AHRQ Grant Final Progress Report

- Title of Project: Atherosclerosis Risk Factor Reduction in Ecuador: Training Primary Care Physicians in Behavioral Counseling and Establishing Office Support and Patient Follow-up Systems.
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Report Components

Structured Abstract

Purpose: To evaluate the feasibility of a training program for physician-delivered nutrition counseling, in combination with an office-support program for patients at increased risk for developing diabetes as defined by a ≥30% risk of developing the disease within 7.5 years as judged by the Stern predictive equation.

Scope: Helping primary care providers (PCP) and health care systems to implement cardiovascular disease (CVD) risk factor reduction interventions is crucial to improving the health of the Ecuadorian population. However, no prior models existed in Ecuador for PCP-delivered risk-reduction interventions.

Methods: A randomized clinical trial was conducted in 6 primary care clinics in Quito, Ecuador. Participants included 15 primary care physicians (PCPs) and 197of their adult patients at high risk for type-2 diabetes. A twelve-step physician-based counseling intervention taught to physicians in a single four-hour patient-centered counseling training program aimed to decrease cardiovascular risk was delivered to the eight PCPs in the intervention group. After the group training, a member of the research team carried out individual follow-up 30-minute tutorials in the physicians' offices as requested by the PCPs. Seven additional PCPs who did not receive the training and continued to provide usual care comprised the control group. The patient experience was assessed by patient exit interviews administered immediately following the patient appointment. Assessment of patients' compliance with medication, anthropometrics, blood pressure, and blood biochemistry parameters were conducted at baseline, and at the 6-month end of the patient's involvement. Changes before and after the training as well as differences between groups were estimated utilizing Chi-square and ANOVA tests.

Results: A total of 197 patients were enrolled in the study, 113 in the intervention (IC) group and 84 in the usual care (UC) group; 99 patients (87.6%) in the intervention group and 63 (75%) in the control group completed the study between June 2014 and July 2016. Overall, participants from both groups had similar socio-demographic characteristics. The mean number of completed counseling steps, as measured by the patient exit interview, was significantly higher in the IC group (8.5±2.0 versus 6.1±2.6; $p<0.001$). Data also showed that in the IC group there were significant improvements in the following parameters: weight, BMI, HbA1C, TC, and LDL-cholesterol. There was also a higher percentage of self-reported medication compliance in the intervention group than in controls ($p=0.042$).

Conclusions: Our findings suggest that training PCPs in behavioral intervention for risk factor reduction is efficacious. Implementation of this educational strategy in Ecuador may result in reduction of cardiovascular risk among high-risk patients.

Key Words: coronary heart disease, cardiovascular disease, Latin America, diabetes, Ecuador, patient-centered counseling

I. **Purpose**

We assessed the feasibility of an evidence-based intervention model involving physician-delivered patient-centered counseling plus office support to improve the ability of Ecuadorian PCPs to reduce their patients' cardiovascular disease (CVD) risk. We randomized six participating clinics, and recruited 197 of their patients without CVD but at high risk of diabetes, to either intervention (IC) or usual care (UC) 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 (PEIs). We assessed the effect of the intervention on patient risk factor outcomes, including: LDL, weight, BMI, fasting

blood sugar, HgbA1C and insulin resistance (HOMA); and health behaviors including diet, physical activity, and medication adherence.

II. Scope

Background

Overweight and obesity are public health problems worldwide. As in other middle-income countries, Ecuador is simultaneously experiencing the presence of malnutrition characterized by both deficient and excess nutrition (1). It has been estimated that in developing countries including those of the Andean region poor nutrition/obesity and the diseases associated with it can have a greater negative impact on morbidity and mortality due to non-communicable diseases than is seen in developed countries (2). In recent decades the leading causes of death in Ecuador have included cardiovascular diseases, type-2 diabetes, and hypertension (3).

