CIIPEC

CENTRO INTEGRAL DEL INCAP PARA LA PREVENCIÓN DE ENFERMEDADES CRÓNICAS

PROTOCOL:

Primary health and community-based support model to lower the risk of cardiovascular diseases in individuals with type 2 diabetes *mellitus* and/or arterial hypertension, in urban areas of San Jose, Costa Rica and Tuxtla Gutierrez, Chiapas.

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Primary health and community-based support model to lower the risk of cardiovascular diseases in individuals with type 2 diabetes mellitus and/or arterial hypertension in urban areas of San Jose, Costa Rica and Tuxtla Gutierrez, Chiapas

The **main goal** of this project is to adapt an applicable intervention model that can be delivered at the primary health care (PHC) level. The model is intended to improve adherence to treatment and lifestyle changes aimed to reduce the risk of developing cardiovascular disease (CVD) as a complication of type 2 diabetes *mellitus* (DM) and/or arterial hypertension (HT).

The proposed model incorporates several innovative components, including:

- The use of simple methods that can be implemented at the PHC level without the need for laboratory tests to detect and classify cardiovascular risk for individuals with HT or DM
- Individualized treatment, in accordance with international standards, that is tailored to the level of cardiovascular risk detected, including changes in lifestyle with or without pharmacological treatment
- Training sessions for both individuals and groups, using materials and concepts that are easily understood even for persons with low literacy
- Reinforcement of the educational concepts offered by auxiliary PHC workers (technicians or other health care auxiliaries).

The model was initially developed in a pilot study in urban areas of Guatemala. For the current project, we will incorporate culturally relevant elements into the educational intervention so that the model can be adapted for use in urban areas in the cities of San Jose de Costa Rica and Tuxtla Gutierrez, Chiapas, Mexico.

The specific aims of this project are:

1. To describe current CVD control and prevention capabilities at the PHC level in the cities of San Jose de Costa Rica and Tuxtla Gutierrez, State of Chiapas, in the south of Mexico.

2. To adapt and validate a cardiovascular risk prevention model (based on one initially developed for Guatemala) that incorporates the most recent concepts promoted by the World Health Organization (WHO) so that it can be implemented in PAL centers and urban communities of San Jose de Costa Rica and Tuxtla Gutierrez, Chiapas.

3. To adapt and validate the educational materials initially developed for Guatemala so that they are culturally relevant in the urban contexts of San Jose, Costa Rica, and Tuxtla Gutierrez, Chiapas.

4. To assess the capability of the proposed intervention model to provide short-term improvement in adherence to treatment; this assessment will evaluate knowledge, attitudes, and practices related to the prevention, detection, and management of the risk of CVD in adults who suffer from DM and/or arterial HT.

Study design
The study will be carried out in three stages:

Stage 1: (3 months) First, the study team will conduct **formative research,** including interviews with government health care administrators and decision makers to identify the capabilities, resources, and programs offered by the state and local health system for CVD care, including DM and HT. We will also explore knowledge, perceptions, and opinions regarding CVD among PHC staff (including both medical and paramedical staff) and residents of the participating communities, via focus groups.

Stage 2: (4 months) Next, the team will **adapt and validate** clinical care protocols and educational materials, taken from the background model developed in Guatemala, and ensuring that the resulting educational materials are culturally relevant for each of the areas

participating in the study.

Stage 3: (10 months) We will next apply the **intervention**, and evaluate the feasibility, acceptability, and short-term effectiveness of the proposed model, using a quasi-experimental design that includes both an intervention group and control group in each of the participating countries.

STAGE 1. FORMATIVE RESEARCH

This stage includes structured interviews and focus groups with health system administrators and decision-makers, PHC providers and staff, and individuals affected by DM or HT.

a) **Health system administrators and decision-makers.** A structured interview protocol will be used for discussions with key health system officials in each country. The interview will ask about health policies used to manage CVD in the population. Questions will focus on infrastructure, resources, programs, and clinical standards regarding the treatment of DM and HT, as well as CVD prevention approaches at the community level. During this stage, we will identify educational materials that have been prepared by the government to offer information to the PHC population regarding actions to manage and control DM and HT.

b) **PHC providers and staff.** In each country, the study team will conduct a focus group with PHC providers and staff at the health center. The purpose will be to explore the following issues regarding DM and HT:
- epidemiological spectrum of those conditions in the community
- scope of prevention and control of biological and behavioral risk factors
- diagnosis and treatment at the primary health care level

The guidelines for health care provider focus groups are included in Appendix 1.

c) **Individuals affected by DM and/or HT.** In each country, the study team will conduct two focus groups, one for each of the diseases. The following topics will be explored:
- Magnitude and symptoms of CVD
- Impact of CVD on the economic and socioeconomic status of families and the community
- Risk factors (biological and behavioral) of CVD
- Scope of the prevention and treatment programs
- Adequacy of the existing infrastructure for the prevention and control of CVD
- Identification of deficiencies in health services

Appendix 2 contains the corresponding guidelines.

Selection of participants

a) **Health system administrators and decision-makers.** The research team will identify the persons best able to provide the required information and invite them to accept an individual interview.
b) **PHC providers and staff.** The team will invite all professional and technical staff (i.e., physicians, nurses, primary care technicians) from the participating health centers to take part in a focus group.
c) **Individuals affected by DM and/or HT.** The team will conduct two focus groups with individuals affected by the targeted conditions, one group for DM and another for HT. These individuals will include both health center patients as well as people in the community who do not go to the health center but who have the relevant conditions. Participants will include a mixture of patients registered at the clinic and community members who do not attend the clinic. Clinic attendants will be selected by clinical staff from the list of patients at the clinic based on their diagnosis. They will be referred to research staff, who will offer the information required in the informed consent process and collect, if granted, oral consent. Community participants will be recruited from the community, posting a flier on public places to invite people to participate in the focus group discussion. Those who volunteer will receive from research staff the information required in the informed consent process and collect, if granted, oral consent. Participants will include both men and women who are at least 21 years old and have either of the two conditions targeted in the study. Each focus group will consist of 6-8 people.

STAGE 2. DEVELOPMENT AND VALIDATION OF MATERIALS

This stage includes two activities: consensus workshops and focus groups.

1) The first activity includes running two **consensus workshops** in each country with the PHC staff to discuss and reach consensus on the criteria for diagnosis, risk identification, and clinical management of patients with DM and/or HT.

Two weeks prior to the first workshop, participants will receive a copy of the medical care program developed for the pilot study in Guatemala and will be asked to review it. This program is based on recommendations and algorithms supported by the World Health Organization (WHO) and other international organizations for the integrated management of HT and DM and the identification of CVD risk. The program proposes steps to reduce such risk and is designed to be implemented by the staff of low-resource health centers. Appendix 3 contains the registration form used to collect clinical data from each individual participating in the project.

During the workshop, participants will review the key concepts in the medical care program, and those concepts will be compared with the treatment guidelines or rules applicable in the country. If discrepancies are found, participants will be asked to suggest ways to reconcile them. In addition, if there are concepts in the WHO guidelines that have not been incorporated into national standards, the appropriateness / applicability of including the WHO concepts will be discussed.

Following this approach, participants in the second workshop will review an algorithm recently developed by WHO for use in Latin American countries. The algorithm proposes a way to rate the risk of cardiovascular disease in people affected by DM or HT. To assess cardiovascular risk, this algorithm uses easy-to-measure risk factors that do not require laboratory tests, and cost remains low (Appendix 3).

2) The second activity involves the adaptation and validation of the educational materials that will be used to train PHC workers who will deliver health promotion messages and activities with patients. We will do this based on opinions collected from community members and primary health care workers in two consecutive **focus groups**.

Educational materials will be adapted from the manual “Healthy and Happy Heart" (Appendix 4), which is based on a program developed in the United States by the National Heart, Lung and Blood Institute (NHLBI) for use by cardiovascular health promotion in Latino communities. The manual has been adapted in a pilot study for Latin American countries, including Argentina, Peru, and Guatemala. The manual describes activities related to CVD and its risk factors as well as practical methods to promote physical activity, a healthy diet, and abstention from smoking. Before educational materials are distributed, the manual will be reviewed and adapted to ensure that its advice is culturally relevant to Chiapas and Costa Rica.

We will carry out two focus groups in each country to validate the contents of the manual. These groups will include members of the community (i.e., one group of DM patients and another of HT patients) whose educational and socioeconomic characteristics are similar to those of the target population. At least three PHC workers from participating communities will be invited to participate in these focus groups; they will be responsible for the training in the use of the educational materials. In the first focus group meeting, participants will be asked to identify the positive features of the educational materials as well as any features that need to be adjusted to make them suitable for the health system in each country and compatible with the needs, knowledge, and practices of the populations targeted for the intervention. Educational materials will be revised to address the issues identified in the focus groups. In the second focus group, educational materials that have already been adapted will be given to participants, who will be asked to provide additional comments as well as suggestions to promote their use. To the extent possible, the second focus group will involve the same participants who were in the first focus group.

STAGE 3. INTERVENTION

The intervention stage will involve an intervention and a control group, including the health center in each community. Health centers will be selected using a quasi-experimental non-random design. Random selection is not appropriate since the implementation of the intervention model requires an extensive process of consensus with officials and health workers, which could be compromised if there were problems with a community randomly selected for intervention. In

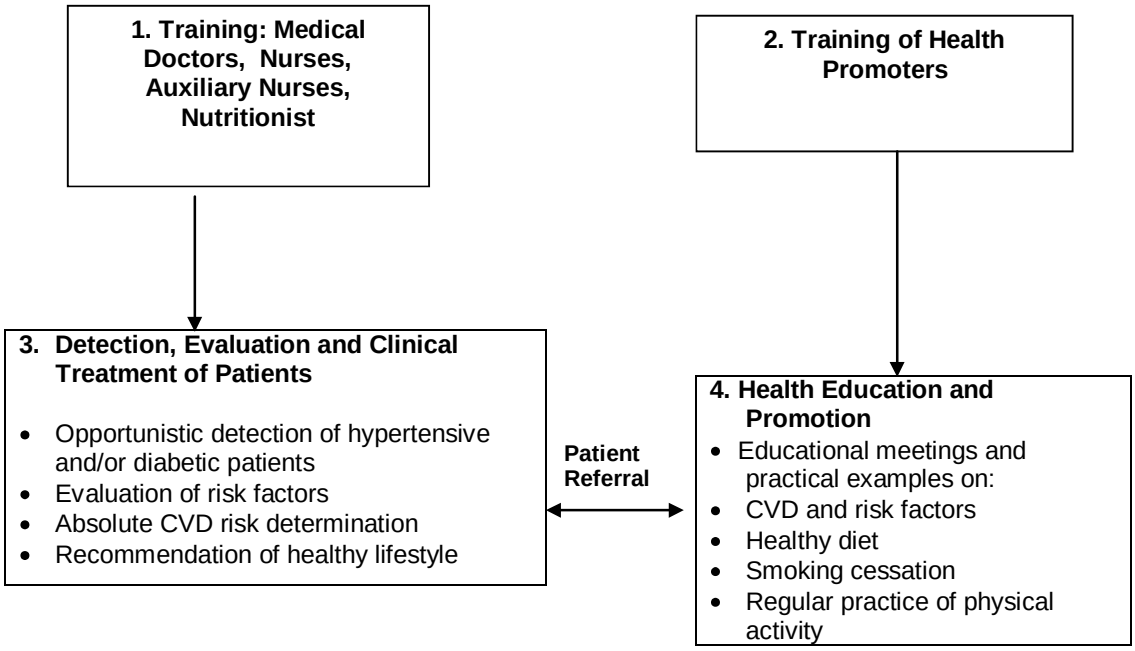
selecting the intervention and control communities, we will seek to include communities that are comparable in terms of socioeconomic conditions; participants at each location will be matched by diagnostic criteria (diabetes and hypertension), age (± 3 years), and sex. The control group will not receive any specific intervention (i.e., the control group will receive the standard treatment).

Sample size: Our sample is calculated based on the experience of the pilot study of Guatemala, in which 75 patients were recruited and with a similar follow-up time to that proposed here, patients experienced significant reductions in blood pressure of up to 30 mmHg. Similarly, participants in the Guatemala pilot who complied with at least 80% of the educational meetings experienced significant changes diet and physical activity. Therefore, in our study we will require a sample size of 75 patients in the intervention group and 75 in the control group. Due to the likely loss to follow up, this sample will be increased by 20%, for a total of 90 patients recruited in each group (total of 180 participants). We are not planning to recruit an equally distributed sample of patients with low cardiovascular risk, medium or high. The distribution in the sample will reflect the prevailing distribution in the clinic.

Inclusion criteria: Male or female participants must be 21 years or older, residents of the area served by the selected health center, literate (i.e., able to read and write) and diagnosed with DM or HT. Intervention group participants must also be willing to comply with proposed educational activities, including attendance at training sessions with support staff of the health center.

Exclusion criteria: Patients will be excluded from the study if they have experienced complications from diabetes (kidney problems, peripheral circulation of the retina, organ damage) or a history of stroke (thrombosis, ischemia, aneurysm) or cardiac problems (angina, infarction). Other criteria for exclusion include presence of disease or mental impairment that prevents understanding of the instructions provided as part of the educational strategy; physical defect, or disability preventing regular physical exercise.

Schematically, the activities to be performed include:



Each of these steps is detailed below.

1. Training of doctors, nurses and community health workers in PHC centers, using the material that was valid for Stage 2. This activity will ensure that health personnel are trained to identify, assess, and treat people with HT and/or DM following a simple methodology based on recent international standards. Training of health personnel will be conducted through workshops

and distribution of educational materials. These activities will use clinical protocols previously validated in Stage 2.

2. Selection and training of community workers using the materials produced in Stage 2. For this stage of the study, at least three health workers will be selected for each PHC center. Workshops will provide training, including discussion of the symptoms of DM and HT, CVD risk factors, prevention methods (e.g., healthy diet, exercise, smoking cessation), according to the general content of the manual validated in Stage 2. Participants will review the correct procedure for taking measurements of blood glucose, blood pressure, and anthropometry (abdominal circumference). After training, community workers will be integrated into the care team to work directly with patients with DM or HT.

3. Detection, evaluation, and clinical management of patients with hypertension and diabetes. The goal is to recruit 90 patients in each health care center (intervention and control), selected from persons previously or currently diagnosed with DM or HT who are patients at the health center. We estimate that 1 to 2 months will be needed to recruit the required sample. This activity will be implemented in the PHC centers by health staff, doctors, nurses, nurse assistants, dietitians, and health promoters.

Activities 1 and 2 will each take 1 month and will be performed simultaneously. Activity 3 will last about 9 months (1 month for recruitment and 8 months follow-up).

Identification and recruitment of participants
The identification and recruitment of individuals with DM or HT will be conducted at the health center and may include people who attend to the health center for any other illness, or walk-in in response to information campaigns that will be part of this program.

The detection of new hypertensive patients will include the following steps:
- Identify adults (men and women) 21 years or older
- Take blood pressure (BP). If the patient is hypertensive (systolic BP ≥ 140 mmHg and diastolic ≥ 90), confirm the first result, taking a second measurement five minutes after the first one, with the patient at rest. If there is a difference of more than 10 mm Hg in these two results, a third measurement take will be performed 1 minute after the second. Hypertensive patients will be referred to the health center within the following one or two weeks to confirm the diagnosis.

Detection of new diabetic patients will include the following steps:
- Identify adults (men and women) over 21 years old.
- Identify adults with abdominal obesity
- Identify adults with high blood pressure (systolic ≥ 140 mmHg and diastolic ≥ 90 mmHg)
- On patients who meet any of the previous criteria, take blood glucose measurement by finger prick with a portable glycometer (HemoCue®) and, if health center resources permit, perform a blood glucose test.

Evaluation of cardiovascular risk factors
When patients arrive at the health center 1 to 2 weeks after initial screening (Visit 1), a new blood pressure measurement will be taken. Other risk factors will be evaluated in patients with confirmed HT (systolic pressure ≥ 140 mmHg or diastolic pressure ≥ 90 mmHg in at least two consecutive measurements) and in patients already known to suffer from DM and / or HT:
- Measurement of waist circumference to identify abdominal obesity. In men, abdominal obesity will be defined by a waist circumference greater than 102 centimeters; in women, obesity will be defined by a waist circumference is greater than 88 centimeters.
- Taking of blood glucose using a portable glycometer (HemoCue®).
  - In people with BP ≥ 140/90 mmHg and abdominal obesity: The presence of these two factors predicts a high probability that the person has diabetes or pre-diabetes. Thus, the use of glycometer is more cost-effective. Diabetics are defined as those individuals with fasting blood levels of glucose ≥ 126 mg / dl or ≥ 200 mg / dl when the person is not fasting
  - People with previously diagnosed diabetes and patients undergoing treatment with insulin and /or hypoglycemic will also require blood glucose testing
- Registration of patient's sex and age

- Investigation about smoking habit
- Medical history to rule out complications (see exclusion criteria).

Determination of total and absolute cardiovascular risk

The cardiovascular risk assessment determines the patient's risk of suffering a heart attack or stroke in the next 10 years. Absolute cardiovascular risk is determined by the risk factors the patient has and is used to design a more cost-effective treatment. Absolute cardiovascular risk is determined by means of a WHO-endorsed algorithm recently developed for use in Latin American countries. In determining the absolute cardiovascular risk using this algorithm, risk factors can be identified through simple measurement that do not require laboratory analysis, and are inexpensive.

