Simplified Cardiovascular Management (SimCard) Study in Tibet, China and Haryana, India

Dr. Maoyi Tian on behalf of SimCard working group
Background – CVD
Aim

• To develop,
• Pilot-test and
• Evaluate the feasibility and effectiveness of a

SIMPLIFIED, but GUIDELINE-BASED cardiovascular disease management program delivered by the COMMUNITY HEALTH WORKERS (CHWs) in resource-constrained settings in Tibet, China and Haryana, India
Method – subjects

Inclusion criteria

• Age ≥ 40
• Resident in the selected village

Exclusion criteria

• Bed-ridden
• Life-threatening disease
• Unable to stay >8 months in a year
• CVD related complications that can’t be managed

Screening

Single-blinded cluster randomized controlled trial (47 clusters)
CVD high-risk

Meeting any one of the following conditions:

- History of diabetes
- History of stroke
- History of coronary heart disease
- Both SBP ≥ 160mmHg at two different time points in the same day during the survey
Method – intervention

Electronic Decision Support System (EDSS)

Salt Reduction | Smoking Cessation

BP lowering agent | Aspirin

2 Lifestyle Modifications

2 Drug Prescriptions
Method – outcome

• **Primary outcome**: The binary outcome of anti-hypertensive medication use of all high-risk individuals. The significance test is for the net difference in the proportion of anti-hypertensive medication use between the groups.

• **Secondary outcomes**:  
  • The binary outcome of aspirin use of all high-risk individuals;  
  • The difference in pre-and-post mean SBP of high-risk individuals.  
  • Others

• **Outcome evaluation**:  
  • Baseline and post-intervention follow-up survey  
  • Identical standardized instruments for both surveys
Method – statistical analysis

- **Power (>90%)**
  - Primary outcome: assuming 20% in control group, detect a 10% difference, ICC=0.02
  - Secondary outcome: assuming SD of the change in SBP =15mmHg, detect a 3mmHg difference, ICC=0.02
  - Adequate power for sub-group analysis by country

- **Method**
  - Intent-to-treat using last observation carried forward
  - Analysis accounts for cluster effect and repeated measurements
  - Mixed models were used – logistic model (binary), linear model (continuous)
Result – flow chart

Enrollment
52 villages (China: 30, India: 32)
5 villages were excluded
47 villages were recruited. 2,086 high-risks were identified (China: 1,036, India: 1,050) as high-risk.

Allocation
Intervention Group
1,095 high-risks from 23 villages
(China: 557, India: 538)

Control Group
991 high-risks from 24 villages
(China: 479, India: 512)

Follow-up
962 high-risks from 23 villages
(China: 478, India: 484)

866 high-risks from 24 villages
(China: 431, India: 435)

Analysis
IIT: 1,095 were analyzed.
IIT: 991 were analyzed.
## Result – baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics (Mean, SD or %)</th>
<th>China</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Intervention</td>
</tr>
<tr>
<td>Age (years)</td>
<td>59.7, 11.7</td>
<td>59.9, 11.8</td>
</tr>
<tr>
<td>Female (%)</td>
<td>65.4</td>
<td>58.6</td>
</tr>
<tr>
<td>Illiterate (%)</td>
<td>59.3</td>
<td>56.4</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>23.6, 4.2</td>
<td>24.1, 4.7</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>36.7</td>
<td>35.9</td>
</tr>
<tr>
<td>Coronary heart disease (%)</td>
<td>39.5</td>
<td>28.4</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>10.4</td>
<td>14.1</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>13.4</td>
<td>24.3</td>
</tr>
</tbody>
</table>
Result – primary outcome

Total

- Intervenion (n=1,095): 32.3%
- Control (n=991): 8.8%
- Net: 22.1%
- P<0.001

China

- Intervenion (n=557): 22.4%
- Control (n=479): 1.7%
- Net: 20.8%
- P<0.001

India

- Intervenion (n=538): 42.6%
- Control (n=512): 3.9%
- Net: 24.4%
- P<0.001
## Result – secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>Aspirin (%)</th>
<th>SBP (mmHg)</th>
<th>Current smoker (%)</th>
<th>Awareness of high salt harm (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>India</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>5.0</td>
<td>156.2, 27.4</td>
<td>35.9</td>
<td>29.1</td>
</tr>
<tr>
<td>Post</td>
<td>13.8</td>
<td>146.6, 25.3</td>
<td>36.5</td>
<td>31.1</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>3.7</td>
<td>158.5, 26.5</td>
<td>38.7</td>
<td>21.4</td>
</tr>
<tr>
<td>Post</td>
<td>3.7</td>
<td>149.5, 25.7</td>
<td>37.2</td>
<td>36.7</td>
</tr>
<tr>
<td><strong>Net</strong></td>
<td>8.8</td>
<td>-0.5</td>
<td>2.1</td>
<td>-13.3</td>
</tr>
<tr>
<td><strong>P value</strong></td>
<td>&lt;0.001</td>
<td>0.71</td>
<td>0.22</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Result - summary

- Effectively changed CHWs and patients' behaviors in increasing uptake of evidence-based medicine (anti-hypertensive medication and aspirin)
- No significant changes in lifestyle factors
- Reduced systolic blood pressure by 2.1 mmHg
Strength/Limitation

**Strength**
- Strong local government support
- Adaptive intervention design in two countries
- Active engagement of the CHWs
- The use of EDSS

**Limitation**
- Generalizability
- Unable to distinguish the effectiveness of different intervention component
Conclusion

Simplified evidence-based culturally-appropriate interventions based on the high-risk approach could improve quality of primary care and have the potential to reduce disease burden in resource-constrained settings.
Acknowledgement

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I Rawal, M Ali, R Amachand
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