HOPE 4:

Heart Outcomes Prevention and Evaluation 4 Study

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Declaration of interest

- I have nothing to declare

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  - Population Health Research Institute, HHS Research Institute
  - Faculty of Medicine, Universiti Teknologi MARA, Selayang
  - Santander Departmental Secretary of Health

Background

- Hypertension is the leading cause of cardiovascular disease (CVD) worldwide/ There is clear evidence that lowering BP will reduce CVD and mortality.
- Yet, hypertension detection, treatment, and control is low globally.
- Combination of 2 or more low-dose antihypertensives is more effective and has less adverse effects than a high dose single agent
- Statins reduce CVD in hypertension (ASCOT, HOPE 3) but use is very low (<5%)
- *Combined BP + LDL lowering has the potential to reduce CVD events by >50%*

Goals of the HOPE 4 Program

- Improving the control of hypertension and cardiovascular risk factors in people with hypertension in the community:

  Step 1: Identified *contextual barriers* to hypertension management through systematic reviews and health system appraisals in Colombia and Malaysia. (Khatib 2014 Risso-Gill 2015, Legido-Quigley H 2015, Maimarisl. 2013)

  Step 2: Developed a community-based comprehensive intervention informed by Step 1

  Step 3: Evaluation in a cluster-randomized controlled

HOPE 4 Intervention

Barriers

Patient:
- Conflicting knowledge/beliefs, high costs
- Challenging to implement treatment plans

Health Care Provider:
- Limited time and resources of physicians
- Treatment inertia
- Low use of ≥ 2 antihypertensives and statin

Health System:
- Fragmented care
- Availability of medications
- Costs/Travel/Access to care

Intervention

Task Sharing with NPHW:
- Community-based identification and treatment of HTN and CV risk factors
- Tablets with counselling and simplified management algorithms
- Supervised by primary care physicians

Provision of Free CV Medications:
- Combination antihypertensives (2 of ACEI/ARB/CCB/HCTZ)
- Statin (atorvastatin 20mg or rosuvastatin 10 mg)

Enhancing Adherence
- Family/friends (Treatment Supporters)

Non-Physician Health Worker Curriculum

- Developed, tested, and implemented a one-week training curriculum for NPHW on CVD risk assessment and management

- The HOPE-4 curriculum has been adapted to the WHO's HEARTS Technical Package(2016) to improve management of CVD in primary health care

Modules
1. Health and Disease
2. Organization and Communication Skills
3. The Cardiovascular (CV) System
4. Risk Factors for Cardiovascular Disease
5. CV Risk Assessment
6. CV Risk Prevention & Treatment
7. Pharmacological Management of CVD
8. Country Specific Training
9. Clinical Evaluation

Khan. Global Heart 2017

HOPE 4 Study

1) STUDY DESIGN

- Parallel-group, cluster-randomized controlled trial
- 30 urban and rural communities from Colombia and Malaysia
- Communities randomized to usual care or a comprehensive CVD risk detection and management program for 12 months

2) STUDY PARTICIPANTS

- ≥ 50 years: new or uncontrolled hypertension (SBP > 140 mmHg)

Study Outcomes (12 months)

