

## Project RICE Pilot Protocol

### *Overview*

#### Project Goal and Specific Aims

The **primary goal** of this five-year study is to develop, implement, and test a community health worker (CHW) program designed to promote diabetes prevention among recently immigrated Korean Americans and South Asian Americans in New York City.

In particular, the **specific aims** of this study are:

1. To utilize community based participatory research (CBPR) methods to expand upon an existing campus-community partnership to develop and implement a CHW program among Korean and South Asian Americans that promotes diabetes prevention;
2. To gather descriptive information on access to care, health behaviors, and beliefs as related to diabetes prevention among these two populations in NYC; and
3. To develop, implement, and assess the efficacy of a CHW intervention to promote diabetes prevention and access to care among NYC Koreans and South Asians.

We **hypothesize** that individuals in the case group, when compared to the control group, will experience:

H2: Greater reductions in weight, BMI, and hip-to-waist ratio measurements

H3: Improved access to and utilization of healthcare services

H4: Greater knowledge and improved changes in dietary and physical activity

#### **Outcome Variable(s)**

Reframe study as decreasing diabetes risk

##### *Primary outcomes:*

- weight loss
- diabetes knowledge

##### *Secondary outcomes:*

- improved physical activity
- improved diet/nutrition
- decreased levels of smoking
- reduction in glucose levels
- reduction in blood pressure
- reduction in cholesterol (lipid profile?)
- improved self efficacy
- improved social support
- improved access to care/confidence using physician/medical facility

#### Eligibility

An individual is *eligible* for the intervention if she or he :

- (a) is a Korean or South Asian American immigrant;
- (b) is identified as at-risk by a diabetes risk assessment
- (c) *has an 8-hour fasting blood glucose level above 140 mg/dl*;
- (d) is between 18-75 years of age; and
- (e) is willing to be randomized to either treatment or control groups.

An individual is *ineligible* for enrollment in the study if s/he:

- (a) is a confirmed diabetic;
- (b) is on renal dialysis,
- (c) has an acute or terminal illness or serious mental illness,
- (d) has a history of recent coronary event within the last 12 months;
- (e) has a recent history of acute medical problem or admission to hospital;
- (f) (g) has any other severe medical conditions that might preclude frequent visits to a clinic;
- (h) has poor short-term prognosis (expected death in <2 years);
- (i) is planning to travel for longer than 6 weeks during the 6-month intervention period; or
- (j) is participating in another CVD study.

#### Recruitment

Community outreach at community health screening events

Two-step eligibility confirmation:

- Identify diabetes risk based on ADA or CDC risk assessment tool (based on family history of diabetes, BMI, etc.)
- Those who are at risk based on the assessment will be given an 8-hour fasting finger stick test as to confirm individuals at high risk

#### Intervention Schedule

6-month intervention

The intervention group will get 6 workshop sessions (frequency to be determined) and weekly phone calls.

#### Data Collection Tools/ Data Sources

To be finalized

#### Primary Outcomes

*According to the original protocol:*

Primary client outcomes will be measured at baseline, 3, and 6 months. To determine the effectiveness of the community health worker intervention, the primary client outcomes will include measures of fasting blood glucose (via finger prick test), weight, BMI, and hip-to-waist ratio reduction, access to and utilization of care (i.e. appointment keeping and visit to PCP), and greater knowledge and practice of physical activity and healthful eating.

<b>(Possible) Outcome</b>	<b>Type of Outcome</b>	<b>Data Source</b>
Glucose finger stick test	Clinical	TBD
Lipid Profile	Clinical	TBD
BMI / weight / waist-to-hip ratio	Clinical	TBD
Knowledge/Practice of physical activity and dietary guidelines	Behavioral	TBD
Access to care	Behavioral	TBD

#### Type and Frequency of Data Collected During the Study Period

<b>Measures</b>	<b>Baseline</b>	<b>X</b>	<b>3 months</b>	<b>X</b>	<b>6 months</b>
Predisposing Characteristics	X				
Reinforcing Characteristics	X		X		X
Client Outcomes	X		X		X
Intensity of and Fidelity to the Intervention		X		X	

#### Predisposing Characteristics

At baseline only, we will collect data on predisposing characteristics of the study participants. These questions include health access and insurance status, length in the United States, acculturation, marital status, socioeconomic status, personal and family history of Type II diabetes and its risk factors. Measures will be drawn from the BRFSS survey, the Suinn-Lew Asian Self-Identity Acculturation Scale, and the Multidimensional Acculturation Scale.

#### Reinforcing Characteristics

At baseline, 3 months, and 6 months we will collect data on reinforcing characteristics. Using measures from the source documents described, we will assess the following reinforcing characteristics:

- Self-efficacy: whether participants feel that they can successfully or competently complete the task of seeking screening or preventing diabetes by engaging in healthful behaviors. Measures will be drawn from the Personal Mastery Scale, the Rosenberg Self-Esteem Scale, and the Bandura Self-Efficacy Scale.
- Cues to Action: whether internal or external cues (i.e. CHW) provide the motivation for participants to engage the desired behavior.

- Social Support: number of friends and family members in participants' social network, type of support received (e.g., enabling, tangible, emotional support), the density and degree of homogeneity of their social network, the use of faith-based organizations or religious counselors for support. Measures will be drawn from the Arizona Social Support Interview Schedule and the UCLA Social Support Interview
- Spousal Support: the degree and nature to which participants receive support and encouragement from spouses or partners to initiate and/or maintain screening and prevention services. Measures will be drawn from Multi-dimensional Scale of Perceived Support.

### Knowledge and Health Behaviors

At baseline, 3-months, and 6-months, we will also assess knowledge and behaviors. Again using the source documents described above, a knowledge scale will be constructed. This knowledge index will be used to assess whether the intervention increased participants' knowledge, particularly with respect to the following: Perceived severity – i.e., obesity and low physical activity can lead to higher risk for diabetes; Perceived susceptibility – i.e., participant can be pre-diabetic without being obese or have high BMI; Perceived benefits – i.e., engaging in physical activity will reduce the risks of diabetes; and Perceived barriers – i.e., limited time or capacity to engage in physical activity or change dietary habits.

### Sources of Measures Used

Measures to be Used in Proposed Intervention	Scale/ Survey	Information on reliability and validity
Pre-disposing characteristics (health access and insurance status, length in the United States, acculturation, marital status, socioeconomic status, personal and family history of Type II diabetes and its risk factors)	Suinn-Lew Asian Self Identity Scale (Suinn et. al 1992)	Validated in Asian communities
	Multi-dimensional Acculturation Scale (Nelson et. al 2001)	Validated in Asian communities
	Behavioral Risk Factor Surveillance Survey (BRFSS)	Validated in Asian communities
Self Efficacy	Personal Mastery Scale (Pearlin et. al 1981)	Validated in minority communities
	Rosenberg Self-Esteem Scale (1965)	Validated in minority communities

	Bandura Self-Efficacy Scale	Validated in minority communities
Social Support	Arizona Social Support Interview Scale (Barrera 1980, 1981)  UCLA Social Support Interview (Dunkel-Schetter et al. 1987)	Validated in minority communities
Spousal Support	Multi-dimensional Scale of Perceived Support (Zimet 1988)	Validated in minority communities
Knowledge & Health Behaviors	24-hour diet questionnaire (Gary et. al 2004)	Validated in minority communities
Physical Activity & Diet	IPAQ 2006; Satia et. al 2001	Validated in Asian communities