

# *Effectiveness of mHealth Based Decision Support System for Integrated Management of Chronic Conditions in Primary Care: The mWellcare Trial*



**SCIENTIFIC 20**  
**SESSIONS 18**

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**On behalf of mWellcare Trial investigators**



# Disclosures

## **Grants:**

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## **Copyright:**

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# Background

- **Chronic diseases and their risk factor burden is high in India and worldwide**
- **Shortage of skilled healthcare providers impose huge constraints on healthcare services in India particularly in the prevention and management of Chronic Diseases**
- **Innovative strategies such as electronic clinical decision support (EDS) and task sharing for integrated, multiple chronic condition management in primary care have not been evaluated.**

# Methods

**Study design** : Cluster-randomized controlled clinical trial

**Duration** : April 2016 to September 2017

**Study setting** : 20 Community Health Centres each in Haryana (North India) and Karnataka (South India)

**Participants** : Age  $\geq 30$  years, diagnosed with:

Hypertension [with SBP  $\geq 140$  mmHg and/or DBP  $\geq 90$  mmHg]

OR

Type-2 diabetes [fasting blood glucose  $\geq 140$ mg/dL and/or post-prandial blood glucose  $\geq 200$ mg/dL]

**Total participants enrolled: 3698**

# mWellcare System

- An Android application, on a tablet computer
- Ability to generate tailored management plan for hypertension, diabetes and comorbid depression, alcohol and tobacco use
- Capability to store health records electronically, enabling long-term monitoring and follow-up

CHC: Test CHC 1

**mWellcare**

Date: 2017-01-11

<b>A. Patient</b> Male 52 years	Address: Near temple, Mullana, Ambala, Haryana 133203 Phone: 1234567890	Patient ID: ZZ0099B0052
<b>Diagnosis:</b> Hypertension, Diabetes <b>Medical History:</b> Stroke or Paralytic Attack		

**Patient History**

Date	2017-01-11	2016-12-01			
SBP	162	164			
DBP	100	102			
Weight	84	86			
BMI	26.51	27.14			
FBS	80	160			
PPBS	120	220			
RBS					
Depression		None			
Alcohol Use		No			
Tobacco	Yes	Yes			

**Current Medication**

Enalapril 5 mg  
Metformin 500 mg

**Previous Prescription**

Enalapril 5 mg  
Metformin 500 mg  
None

**Treatment**

**Next Visit:** 2017-02-08

Side effects of current medication:  Yes  No

*Preferable to prescribe the drug recommended by DSR but doctor may select other classes of drug if recommended drug is not available.*

Recommendation (DSR) for	Agree?	Reason (if not agreed)	New Drug Treatment Plan
<b>Hypertension:</b> Add Hydrochlorthiazide 12.5 mg+ Statin (Atorvastatin 20 mg or Rosuvastatin 10 mg)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Recommended drugs not available <input type="radio"/> No drug recommended <input type="radio"/> Other: _____	
<b>Diabetes:</b> Continue with existing regimen.	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Recommended drugs not available <input type="radio"/> No drug recommended <input type="radio"/> Other: _____	
<b>Depression:</b> N/A.	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Recommended drugs not available <input type="radio"/> No drug recommended <input type="radio"/> Other: _____	
<b>Alcohol Use Disorder:</b> N/A.	<input type="radio"/> Yes <input type="radio"/> No		

Referral for:  None  Hypertension  Diabetes  Depression  Alcohol Use Disorder

Lifestyle advices:  Physical Activity  Healthy Diet  Medicine Adherence  Alcohol Counseling  Tobacco Cessation

# Comparison of mWellcare and EUC

mWellcare arm	Enhanced usual care arm
<b>Training of Physicians &amp; NCD Nurses</b> <ul style="list-style-type: none"><li>• Clinical management guidelines</li><li>• Using the mWellcare system</li></ul>	<b>Training of Physicians</b> <ul style="list-style-type: none"><li>• Clinical management guidelines</li></ul>
<b>Charts on clinical management guidelines</b>	<b>Charts on clinical management guidelines</b>
<b>Physician either agreed with DSR or modified the treatment plan</b>	<b>Physicians managed patients based on their clinical judgement</b>
<b>NCD nurse provided lifestyle advice using the DSR prompts and pamphlets</b>	<b>NCD nurse provided lifestyle advice using pamphlets</b>
<b>Every visit detail recorded in the mWellcare system to generate longitudinal trend/summary</b>	<b>NCD nurse maintained registers for recording clinical parameters</b>
<b>SMS reminders for follow-up and medication adherence</b>	<b>No SMS reminders</b>