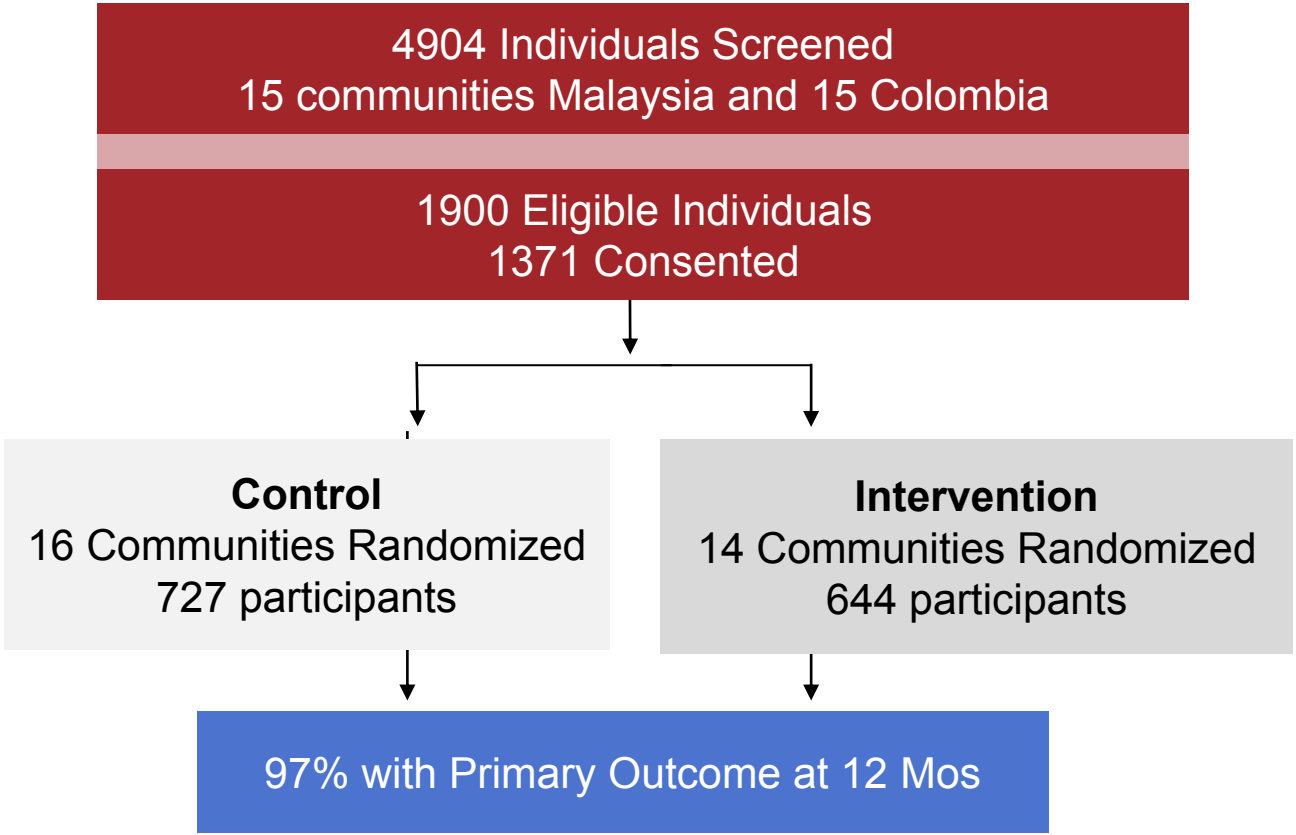
1) Primary

- Mean difference in change in Framingham Risk Score (FRS) between intervention and control

2) Other Outcomes (Difference in Changes)

- SBP between the intervention and control
- Proportion of participants with well-controlled SBP (SBP < 140 mmHg)
- LDL, total cholesterol, and glucose levels
- Smoking and other health behaviours

Study Profile



Characteristics of Communities

Factors	Control	Intervention
Communities	16	14
Population of Communities (Thousands-mean)	56.9	58.3
Age ≥ 50 Years (%)	25.9	23.3
Female (%)	50.7	49.4
Distance from Coordinating Centre (km-mean)	68.4	68.3
Number of Clinics (mean)	6.9	6.6
Number of Hospitals (mean)	1.5	1.5

Characteristics of Participants

Characteristics	Control	Intervention
Randomized	727	644
Mean Age (Yrs)	66	65
% Women	54	58
% Smoker	9	8
% Diabetes	37	32
% Hypertension & taking antihypertensives	61	69
% Two or More Antihypertensives	21	24
% Newly diagnosed Hypertension	22	25
SBP/DBP (mmHg)	Mean	
	152/85	152/85
Total Cholesterol (mmol/L)	5.4	5.4
LDL (mmol/L)	3.4	3.3
Glucose (mmol/L)	6.8	6.5

