Control of Blood Pressure and Risk Attenuation-Post Trial Follow-up (COBRA STUDY)

Department: Community Health Sciences **Project Sponsors:** Wellcome Trust, UK

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Cardiovascular disease (CVD) has become the leading cause of mortality worldwide, accounting for 30% of deaths annually in low and middle income countries. High BP confers the highest attributable risk to death and disease associated with CVD.

The post-trial follow-up of COBRA participants (Wellcome Trust funded population based cluster randomized trial conducted during 2004 – 2007) will provide valuable insights on the presence of sustained benefit of interventions after their discontinuation. This information will be the key for up-scaling a national programme modeled on similar interventions for Pakistan and potentially scalable in neighboring countries.

Aims of the project:

To determine the sustained impact of HHE and annual GP training, alone and in combination, at 7 years, including 4 years of post-intervention follow-up on:

a) Primary

- i. BP levels of all participants.
- ii. Cardiovascular morbid events and all-cause mortality in the high risk cohort

b) Secondary

- i. behavioral risk factors including diet, physical activity, weight and tobacco use in all trial participants
- ii. Clinical risk factors for CVD including plasma glucose and lipids, and albuminuria in the high risk cohort.
- iii. Left ventricular (LV) mass index and diastolic dysfunction in the high risk cohort

Methods:

All participants in the trial will be visited by trained field staff masked to randomization status. Information on socioeconomic status, diet, physical activity, and tobacco use would be collected; and anthropometric indices and BP would be measured. In addition, a questionnaire on health related quality of life will be administered to all subjects aged 40 and over with hypertension. Moreover, echocardiograms will be performed and the blood and urine samples will be collected from these patients.

Outcome measures:

Primary:

- i. Change in systolic BP from baseline to mean of two post trial follow-up visits.
- ii. Composite of CVD morbid events and all-cause mortality

Secondary:

• Change from baseline to post trial follow-up in the following: body mass index (BMI), waist hip ratio, current tobacco use, total physical activity, and dietary intake of fruit and vegetables