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

Dorairaj Prabhakaran, MD, DM, MSc, FRCP, FNASc
Centre for Control of Chronic Conditions
Public Health Foundation of India, India

On behalf of mWellcare Trial investigators
Disclosures

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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 ≥30 years, diagnosed with:
- Hypertension [with SBP ≥140 mmHg and/or DBP ≥90 mmHg]
- OR
- Type-2 diabetes [fasting blood glucose ≥140mg/dL and/or post-prandial blood glucose ≥200mg/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

Glob Health Action. 2018;11:1517930
## Comparison of mWellcare and EUC

<table>
<thead>
<tr>
<th>mWellcare arm</th>
<th>Enhanced usual care arm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training of Physicians &amp; NCD Nurses</strong></td>
<td>Training of Physicians</td>
</tr>
<tr>
<td>• Clinical management guidelines</td>
<td>• Clinical management guidelines</td>
</tr>
<tr>
<td>• Using the mWellcare system</td>
<td></td>
</tr>
<tr>
<td><strong>Charts on clinical management guidelines</strong></td>
<td>Charts on clinical management guidelines</td>
</tr>
<tr>
<td><strong>Physician either agreed with DSR or modified</strong></td>
<td>Physicians managed patients based on their clinical judgement</td>
</tr>
<tr>
<td>the treatment plan</td>
<td></td>
</tr>
<tr>
<td><strong>NCD nurse provided lifestyle advice using the</strong></td>
<td>NCD nurse provided lifestyle advice using pamphlets</td>
</tr>
<tr>
<td>DSR prompts and pamphlets</td>
<td></td>
</tr>
<tr>
<td><strong>Every visit detail recorded in the mWellcare</strong></td>
<td>NCD nurse maintained registers for recording</td>
</tr>
<tr>
<td>system to generate longitudinal trend/summary</td>
<td>clinical parameters</td>
</tr>
<tr>
<td><strong>SMS reminders for follow-up and medication</strong></td>
<td>No SMS reminders</td>
</tr>
<tr>
<td>adherence</td>
<td></td>
</tr>
</tbody>
</table>
Outcomes

Primary Outcomes
Between-group differences in mean change in (from baseline to one year):
  o SBP among participants with hypertension
  o HbA1c among participants with diabetes

Secondary outcomes
Between-group difference in mean change in (from baseline to one year):
  o fasting plasma glucose
  o total cholesterol
  o predicted 10-year risk of CVD using recalibrated Framingham risk score
  o tobacco use
  o body mass index
  o alcohol use
  o depression score - measured only at the end of study evaluation
  o alcohol use score - measured only at the end of study evaluation
Consort flow chart: Analysis ITT

Total clusters (CHCs) included in study, N=40

Randomised

Allocated to EUC; N=20 clusters

Participants screened for eligibility = 2130

Eligible participants = 2021

Participants refused = 25
No baseline assessment = 140

Participants enrolled = 1,856

Clusters analysed = 20
Participants analysed = 1856
Participants assessed at endline = 1687 (90.9%)
Lost to follow up = 148
  • Migrated = 29
  • Refused = 86
  • Unable to contact = 33
  Death = 21

Allocated to mWellcare; N=20 clusters

Participants screened for eligibility = 2140

Eligible participants = 2035

Participants refused = 38
No baseline assessment = 155

Participants enrolled = 1,842

Clusters analysed = 20
Participants analysed = 1842
Participants assessed at endline = 1637 (88.9%)
Lost to follow up = 171
  • Migrated = 31
  • Refused = 84
  • Unable to contact = 56
  Death = 34
### Baseline characteristics of key variables