Table 1 presents the algorithm used to estimate the absolute cardiovascular risk in patients (probability of having CVD in 10 years). This estimate takes into account:

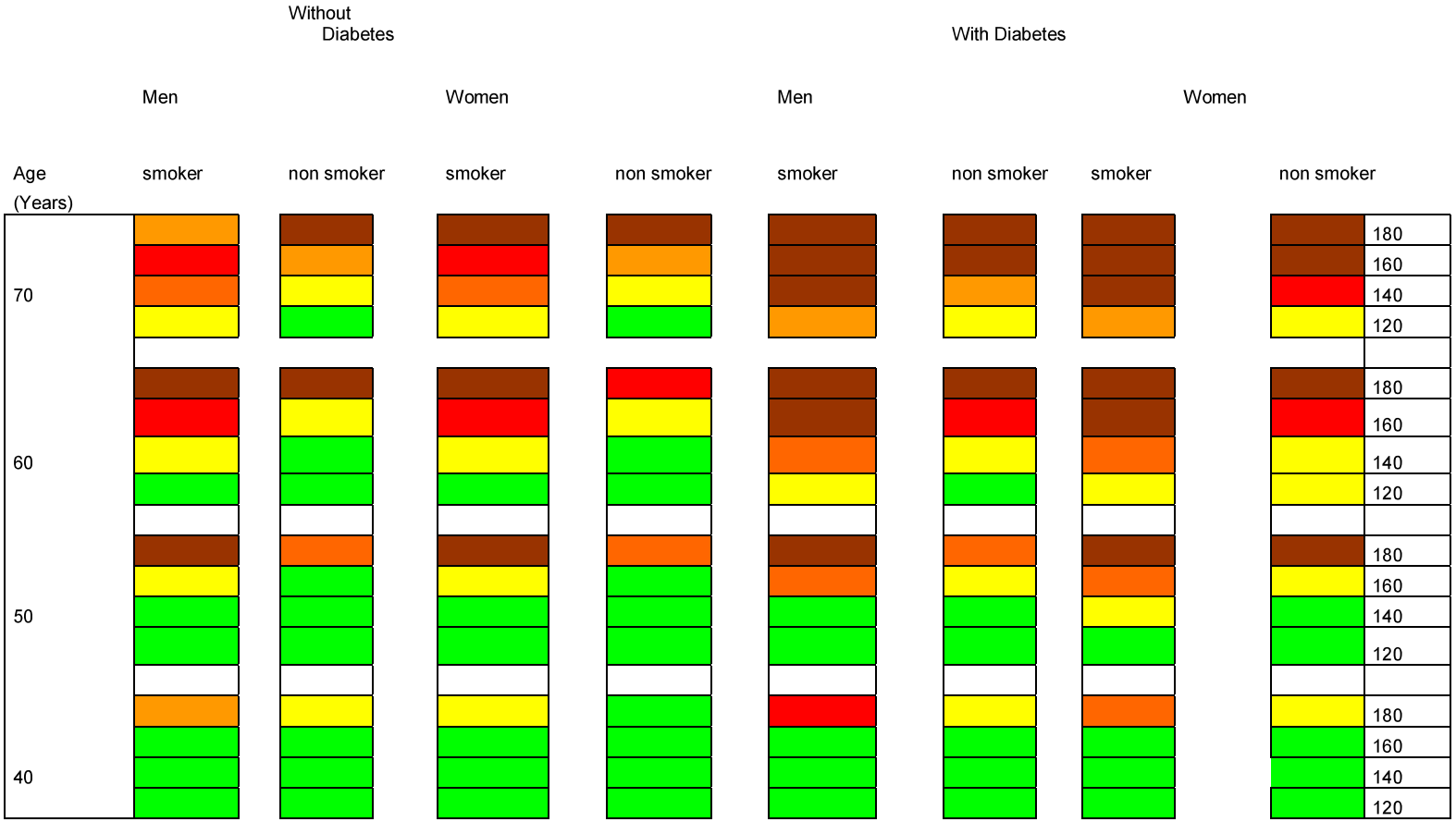
- Presence or absence of diabetes
- Sex
- Age
- Smoking habits
- Value of systolic blood pressure (SBP)

Using this information, the absolute cardiovascular risk is estimated as follows:

1. Select the appropriate section of the table depending on the presence or absence of diabetes
2. Select the appropriate section of the table for men or women
3. Select the appropriate box for smoking or non-smoking
4. Select the row corresponding to the age of the patient
5. In this row, locate the nearest cell for systolic blood pressure (SBP) in mm Hg. The color of this cell indicates the risk of cardiovascular disease for the next 10 years, from low to extremely high, according to the likelihood of suffering from CVD:
   - Low (green) = <10%
   - Medium (yellow) = 10-19.9%
   - High (orange) = 20-29.9%
   - Very high (red) = 30-39.9%
   - Extremely high (magenta) => 40%

Risk stratification is used to determine treatment (see Table 2).

Table 1. Algorithm to determine the absolute cardiovascular risk in 10 years when CVD is present, by sex, based on age and the presence of type 2 diabetes mellitus, smoking habit and systolic blood pressure values (SBP).



The clinical treatment offered to patients with HT and/or DM consists of a combination of recommendations on healthy lifestyles and drug therapy, according to the schedule described in Table 2.

Promotion of Healthy Lifestyles
A medical doctor or nurse will recommend to all patients the practice of the following healthy lifestyle habits:

- Smoking cessation
- Healthy diet
  - Increased intake of fruits and vegetables
  - Reduced consumption of salt, fat, sugar, and alcohol
- Regular practice of physical activity
- If the patient is not overweight or obese: 30 minutes of moderate physical activity every day of the week
- If the patient is overweight or obese: 60 minutes of moderate physical activity every day of the week

Drug Therapy
Pharmacological treatment of new diabetic patients will be based on hypoglycemic medication (metformin), restricted to those patients who, during follow-up visits, have glucose levels higher than 226 mg / dl while fasting. The pharmacological control of new hypertension patients (with thiazide type diuretics such as indapamide) will be initially restricted to patients with absolute high cardiovascular risk and to some patients with medium cardiovascular risk with systolic blood pressure (SBP) ≥ 160 mm Hg. For patients already known and have an established treatment, treatment will be reviewed and adjusted taking into account the history of previous controls and standards of care.

To facilitate the adoption and maintenance of the healthy lifestyles and drug therapy needed to control patients' risk factors, the clinic staff will recommend that all patients attend bi-monthly educational sessions led by health promoters as part of the intervention.

Control and monitoring of patients
All patients will visit the health center at least twice to perform the procedures described in Table 2. During each visit, health personnel will:

- Measure blood pressure
- Measure waist circumference
- Measure blood glucose (in diabetic patients)
- Ask about smoking habit
- Assess physical activity
- Assess eating habits
- Remind patients of the goals of treatment

Based on this information, health personnel will assess progress made by the patient and recommend continuation or modification of treatment.

Depending on the level of absolute risk of CVD, there may be the need for more frequent visits, according to the following schedule:

- Patients with low cardiovascular risk (LR) will be asked to return to the clinic every 4 months (at beginning, at the fourth month, and at the eighth month) for a total of 3 assessments for each patient over a period of 8 months.

- Patients with medium cardiovascular risk (MR) will be evaluated on five occasions.

- Patients with high cardiovascular risk (including very high and extremely high risk) (HR) will be evaluated each month at the clinic.

Table 2. Schedule for the treatment and follow-up of hypertensive and diabetic patients.

CVD Risk Level	Visit 1	Visit 2	Visit 3
Low Risk	• Confirmation of HT diagnosis, evaluation of risk factors and DM • Counseling for smoking cessation, changes in diet, and regular physical activity • Schedule visit No. 2 at 3 months	• Counseling for smoking cessation, changes in diet, and regular physical activity • Measurement of waist circumference • Schedule visit No. 3 at 3 months • For patients whose glucose levels persistently exceed 6mmol/l when fasting and in spite of a healthy lifestyle, prescribe metformin according to current standards	• Counseling for smoking cessation, changes in diet, and regular physical activity • Measurement of waist circumference • For patients whose glucose levels persistently exceed 6mmol/l when fasting and in spite of a healthy lifestyle, prescribe metformin according to current standards
Medium Risk	• Confirmation of HT diagnosis, evaluation of risk factors and DM • Counseling for smoking cessation, changes in diet, and regular physical activity • Schedule visits No. 2 at 3 months.	• Counseling for smoking cessation, changes in diet, and physical activity • Measurement of waist circumference • If SBP ≥ 140: Start low dose of anti-hypertensive according to standards of care • Schedule visits No. 3 at 3 months • For patients whose glucose levels persistently exceed 6mmol/l, when fasting and in spite of a healthy lifestyle, prescribe metformin according to current standards	• Counseling for smoking cessation, changes in diet, and regular physical activity • Measurement of waist circumference. • Continue with medication. If SBP ≥ 140, increase doses of anti-hypertensive according to standards of care • For patients whose glucose levels persistently exceed 6mmol/l, when fasting and in spite of a healthy lifestyle, prescribe metformin according to current standards
High Risk	• Confirmation of the diagnosis of hypertension, evaluation of risk factors and diabetes • Counseling for smoking cessation, changes in diet, and regular physical activity • Start low dose of anti-hypertensive, according to standards of care • Schedule visits No. 2 in	• Counseling for smoking cessation, changes in diet, and regular physical activity • Measurement of waist circumference • Continue with medication. Prescribe aspirin (100 mg / day) • Schedule visits No. 3 in two months. If SBP ≥ 140: Increase dose of anti hypertensive • Schedule visits No. 3 at	• Counseling for smoking cessation, changes in diet, and regular physical activity • Measurement of waist circumference • Continue with medication. If SBP ≥ 140, refer the patient to a higher level of care • For patients whose fasting glucose levels persistently exceed 6mmol/l in spite of a

	4 weeks	2 months • For patients whose fasting glucose levels persistently exceed 6mmol / l, in spite of a healthy lifestyle, prescribe metformin according to current standards	healthy lifestyle, prescribe metformin according to current standards

To improve patient follow-up, the following strategies will be used:

- The date and time of the next appointment will be set, taking into account the availability and time preference of the patient
- Health promoters will telephone or make a home visit to remind the patient of the appointment. If the patient fails to appear, the nurse will call to ask for the reason for the absence and to offer another appointment

Education and health promotion

Health promoters will be responsible for organizing and conducting educational sessions and practical demonstrations on CVD, risk factors, and healthy lifestyles. These activities are intended to help patients adopt the necessary behavioral changes to reduce the risk of CVD. These meetings should be carried out in groups every two weeks in a location that is convenient for patients, which could be the health center or another nearby location. Educational sessions may include the patient's family members (e.g., spouse). In the educational sessions, health promoters, using the manual "Healthy and Happy Heart" (adapted and validated during Stage 2 of the study), will discuss issues related to the symptoms of CVD risk factors, body weight control, healthy diet, physical activity, and smoking. Patients can begin to participate during any of the meetings. This will facilitate the incorporation of new patients.

On the days that educational sessions are conducted, blood pressure and glucose tests will be offered to people accompanying patients to detect new cases of HT or DM. Individuals found to have risk factors will be advised to consult with staff at the health center to receive a more thorough assessment and proper treatment.

Evaluation

Effectiveness: The program's effectiveness will be measured by increasing adherence to prescribed treatment, using indicators of short-term results, including the rate of individuals who come to their control appointments at health center according to the set schedule, the rate of patients who attend the educational sessions, the proportion of patients who adopt the recommended lifestyle changes (changes in eating habits, physical activity, reduction or elimination of smoking) and, changes in knowledge, attitudes, and practices in relation to CVD risks.

Although it is not the purpose of this study to evaluate the effectiveness of the treatment offered, the clinical evolution of the patients will be taken into account, measuring the proportion of patients showing improvement in controlling blood glucose and blood pressure, and the proportion of patients showing changes in risk anthropometric parameters (waist circumference, BMI). Similarly, the occurrence of any CVD event among participants will be recorded during the project period.

Feasibility: This will be evaluated in terms of cost, infrastructure, and the need for staff. The following costs will be included: time of professional and auxiliary staff in charge of medical care and educational activities; time for professional staff to conduct focal groups, workshops, materials design, training, and preparation of educational materials; transportation costs and operational costs, such as telephone calls.

Acceptability: This will be determined in terms of the desire and willingness of health workers to be trained, to participate in the study, and to follow the guidelines. The willingness of patients to participate will be assessed in the screening as well as in the intervention, especially in the compliance with steps and treatment for each case.

Satisfaction: A satisfaction survey from the service provider (medical doctor and paramedic) will

be included, as well as the user satisfaction with the care received.

Flow pattern in patient care: The flow of care in each health center will be observed and measured with variables such as space, time of patient care, and the number of new patients who enter the health center each day. This information will be useful to optimize patient flow and to plan the adoption of this (or other) interventions in more health centers, with emphasis on space available and time devoted o patient care.

Table 3. Time and main activities of the three stages of the project to be developed in each country

Stage 1. Formative research **(August-October 2010)**	**Stage 2. Adaptation and validation of materials** **(November 2010 - February 2011)**	**Stage 3. Intervention** **(March-December 2011)**
Activities: In-depth interviews with professional staff of the clinics, including managers responsible for making decisions and physicians to identify the skills of health service providers and decision-makers on CVD magnitude, risk factors (biological and behavioral), and methods for the diagnosis and treatment of these diseases. Focus Groups: A focus group with health providers of the participating clinics. Two focus groups, one for each condition, consisting of people affected by the diseases, including both health center patients and people in the community who do not get care at the health center.	Activities: Two consensus workshops in each participating health center in each country, to publicize the proposed model for the management of diabetes and hypertension, to classify CVD risk, and (from the group discussion) to obtain consensus from health workers on the adaptation and validation of clinical and educational materials to be used in patients with diabetes and hypertension. Two focus groups with patients in clinics or health centers in the intervention community (one for people with HT and one for people with DM) and PHC staff assistant to ensure that they understand the educational materials prepared for them.	Activities: Training for professional health staff and the community in the application of clinical protocols and the use of educational materials developed during Stage 2. Development of an intervention study in a PHC center in each country, including 90 patients with HT and/or DM per center. Patients will receive care in accordance with the model of cardiovascular prevention and control, which includes clinical care and health promotion by community promoters using educational materials developed in the previous stage. The study will be assessed through a combination of process and impact indicators, contrasting the results with those observed in a control group community that is similar to the intervention community.

Data analysis

Information from the focus groups will be transcribed from recordings in a word processing program. The data will then be coded using qualitative analysis software specialized for this purpose (Atlas TI, Scientific Software Development). The analysis of focus groups and in-depth interviews in Stage 1 and 2 will be organized under three main themes: magnitude and

symptoms of CVD; perceptions of risk factors; and prevention and characteristics of the health infrastructure.

Short-term outcome indicators will be used during Stage 3 to assess the program's effectiveness in achieving compliance with treatment, such as the proportion of individuals who came to their appointments at the health center according to the set schedule, the proportion of patients who attended the educational sessions, the proportion of patients who adopted the recommended lifestyle changes (changes in eating habits, physical activity, reduction or elimination of smoking) and changes in knowledge, attitudes and practices in relation to risk of CVD. The stratification of individuals according to their risk of CVD in low, medium, and high will be used as a co-variable in these analyses.

Acceptability will be assessed according to the proportion of health workers who are trained and participate in the study as well as adherence to program guidelines. The acceptability of of the intervention to patients will be assessed according to their willingness to be screened and recruited and to participate in the study as well as their willingness to follow the guidelines and attention protocols.

The feasibility of the program will be evaluated in terms of cost, staff, and infrastructure required for implementation of the study. The program cost will be determined using the expenditure records of the items set out in the budget for the implementation of the intervention. Diaries will also be used, as well as records and schedules taken to control by health officials participating in the study. Plans also exist to carry out a detailed assessment of the feasibility of managing the clinical protocol.

Satisfaction in service provision will include a survey for service providers (medical doctors and paramedics) and one for users.

The optimal flow patterns of patients will be assessed, including the space required for their care and counseling, the time required for patient care, and the number of patients that can be seen and evaluated daily by the health care center. This information will be helpful in establishing the flow patterns and in optimizing space, staff, and resources in the care of patients in future models. Because the results of this pilot study are preliminary regarding the effectiveness of an intervention model in reducing CVD risk, statistical tests to assess the effectiveness of the model have not been yet established

Duration of Participation of the subjects in the study
Health authorities that take part in in-depth interviews will be interviewed once. Subjects participating in the focus groups in Stage 1 will also participate one time.

Health care providers participating in consensus workshops in Stage 2 will participate for the duration of the workshops.

Individuals with HT or DM who participate in the first focus group will be asked to participate in the second.

Patients who participate in the Stage 3 study will do so for an eight-month period, and the health staff will participate for a 10-month period (training, recruitment and patient follow-up).

Protection of human subjects
The project will involve health care workers and individuals with DM and/or HT. A process of informed consent will be performed with all participants, to explain the purpose and scope of their participation, and to ensure the confidentiality of information. The study proposal will be submitted for review by the Institutional Review Board of INCAP, RAND Corporation, the University of Costa Rica and the University of Sciences and Arts of Chiapas.

Confidentiality of information
Guarantees on privacy and confidentiality of the information will be offered to all participating subjects, in conformity with the guidelines of the National Institutes of Health (NIH) and the countries where the study is being developed.

The study will involve human subjects in all three stages. In the first and second stages the human subjects will participate in focus groups. These participants may do so anonymously if

they so prefer, using numbers or pseudonyms rather than their own names. In-depth interviews with health officials and consensus workshops with health workers and community members will not collect personal identifiers.

In Stage 3 of the study, 180 adults over 21 years of age with DM and /or HT will participate, 90 in the intervention group and 90 in the control group. The latter will be matched to the intervention group in terms of diagnosis, age and sex. The control group will be selected from a different community of the city. All participants will be followed-up for 8 months.

Sources of materials
Qualitative data collected during the focus groups will include questions to assess the issues outlined above concerning the "Involvement and characteristics of human subjects." Information on blood pressure, fasting blood glucose, and lipid will be obtained from medical records, through tests performed routinely at the health center.

Anthropometric measures, socio-demographic information, dietary intake and other health-related aspects of the individuals will also be asked from each participant. Clinical records may be reviewed if available in health centers. Physicians will conduct a physical examination on each participant at each visit to the health center. To ensure the protection of human subjects, the standards of care for patients in health centers in each country must be followed.

Risks to subjects
During Stage 1, health authorities in charge of chronic diseases will be interviewed to collect information about CVD burden, existing health care facilities, and issues related to addressing risk factors. This information is available to the public, so no private or sensitive information will be collected. There is no risk associated to this procedure.

