Non-physician health workers to increase tobacco cessation in heart attack survivors:

Lessons from the SPREAD trial

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St. John’s Medical College and Research Institute, Bangalore, India

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Post heart attack in LMICs

• Adherence to medications and lifestyle modification is poor
• PURE: 4.5 years after heart attack
  – >80% were not on any EB medications
  – Only 38% quit smoking (HIC 75%)
  – Only 28% ate healthy (HIC 43%)
• Compared to HIC
  – Higher mortality although risk factors were low and patients younger.
Need for study

• India needs
  – Cost-effective and innovative strategies to improve outcomes after a heart attack.

• Community Health Workers (CHW)
  – Use established in communicable disease

• Their utility
  – Not been evaluated in CVD
Rationale and design of a randomized controlled trial evaluating community health worker–based interventions for the secondary prevention of acute coronary syndromes in India (SPREAD)

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Background There is a need to evaluate and implement cost-effective strategies to improve adherence to treatments in coronary heart disease. There are no studies from low- to middle income countries (LMICs) evaluating trained community health worker (CHW)-based interventions for the secondary prevention of coronary heart disease.
SPREAD Trial Objectives

Among patients discharged after an acute coronary syndrome (ACS) in India

– To evaluate the impact of CHW based intervention at one year on:
  • Adherence to Evidence Based meds, and
  • Lifestyle modification
    – Diet, exercise, tobacco, alcohol, stress
Trial Design

– Open, multi center randomized controlled trial
– Central telephone randomization
Study Staff and Training

• Community Health Worker (CHW)
  – 10 -12 grade education
  – Proficient in 1-2 local languages; working knowledge of English
  – Training: manuals, central (5 da)+onsite (3 mo)

• SPREAD Project Officer (SPO)
  – Graduate level education
  – At least one year experience in clinical trial
  – Training: central 3 days + refresher 2 days
SPREAD TOOLS

• Developed in-house

• Translated in to 6 languages
  – VITA – Visual Tool for Adherence
    • Calendar with health messages
    • Slots to mark medication intake: one year
Visual Tool for Adherence: VITA
Visual tool for adherence: VITA

- Calendar for one year
- Each of 12 sheets has slots for 6 EB secndry prevention meds
- To mark drug intake each day.
SPREAD: Patient diary

- Simple information on medications and lifestyle modification
- Customized for each patient
- Verified at each visit
Interventions and outcomes

• Intervention:
  – 7 CHW visits:
    • 5 hospital, 2 home; 45 - 60 mins each
  – CHWs Identify Barriers; develop Strategies

• Outcomes at 1 year
  – Adherence (≥80%) to evid based meds
  – Adherence to life style modification
Barriers - general applicable to all domains

• Lack of knowledge
• Indifference (not motivated, not convinced about the benefits, not bothered)
• Lack of family support
  – Not motivating the patient
  – Not accompanying the patient for visits
  – Not cooking healthy food.
• Financial
Specific barriers – 5 domains

1. Adherence to medications
2. Tobacco cessation
3. Alcohol
4. Diet
5. Physical activity
Barriers to medication adherence

- Cost of medication
- Side effects
- Complex regimens
- Difficulty in accessing medications
  - long queues, pharmacy far away
Barriers to tobacco cessation

• Physical and psychological dependence
• Tobacco in environment
  – Family, co-workers and friends
• Lack of tobacco de-addiction programs
• No knowledge about the ill effects of tobacco
Barriers to alcohol cessation

- Physical and psychological dependence
- Alcohol in environment
  - family and friends
- Lack of alcohol de-addiction programs
- No knowledge about the ill effects of alcohol
Barriers to dietary changes

• Cost of healthy food like fruits and vegetables
• Healthy food is not tasty or not satisfying
• Cultural factors
  – excess rice, red meats, sweets, or deep fried snacks.
Barriers to physical activity

• Physical constraints
  – associated fractures, osteoarthritis, stroke, congenital abnormalities.

