



# A Novel Family-based Intervention Trial to Improve Heart Health (FIT HEART): Results of a Randomized Controlled Trial

Dr. Lori Mosca  
Professor of Medicine  
Columbia University Medical Center  
Director, Preventive Cardiology  
New York-Presbyterian Hospital

**Disclosures:** Consultant for Anthera, Astra Zeneca, Merck, Pfizer  
Honoraria from Daiichi-Sankyo, Merck/Schering-Plough, Takeda

**Funding:** National Heart, Lung and Blood Institute (RO1 HL075101)

**Trial Registration:** Clinicaltrials.gov Identifier NCT00728637

**Complete Results:** Circulation: Cardiovascular Quality and Outcomes, November 2008

# Background/Rationale

- Family members of patients with cardiovascular disease (CVD) may be at increased risk of vascular events due to shared genes and/or lifestyle risk factors that aggregate in families (e.g. nutrition and physical activity)
- Many individuals at risk of CVD are unaware, a critical block in the pathway to take personal action to lower risk
- Perceived susceptibility to disease can trigger preventive behavior and interventions that are timed to take advantage of a “motivational moment” such as hospitalization of a relative with a cardiac crisis might increase effectiveness of low-intensity, low-cost preventive interventions

## Study Purpose

To evaluate a “systems approach” to identify family members of hospitalized cardiac patients and provide CVD risk factor screening with results, lifestyle counseling by health educators, and regular progress reports sent to physician(s) compared to a control intervention (CIN) on adherence to primary prevention goals.

# Main Outcomes

## Primary Outcome Measure:

Difference in mean % change in LDL in special intervention (SI) vs. CIN

## Secondary Outcomes:

Change in diet/lifestyle and standard CVD risk factors

# Methods: Study Design

Hospitalized patients with CVD systematically identified through daily hospital admission records by ICD code (410.0, 411.1, 36.0, 36.09, 36.3, 38.12, 38.44, 38.48, 39.4-39.9)



Family members were recruited by visiting patient rooms, family waiting rooms, and through invitations included in admission packages  
AND  
prescreened for eligibility and interest  
(n=3649)



Family members completed informed consent  
Randomized  
(n=501)



Special Intervention  
(n=250)



Control Intervention  
(n=251)

# Methods: Participants

## Inclusion Criteria

- English or Spanish Speaking
- Age 20 – 79 years
- Live within a 3 hour commute of hospital
- Blood relative or cohabitant of a hospitalized CVD patient

## Exclusion Criteria

- Established CVD, diabetes, active liver or kidney disease
- Current or planned pregnancy
- Life expectancy < 5 years
- Prescription of special diet not compatible with TLC diet
- Participation in a clinical study within 3 months
- Another family member is enrolled in the trial

# Methods: Measurements

## Laboratory:

- Venous fasting blood samples were collected at baseline and 1-year and direct LDL and other lipids and glucose were measured in the Columbia University CTSA Biomarker Laboratory using standard methods
- For educational purposes, SI subjects had fasting point-of-service finger-stick lipid and hsCRP measures using desktop analyzers

## Diet

- Assessed using food frequency questionnaires at baseline and 1-year
- Adherence to the TLC diet was assessed using the NHLBI MEDFICTS Questionnaire validated in this population (*Mochari H, J Am Diet Assoc 2008*)
- Intake of saturated fat, dietary cholesterol, and other diet components were measured by Block 98 Food Frequency Questionnaires

## Other Risk Factors

- Blood pressure was measured in the CTSA using standard protocol
- Height, weight and waist circumference were measured using NCEP ATP III Guidelines and Body Mass Index was calculated

# Control Intervention (CIN)

## Participants randomized to the CIN received:

- A 1-page handout to 1) avoid tobacco, 2) choose good nutrition, and 3) be more active
- A report was sent to their healthcare providers if a critical threshold value for a CVD risk factor was determined:

(blood pressure  $\geq$  140/90, LDL-C  $\geq$  190mg/dL, HDL-C  $<$  25mg/dL, triglycerides  $\geq$  500mg/dL, or total cholesterol  $\geq$  300mg/dL)

# Special Intervention (SI)

## Participants randomized to the SI received:

- The same handout at baseline as the CIN
- Personalized risk factor screening
- Immediate feedback (including lipid results) and education provided by a master's level health educator with  $\geq 6$  months experience trained by an RD and MD
- Structured 1 hour behavioral counseling based on the 5 A's construct (Assess, Advise, Agree, Assist, Arrange)  
Reinforcement phone calls at 2 and 6 weeks
- Clinic visit and recheck abnormal lipids at 3, 6, and 9 months
- Regular physician reports sent following each clinic visit

# Study Flow and Follow Up

3649 Family Members of Hospitalized Patients were Prescreened for Eligibility

## 909 Excluded:

321 lived  $\geq 3$  hours away, 278 had established CVD, 100 not blood relative/cohabitant, 88 did not meet age requirement, 49 did not speak English/Spanish

## 2239 Potentially Eligible Declined:

1027 wanted to think about it, 473 not interested, 121 satisfied with care from MD

Randomized

N=501

250 Special Intervention

251 Control Intervention

3 Pregnant Excluded

2 Pregnant Excluded

15 Lost to Follow-up

17 Lost to Follow-up

232 included at 1-year

232 included at 1-year

94% follow-up rate  
for primary outcome

# Characteristics of Participants\*

Characteristic	Special Intervention (n=250) %	Control Intervention (n=251) %
Age ( $\geq 65$ years)	12	12
Female	66	67
White race/ethnicity	64	65
Married/living w/partner	65	67
Education $\leq$ high school	23	21
No health insurance	16	13
Family history early CHD	55	49
BMI $\geq 30\text{kg}/\text{M}^2$	32	36
Waist circ $>40\text{in}$ (male); $>35\text{in}$ (female)	35	41
Abnormal lipids**	69	70
Statin therapy	13	16
Hypertension	34	34
Antihypertensive therapy	21	21
Framingham risk $\geq 10\%$	9	9

\*There were no significant between-group differences at baseline

\*\*Defined as LDL  $\geq 130\text{mg}/\text{dL}$  or TG  $\geq 150\text{mg}/\text{dL}$  or HDL  $\leq 40\text{mg}/\text{dL}$  or on lipid medication

# Results: Primary Endpoint

- No difference in mean % change in LDL in SI vs. CIN from baseline to 1 year

-1.0% (95% CI -4.3 to 2.3) vs. -2.0% (95% CI -4.4 to 0.4)

- LDL significantly declined in both groups:

SI (-4.4mg/dL, p=.03) and CIN (-4.5mg/dL, p=.005)



- No between group difference in % of subjects at LDL goals (<130 or <100) at 1 year

SI (59% and 22%) and CIN (60% and 25%)

# Results: Change in CVD Risk Factors

	Special Intervention		Control Intervention		Difference in mean % change p-value
	Baseline Mean	1-Year Mean	Baseline Mean	1-Year Mean	
Total Chol (mg/dL)	202.7	202.2	205.9	203.1	0.89
HDL-C (mg/dL)	<b>58.5</b>	<b>58.7</b>	<b>59.9</b>	<b>57.6*</b>	<b>0.01</b>
TC/HDL Ratio	<b>3.8</b>	<b>3.7</b>	<b>3.7</b>	<b>3.9</b>	<b>0.04</b>
Triglycerides (mg/dL)	115	113.5	118.0	119.2	0.53
Glucose (mg/dL)	97.9	98.1	99.3	98.6	0.22
Systolic BP (mmHg)	126.7	129.7*	126.4	129.8*	0.90
Diastolic BP (mmHg)	77.9	79.0*	77.0	78.9*	0.59
Body Mass Index	27.8	27.7	28.4	28.4	0.88
Waist size (inches)	35.6	36.2*	35.9	36.6*	0.43

\*Significant within group mean change (p <.05)