Implementation of the Intervention

A) Agreement between NPHW and Physicians:

- Cardiovascular Risk Assessment: 99%
- Contraindications to CV Medications: 98%
- Treatment Recommendations: 93%

B) Follow-up and Treatment supporters:

- Participants attended 94% of scheduled NPHW visits
- Treatment Supporter present at 74% of visits
  - Family members (93%) , other individual (7%)

Medication and Adherence at 12 Months

	Characteristics	Control	Intervention	P Value
	Randomized	727	644	
Medications (%)	≥ 2 Antihypertensives	65	84	P<0.0001
	Statins	38	84	P< 0.0001

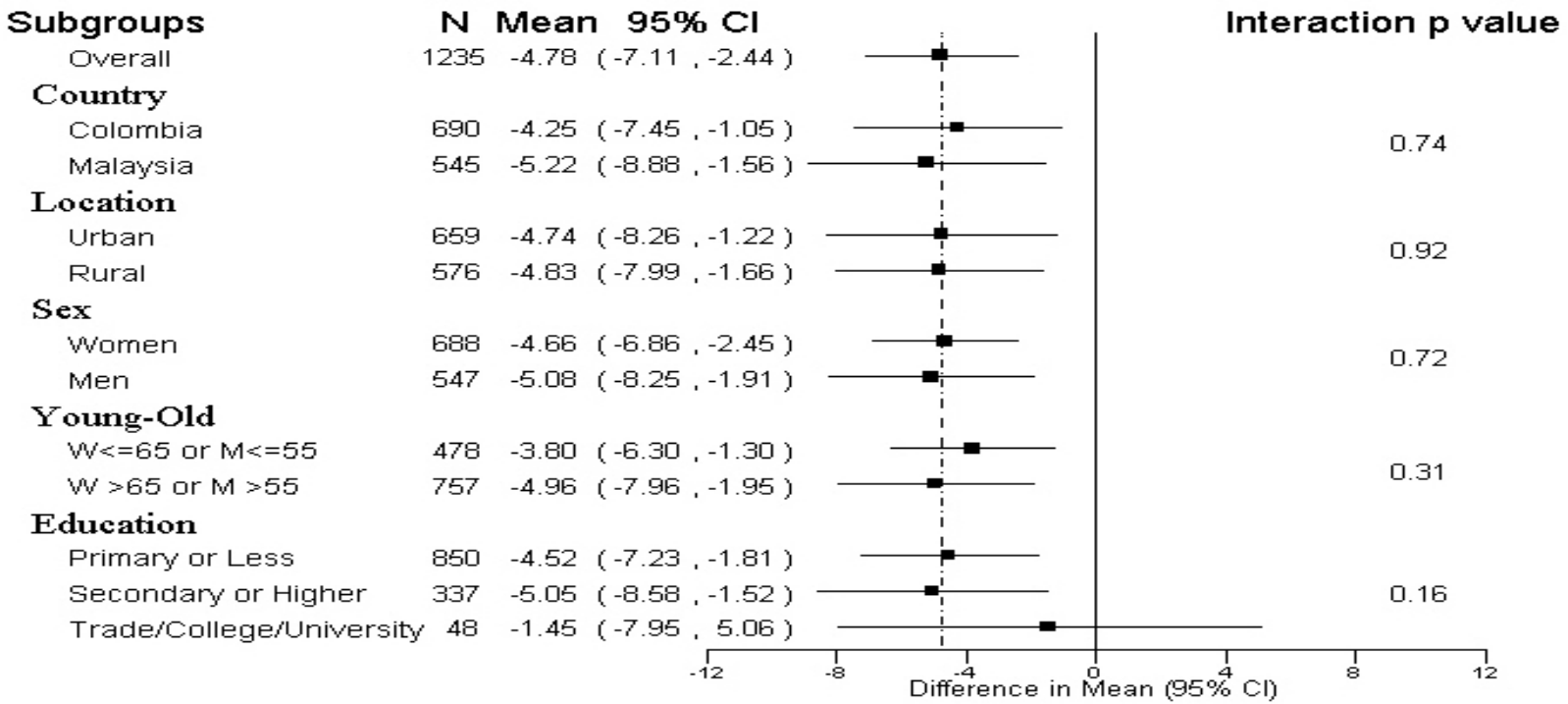
- Medication adherence to antihypertensives was 50% greater in the intervention group, P < 0.0001.