Subjects who participate in the focus groups of Stages 1 and 2 will do so voluntary and they may use pseudonyms to ensure the confidentiality of their views. Informed consent will request oral approval to avoid keeping a written form that may identify the participants. (Appendix 5 provides the informed consent form to be used with subjects participating in the focus groups.)

We do not anticipate that there will be any potential risks to participants in Stage 3 since the study is focused on the prevention and control of CVD and will facilitate the control and monitoring of their health status. Participants' level of risk will be the same as if they were not part of the study. Potential risk includes adverse reaction to medication. However, we do not anticipate that there will be potential risks attributable to study because it does not involve any experimental drugs, but only the usual medications offered to patients in health centers. All medication will be provided under medical supervision according to medical protocols established by the Ministry of Health care in each country. There is a low potential risk of psychological or social damage if there is any compromise in the confidentiality of information. The research team will take all necessary precautions to keep participants' information safe.

Adequate protection against risks
As part of the informed consent process, each participant will be advised that his or her participation in the study is completely voluntary and that he/she can withdraw from the research at any time after signing the written consent without penalty.

The risk of violating the privacy of the information given by participants will be minimized by identifying the subjects involved only with a numerical code. Data and information permitting the identification of participants will be stored in locked files in an office with restricted access. The electronic use of data will be restricted to project managers only. Physicians can assess and treat any complication during the course of the study.

Inclusion of women
Women will be included in all stages of the study. The proportional distribution of women in the population study will be determined by the presence of the diseases under study, and their own agreement to participate in this study.

Inclusion of minorities
The population participating in the study is mostly of mixed descent (as a result of four centuries of racial mixture of mainly Caucasian, Native American, and Black individuals). Culturally, the population is considered Central American.

Inclusion of children
Children are not included in this study.

Data Safety and Monitoring Board (DSMB)
The DSMB will consist of three persons with experience in the fields of nutrition, primary health care, internal medicine, and cardiovascular diseases. None of them will be part of the research team. One member belonging to a research institute with experience in nutrition and CVD will be the security monitor. A second member will be a health care provider, and the third member will be an internist with expertise in CVD. This internist will review the data related to dietary intake, biochemical markers (glucose, lipid profile), and blood pressure.

Responsibilities of the Monitoring Board
Initially, the DSMB will review the protocol and design of the forms for the measurement of food intake, anthropometry, blood pressure, and laboratory results. If any changes are needed, this will be incorporated into the forms. Based on the review of the protocol, the committee will identify the parameters for analyzing the data and will determine the format for the progress and final reports. The committee may request information about the study from the senior researcher at any time. Any changes made by the researcher during the time of the study must be reported to the committee. The IRB of RAND Corporation, INCAP, and the participant countries will be notified of any changes to the research protocol, once they been approved. In addition, immediate notification will be made regarding any adverse effects on the participants and a description of such effects will be included in the annual reports to NIH and the Committee. Based on a review of data security, the Committee will make recommendations concerning the conduct of the study. These recommendations may include procedures, modifications to the security process, modifications to the protocol or informed consent, termination or continuation of the study. All communications with the committee will be shared with the Ethics Committee and the NIH.

The Committee will meet in person or via conference call every 4 months starting at the fifth month after the beginning of Stage 3. Additional meetings will be scheduled if needed.

The discussions and decisions of the Committee will be summarized in written reports, which will be sent to the ethics committees annually.

Potential benefits of the proposed research
Direct benefits to individuals who participate in the study include knowledge of the important indicators of health status including blood glucose, lipid profile, and blood pressure. Abnormal values in any of these indicators will receive standard treatment and monitoring. Subjects will also benefit psychologically by feeling good when contributing to the research.

This study may contribute to the adoption of a community care model for prevention and control of CVD in other countries in Mesoamerica and elsewhere in the developing world.

The study will be conducted under the direction and direct responsibility of INCAP, and includes the participation of the RAND Corporation, the School of Nutrition of the University of Costa Rica, and the Faculty of Nutrition, University of Science and Arts of Chiapas, Mexico.

Primary health and community-based support model to lower the risk of cardiovascular diseases in individuals with type 2 diabetes *mellitus* and/or arterial hypertension, in urban areas of San Jose, Costa Rica and Tuxtla Gutierrez, Chiapas.

Appendices

APPENDIX 1

Guidelines for conducting focus groups with primary health care providers for participants with diabetes or hypertension, Stage I

Date:

Moderator:

Observer:

Description of the participants.
Number.
Gender.
Comments.

Objective of the focus group: To explore the opinions of primary health care providers who provide care for participants affected by diabetes or hypertension on:

1. Magnitude and symptoms of CVD
2. Impact of CVD on the social and economic situation of families and community
3. Risk factors (biological and behavioral) of CVD
4. Scope of prevention and control programs
5. Adequacy of existing infrastructure for the prevention and control of CVD
6. Identification of PHC services

1. Magnitude and symptoms of diabetes, hypertension and CVD

- Most commonly seen health problems caused by diabetes
- Common symptoms of high blood pressure
- Common complications of high blood pressure
- With respect to CVD, including heart disease (angina pectoris and myocardial infarction) and stroke. Common terms used to refer to these diseases
- Common symptoms of heart disease and stroke
- How frequent is CVD in the community?

2. Impact of CVD on the social and economic situation of families and community

- Impacts of CVD in a family
- If not mentioned spontaneously, inquire about:
  - Loss of a member who contributes to family income
  - High cost of treatment
  - Impacts on the budget for children's education
  - Some other impact?
  - (Collect data on age and sex of victims of the disease)
- Impacts of CVD in the community

3. Risk factors (biological and behavioral) of CVD

- Involvement of family members when one of them develops diabetes or high blood pressure
- Common risk factors of heart disease and stroke
- Effective preventive actions for heart disease and stroke
- Relationship between dietary patterns and heart disease
- Relationship between body weight and heart disease
- Common harmful effects of smoking on health (active or passive smoking)

4. Scope of prevention and control programs

- Description of health center programs to guide people with hypertension or diabetes on what to do to manage their disease
- Description of actions to promote physical exercise
- Common problems encountered by patients to follow these recommendations

5. Adequacy of existing infrastructure for the prevention and control of CVD

- What can be done if you know that you are suffering from diabetes or hypertension, or a family member is sick?
- Who can turn to for guidance on what to do about your illness?
- What resources are available to meet community health needs? General practitioner, public hospital, private hospital, others?
- If considered necessary to go to the doctor, where do you prefer to go? Why? How far is your home? How difficult is transportation? How expensive is transport and service?

6. Identification of PHC services

- Identification of PHC services available for the community
- Availability of health care personnel for follow-up (phone call or home visit)
- Is it appropriate to pay home visits or calls at home
- Availability and use of educational materials
- Availability of medication to treat these diseases
- Cost of drugs
- Availability and costs of in-hospital care
- Availability and costs of facilities for referral

APPENDIX 2

Guidelines for conducting focus groups with community members with diabetes or hypertension, Stage I

Date:

Moderator:

Observer:

Description of the participants.
Number.
Gender.
Comments.

Focus group objective: To explore the opinions of community members affected by diabetes or hypertension on:

1. Magnitude and symptoms of CVD
2. Impact of CVD on the social and economic situation of families and community
3. Risk factors (biological and behavioral) of CVD
4. Scope of prevention and control programs
5. Adequacy of existing infrastructure for the prevention and control of CVD
6. Identification of PHC services

1. Magnitude and symptoms of diabetes, hypertension, and CVD

- Description of how people feel when they have diabetes
- What are the health problems caused by diabetes
- Description of how people feel when they have high blood pressure
- Description of health problems that come along with high blood pressure
- Common terms used to refer to CVD, including heart disease such as angina pectoris and myocardial infarction, and stroke.
- Knowledge about symptoms of heart disease and stroke
- Knowledge about the extent of heart disease and stroke in the community

2. Impact of CVD in the social and economic situation of families and community

- Description of the impact that CVD may have on families
- If not mentioned spontaneously inquire about:
  - Loss of a member who contributes to family income
  - High cost of treatment
  - Decrease the budget for education of children
  - Some other impact?
  - (Collect data on age and sex of victims of the disease)
- How do these health problems affect the community?

3. Risk factors (biological and behavioral) of CVD

- What can be done when someone in the family develops diabetes or high blood pressure
- Causes (or "risk factors") of heart disease and stroke
- How can you prevent heart disease and stroke? (Discuss risk factors in the order mentioned by the participants. The moderator may suggest specific risk factors if these were not mentioned by the participants.)
- Explore the relationship between dietary patterns and heart disease
- Explore the relationship between body weight and heart disease (Explore whether

participants recognize obesity as a risk factor for CVD. Ascertain whether the participants have received advice from doctors or other sources on obesity).
- Explore whether participants can describe any harmful effects of smoking on health (active or passive smoking). Is there any relationship between smoking and heart disease and stroke?

4. Scope of prevention and control programs
- Knowledge about programs from the health center designed to guide people with hypertension or diabetes on what to do to manage their disease
- Recognition about the contribution of physical exercise to good health
- Availability of advice and information on the importance of exercise and the types of exercise benefits from doctors or other sources
- What are the recommendations? Have you been able to follow these recommendations? What problems need to have a follow-up?

5. Adequacy of existing infrastructure for the prevention and control of CVD
- What can you do if you know you are suffering from hypertension, or a family member is sick?
- Who can you turn to for guidance on what to do about your illness?
- What resources are available in the community to address health issues? General practitioner, public hospital, private hospital, others?
- If it is considered necessary to go to the doctor, where do you prefer to go? Why? How far is your home from the doctor's office? How difficult is transportation? How expensive is (transport and service)?

6. Identification of PHC services
- Have you visited the health center? Can you describe how the care was? How did you feel? Does the care seem appropriate?
- Have you ever received any communication or personal visit by someone from the health center? Who visited? What did they say? Did you understand? How long did the visit or call last?
- Does it seem appropriate for them to visit or call you at home? What do you prefer?
- Did they use educational materials? Did they seem appropriate? Could you suggest how to improve communications or visit?
- If medication is required to treat the disease, how will you get the drugs? Is it difficult? Is there ever a shortage of drugs? Are they expensive?
- In case you require hospitalization for your illness, which hospital should you be taken to? Are there typically available beds? Is it expensive?
- If you had to move to another level of care, do you know where you would go? What do you think of this place? Is it appropriate? Is it expensive?

APPENDIX 3

Form for registering clinical data

Name: _____

Participant ID Number: _____

Date of birth: ... ...Age: ... . Sex F / M: ... ...

_____

Address: ... ...

Phone: ... ...

_____

Name of person completing form:

_____

_____

Center / health post where the patient received clinical evaluation and treatment:

…….

Place where the patient will receive educational sessions
"Healthy and Happy Heart" Program:_____

Fitness center which the patient attends_____

- - - - - - - - - - - - - - - - - - -

	VISIT 1 **Date:** ___ / ___ / ___	**VISIT 2** **Date:** ___ / ___ / ___	**VISIT 3** **Date:** ___ / ___ / ___
Blood pressure • Systolic • Diastolic	_____mmHg _____mmHg	_____mmHg _____mmHg	_____mmHg _____mmHg
Overweight and obesity • Height • Weight • Body Mass Index (BMI) • Waist circumference	 _____mt _____Kg _____Kg/mt2 _____Inches	 _____mt _____Kg _____Kg/mt2 _____Inches	 _____mt _____Kg _____Kg/mt2 _____Inches
Blood glucose level • Not fasting • Fasting	_____ mg / dl _____ mg / dl	_____ mg/dl _____ mg / dl	_____ mg/dl _____ mg/ dl
Smoking habit	Yes ... ... No	Yes ... ... No	Yes ... ... No ... ...

Absolute cadiovascular risk	Low ... ... Medium ... ... High ... ... Very high	Low ... ... Medium ... ... High ... ... Very high	Low ... ... Medium ... ... High ... ... Very high ... ...
Prescription medication ***(Name and dose)***			

APPENDIX 4

Educational materials "Healthy and Happy Heart "
(See enclosure)

APPENDIX 5

INFORMED CONSENT FORMS

A. Focus groups with health care providers (example for the University of Costa Rica. The same document will be used for the University of Science and Arts of Chiapas, with the corresponding changes in the name and contact information of the principal investigator).

INCAP INTEGRAL CENTER FOR THE PREVENTION OF CHRONIC DISEASES - CIIPEC

UNIVERSITY OF COSTA RICA - SCHOOL OF NUTRITION

INFORMED CONSENT

Project Title: Model based on primary health care and community for the prevention and control of cardiovascular diseases in high-risk individuals living

We want to invite you to participate in a focus group meeting that will explore your views regarding the provision, capabilities, needs and response of the government health services with regard to health care programs for the prevention of cardiovascular diseases.

1. What is the purpose of the study?

The purpose of this study is to evaluate an intervention based on primary health care, "PHC" for the prevention of cardiovascular disease in patients with diabetes and hypertension. This model was adapted and applied in Guatemala and will be evaluated in Costa Rica and Mexico in the period between August 2010 and December 2011. This study is funded by the Institute of Nutrition of Central America and Panama (INCAP), an institution dedicated to research in nutrition and health, based in Guatemala City and with coordinating offices in all countries of Central America and Dominican Republic.

2. Who will participate in this study?

Health care staff providing first level primary health care services in San Jose, Costa Rica. A total of 32 people will participate in the focus groups.

3. What is my involvement?

Your participation is requested to attend a focus group session with 6-8 people. During this meeting, we will ask for your opinions and comments regarding the quality of the provision, capabilities, needs and governmental response regarding health care programs for chronic, non-transmissible diseases such as diabetes and hypertension.

The session will be led by a moderator and opinions and comments will be recorded and noted by a research team member.

The session will last up to two hours and will take place in a classroom at the School of Nutrition at the University of Costa Rica, on December 4, 2010 from 8:00 to 10:00 in the morning.

4. How do you handle confidentiality?

The views and comments expressed at the meeting will be used solely for the purposes of the study. You will not be identified by name, but by a pseudonym.

All information handled in these sessions will be kept confidential by the research staff. At no time will your personal opinions be communicated to managers or staff of the place where you work, and your views will not in any way affect your performance or work environment. We will take all necessary precautions to safeguard the confidentiality of information.

Participants will be asked to ensure the confidentiality (keep secret) of everything discussed during the meeting. However, we cannot guarantee that all participants will keep the information confidential, so if you feel uneasy expressing an opinion to others, you may refrain to do so.

5. What benefits will I get?

If you attend the meeting, we will provide transportation and a snack at the end of the meeting. Apart from this, you will not receive any form of payment.

It is possible that your participation in this focus group will help us to better understand and improve health care processes. Your opinions are extremely valuable. Your involvement may eventually lead to a better program and better care for the population.

6. What are the risks?

It is possible that despite all precautions taken, confidentiality may not be respected by someone attending the meeting, so if you believe that your views may have any negative repercussion on you or your work, you may want to avoid expressing them.

7. Should I answer all the questions?

If you feel uncomfortable and do not want to answer any or some of the questions or participate in the discussion of a topic, you may choose not answer the question and/or discuss the issue.

8. Is there a monetary cost for my participation?

Participation in this study has no cost to you, since relevant authorities at your workplace have agreed that invited staff can participate during working hours. No salary will be deducted from the two hours that you are in the meeting nor the time taken to get there and back.

9. Should I participate in the study?

Your participation in the study is completely voluntary, and failure to participate will not affect in any way your employment status.

10. May I withdraw from the study?

If before or during the session you choose not to participate, you may withdraw at the time you deem appropriate, without affecting your rights. You may even leave after signing the informed consent.

11. Who should I contact if I have questions?

If you have any questions about this study, please contact Ana Laura Dengo, Principal Investigator, phone 22242714 (8:00 to 17:00 hours) or via email: adengo@nutricion.ucr.ac.cr, School of Nutrition, University of Costa Rica. If you have questions about your rights as a participant you may contact Valentina Santacruz at the IRB of INCAP at (502) 24723762 during business hours (8:00 to 17:00 hours).

B. Focus groups with community members (example for the University of Costa Rica. The same document will be used for the University of Science and Arts of Chiapas, with the corresponding changes in the name and contact information of the principal investigator).

INCAP INTEGRAL CENTER FOR THE PREVENTION OF CHRONICAL DISEASES - CIIPEC

UNIVERSITY OF COSTA RICA - SCHOOL OF NUTRITION

INFORMED CONSENT

Project Title: Model based on primary health care and community for the prevention and control of cardiovascular diseases in high-risk individuals living

You are hereby invited to participate in a focus group meeting that will explore your perception regarding the provision, capabilities, needs, and response of the government health services with regard to the attention programs for chronic/non-transmissible diseases.

1. What is the purpose of the study?

The aim of this study is to evaluate an intervention based on primary health care ("PHC") for the prevention of cardiovascular disease in patients with diabetes and hypertension. This model was adapted and first applied in Guatemala and will be evaluated in Costa Rica and Mexico in the period between August 2010 and December 2011. This study is funded by the Institute of Nutrition of Central America and Panama (INCAP), an institution dedicated to research in nutrition and health, based in Guatemala City and with coordinating offices in all countries of Central America and Dominican Republic.

2. Who will participate in this study?

People from this community attending EBAIS and Health Care Centers of the Costa Rican Social Security in San Jose, Costa Rica. A total of 32 people will participate in the focus groups.

3. What is my involvement?

Your participation is requested to attend a focus group with 6-8 people. During this meeting, we will ask for your opinions and comments regarding the quality of the provision of health care, the capabilities, needs, and governmental response to chronic diseases like diabetes and hypertension.

The session will be led by a moderator, and his or her opinions and comments will be recorded and noted by a research team member.

The session will last up to two hours and will take place in a classroom at the School of Nutrition at the University of Costa Rica, on December 4, 2010 from 8:00 to 10:00 in the morning.

4. How do you handle confidentiality?

The views and comments expressed at the meeting will be used solely for the purposes of the study. You will not be identified by name, but by a pseudonym.

All information discussed in these sessions will be kept confidential by the staff conducting the research. At no time will your personal opinions be communicated to anyone outside of the group, and your views will not affect in any way your right to health care or any service you receive at the clinic. Researchers will take all necessary precautions to safeguard the confidentiality of information.