In 2013, the Ministry of Public Health of Ecuador Health published the results of the National Health and Nutrition Examination Survey (ENSANUT-EC) carried out between 2011 to 2013, which indicated that 62.8% of the adult population is overweight or obese (4). In addition, that survey also indicates that there is an increasing prevalence of cardiovascular (CDV) risk factors among the Ecuadorian population. Among Ecuadorian adults over 50 years of age approximately half of are dyslipidemic, 22.7% have hypertension, 10.3% have diabetes, and 57.2% smoke cigarettes. Other metabolic conditions associated with CDV are also common, for this age range prevalence rates of the metabolic syndrome (27.7%) are higher than those reported in the US adult population (22%) in 2010. The same national survey also indicates that 45% of Ecuadorian adults engage in low levels of physical activity, and that medication adherence is poor (48.9% of hypertensive patients reported not taking their medication). In addition, According to the official report by the “Instituto Nacional de Estadisticas y Cenos” type II diabetes, the primary cause of death in Ecuador and is a major risk factor for CVD. It is therefore necessary to implement novel strategies to decrease the indicated metabolic problems in the Ecuadorian population.

The UMMS team has demonstrated the efficacy and effectiveness of a physician-delivered patient-centered counseling plus office support intervention model (5-7). In the United States (US) we have successfully used patient-centered approaches in community settings in patients with elevated diabetes risk and in patients with type-2 diabetes (8). The training of PCPs to learn and implement this model is sustainable and scalable in a variety of settings, and we believe that adoption of this program by Ecuadorian PCPs will not only reduce CVD risk in their patients, but will also demonstrate the usefulness of this methodology in other developing countries.

Helping primary care providers (PCPs) and health care systems to implement CVD risk factor reduction interventions is crucial to improving the health of the Ecuadorian population. However, no prior models existed in Ecuador for PCP-delivered risk-reduction interventions.

Setting

Six primary care clinics in Quito, Ecuador were randomized to one of two conditions: an intervention condition (IC) in which the site PCPs receive training in patient-centered counseling methodology and received office system prompts to deliver the intervention, and a usual care condition (UC) in which the sites continued their usual practice. There were 3 intervention and 3 usual care participating clinics; and, 8 intervention and 7 usual care participating physicians. These clinics all had electronic medical records to facilitate the participant identification process.

Participants

Close to two thirds (62.8%) of 20-60 year-old Ecuadorians are overweight or obese, approaching adult US rates (69%); for this age range, prevalence rates of metabolic syndrome (27.7%) are higher than those reported in the US adult population (22%) in 2010 (4). The same national survey also indicates that 45% of Ecuadorian adults engage in low levels of physical activity, and that medication adherence rates are less than optimal (48.9% of hypertensive patients reported not taken their medication). In addition, Type-2 diabetes is a major risk factor for CVD, the primary cause of death in Ecuador. As a result we decided to recruit prediabetic patients, who represent about 28% of Ecuadorians between 20 and 60 years of age, and have a high prevalence of lipid abnormalities and hypertension.

III. Methods

Study Design

The study utilized intervention and assessment methods modeled after those used in the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH) (5) in which UMMS investigators found that a physician-delivered patient-centered counseling plus office support intervention, resulted in significant beneficial changes in patients' diet, weight, and blood lipid levels at one year of follow-up. Primary care sites in Quito, Ecuador were randomized to one of two conditions: an intervention condition (IC) in which the site PCPs received training in patient centered counseling methodology and received Spanish translated office system prompts to deliver the intervention, or a usual care condition (UC) in which the PCPs were not trained. The prompts in the intervention group included an initial visit algorithm to prevent diabetes, patient risk factor card, a patient/MD goal negotiation forms and the latest lipid results along with the completed Diet and Physical Activity Risk Assessment (DARA) filled out by the patient, lab results, and a DARA Goal Booklet. All materials were culturally appropriate and translated into Spanish. IC patients also received a pedometer and a pill organizer. The physicians in the UC condition did not receive study prompts and continued their usual practice. Each physician and

patient was followed for six months. Following the initial MD visit, each patient was administered the Patient Exit Interview by the clinic coordinator.

To facilitate the test of the intervention in the present absence of Ecuadorian guidelines, we distributed the U.S. guidelines for the management of lipids to all PCPs in the IC sites (9,10). At the end of the study the UC PCPs also received training in patient-centered counseling and U.S. guidelines for the management of lipids.

