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A Mobile Health Intervention to Reduce Diabetes Disparities in Chinese Americans

Principal Investigator: Lu Hu, PhD
NYU School of Medicine
Department of Population Health
180 Madison Ave
New York, NY 10016
646-501-3438
lu.hu@nyulangone.org

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1. ABSTRACT

Chinese Americans are one of the fastest growing immigrant groups in the US, who suffer disproportionately high type 2 diabetes (T2D) burden and have poorly controlled T2D. Despite the well-documented T2D disparities in this minority group, limited work has been conducted to improve health outcomes in Chinese Americans. The goal of this Pathway to Independence Award (K99/R00) is to expedite the candidate's transition to an independent investigator who possesses focused expertise in development and evaluation of culturally and linguistically tailored and sustainable interventions to reduce T2D disparities in Chinese Americans. In the K99 phase of this award, the candidate will obtain critical training needed to accomplish this goal and will develop a short message service (SMS) intervention to improve T2D management in Chinese Americans. In the R00 phase, the candidate will utilize acquired skills to conduct a pilot randomized controlled trial to examine the potential efficacy of the SMS intervention. In the K99 phase, the candidate will also conduct pilot work to develop linguistically and culturally tailored SMS intervention content and to refine the intervention to be tested in the R00 phase. More specifically, the aims are to 1) characterize barriers and facilitators of glycemic control in Chinese Americans with T2D (Aim 1a); 2) develop culturally and linguistically tailored SMS intervention content (Aim 1b); and 3) assess the feasibility and acceptability of the SMS intervention in a pre-, post-test study (Aim 1c). In the R00 phase, the candidate will refine the SMS intervention based on the K99 pilot data and evaluate the proof-of-concept regarding its efficacy in a pilot randomized controlled trial among 60 Chinese Americans with T2D (Aim 2). Participants will be randomized to one of 2 arms (n=30 each): 1) wait-list control and 2) SMS intervention. Both groups will continue to receive standard of care treatment for their T2D. The SMS group will receive brief lifestyle counseling videos via SMS links. At the end of the study, the wait-list control group will be provided the opportunity to receive the SMS-based counseling videos. Measurements will be obtained at baseline, 3, and 6 months. The primary outcome is HbA1c and secondary outcomes include self-efficacy, diabetes self-management behaviors, dietary intake and physical activity behaviors. Linear mixed modeling will be used to examine the group and group by time interaction effects between the SMS intervention and wait-list control group. Findings from this R00 study will inform a larger full-scale R01 efficacy trial of the SMS intervention, and ultimately, establish the candidate's program of research focused on developing and testing sustainable interventions to reduce disparities in chronic disease outcomes in Chinese Americans. This project can serve as a program model for other chronic disease interventions in Chinese Americans that require lifestyle modification (e.g., prediabetes, hypertension), or for disparities research in other high-risk immigrant populations (e.g., South Asians, Hispanic Americans).

In Year 4 of this K99/R00 award (Year 2022), PI Dr. Lu Hu received additional pilot funding from Rutgers University to expand the goal of this study. Accumulating evidence shows that patients with T2D are more likely to have mental health issues, including depression, anxiety, eating disorders, diabetes distress, and other mental health issues than those without the disease.[1] These mental health issues were often linked to suboptimal adherence to diabetes self-care behaviors and poor glycemic control.[2,3] Thus, there are increasing calls from national organizations such as the American Diabetes Association and the Association of Diabetes Care and Education Specialists to screen for mental health issues and integrate mental health in diabetes care.[4,5] Yet, there is a dearth of data on the mental health burden among Chinese Americans with T2D. To address these important gaps, the goal of this Rutgers pilot project is to characterize the mental health burden and understand barriers to seeking mental health services in Chinese Americans with T2D. We are going to contact and consent participants from PI Dr. Lu Hu' prior and current studies (K99, R00 Protocol Number: s18-00609; FAMILY Protocol Number: s19-01275)to administer surveys related to mental health and conduct focus groups with participants to gain a deeper understanding of barriers. K99 phase includes 2 pilots, the first pilot is qualitative focus groups with **20** participants, and the second pilot is about quantitative pre-,

post-test evaluation with **30** participants. R00 phase is pilot RCT and sample size is **60**. FAMILY study is also a pilot RCT, there are **23** pairs of participants: 23 T2D patients and 23 corresponding family members. In total, our target sample size for this Rutgers pilot project is 133 (50 from K99 phase, 60 from R00 phase and 23 from FAMILY study).

2. PURPOSE OF THE STUDY AND BACKGROUND

2.1 Background

Chinese Americans are one of the fastest growing immigrant groups in the United States.[6–8] Multiple studies show that, compared to non-Hispanic whites, Chinese Americans suffer disproportionately higher rates of type 2 diabetes (T2D),[9–13] have poorer self-management and glycemic control,[14–18] and are at elevated risk of developing renal complications.[19] Lack of culturally and linguistically sensitive healthcare providers and programs are the most commonly cited reasons for disparities in T2D care and health outcomes in Chinese Americans.[20–23] High rates of limited English proficiency, poor access to healthcare and patient-provider communication barriers have played a critical role in prevention and management of T2D for this population.[20–23] Given the substantial and growing limited English proficient Chinese American population in the United States and the continued rising prevalence of T2D, there is an urgent need to develop, culturally-adapt, and test evidence-based interventions for diabetes control in this population.[24]

