

Review Article

A Systematic Review of Strategies Used to Increase Recruitment of People With Cancer or Organ Failure Into Clinical Trials: Implications for Palliative Care Research

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Abstract

Context. The challenges of palliative care clinical trial recruitment are well documented.

Objectives. The aim of the study was to review tested strategies to improve recruitment to trials of people with a range of conditions who may access palliative care services but are not explicitly stated to be “palliative.”

Methods. This was a systematic review with narrative description. The Cochrane, Embase, PubMed, PsycINFO, and CINAHL electronic databases were searched (English; January 2002 to February 2014) for quasi-experimental and randomized controlled trials (RCTs) testing the effect of recruitment strategies on accrual to clinical trials of people with organ failure and cancer. Titles, abstracts, and retrieved articles were screened by two researchers and categorized by recruitment challenge: 1) patients with reduced cognition, 2) those requiring emergency treatment, and 3) willingness of patients and clinical staff to contribute to trials.

Results. Of 549 articles identified, 15 were included. Thirteen reported RCTs and two papers reported three quasi-experimental studies. Five were cluster RCTs of recruiting sites/institutions. One was a randomized cluster, crossover, feasibility study. Seven studies recruited patients with cancer. Others included patients with dementia, stroke, cardiovascular disease, diabetes, frail elderly, and bereaved carers. Some interventions improved recruitment: memory aid, contact before arrival, cluster consent, “opt out” consent. Others either reduced recruitment (formal mental capacity assessment) or made no difference (advance research directive; a variety of educational, supportive, and advertising interventions).

Conclusion. Successful strategies from other disciplines could be considered by palliative care researchers. Tailored, efficient, evidence-based strategies must be developed, acknowledging that strategies with face validity are not necessarily the most effective. *J Pain Symptom Manage* 2015;49:762–772. © 2015 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

Patient selection, clinical trials, disease progression, palliative care, research subject recruitment

Introduction

The challenges faced when recruiting participants into palliative care trials are cited as the reason for

poor accrual, resulting in abandoned or underpowered studies.^{1–4} This represents a poor return for the time and effort of the participants and the funding

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bodies and fails to address the need for interventions to have high-level evidence to support their use in the palliative care population, with regard to efficacy, safety, and tolerability.^{5,6}

The difficulties of recruitment to clinical trials in palliative care have been well documented.^{1–3,7,8} Mostly, these center on ethical and logistical issues. Ethical issues relate to the burden and intrusiveness of study measures on the participants, concerns regarding randomization, and gatekeeping by clinicians, carers, and Ethics Committees. Logistical issues include lack of research infrastructure such as trials unit support, research funding, collaborative centers, sponsorship, indemnity, and research time, particularly for clinicians. Furthermore, palliative care patients have an expected trajectory of deterioration and death that may complicate the ethical issues in this population and increase the risk of underpowered trials.⁹

The remit of palliative care is evolving to include people with noncancer conditions. Despite similar recruitment challenges, clinical trials have been successfully completed in this population even with advanced disease.¹⁰ Indeed, some recruitment strategies (Table 1) have already been successfully applied in palliative care trials, increasing the number of adequately powered clinical trials of palliative care interventions.^{8,11–14}

As people with a range of conditions are increasingly cared for by palliative care services, recruitment strategies tested in such populations, which may not be explicitly named as “palliative care,” may provide useful information for palliative care researchers. Previous reviews have restricted the search to studies in explicitly palliative care populations or conversely have reviewed an extensive range of conditions and study interventions, including public health interventions.^{1,10,15} For this review, a “palliative care patient” is defined in terms of the health status (progressive incurable illness) and the care given (multidisciplinary, holistic approach).^{1,16}

The aims of this study were to 1) identify, assess, and summarize the findings of randomized or quasi-experimental trials of strategies designed to optimize trial recruitment of people with cancer or organ

failure (including cognitive failure) compared with usual methods with regard to effect on trial accrual and 2) identify those strategies applicable to palliative care clinical studies.

Methods

Cochrane, Embase, PubMed, PsycINFO, and CINAHL electronic databases were searched using terms developed from those used by Wohleber et al.,⁷ Lovato et al.,¹⁰ Rinck et al.,¹⁵ and Sladek et al.¹⁷ (Table 2). These were extended to include other conditions mapped to medical subject heading terms. Search #17 had titles and abstracts reviewed for inclusion; eligibility criteria are listed in Table 3. Reference lists from identified reviews were handsearched. An initial search was performed in November 2012 and updated in February 2014.

Inclusion Criteria

Types of Participants. Studies of patients with cancer or conditions affecting vital organ(s) including dementia, delirium, and stroke were included.

Types of Studies. Studies that tested the effect of a recruitment strategy on recruitment to a clinical study

Table 2
Search Strategy

Search Strategy
Limits:
Date: 2002–2012 (#1–#17);
Language: English—all searches
Study design: randomized or controlled clinical trials; therapy—all databases except Cochrane
Methodological studies—Cochrane database search only
Humans; adults—all searches
Terms were mapped to MeSH headings and text word searches used the terms:
“Recruit*,” OR “Recruitment strategy,” OR “ethics research,” OR “Experimental ethics,” OR “informed consent,” OR “methodology,” OR “experimental subjects” “end stage”, OR “advanced disease”, AND “lung”, OR “pulmonary”, OR “renal”, OR “heart”, OR “cardiac” OR “oncology” OR “cancer”
Searches:
#1 exp Patient, selection/
#2 exp Ethics, Research/
#3 exp Research subjects/
#4 exp Patient recruitment/
#5 #1 or #2 or #3 or #4
#6 remove duplicates from #5
#7 exp Lung/
#8 exp Kidney/
#9 exp Heart/
#10 exp Liver/
#11 exp Neoplasm/
#12 exp Dementia/
#13 exp Delirium
#14 exp Stroke/
#15 #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
#16 remove duplicates from #15
#17 #6 and #16

MeSH = medical subject heading.

Table 1
Strategies Used in Successful Palliative Care Clinical Trials

<ul style="list-style-type: none"> • Realistic recruitment timescales • Close monitoring of recruitment with regular adjustment of strategy as necessary • Adequate dedicated research staff • Multicenter • Adequate trial unit infrastructure support • Careful attention to the consenting process, study design, study duration, and study assessment burden
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