The study was approved by the Institutional Review Boards of the University of Massachusetts Medical School and the Universidad de las Américas (UDLA).

MD Training

The training included a didactic component teaching the relationship of behavioral and cardiovascular risk factors to CVD and a review of the guidelines for statin therapy. Subsequently, physicians were introduced to patient-centered counseling, the patient-centered counseling algorithms, a Diet and Physical Activity Risk Assessment (DARA) tool, and the statin use algorithm per the latest U.S. guidelines. Physicians in the intervention group were also taught to implement a 7-10 minute patient-centered counseling protocol that included information on walking and other easy physical activities as well as dietary counseling including reduced consumption of simple carbohydrates, saturated fat, and salt and increased consumption of fruits and vegetables. After the small group training, a member of the research team carried out individual follow-up 30-minute tutorials in the physicians' offices as requested by the PCPs. In the four-hour training sessions physicians were taught to use these materials with their patients using live examples followed by role-playing with fellow PCPs, with alternating roles as clinician, patient, and observer. Physicians received a training binder with: lecture slides, the counseling intervention algorithms, a sample script, and other intervention materials (diet and exercise goal sheets, the DARA guide, and the counseling algorithm), patient education materials, and a step counter. Physicians at the intervention sites delivered the interventions using a package, affixed to each study patient's chart at their first post-eligibility MD visit. The office support materials provided included a folder containing: the patient's most recent lipid levels, with a prompt highlighting LDL-C value, a completed DARA questionnaire, diet and physical activity goal sheets to use with the patient, the counseling algorithm, and a copy of the national lipid management guidelines.

Patient Recruitment & Follow-up Methodology

Pre-eligibility/Patient selection: Study participants were selected from each of the six Quito clinic patient panels. Clinic recruitment call lists were generated as needed. Each list was checked to remove patients who had already been

approached to be in the study and the clinic's tracking database was updated. Those identified received a telephone pre-screening recruitment call.
Prescreening recruitment call: The clinic coordinators made the pre-screening recruitment telephone calls. The call included an assessment of preliminary eligibility using the UMMS/UDLA IRB-approved script. For those found to be pre-eligible and interested, a fasting screening appointment was scheduled. For those patients who were scheduled for a screening appointment, a study ID was assigned and they were entered into the clinic's tracking database.
Screening assessment visit: The clinic coordinator reminded each patient of his or her screening appointment and reminded each to fast for 12 hours. The clinic coordinator met each patient the day of the appointment. During the screening visit, each patient provided informed consent and met with a clinic coordinator who assessed eligibility based on the inclusion and exclusion criteria. Each appointment lasted about 30 minutes. A fasting blood sample was collected for total cholesterol, HDL and blood sugar measurement. Height, weight, and waist circumference were measured wearing light clothing and no shoes (11). After resting for 10 minutes the patient's blood pressure was measured. The patient's medications were recorded. The clinical laboratory (NetLab) processed the blood and screening data and sent the information to the clinic coordinator to calculated the Stern risk using the Stern predictive equation, which includes age, gender, Hispanic or no, FBS, systolic BP, HDL, BMI, and family history of diabetes.(12). The clinic coordinator informed each screened individual by phone of his or her study eligibility, and if eligible the study was explained. Each patient's MD also received the patient's screening lab results. Each eligible patient was invited to return for a baseline assessment visit with the clinic coordinator and for those who agreed, a baseline appointment was scheduled. A $6 incentive was provided to everyone screened.
Baseline assessment visit: The clinic coordinator reminded each patient of his or her baseline appointment, which was the patient's first MD appointment after screening. The baseline assessment visit lasted approximately 30 minutes. Each patient signed an IRB approved study consent form and completed a baseline survey (CES-D depression scores (13,14) were calculated and a letter sent to each MD whose patient depression score was 16 or above). NetLab was notified to complete the remaining patient study assays. A $6 incentive was provided to everyone and a pedometer and pill organizer was provided to IC patients. The tracking database was updated. For patients in the intervention condition, their MD received the culturally appropriate and Spanish study prompts that included a completed Diet and Activity Risk Assessment (DARA) (completed by the patient before seeing the physician), DARA goal booklet; completed lab result summary; completed patient risk factor card; and the patient-centered counseling algorithm. The physicians in the Usual Care (UC) continued their usual practice and did not receive any study prompts.
Patient Exit Interview Administration: Following the first post-eligibility MD visit, each study patient was administered the Patient Exit Interview by the clinic coordinator. The tracking database was updated with the MD appointment and PEI data (15,16).