Diabetes self-management education and counseling programs have been widely recognized as effective strategies to promote diabetes self-management and improve glycemic control.[25,26] However, these programs are usually labor-intensive and especially challenging to implement in real world settings, because T2D patients only have limited time (e.g., 10-15 mins) with their clinicians during scarce clinical encounters.[27,28] When language and cultural barriers come into play for Chinese immigrants, the lifestyle counselling at clinical settings is even more difficult.[20,22,23,29,30] Given high rates of mobile technology usage among Chinese American communities,[31–33] an intervention program based on mobile technology has unprecedented advantages for engaging patients with lifestyle changes in real time and in their natural settings (e.g., at homes).[34–36] Emerging evidence shows that a text message-based approach (e.g., SMS, short message service) is a potentially low-cost, sustainable, and scalable strategy to deliver targeted and consistent diabetes education and support.[37–39] While evidence demonstrates effectiveness of SMS interventions in young or middle aged adults,[40] their efficacy or effectiveness remains untested in Chinese Americans with T2D, who often are older (~60 years old) and are limited English proficient.[13]

This K99/R00 study provides a unique opportunity to address this knowledge gap. **In the K99 phase,** we will conduct qualitative interviews to characterize barriers and facilitators of glycemic control in Chinese Americans with T2D (**Aim 1a**). Findings from these interviews will inform the cultural tailoring of the intervention content. Then we will develop the SMS intervention, which includes brief lifestyle counseling videos sent to participants via SMS links (**Aim 1b**). We will assess the feasibility and acceptability of the SMS intervention in a 3-month, single group pre-, post-test study among 30 Chinese Americans with T2D (**Aim 1c**). **In the R00 phase,** we will refine the intervention based on the K99 pilot data and evaluate the proof-of-concept regarding its efficacy in a pilot randomized controlled trial among 60 Chinese Americans with T2D (**Aim 2**). Participants will be randomized to one of 2 arms (n=30 each): 1) wait-list control; and 2) SMS intervention.

For the Rutgers mental health pilot, we will leverage participants in the K99, R00 phase (s18-00609), and FAMILY (s19-01275) studies (N=133), and add some mental health-related questions to understand the mental health burden in Chinese immigrants with T2D. To understand barriers to accessing mental health services, we will conduct two focus groups (n=10-16) with Chinese immigrants with T2D to gain a deeper understanding of barriers to mental health services.

2.2 Aims

K99 phase
Primary Aim 1a: Characterize barriers and facilitators of glycemic control in Chinese Americans with T2D
Primary Aim 1b: Develop culturally and linguistically tailored SMS intervention content
Primary Aim 1c: Assess the feasibility and acceptability of the SMS intervention

R00 phase
Primary Aim 2a: Establish the proof-of-concept regarding the efficacy of the SMS intervention for glycemic control in Chinese Americans with T2D

Exploratory Aim 2b: Explore the potential effects of the SMS intervention on psychosocial and behavioral factors in glycemic control.

Rutgers Mental Health Pilot

Exploratory Aim 2c: Examine current mental health burden and psychosocial support and how they are related to diabetes self-care behaviors and glycemic control in Chinese Americans with T2D (via validated surveys)

Exploratory Aim 2d: Characterize barriers to accessing mental health services and understand needs and preferences in Chinese Americans with T2D (via focus groups)

3. METHODS AND PROCEDURES

3.1 Study Design

K99 Phase
Qualitative focus groups/interviews (N=20): We will conduct focus groups/interviews to understand barriers and facilitators of glycemic control in Chinese Americans with T2D and to develop culturally and linguistically tailored SMS intervention content.

Quantitative pre-, post-test evaluation (N=30): We will assess the feasibility and acceptability of the SMS intervention in a 3-month, single group pre-, post-test study among 30 Chinese Americans with T2D.

R00 Phase
Pilot RCT (N=60): Participants will be randomized to one of 2 arms (n=30 each): 1) wait-list control; or 2) SMS intervention. We will evaluate changes in HbA1c at baseline, 3-, and 6-months. In exploratory analyses, we will test mediators (e.g., self-efficacy, diabetes self-management behaviors, diet intake, and physical activity).

Rutgers Mental Health Pilot

Cross-sectional quantitative survey (N=133): We will contact the participants from K99, R00 phase (s18-00609), and FAMILY study (s19-01275) to ask whether they are interested in joining this mental health pilot and answering a few additional questions. Our target goal is 133. As of 9/28/2022, all participants from K99, R00 and FAMILY completed their assessments, intervention and participation with us. We will administer this mental health survey once this pilot modification was approved by the IRB. This will be a one-time survey administration because the goal of the pilot was to get a snapshot of the mental health burden in Chinese Americans with T2D. We are

not examining changes over time in mental health, thus, we will not repeat the survey at 3 or 6 months.

Qualitative focus groups (N=10-16): Guided by the NIMHD Research Framework,[41] we will assess facilitators and barriers to accessing mental health services in Chinese Americans with T2D. We will explore factors on multiple levels, including individual, interpersonal, community, health system, and societal levels. We will select 10-15 participants based on their survey responses (who reported elevated stress, anxiety, or depressive symptoms) to join the focus groups (2 focus groups; 5-8 participants per group) to gain a deeper understanding of barriers to utilizing mental health services. We will also ask participants' preferences for mental health support (e.g., individual vs. group-based, in-person vs. phone vs. video-based).

3.2 Sites

The study will be conducted at the Charles B. Wang Community Health Center (CBWCHC), a federally qualified health center located in both Manhattan Chinatown and Queens Flushing Chinatown. In 2015, it provided a total of 275,749 service visits to 50,008 underserved Asian Americans in Greater NYC. The majority of patients are Chinese. CBWCHC is one of the largest and leading community centers in NYC, having established a trusting relationship with the Chinese American community. In 2016, approximately 5,000 patients with T2D were seen at the CBWCHC; the vast majority of them are Chinese.