Participants will be asked maintain the confidentiality (keep secret) of everything discussed during the meeting.

5. What benefits will I get?

If you attend the meeting, we will provide transportation to and from the meeting place and a snack at the end of the meeting. Apart from this, you will not receive any form of payment.

It is possible that your participation in this focus group may help to better understand the care processes and improve them. Your opinions are extremely valuable, so your participation may eventually lead to improve the health care program and provide better care for the population.

6. What are the risks?

It is possible that, despite all precautions taken, confidentiality may not be respected by someone attending the meeting, so if you believe that your views can have a negative impact on you, you may want to avoid expressing them.

7. Should I answer all the questions?

If you feel uncomfortable and do not want to answer any or some of the questions or participate in the discussion of a topic, you may choose not answer the question and/or discuss the issue.

8. Is there a price for my participation?

Participation in this study has no cost to you.

9. Should I participate in the study?

Your participation in the study is completely voluntary, and failure to participate will not affect your employment status or your attention at the health center.

10. May I withdraw from the study?

If before or during the session you choose not to participate, you may withdraw at the time you deem appropriate, without affecting your rights. You may leave even after signing the informed consent.

11. **Who should I contact if I have questions?**

If you have any questions about this study, you may contact Ana Laura Dengo, Principal Investigator, phone 22242714 (8:00 to 17:00 hours) or via e-mail: adengo@nutricion.ucr.ac.cr, School of Nutrition University of Costa Rica. If you have questions about your rights as a participant you may contact Valentina Santacruz at the Ethics Committee of the INCAP at telephone number (502) 24723762 during business hours (8:00 to 17:00 hours).

C. Participants in Stage 3, for the University of Science and Arts of Chiapas.

CENTER FOR INTEGRAL OF INCAP FOR THE PREVENTION OF CHRONIC DISEASES-CIIPEC-
INSTITUTE OF NUTRITION OF CENTRAL AMERICA AND PANAMA-INCAP-
UNIVERSITY OF SCIENCE AND ART OF CHIAPAS, MEXICO
SCHOOL NUTRITION
HEALTH CENTER .....

INFORMED CONSENT FORM

STAGE 3: Implementation of a Model for Diabetes Care and High Blood Pressure Health Centers.

Project Code: ... ...

Name of the Researcher: ... ...

Participant Name: ... ...

OBJECTIVE OF THE STUDY

To apply a model of specialized care in the prevention of heart disease for people with diabetes and high blood pressure in primary care centers in health of the city of Tuxtla Gutierrez, Chiapas, Mexico.

What will be done?

We want to invite you to participate in a study carried out in this health center regarding the care you receive for your illness. The study is being coordinated by the INCAP's Center for Integrated Chronic Disease Prevention-CIIPEC in conjunction with the School of Nutrition at the University of Science and Arts of Chiapas, UNICACH. The research is funded by the Institute of Nutrition of Central America and Panama (INCAP), which is a non-governmental, non-profit institution based in Guatemala, Central America, and which has extensive experience in issues related to nutrition and health. The principal investigator is Dr. Nelly Isabel Cruz Serrano from the School of Nutrition UNICACH.

A. WHAT IS INVOLVED IN MY PARTICIPATION?

If you agree to participate, the project staff will:

- Review your files and record information such as age, sex, nutritional status, history of personal and family diseases, weight, height, blood pressure, diabetic foot exams and results of laboratory tests related to diabetes and/or hypertension.
- Conduct an interview in which you will be asked about your physical activity and recreation practices.
- Call you at a pre-arranged telephone number to ask how are you doing with the practice of the recommendations received at the clinic involving dietary practices and physical activity.

Depending on the risk of cardiovascular disease that you have, you will be asked to visit the health center more frequently, like monthly, every two months, or every four months.

B. RISKS

Your participation in this study does not involve any further risk than you would have

if you did not participate, nor any risk greater that any person attending the health center. If any of the questions in the interview makes you feel uncomfortable, you may choose not answer them. There is a very low risk that your health information be known by people outside of the research study, but we will take all necessary precautions to keep your information confidential.

C. BENEFITS

If you choose to participate in the study, you may benefit from the individualized care you will receive. On every visit to the health center you will receive information about your illness.

If the study shows a beneficial effect to participants, you may have provided benefits to the diabetic and/or high blood pressure population treated in health centers, resulting in better health care programs.

You will not receive financial compensation for participating in the study.

D. CONFIDENTIALITY

Your participation in this study is confidential, so your name and any personal information will not be released to the public. Access to your medical records, results form your interviews and telephone calls will be known only by the study's research team. At the end of the study we plan to present results in scientific meetings and publications, but all information will be presented at the group level, and no person will be identified by name.

E. ALTERNATIVES TO PARTICIPATION

You have the option to choose not to participate or to withdraw from the study at any time you wish, and this will not bring any negative consequence in the medical care that you receive at the clinic. Should you choose not to take part in the program, you will continue to receive the usual clinical care and control at the clinic.

F. RIGHTS

Your participation in this study is completely voluntary. You have the right to withdraw at any time you wish without any justification. The only requirement is to notify the researchers. You are not obliged to respond to any question you may choose not to answer.

WRITTEN CONSENT

I _____, have talked to _____regarding this study and have had the opportunity to ask questions and all my concerns have been addressed. If I would like more information I can obtain it by calling: and talking to Dr. Nely Isabel Serrano Cruz, Principal Investigator or to Ms. Erika Judith Lopez, Director of the School of Nutrition at the UNICACH.

For any further information about my rights as participant in this study I may contact the Scientific Ethics Committee of the University of Science and Arts of Chiapas, phone:

_____ __ / __ / ____
Name and signature of participant date

_____ __ / __ / ____
Name and signature of witness date

_____ __ / __ / ____
Name and signature of investigator Date

VERSION APPROVED BY THE SCIENTIFIC ETHICS COMMITTEE (CEC),

UNIVERSITY OF SCIENCE AND ART OF CHIAPAS, MEXICO

D. Participants in Stage 3, for the University of Costa Rica

INCAP INTEGRAL CENTER FOR OF CHRONIC DISEASE PREVENTION - CIIPEC
UNIVERSITY OF COSTA RICA - SCHOOL OF NUTRITION

Model of primary health care and support in the community to reduce the risk of cardiovascular disease in individuals with type 2 diabetes mellitus and / or hypertension, in urban areas of San José, Costa Rica

Informed consent to participate in the implementation of a personalized care model to improve control of diabetes mellitus and hypertension, reducing the risk of cardiovascular disease. Stage 3

INTRODUCTION

We would like to provide information about a study being conducted at this health center regarding the medical care offered to people with diabetes or high blood pressure (hypertension). The purpose of this study is to apply a customized model of care to improve the control of diabetes mellitus and hypertension, which helps reduce the risk of heart disease, applied from centers of primary health care in Costa Rica.

A. WHO IS IN CHARGE OF THE STUDY?

The study is coordinated by the Center for INCAP's Integrated Chronic Disease Prevention-CIIPEC, depending on the Institute of Nutrition of Central America and Panama (INCAP), based in Guatemala. INCAP is a non-profit non-governmental organization, with extensive experience in issues related to nutrition and health, and has proposed to perform this study in conjunction with the School of Nutrition at the University of Costa Rica. The research is funded by the INCAP and also receives support from the University of Costa Rica. The senior researcher is Dr. Ana Laura Dengo, from the School of Nutrition at the University of Costa Rica.

B. WHY WAS I SELECTED TO PARTICIPATE?

You have been invited to participate because you have been seen regularly at this health center, and have diabetes mellitus (blood sugar) or have high blood pressure (hypertension).

C. WHAT DOES MY PARTICIPATION CONSIST OF?

If you accept our invitation and decide to participate, the project staff will:

- Review your files and record information such as age, sex, nutritional status, history of personal and family diseases, weight, height, blood pressure, diabetic foot exams and results of laboratory tests related to diabetes and /or hypertension.
- There will be an interview with you, requesting information about your physical activity and recreation.
- Using the information collected, an assessment will be done regarding your risk of developing cardiovascular disease over the next 10 years.
- For better control of your disease, the health center will guide you on how you can adopt a healthy lifestyle, including the regular practice of physical activity, eating a healthy diet, and smoking cessation
- Depending on the level of cardiovascular risk that you have, your doctor may prescribe one or more drugs.
- In order to work with you to strengthen the information received at the clinic and help meet medical advise and adoption of healthy living behaviors offered to you

at the health center, you are invited to attend group talks by primary care staff, which will be offered every 15 days. If appropriate, you may invite a family member to participate in these talks.

- Depending on the cardiovascular risk you have, you will be asked to go to the health center for check-ups. If your risk is low, you will be asked to go every four months; if your risk is moderate, every two months, if your risk is high, your appointments will be on a monthly basis. At these appointments, your doctor will perform a clinical and laboratory evaluation, and some questionnaires will be submitted to find out how well you are following the instructions you received.
- To remind you of your appointment, you may receive a phone call from a member of the health center, or even a home visit.

E. RISKS

Your participation in this study does not carry a greater risk than normal for any individual receiving care at a health center of the Social Security Fund. During the study, we will not prescribe any additional medication in addition to those prescribed by your medical doctor nor we will apply any procedure that involves risk to your health. Your participation is based on attending educational meetings and listening to the advice and recommendations of the project's staff to help you better follow the treatment given to you at the health center. During follow-up visits, some questionnaires will be given to you to evaluate your progress, if answering any of the questions of the interview could cause you discomfort, you may choose not to answer. There is a very low risk that your health information become known by third parties, but we will take all necessary precautions to keep your information confidential.

D. BENEFITS

- You may benefit from the individualized care you will receive.
- You will receive information about the control of your illness at every visit.
- You will receive specific education on the prevention and control of diabetes and hypertension, which will help reduce the risks of having cardiovascular disease, and help you have a better quality of life.
- If the study shows a beneficial effect to individuals, you may have contributed to improved care for the diabetic and/or high blood pressure population treated in health centers, resulting in better health care programs.
- You will not receive financial compensation for participating in the study.

F. CONFIDENTIALITY

Your participation in this study is strictly confidential, so that your name and personal data will not be disclosed to any person not directly involved in the research. In this way, access to your medical record, interview records, and home visits will be known only by the study's research team. We plan to use the collected information to prepare reports and scientific publications, but the names of the participants will not be shown. The information will be handled at group level, and in no case will any participant be identified. The research team will take various measures to protect the confidentiality of data, including identifying participants in the questionnaires only by number, and keeping information containing personal data locked away and in care of the researchers.

G. ALTERNATIVES TO PARTICIPATION

You have the option to choose not to participate or to withdraw from the study at any time you wish, and this action will not have consequences for the medical care offered by this clinic, and you may continue with your usual clinical care and control at the clinic.

H. RIGHTS

Your participation in this study is completely voluntary. You can choose not to

participate and still receive the usual treatment in your health center. You have the right to withdraw at any time you wish without giving any reason. The only requirement is to notify the researchers. If you choose to withdraw from the research, this will not bring any negative consequences on your usual care at the health center, and we will not collect more data about you, although we can use information already collected in our analysis. You are not required to answer any questions you are uncomfortable with, and health personnel will not insist on this.

SIGNATURE OF INFORMED CONSENT

I,_____ have received the information provided about this study in which I am invited to participate, and have had the opportunity to ask questions that I considered necessary, and all my concerns have been addressed. By agreeing to participate, I will receive a copy of this consent form to keep so that I can consult it further later.
If I would like to acquire more information about the project, I can get it by calling Dr. Ana Laura Dengo, principal investigator, at: 22241427, or with Dr. Emilce Ulate, Director of the School of Nutrition at the University of Costa Rica.
For any further information on the rights of participants in the study mentioned, I may contact the Scientific Ethics Committee of the University of Costa Rica, by calling the following telephone:

By signing this document I grant my consent to participate in this study.

_____ ____/____/____
Name and signature of participant Date

_____ ____/____/____
Name and signature of participant Date

_____ ____/____/____
Name and signature of participant Date

Extension of Project:
"Primary Healthcare and Community Support Model to Decrease Cardiovascular Disease Risk in Type2 Diabetes Mellitus and/or Hypertensive Patients in Urban Areas of San José, Costa Rica and Tuxtla Gutiérrez, Chiapas"
in order to include Stage 4 with objectives of understanding the low participation of men and involving families in the care of sick relatives

The **main objective** of this project is to adapt an applicable intervention model in the primary healthcare level (PHC) that improves adherence to treatment and lifestyle changes proposed to reduce cardiovascular disease (CVD) risk as a secondary complication of type 2 diabetes mellitus (DM) and/or high blood pressure (HBP). Adherence to treatment means that the patient follows all prescribed instructions included in the clinical and educational treatment, as well as in the check-ups in order to improve.

The model proposed incorporates several innovative aspects, which include:

- Use of simple methodologies that don't require lab tests, applicable in the PHC level to classify CVD risk of patients with HBP or DM.
- Individualized treatment, according to risk detected, that includes lifestyle changes with or without pharmacological treatment based on accepted international guidelines for managing these diseases.
- Group and individual educational sessions using easy-to-understand concepts and material for people with low literacy levels.
- Reinforcement of the taught educational concepts by auxiliary PHC staff (PHC technicians or assistants).

The model has been initially developed in a pilot study in urban areas of Guatemala. This project aims to adapt the model to urban areas of San José, Costa Rica and Tuxtla Gutiérrez, Chiapas in Mexico incorporating culturally relevant elements into the educational intervention.

The **specific objectives** include:

1. Describe the current CVD prevention and control capacities at PHC level in the cities of San José, Costa Rica and Tuxtla Gutiérrez, Chiapas, in southern Mexico.
2. Adapt and validate a CVD risk prevention model originally developed in Guatemala, that can be implemented in PHC centers and communities of urban areas in San José, Costa Rica and Tuxtla Gutiérrez, Chiapas, incorporating into clinical care protocols the most recent concepts promoted by the World Health Organization to treat these diseases.
3. Adapt and validate educational material originally developed in Guatemala to be culturally accepted in the urban contexts of San José, Costa Rica and Tuxtla Gutiérrez, Chiapas.

4. Determine the effectiveness of the proposed intervention model in improving, in the short term, adherence to treatment by assessing concepts, attitudes and practices related to CVD risk prevention, detection and management in adults with type 2 DM and or HBP.

Objectives Corresponding to Stage 4 of the Study:

5. Understand the reasons for low participation of men.
6. Find out how families are affected when there is a member with HBP or type 2 DM.
7. Characterize providers' recommendations on including men and relatives in cardiovascular health-related promotion activities.

Study Design

The study will be implemented in three stages:

Stage 1: (3 months) Formative research centered on identifying the capacity, resources and programs offered by the national, state and local Health System regarding CVD care, including type 2 DM and HBP, through officials and decision makers. Likewise, the knowledge, perceptions, and opinions of healthcare providers (including physicians and paramedics) and people from participating communities regarding CVD will be explored.

Stage 2: (4 months) Adaptation and validation of healthcare protocols and educational material previously developed, in order to incorporate the proposed model into the installed system and ensure that the educational material is culturally relevant for each of the regions participating in the study.

Stage 3: (10 months) Application of proposed model, in order to assess its feasibility, acceptability and short-term effectiveness, using a quasi-experimental design with an intervention group and a control group, in each participating country.

Stage 4: (10 months) Qualitative research on family and gender dynamics to define possible adaptations to the proposed model and expand its scope, with a focus on men and relatives of patients with diabetes or HBP. Regardless of whether their relatives are sick or not, male patients, healthcare workers and patients' relatives will be interviewed.

STAGE 1. FORMATIVE RESEARCH

This stage includes structured interviews and focus groups with different groups:

a) Health system officials. A structured interview will be carried out with key officials in each country to identify health policies related to CVD management in the population. The interview will include questions about infrastructure facilities, resources and programs, and clinical standards regarding DM and HBP treatment, as well as CVD prevention among people of the community. During this stage we will also seek to identify educational material

designed by the government to inform patients at PHC level about actions they should follow in order to keep DM and HBP under control.

b) Healthcare providers. A focus group will be carried out in each country with healthcare staff at the care center with the purpose of exploring the following aspects related to DM, HBP and CVD:
    - Epidemiological spectrum of these conditions in the community
    - Prevention scope and control of biological and behavior risk factors
    - Existing diagnosis and treatment capacities at the PHC level
    - (The corresponding guide is presented in Annex 1)

c) People affected by DM and/or HBP. Two focus groups will be carried out (one for each disease) in each country, where the following topics will be explored:
    - CVD magnitude and symptoms
    - Impact of CVD on the social and economic situation of families and the community
    - CVD risk factors (biological and behavior)
    - Prevention scope and program control
    - Adjustment of existing infrastructure for CVD prevention and control
    - Identification of shortcomings in healthcare services
    - (The corresponding guide is presented in Annex 2)

Selection of Participating Subjects

a) Health system officials. The most suitable people to provide the required information will be identified and invited to participate once in the described interview.
   Medical and paramedical staff in charge of PHC. All professional and technical staff (i.e. physician, nurse, PHC technician, secretary) that takes part in providing healthcare to DM or HBP patients will be invited to participate in a focus group only once.
   The healthcare staff of the community where the intervention is intended will be invited personally. The principal investigator in each country will go to each healthcare center and hold a brief meeting with the healthcare staff to introduce the study protocol and invite them to participate in the focus group. The time, date and place for the focus group will be indicated then.

b) People from the community who suffer from DM and/or HBP. There will be two focus groups, one for each disease, integrated by people who suffer from these diseases, including both healthcare center patients and people from the community that don't go to the healthcare center. The first will be identified opportunistically through the list of patients of the clinic. The latter will be sought for among the community through an open recruitment, by means of public notices posted in sites of interest. This process will include both men and women with any of the two diseases under study, who are 21 or older. There will be from 6 to 8 people in each focus group, including male and female adults over 21 years of age.

c) In this stage of the protocol, "opportunistically" selecting the sample means that we will take advantage of the presence of patients in the clinic at the moment of the study to invite them

to participate. “Opportunistic” refers to the fact that patients who have already been identified as diabetics or hypertensive will be approached by the same healthcare staff to invite them to be part of the focus groups, using the healthcare center facilities, medical records and any other activity that the staff carries out with those patients.

