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

Lessons from the SPREAD trial

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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.

Am Heart J, 2014

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

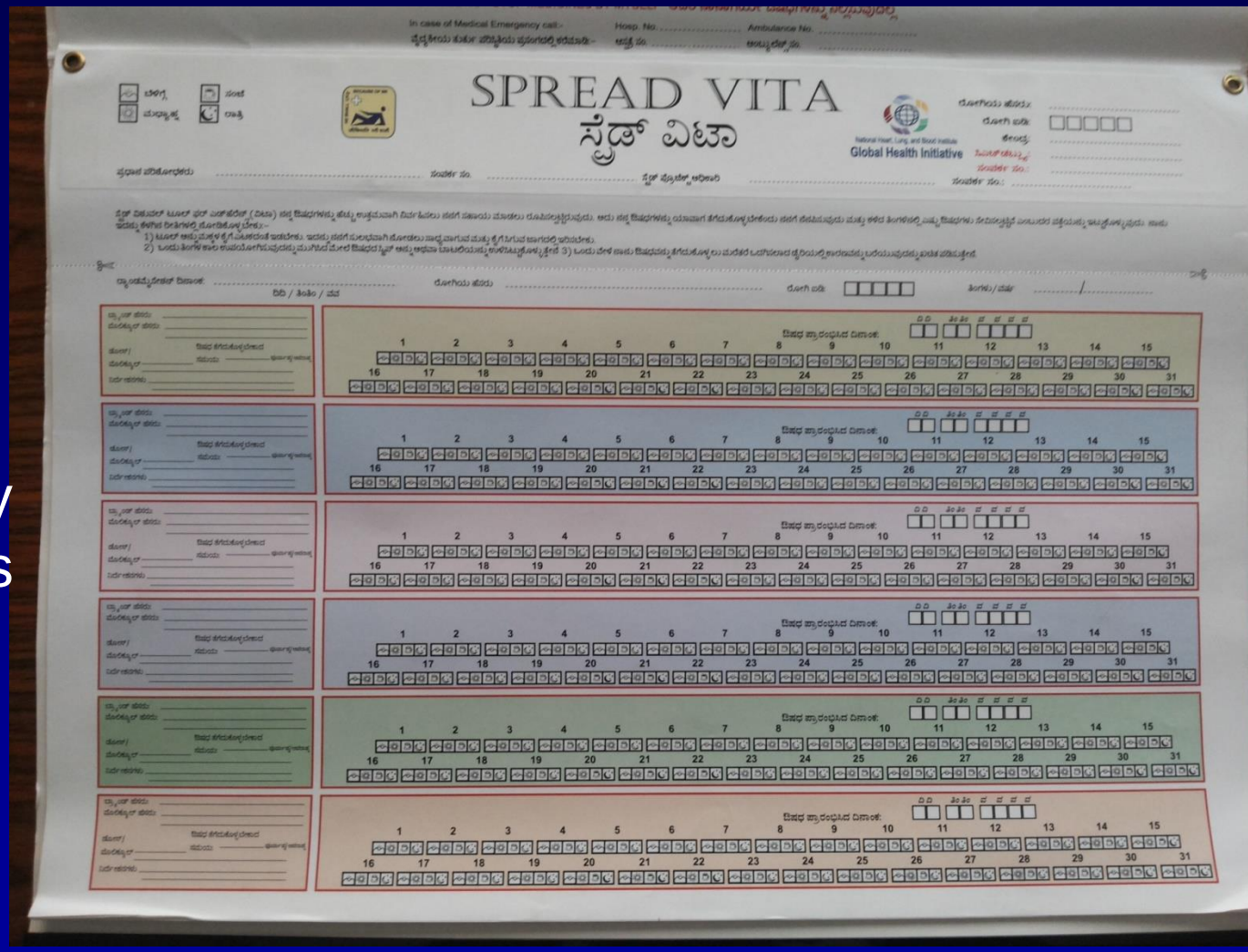
SPREAD TOOLS

- 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

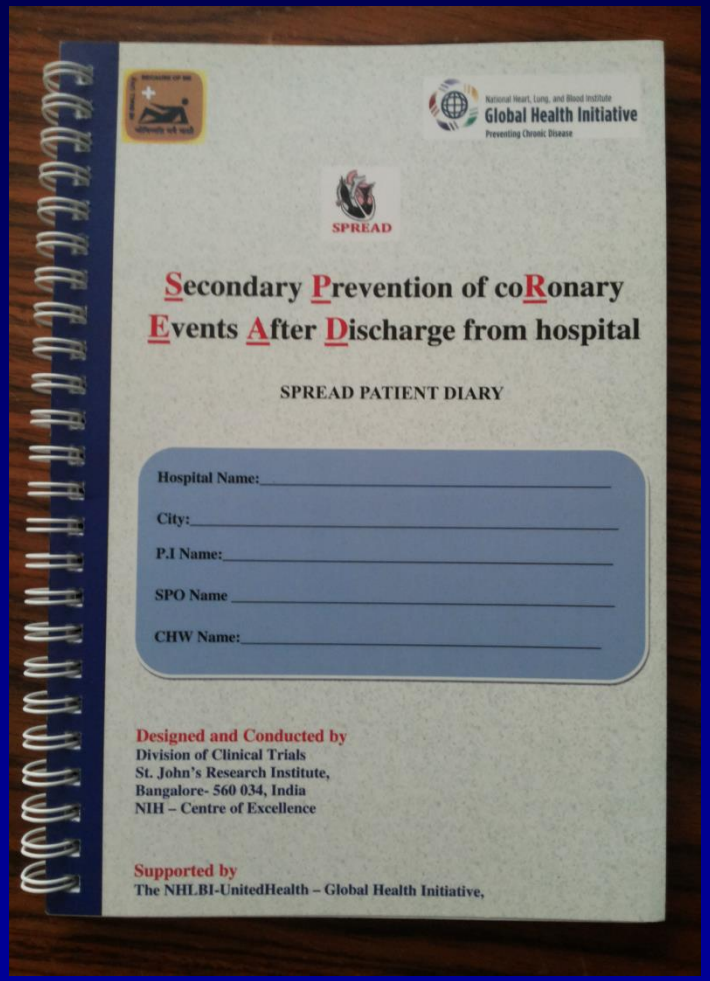
Visual tool for adherence: VITA

- 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




Dangers of Smoking
Cardiovascular System
Understanding Hypertension
Diet
Separate Cooking
Taste/Habits
