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## **Funding Sources**

### Funding Sources

- NIDDK (R18DK083936).
- LifScan provides study devices (OneTouch® glucometer, OneTouch® UltraSoft® test strips & OneTouch® UltraSoft® lancets).

## Clinical Trial Registration

clinicaltrials.gov identifier NCT0126479



## **Background**

- Type 2 diabetes mellitus is a serious health problem in Asian-American communities, including the Korean Americans (KAs).
- Today's Korean Americans (KAs)
  - have low literacy levels
  - experience a scarcity of personal and community resources
  - face institutional and cultural barriers



## **Objective**

### Objective

 The project tested a community-based, culturally tailored, multifaceted behavioral intervention program designed for Korean Americans (KAs) with type 2 diabetes on critical behavioral and clinical outcomes.

### Specific Aims

 Enroll 250 Korean Americans with type 2 diabetes in a clinical trial comparing a comprehensive community-based RN/CHW behavioral intervention to usual care to reduce HbA1c levels over 12 months

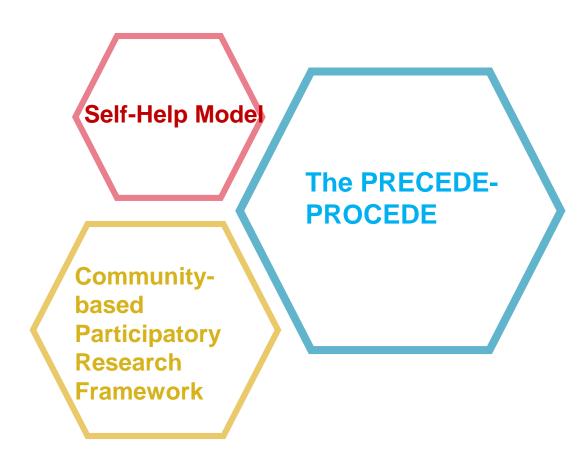
## **Methods**

- Design: Open Label Randomized Clinical Trial
- Setting: Baltimore Washington metropolitan area
- Period: September 2010 June 2013
- Community partner, The Korean Resource Center (KRC), in charge of recruitment, enrollment, retention of participants, and active engagement in interventions.
- Intervention has three components
  - 1) 12-hour group education sessions
  - 2) Home blood sugar monitoring for 12 months
  - 3) Monthly telephone coaching session using motivational counselling method





Integrated Theoretical Framework



### **ANTECEDENTS**

#### **Predisposing Factors**

- Individual characteristics
- Acculturation status
- Cultural beliefs/attitudes
- Severity of disease
- Depression

#### **Enabling Factors**

- Health literacy
- DM knowledge
- DM related self-efficacy
- Accessibility to care

### **Reinforcing Factors**

- Family/peer support
- Community support

#### **INTERVENTIONS**

## **Culturally Tailored Behavioral Education Program**

- Classroom education with culturally sensitive materials
- Health literacy tailored education

### **Ongoing Home Glucose Monitoring**

- Tele-transmission of home glucose monitoring
- Individually tailored monitoring reports to promote patient-provider communication
- Telephone reminders of follow-up appointment

## Individualized Case Management via Telephone Counseling

- Individually tailored behavioral counseling via phone
- Guidance for optimal utilization of healthcare
- Referrals to community resources for care as needed

### **OUTCOMES**

### **Predisposing Factors**

- Glucose control ↑
- BP control ↑
- Total cholesterol control 个

## Psycho-Behavioral Outcomes

- DM knowledge 个
- Self-care skills ↑
- QOL ↑

#### **CBPR Process**

- Active engagement with community collaborators in all phases of the study
- Empowering community-Supervision, consultation, feedback by community advisory board
- Expanding community infrastructure by using coalitions
- Direct Communication to patients, families, & the target KA community to sustain established infrastructure
- Developing dissemination strategies with community partners

### **Community Outcomes**

- Community readiness/awareness about diabetes
- Culturally tailored, literacyfocused DM management protocol
- Readily transferable education materials to other communities
- Community empowerment for self-care for DM control

## **Eligibility Criteria**

- The first generation of Korean American immigrant
- Physician diagnosis Type 2 DM
- Age 35 years or older
- Difficulty of managing glucose level as demonstrated by HbA1c at 7.0 or above
- Able to stay in the program for at least a year.