STAGE 2. DEVELOPMENT AND VALIDATION OF MATERIAL

This stage includes two activities that cover complementary aspects: consensus-building workshops and focus groups.

1. The first activity consists in carrying out two consensus-building workshops per country with the PHC staff to introduce and discuss criteria for diagnosis, risk detection and clinical management of DM and/or HBP patients.

- During the first workshop, the clinical care program developed in the pilot study in Guatemala will be introduced. This program is based on the recommendations and algorithms advised by the WHO and other international organizations for comprehensive management of hypertension and diabetes, assessment of absolute CVD risk. It was designed to identify individuals with hypertension and/or diabetes and evaluate cardiovascular risk of these patients; it proposes measures to reduce such risk, and is intended for implementation by healthcare staff at health centers and posts with limited resources. Annex 3 contains the registration form for each participant’s clinical data. The material will be handed out to participants two weeks in advance, requesting them to read it critically. During the workshop, the basic concepts contained in the said guides will be reviewed, and these will be compared with the country’s current treatment guides or standards. In the event of finding discrepancies, conciliation among them will be sought. If there are concepts in the WHO guidelines that have not been included in the national standards, the convenience/applicability of integrating these will be discussed (“validation” of clinical protocols).
- During the second workshop and following the same dynamic, an algorithm recently developed by WHO to be used in Latin American countries will be reviewed. This algorithm advises how to qualify CVD risk in people who suffer from DM or HBP. For absolute cardiovascular risk assessment, this algorithm involves low-cost easy-to-measure risk factors that don’t require lab tests (Annex 3).

2. The second activity refers to the process of adaptation and validation of educational material that will be used to train promoters and implement health promotion sessions for patients. The development of this material will be based on the handbook “*Corazón sano y feliz”* (Healthy and Happy Heart), which is rooted in a program created in the United States by the National Heart, Lung and Blood Institute –NHLBI– to train cardiovascular health promoters in Latin communities of that nation, and has been adapted through a pilot study for Latin American countries, including Argentina, Peru and Guatemala. The handbook has 10 sections that include different activities with CVD concepts and risk factors, as well as practical methods to encourage physical activity, healthy diet and

smoking cessation. Prior to its implementation, the handbook will be revised and validated according to the cultural conditions of Chiapas and Costa Rica.

To validate the material, two focus group sessions will be held in each country with members of the community to be intervened, who have similar educational socio-economic characteristics to those of patients that will be part of the intervention. At least three healthcare workers from the participating communities will be invited to the focus groups, and they will be in charge of training with the educational material. This activity will enable identifying positive aspects and those that need adjustment, with the aim of obtaining work tools that are in line with both the community's health system context in each country and also with the needs, knowledge and practices of the target population. A second focus group session will be held later on, trying to have the same participants of the first one, where the adjusted material will be presented to gather additional comments and useful suggestions to encourage its use, seeking that the changes made respond to the identified needs. Participants in the validation must have similar characteristics to people who will later be part of the intervention. There will be no other stratification by age.

STAGE 3. INTERVENTION

This stage will include an intervention community and a control community, with a healthcare center participating in each of them. In Tuxtla Gutiérrez, Chiapas, the communities chosen are Chiapas de Corzo (control) and Planes de Ayala (intervention). In San José, Costa Rica the communities chosen are Gravillas, Desamparados (control) and Moravia (intervention). A quasi-experimental design is proposed without random selection, given that in order to apply the intervention model, an extensive consensus process with healthcare officials and workers at different levels must be carried out prior to the intervention, and this could jeopardize it if the community chosen randomly faces problems, for instance, with the healthcare staff stability. Comparable communities in terms of socio-economic conditions of the area will be sought, and participants at each site will be paired by diagnosis criteria (diabetes and hypertension), age (±3 years) and sex.

In the intervention community, 90 individuals who meet the criteria will be invited to participate; to those who agree to do so, the informed consent process will be explained. In the control community, 90 healthcare center patients (per quota) will be chosen to evaluate their clinical evolution during the project without any specific intervention (that is, the control group will be treated as usual).

Sample size. The sample will be calculated based on the previous experience of the pilot study at Guatemala, which recruited 75 patients and, during a similar follow-up period, significant blood pressure reductions of up to 30 mmHg were observed. Likewise, among patients who attended at least 80% of the educational sessions, significant changes in their diet and physical activity were observed. Therefore, we propose recruiting 75 patients for the intervention group and 75 for the

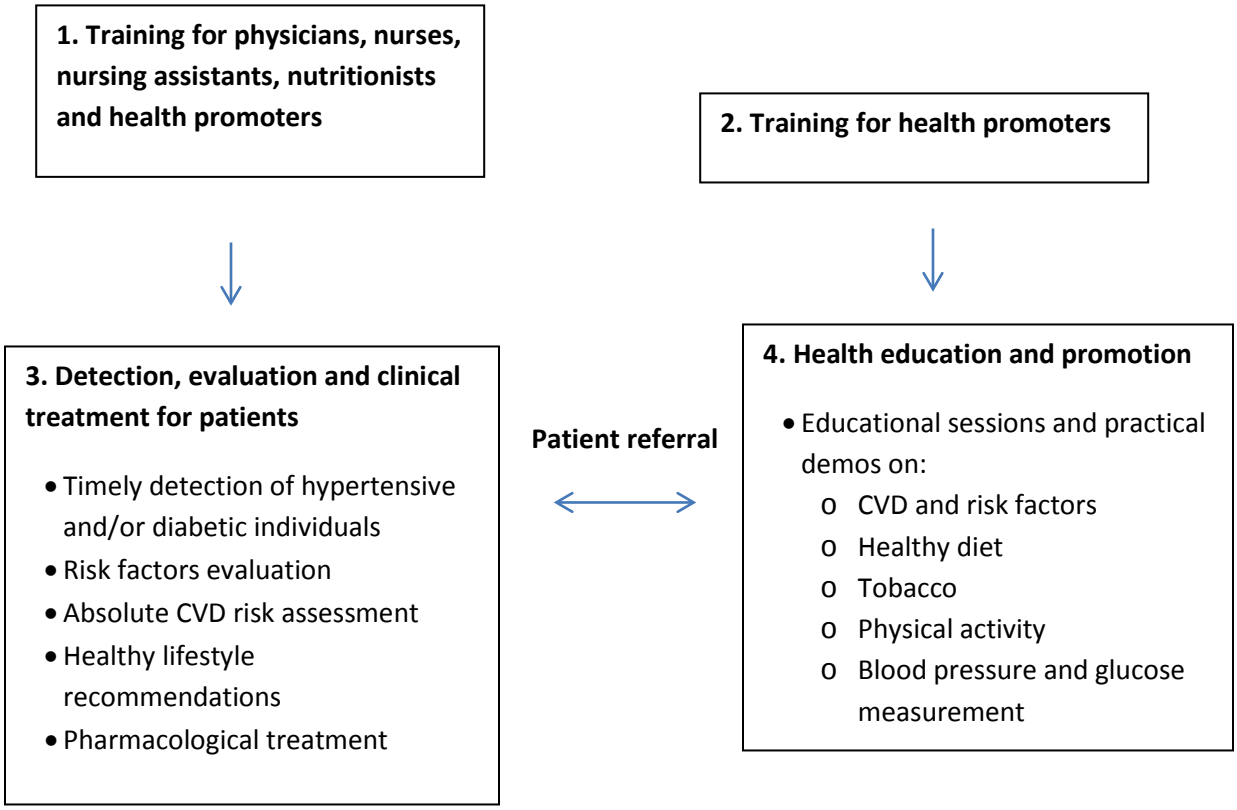
control group. Due to the possibility of patients failing to follow up, this sample will be increased by 20% for a total of 90 patients per group (a total of 180 participants). The sample is not intended to be evenly distributed among patients with low, medium or high cardiovascular risk, but to reflect the prevailing situation at the clinic.

Inclusion criteria. Participants must be over 21 years of age, residents of the area or sphere of influence of the healthcare center chosen, literate (must be able to read and write), with diabetes or hypertension diagnosed (or confirmed) by the participating clinic, willing to follow the education outline (in the intervention group), including attending to training sessions instructed by auxiliary staff of the healthcare center.

Exclusion criteria. Participants must not have diabetes complications (renal, peripheral circulation or retinal alterations, organic damage) or history of stroke (thrombosis, ischemia, aneurism) heart attack (angina, infarction), mental disorders that prevent understanding instructions that are part of the educational strategy, deformity, physical impairment or disability that prevents regular physical activity.

People who will be part of the control group will not receive any particular incentive during the study. Their participation does not entail any nuisance or risk, since they will receive the usual treatment provided by the healthcare centers they go to. The researchers will not have contact with these patients nor will they intervene in any way with their treatment. Their development as a group during the 8-month period of this stage will be compared to that of patients in the intervention group. A potential benefit they could have is that, once the research has concluded, the health system might adopt a more effective healthcare policy than the current one; but, this cannot be determined beforehand. After the study has ended, the educational material and the methodologies developed and used in the intervention will be provided to health authorities of each country.

In outline form, the activities to be carried out include:



In further detail:

1. **Training for physicians, nurses, nursing assistants, nutritionists and health promoters** at PHC centers, using the material validated in Stage 2. This activity will prepare healthcare staff to identify, evaluate and provide treatment to people with HBP and or diabetes, following simple methods based on recent international standards. The staff will be trained through workshops and distribution of the educational material. The clinical protocols previously validated in Stage 2 will be used for these activities.

2. **Selection and training of community promoters** using the material of Stage 2. For this stage, at least 3 health workers will be selected for every PHC center. They will be trained through workshops that will include concepts about diabetes and hypertension symptoms; CVD risk factors; prevention methods, including a healthy diet, exercise and smoking cessation; according to the general content of the manual validated in Stage 2. Procedures for correct measurement of blood glucose, blood pressure and anthropometry will be examined. During the training, they will be advised to be sensible to the patients' psychological aspect. After the training, promoters are expected to become members of the healthcare team specialized in patients with diabetes, hypertension and other CVD risk factors.

It is worth mentioning that these tasks will be carried out by the principal investigator of the project, the research fellow and the healthcare staff appointed by the director at each participating healthcare center. This task will require a relatively short time from the healthcare staff.

In relation to the staff training:
1. The healthcare staff training (physician and nurses) will take 2 one-hour workshops at the healthcare center. The researchers group will be in charge of this training.
2. The group of promoters will be trained through 6 two-hour workshops at the healthcare centers or a venue chosen by the participants.
3. For the healthcare staff training, the time usually assigned for their continuing education can be used.

3. **Detection, evaluation and clinical treatment for patients with hypertension or diabetes.** In each healthcare center, 90 of their patients previously diagnosed with diabetes or hypertension and who are under treatment will be recruited (intervention control). From one to two months will be needed for recruiting the sample. This activity will be carried out in the PHC centers by the healthcare staff, physicians, nurses, nursing assistants, nutritionists and health promoters.

Activities 1 and 2 will take one month and will be carried out simultaneously. Activity 3 will be approximately 9 months long (1-2 months for recruitment and 8 months for follow up of each subject).

Patient Detection Sources

Patients with DM or HBP will be detected and recruited at the healthcare center and may include people who:

- Visit the healthcare center for any cause
- Participate in health promotion community activities that the promoters will carry out
- Self-refer in response to the information campaigns that will be part of this program

Detection of new hypertensive patients will include the following steps:

- Identify male and female adults over 21 years of age.
- Measure blood pressure (BP). If the patient is hypertensive (systolic BP≥ 140mmHg and diastolic BP ≥90), confirm the first measurement by repeating it after 5 minutes with the patient at rest. If the difference between these two measurements is above 10mmHg, a third measurement must be taken 1 minute after the second one. An appointment in one or two weeks' time at the healthcare center must be scheduled for these patients in order to confirm the hypertension diagnosis.

Detection of new diabetic patients will include the following steps:

- Identify male and female adults over 21 years of age
- Identify adults with abdominal obesity
- Identify adults with systolic BP≥ 90mmHg and diastolic BP ≥140mmHg
- With glucometer, measure blood glucose of patients who meet criteria a, b or a, c, and if possible, run a blood glucose test.

Evaluation of Risk Factors at the Healthcare Center

In one or two weeks, during the patients' appointment at the healthcare center ("Visit 1"), BP must be measured again. In the case of patients with confirmed hypertension (systolic BP≥ 140mmHg or diastolic BP ≥90mmHg in at least two consecutive measurements) and patients already diagnosed with DM and/or HBP, other risk factors will be evaluated:

- Waist circumference will be measured to identify abdominal obesity. For men, the presence of abdominal obesity will be determined if waist circumference is above 102 cm; and for women, if it is above 88 cm.
- Blood glucose using glucometer. Blood glucose will be determined with:
    a. Subjects with BP ≥ 140/90mmHg and abdominal obesity. The presence of these factors predicts a high chance of diabetes or pre-diabetes. This way, the use of glucometers is more cost-effective. Individuals will be diagnosed as diabetics if their fasting glucose levels are ≥ 126 mg/dl, or ≥200mg/dl when they have not fasted.
    b. The glucose blood test will be run also with subjects who have been previously diagnosed with diabetes and patients who are under treatment with insulin and/or glucose-lowering drugs.
- Registration of patient's sex and age
- Inquiry about smoking habit
- Medical history to rule out complications (see exclusion criteria)

Assessment of Absolute or Total CVD Risk

The assessment of cardiovascular risk enables establishing the patient's chance of having a heart attack or stroke within the next 10 years. The absolute cardiovascular risk is determined by the patient's grouping of risk factors, and it allows designing a more cost-effective treatment. The absolute cardiovascular risk will be assessed through an algorithm recently developed by the WHO for Latin American countries. The use of this algorithm involves low-cost risk factors that are easily measured and don't require lab tests.

Most of the actions in the Intervention Stage will be carried out by the research team that will be hired to that end, so as not to overload the healthcare center staff where the intervention will take place. Avoiding such overloading due to this project will be attempted at all times. In addition, the healthcare center staff will use the educational material distributed in Stage 2 during their daily educational assignments and for which they were trained. This complement will help patients reassure their knowledge and skills to begin, practice and maintain the recommended treatment and daily routines regarding diet, physical activity, personal care and others.

The benefits of being trained, not only to teach, but also to produce changes in their patients will be explained to the healthcare staff; and their contribution to the development of a community healthcare model for patients with type 2 DM and or HBP will be explained to them as well.

Table 1 shows the algorithm to estimate patients' absolute cardiovascular risk (chance of suffering CVD within 10 years). This estimate takes into account:

- Presence or absence of diabetes
- Sex
- Age
- Smoking
- Systolic Blood Pressure (SBP) value

With this information the absolute cardiovascular risk is estimated as follows:

1. Select the appropriate section of the table, depending on the presence or absence of diabetes
2. Select the appropriate section of the table for men or women
3. Select the cells for smokers or non-smokers
4. Select the corresponding line for the patient's age group
5. Following this line, locate the closest cell corresponding to SBP in mmHg. The color of this cell indicates the risk for CVD within the next 10 years, classified from Low to Extremely high, according to the chance of having CVD:
    - Low (green) = <10%
    - Medium (yellow) = 10-19.9%
    - High (orange) = 20-29.9%
    - Very high (red) = 30-39.9%
    - Extremely high (magenta) = ≥40%

The stratification of risk is used to determine the treatment (see Table 2).

Table 1. Algorithm to assess absolute cardiovascular risk for CVD within 10 years, by sex, based on age and presence of type 2 diabetes mellitus, smoking and systolic blood pressure (SBP).

	Without diabetes				**With diabetes**				
	Men		**Women**		**Men**		**Women**		
Age (Years)	Smoker	Non-smoker	Smoker	Non-smoker	Smoker	Non-smoker	Smoker	Non-smoker	**SBP** (mmHG)
70									180
									160
									140
									120
60									180
									160
									140
									120
50									180
									160
									140
									120
40									180
									160
									140
									120

Total Cardiovascular Risk
Chance of CVD within 10 years

<10%	Low
10-19.9%	Medium
20-20.9%	High
30-39.9%	Very high
≥40%	Extremely high

Intervention Design

The clinical treatment that will be provided to hypertensive and/or diabetic patients in the intervention group is a combination of recommendations about healthy lifestyles and pharmacological therapy, according to the outline described in Table 2.

Healthy lifestyles: the physician or nurse will recommend that every patient adopts the following healthy lifestyles:

- Quit smoking to those who smoke
- Eat a healthy diet
    - Increase intake of fruits and vegetables
    - Reduce intake of salt, fat, sugar and alcohol
- Engage in regular physical activity
    - If the patient is not overweight or obese: 30 minutes of moderate physical activity, every day of the week
    - If the patient is overweight or obese: 60 minutes of moderate physical activity, every day of the week

Pharmacological therapy:

- The pharmacological treatment of new diabetic patients will be based on glucose-lowering drugs (metformin), limiting it for patients who in follow-up check-ups persist with fasting glucose levels above 226mg/dl.
- The pharmacological control of new hypertensive patients (with thiazide diuretics such as indapamide) will be limited, at first, for patients with high absolute cardiovascular risk and some patients with medium cardiovascular risk with SBP ≥ 160mmHg.
- In the case of patients with an already prescribed treatment, it will be examined and adjusted, taking into account their previous records and care standards.

As part of the treatment, the healthcare staff will recommend patients to attend every two weeks to the educational sessions in charge of health promoters, so that adopting and keeping healthy lifestyles and theirpharmacological treatment necessary to control their risk factors will be easier for them.

In the intervention stage, patients will receive healthcare regularly following the corresponding protocols of each country. The educational sessions addressed to patients will serve as informative and educational support to assess the use of additional treatments. Patients will be able to ask questions and solve doubts about their treatment in any moment of this stage. We have no intention of competing with alternative medicine.

In case of national or local emergency, due to weather conditions or of any other nature, coordination with health authorities will be sought by all means to avoid interrupting or delaying

the appointment timetable, medical check-ups or educational sessions, and in such circumstances, patients will be contacted by phone or in person, if necessary.