1º and 2º Outcomes at 12 Months

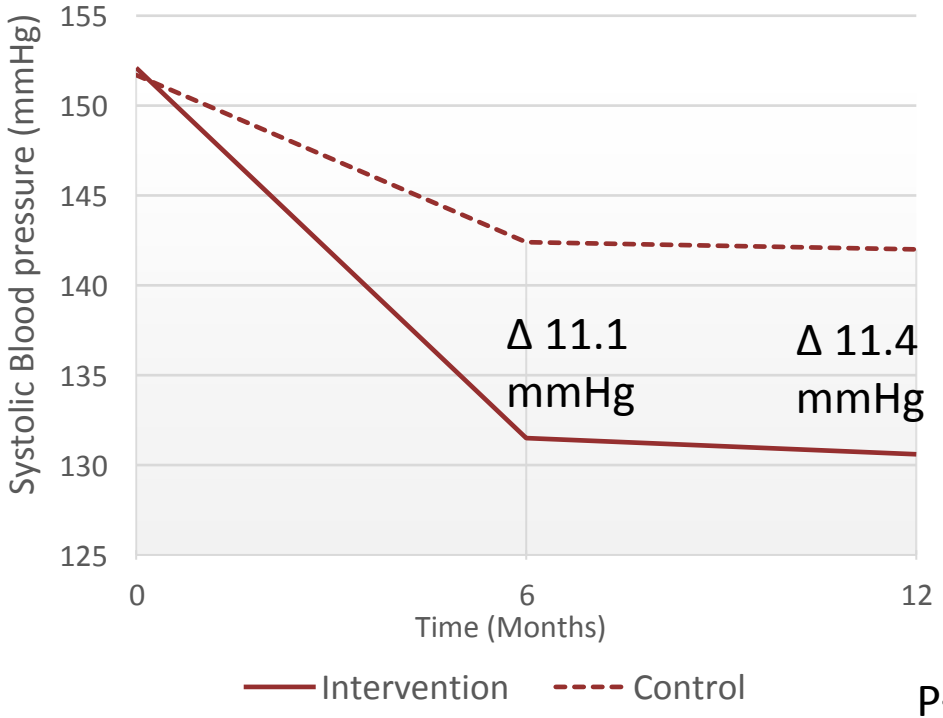
Outcome	Baseline		Change at 12 Months from Baseline		Difference in Change (Intervention- Control)	P-Value
	Control (n = 727)	Intervention (n = 644)	Control (n = 692)	Intervention (n = 607)		
FRS 10-Year Risk (%)	35.5	32.6	-6.40	-11.17	-4.78	<0.0001
LDL (mmol/L): Mean	3.4	3.3	-0.19	-0.60	-0.41	<0.0001
SBP (mmHg): Mean	151.8	152.05	-9.7	-21.1	-11.4	<0.0001
DBP (mmHg): Mean	85.3	84.72	-2.9	-6.9	-4	<0.0001
SBP < 140mmHg: %*	17.2	11.5	30.4	68.9	+38.5	<0.0001

*Controlled systolic blood pressure at 12 months: 48% control and 80% intervention

