

Journal Watch

A Proposed Taxonomy of Terms to Guide the Clinical Trial Recruitment Process

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Abstract

Context. The successful conduct of clinical trials in palliative care is challenged by low accrual rates, high attrition of study patients during trials, difficulties managing comorbidity, and other factors. But what has been learned about improving the feasibility of palliative care research studies?

Objective. To develop standard terms to describe patient accrual, and using these terms, describe an approach to allow investigators to predict trial feasibility.

Methods. We proposed a standard language and definitions for specific elements of feasibility within clinical trial design and conduct. We then developed an approach to apply data generated from the use of these terms to allow researchers to predict feasibility at the design stage of a clinical trial's development.

Results. We developed a taxonomy and then retrospectively applied the approach to four trials selected from our library of completed studies, to provide preliminary validity evidence. The approach includes a framework to help predict the number of patients needed to be assessed to achieve a study's accrual targets, as part of ongoing operational oversight to monitor the conduct and feasibility of a clinical trial.

Conclusion. Challenges to successful completion of palliative care trials are prevalent and serious. A taxonomy to characterize the eligible patient pool, and an approach by which feasibility is systematically investigated, hold the promise to enhance the effectiveness of scarce resources applied to palliative and end-of-life research.

Strengths

- Detailed description of barriers in conducting palliative care research
- Novel taxonomy for estimating clinical trial recruitment and feasibility, specific to palliative care
- Illustration of taxonomy, using four palliative care studies
- Practical framework using standard terminology

Weaknesses

- Examples limited to two validation studies, open-label clinical trial (novel route of administration for opioid) and randomized double-blind trial (novel analgesic and placebo control)
- Insufficient information provided regarding eligibility criteria and types of settings from which patients were being recruited

Relevance to Palliative Care

There are substantial challenges in conducting and completing palliative care research, due to difficulties in patient recruitment and significant drop-out rates. This proposed taxonomy offers a practical, standard framework for designing palliative care studies, including estimating the target population, establishing accrual targets and implementing appropriate interventions if study targets are not feasible.