CBWCHC will not be engaged in research activities and their role is to identify/refer patients and provide space for this study. All research related activities (e.g. recruitment, consenting, conducting study procedures) will be performed by NYU study staff. The letter of support has been uploaded in the attachment section.

To maximize recruitment efforts, we will also identify potential private practices or community based organizations in Chinatown areas and work with them to recruit potential participants. In addition, we will identify and recruit participants into the study from NYU Langone Health. **Similar to the procedures at CBWCHC, all of the research related activities (e.g. recruitment, consenting, conducting study procedures) will be performed by NYU study staff. The role of NYU Langone Health, these private practices or community-based organizations is to help to identify/refer patients and/or provide space for this study.**

3.3. Characteristics of the Research Population

Phase 1: K99 Phase Feasibility Study Inclusion criteria: To be eligible for the study, participants must: 1) self-identify as Chinese Immigrant or Chinese American; 2) be 18-75 years old, 3) be able to speak and understand Mandarin; 4) self-report a diagnosis of T2D; 5) know how to do a finger stick blood sugar test; 6) be willing to do a finger stick blood glucose test for each study visit; 7) baseline HbA1c ≥ 7%; 8) be currently using WeChat; 9) be willing to receive WeChat messages regarding T2D management, 9 10) express strong interest and confidence in finishing watching 2 diabetes videos each week for a total of 12 weeks; 11) be motivated to make lifestyle changes to control their diabetes.

Phase 1: K99 Phase Feasibility Study Exclusion criteria: Individuals will be excluded from participation if they meet any of the following:(1) unable or unwilling to provide informed consent; (2) unable to participate meaningfully in the intervention (e.g., uncorrected sight and hearing impairment); (3) unwilling to accept randomization assignment; (4) pregnant, plans to becomes pregnant in the next 6 months, or who become pregnant during the study, or (5) breastfeeding or

(6) live in a facility or other health care setting where they have no control over diabetes self-management.

Phase 2 R00 Phase pilot RCT Inclusion criteria: To be eligible for the study, participants must: 1) self-identify as Chinese Immigrant or Chinese American; 2) be 18-70 years old, 3) be able to speak and understand Mandarin; 4) self-report a diagnosis of T2D; 5) baseline HbA1c ≥ 7%; 6) be currently using WeChat or text messages; 7) be willing to receive WeChat or text messages regarding T2D management, 8) express strong interest and confidence in finishing watching 2 diabetes videos each week for a total of 12 weeks; 9) be motivated to make lifestyle changes to control their diabetes; 10) be willing to wear ActiGraph for 8 days.

Phase 2 R00 Phase pilot RCT Exclusion criteria: Individuals will be excluded from participation if they meet any of the following:(1) unable or unwilling to provide verbal consent; (2) unable to participate meaningfully in the intervention (e.g., uncorrected sight and hearing impairment); (3) unwilling to accept randomization assignment; (4) pregnant, plans to becomes pregnant in the next 6 months, or who become pregnant during the study, or (5) breastfeeding or (6) live in a facility or other health care setting where they have no control over diabetes self-management.

Rutgers Mental Health Pilot: For the quantitative survey, because we will call K99, R00 phase (s18-00609), and FAMILY study (s19-01275) participants, the inclusion and exclusion criteria will be the same as each parent study. In addition, participants are eligible to participate in this pilot if they are willing to answer additional mental health related questions. For the focus group participants, we will review the mental health survey responses from participants and invite those who reported elevated stress, anxiety or depressive symptoms to join the focus group discussion.

4. PROCEDURES

4.1 Patient Recruitment

Participants will be identified and recruited into the study from NYC health care facilities, including CBWCHC, private practices, community-based organizations, and NYU Langone Health and affiliated provider practices.

We will recruit participants using the following methods**:**

a. Posters. Posters will be placed in NYC health care facilities waiting and examination rooms. Posters will list a contact telephone number that patients can call if interested in enrolling. Patients who self-refer will be screened for eligibility. Posters will also be placed in Chinese community centers (e.g., senior centers) and distributed during Chinese community events. Posters will also be posted electronically on WeChat, which is a popular chatting smartphone application among Chinese Americans and Chinese Immigrants.

b. Direct referral by health care providers. CBWCHC, NYU Langone Brooklyn site providers, and private practice health care providers will approach patients who are potentially eligible for the study, solicit their interest in the study. If patients express verbal interest in the study participation, their health care providers will share the patient's contact information with the study staff, or patients will also be able to call (self-refer to) to the number provided in the recruitment flyer and speak with a study staff if they are interested in participating. Study staff will call the patient and with the patient's verbal consent the staff will conduct a quick phone pre-screening to confirm eligibility prior to study enrollment. Dr. Qiuqu Zhao is the medical director at NYU Brooklyn Family Health Center. We are collaborating with Dr. Zhao and her team at NYU Brooklyn. They would help refer potential study participants that are eligible and interested in our study. The initial referral list from health care providers will only include patient's name and phone number for those verbally expressed interest in the study. After verbal consent is obtained and documented, the study staff will request the patient's medical information from the

medical record.

c. Registry lists. From our previous study, we have created a registry list of potential participants who indicated interest in future studies from NYU School of Medicine. We will call participants from the registry list, explain the study, and assess the eligibility to participate.

d. EPIC and DataCore. We will work with DataCore to generate a report to identify potentially eligible subjects across NYU Langone Manhattan, Brooklyn, and Long Island campuses. Using a query, search will be conducted in EPIC to identify Chinese patients aged 18-70 and with type 2 diabetes whose most recent HbA1c value ≥ 7%. The report will also include demographics including patient name, gender/sex, date of birth, address, phone number, weight, height, BMI, name of primary care physician, most recent HbA1c value and date of measurement. Only the principal investigator and all members of the research team will have access to this report. The report will be generated prior to the recruitment process to help us find potential participants. The report will be kept on a secure electronic NYU research drive to ensure the confidentiality of health information and identifying information from potential participants. These patients will receive a mailing describing the study and letting them know how they can opt out of further contact. The study staff will call eligible patients who have not opted out to describe the study, complete the brief eligibility screener and offer enrollment. While screening potential participants by telephone, demographics and the most recent HbA1c value will be confirmed or updated.