Patient Check-ups and Follow-up

Every patient will have at least two appointments at the healthcare center for the procedures described in Table 2. In each visit, the healthcare staff will:

- Measure blood pressure
- Measure waist circumference
- Measure blood pressure in diabetic patients
- Inquire about smoking habit
- Evaluate physical activity
- Evaluate eating habits
- Remind treatment goals of each patient

Based on this information, the patient's progress will be assessed in order to continue or modify the treatment.

In addition, depending on the absolute CVD risk, appointments can be more frequent, according to the following scheme:

- Patients with low cardiovascular risk (LR) will have appointments every 4 months, so that each of them will be evaluated 3 times in total (beginning, fourth month, and eighth month) in the course of an 8-month period.
- Patients with medium cardiovascular risk (MR) will be evaluated 5 times. They will visit the healthcare center three times, according to the corresponding healthcare standards (which indicate check-up at the first, fourth and eighth months),and two complementary home visits in between, which can be scheduled along with the attending physician.
- Patients with high cardiovascular risk –including very high risk and extremely high risk– (HR) will be evaluated every month at the healthcare center.

Table 2. Outline for treatment and follow-up of hypertensive or diabetic patients

CVD risk level	Visit 1	Visit 2	Visit 3
Low risk	- Hypertension diagnosis confirmation, diabetes and risk factors evaluation - Assistance for smoking cessation, diet modification and regular practice of physical activity - Schedule visit #2 in three months'time	- Assistance for smoking cessation, diet modification and regular practice of physical activity - Measurement of waist circumference - Schedule visit #3 in three months'time - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations	- Assistance for smoking cessation, diet modification and regular practice of physical activity - Measurement of waist circumference - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations
Medium risk	- Hypertension diagnosis confirmation, diabetes and risk factors evaluation - Assistance for smoking cessation, diet modification and regular practice of physical activity - Schedule visit #2 in three months' time	- Assistance for smoking cessation, diet modification and regular practice of physical activity - Measurement of waist circumference - If SBP ≥140, begin with low doseof antihypertensive, according to healthcare regulations - Schedule visit #3 in three months' time - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations	- Assistance for smoking cessation, diet modification and regular practice of physical activity - Measurement of waist circumference - Continue withmedication. If SBP ≥140, increase doseof antihypertensive - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations
High risk	- Hypertension diagnosis confirmation, diabetes	- Assistance for smoking cessation, diet	- Assistance for smoking cessation, diet

	and risk factors evaluation - Assistance for smoking cessation, diet modification and regular practice of physical activity - Begin with low dose of antihypertensive, according to healthcare regulations - Schedule visit #2 in four weeks' time	modification and regular practice of physical activity - Measurement of waist circumference - Continue with medication. Prescribe aspirin (100/mg daily). If SBP ≥140, increase doseof antihypertensive - Schedule visit #3 in two months' time - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations	modification and regular practice of physical activity - Measurement of waist circumference - Continue with medication. If SBP ≥140, refer patient to a higher healthcare level - Patients with fasting glucose levels persistently above 6mmol/l despite having healthy lifestyles, must be prescribed metformin, according to current regulations

These strategies will be used for better patient follow-up:

- The date and time for the next appointment will be set taking into consideration the patient's preference and availability.
- Health promoters will remind patients about their appointment, through a phone call or home visit. If the patient misses the appointment, the nurse will call again to know the reason and offer another appointment.
- Each patient will be informed about his/her evaluation results in each medical check-up during the intervention stage.

Health Education and Promotion

This activity will be implemented by the health promoters, who will be in charge of organizing and conducting educational sessions and practical demos about CVD and their risk factors and about healthy lifestyles that will help patients referred by physicians and nurses to adopt the behavior changes necessary to reduce CVD risk. These group sessions should be held every two weeks at a convenient place for patients; it could be the healthcare center or a nearby venue. Patients' relatives (e.g. spouse) can also attend these educational sessions. Using the handbook "*Corazón sano y feliz"* (adapted and validated during Stage 2) as support, we will address topics related to CVD symptoms, risk factors, weight control, healthy diet, physical activity and tobacco. New patients can be incorporated into the cycle of sessions at any session, making it easier to have new members.

During educational sessions, people who accompany patients will have their blood pressure measured and glucose tests will be run with the purpose of detecting new hypertension or diabetes cases. If new cases are identified, promoters will recommend visiting the healthcare center for a more thorough evaluation and appropriate treatment.

Evaluation

Effectiveness: The effectiveness of the program will be measured by the adhesion to the prescribed treatment, using short-term result indicators which include the ratio of individuals that attended to their follow-up appointments at the healthcare center as scheduled; ratio of patients that attended to educational sessions; ratio of patients that adopted the recommended lifestyle changes (eating habits, physical activity, smoking reduction or cessation if applicable); andchanges in knowledge, attitudes and practices related to CVD risks.

Even though evaluating the effectiveness of the treatment provided is not a purpose of the study, the clinical evolution of participants will be taken into account by measuring the ratio of patients that show improvement in plasma glucose and blood pressure control, and ratio of patients that show changes in anthropometric risk parameters (waist circumference, BMI). Likewise, any CVD event among participants during the project will be registered.

Feasibility: It will be assessed in terms of cost, infrastructure and staff required. Among costs, the following will be included: time of professional and auxiliary staff in charge of providing healthcare and educational activity; time of staff in charge of conducting focus groups, workshopsand training, designing material, creating teaching resources; transportation expenses; operational costs –such as phone calls.

Acceptability: It will be assessed in terms of the healthcare workers' disposition and readiness to be trained, participate in the study and comply with the healthcare guides that will be provided. Patients' willingness to participate both in the screening and in the intervention, especially to adhere to the measures and treatment prescribed in each case. Additionally, other factors will be assessed such as willingness to collaborate and participate in the study, implementation of what is learned during training, use of educational material in informative/educational activities with patients, and other factors that workers themselves will indicate during the workshops of Stage 2.

Satisfaction: A survey on the healthcare providers' satisfaction (physician and paramedic), as well as the users' satisfaction on the care received will be included.

Flow pattern of patient care: The flow of care at each healthcare center will be observed and assessed with variables such as space, time for patient care and amount of new patients that can be registered every day at each center. This information will be very useful to advise how to optimize flow of patients and plan the adoption of this (or other) intervention in more centers, with special attention to space available and time for patient care.

STAGE 4: QUALITATIVE RESEARCH ON FAMILY DYNAMIC AND GENDER

Justification

During the implementation of the first three stages of the study, the research team noticed that, mainly in Chiapas, few men attended the educational sessions. In this site, 92% of the 95 patients in the intervention group who signed the informed consent to participate in the study were women. Low male participation has not occurred only in Chiapas. Although less evident, in San José, Costa Rica 60% of the intervention group were women. Another aspect identified by the research team is the opportunity of expanding the scope of the health promotion and chronic disease management efforts through strategies that involve family members, instead of focusing only on the diagnosed individual and that shows up for an appointment at the healthcare center.

Based on the situation found of few men participating in the study at Tuxtla Gutiérrez, Chiapas, and data from other studies pointing out the potential for strategies that involve other family members, a new stage is proposed for which additional funding from NHLBI has been obtained. The three specific objectives for stage 4 of the study are explained below, as well as the corresponding participants, recruitment and procedures for each objective. Data processing and the analysis proposed are also described in this section.

Objective 1: Understand the reasons for low participation of men with hypertension and/or type 2 diabetes mellitus in health promotion activities in the primary healthcare level in Tuxtla Gutiérrez, Chiapas

Participants and Recruitment

We will identify and recruit men that are 21 or older with hypertension and/or type 2 diabetes mellitus and who receive care at healthcare centers of the Secretariat of Health. To respond to this objective that focuses on the low male participation, only men will be included.

The team will use a variety of strategies to recruit men: contact men that participated in the third stage of the study, talk to men in the waiting room at the healthcare center, ask providers to explain the study to male patients, and offer to conduct the interviews during hours men are not at work.

Procedures

The research team will conduct from 8 to 10 in-depth interviews with men that have not participated in educational activities offered by the healthcare centers in order to understand the reasons for not doing so and to ask for their recommendations for reaching men in the future. The team will also interview 4 men who have participated in educational activities to control their illness with the intention of understanding the factors that enabled their participation. Upon finishing interviews, the team will go over the transcriptions to determine if a point of information saturation has been reached, if not, additional interviews will be conducted.

Objective 2: Find out how families are affected and involved in the cardiovascular risk management and reduction when there is a member with HBP or type 2 DM

Participants and Recruitment

The research team will recruit from 6 to 8 families to participate in this study. These families will have at least one member (minimum 21 years old) that receives care at a healthcare center of the Secretariat of Health in Tuxtla Gutiérrez and two other adults that are willing to participate in a family interview.

Procedures

The family must be willing to receive one or two home visits over a period of 5 months from a member of the research team. During the visit, the team member will interview the sick family member and a minimum of two additional family members. People who participated in the study that concluded in late 2012 will be able to be part of this study.

During the family interview the following techniques will be used: in-depth interviews and diagrams to characterize relationships in the family, which are called ecomaps and genograms (McGoldrick, Gerson, Shellenberger, 1999).

Objective 3: Characterize providers' recommendations on including men and relatives in health promotion activities and HBP or type 2 DM management

Participants and Recruitment

The research team will also conduct interviews with healthcare workers to understand their ideas about feasible ways to reach relatives and men. From 8 to 10 healthcare workers (physicians, nurses, nutritionists and promoters) in the healthcare center of the Secretariat of Health in Tuxtla Gutiérrez will be interviewed.

Procedures

The research team will interview healthcare workers to hear their recommendations for reaching men and relatives in the future.

Data Analysis and Dissemination of Stage 4

Recorders will be used to register the interviews using guides in Annex 7. A qualitative analysis of this information will be made. In other words, this information will not be summarized in frequency or ratio charts. Accordingly to the qualitative analysis proposed, the research team will use a thematic analysis which consists in codifying transcriptions with the software Atlas TI. The three researchers will define a list of codes to analyze the transcriptions with the intention of finding issues related to the limited male participation in health promotion activities, family

support and barriers for chronic disease management, as well as healthcare providers' recommendations to reach men and relatives. The team will identify quotes that best represent the topics.

Genograms and ecomaps will be used to build case studies to illustrate interactions among family members, gender, and caregivers' role, as well as to explore available resources within families that could help manage the disease.

Table 3, shown below, summarizes timeframes and main activities of the three stages of the project.

Table 3. Time frames and main activities of the three stages of the project to be implemented in each country

Stage 1. Formative research (Aug-Oct 2010)	**Stage 2. Adaptation and validation of material (Nov 2010 - Feb 2011)**	**Stage 3. Intervention (Mar - Dec 2011)**
Activities: In-depth interviews with professional staff at clinics, including managerial decision-making staff and attending physicians, to identify the knowledge of health providers and decision makers about CVD magnitude and risk factors (biological and behavior-related) and the diagnosis and treatment methods for these diseases. Focus groups A focus group with health providers of participating clinics. Two focus groups, one for each disease, integrated by people who suffer from these diseases, including both healthcare center patients, and people from the community that don't go to the healthcare center.	Activities: Two consensus-building workshops at each participating healthcare center in each country will be held in order to introduce the model proposed for DM and HBP management, as well as CVD risk classification, and based on the group discussion, to reach the healthcare workers' consensus for the adaptation and validation of clinical and educational material that will be used with hypertensive and diabetic patients. Two focus groups will be carried out with healthcare centers of the community were the intervention is planned (one with hypertensive people and the other with diabetic people), as well as auxiliary PHC staff to validate the comprehension of the educational material prepared for them.	Activities: Training for professional and community healthcare staff in implementation of clinical protocols and use of teaching material developed during Stage 2. Development of the intervention study at one participating healthcare center in each country, including 90 hypertensive and/or diabetic patients per center. Patients will receive care according to the CV prevention and control model, which includes clinical care and health promotion in charge of community promoters, using teaching material developed in the previous stage. The study will be evaluated through a combination of process and impact indicators, contrasting results with those observed in a community similar to the one intervened, that participated as control group (without intervention).

A summary of timeframes ad activities planned for stage 4 of the project is shown below:

	2013							2014		
Activities	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1. Interview healthcare workers	X	X	X							
2. Interview families		X	X	X	X	X				
3. Interview men		X	X	X	X	X				
4. Transcribe interviews		X	X	X	X	X	X			
5. Code and analyze data				X	X	X	X	X	X	
6. Prepare manuscript								X	X	
Disseminate results in Chiapas										X

Data Processing and Analysis

Using a word processor, all data from the focus groups will be transcribed from the recordings. Data will then be coded with specialized qualitative analysis software (Atlas TI, Scientific Software Development). The analysis of focus groups and in-depth interviews of Stages 1 and 2 will be organized under three main topics: CVD magnitude and symptoms, risk factor and prevention perceptions, and characteristics of healthcare infrastructure.

During Stage 3, short-term indicators will be used to measure the program effectiveness in achieving treatment adherence, such as ratio of individuals that attended to their follow-up appointments at the healthcare center as scheduled; ratio of patients that attended to educational sessions; ratio of patients that adopted the recommended lifestyle changes (eating habits, physical activity, smoking reduction or cessation if applicable); and changes in knowledge, attitudes and practices related to CVD risks. Stratification of individuals according to their low, medium or high CVD risk will be used as co-variable in these analyses.

Acceptability will be assessed according to the healthcare workers' disposition to be trained, participate in the study and comply with the program guides. Patients' acceptability will be assessed by the willingness to participate in the screening, recordings and in the study, as well as to follow the healthcare guides and protocols.

Feasibility will be assessed in terms of cost, staff and infrastructure required to implement the study. The cost of the study will be estimated using the expense records of items established in the budget for the intervention execution. Control journals, records and timetables kept by health system officials will also be used for this purpose. Evaluating in detail the management feasibility of the clinical protocol has also been planned.

Satisfaction of service provision will include a survey addressed to service providers (physician and paramedic) and another one to users.

Optimal flow patterns of patients, such as the space required for care and counsel, the time required for patient care and the number of patients registered per day in the healthcare center will be assessed. This information will be useful to establish flow patterns in order to optimize space, staff and resources for patient care in future models. The results of this pilot study on the effectiveness of a CVD risk reduction intervention model will be preliminary; therefore, the statistical tests to value this effectiveness have not been yet determined.

Participation Period of Subjects in the Study

The officials of the healthcare centers will participate once in in-depth interviews. Likewise, subjects will participate once in the focus groups of Stage 1.

Healthcare providers will participate in consensus-building workshops of Stage 2 during the length of the workshops. Individuals with high-blood pressure and diabetes who participate in the first focus group are expected to participate in the second one too.

Patients who participate in Stage 3 of the study will do so for eight months, and healthcare staff, for ten months (training, recruitment and patient follow-up). Men and health workers who participate in Stage 4 will do so only once. Families taking part in the interviews on Stage 4 will participate in a maximum of two interviews during a maximum period of five months.

Protection of Human Subjects

The project will involve healthcare workers and people with high-blood pressure and/or diabetes and their families. An informed consent process will take place, in which the purpose and significance of their participation will be explained to participants and their families; likewise, confidentiality of their information will be promised.

In Stage 4 an individual informed consent process will take place separately with each family member in order to avoid pressure to participate from other members.

The study proposal will be submitted for revision to the Institutional Ethics Committee of INCAP and RAND Corporation; as well as to the Ethics Committee of *Universidad de Costa Rica* and *Universidad de Ciencias y Arte de Chiapas*.

Information Confidentiality

Privacy and confidentiality of subjects' information will be guaranteed, according to the guidelines of the National Institute of Health (NIH) and of those countries where the study will take place.

The study will involve human subjects in the four stages. During the first and the second stage, human subjects will participate in focus groups. If participants wish to participate anonymously, they may use numbers or pseudonyms instead of their names. In-depth interviews with healthcare

officials will be carried out, as well as consensus-building workshops with healthcare workers and community members (some of which may suffer from high-blood pressure or diabetes).

In Stage 3 of the study, 180 individuals will participate: in the intervention group, 90 adults over 21 years of age suffering from diabetes and/or high-blood pressure; and 90 in the control group. Individuals in the control group will have the same characteristics, diagnosis, sex and age as the ones in the intervention group, but will be part of another community in the city. All the patients will be observed during eight months.

In Stage 4, human subjects will participate in interviews. An informed consent process will take place in which the purpose and significance of their participation will be explained to all participants; and respect and confidentiality of their information will be promised (see Annex 6).

Source of Material

Data collected during focus groups will be of qualitative nature and will include questions to assess the aspects described before on "participation and characteristics of human subjects". In Stage 3, information on blood pressure, fasting glucose levels and lipids will be collected through tests that will be run in the healthcare centers in each country.

Anthropometric measurements will be taken; and socio-demographic data, dietary intake information and other aspects related to people's health will be obtained. Clinical records will be reviewed, if available at the healthcare centers. In each visit to the healthcare center, physicians will practice a physical examination to each participant. For all of the above, current healthcare standards in each country will be followed.

Risks for the Subjects

During Stage 1, a structured interview will be carried out with the central and community level political decision makers on addressing CVD burden in the country, existing healthcare facilities and aspects related to risk factor prevention. This information will be used with the interviewee's authorization, for which, he/she will be explained the purposes of it beforehand. The only potential risk could be expressing an opinion that could lead to adverse consequences at work, in case of loss of confidentiality; but, in order to minimize this risk, the procedures outlined under Data Protection will be applied.

Subjects participating in the focus groups of Stage 1 and Stage 2 will not be exposed to any risk. Their participation in these groups will be completely voluntary, and confidentiality will be kept by using pseudonyms. Additionally, the informed consent procedure will be followed asking only for their oral consent in order to avoid keeping written records which may allow identifying participants. The informed consents for participating in focus groups in Stage 3 can be found in Annex 5. The informed consents for San José, Costa Rica and Tuxtla Gutiérrez, Chiapas may differ in some parts due mainly to cultural aspects and health systems of each country. Likewise, each university has its own administrative system which leads to differences in some details of the informed consents among countries.