# Outcomes

## Primary Outcomes

Between-group differences in mean change in (from baseline to one year):

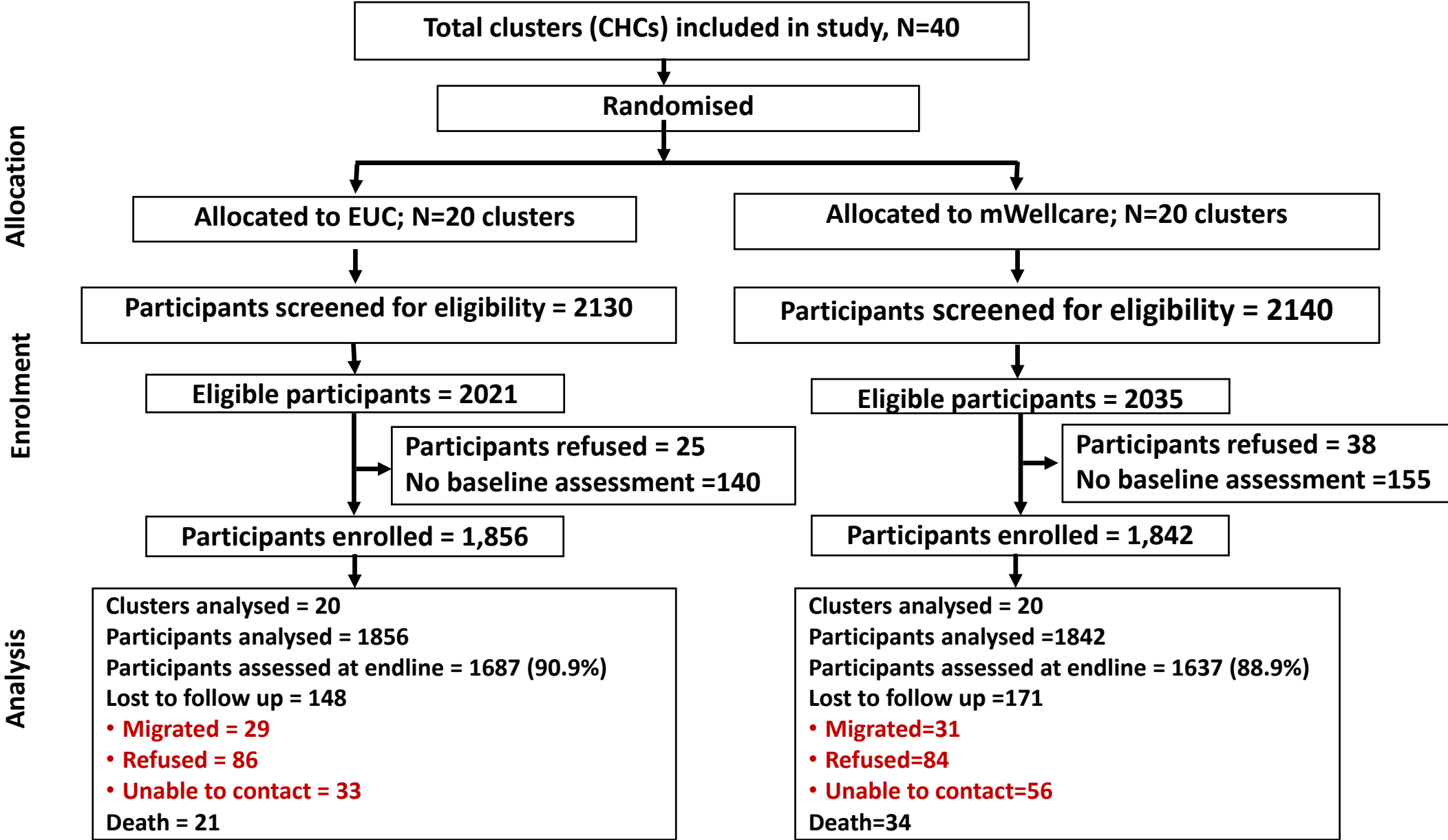
- SBP among participants with hypertension
- HbA1c among participants with diabetes