4.2 Patient Consent

The NYU study staff will be recruiting and consenting the participant by reading the approved telephone verbal consent script to the participant. The study staff will first complete a brief phone screener to screen whether or not the participant is eligible. Once eligibility is confirmed, the study staff will discuss with the patient what active participation in this study means (review verbal consent, interviews, potential benefits, and risks of participations), the purpose and limitations of the study, and requirements of the study. If the patients verbally agree to participate, the patient's primary care physician will also be notified that the patient is being enrolled in this study. The verbal consent process will be audiotaped with the patient's permission. The verbal consent is an accommodation due to the rising COVID-19 infection rate in New York, and that the target population for this study is low-income aging immigrants with limited education and low digital literacy. All interventions will be conducted via phone or text message. A waiver of documentation of consent has been requested.

The study team has requested a waiver of signed HIPAA authorization and all HIPAA information will be presented verbally. Under the HIPAA section, we will explain the potential risks of WeChat platforms. Participants can decide on their own whether they would like to continue to participate.

An IRB-approved verbal consent script will be used and will include the HIPAA and audio recording information, the subject will verbalize comprehension of the consent form and study enrollment. The consent process will be recorded via audio the consent and the date of consent will be documented on the Enrolled Participants Log. The Enrolled Participants Log is the only record linking a participant's name and Subject ID, this information will be kept on a secure electronic drive to ensure the confidentiality of health information and identifying information from participants. Only the principal investigator and all members of the research team will have access to this information and the audio recordings of their verbal consent.

We will have the verbal consent script available in both English and Chinese. The participant can choose their own preferred language and our bilingual study staff will explain the study to

the participant. The participant will be encouraged to ask any questions they may have before providing the verbal consent.

After verbal consent is obtained, we will ask patients if we can send them via text message a copy of the key information sheet for their records before we collect any data from them.

The Informed Consent is a continuous and dynamic process, all participants will be reminded at every phone call about the A/V recordings, study assessments and that they are free to withdraw at any time.

For the Rutgers Mental Health Pilot study, we will use an IRB-approved verbal consent to ask whether the K99, R00 phase (s18-00609), and FAMILY study (s19-01275) participants are willing to join this pilot and answer a few additional questions about their mental health. The consent process will be recorded via audio.

4.3 Study Procedures

Our NYU study staff will be conducting ALL of the following study procedures.

4.3.1 K99 Phase Patient Focus Groups/Interviews Procedures

We will recruit a convenience sample of 20 Chinese Americans with T2D from the CBWCHC, and conduct 4-5 focus groups, with 4-5 participants per group. Focus groups will be held at a private and quiet location at the CBWCHC. Focus groups will be audio-recorded and transcribed. Using a semi-structured interview guide, a trained interviewer will use open-ended questions and follow-up probes to understand barriers to and facilitators of diabetes self-care in their daily life.

Patients will be paid $30 for participating in the focus groups. We will transcribe audio recordings verbatim. Transcriptions of audio recordings will be stored separately from signed consent and authorization forms.

4.3.2 K99 Phase Pre-, Post-Test Evaluation Procedures

We will conduct a 3-month, single group, pre-, post-test study to assess the feasibility and acceptability of the SMS-based diabetes video counseling. We will recruit a randomly selected sample of approximately 30 Chinese Americans with T2D from the CBWCHC or private practices or community centers.

We will first conduct phone screening for the interested participants. After they pass the phone screening, we will schedule the first baseline visit. During the baseline visit, the study staff will first explain the study and consent form to the participants. After the consent form is signed, study staff will ask participants to perform a finger stick to check their HbA1c levels. If the A1c level is greater or equal to 7%, the study staff will continue with the study survey. Otherwise, study staff will thank participants for their interest and time and pay $30 for their time.

For those who are eligible to continue to participant, they will be asked several survey questions and then subscribed to our diabetes videos. They will receive 1-2 SMS-based counseling videos every week for 12 weeks (each video is about 5-10 minutes in duration). HbA1c will be assessed at baseline and again at 3 and 6 months. At the end of the 3-month intervention, we will conduct focus groups with participants to assess the feasibility and acceptability of SMS-based video sessions, perceived usefulness of the video sessions, and recommendations for improvement. All of the focus group interviews will be recorded and transcribed. Acceptability will also be assessed by a satisfaction questionnaire used in a prior study. Changes and refinements will be made to the preliminary intervention content and delivery based on the feedback, which will be tested in the R00 study. We will also help participant to set goals for their diabetes management and then have biweekly phone call follow-ups to check in their progress toward the goal and

problem solve any raised questions/concerns.

Patients will be paid $30 for completing baseline visit and $30 for completing 3-month and 6-month follow-ups. At the end of 3-month intervention, we will host 2 focus group discussions to understand their experience with our study. One focus group will invite highly engaged participants, defined as who have watched at least 60% of the diabetes videos. The other focus group is with poorly engaged group, defined as participants who have watched less than 60% of the videos. For those participated in the focus group discussion, they will receive $30 for their time and participation.