## Randomization (n=250)

## Integrate Care Group (ICG) (n=120)

- 6 weeks in-class training (12 hours)
- 2) Home glucose monitoring
- 3) Monthly telephone counseling

## Usual Care Group (UCG) (n=130)

Delayed intervention after month12

0 Month 3 Month 6 Month 9 Month 12 Month

## Interventions



## **Culturally Tailored Behavioral Education Program**

- Classroom education with culturally sensitive materials
- Health literacy tailored education

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## Individualized Case Management via Telephone Counseling

- Individually tailored behavioral counseling via phone
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DM knowledge ↑

Problem solving ↑

Confidence 1

Self-care skills ↑

Confidence 1

Problem solving ↑

Positive cognitive reframing 1



### Culturally-tailored protocol:

- Acknowledging cultural myths about each component of the behavioral intervention
- Crafting intervention messages based on relevant cultural philosophy or values

Adapting the most popular cultural practices to reinforce the behavioral modifications

## Intervention 2 Ongoing Home Glucose Monitoring

### **INTERVENTIONS**

## **Culturally Tailored Behavioral Education Program**

- Classroom education with culturally sensitive materials
- Health literacy tailored education

### **Ongoing Home Glucose Monitoring**

- Tele-transmission of home glucose monitoring
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## Individualized Case Management via Telephone Counseling

- Individually tailored behavioral counseling via phone
- Guidance for optimal utilization of healthcare
- Referrals to community resources for care as needed

Self-care skills ↑

Confidence 1

## **Evidence-based DM-specific behavioral** intervention components

 Power of self-monitoring and documenting in chronic disease management as a tool to enhance selfefficacy and promote adherence to treatment recommendations, and ultimately treatment outcomes

# Intervention 3 Individualized Case Management via Telephone Counseling

### **INTERVENTIONS**

## **Culturally Tailored Behavioral Education Program**

- Classroom education with culturally sensitive materials
- Health literacy tailored education

### **Ongoing Home Glucose Monitoring**

- Tele-transmission of home glucose monitoring
- Individually tailored monitoring reports to promote patient-provider communication
- Telephone reminders of follow-up appointment

## Individualized Case Management via Telephone Counseling

- Individually tailored behavioral counseling via phone
- Guidance for optimal utilization of healthcare
- Referrals to community resources for care as needed

Evidence-based DM-specific behavioral intervention components

 Mobilization of social support by interacting with trained bilingual nurse counselor

Problem solving 1

Positive cognitive reframing 1

## Results

### Sample Characteristics at Baseline (n=250)

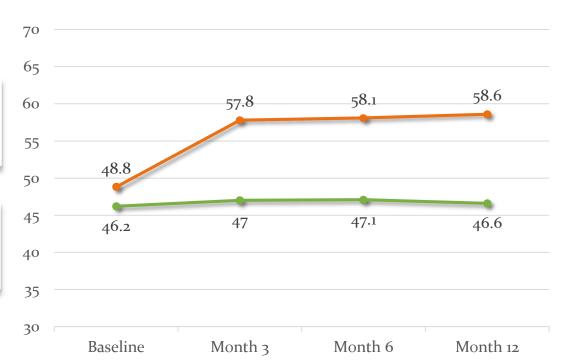
Subject	Total
Age, years (SD)	58.9 (8.44)
Male, n (%)	142 (56.8%)
Female, n (%)	108 (43.2%)
Married, n (%)	224 (89.6%)
Family size, persons (SD)	3.0 (1.22)
Working: full/part time (%)	148 (59.7%)
Years in USA (SD)	23.7 (11.1)
Education, years (SD)	13.3 (3.22)
Housing own, n(%)	160 (64.0%)
Comfortable living/OK, (%)	169 (68.1%)
Monthly income, \$(SD)	\$4,269 (\$7,379)