• Intolerance to exercise
  – cardiac insufficiency (chest pain, breathlessness, increased heart beat, faintness)

• Lack of space for exercise

• Lack of knowledge
  – benefits of exercise.
Strategies

• Education and counseling
• Seek help from family, society or government
• Counseling — reduction of risk factors causes a significant reduction in illness and death
• SPO can counsel family about the need for active involvement in patient care
• Use cheaper brands of drugs or change to fixed drug combinations
• Alternative drugs wherever possible
• Simplify the drug regimens or use fixed drug combinations
• Buy larger supplies at a time
Strategies

• Tobacco:
  – Education: Patient, family and friends
  – Change of environment
  – Refer to closest available nicotine de-addiction program
  – Consider counseling or drugs for de-addiction
  – Form support groups.
  – Education regarding harms related to smoking
Strategies

• Education of family and friends or change of environment
• Provide counseling or drugs to help in de-addiction or form support groups.
• Education on ill effects of alcohol
• Alternative healthy foods that are less expensive
• Explain adaptation to new taste over time
Strategies

• Explain harm of eating an unbalanced diet
• Consider alternative exercises
  – swimming or upper body exercises
• Refer the patient
  – optimum treatment of symptoms and restart exercises as tolerated.
• Remain active
  – use stairs, park a few blocks away from work place, indoor exercises or dancing.
• Explain the benefits of exercise
Tobacco questions

- Status at discharge
- Current status
- Achieved target set?
- Goal for next visit
- Barriers identified
- Strategies offered
- Second hand smoke
Community health worker-based intervention for adherence to drugs and lifestyle change after acute coronary syndrome: a multicentre, open, randomised controlled trial

Denis Xavier, Rajeev Gupta, Deepak Kamath, Alben Sigamani, PJ Devereaux, Nisha George, Rajnish Joshi, Janice Pogue, Prem Pais, Salim Yusuf

Summary
Background Adherence to drugs and healthy lifestyles is low after acute coronary syndrome. We assessed whether trained community health workers could improve adherence to drugs, lifestyle changes, and clinical risk markers in patients with acute coronary syndrome in India.

Methods In this study done at 14 hospitals in India we randomly assigned (1:1) patients with acute coronary syndrome 1 or 2 days before discharge from hospital to a community health worker-based intervention group or a standard care group. Patients were randomly assigned with a telephone randomisation service. In the intervention group, during
SPREAD : Study Flow

Randomized = 806

Intervention Group = 405
- Death = 22
- LTFup = 8
- Final analysis – 375 (97.9%)

Standard Care = 401
- Death = 18
- LTFup = 8
- Final analysis – 375 (97.9%)

