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Nursing's Focal Points

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Effective Strategies for Implementing a Multicenter International Clinical Trial

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Purpose

International collaboration in research is essential in order to improve worldwide health. The purpose of this paper is to describe strategies used to administer an international multicenter trial to assess the effectiveness of a nursing educational intervention.

Design

The study design was a two-group randomized multicenter international clinical trial conducted to determine whether a brief education and counseling intervention delivered by a nurse could reduce prehospital delay in the event of symptoms suggestive of acute coronary syndrome (ACS) in patients previously diagnosed with cardiovascular disease.

Method

A flexible but well-defined project structure showed intervention consistency in five sites among three countries and included experienced project coordinators, multidimensional communication methods, strategies to optimize intervention fidelity, site-specific recruitment and retention techniques, centralized data management, and consideration of ethical and budgetary requirements.

Findings

Staff at five sites enrolled 3,522 participants from three countries and achieved 80% follow-up obtained at both 12 and 24 months.

Clinical Relevance

In order to support appropriate development of an evidence base for practice, nursing interventions should be tested in multiple settings. A range of strategies is described in this paper that proved effective in conducting a multicenter international trial.

Conclusions

Multidimensional approaches to maintain consistency across study sites, while allowing flexibility to meet local expectations and needs, contributed to the success of this trial.

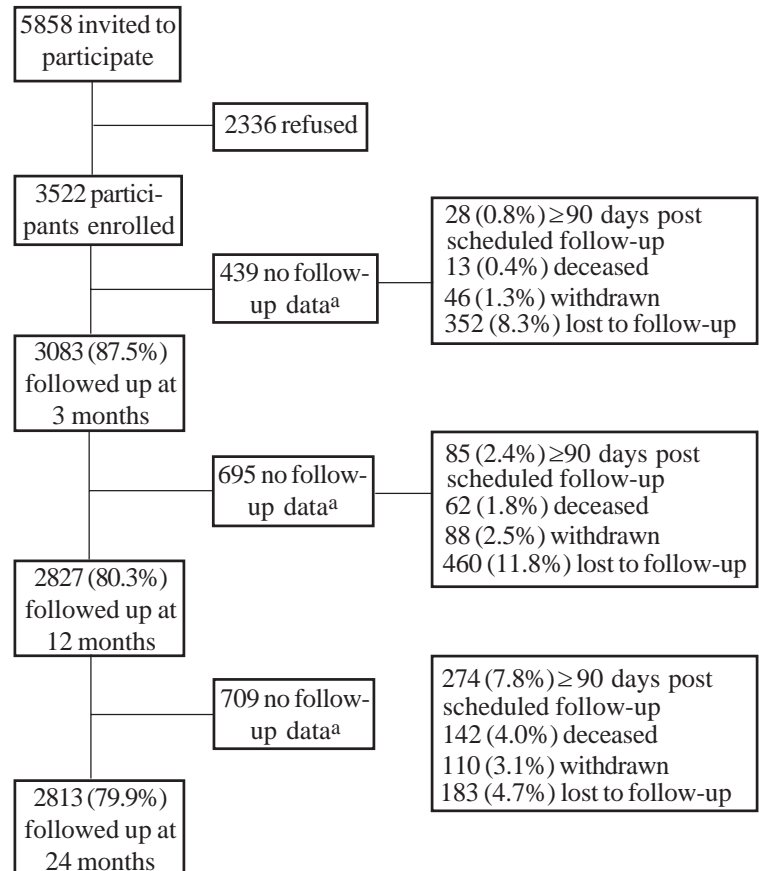
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Figure: Recruitment and follow-up of participants

Patients intermittently had no follow-up data, for example, they may have missed 3 month follow-up but were contacted for 12 month follow-up, therefore these numbers are not cumulative.



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