possible due to limitations in participant recruitment; many of these recruitment issues are unique to palliative care (Table 1).

TABLE 1. Barriers to Recruitment

Unique to Palliative Care	
Patient Issues	Frail, ill, nearing death Competing demands Participation in research = constant reminder Difficulty fulfilling protocol, may withdraw Study requirements may be exhausting Die early before completing study protocol
Gatekeeping by professionals and informal caregivers	Concern that research is burdensome and upsetting No benefit to the participant Research seen as unnecessary intrusion at the end of life Concerns about false hope Ethical concerns
Ethical Issues	Increased vulnerability Decreased capacity to give informed consent Consent documents can be exhausting and confronting

- Presented here are the strategies that enabled the Palliative Care Trial (PCT) to fully recruit the required number of participants within the specified recruitment timeframe.
- A potential framework for future RCTs in palliative care.

The Palliative Care Trial

- 2x2x2 factorial cluster randomised control trial.
- Sample size goal of 460 palliative care patients and their GPs.
- Recruitment time frame of 26 months.

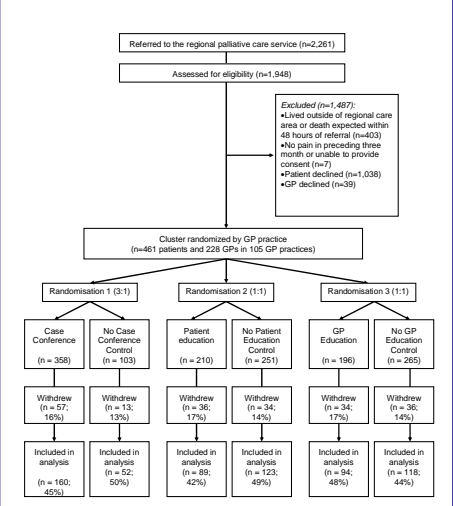
STUDY SETTING

- All participants were recruited from a single region - Southern Adelaide, South Australia (population 350,000).
- This region is serviced by a comprehensive palliative care program, Southern Adelaide Palliative Services (SAPS).
- SAPS has approximately 1100 referrals per year, 85% of whom have cancer.

STUDY PARTICIPANTS

- Participants were adult patients referred to Southern Adelaide Palliative Services (SAPS).
- They had to have experienced some pain of any form in the last 3 months.
- Participants were excluded if they:
 - were expected to die within 48 hrs of referral
 - did not live in the geographic area
- Both GP and patient consent required for randomisation.

Participant flow



Recruitment Strategy

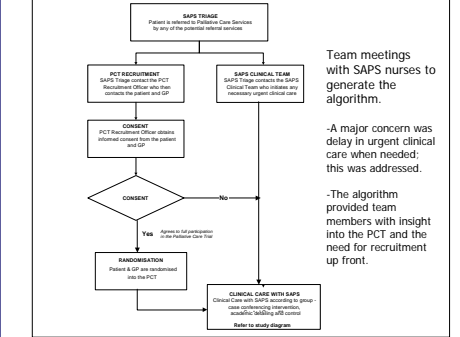
Strategy Development

- Comprehensive structured review of the English language medical literature was undertaken, focusing on:
 - successful recruitment strategies for large clinical trials in general
 - specific focus on clinical trials in oncology, palliative care, cardiology and health services research
 - identified strategies were matched to the needs of the PCT and research setting
- Seven key strategies were identified.
- All strategies were piloted prior to beginning recruitment for the trial.

Strategy 1: Triage Algorithm

- Goal was to institutionalise recruitment into the service referral and triage process
- All referrals to the service screened at time of referral to see:
 - If the patient was eligible for inclusion into the trial?
 - If the eligible patient was interested in contact from the trial?
- Triage was conducted by experienced senior palliative care nurses
- Nurses were provided with scripts to standardise the trial introduction.

FIGURE 1. PCT Recruitment Algorithm



Strategy 2: Recruitment Nurse

- The trial employed a dedicated full-time nurse for study recruitment.
- The recruitment nurse could only contact patients once permission was given through the triage process.

Strategy 3: Choreography

- Recruitment visits in the patient's home or hospital room.
- Patients and/or caregivers were encouraged to be present during the consenting process.
- At recruitment visits:
 - Eligibility was reviewed.
 - The study was explained in depth.
 - Informed consent from the patient was obtained.
 - Information booklet, consent documents and withdrawal forms were left for the patient.
- All aspect of the recruitment visit was scripted, role-played & piloted.
- Recruitment of GP occurred after the patient.

Strategy 4: Key Messages

- Based upon social marketing principals, a pre-defined set of key messages were incorporated into the recruitment visit (Table 2).
- Messages were written with specific attention to the defined barriers to participation in palliative care clinical trials (Table 1).
- Consent documents were simplified and organised to reflect the key messages.

TABLE 2. Recruitment and Consent Key Messages

- The results may benefit others.
- Participation is voluntary.
- There are ways of reducing participant burden.
- Randomisation = "a lucky dip".
- You can withdraw at anytime.

Strategy 5: Proxy consent procedure

- Consent could be provided by a legal proxy or Power of Attorney extending to medical decisions.
- In addition, caregivers could consent on the patient's behalf if:
 - the GP provided a letter advising that the patient did not have the mental or physical capacity to consent on his/her own, and participation in the trial was not contrary to the patient's best interests.
 - the caregiver provided a letter attesting to the fact that he/she usually made decisions on behalf of the incapacitated patient.
- This procedure was approved by 11 Australian Ethics Committees and 1 American Internal Review Board.

Strategy 6: Marketing

- Prior to, and during the trial, meeting with local stakeholders including GPs and aged care facilities were held.
- Print and electronic information was provided to local GPs and the public about the trial to raise awareness. This information was not designed to recruit participants.
- Marketing within SAPS was undertaken to address gatekeeping. Activities included:
 - Involving clinical staff in the development of all trial procedures.
 - Weekly coffee meetings with staff to feed back recruitment numbers, discuss problems with the trial, and identify potential participants not screened by the triage process.
 - Focus groups (external facilitator) with all staff throughout the trial to identify issues relating to the trial.
 - Social events to "celebrate" key achievements in the trial.
- The marketing strategies were designed to increase buy-in by staff and stakeholders.

Strategy 7: Monitoring and Quality Assurance

- Key performance indicators (KPIs) were monitored weekly allowing potential problems to be quickly identified and appropriate action taken.
- KPIs included:
 - % of referrals screened
 - % of triages enrolled
 - time from referral to triage
 - time from referral to recruitment
 - number of patients and GPs providing consent
- Monitoring of KPIs was assisted by the development of an information system with KPI reporting functions built in.

Recruitment Outcomes

- 2,261 Referrals to the service
- 1,948 participants screened by the triage nurses
- 614 participants referred to the PCT Recruitment Nurse
- 607 participants were eligible
- 500 (82%) of participants consented
- 461 (92%) of GPs consented
- Overall recruitment rate of 18 participants per month

31% of the screened population eligible for the trial
76% of the screened population randomised into the trial

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