We will reimburse $5 each week to each participant for cell phone data usage if they finish viewing both of the sent videos for that week. Given that we will send videos over a total of 12 weeks, participants may expect to receive a range of $0-$60 (=$5*12) depending on the number of weeks they have completed the videos.

Due to COVID-19, we will conduct the 3-month and 6-month survey over the phone. For the 3-month weight measurement, we will ask participants to weigh themselves at home if they have a scale at home. For those who do not have scales at home, this will be treated as missing data.

4.3.3 R00 Phase Pilot RCT Procedures

The R00 phase study is a pilot randomized controlled trial (RCT) of 6 months duration. Participants will be randomized to one of 2 arms (n=30 each): 1) wait-list control; or 2) SMS intervention. The study will include 3 measurement visits, baseline, 3, and 6 months. Patients will be paid $30 for each measurement visit.

Upon receiving the referral list (interested patient's name and phone number) from the providers, the bilingual study staff will call the patient and provide more details about the study. If patients expressed interest in participation, the study staff will administer several screening questions over the phone. After eligibility is determined and verbal consent is obtained, we will collect baseline surveys over the phone and randomize them via a computer-generated randomization scheme with equal allocation to one of the 2 groups: 1) wait-list control; or 2) SMS.

Independent variable: randomization arm

Wait-list control group: All participants will continue to receive the standard of usual care for their T2D at their providers' office during the course of our study. At the end of the study, the wait-list control group will be provided the opportunity to receive the counseling videos delivered to them via SMS links.

SMS intervention: Participants in the intervention group will receive SMS-based video counseling, which include both educational and SCT-based behavioral content (see Table 1 below for a tentative outline of the intervention content). Given the system and personal barriers, we believe this SMS-based approach will improve access to culturally and linguistically tailored diabetes counseling. Additionally, this approach will allow participants to review the videos later on or share with their loved ones who often want to be supportive but do not know how. We will send 2 videos each week for a total of 12 weeks with each video about 5-10 minutes in duration. The videos will be sent via WeChat or regular text messages (SMS). We will contact participants mainly through phone calls from an NYU Langone Study Phone. WeChat will be only used to send the health education videos. No other communication will occur via WeChat. Our study team will remind participants at the beginning of the study and

during the bi-weekly phone calls about not sending any Protected Health Information via WeChat. In addition, our education videos do not contain any Protected Health Information and it will teach participants about diet, exercise, and stress management in general. We will ask participants' permission to use WeChat platform and advise that sending messages over an unsecured application like WeChat is an unsecure and unencrypted form of communication and there is a potential risk of disclosing information to an individual who is not authorized to receive it (unauthorized disclosure).

We will also let participants know that they can still participate in the study if they decline to receive the health education videos on WeChat. As an alternative, we will send the education videos as regular text messages to their phones. They can decline at any time during the study to receive the videos on WeChat and then we will switch to regular text messages.

We will also help participants to set goals for their diabetes management and then have biweekly phone call follow-ups to check in their progress toward the goal and problem solve any raised questions/concerns.

Table 1: Tentative Outline of the Intervention Content

Sess. #	Education Materials	Social Cognitive Theory-Based Behavioral Materials
1	Overview of diabetes, self-management	Setting goals; Establishing the relevance of behavior change.
2	T2D diet, healthy eating, portion control	Self-Reward. Turning goals into habits.
3	Glucose self-monitoring	Social support. Developing and working your social support network
4	Medication management	Problem solving: Barriers and setbacks. Problem solving model.
5	Exercise and diabetes; home exercise demo	Problem solving: Behavioral triggers and stimulus-control
6	Attending doctor appointments	Problem solving: Lapse and Relapse
7	Chinese holidays and eating at restaurants	Problem solving: Coping with lapses and setting new goals
8	Stress and T2D	Problem solving: Stress management.
9	Grocery shopping demo at Chinese grocery store	Problem solving: Cutting carbohydrates and finding replacements
10	Healthy cooking demo for a Chinese diet	Problem solving: Eliminating negative self-talk
11	Navigating the US healthcare system	Problem solving: Cravings for white rice, noodle, bun, dumplings etc
12	Review of lifestyle recommendations	Problem solving: Anticipating high-risk situations

Procedures: The study will include 3 measurement phone calls, baseline, 3, and 6 months. Patients will be paid $30 for each measurement call. Due to COVID-19, all data will be collected over the telephone. Each survey calls will include audio/Video recordings if verbal consent from the study participants was obtained. For participants randomized to the SMS intervention group, we will reimburse $5 each week to each participant for cell phone data usage if they finish viewing both of the sent videos for that week. Given that we will send videos over a total of 12 weeks, participants may expect to receive a range of $0-$60 (=$5*12) depending on the number of weeks they have completed the videos. We will also provide $60 to control participants if they finish all study related procedures at 3 months assessment.

Study Variables **covariates**

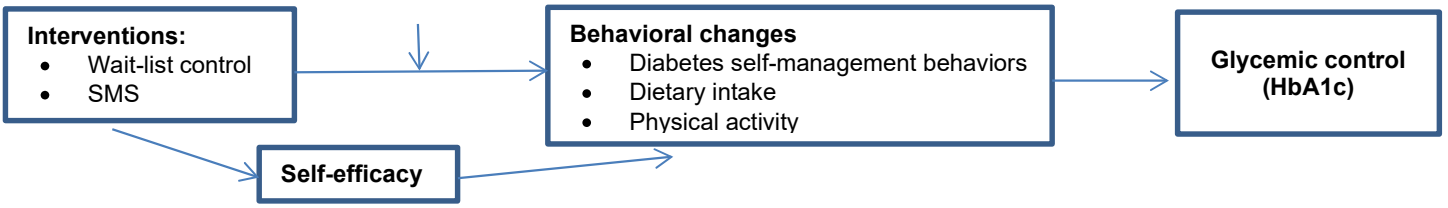

Figure 1. Conceptual Model

Primary & Exploratory Outcomes

Primary outcome: HbA1c: As part of the usual care, patients with T2D receive a HbA1c blood test at their doctors' office every 3-6 months. To minimize participants' burden, we will not conduct additional blood tests for this study. Instead, we will abstract the HbA1c testing results from the medical record at the participant's health care facility. Once we obtain the consent from participants, we will contact their doctors' offices for HbA1c results.