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>EUC arm (N=1856)</th>
<th>mWellcare arm (N=1842)</th>
<th>Standardized mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants with hypertension, N (%)</td>
<td>932 (50.2)</td>
<td>906 (49.2)</td>
<td>-0.021</td>
</tr>
<tr>
<td>Participants with diabetes, N (%)</td>
<td>625 (33.7)</td>
<td>683 (37.1)</td>
<td>0.071</td>
</tr>
<tr>
<td>Participants with both conditions, N (%)</td>
<td>299 (16.1)</td>
<td>253 (13.7)</td>
<td>-0.067</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>54.5(10.9)</td>
<td>55.8(11.0)</td>
<td>0.086</td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>985 (53.1)</td>
<td>1056 (57.3)</td>
<td>0.159</td>
</tr>
<tr>
<td>Current tobacco user, N (%)</td>
<td>325 (17.5)</td>
<td>184 (10.0)</td>
<td>-0.152</td>
</tr>
<tr>
<td>Current alcohol user, N (%)</td>
<td>229 (12.3)</td>
<td>143 (7.8)</td>
<td>0.222</td>
</tr>
<tr>
<td>BMI (Kg/m²), mean (SD)</td>
<td>25.8 (4.6)</td>
<td>26.0 (4.7)</td>
<td>0.031</td>
</tr>
<tr>
<td>SBP (mmHg), mean (SD)</td>
<td>157.0 (16.3)</td>
<td>152.5 (14.7)</td>
<td>-0.238</td>
</tr>
<tr>
<td>DBP (mmHg), mean (SD)</td>
<td>93.3 (10.0)</td>
<td>88.8 (10.8)</td>
<td>-0.331</td>
</tr>
<tr>
<td>Fasting blood glucose (mg/dl), mean (SD)</td>
<td>197.7 (67.0)</td>
<td>185.9 (60.5)</td>
<td>-0.21</td>
</tr>
<tr>
<td>Hemoglobin A1c (%), mean (SD)</td>
<td>9.3 (2.4)</td>
<td>9.5 (2.2)</td>
<td>0.049</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl), mean (SD)</td>
<td>191.8 (44.8)</td>
<td>194.5 (45.0)</td>
<td>0.061</td>
</tr>
<tr>
<td>CVD risk score (%), mean (SD)</td>
<td>41.0 (21.9)</td>
<td>38.5 (20.2)</td>
<td>-0.120</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Change in parameters</th>
<th>Mean change</th>
<th>Unadjusted</th>
<th>Adjusted *</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EUC arm</td>
<td>mWellcare arm</td>
<td>Effect size (95%CI)</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>-12.7</td>
<td>-13.7</td>
<td>-1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(-4.6 to 2.7)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>-0.58</td>
<td>-0.48</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(-0.24 to 0.45)</td>
</tr>
</tbody>
</table>

* 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

**Effect on SBP**

<table>
<thead>
<tr>
<th>Strata</th>
<th>Effect [95%CI]</th>
<th>Pval-Het</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Town type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Village</td>
<td>-1.96 [-4.43 to 2.50]</td>
<td>0.56625</td>
</tr>
<tr>
<td>Town</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population size</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50k</td>
<td>1.60 [-1.67 to 10.14]</td>
<td>0.45944</td>
</tr>
<tr>
<td>20-50k</td>
<td>-2.22 [-7.93 to 3.50]</td>
<td>0.60292</td>
</tr>
<tr>
<td>10-20k</td>
<td>-6.40 [-11.32 to -1.48]</td>
<td>0.00231</td>
</tr>
<tr>
<td>5-10k</td>
<td>3.44 [-7.47 to 14.36]</td>
<td>0.58271</td>
</tr>
<tr>
<td>&lt;5k</td>
<td>-1.10 [-5.38 to 3.17]</td>
<td>0.59299</td>
</tr>
</tbody>
</table>

**Project nurse**

- NPCDCS

**HTN stage**

- Stage2
- Stage1

**Diabetes Control**

- very_poor
- likely_poor
- good

**Education**

- Up to Primary
- Secondary
- College

**Age group**

- >59
- 50-59
- 40-49
- 30-39

**Sex**

- Men
- Women

**Smoker**

- Yes
- No

**Alcohol drinker**

- Yes
- No

**Overall Unadjusted**

- -0.98 [-4.64 to 2.67]
- -0.31 [-3.91 to 3.29]

**Overall Adjusted**

- -0.50 [-3.60 to 2.60]