Cost of Healthy Food
Exercise
Space/Safety
Physical
Time

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 ($\geq$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

SPREAD Results

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Community health worker-based intervention for adherence to drugs and lifestyle change after acute coronary syndrome: a multicentre, open, randomised controlled trial

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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

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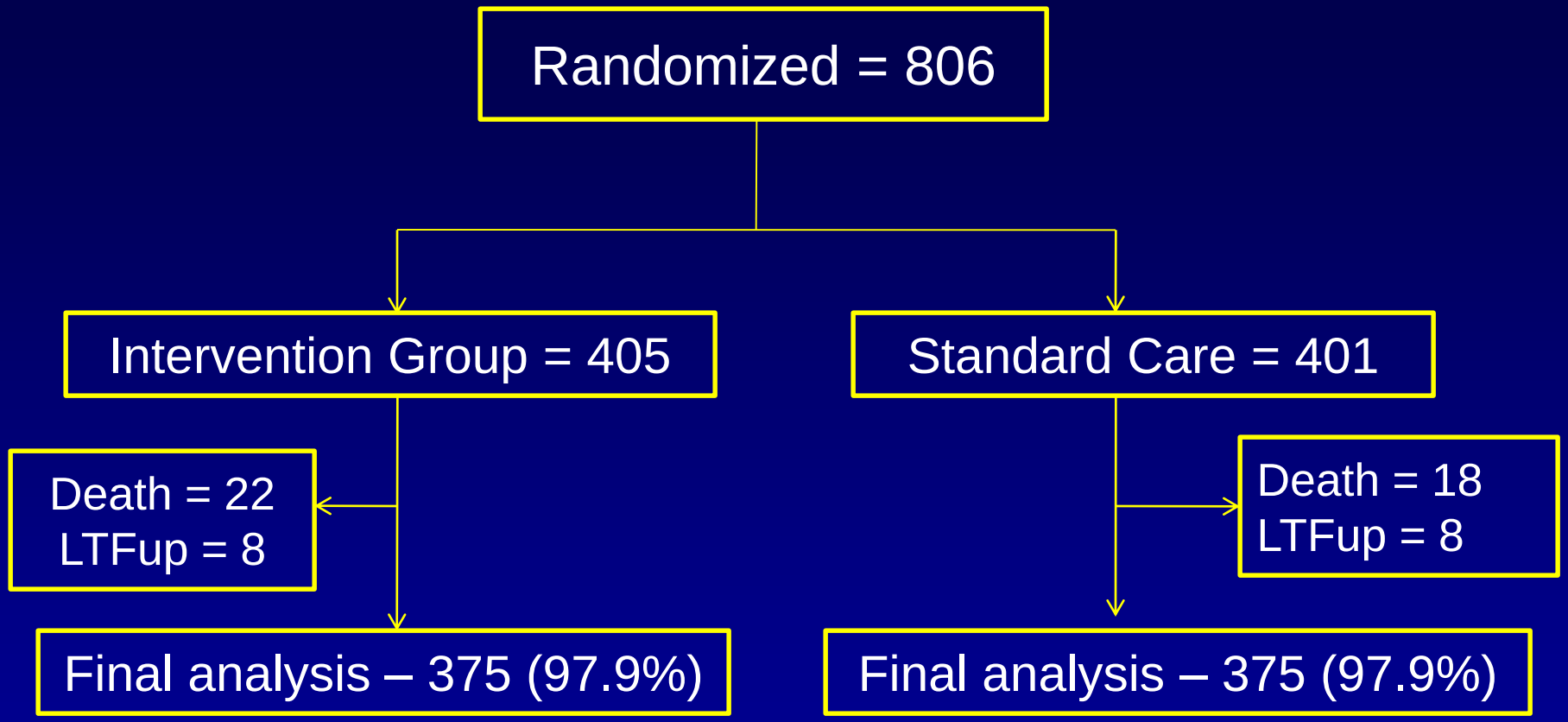
SPREAD : Study Flow