Six-month assessment visit: The clinic coordinator scheduled a 30-minute assessment visit six months after the baseline appointment. The clinic coordinator reminded each patient to fast for 12 hours. The clinic coordinator met with each patient the day of the appointment. The day of the appointment the clinic coordinator requested that the follow-up survey be completed; (CES-D scores were calculated and a letter sent to each MD whose pt scores 16 or above); and the patient's weight, blood pressure and waist circumference was measured. A blood sample was obtained to complete lipid profile, HbA1c, FBS, AST, and ALT assays. The medications the patient was taking were also recorded. The tracking database was updated and a $6 incentive given after completing the follow-up visit. The insulin samples were assayed at the end of the study. The study methodology is illustrated in Appendix A.

Intervention

The proposed study utilized similar intervention methods to those used in the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH) (16) in which UMMS investigators demonstrated that a physician-delivered patient-centered counseling plus office support intervention could produce beneficial changes in diet, weight, and blood lipids. In this study IC physicians delivered a patient-centered counseling intervention and utilized office system prompts including a counseling algorithm and patient lipid results along with the completed Diet and Activity Risk Assessment (DARA), patient risk factor card, patient/MD goal negotiation form and, a DARA Goal Booklet given to the patient. The intervention patients also received a step counter and a pill organizer. The physicians in the usual care condition (UC) didn't receive the system prompts and continued their usual practice. There were 8 intervention and 7 usual care physicians, with physicians in each study clinic being of the same group.

Measures/Data Sources/Collection

The Patient Exit Interview (PEI) is a brief measure of a patients' perception of content and quantity of the intervention received from their PCPs and was used to assess the degree to which clinicians delivered each of the counseling algorithm steps. Responses are summarized in a PEI index score. The PEI was administered to patients immediately following their 1st PCP visit (15,16).
Patient satisfaction is an important measure of health care quality, and a component of intervention feasibility. Patient satisfaction with medical care was measured using a subscale of the PSQ-18 (17).
Venous blood samples from an antecubital vein were collected in the morning after approximately 12 hours fasting. Samples were centrifuged to harvest serum within 2 hours. Serum glucose, total cholesterol, triglycerides, HDL, and direct LDL-C was measured using colorimetricenzymatic methods (Roche-Diagnostics) in a Hitachi Roche-917 full-automated analyzer system. Serum insulin was determined by an electro-chemiluminescent immunoassay using an automated ELECSYS 2010 analyzer system (Roche/Hitachi, Quito); HbA1c was measured

by inmunoturbidimetric methodology (Roche-Diagnostics. Blood biochemistry was carried out at NetLab Laboratory); NetLab maintains an internal and external quality control system (College of American Pathologists, Brazilian society of Clinical Pathologists). All assays met the criteria of the CDC-NHLBI Lipid Standardization Program.
The homeostatic model assessment (HOMA) was used to yield an estimate of insulin sensitivity from fasting plasma insulin and glucose concentrations.
Blood pressure was measured in a standardized manner in the right arm after 10 minutes of quiet sitting (18).
The Block fruit/vegetable and fat screeners were used to assess multiple areas of dietary behaviors (19).
The Women's Health Initiative (WHI) physical activity questionnaire was used to assess mild, moderate and strenuous activity (20).
Medication Adherence was measured by a single question in the surveys; "On average in the past month, how many days per week did you take your medication in a way the doctor prescribed it"?
The Center for Epidemiological Studies Depression Scale (CES-D), a 20-item survey assessing frequency of depressive symptoms (cognitive, affective, behavioral and somatic symptoms and positive affect) in the previous week was used at each study visit to assess depression (13,14).
Socio-demographic characteristics including education, income, employment, race/ethnicity, age, marital status, living situation, smoking, and chronic conditions were also assessed.

