DGIM Project Summary

Name of Project: Pilipino Americans Go4Health Weight Loss Program to Prevent Heart Disease (PilAm Go4Health)

Investigator(s): PI and primary contact: Bender, Melinda S, PhD, APRN melinda.bender@ucsf.edu
Other significant research staff: Fukuoka Yoshimi, PhD, RN yoshimi.fukuoka@ucsf.edu

Research question(s):
- What is the feasibility and acceptability of the PilAm Go4Health intervention among Filipino Americans with type 2 diabetes, as measured by recruitment, engagement, adherence, and retention.
- What is the efficacy of the PilAm Go4Health intervention on change in: % weight, fasting plasma glucose, and HgbA1c).
- What are the Filipino perceptions regarding cultural relevancy, barriers to use, efficacy, and suggested improvements with respect to the PilAm Go4Health Weight Loss Program intervention?

Brief Background/Significance:
Filipino Americans At-Risk: Filipino Americans (FA) have one of the highest risks for lifestyle related diseases, such as obesity, diabetes, and metabolic syndrome leading to subsequent cardiovascular disease and stroke sooner than other racial ethnic populations. Although one of the fastest growing US ethnic groups, FA are seriously under-represented in health related research. This overt research gap underscores the need for effective interventions to reduce the prevalence obesity and type 2 diabetes (T2DM), and the subsequent risk for metabolic syndrome in this high-risk population. Therefore, we leveraged advances in mobile technology, along with the rapid penetration of smartphone use among Filipinos and their propensity for social media to develop a culturally relevant mobile phone-based lifestyle intervention program for FA.

This proposed pilot randomized controlled trial (RCT) is a mobile phone-based 3-month intervention with a 3-month maintenance phase for Filipinos with T2DM on metformin. The objective is to assess the potential efficacy of the PilAm Go4Health Weight Loss program is to reduce risks for metabolic syndrome and subsequent heart disease in Filipinos with T2DM. To our knowledge, this will be the first such intervention study targeting Filipinos with T2DM.

The PilAm Go4Health intervention incorporates an innovative approach for promoting weight loss through physical activity and healthy eating using a mobile health (mHealth) app to track health behaviors, pedometer to monitor physical activity, and a private Facebook group for education, coaching and social support.

Findings from this study will help to advance science by: 1) identifying effective strategies to reduce heart disease risks in Filipino Americans that combine mHealth technology with the power of virtual social networking (e.g., Facebook) to deliver personally tailored interventions to promote healthy behaviors; 2) helping to provide practical insights in developing culturally relevant lifestyle interventions; and 3) providing a model for delivering lifestyle interventions to other at-risk populations at relatively low-cost. If this study demonstrate feasibility and potential efficacy, it will lay the foundation for a full-scale RCT to demonstrate cost-effectiveness, operational effectiveness, sustainability, and scalability of an intervention that could be adapted and widely disseminated to other high-risk populations.

Inclusion/exclusion criteria (list) are based on American Heart Association (AHA) metabolic syndrome risks, diagnosis, and management, and the Diabetes Prevention Program trial.

Inclusion Criteria: 1) Self-identified as Filipino, 2) Age ≥ 18 years, 3) BMI for Asians > 23 kg/m2, 4) Physician diagnosed T2DM diabetes confirmed by clinical data (e.g. documentation of fasting blood glucose >100 mg/dL or a positive oral glucose tolerance test (OGTT) > 200mg/dl, HbA1c >
6.5%), 5) On metformin for T2DM, 4) waist circumference: men > 40 inches, women > 35 inches, 6) No cognitive impairment per the Mini-Cog test, and 8) English speaking; 9) No physical disabilities preventing walking at least 20 minutes continuously or 1 mile; and 10) Have a smartphone (iPhone or android phone) or tablet.

**Exclusion criteria:** 1) Uncontrolled T2DM, 2) Glucose metabolism associated disease (Cushing's syndrome, Acromegaly, and Pheochromocytoma currently under treatment, chronic pancreatitis), 2) Thyroid disease - sub-optimally treated, 3) Known medical conditions or other physical problems needing a special exercise program (e.g., prior myocardial infarction, history of angioplasty or angina, admission for hospital evaluation of chest pain, use of nitroglycerin for angina, COPD, or uncontrolled hypertension), 4) Recent acute coronary syndrome or revascularization, CHF, 5) Currently participating in a lifestyle modification program, 6) Planning a trip outside of the US during the 6-month study period, 7) Known eating disorder, 8) Planning a surgery in the next 7-months, 9) Taking long-term antibiotics (including HIV-related agents), anti-TB agents (except INH alone as prophylaxis), or prescription weight-loss drugs.

**Note:** Only one member per household allowed to enroll in the study to reduce risks for cross contamination of study.

**Method of contact/recruitment (be specific):** DIGM healthcare providers and staff will be provided with information about our study and asked to make this information available to their patients during clinic visits. Study flyers will be provided and posted in clinic exam rooms and waiting room. DIGM providers and staff will be asked to identify potential participants and refer potential participants to contact the Pilipino Go4Health staff. Our PilAm Go4Health research staff will then screen potential participants for eligibility for the study.

**Benefits/burden for participants (clearly identify potential for harm):** Some subjects may try to rapidly increase their amount of daily physical activity and rapidly lose weight. A potential risk of the study is muscle pain and injury due to physical activity. Participants may feel pain during the needle stick during blood draw. There is also a very small risk of bruising, and a rare risk of infection. Participants may also feel emotional discomfort when completing the questionnaires.

Potential risks to participants in this pilot study are minimal. In contrast, the anticipated benefits may be substantial, since the program may help participants with type 2 diabetes become more aware of heart disease prevention and motivate them to improve personal weight loss and healthy lifestyle behaviors.

**Any benefits or burden to DGIM practitioners?** There is no burden to DGIM practitioners except the incremental time required to inform potential participants about the PilAm G4Health study. Although there are no direct benefits to the DGIM practitioners, overall, they will be helping research investigators understand why Filipinos are at high risk for diabetes and heart disease and identify effective strategies to reduce lifestyle related disease risks in this at risk population.

**Timeline for recruitment (projected start and stop dates):** We are hoping to reach our target recruitment: N=40 Filipino Americans (men and women) with type 2 diabetes on metformin (not taking insulin)

**Funding source:** American Heart Association, Grant # 14CRP19560008, RAS P# 14-14158

**Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular):** Tung Nguyen, MD, Alka Kanaya, MD, and Jane Jih, MD

**Do you agree to notify us when recruitment is completed?** Yes.

**Date form completed:** 5/26/2015