## Secondary outcomes

Between-group difference in mean change in (from baseline to one year):

- fasting plasma glucose
- total cholesterol
- predicted 10-year risk of CVD using recalibrated Framingham risk score
- tobacco use
- body mass index
- alcohol use
- depression score - measured only at the end of study evaluation
- alcohol use score - measured only at the end of study evaluation

# Consort flow chart : Analysis ITT





# Baseline characteristics of key variables

Baseline characteristics	EUC arm (N=1856)	mWellcare arm (N=1842)	Standardized mean difference
Participants with hypertension, N (%)	932 (50.2)	906 (49.2)	-0.021
Participants with diabetes, N (%)	625 (33.7)	683 (37.1)	0.071
Participants with both conditions, N (%)	299 (16.1)	253 (13.7)	-0.067
Age, mean (SD)	54.5(10.9)	55.8(11.0)	0.086
Male, N (%)	985 (53.1)	1056 (57.3)	0.159
Current tobacco user, N (%)	325 (17.5)	184 (10.0)	-0.152
Current alcohol user, N (%)	229 (12.3)	143 (7.8)	0.222
BMI (Kg/m <sup>2</sup> ), mean (SD)	25.8 (4.6)	26.0 (4.7)	0.031
SBP (mmHg), mean (SD)	157.0 (16.3)	152.5 (14.7)	-0.238
DBP (mmHg), mean (SD)	93.3 (10.0)	88.8 (10.8)	-0.331
Fasting blood glucose (mg/dl), mean (SD)	197.7 (67.0)	185.9 (60.5)	-0.21
Hemoglobin A1c (%), mean (SD)	9.3 (2.4)	9.5 (2.2)	0.049
Total cholesterol (mg/dl), mean (SD)	191.8 (44.8)	194.5 (45.0)	0.061
CVD risk score (%), mean (SD)	41.0 (21.9)	38.5 (20.2)	-0.120

