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THE DESIGN AND RATIONALE OF A CLUSTER RANDOMIZED TRIAL TESTING THE EFFECT OF A COLLABORATIVE CARE INTERVENTION ON METABOLIC RISK FACTORS AND CARDIOVASCULAR EVENTS: DIABETES COMPLICATION CONTROL IN COMMUNITY CLINICS (D4C) TRIAL

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Most patients with diabetes have multiple uncontrolled metabolic risk factors. The overall objective of this cluster randomized trial is to test whether a collaborative care intervention will improve metabolic risk factors (glycated haemoglobin [HbA1C], systolic blood-pressure [SBP], and LDL-cholesterol) over 18 months (primary outcome in phase 1) and reduce major cardiovascular disease (CVD) over 3 years (primary outcome in phase 2) among patients with type-2 diabetes and increased CVD risk in China. The collaborative care intervention will be delivered by a team of primary care physicians, health managers, and nurses supported by diabetes specialists. The multicomponent interventions include health coaching for lifestyle modification and medication adherence and a decision support system using a stepped-care protocol for managing diabetes, hypertension, and dyslipidaemia based on clinical guidelines. The D4C trial will recruit 11,780 patients with diabetes and increased CVD risk from 38 community clinics in Xiamen, China. Nineteen clinics with approximately 310 patients each will be randomly assigned to intervention and 19 clinics to control. Study outcomes will be obtained at follow-up visits every 6 months. The D4C trial is designed to provide 90% statistical power to detect a 3.6% reduction in the combined changes in HbA1C, SBP, and LDL-cholesterol levels in phase 1 and a 20% reduction in major CVD in phase 2 at a significance level of 0.05 for a two-sided test. This trial will generate important data on an effective, practical and sustainable intervention program aimed at reducing the CVD burden among diabetes patients in populations with health disparities.

Biography

Jiang He is a professor and Joseph Copes Chair of Epidemiology at the Tulane University School of Public Health and Tropical Medicine. He is also the Director of the Tulane University Translational Science Institute in New Orleans. He is an internationally well-known expert in the clinical, translational, and epidemiological research of cardio-metabolic diseases. He has conducted novel, NIH-funded studies in obesity, hypertension, diabetes, stroke, and cardiovascular disease. He has been the principal investigator and co-investigator for more than 30 major research awards from the NIH. Additionally he has authored more than 400 scientific articles which have been published in high-impact biomedical journals

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