Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems

The University of Massachusetts Medical School, Worcester, Massachusetts: Divisions of Cardiovascular Medicine and Preventive and Behavioral Medicine

The Universidad de las Américas Medical School, Quito, Ecuador: The Center for Translational Research

Ira Ockene, MD
Milagros Rosal, PhD
Philip Merriam, MSPH

Juan Carlos Zevallos, MD

Manuel E. Baldeón, MD, PhD
Marco Fornasini, MD, PhD
Nancy Flores, MSc

- The study assessed the feasibility of an evidence-based intervention model involving physician-delivered patient-centered counseling plus office support to improve the ability of Ecuadorian primary care physicians (PCPs) to reduce their patients' cardiovascular disease (CVD) risk.

- In this 27 month study we randomized 6 participating clinics, included 15 PCPs, and recruited 197 of their patients without CVD but at high risk of diabetes, to either intervention or usual care conditions.

- Feasibility was the study's primary goal and was measured by level of implementation of a patient-centered counseling algorithm as assessed by Patient Exit Interviews.

Study Methodology

Recruitment & Screening

- Select patients with continued treatment appointment.
- Check if the patient was contacted previously.
- Pre-eligible patients are called using approved recruitment script.
- Update the tracking database.

↓

- Screening and blood draw appointments scheduled.
- Update the tracking database.

↓

Screening Appointment
- Obtain written informed consent.
- Weight, height, waist and blood pressure measured
- Medications recorded.
Blood drawn and sent to lab (FBS, TC & HDL) along with stern formula patient data.
- Copy of screening consent, and incentive provided.
- Lab calculates Stern risk & BMI; and the patient notified of eligibility.

Didn't Meet Criteria (< 30% stern risk)
- Provide screening results to patient and MD.
- Update tracking database.

Met Criteria (> 30% stern risk)
- Provide screening results to patient and MD.
- Schedule baseline appt.
- Update tracking database.

Baseline & Follow-up

1st Post-eligibility MD visit & Baseline Assessment
- Baseline survey completed. (check CESD score & notify MD if patient scored 16 or above).
- Obtain written informed consent.
- Notify lab to complete baseline assays (direct LDL, trigs, HbA1c, AST, ALT) and to save insulin until end of study.
- Administer PEI & incentive provided.
- Pedometer & pill organizer provided to IC patients.
- Schedule six-month study and blood draw assessment.
- Update tracking database.

Usual Care Clinics (UC)
- *No MD prompts provided.*
Intervention Clinics (IC)
- MD prompts provided and include *a completed Diet and Activity Risk Assessment (DARA), goal booklet; completed lab result summary; patient risk factor card; a Patient/MD negotiation form; and a visit algorithm.*

↓

Six-Month Follow-up Assessment
- Follow-up Visit Survey completed (check CESD score & notify MD if patient scored 16 or above)
- Weight, waist and blood pressure measured.
- Medication recorded.
- Blood drawn & sent to lab (lipid profile, HbA1c, FBS, AST, ALT).
- Incentive provided.
- Update tracking database.
- Lab completes insulin assays.

Mean Score of the Counseling Steps by Group of Study

PEI Step	Overall (%)	Intervention (%)	Usual Care (%)	p-value
1 MD discussed cholesterol	175/192 (91.1)	103/111 (92.8)	72/81 (88.9)	0.442
2 MD discussed diet-cholesterol connection	183/193 (94.8)	109/112 (97.3)	74/81 (91.4)	0.098
3 MD advised dietary change to lower cholesterol	176/192 (91.7)	107/111 (96.4)	69/81 (85.2)	0.007
4 MD discussed past efforts to lower cholesterol	100/189 (52.9)	76/111 (68.5)	24/78 (30.8)	0.000
5 MD discussed problems making dietary change	92/187 (49.2)	62/109 (56.9)	30/78 (38.5)	0.017
6 MD discussed solutions to problems	94/102 (92.2)	61/64 (95.3)	33/38 (86.8)	0.145
7 MD & patient (pt) negotiated an agreement regarding specific dietary changes or goals to pursue	169/190 (88.9)	103/110 (93.6)	66/80 (82.5)	0.019
8 MD gave nutrition materials or mailed after visit	126/192 (65.6)	109/112 (97.3)	17/80 (21.3)	0.000
9 MD referred pt for nutrition counseling	22/192 (11.5)	11/111 (9.9)	11/81 (13.6)	0.494
10 MD planned future action (visit) to address cholesterol	127/193 (65.8)	81/112 (72.3)	46/81 (56.8)	0.031
11 MD prescribed medication to lower cholesterol	34/193 (17.6)	28/112 (25.0)	6/81 (7.4)	0.000
12 MD discussed beginning or continuing exercise	171/190 (90.0)	108/110 (98.2)	63/80 (78.8)	0.000

Counseling Steps by Group of Study

Group	Number of Patients	Mean PEI Score ± SD
Intervention	113	8.5 ± 2.0
Usual care	84	6.1 ± 26
Total	197	7.5 ± 2.5

P <.0001 (ANOVA)

Changes in blood biochemistry parameters within treatment groups from base line and after 6 months of intervention.

	Usual Care group		Mean change	p-value	Intervention group		Mean change	p- value
	Baseline	Final			Baseline	Final		
Glucose	100.3±12.7 n=63	97±16.8 n=63	-3.3	0.087	101.7±30.9 n=92	101.5±13.4 n=92	-0.2	0.951
HbA1C	5.9±1.1 n=59	5.9±0.7 n=59	0	0.772	6.5±1.4 n=81	5.8±0.5 n=81	-0.7	0.000
TC	203.4±34.4 n=63	198.1±33.5 n=63	-5.3	0.129	210.1±38.1 n=92	194.6±41.5 n=92	-15.5	0.000
LDL	126.7±29.9 n=60	119.7±29.9 n=60	-7.0	0.033	129.7±29.9 n=82	115.5±35.5 n=82	-14,2	0.001
HDL	42.6±10.5 n=63	43.7±12.6 n=63	+1,1	0.347	43.1±10.3 n=91	42±11.2 n=91	-1	0.165
TG	171.3±95.5 n=63	180.3±106.5 n=63	+9	0.326	193.8±111.4 n=91	181.1±105.4 n=91	-12.7	0.136
Insulin	21.4±24.1 n=42	27.1±33.4 n=42	+5.7	0.377	18±9.7 n=55	20.1±20.1 n=55	+2.1	0.417
HOMA	5.9±9.1 n=42	7.5±12.7 n=42	+1.6	0.497	4.3±2.4 n=55	5.1±5.7 n=55	+0.8	0.307

- The study demonstrated that it is possible to implement an effective physician-based and patient-centered counseling plus office support intervention program to decrease cardiovascular risks in primary care clinics in the city of Quito.

- The PCPs from the intervention group more frequently performed the counseling steps and followed the guidelines to decrease CVD risk factors in their patients.

- In addition, we observed that patients in the intervention group significant decreased their fat consumption and improved their weight, BMI, HbA1C, total cholesterol, and LDL-cholesterol by the end of the study period.