Trial Design

Rationale and design of a cluster randomized trial of a multifaceted intervention in people with hypertension: The Heart Outcomes Prevention and Evaluation 4 (HOPE-4) Study

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ABSTRACT

Background: Cardiovascular disease is the leading cause of death throughout the world, with the majority of deaths occurring in low- and middle-income countries. Despite clear evidence for the benefits of blood pressure reduction and availability of safe and low-cost medications, most individuals are either unaware of their condition or not adequately treated.

Objective: The primary objective of this study is to evaluate whether a community-based, multifaceted intervention package primarily provided by nonphysician health workers can improve long-term cardiovascular risk in people with hypertension by addressing identified barriers at the patient, health care provider, and health system levels.

Methods: HOPE-4 is a community-based, parallel-group, cluster randomized controlled trial involving 30 communities (1,376 participants) in Colombia and Malaysia. Participants ≥50 years old and with newly diagnosed or poorly controlled hypertension were included. Communities were randomized to usual care or to a multifaceted intervention package that entails (1) detection, treatment, and control of cardiovascular risk factors by nonphysician health workers in the community, who use tablet-based simplified management algorithms, decision support, and counseling programs; (2) free dispensation of combination antihypertensive and cholesterol-lowering medications, supervised by local physicians; and (3) support from a participant-nominated treatment supporter (either a friend or family member). The primary outcome is the change in Framingham Risk Score after 12 months between the intervention and control communities. Secondary outcomes including change in blood pressure, lipid levels, and Interheart Risk Score will be evaluated.

Significance: If successful, the study could serve as a model to develop low-cost, effective, and scalable strategies to reduce cardiovascular risk in people with hypertension.

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Background

Cardiovascular disease (CVD) is the major cause of mortality and morbidity globally and affects half of all individuals over their lifetimes. Despite large reductions in age-adjusted mortality in many high-