# Results: Change in CVD Lifestyle Factors

	Special Intervention		Control Intervention		Difference in mean % change p-value
	Baseline Mean	1-Year Mean	Baseline Mean	1-Year Mean	
<b>MEDFICTS score</b>	<b>46.3</b>	<b>31.3*</b>	<b>50.3</b>	<b>40.2*</b>	<b>0.04</b>
Sat fat (%)	10.7	9.9*	10.7	10.3*	0.11
Mono fat (%)	14.8	14.9	15.0	14.6	0.36
Poly fat (%)	9.2	9.0	9.1	8.6	0.66
Trans fat (%)	2.6	2.3*	2.5	2.3	0.96
Cholesterol (mg)	238.4	193.3*	241.5	211.3*	0.39
Carbohydrate (%)	0.50	0.50	0.50	0.50	0.52
Fruit+Vegetables (servings)	4.8	4.7	4.9	4.9	0.65
Fiber (g)	18.3	18.2	18.8	17.7*	0.26
Exercise (days/wk)	1.9	2.5*	1.6	2.0*	0.20

\*Significant within group mean change (p <.05)

## Results: Adherence to CVD Primary Prevention Goals

	Baseline		1-Year	
	SI %	CIN %	SI %	CIN %
TC <200mg/dL	51	47	51	47
LDL-C <130mg/dL	56	53	59	60
<100mg/dL	22	20	22	25
HDL-C ≥40mg/dL	89	87	87	84
Trigs <150mg/dL	79	78	82	77
Glu <100mg/dL	62	58	64	66
BP <140/90mmHg	77	78	66	69
<120/80mmHg	30	32	27	25
BMI 18.5-24.9kg/M <sup>2</sup>	38	35	38	33
Waist ≤35in (female)	61	56	57	51
≤40in (male)	73	67	62	59
Non-smoking	90	90	92	90
Sat fat <10% of kcals	43	39	52	46
Sat fat <7% of kcals	6	6	10	10
Diet chol. <300mg	73	72	87	80
<b>Exercise &gt;3 days/week</b>	<b>25</b>	<b>18</b>	<b>33</b>	<b>24*</b>

\* Between Group Difference at 1 year p<.05

# Additional Interesting Findings

## Risk Factor Awareness

- Among subjects with LDL  $\geq 130$ , 39% reported no history or awareness of cholesterol problem
- Among those with blood pressure  $\geq 140/90$ , 39% reported no history or awareness of hypertension

## Non-Adherence to Diet/Lifestyle

- At baseline, 93% of subjects had a saturated fat intake  $\geq 7\%$  of calories and the mean number of days of physical activity was less than 2 days among family members of patients with CVD.

# Conclusions

- The SI was not more effective than the CIN in reducing the primary endpoint LDL
- The SI was associated with significantly greater dietary improvement and a beneficial effect on change in HDL compared to the CIN, both secondary endpoints
- The overwhelming majority of family members of cardiac patients were not at primary prevention goals for optimal LDL, blood pressure, sat fat intake, or exercise
- The screening process identified many family members of patients with CVD who were unaware of their risk factors

# Limitations

- Dietary data based on 2 food frequency questionnaires (a subset was validated with food records)
- Possible misclassification of physical activity levels (likely non-differential)
- Results may not generalize to other populations or less motivated individuals

# Significance

- Systematic screening of family members of cardiac patients may represent an opportunity to identify individuals at risk before a cardiovascular event occurs
- Small changes in lipids may have clinical significance
- Improvements in lifestyle associated with the SI may have beneficial effects beyond the outcomes measured
- More intense interventions are likely needed to have a significant impact on LDL beyond changes observed in the controls

## Co-Authors

Heidi Mochari, MPH, RD

Ming Liao, BS

Allison H. Christian, EdD

Dana J. Edelman, MPH

Brooke Aggarwal, EdD

Mehmet C. Oz, MD

## Acknowledgements

We would like to thank Lisa Rehm for her assistance