There are no potential risks anticipated for subjects participating in Stage 3 since the study is on CVD prevention and control, and will simplify their health control and monitoring. The risk they could have is the same they would if they did not participate in the study. Such potential risk includes adverse reaction to medication. However, no potential risks attributable to the study are anticipated since there will be no experimental medication, only the usual one offered to patients in healthcare centers under medical supervision, according to care protocols of each country. On the other hand, a minor psychological or social damage potential risk exists in case of compromised confidentiality of information. The research team will take all the necessary precautions to protect this information.

A minimum risk for the participants in Stage 4 is anticipated. During interviews to men, families and health workers, information will be collected; and, with the interviewee's authorization, it will be used for the purposes explained in advance. The only potential risk for healthcare workers could be expressing an opinion which could lead to adverse consequences at work, in case of loss of confidentiality. The only potential risk for men and healthy families would be the loss of confidentiality. To minimize this risk, the procedures outlined under Data Protection will be applied. The informed consents for subjects participating in Stage 4 can be found in Annex 6.

Proper Risk Protection

As part of the process of obtaining the informed consent, individuals will be informed that participating is completely voluntary, and that they are free to withdraw from the research at any moment after having signed the written consent with no penalty.

The risk of breaching information privacy will be minimized by identifying the participating subjects only through a number code. Identifiable data and information will be kept in locked cabinets in a restricted-access office. Likewise, electronic use of the information will be limited to the managers of the project. Physicians may evaluate and treat any complication during the study.

Inclusion of Women

Women will be included in all the stages of the study. The proportional distribution of women in the population study will be determined by the presence of the diseases under study, as well as their acceptance of the study.

In Stage 4, women will be included in the interviews with families and healthcare workers.

Inclusion of Minorities

Most of the population participating in the study is mestizo (as a result of 400 years of racial mix mainly between Caucasians, Black people and Amerindians), and culturally they are considered Central Americans.

Inclusion of Children

Children will not be included in this study.

Data Security Monitoring Committee

This committee will be integrated by three experts in nutrition, PHC, internal medicine and CVDs. None of them will be part of the research team. One of the members will be an experienced security monitor of a nutrition and CVD research institute. The second person will be a healthcare provider, and the third member, an internist with CVD expertise. This internist will review all data related to dietary intake, biochemical markers (glycaemia, lipid profile) and blood pressure. These data will also be reviewed by the team conducting the study.

Monitoring Committee's Responsibilities

The initial task includes revision of protocol and creation of forms to measure food consumption, anthropometry, blood pressure, and lab results. If any modification is indicated, it will be institutionalized. Based on the protocol revision, the committee will identify parameters for data analysis, as well as the format for the progress and final reports. The committee may require the Principal Investigator to provide information on the study at any moment. The investigator must report to the committee any change performed during the study. The Ethics Committee of RAND Corporation, INCAP and countries involved will be notified about the changes made to the research protocol, if any, once they have approved them. Any adverse effect on the participants will also be notified immediately and will be included in the annual reports to NIH and the Committee. Based on the data security review, the Committee will make recommendations related to the study conduction. These recommendations may include procedures, modifications to the security process, modifications to the protocol or informed consent, termination or continuance of the study. All communications with the Committee will be shared with the Ethics Committees and the NIH.

The Committee will meet in person or through telephone conference every four months, starting on the fifth month since the beginning of Stage 3. If more frequent meetings are necessary, they will be programmed.

The Committee discussions and decisions will be summarized in written reports, which will be sent yearly to the Ethics Committees.

Potential Benefits for the Subjects in the Research Proposal

Among the direct benefits to the subjects participating in the study are learning about important indicators of their state of health, including glucose levels, lipid profile and blood pressure. Subjects with abnormal values in any of these indicators will receive treatment and standard monitoring. They will also benefit psychologically through the satisfaction of their contribution to the research.

This study will contribute to recommend the implementation of a community care model for CVD prevention and control in Mesoamerican countries, as well as to achieve better healthcare for

patients, families and healthcare workers participating in it. Receiving recommendations to improve the intervention model is the focus of the study, especially in Stage4.

RAND Corporation, School of Nutrition of *Universidad de Costa Rica* and the School of Nutrition of *Universidad de Ciencias y Arte de Chiapas*, Mexico participate in the study.

Primary Healthcare and Community Support Model to Decrease Cardiovascular Disease Risk in Type 2 Diabetes Mellitus and/or Hypertensive Patients in Urban Areas of San José, Costa Rica, and Tuxtla Gutiérrez, Chiapas

ANNEXES

ANNEX 1

INCAP'S COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC DISEASES –CIIPEC for its initials in Spanish-

***UNIVERSIDAD DE COSTA RICA* –SCHOOL OF NUTRITION-**

***UNIVERSIDAD DE CIENCIAS Y ARTES DE CHIAPAS* – SCHOOL OF NUTRITION-**

Primary Healthcare and Community Support Model to Decrease Cardiovascular Disease Risk in Type 2 Diabetes Mellitus and/or Hypertensive Patients in Urban Areas of San José, Costa Rica, and Tuxtla Gutiérrez, Chiapas

Guide for conduction of focus groups of community people with diabetes or hypertension

Stage 1

Date:

Moderator:

Observer:

Participants' Description:

Number:
Sex:
Disease:

Purpose of the focus group: Find out the opinion of the community members suffering from diabetes or hypertension, about:

1. CVD magnitude and symptoms

2. Impact of CVDs on the social and economic situation of families and the community

3. CVD risk factors (biological and behavior)

4. Prevention scope and program control

5. Adjustment of existing infrastructure for CVD prevention and control

6. Identification of shortcomings in healthcare services

1. **CVD, diabetes and hypertension magnitude and symptoms**

- Can you describe how a person suffering from diabetes feels?
- What health issues are caused by diabetes?
- Can you describe how a person with high blood pressure feels?
- What health issues are caused by hypertension?
- We are now going to discuss CVDs, which include heart diseases such as angina (chest pain), heart attack and stroke. Can you mention common names to refer to these diseases?
- Do you know what the symptoms of heart diseases and stroke are?
- Do you think CVDs (heart diseases and stroke) are common in your community? Do you know anybody who has suffered from these illnesses? What did that person have? Why?

2. **Impact of CVDs on the social and economic situation of the families and the community**

- Sometimes, these diseases may cause permanent disability or even death to the person suffering from them. When this happens the family is affected in different ways. Can you describe the effects of CVDs on a family?
- If these are not mentioned spontaneously, ask about:
    - Loss of a member that contributes to the household income
    - High cost of treatment
    - Reduction in the school budget
    - Any other effect?
    - (Gather information about age and sex of persons suffering from these diseases)

3. **CVD risk factors (biological and behavior)**

- What can be done when someone in the family suffers from diabetes or hypertension?
- What are the causes (or risk factors) for heart diseases or stroke?
- How can heart diseases and stroke be prevented? (Begin the discussion in the order that risk factors are mentioned. The moderator may suggest specific risk factors, if these are not mentioned by the participants).
- Do you think there is a relation between eating habits and heart diseases?

- Do you think there is a relation between body weight and heart diseases? (Find out if participants recognize obesity as a CVD risk factor. Ask if the participants have received medical advice, or from any other source, about obesity).
- Can you mention the harmful effects of tobacco on health (active or passive smoker)? Is there any relation between smoking and heart diseases and stroke?

4. Prevention scope and program control

- Do you know if the healthcare center offers programs for persons suffering from hypertension or diabetes on how to control their disease?
- Do you think that exercise contributes to good health? Why?
- Have you ever received advice and information from doctors, or any other source, about the importance of physical exercise and the beneficial types of exercise? If so, what where the recommendations? Have you been able to follow these recommendations? What obstacles keep you from following them?

5. Adjustment of existing infrastructure for CVD prevention and control

- How can you take care of yourself if you suffer from diabetes or hypertension, or any member of your family is sick?
- Whose advice may you seek for on how to manage the disease?
- What healthcare resources are there available in the community? General physicians, public hospital, private hospital, other?
- If going to the doctor is necessary, where do you prefer to go? Why? How far away is it from your home? How difficult is transportation? How expensive is it (transportation and service)?

6. Identification of shortcomings in healthcare services

- Have you attended the healthcare center? Can you describe the care you received? How did you feel? Was it appropriate?
- Have you ever received any communication or visit from the healthcare center staff? Who visited you? What did he/she say? Did you understand them? How long was the visit or call?
- Do you find appropriate receiving visits or calls in your home? What do you prefer?

- Did they use teaching material? Did you find it appropriate? Can you make any suggestions on how to improve this communication or visit?
- In case of needing medication for your disease, how do you get your medication? Is it hard? Is there ever a shortage? Is it expensive?
- In case of needing hospitalization, where would you go to? Are there beds available? Is it expensive?
- If you had to be moved to another level, do you know where would they move you to? What do you think of that place? Is it appropriate? Is it expensive?

ANNEX 2

INCAP'S COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC DISEASES –CIIPEC for its initials in Spanish-

***UNIVERSIDAD DE COSTA RICA* –SCHOOL OF NUTRITION-**

***UNIVERSIDAD DE CIENCIAS Y ARTES DE CHIAPAS* – SCHOOL OF NUTRITION-**

Primary Healthcare and Community Support Model to Decrease Cardiovascular Disease Risk in Type 2 Diabetes Mellitus and/or Hypertensive Patients in Urban Areas of San José, Costa Rica, and Tuxtla Gutiérrez, Chiapas

Guideline for conduction of focus groups of community people with diabetes or hypertension Stage 1

Date:

Moderator:

Observer:

Participants' Description:

Number:
Sex:
Disease:

Purpose of the focus group: Find out the opinion of the community members suffering from diabetes or hypertension, about:

7. CVD magnitude and symptoms

8. Impact of CVDs on the social and economic situation of families and the community

9. CVD risk factors (biological and behavior)

10. Prevention scope and program control

11. Adjustment of existing infrastructure for CVD prevention and control

12. Identification of shortcomings in healthcare services

CVD, diabetes and hypertension magnitude and symptoms

- Can you describe how a person suffering from diabetes feels?
- What health issues are caused by diabetes?
- Can you describe how a person with high blood pressure feels?
- What health issues are caused by hypertension?
- We are now going to discuss CVDs, which include heart diseases such as angina (chest pain), heart attack and stroke. Can you mention common names to refer to these diseases?
- Do you know what the symptoms of heart diseases and stroke are?
- Do you think CVDs (heart diseases and stroke) are common in your community? Do you know anybody who has suffered from these illnesses? What did that person have? Why?

Impact of CVDs on the social and economic situation of the families and the community

- Sometimes, these diseases may cause permanent disability or even death to the person suffering from them. When this happens the family is affected in different ways. Can you describe the effects of CVDs on a family?
- If these are not mentioned spontaneously, ask about:
    - Loss of a member that contributes to the household income
    - High cost of treatment
    - Reduction in the school budget
    - Any other effect?
    - (Gather information about age and sex of persons suffering from these diseases)

CVD risk factors (biological and behavior)

- What can be done when someone in the family suffers from diabetes or hypertension?
- What are the causes (or risk factors) for heart diseases or stroke?
- How can heart diseases and stroke be prevented? (Begin the discussion in the order that risk factors are mentioned. The moderator may suggest specific risk factors, if these are not mentioned by the participants).
- Do you think there is a relation between eating habits and heart diseases?

- Do you think there is a relation between body weight and heart diseases? (Find out if participants recognize obesity as a CVD risk factor. Ask if the participants have received medical advice, or from any other source, about obesity).
- Can you mention the harmful effects of tobacco on health (active or passive smoker)? Is there any relation between smoking and heart diseases and stroke?

Prevention scope and program control

- Do you know if the healthcare center offers programs for persons suffering from hypertension or diabetes on how to control their disease?
- Do you think that exercise contributes to good health? Why?
- Have you ever received advice and information from doctors, or any other source, about the importance of physical exercise and the beneficial types of exercise? If so, what where the recommendations? Have you been able to follow these recommendations? What obstacles keep you from following them?

Adjustment of existing infrastructure for CVD prevention and control

- How can you take care of yourself if you suffer from diabetes or hypertension, or any member of your family is sick?
- Whose advice may you seek for on how to manage the disease?
- What healthcare resources are there available in the community? General physicians, public hospital, private hospital, other?
- If going to the doctor is necessary, where would you prefer to go? Why? How far away is it from your home? How difficult is transportation? How expensive is it (transportation and service)?

Identification of shortcomings in healthcare services

- Have you attended the healthcare center? Can you describe the care you received? How did you feel? Was it appropriate?
- Have you ever received any communication or visit from the healthcare center staff? Who visited you? What did he/she say? Did you understand them? How long was the visit or call?
- Do you find appropriate receiving visits or calls in your home? What do you prefer?

- Did they use teaching material? Did you find it appropriate? Can you make any suggestions on how to improve this communication or visit?
- In case of needing medication for your disease, how do you get your medication? Is it hard? Is there ever a shortage? Is it expensive?
- In case of needing hospitalization, where would you go to? Are there beds available? Is it expensive?
- If you had to be moved to another level, do you know where would they move you to? What do you think of that place? Is it appropriate? Is it expensive?

ANNEX 3

REGISTRATION FORM FOR PARTICIPANTS' CLINICAL DATA

Patient's full name_____

Participant's ID _____

Date of birth _____ Age_____ Sex F/M _____

Mother tongue _____ Indicate if interpreter is needed _____

Indicate if the person has never had a clinical evaluation _____

Indicate if the person has never had a pharmacological prescription _____

Address _____

Phone number_____

Name of the person filling out the form

_____

Healthcare center/post where the patient receives clinical evaluation and treatment

_____

Place where the patient receives educational sessions of *Programa Corazón Sano y Feliz* (Happy and Healthy Heart Program) _____

Physical activity center to which the patient attends _____

	VISIT 1 Date: ___/___/___	**VISIT 2** Date: ___/___/___	**VISIT 3** Date: ___/___/___
Blood pressure • Systolic • Diastolic	_____mmHg _____mmHg	_____mmHg _____mmHg	_____mmHg _____mmHg
Overweight and obesity • Height • Weight • Body mass index (BMI) • Waist circumference	Mt. Kg. Kg/m² Cm	Mt. Kg. Kg/m² Cm	Mt. Kg. Kg/m² Cm
Glucose blood level • Not fasting • Fasting	Mg/dl Mg/dl	Mg/dl Mg/dl	Mg/dl Mg/dl
Smoking habit	Yes_____ No _____	Yes_____ No _____	Yes_____ No _____
Absolute cardiovascular risk	Low Medium High Very high	Low Medium High Very high	Low Medium High Very high
Medication prescription **(name and dose)**			

ANNEX 4

Educational material *"Corazón Sano y Feliz"*
(See attached material)

ANNEX 5
INFORMED CONSENTS

A. Consent for focus groups with healthcare service providers (example for *Universidad de Costa Rica*; the same consent will be used for *Universidad de Ciencias y Arte de Chiapas*, just the name of the investigator in charge must be changed).

INCAP's COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC DISEASES –CIIPEC for its initials in Spanish–
UNIVERSIDAD DE COSTA RICA –SCHOOL OF NUTRITION
INFORMED CONSENT

Title of the project: **Primary Health Care and Community-based Model for Cardiovascular Disease Prevention and Control in High-risk Individuals in Urban Areas of San José, Costa Rica and Southern Mexico, Chiapas**

You are hereby invited to participate in a focus group session to determine your perspective on the government's health service provision, capacities, needs and response regarding cardiovascular disease care programs.

1. **What is the purpose of the study?**
   The purpose of this study is to asses an intervention based on "primary health care" in order to prevent cardiovascular diseases in patients suffering from diabetes and hypertension. This model was adapted and applied in Guatemala and will be assessed in Cost Rica and Mexico from August 2010 to December 2011. This study is funded by the Institute of Nutrition of Central America and Panama (INCAP), which specializes in health and nutrition research and is headquartered in Guatemala, with coordinating offices in every country of Central America and the Dominican Republic.

2. **Who will participate in this study?**
   Healthcare staff attending the primary healthcare services in San José, Costa Rica.
   People from the community who attend Basic Integrated Healthcare Teams –EBAIS, for its initials in Spanish– and Healthcare centers of *Caja Costarricense del Seguro Social* (Costa Rica's public healthcare system) in San José, Costa Rica.
   A total of 32 individuals will participate in the focus groups. Participants of each group will be chosen from different health services.

3. **What does participating imply?**
   Your participation consists in attending a focus group session where 6 - 8 persons will take part. We will be require your opinion and comments on the quality of the government's health

service provision, capacities, needs, and response regarding chronic non-communicable disease care programs, such as diabetes and hypertension.

The session will be guided by a moderator and your opinions and comments will be recorded and written down by a member of the research team.

The session will last a maximum of two hours and will be held in a classroom at the School of Nutrition of *Universidad de Costa Rica* on August 4, 2010, from 8:00 a.m. to 10:00 a.m.

4. **How will confidentiality be managed?**
The opinions and comments discussed in the session will be exclusively used for purposes of the study. You will be identified through a pseudonym, not your name.

All the information handled in these sessions will be kept confidential by the research staff. At no point will your personal opinions be disclosed to directors or staff at your workplace; and your opinions will not influence in any way your work environment or job performance. All the necessary precautions will be taken in order to protect information confidentiality.

Commitment to keep confidentiality (secret) of everything discussed during the session will be requested from all participants. However, we cannot guarantee that all participants will do so; therefore, if you feel uncomfortable expressing a particular opinion in the presence of other participants, you may choose not to.

Remember that your participation could eventually entail an improvement to the program and better health care for the population.

5. **How will I benefit?**
If you attend the session, you will be offered transportation from the Healthcare center to the place where the focus group session will be held and back to the healthcare center in a small bus hired for this purpose. You will receive refreshments at the end of the session. There will be no other forms of payment.

It is possible that through your participation in this focus group, care processes are better understood, and thereby, improved. Your opinions are extremely valuable.

6. **What are the risks?**
Despite all the precautions taken, the possibility that any of the participants fails to keep confidentiality exists. Therefore, if you consider that your opinions could have labor repercussions, refrain from expressing them.