## Proximal outcome (1)

## **Diabetes self-efficacy (8-80)** ( $\alpha = .86$ )

Usual Care Group (UCG) (n=130)

Integrate Care Group (ICG) (n=120)



	Baseline	Month 3	Month 6	Month 12	Total (M0-12)
diff(ICG-UCG	i) 2.6	10.8	11.0	12.0	8.9
P( diff )	.179	.000	.000	.000	.000

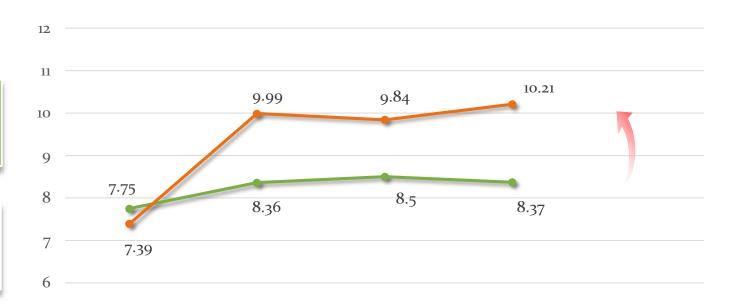
## Proximal outcome (2)

## Oiabetes knowledge (0-14) $(\alpha = .82)$

Usual Care Group (UCG) (n=130)

Integrate
Care Group
(ICG)
(n=120)

5



Baseline	Month 3	Month 6	Month 12

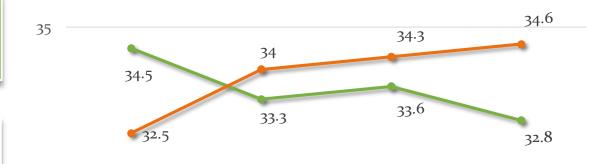
	Baseline	Month 3	Month 6	Month 12	Total (M0-12)
diff(ICG-UCG)	-0.36	1.63	1.34	1.84	1.09
P( diff )	.348	.000	.000	.000	.000

## Proximal outcome (3)

### **Attitudes toward diabetes (10-50)** $(\alpha = .80)$

Usual Care Group (UCG) (n=130)

Integrate
Care Group
(ICG)
(n=120)



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	Baseline	Month 3	Month 6	Month 12	

	Baseline	Month 3	Month 6	Month 12	Total (M0-12)
diff(ICG-UCG)	-2.0	0.7	0.6	1.9	0.936
P( diff )	.037	.435	.515	.072	.644

## **Proximal outcome (4)**

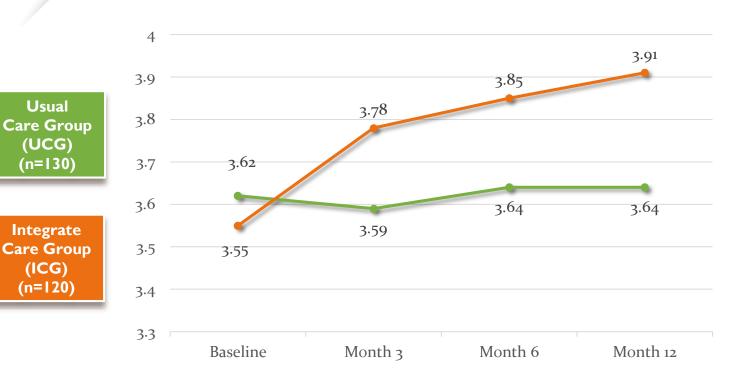
### **DM Quality of Life (1-5)** ( $\alpha = .8407$ )

Usual

(UCG) (n=130)

Integrate

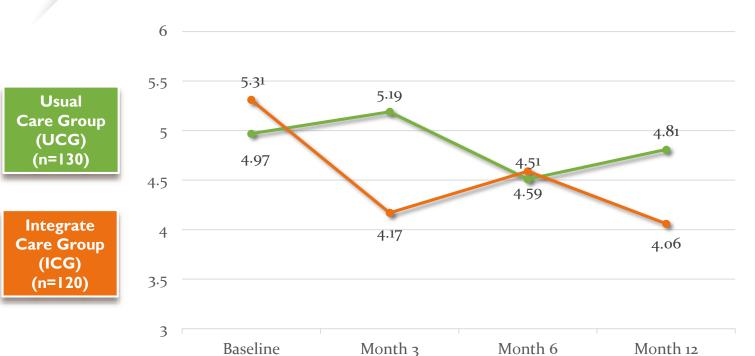
(ICG) (n=120)