* 2 cross overs and 1 ineligible patient randomized
<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall 806</th>
<th>Intervention 405</th>
<th>Standard Care 401</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Mean (SD)</strong></td>
<td>56.4 (11.3)</td>
<td>55.9 (11.4)</td>
<td>56.9 (11.2)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>667 (82.8)</td>
<td>334 (82.5)</td>
<td>333 (83)</td>
</tr>
<tr>
<td><strong>Past History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>350 (43.4)</td>
<td>174 (43)</td>
<td>176 (43.9)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>257 (31.9)</td>
<td>130 (32.1)</td>
<td>127 (31.7)</td>
</tr>
</tbody>
</table>
# SPREAD – Patient Characteristics (Baseline)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall 806</th>
<th>Intervention 405</th>
<th>Standard Care 401</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior CAD</td>
<td>107 (13.3)</td>
<td>47 (11.6)</td>
<td>60 (15.0)</td>
</tr>
<tr>
<td><strong>Lifestyle Factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco Use (Current)</td>
<td>285 (35.4)</td>
<td>138 (34.1)</td>
<td>147 (36.7)</td>
</tr>
<tr>
<td>Physical Activity (Moderate/ Intense)</td>
<td>238 (29.5)</td>
<td>125 (30.9)</td>
<td>113 (28.1)</td>
</tr>
<tr>
<td>Alcohol (Current)</td>
<td>155 (19.2)</td>
<td>80 (19.8)</td>
<td>75 (18.7)</td>
</tr>
<tr>
<td><strong>Dietary Patterns (UH)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruits/ veg &lt; 5/ week</td>
<td>477 (59.2)</td>
<td>234 (57.8)</td>
<td>243 (60.6)</td>
</tr>
<tr>
<td>Whole grain &lt; 5/ week</td>
<td>495 (61.4)</td>
<td>252 (62.2)</td>
<td>243 (60.6)</td>
</tr>
<tr>
<td>Sugary food &gt; 3/ week</td>
<td>293 (36.4)</td>
<td>139 (34.3)</td>
<td>154 (38.4)</td>
</tr>
<tr>
<td>Fried food &amp; red meat &gt; 5/ week</td>
<td>413 (51.2)</td>
<td>190 (46.9)</td>
<td>223 (55.5)</td>
</tr>
<tr>
<td>Variable</td>
<td>Overall 806</td>
<td>Intervention 405</td>
<td>Standard Care 401</td>
</tr>
<tr>
<td>---------------------------</td>
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</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable Angina</td>
<td>230 (28.5)</td>
<td>123 (30.4)</td>
<td>107 (26.7)</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>143 (17.7)</td>
<td>68 (16.8)</td>
<td>75 (18.7)</td>
</tr>
<tr>
<td>STEMI</td>
<td>433 (53.7)</td>
<td>214 (52.8)</td>
<td>219 (53.6)</td>
</tr>
<tr>
<td>Acute Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary Intervn</td>
<td>475 (58.9)</td>
<td>235 (58)</td>
<td>240 (59.9)</td>
</tr>
<tr>
<td>Medically managed</td>
<td>331 (41.1)</td>
<td>170 (42)</td>
<td>161 (40.1)</td>
</tr>
<tr>
<td>Physical Exam</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SBP</td>
<td>124.7 (18.3)</td>
<td>124.1 (17.9)</td>
<td>125.3 (18.6)</td>
</tr>
<tr>
<td>DBP</td>
<td>78.2 (10)</td>
<td>78 (9.7)</td>
<td>78.4 (10.3)</td>
</tr>
<tr>
<td>BMI</td>
<td>25.2 (4)</td>
<td>25.3 (4.2)</td>
<td>25 (3.8)</td>
</tr>
<tr>
<td>WHR</td>
<td>1.0 (0.1)</td>
<td>1.0 (0.07)</td>
<td>1.0 (0.13)</td>
</tr>
</tbody>
</table>
## SPREAD – Medications at discharge

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall N (%)</th>
<th>Intervention N (%)</th>
<th>Standard Care N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>787 (97.9)</td>
<td>395 (97.5)</td>
<td>392 (97.8)</td>
</tr>
<tr>
<td>Other antiplatelet</td>
<td>641 (79.7)</td>
<td>317 (78.3)</td>
<td>324 (80.8)</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>560 (69.5)</td>
<td>288 (71.1)</td>
<td>272 (67.8)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>555 (69.0)</td>
<td>274 (67.7)</td>
<td>281 (70.1)</td>
</tr>
<tr>
<td>Lipid Lowering</td>
<td>762 (94.8)</td>
<td>385 (95.1)</td>
<td>377 (94)</td>
</tr>
</tbody>
</table>
## Primary Outcomes (one year)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Interven N=375</th>
<th>Standard N=375</th>
<th>OR/ Mean diff</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td>2.60</td>
<td>0.006</td>
</tr>
<tr>
<td>Adherent n (%)</td>
<td>361 (96.8)</td>
<td>345 (92.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SPREAD: Outcomes at 1 year