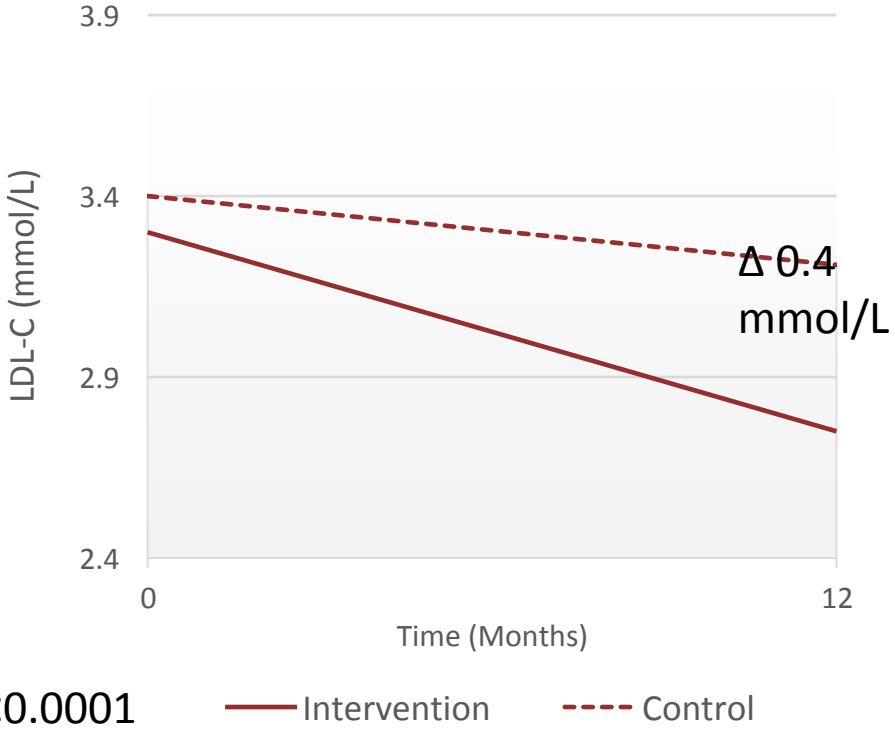
Subgroup Analysis of the Primary Outcome (FRS)



Change in: (1) SBP



(2) LDL



2º and 3º Outcomes at 12 Months

Outcome*	Change at 12 Months From Baseline		Intervention vs Control at 12 Months
	Control (n = 692)	Intervention (n = 607)	P-Value
Non-Lab-Based INTERHEART Risk Score	-1.9	-4.9	<0.0001
Physically Active: %	20.2	23.0	0.0467
Daily Vegetables: %	7.3	15.4	0.0070
Daily Fruits: %	6.6	21.6	0.0910
Daily Salty Foods: %	-7.9	-14.6	0.0275
Fried/Fast Food ≥ 3/Week: %	6.9	-2.7	0.0786
Daily Meat/Poultry: %	0.1	-6.0	0.1061

*No Change in smoking, weight, stress or depression

Conclusion

- A comprehensive model of care led by NPHWs, guided by algorithms on a tablet, involving primary care physicians and family, along with the provision of free antihypertensive drugs and a statin, substantially improved CVD risk and blood pressure.

- Success of the HOPE 4 NPHW-led strategy:
  1. Simultaneously addressed multiple barriers to CVD risk
  2. Community-based intervention adapted to local context
  3. Reinforcing adherence with treatment supporters
  4. Comprehensive intervention with computer-based algorithms

Implications

- Adaptation of the HOPE 4 strategy to specific contexts and their widespread implementation, including community screening, can achieve the United Nations General Assembly Action Plan for a one-third reduction in premature mortality from CVD

Today in *The Lancet*

A community-based comprehensive intervention to reduce cardiovascular risk in hypertension (HOPE 4): a cluster randomised controlled trial

Jon-David Schwalm, Tara McCready, Patricio Lopez-Jaramillo, Khalid Yusoff, Amir Attaran, Pablo Lamelas, Paul A Camacho, Fadhlina Majid, Shrikant I Bangdiwala, Lehana Thabane, Shofiqul Islam, Martin McKee, Salim Yusuf