***EUC arm had higher proportion of participants with tobacco use, alcohol use, and SBP***

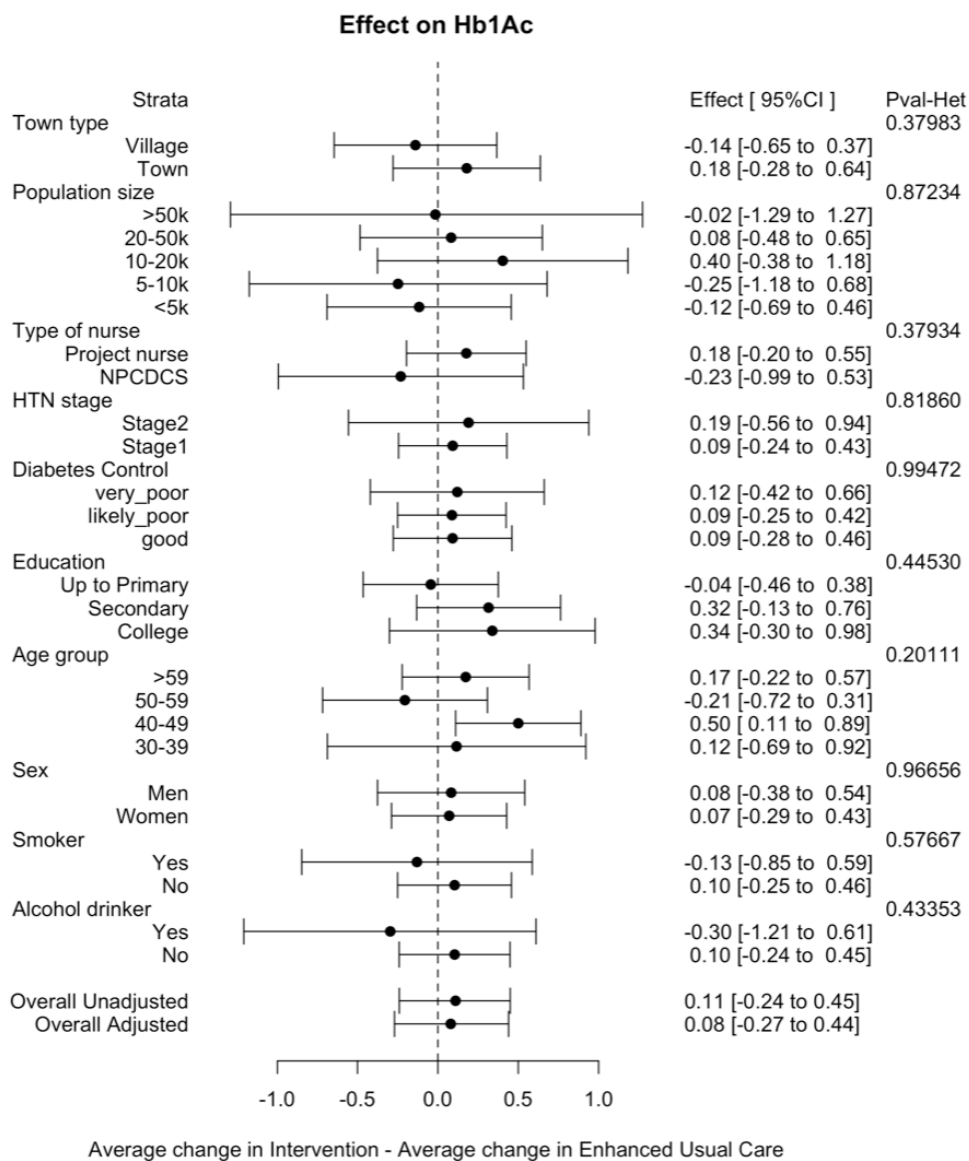
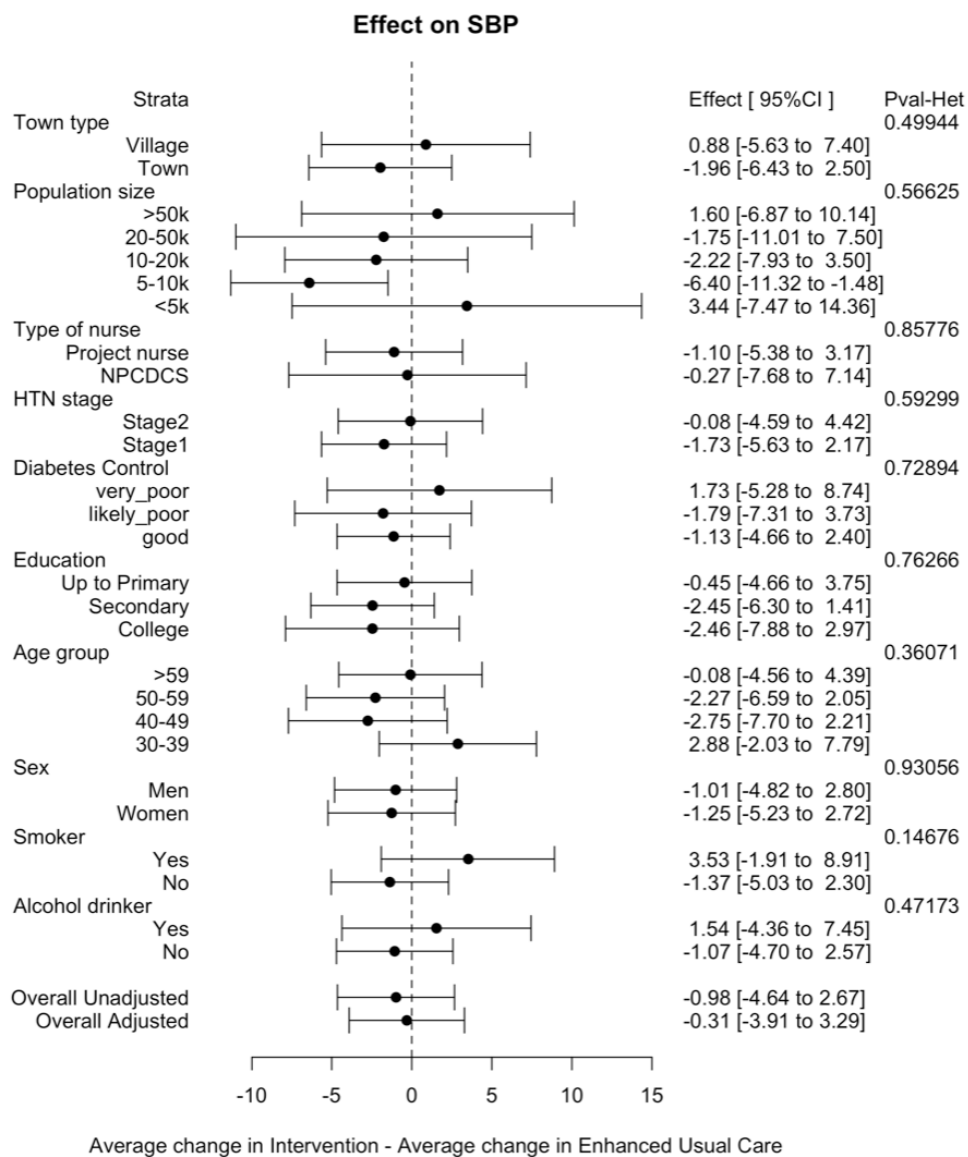
# Primary outcomes