<table>
<thead>
<tr>
<th></th>
<th>Intervention N=375</th>
<th>Standard N=375</th>
<th>Differn</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>124.4 (13.5)</td>
<td>128 (15.9)</td>
<td>-3.59</td>
<td>0.0009</td>
</tr>
<tr>
<td>DBP</td>
<td>78.7 (8.7)</td>
<td>79.6 (8.8)</td>
<td>-0.85</td>
<td>0.185</td>
</tr>
<tr>
<td>Heart rate</td>
<td>74.61</td>
<td>75.97</td>
<td>-1.36</td>
<td>0.020</td>
</tr>
<tr>
<td>BMI</td>
<td>24.4 (3.2)</td>
<td>25.0 (3.8)</td>
<td>-0.6</td>
<td>0.038</td>
</tr>
<tr>
<td>Chnge Wt Kg</td>
<td>-2.03</td>
<td>-0.20</td>
<td>-1.83</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Waist males</td>
<td>90.60</td>
<td>92.58</td>
<td>-1.97</td>
<td>0.0009</td>
</tr>
<tr>
<td>Waist female</td>
<td>92.98</td>
<td>90.17</td>
<td>2.81</td>
<td>0.246</td>
</tr>
<tr>
<td>Outcome</td>
<td>Intervention Group N=375</td>
<td>Standard Care N=375</td>
<td>P value</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------</td>
<td>---------------------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td><strong>Tobacco</strong> n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stopped (181/267 smokers)</td>
<td>110 (85.3)</td>
<td>71 (51.5)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td><strong>Alcohol Use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current n (%)</td>
<td>11 (2.9)</td>
<td>28 (7.5)</td>
<td>0.007</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Activity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modr to intense n (%)</td>
<td>333 (88.8)</td>
<td>226 (60.3)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td><strong>Diet</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet score Med (IQR)</td>
<td>5 (3 – 5)</td>
<td>3 (3 – 5)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
</tbody>
</table>
### SPREAD: Outcomes at 1 year

**Variables**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intervention N=375</th>
<th>Standard N=375</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>7.1 (0.65)</td>
<td>8.0 (2.2)</td>
<td>0.051</td>
</tr>
<tr>
<td>Total Chol</td>
<td>157 (40.2)</td>
<td>166.9 (48.4)</td>
<td>0.184</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>127.7 (43.8)</td>
<td>141.7 (48.7)</td>
<td>0.119</td>
</tr>
<tr>
<td>LDL</td>
<td>81 (20.6)</td>
<td>87.3 (29.9)</td>
<td>0.191</td>
</tr>
<tr>
<td>HDL</td>
<td>42 (11.4)</td>
<td>38.2 (6.5)</td>
<td>0.042</td>
</tr>
</tbody>
</table>

*Done in a subset of patients
## SPREAD: Outcomes at 1 year

<table>
<thead>
<tr>
<th>Events</th>
<th>Intervention Group 405</th>
<th>Standard Care Group 401</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>22 (5.4)</td>
<td>18 (4.5)</td>
<td>0.538</td>
</tr>
<tr>
<td>Composite Outcome*</td>
<td>29 (7.2)</td>
<td>21 (5.3)</td>
<td>0.12</td>
</tr>
<tr>
<td>CV Deaths</td>
<td>17 (4.2)</td>
<td>16 (3.9)</td>
<td></td>
</tr>
<tr>
<td>Non fatal MIs</td>
<td>9 (2.2)</td>
<td>4 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Non fatal stroke</td>
<td>3 (0.7)</td>
<td>1 (0.3)</td>
<td></td>
</tr>
</tbody>
</table>
SPREAD: Limitations

- Open trial
- Self reports
  - Adherence to medications
  - Tobacco use, diet and activity
- Potential for bias
What more could have been done to verify tobacco use?

• Corroboration of patient reports with
  – Cotinine blood levels
  – Independent/ confidential care-giver reports
SPREAD: Summary & Conclusions

• First CHW, urban RCT
  – ACS secondary prevention - LMIC setting
• Established feasibility in
  – Urban large hospital based RCT
• CHW interventions over one year
  – Improved Adherence to medications
  – Reduced CV risk levels (BP, HR, Weight)
  – Reduced Tobacco use,
  – Improved, Diet and Physical Activity
Next steps

• Simplifying and Scaling up training and interventions
• Clinical outcomes trial