---

**Effect on Hb1Ac**

<table>
<thead>
<tr>
<th>Strata</th>
<th>Effect [95%CI]</th>
<th>Pval-Het</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Town type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Village</td>
<td>-1.96 [-4.43 to 2.50]</td>
<td>0.56625</td>
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<tr>
<td>Town</td>
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</tbody>
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<table>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50k</td>
<td>-0.02 [-1.29 to 1.27]</td>
<td>0.87234</td>
</tr>
<tr>
<td>20-50k</td>
<td>-0.08 [-1.48 to 0.65]</td>
<td>0.40 [-0.38 to 1.18]</td>
</tr>
<tr>
<td>10-20k</td>
<td>0.25 [-1.15 to 1.69]</td>
<td>0.12 [-0.69 to 0.46]</td>
</tr>
<tr>
<td>5-10k</td>
<td>0.18 [-0.20 to 0.55]</td>
<td>0.95 [-0.05 to 0.33]</td>
</tr>
<tr>
<td>&lt;5k</td>
<td>0.49 [-0.56 to 0.94]</td>
<td>0.09 [-0.24 to 0.43]</td>
</tr>
</tbody>
</table>

**Project nurse**

- NPCDCS

**HTN stage**

- Stage2
- Stage1

**Diabetes Control**

- very_poor
- likely_poor
- good

**Education**

- Up to Primary
- Secondary
- College

**Age group**

- >59
- 50-59
- 40-49
- 30-39

**Sex**

- Men
- Women

**Smoker**

- Yes
- No

**Alcohol drinker**

- Yes
- No

**Overall Unadjusted**

- 0.11 [-0.24 to 0.45]
- 0.08 [-0.27 to 0.44]

---

Average change in Intervention - Average change in Enhanced Usual Care
# Secondary outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean change</th>
<th>Unadjusted</th>
<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>EUC arm</td>
<td>mWellcare arm</td>
</tr>
<tr>
<td>Fasting blood glucose (mg/dl)</td>
<td>-22.7</td>
<td>-15.0</td>
<td>7.7 (-10.3 to 25.6)</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>2.0</td>
<td>0.1</td>
<td>-1.8 (-6.3 to 2.7)</td>
</tr>
<tr>
<td>CVD risk score (%)</td>
<td>0.6</td>
<td>2.4</td>
<td>1.7 (-0.8 to 4.3)</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>0.08</td>
<td>0.16</td>
<td>0.07 (-0.37 to 0.52)</td>
</tr>
<tr>
<td>Change in tobacco use (%)</td>
<td>-7.0</td>
<td>-6.0</td>
<td>0.9 (-3.2 to 5.0)</td>
</tr>
<tr>
<td>Change in alcohol use (%)</td>
<td>-3.8</td>
<td>-2.4</td>
<td>1.4 (-2.6 to 5.4)</td>
</tr>
<tr>
<td>Alcohol use score</td>
<td>10.0</td>
<td>9.4</td>
<td>-0.6 (-3.3 to 2.0)</td>
</tr>
<tr>
<td>Depression score</td>
<td>12.4</td>
<td>10.9</td>
<td>-1.4 (-4.2 to 1.4)</td>
</tr>
</tbody>
</table>

Variables assessed only at endline

* 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:
  o presence of NCD nurses in both arms
  o training of nurses and physicians in the EUC arm
  o charts on treatment algorithms in the EUC arm
  o research team advocating improved drug availability
  o “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.
Effectiveness of an mHealth-Based Electronic Decision Support System for Integrated Management of Chronic Conditions in Primary Care
The mWellcare Cluster-Randomized Controlled Trial
Acknowledgement

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Prof D Prabhakaran
Prof Vikram Patel
Prof Nikhil Tandon
Dr Ambuj Roy
Prof Pablo Perel
Dr C Venkat S Ram
Mr Sudhir Saxena
Prof K Venugopal
Dr Lars Gredsted
Dr Vikram Sheel Kumar
Dr Shirshendu Mukherjee
Dr Rekha Singh
Dr B G Prakash-Kumar

Investigators:
Prof D Prabhakaran
Prof Pablo Perel
Prof Vikram Patel
Prof K Srinath Reddy
Prof Nikhil Tandon
Dr Ambuj Roy

Members of the Data Safety and Monitoring Board :
Prof Nitish Naik
Prof S N Dwivedi,
Dr Unnikrishnan AG
Dr Meenakshi Sharma

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THANK YOU!