Statistical Analysis

Descriptive statistics with respective measures of dispersion were calculated for continuous variables; frequencies and percentages were calculated for categorical variables. Analyses were performed using an intention to treat model. Differences between groups were assessed with Chi Square and ANOVA or Kruskal Wallis tests. Differences within groups were assessed with paired t-test or the corresponding non-parametric statistics. Statistical analyses were performed with SPSS v.22.0 software (Armonk, NY: IBM CORP). Descriptive statistics are presented as means and SDs. Results are presented as means and 95% CIs in the text or as means SEMs in the figures; $p < 0.05$ was considered statistically significant.

Limitations

Although more clinics expressed an interest in participating in the study and many MDs were trained, there were 3 intervention and 3 usual care clinics and 8 intervention and 7 usual care participating physicians.

IV. Results

Principal Findings & Outcomes

Consort Diagram

Recruitment began in October 2014 and was completed in January 2016. The 6-month follow-up assessment visits began in April 2015 and continued to July 2016. Because of the longer than anticipated start-up period and the slower than anticipated recruitment a no-cost extension was requested and granted. With the extension we were able to meet the recruitment goal with 14.6% of those eligible to be screened being randomized to the study. Seventy-six percent of the patients who agreed to be screened never came in for their appointment. Of the 225 patients randomized, 113 patients received the intervention and 84 comparison patients came in for their MD appointment, for a total of 197 recruited. Although the lost-to-follow up rate was anticipated to be 10%, the comparison group had a 21% rate due in part to a single MD's discontent with the study at his site. A Consort Diagram is included in Appendix B.

Descriptive Statistics

A total of 197 patients were included in the study, 138 (70%) women and 59 (30%) men. Six clinics from two private, one public and one private/public-system were included in the study. There were a total of 3 intervention and 3 usual care clinics. At baseline, intervention and usual care groups were similar in age, gender, marital status, employment, family income and the proportion of first-degree relatives with type-2 diabetes. However, the level of education was higher in the intervention group; whereas the mean number of hours of work per week was higher in the usual care group. A table with the Socio-demographic characteristics of the study population is included in Appendix C, Table 1.

Patient Exit Interviews

To evaluate patient perception of PCPs regarding present educational intervention, a Patient Exit Interview was done after the first medical appointment. It was expected that the physicians would provide 12 counseling steps to their patients during the clinical visit. The indicated interview asked for the use of those steps by the PCPs. Data showed that patients in the intervention group received a significant higher number of counseling steps than the usual care group, score of 8.5 ± 2.0 compared to 6.1 ± 2.6 respectively, $p<0.001$, PEI results are included in Appendix C, Tables 2a and 2b.

Changes in anthropometric parameters and blood pressure

Comparison between treatment groups showed that there were no significant differences in height, weight, and BMI at base line or at the end of the study period. However, both treatment groups showed a significant decrease in the mean of BMI index and weight from baseline until the end of the study period. Blood pressure (systolic and diastolic) was comparable between groups at the beginning and at the end of the study period). Results are included in Appendix C, Table 3.

Changes in blood biochemical parameters

Baseline comparison between the groups showed that serum concentrations of HbA1C were significantly lower in the usual care group (6.0±1.1) than in the intervention group (6.4±1.3) (p=0.023). Other parameters such as glucose, total cholesterol, LDL, HDL, triglycerides, insulin, and HOMA were similar between groups at base line. After 6 months of intervention, comparisons between groups showed that concentrations of all serum biochemical parameters were similar in both groups. Assessment of changes within groups showed that in the UC group only serum concentrations of LDL significantly decreased from base line to the end of the study period, -7mg/dL. Contrary, in the IC group we observed a significant decrease in serum concentrations of HbA1C, total cholesterol, and LDL, Table 4. The decrease in LDL in the IC group was -14.2 mg/dL, Appendix C, Table 4. It is important to indicate that patients in the IC treatment group had a significantly higher frequency of having been provided with lipid-lowering medications than the UC group, 25.0% versus 7.4% respectively, p=0.001. Nineteen patients in the IC group received statins, and 6 fibrates whereas in the UC group none received statins, 5 received fibrates and 1 received an inhibitor of PCSK9. Further analysis considering only the individuals that did not received statin treatment showed that patients from the IC group improved their serum LDL concentrations from 125.8±26.1 to 122.0±33.0, p=0.001. However, patients that did not receive statins in the UC group decreased serum LDL concentrations from 127.7±30.7 to 121.0±30.4; this decrease was not statistically significant, p=0.057.