* 2 cross overs and 1 ineligible patient randomized

SPREAD – Baseline Patient Characteristics

Variable	Overall 806	Intervention 405	Standard Care 401
Age Mean (SD)	56.4 (11.3)	55.9 (11.4)	56.9 (11.2)
Gender			
Male	667 (82.8)	334 (82.5)	333 (83)
Past History			
Hypertension	350 (43.4)	174 (43)	176 (43.9)
Diabetes	257 (31.9)	130 (32.1)	127 (31.7)

SPREAD – Patient Characteristics (Baseline)

Variable	**Overall 806**	**Intervention 405**	**Standard Care 401**
Prior CAD	107 (13.3)	47 (11.6)	60 (15.0)
Lifestyle Factors			
Tobacco Use (Current)	285 (35.4)	138 (34.1)	147 (36.7)
Physical Activity (Moderate/ Intense)	238 (29.5)	125 (30.9)	113 (28.1)
Alcohol (Current)	155 (19.2)	80 (19.8)	75 (18.7)
Dietary Patterns (UH)			
Fruits/ veg < 5/ week	477 (59.2)	234 (57.8)	243 (60.6)
Whole grain < 5/ week	495 (61.4)	252 (62.2)	243 (60.6)
Sugary food > 3/ week	293 (36.4)	139 (34.3)	154 (38.4)
Fried food & red meat > 5/ week	413 (51.2)	190 (46.9)	223 (55.5)

SPREAD – Patient Characteristics (Baseline)

Variable	Overall 806	Intervention 405	Standard Care 401
Diagnosis			
Unstable Angina	230 (28.5)	123 (30.4)	107 (26.7)
NSTEMI	143 (17.7)	68 (16.8)	75 (18.7)
STEMI	433 (53.7)	214 (52.8)	219 (53.6)
Acute Management			
Coronary Intervn	475 (58.9)	235 (58)	240 (59.9)
Medically managed	331 (41.1)	170 (42)	161 (40.1)
Physical Exam			
SBP	124.7 (18.3)	124.1 (17.9)	125.3 (18.6)
DBP	78.2 (10)	78 (9.7)	78.4 (10.3)
BMI	25.2 (4)	25.3 (4.2)	25 (3.8)
WHR	1.0 (0.1)	1.0 (0.07)	1.0 (0.13)

SPREAD – Medications at discharge

Variable	Overall N (%)	Intervention N (%)	Standard Care N (%)
Medications			
Aspirin	787 (97.9)	395 (97.5)	392 (97.8)
Other antiplatelet	641 (79.7)	317 (78.3)	324 (80.8)
ACEI/ARB	560 (69.5)	288 (71.1)	272 (67.8)
Beta blockers	555 (69.0)	274 (67.7)	281 (70.1)
Lipid Lowering	762 (94.8)	385 (95.1)	377 (94)

Primary Outcomes (one year)

Outcome	Interven N=375	Standard N=375	OR/ Mean diff	P value
Medications Adherent n (%)	361 (96.8)	345 (92.0)	2.60	0.006

SPREAD: Outcomes at 1 year

	Intervention N=375	Standard N=375	Differn	P value
SBP	124.4 (13.5)	128 (15.9)	-3.59	0.0009
DBP	78.7 (8.7)	79.6 (8.8)	-0.85	0.185
Heart rate	74.61	75.97	-1.36	0.020
BMI	24.4 (3.2)	25.0 (3.8)	-0.6	0.038
Chnge Wt Kg	-2.03	-0.20	-1.83	<0.0001
Waist males	90.60	92.58	-1.97	0.0009
Waist female	92.98	90.17	2.81	0.246

SPREAD: Outcomes at 1 year

Outcome	Intervention Group N=375	Standard Care N=375	P value
Tobacco n (%)			
Stopped (181/267 smokers)	110 (85.3)	71 (51.5)	<0.0001
Alcohol Use			
Current n (%)	11 (2.9)	28 (7.5)	0.007
Physical Activity			
Modr to intense n (%)	333 (88.8)	226 (60.3)	<0.0001
Diet			
Diet score Med (IQR)	5 (3 – 5)	3 (3 – 5)	<0.0001

SPREAD: Outcomes at 1 year

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

*Done in a subset of patients

SPREAD: Outcomes at 1 year

Events	Intervention Group 405	Standard Care Group 401	P value
Deaths	22 (5.4)	18 (4.5)	0.538
Composite Outcome*	29 (7.2)	21 (5.3)	0.12
CV Deaths	17 (4.2)	16 (3.9)	
Non fatal MIs	9 (2.2)	4 (0.9)	
Non fatal stroke	3 (0.7)	1 (0.3)	

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