Secondary outcomes: Consistent with our conceptual model (Fig. 1), we will also measure self-efficacy, diabetes self-management behaviors, dietary intake, and physical activities at each time points (baseline, 3-, and 6-months). All of these scales have been used and validated in the Chinese population.

1. **Self-efficacy:** We will use the well-validated Stanford Diabetes Self-Efficacy Scale[42] to measure participants' confidence to manage T2D. This instrument contains 8 items and asks participants to rate their confidence level in performing specific self-management behaviors, using 10-point Likert scale ranging from 1 (not at all confident) to 10 (totally confident).
2. **Diabetes Self-Management Behaviors:** We will administer the adapted Summary of Diabetes Self-Care Activities (SDSCA) measure[43] to assess participants' adherence to diabetes self-management behaviors. This scale consists of 13 items and asks participate to describe their diabetes self-care activities over the past 7 days.
3. **Dietary Intake:** Informed by a previous study in Chinese Americans,[44] we will use the adapted Mediterranean Dietary Screener[45] to estimate dietary intake behaviors in our participants at baseline, 3- and 6-months.
4. **Physical Activity:** We will use the International Physical Activity Questionnaire (IPAQ)[46,47] short version to assess the frequency and duration of various physical activities undertaken by adults over the past 7 days. This scale will provide an estimate of the number of minutes per week participants engage in each category of physical activity (e.g., vigorous, moderate, and mild intensity). We will also use the ActiGraph to objectively measure physical activity and sleep. Our study staff will distribute and collect the device to participants once they are eligible for the study. Once we receive the device, we will download the data.

Covariates: Sociodemographic, health characteristics, and acculturation. We will use a sociodemographic questionnaire to collect basic information about the participant such as age, gender, education, income, duration of residence in the US, health insurance, the diabetes medication regimen, duration of T2D, and medical history. Informed by prior literature, we will also include surveys to measure Health Beliefs, Diabetes Knowledge, Diabetes Distress, Social Support, Mental Health, the Impact of COVID-19, and memory test, which also play essential roles in diabetes management.

Rutgers Pilot Mental Health and Psychosocial Related Surveys: Accumulating evidence shows that patients with T2D are more likely to have mental health issues, including depression, anxiety, diabetes distress, and other mental health issues than those without the disease. We will add several mental health and psychosocial related surveys and administer this survey to the study participants via telephone at one survey only.. This survey phone call will not be audio or video recorded but the consent process will be audio recorded. We are going to use validated measures to assess general stress,[48,49] acculturation,[50] minority stress (discrimination),[51] symptoms of depression,[52,53] anxiety,[54] loneliness,[55]social support,[56,57] stigma towards mental health[58], mindfulness[59, 60], and mental health seeking behaviors. See Table 2 below. We will provide a $20 clincard incentive to participants who complete this survey with us.

Rutgers Pilot Focus Groups (N=10-16): We will select 10-15 participants based on their mental health survey responses to join the focus groups (2 focus groups; 5-8 participants per group) to gain a deeper understanding of barriers to utilizing mental health services. Participants who reported elevated stress, anxiety or depressive symptoms will be invited for this focus group discussion. We will collect their AV consent to record the focus group discussion. We will also ask participants' preferences for mental health support (e.g., individual vs. group-based, in-person vs. phone vs. video-based). Participants will receive additional $20 clincard incentive for their time. We will submit the interview guide as a modification later.

Table 2. Mental health and psychosocial related surveys

Variables	Surveys/Scales	Any Adaptations?
General stress	Perceived Stress Scale	Validated scale
Acculturation	Short Acculturation Scale for Hispanics	Adapted from the Hispanics version. In the response options, we changed "Spanish" to "Chinese".
Minority stress	Everyday Discrimination Scale	Validated scale
Depressive symptoms	PHQ-9	Validated scale
Anxiety	Hospital Anxiety and Depression Scale (HADS)	Validated scale
Loneliness	Revised UCLA Loneliness Scale	Validated scale
Social support	Social support Availability Online social support	Validated scales
Stigma towards Mental Health	Perceived Devaluation and Discrimination Scale	Validated scales
Current and Past Mental Health Seeking Behaviors	Self-developed	Investigator developed
Mindfulness	FFMQ-15	Validated scales

5. RISK/BENEFIT ASSESSMENT

5.1 Potential Risks

Risks of participation in this study are minimal and unlikely to occur given the safeguards in place. Psychological risks include: 1) the possibility that some participants may perceive some questionnaire or background data assessment as intrusive or causing them to feel uncomfortable; 2) breach of confidentiality. The study involves an intervention designed to enhance adherence to standard diabetes care (e.g., adherence to the prescribed diabetes medication, healthy eating, and physical activity behaviors). If our intervention improves adherence to the medication regimen or if participants make lifestyle changes (e.g., increased physical activity), more episodes of hypoglycemia may result. We will advise participants of the importance of monitoring their blood sugar as suggested by their doctors, and to contact their doctors as soon as they experience low blood sugar.