7. **Do I have to answer all the questions?**
If you feel uncomfortable and do not wish to answer a particular question or participate in the discussion of a particular issue, you may refrain from answering or discussing that issue.

8. Is there a cost for participating?

There is no cost for participating in this study, since the corresponding authorities have approved your participation during work hours. Neither the time spent at the session, nor in transportation, will be deducted from your paycheck.

9. Do I have to participate in the study?

Your participation in the study is voluntary. If you decide not to participate, there will be no repercussions in your work status or treatment at the healthcare center.

10. Can I withdraw from the study?

If you decide not to participate, before or during the session, you will be able to leave whenever you consider convenient, without any effect on your rights. You may withdraw even after signing the informed consent.

11. Who should I contact in case of doubts?

If you have any questions about this study, you may contact Ana Laura Dengo, Principal Investigator, at 22242714 (8:00 a.m. to 5:00 p.m.) or via e-mail at adengo@nutricion.ucr.ac.cr, School of Nutrition, Universidad de Costa Rica. If you have doubts regarding your rights as participant, you may contact Valentina Santacruz from INCAP Ethics Committee at (502) 24723762 during office hours (8:00 a.m. to 5:00 p.m.). This call will have no cost if it is a collect call to INCAP.

I have read this consent and had the opportunity to ask questions. If I expressed any doubts, they were all solved. I understood the previous explanations about the study that INCAP and the School of Nutrition of *Universidad de Costa Rica* are carrying out. I voluntarily accept to take part in this study.

_____	_____	_____
Participant's name	Participant's signature	Date (mm/dd/yy)

_____	_____	_____
Name of the person who administered the consent	Signature of the person who administered the consent	Date (mm/dd/yy)

Best regards,

Ana Laura Dengo
Researcher in charge
School of Nutrition
Universidad de Costa Rica

B. Consent for focus groups with people from the community (example for Universidad de Costa Rica; the same consent will be used for *Universidad de Ciencias y Arte de Chiapas*, just the name of the investigator in charge must be changed).

INCAP's COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC DISEASES –CIIPEC (for its initials in Spanish)
UNIVERSIDAD DE COSTA RICA –SCHOOL OF NUTRITION-
INFORMED CONSENT

Title of the project: **Primary Health Care and Community-based Model for Cardiovascular Diseases Prevention and Control in High-risk Individuals in Urban Areas of San José, Costa Rica and Southern Mexico, Chiapas**

You are hereby invited to participate in a focus group session to determine your perspective on the government's health service provision, capacities, needs and response regarding cardiovascular disease care programs.

1. **What is the purpose of the study?**
   The purpose of this study is to asses an intervention based on "primary health care" in order to prevent cardiovascular disease in patients suffering from diabetes and hypertension. This model was adapted and applied in Guatemala and will be assessed in Cost Rica and Mexico from August 2010 to December 2011. This study is funded by the Institute of Nutrition of Central America and Panama (INCAP), which specializes in health and nutrition research and is headquartered in Guatemala, with coordinating offices in every country of Central America and the Dominican Republic.

2. **Who will participate in this study?**
   Healthcare staff attending the primary healthcare services in San José, Costa Rica. People from the community who attend Basic Integrated Healthcare Teams –EBAIS, for its initials in Spanish and Health Care centers of *Caja Costarricense del Seguro Social* (Costa Rica's public healthcare system) in San José, Costa Rica.

   A total of 32 individuals will participate in the focus groups.

3. **What does participating imply?**
   Your participation consists in attending a focus group session where 6 - 8 persons will take part. We will require your opinion and comments on the quality of the government's health service provision, capacities, needs, and response regarding chronic non-communicable disease care programs, such as diabetes and hypertension.

The session will be guided by a moderator and your opinions and comments will be recorded and written down by specialists.

The session will last a maximum of two hours and will be held in a classroom at the School of Nutrition of *Universidad de Costa Rica* on August 4, 2010, from 8:00 a.m. to 10:00 a.m.

4. **How will confidentiality be managed?**
   The opinions and comments discussed in the session will be exclusively used for purposes of the study. You will be identified through a pseudonym, not your name. Participants in the study will be chosen from different health services.
   All the information handled in these sessions will be kept confidential by the research staff. At no point will your personal opinions be disclosed to directors or staff at your workplace; and your opinions will not influence in any way your work environment or job performance. All the necessary precautions will be taken in order to protect information confidentiality.
   Commitment to keep confidentiality [secret] of everything discussed during the session will be requested from all participants.
   Remember that your participation could eventually entail an improvement to the program and better health care for the population.

5. **How will I benefit?**
   If you attend the session, you will be offered transportation from the healthcare center to the place where the focus group session will be held and back to the healthcare center in a small bus hired for this purpose. You will receive refreshments at the end of the session. There will be no other form of payment.
   It is possible that through your participation in this focus group, care processes are better understood, and thereby, improved. Your opinions are extremely valuable.

6. **What are the risks?**
   Despite all the precautions taken, the possibility that any of the participants fails to keep confidentiality exists. Therefore, if you consider that your opinions could have labor repercussions, refrain from expressing them.

7. **Do I have to answer all the questions?**
   If you feel uncomfortable and do not wish to answer a particular question or participate in the discussion of a particular issue, you may refrain from answering or discussing that issue.

8. **Is there a cost for participating?**
   There is no cost for participating in this study, since the corresponding authorities have approved your participation during work hours. Neither the time spent at the session, nor in transportation will be deducted from your paycheck.

9. **Do I have to participate in the study?**
   Your participation in the study is voluntary. If you decide not to participate, there will be no repercussions in your work status or attention at the healthcare center.

10. Can I withdraw from the study?

If you decide not to participate, before or during the session, you will be able to withdraw whenever you consider convenient, without any effect on your rights. You may withdraw even after signing the informed consent.

11. Who should I contact in case of doubts?

If you have any questions about this study, you may contact Ana Laura Dengo, Principal Investigator, at 22242714 (8:00 a.m. to 5:00 p.m.) or via e-mail at adengo@nutricion.ucr.ac.cr, School of Nutrition, *Universidad de Costa Rica*. If you have doubts regarding your rights as participant, you may contact Valentina Santacruz from INCAP Ethics Committee at (502) 24723762 during office hours (8:00 a.m. to 5:00 p.m.). This call will have no cost if it is a collect call to INCAP.

I have read this consent and had the opportunity to ask questions. If I expressed any doubts, they were all solved. I understood the previous explanations about the study that INCAP and the School of Nutrition of *Universidad de Costa Rica* are carrying out. I voluntarily accept to take part in this study.

_____	_____	_____
Participant's name	Participant's signature	Date (mm/dd/yy)
_____	_____	_____
Name of the person who administered the consent	Signature of the person who administered the consent	Date (mm/dd/yy)

Best regards,

Ana Laura Dengo
Researcher in charge
School of Nutrition
Universidad de Costa Rica

C. Informed consent for subjects participating in Stage III for *Universidad de Ciencias y Arte de Chiapas*

INCAP'S COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC DISEASES – CIIPEC (for its initials in Spanish)

INSTITUTE OF NUTRITION OF CENTRAL AMERICA AND PANAMA – INCAP

***UNIVERSIDAD DE CIENCIAS Y ARTES DE CHIAPAS*, MEXICO – SCHOOL OF NUTRITION**

HEALTH CENTER…

INFORMED CONSENT SHEET

STAGE III: Application of a Diabetes and High Blood Pressure Care Model in Healthcare Centers

Project Code:

Researcher's name:

Participant's name:

PURPOSE OF THE PROJECT

To apply a specialized care model on heart disease prevention for individuals with diabetes and high blood pressure, in primary healthcare centers in Tuxtla Gutiérrez, Chiapas, Mexico.

WHAT WILL BE DONE?

We have the opportunity to invite you to participate in a study that will take place in this healthcare center, regarding the care you receive here. The study is coordinated by INCAP's Comprehensive Center for the Prevention of Chronic Diseases – CIIPEC-, along with the School of Nutrition of *Universidad de Ciencias y Artes de Chiapas* –UNICACH. The research is financed by the Institute of Nutrition of Central America and Panama – (INCAP, for its initials in Spanish). INCAP is a non-governmental and non-profit organization, headquartered in Guatemala, Central America, with broad experience in nutrition and health-related issues. Nelly Isabel Cruz Serrano, Ph.D., of the School of Nutrition of UNICACH, is the researcher in charge.

A. WHAT DOES PARTICIPATING IMPLY?

During the study, the project staff will:

- Examine your file and register data such as your age, sex, nutritional state, family and personal disease background, weight, size, blood pressure, diabetic foot examinations, and results of your lab tests related to diabetes and/or hypertension.

- Carry out an interview to ask you about your physical and recreational activities.

- Carry out periodical home visits to reinforce clinic actions and to help you follow the indications. Depending on your cardiovascular disease risk, visits may be on a monthly basis, every two months, or every four months.

- During the sessions detailed information for adopting changes in your lifestyle will be provided. This information will include diet, physical activity, pharmacological treatment when necessary, importance of medical check-ups, and other issues that will help you and your family understand better your disease and how to improve your health condition.

- In case you need medication, it will be prescribed according to the health center care regulations.

- Group sessions will be held every two weeks in your local healthcare center, and these will be one hour long.

- In case a relative wishes to join you at the educational sessions, he/she is welcome to do so.

During these sessions, you will be reminded to attend your medical check-ups, depending on your cardiovascular risk. In case you need more information, you will be assisted by the appointed health promoter.

B. RISKS

Your participation in this study does not imply more risks than that of any person who attends healthcare centers. If any of the questions in the interview makes you feel uncomfortable, you may refrain from answering it. There is a very low risk that your medical information is seen by other persons, but we will take all the necessary precautions to keep your information confidential.

C. BENEFITS

- You may benefit from the individualized attention received.

- You will receive information on the progress of your disease.

- If the study proves to be beneficial, you will have contributed with population with diabetes and/or hypertension who receives care at healthcare centers, for they will also benefit from better healthcare programs.

- You will not receive any economic compensation for participating in the study.

D. CONFIDENTIALITY

Your participation in this study is strictly confidential. Your name and personal data will not be disclosed. Only the study research team will have access to your medical records, interview, and home visits. Group information may appear in a publication or scientific meeting, without identifying any participant.

E. PARTICIPATION OPTIONS

You may choose not to participate or to withdraw from the study at any moment, and this will not represent a negative consequence in the medical care provided by this clinic; therefore, you may continue with your regular check-ups.

F. RIGHTS

Your participation in this study is completely voluntary. You will have the right to withdraw at any moment needless of any explanation. It is only necessary to inform the researchers. In addition, you are not obliged to answer.

CONSENT

I, _____, have talked to _____, about this study and have had the opportunity to ask questions and all my doubts have been solved. For more information, I may contact Nely Isabel Cruz Serrano, PhD., Principal Investigator, or Professor Erika Judith López, Director of the School of Nutrition of UNICACH at: 9611556335 or 9611381707. I may also contact Valentina Santacruz at INCAP at: (502) 24723762. This will be a collect call to INCAP; therefore, it must be indicated to the operator.

For any additional information about participants' rights in the mentioned study, I may contact the Scientific Ethics Committee of *Universidad de Ciencias y Artes de Chiapas,* telephone:

_____ ___/___/___

Participant's name and signature Date

_____ ___/___/___

Witness's name and signature Date

_____ ___/___/___

Researcher's name and signature Date

VERSION APPROVED BY THE SCIENTIFIC ETHICS COMMITTEE (CEC, for its initials in Spanish) of UNIVERSIDAD DE CIENCIAS Y ARTE DE CHIAPAS, MEXICO

D. Informed consent for subjects participating in Stage III, *Universidad de Costa Rica*

INCAP'S COMPREHENSIVE CENTER FOR THE PREVENTION OF CHRONIC

DISEASES –CIIPEC (for its initials in Spanish)

SCHOOL OF NUTRITION, *UNIVERSIDAD DE COSTA RICA*

Primary Health Care and Community Support Model to Decrease Cardiovascular Disease Risk in Type 2 Diabetes Mellitus and/or Hypertensive Patients in Urban Areas of San José, Costa Rica

Informed consent to participate in a personalized care model application to improve diabetes mellitus and hypertension control to reduce heart disease risk

Stage III

INTRODUCTION

We would like to inform you about the study carried out in this healthcare center regarding the care provided to patients with diabetes and high blood pressure (hypertension). The purpose of this study is to apply a personalized care model to improve diabetes *mellitus* and hypertension control in order to help reduce heart disease risk, implemented in primary healthcare centers in Costa Rica.

WHO IS IN CHARGE OF THE STUDY?

The study is coordinated by INCAP's Comprehensive Center for the Prevention of Chronic Diseases – CIIPEC, which depends on the Institute of Nutrition of Central America and Panama (INCAP, for its initials in Spanish) headquartered in Guatemala. INCAP is a non-governmental and non-profit organization with broad experience in health and nutrition-related issues, and has proposed to carry out this study, along with the School of Nutrition of *Universidad de Costa Rica*. The research is funded by INCAP and is also supported by *Universidad de Costa Rica*. Ana Laura Dengo, PhD of the School of Nutrition of *Universidad de Costa Rica* is the researcher in charge.

WHY WAS I SELECTED TO PARTICIPATE?

You have been invited to participate because you are regularly treated in this healthcare center, and you suffer from diabetes *mellitus* (sugar in blood), or have high blood pressure (hypertension).

WHAT DOES PARTICIPATING IMPLY?

If you accept our invitation, and decide to participate, the project staff will:

- Examine your file and register data such as your age, sex, nutritional state, personal and family disease background, weight, size, blood pressure, diabetic foot examination, and results of your lab tests related to diabetes and/or hypertension.
- Carry out an interview to ask you about your physical and recreational activities.
- Evaluate your risk for cardiovascular diseases within the next 10 years, based on the information collected.
- Advise you at the healthcare center on how to control your disease better by adopting a healthy lifestyle, including regular physical activity, a healthy diet, and smoking cessation.
- Depending on your cardiovascular risk, your physician may prescribe one or more medications.
- In order to reinforce the information that you receive at the clinic, and to help you follow the medical and the behavior indications provided in the healthcare center, we will invite you to attend group talks that will take place every two weeks and will be delivered by primary healthcare staff. These talks will be one hour long. If you consider it appropriate, you may invite a member of your family. The participation of a family member may help you understand better the topics discussed, and could support you in adopting healthy lifestyles.
- Depending on your cardiovascular risk, you will be asked to go to the healthcare center for a check-up at different intervals. If your risk is low, you will have appointments every four months; if it is moderate, your appointments will be every two months; and if it is high, you will have monthly appointments. In these appointments, the physician will carry out clinical and laboratory evaluation; and we will administer some questionnaires to find out how well you are following the instructions.
- You will receive a phone call from the healthcare center reminding you about your appointment. If we cannot reach you, we will make a home visit for this reminder. In such case, the visit will last about 15 minutes.

RISKS

Your participation in this study does not imply any other risk than that of any person who attends a healthcare center of the Social Security. During this study, we will not use additional medications to the ones prescribed by your physician; nor will we carry out any procedure that represents risk for your health. Your participation consists in your attendance to educational sessions, and listening to the advice and recommendations from the project staff to help you follow better the treatment prescribed in the healthcare center. During follow-up visits, we will administer questionnaires in order to assess your evolution. If any of the questions makes you feel uncomfortable, you may refrain from answering it. There is very little risk that your medical information is seen by other persons, but we will take all the necessary precautions in order to keep your information confidential.

BENEFITS

- You may benefit from the individualized attention received.
- You will receive periodical information on your disease control.
- You will receive specific instruction on diabetes and hypertension prevention and control, which will help reduce your cardiovascular disease risk and have a better quality of life.
- If the study proves to be beneficial, you will have contributed with population with diabetes and/or hypertension who receives attention at healthcare centers, for they will also benefit from better healthcare programs.
- You will not receive any economic compensation for participating in the study.

CONFIDENTIALITY

Your participation in this study is strictly confidential. Your name and personal data will not be disclosed. Only the study research team will have access to your medical records, interview, and home visits. We plan to use the information collected to prepare scientific reports and publications, but participants' names will not be published. Information will be handled by groups, and in no case will the participant be identified. The research team will take different measures to protect data confidentiality. Participants will be identified in questionnaires only through a number, and the information that includes personal data will be kept locked and under the researchers' control.

G. PARTICIPATION OPTIONS

You may choose not to participate or withdraw from the study at any moment, and this will not represent a negative consequence in the medical care provided by this clinic; therefore, you may continue with your regular check-ups.

H. RIGHTS

Your participation in this study is completely voluntary. You may choose not to participate and still receive the usual treatment at your healthcare center. You will have the right to withdraw at any moment needless of any explanation. It is only necessary to inform the researchers. Withdrawing from the research will not represent a negative consequence in the usual attention received at your healthcare center. We will not gather more information about you, although we will be able to use your information previously collected in our analyses. You are not obliged to answer any question that makes you feel uncomfortable and the health staff will not insist.

SIGNING OF THE INFORMED CONSENT

I, _____, have heard the information provided on the project to which I am invited to participate; and I have had the opportunity to ask the questions I considered necessary. All my doubts have been solved. By accepting to participate, I will receive a copy of this consent for future reference.

I may obtain more information about the project by contacting Ana Laura Dengo, PhD., researcher in charge of the study or Emilce Ulate, PhD., Director of the School of Nutrition of *Universidad de Costa Rica* at: 22241427. I may also contact Valentina Santacruz from the INCAP Ethics Committee at: (502) 24723762. This will be a collect call to INCAP; therefore, it must be indicated to the operator.

For any additional information about participants' rights in the mentioned study, I may contact the Scientific Ethics Committee of *Universidad de Costa Rica* at:

My signature indicates my CONSENT to participate in this study.

_____ ___/___/___

Participant's name and signature Date

_____ ___/___/___

Witness's name and signature Date

_____ ___/___/___

Researcher's name and signature Date

VERSION APPROVED BY THE SCIENTIFIC ETHICS COMMITTEE (CEC, for its initials in Spanish) FROM UNIVERSIDAD DE COSTA RICA 2010