A Cluster Randomized Controlled Trial to Evaluate The Effect of a Simplified Multifaceted Management Program in High Cardiovascular Disease Risk Patients in Rural China and India: Simcard Study

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Background: Cardiovascular disease (CVD) is the leading cause of death in China and India. Access to appropriate healthcare remains limited in resource poor settings in these areas, where CVD burdens are high.

Objective: This study aims to develop and evaluate a simplified multifaceted guideline-based CVD management program delivered by the community health workers (CHWs) and targeting high CVD risk subjects.

Methods: This study is a cluster randomized trial conducted in 47 rural villages (23 intervention vs 24 control villages) in Tibet, China and Haryana, India. High CVD risk subjects (aged 40 years or older, history of heart disease, stroke, diabetes, or measured systolic blood pressure of 160mmHg or higher) were screened and recruited. CHWs in the intervention villages were trained and assisted by a customized smartphone or tablet based electronic decision support system (EDSS) to follow-up and manage their patients on a periodic basis following a ‘2+2’ multifaceted intervention model: two lifestyle modifications (smoking cessation and sodium reduction) and appropriate prescription of anti-hypertensive medication and aspirin. Villages in the control group continued their usual practice. The primary outcome is the net between-group difference in the proportion of patients taking anti-hypertensive medication and aspirin. Villages in the control group continued their usual practice. The primary outcome is the net between-group difference in the proportion of patients taking anti-hypertensive medication pre-and-post intervention after one year. The proportion of patients taking aspirin and changes in blood pressure will also be examined. These outcomes will be analysed according to
intent-to-treat principle by logistic-binomial or generalized linear models with random effects to account for clustering effect and repeated measurements.

**Results:** 12596 subjects were screened at baseline, and 2086 subjects (16.6%) were identified as high CVD risk (age: 60.0±11.7 years; 65.3% women). 80 people died during the course of the intervention and 1828 were followed-up at the end of the intervention. Data cleaning and analysis are in progress. Results will be reported at the meeting.

**Conclusions:** To our knowledge, this is the first study to evaluate the effect of a simplified management scheme delivered by CHWs with the help of EDSS on improving the health of high CVD risk patients.

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