Change in parameters	Mean change		Unadjusted		Adjusted *	
	EUC arm	mWellcare arm	Effect size (95%CI)	P-value	Effect size (95%CI)	P-value
SBP (mmHg)	-12.7	-13.7	-1.0 (-4.6 to 2.7)	0.607	-0.3 (-3.9 to 3.3)	0.869
HbA1c (%)	-0.58	-0.48	0.11 (-0.24 to 0.45)	0.563	0.08 (-0.27 to 0.44)	0.660

\* SBP: adjusted for education, lipid lowering drugs, aspirin use, PVD and smoking status

\* HbA1c: adjusted for age, employment, anti-hyperglycemic drugs, PVD and alcohol use

# Primary outcomes by baseline subgroups



# Secondary outcomes

Variable	Mean change		Unadjusted		Adjusted*	
	EUC arm	mWellcare arm	Effect size (95%CI)	P-value	Effect size (95%CI)	P-value
Fasting blood glucose (mg/dl) ‡‡	-22.7	-15.0	7.7 (-10.3 to 25.6)	0.416	8.4 (-9.6 to 26.5)	0.372
Total cholesterol (mg/dl)	2.0	0.1	-1.8 (-6.3 to 2.7)	0.444	-2.5 (-7.1 to 2.0)	0.292
CVD risk score (%)	0.6	2.4	1.7 (-0.8 to 4.3)	0.196	-0.4 (-2.3 to 1.5)	0.658
BMI (Kg/m <sup>2</sup> )	0.08	0.16	0.07 (-0.37 to 0.52)	0.749	-0.05 (-0.47 to 0.37)	0.823
Change in tobacco use (%)	-7.0	-6.0	0.9 (-3.2 to 5.0)	0.649	-0.8 (-5.7 to 4.2)	0.756
Change in alcohol use (%)	-3.8	-2.4	1.4 (-2.6 to 5.4)	0.480	0.7 (-3.7 to 5.1)	0.741
<b>Variables assessed only at endline</b>						
Alcohol use score	10.0	9.4	-0.6 (-3.3 to 2.0)	0.642	-0.6 (-3.2 to 2.1)	0.683
Depression score	12.4	10.9	-1.4 (-4.2 to 1.4)	0.335	-1.6 (-4.4 to 1.2)	0.276

\* Each outcome was adjusted for a different set of variables; ‡ N=participants with diabetes; # Using capillary blood

# Summary of the Findings and the factors influencing the results

- **We did not find an incremental benefit of mWellcare over enhanced usual care in the management of the chronic conditions studied.**
- **Major factors that might have influenced the results:**
  - **presence of NCD nurses in both arms**
  - **training of nurses and physicians in the EUC arm**
  - **charts on treatment algorithms in the EUC arm**
  - **research team advocating improved drug availability**
  - **“Hawthorne effect” due to the open-label nature of the trial**

# Lessons and implications of this Study

- **Demonstrates the feasibility of an ambitious multifactorial EHR and EDS-based mHealth intervention across multiple sites at the primary care level using available trained staff.**
- **The overall null result, likely due to benefits achieved in the “enhanced usual care” arm emphasizes the potential value of leveraging non-physician providers and improving access to needed medications**
- **Highlights the role of task shifting and the primacy of primary health care in the management of NCD risk factors**
- **National health policy makers in low-and-middle income countries, including India, can use this information to inform decisions surrounding rollout of widespread public health interventions.**

Circulation

ORIGINAL RESEARCH ARTICLE



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Decision Support System for Integrated  
Management of Chronic Conditions in Primary Care**

**The mWellcare Cluster-Randomized Controlled Trial**

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## Members of the Research Steering Committee:

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*THANK YOU!*



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