There is also a potential risk for breach of confidentiality on WeChat. To minimize the risk, we will remind participants that they should call our study phone number for any questions related to the study participation. WeChat will only be used to send education videos. No communication will occur via WeChat. Also, we will remind them at the beginning of the study and during the bi-weekly phone calls about not sending any Protected Health Information via WeChat. In addition, our education videos do not contain any Protected Health Information and it will teach participants about diet, exercise, and stress management in general. Based on our recent completed pilot study (a similar WeChat video study in 30 Chinese immigrants), we did not observe any breach of privacy or confidentiality. All of the study team members received sufficient training on protecting privacy and confidentiality and have extensive experience in working with this hard-to-reach immigrant population. The benefits of receiving these culturally and linguistically tailored education videos outweighed the risks.

5.2 Benefits

We do not anticipate that participants will receive any direct benefit from participating. However, information learned during the study may produce benefits for future patients by improving their diabetes care.

6. CONFIDENTIALITY AND DATA STORAGE

We will use the IRB recommended RedCap for data storage (openREDCap.nyumc.org). We will also work with MCIT to set up a NYU shared network drive which is HIPAA compliant (for offsite backup storage) specifically for our study. All study personnel have already taken the mandatory HIPAA and Patient Privacy/Confidentiality training modules required by our institutional IRBs, to ensure that they are aware of the importance of patient confidentiality and all appropriate laws regarding protection against privacy breaches. Procedures will be in place to ensure that all files containing subject information will be kept in locked filing cabinets or password-protected electronic databases on a secure server. The majority of study data and all interview transcripts will be maintained in electronic files with no patient identifiers other than a study ID number; there will be one file maintained separately with its own password protection that links study ID numbers to patient identifying information.

No identifiable information about study participants will be disclosed to individuals outside those approved by the IRB to be on the study protocol. No publications that result from the study will identify individual participants.

Transcript files will also be password-protected and user-restricted. We will delete potential identifiable information from transcripts and audio recordings one year after the study ends. We will also encourage participants to use pseudonyms during focus groups and/or interviews. During each focus group or interview session, the study PI will emphasize the importance of privacy and confidentiality of the discussion within the group. The text-message-based video counseling will be protected via password-enabled access. Only study participants will have access codes to open these videos. Others in the same household would not be able to open the video, unless participants choose to share the access code.

7. DATA ANALYSIS AND DATA MONITORING

7.1 Data Analysis

K99-phase Aim 1: All focus groups will be audio-recorded and transcribed verbatim into Microsoft Word. Atlas will be used to store, organize, retrieve, and analyze the qualitative data. Thematic analysis will be used to analyze qualitative data.[61] To establish coding reliability, the RA and PI will independently code up to 10% of the transcripts and identify kappa coefficient.[62] We will meet weekly to review definitions and assignment of codes, and resolve differences through consensus. If no agreement can be made, the study team will be consulted. The RA and PI will read all transcripts and develop an open coding schema based on emergent theses. We will present coding schemes to study team, discuss emergent themes, refine codes, and develop a codebook that consists of a list of categories and topics. Once all data have been coded based on the codebook, codes most relevant to the research questions will be subject to further analysis. For the quantitative data, a paired t-test will be used to determine pre-post change in HbA1c. Descriptive statistics will be used to summarize participants' satisfaction with the SMS intervention.

R00-phase Aim 2: We will employ the "intent to treat" (ITT) approach in analyses. We will perform a detailed descriptive analysis of all the data collected in the study. These preliminary descriptive statistics will be used to 1) check accuracy and completeness of inputted data, 2) describe univariate distribution of each variable at baseline, and 3) examine the associations between variables. We will also explore features of the data (e.g., amount and pattern of missing data, outliers, excess zeros, departures from distributional assumptions) to determine whether special techniques are needed.

Aim 2a: Establish the proof of concept regarding the efficacy of the SMS intervention for glycemic control in Chinese Americans with T2D. We will test whether the 2 groups are comparable on baseline sociodemographic, health characteristics, and levels of acculturation. If significant differences are found, we will include the variables as covariates in the models. Between group and group by time interaction effects will be examined graphically and via linear mixed modeling for HbA1c. Calculated effect sizes will be used for sample size estimation needed for a two-sided alpha of 0.05 and power of 0.80 for the larger scale R01 study.

Exploratory Aim 2b: Explore the potential effects of the SMS intervention on psychosocial and behavioral factors in glycemic control. For continuous secondary outcome variables (self-efficacy, adherence, and dietary data), linear mixed modeling will be used to examine the group and group by time interaction effects for each outcome at 3- and 6-months. For the physical activity data, we will use a GEE logistic model to examine whether there are group differences in the proportions of participants achieving 150 minutes/week of physical activity at any level of intensity and at a moderate- or greater intensity level.

Rutgers Mental Health Pilot

Aim 2c: Examine current mental health burden and psychosocial support and how they are related to diabetes self-care behaviors and glycemic control in Chinese Americans with

T2D. We will use descriptive statistics to summarize mental health burden and psychosocial support in Chinese immigrants with T2D. We will describe the percent of the sample who has elevated stress, anxiety and depressive symptoms and the current social support and coping strategies. We will also use correlation to examine the relationships between the mental health burden and diabetes self-management behaviors and HbA1c (measured in R00 study).
Aim 2d: Characterize barriers to accessing mental health services and understand needs and preferences in Chinese Americans with T2D. Similar to the analytic approach used in the K99 Aim 1 analyses, all focus groups will be audio-recorded and transcribed verbatim into Microsoft Word. Atlas will be used to store, organize, retrieve, and analyze the qualitative data. Thematic analysis will be used to analyze qualitative data.[59]

7.2 Data Monitoring

The purpose of the data safety monitoring plan is to ensure the safety of subjects and the validity and integrity of the data. Data and safety monitoring will be the shared responsibility of all members of the research team. Personnel involved in monitoring activities will include:

- Dr. Mary Ann Sevick, ScD (co-ivestigator). Professor of Population Health at NYU School of Medicine (NYUSoM).
- Dr. Lu Hu, PhD, PI, Dr. Hu has worked as a graduate student researcher on several NIH-funded projects during her doctoral training and participated in the data and safety monitoring meetings. During her current postdoctoral training, she is also actively participating in Dr. Sevick's project meetings, including data and safety monitoring meetings. Dr. Hu has received intensive training in human subjects research. Dr. Hu will be responsible for data safety monitoring of the overall study and Dr. Sevick will provide close oversight via weekly mentoring meeting.

