

COVER PAGE

Study title: Increasing Physical Activity in Filipino lay leaders

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University of Hawai'i Consent to Participate in a Research Project

Clem Ceria-Ulep and Cheryl Albright, Principal Investigators

Project title: Healthy Living Project for Filipino Lay Leaders from Oahu Council of Filipino Catholic Clubs

Aloha! Our names are Clem Ceria-Ulep, PhD, RN and Cheryl Albright, PhD, MPH and you are invited to take part in our research study called The Kalusugan (Healthy Living) Project. We are faculty at the University of Hawai'i at Mānoa in the School of Nursing. The purpose of our project is to inform church leaders from Filipino Catholic Clubs about ways to improve their health and wellbeing, including having an active lifestyle.

Ten Catholic clubs in the Oahu Council of Filipino Catholic Clubs (OCFCC) have agreed to participate in the project. We are asking whether you would like to participate because you are a member of club in the OCFCC. This project will provide health information and exercise recommendations.

If you decide to participate, we will ask about your current and past health and medical conditions. Some people may need to obtain a letter from their physician stating that it is safe for them to be more active. You are eligible to participate if you are of normal weight or you are overweight. We will ask you some questions about this to make sure you qualify. We will also ask about whether you have had a medical operation in the last six months or are recovering from a major medical condition. If you are recovering, you will not be able to participate. If you have other medical conditions, such as asthma or diabetes, you might be able to participate with your physician's approval.

If you participate, you will be asked to complete an initial survey and have your height and weight taken today (in privacy). Drs. Ceria-Ulep and Albright, and their research staff will interact with you over the course of the project, beginning with this initial survey. You will be one of about 250 people from 10 clubs across Oahu who join this study.

If you decide you would like to participate, brief discussions will occur after a regularly scheduled club meeting and during phone calls with our staff; but, participation will not interfere with your normal club meetings or club-related duties/tasks.

Activities and Time Commitment: The OCFCC's 10 clubs will begin their participation, in sequence, over the next 2 years (between March, 2018 and January, 2020). Your club begin its involvement today and ends on: _____ (*will fill in date 9 months in future*).

If you decide to participate you will be assigned to one of two intervention groups. Both groups will receive health information but the order each group receives the information will be different. The information you receive will focus on either, 1) ways to increase physical activity and decrease the amount of time you spend sitting / reclining (but not sleeping) or 2) general healthy living tips. Regardless of the order of the information you receive, you will also receive weekly telephone calls from our staff to discuss the information you receive (calls will be scheduled at a time convenient to you). You will receive each set of health information for 3 months, with a 3-month period of receiving no information between them.

If you are part of either group, you will learn about lifestyle factors that could improve your health and wellbeing over 9 months. You will be asked to complete surveys today in 3 months, 6-months and 9 months. If you decide to participate, you will be asked to complete the first survey today. You will then receive each follow-up surveys by mail.

Approximately 10% of participants in either group will be asked to wear a waterproof accelerometer (which is a small watch-like device that is worn on the wrist all day) for 7 days: today, and then again in three months, in six months, and then 9 months from now. You will be given a postage paid envelope to return the accelerometer to us in the U.S. mail.

Benefits and Risks: Your participation will give you the opportunity to assist researchers in designing more effective healthy living programs for older adults. Our results may be helpful to people developing effective ways to reduce risk of disease among adults like you. Your current and future health and wellbeing may benefit from receiving important health information including on how to be more active.

We believe there is little risk to you in participating in this project. You may become uncomfortable or unduly stressed by the health information we ask you to report. If you do become uncomfortable, you may choose to not report your information or follow the health recommendations we provide. Potential risks of participation are of several kinds, all of which are rare when exercise is conducted using precautions and following basic safety recommendations. The potential risks involved in this project include minor discomfort resulting from increasing your physical activity (e.g., sore muscles,



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tired feet, etc.). Possible heart problems, orthopedic (i.e., foot or leg problems), or bone and joint problems can occur during exercise, but serious problems are less likely to occur if you follow our advice. Unless there is damage due to previous injury, serious foot or leg problems are uncommon as a result of the exercise programs we will be suggesting. The risks of injury resulting from recommended exercise regimens will be minimized in the following ways: we will provide advice and guidance on how to gradually increase physical activity so as to not have sore muscles or potential injuries. We will help you set short-term gradual goals that increase length of time per exercise session or increase the number of times per week (frequency) of walks, for example, before the overall intensity of any activity is increased. We will also recommend warm-up and cool-down periods before/after each physical activity session. If you are injured we ask that you report this to us or our staff as soon after the injury as possible. We cannot provide payment or compensation for any medical care you might need if you become injured while being active. We will refer you to your personal health care provider if you report an injury. If you do not have one, we will assist you in finding medical care or recommend you go to the nearest emergency room.

Privacy and Confidentiality. We will keep all study data secure in a locked filing cabinet in a locked office on a password protected computer. Only one senior staff member and two health educators trained in motivational interviewing will have access to your name and phone number. Federal agencies that have legal permission have the right to review research records. The University of Hawaii Human Studies Program has the right to review research records for this study. When we report the results of this research project, we will not use your name. We will not use any other personal identifying information that can identify you. We will report our findings in a way that protects your privacy and confidentiality.

Voluntary Participation: Your participation in this project is completely voluntary. You may stop participating at any time. If you stop being in the study, there will be no penalty or loss to you. Your participation will not impact your association with your OCFCC club.

Compensation:

To thank you for your participation in the surveys, you will be provided with gift cards worth a total of \$25 to Longs (CVS). If you decide to participate, you will receive \$5 today, \$10 for sending in your survey after 3 months, \$5 for sending in your survey after 6 months, and \$5 for sending in your survey after 9 months. You will also receive a pedometer which is a step counter you clip onto a waist band to track the number of steps you take in a day.

Questions: If you have any questions about this study, please call or email us directly at Dr. Ceria-Ulep (clem@hawaii.edu; 956 5233) and Dr. Albright (cherylal@hawaii.edu; 956 9716). You may also contact our study email: healthy1@hawaii.edu. You may contact the UH Human Studies Program at 808.956.5007 or uhirb@hawaii.edu to discuss problems, concerns and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol. Please visit <https://www.hawaii.edu/researchcompliance/information-research-participants> for more information on your rights as a research participant.

If you agree to participate in this project, please sign and date the following signature section and return to a staff member. Keep this copy of the informed consent for your records and reference.

Signature(s) for Consent:

I give permission to join the research project entitled: "*The Kalusugan (Healthy Living) Project*"

Name of Participant (Print): _____

Participant's Signature: _____

Signature of the Person Obtaining Consent: _____

Date: _____

Mahalo!