	Baseline	Month 3	Month 6	Month 12	Total (M0-12)
diff(ICG-UCG)	-0.06	0.18	0.21	0.27	0.14
P( diff )	.429	.014	.017	.002	.000

## Proximal outcome (5)

## **Depression-PRQ9 (0-27)** $(\alpha = .87)$



	Baseline	Month 3	Month 6	Month 12	Total (M0-12)
diff(ICG-UCG)	0.34	-1.02	0.08	-0.75	-0.33
P( diff )	.585	.081	.899	.237	.284

## **Distal outcomes**

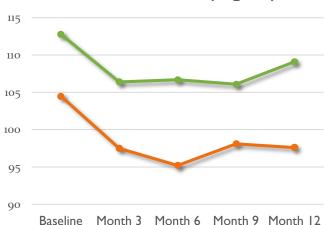
Usual Care Group (UCG) (n=130)

Integrate Care Group (ICG) (n=120)

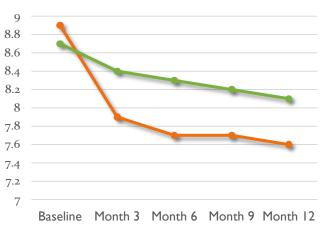




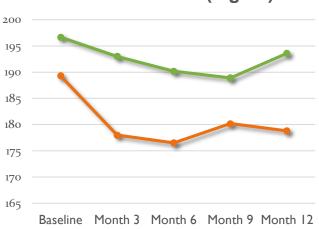
LDL Cholesterol (mg/dL)



### **Hemoglobin A1c**



Total Cholesterol (mg/dL)

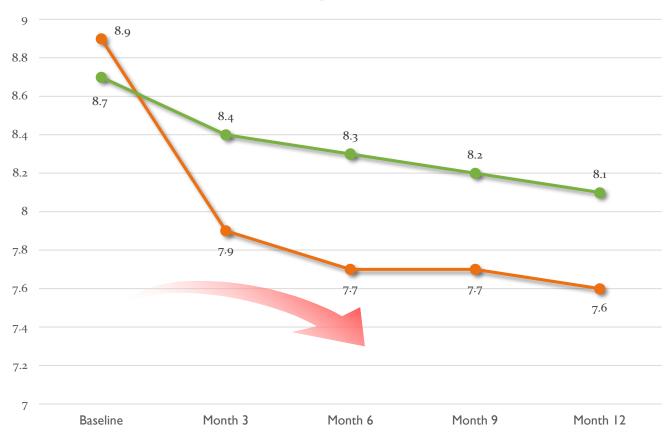


## **Distal outcome**

Usual Care Group (UCG) (n=130)

Integrate Care Group (ICG) (n=120)

### **Hemoglobin A1c**



## **Summary**

- During the 12 month project period:
  - ICG sustained 1.0%-1.3% reductions of HbA1c, while
     UCG maintained 0.3%-0.6% reductions.
- Statistically significant improvement of self-efficacy and quality of life in IG was observed when compared to the UCG.

## **Conclusions**

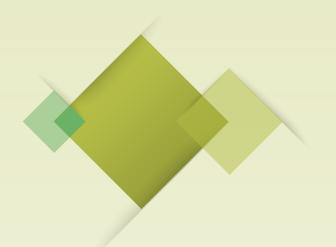
 Community-based interventions provided by healthcare providers (e.g., RNs/CHWs) seem to be effective in helping people manage their chronic conditions in natural settings.



## **Implications**

- This study has the potential to be a sustainable model practice in the community.
- A combination of physician extenders-running MCO and RN/CHWs running community wellness centers may be an answer to ascertain both higher quality standards and cost-containment for the management and control of chronic diseases in general and diabetes in particular.





## Thank You!