Changes in diet and physical activity

Patients in the IC group reduced the amount of fat intake from base line to the end of the study, from 17.2±7% to 14.3±7%, p=0.005 while patients in the UC group did not significantly change their fat intake, p=0.756. There were no significant differences in the consumption of fruits and vegetables either between or within treatment groups during the study. Regarding physical activity, both treatment groups were comparable through out the study period.

Patient Satisfaction

We used a patient satisfaction subscale consisting of 2 questions to assess "global satisfaction with medical care". Patients from the IC group scored significantly higher than patients in the UC group in both questions that were part of the score and also in the subscale $P<0.001$.

DISCUSSION

Previous work has shown that lipid management programs facilitated during physician visits result in a decrease in cardiovascular risk factors (8). Our previous work (NHLBI-supported WATCH study) at the Fallon Community Health Plan in Central Massachusetts that evaluated the efficacy of physician-delivered patient-centered counseling plus office support intervention showed significant beneficial changes in patients' diet, weight, and blood lipid levels after one year of follow-up. In that study, compared with patients that received usual care, patients that were attended by physicians that received the training intervention had lower saturated fat intake (10.3% decrease), reduction in body weight (2.3 Kg), and a decrease in LDL-cholesterol (3.8 mg/dL). In this study, physician's training plus office support also resulted in a reduction of fat intake and weight that was similar in magnitude to the one observed in the WATCH study; decrease in body weight also resulted in a significant decrease in BMI that was greater than the one observed in the WATCH study, -1.8 versus -0.81 Kg/m2 respectively. In addition, the current study showed that patients in the IC group had lower blood HbA1c, TC, and LDL-cholesterol by the end of the intervention. Reduction of LDL-cholesterol (-14.2 mg/dL) was greater than the one observed in the WATCH study (-3.8 mg/dL), although the WATCH study intervention was purely dietary, whereas the present study also involved pharmacologic therapy. Together, these results indicate that implementation of physician-delivered patient-centered counseling plus office support intervention can contribute to decreasing the burden of diabetes and cardiovascular disease in Ecuador.

The present effort was designed as a feasibility study and for this reason it has several differences with the WATCH study. Thus the number of physicians (15 vs. 45) and patients (197 vs. 1162) was lower, and the duration of patient follow-up shorter (6 month vs. one year). However, physicians' training and the components of the patient-centered counseling/office support model were similar in the two studies, and despite the lesser power in the present study there were significant favorable changes in the measured risk factors.

SIGNIFICANCE

These data indicate that physician counseling training and the office support tools used in this study are effective in improving cardiovascular risk factors in at risk populations suggests that it could be widely implemented in both private and public health care systems in Ecuador and other countries where diabetes and cardiovascular disease have become major public health problems.

The present study highlights the importance of clinical studies in the US that can be applied in Latin-American countries. Since the results of both studies found similar beneficial effects with similar counseling training interventions, we plan to expand our initial feasibility study into a larger-scale study with adequate power to explore a number of important clinical endpoints. Finally, we have shown that it is possible to achieve a successful collaboration between academic institutions in the USA and Ecuador, overcoming initial cultural differences and resulting in a successful study outcome and the signing of a Memorandum of Understanding between UMASS & UDLA, and FIU & UDLA

CONCLUSION

This feasibility study showed that it is possible to implement an effective physician-based and patient-centered counseling plus office support intervention program to decrease cardiovascular risk in private and public primary care clinics in the city of Quito, Ecuador. The majority of participating PCPs were very willing to participate in the study, and remained full partners over the course of the trial. PCPs from the intervention group more frequently performed the needed counseling steps to decrease CV 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, TC, and LDL-cholesterol by the end of the study period.

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