Data monitoring
Ongoing quality control will include regular data verification and protocol compliance checks. An ongoing review of study procedures will be done to ensure that the privacy of subjects and confidentiality of data is not violated. Weekly meetings will be held between Dr. Hu and Dr. Sevick and other research staff involved in the project to review the progress of subjects enrolled in the study.

Safety monitoring
It is possible that our intervention might help participants better adhere to the medication regimen or make lifestyle changes (e.g., increased physical activity), which may result in the need for less diabetes medications and thus more episodes of hypoglycemia might happen. We will advise them to continue to monitor their blood sugar levels as suggested by their doctors, and contact their doctors if they experience any low blood sugar levels. This safety information will be emphasized at the beginning and end of each intervention video.

Because the proposed study is minimal risk, we will not establish an independent Data Safety and Monitoring Board. The study team including several experts (Drs. Sevick, Hu) who have extensive experience in conducting clinical trials will perform date safety and monitoring. We will meet regularly to review inclusion and exclusion criteria, and develop a detailed safety protocol, plans for monitoring subjects for adverse events, and a protocol for protection of privacy and confidentiality of participants. The study PI (Dr. Hu) will hold weekly project meeting with the study staff and provide project updates to Dr. Sevick (primary mentor) via weekly mentoring one-on-one meetings. The study PI will provide updates on the study progress, recruitment,

retention, data quality, safety, confidentiality, and the occurrence of adverse events to the whole mentoring team during bi-monthly check-in meetings.

The whole team will provide oversight for the following study procedures:

- Monitoring the safety of the subjects (e.g., review the research protocol and plans for data and safety monitoring)
- Evaluate the progress of the clinical trial, including periodic assessments of data quality and timeliness, subject recruitment, accrual and retention, subjects risk versus benefit, performance of the recruitment site, and other factors that can affect study outcome
- Maintaining the confidentiality and integrity of the data
- Reports of critical or adverse events from research staff. The PI will receive these reports on an event-by-event basis and will inform the whole study team of all such reports
- Make recommendations to the IRB and investigators concerning continuation or conclusion of the trial.

8. INVESTIGATORS QUALIFICATIONS

Mary Ann Sevick, ScD (diabetes mHealth behavioral expert) is a Professor at the NYU School of Medicine. Dr. Sevick has over 25 years of experience in conducting large, theory-based behavioral intervention trials. She has been the PI/Co-I on multiple NIH and foundational grants (R01-NR008792; R01-NR010135; K24- NR012226; HSR&D-IIR07154; AHA-17SFRN33590133). She is currently the PI of an R01 study examining technology-based behavioral interventions in patients with T2D and concurrent kidney disease. She is also the PI of an R21 study examining the use of video-based behavioral counseling interventions in hemodialysis patients and the PI of an American Heart Association (AHA) Obesity Network Center study investigating a novel, personalized dietary weight-loss approach in patients with prediabetes. Dr. Sevick has mentored 10 junior faculty members and 18 postdoctoral fellows. Given her extensive expertise, she will serve as a content expert in T2D, theory-based behavioral intervention, mHealth, and academic career mentor.

Lu Hu, PhD, is well poised to serve as the PI on the proposed study based on 1) her rigorous doctoral training in chronic disease management and postdoctoral and 2016 NIMHD Summer training in health disparity, 2) her current role as a co-investigator on an Aetna-funded study involving the use of a mHealth intervention (e.g., text messages) to remotely titrate the insulin regimen in underserved low-income patients with uncontrolled type 2 diabetes (T2D), 3) a strong publication record of about 20 published/accepted papers, and 4) several national and international awards and fellowships.

All investigator's CV and medical licenses are attached to the protocol submission.
All investigators and staff involved in this project have completed training on the protection of human subjects in research through CITI training and HIPAA certification.

9. STUDY RECORDS RETENTION AND DATA SHARING

We are firmly committed to sharing data with the scientific community so that the data generated from this study can be fully utilized for research. Provided below is the proposed data-sharing plan:

1. We will publish the detailed methodology used for this study. Aggregated statistics will be provided to the broad scientific community via a journal's website or to an individual investigator/team upon request.

2. We will release the data generated from all study participants to qualified researchers who wish to collaborate with the investigators from our study. Investigators who wish to collaborate should submit a proposal that will be reviewed using criteria similar to those used by the NIH \for scientific merit and human subject protection. All data should be used for research only. No data will be provided that could potentially disclose the identities of study participants.

NIH may release new policies regarding data sharing during the study period. We will be willing to discuss such policies with NIMHD program officers and modify the data-sharing plan detailed above.

10. REFERENCES

1. Powers MA, Bardsley JK, Cypress M, et al. Diabetes Self-management Education and Support in Adults With Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association: *https://doi.org/101177/0145721720930959*. 2020;46(4):350-369. doi:10.1177/0145721720930959
2. Gonzalez JS, Safren SA, Cagliero E, et al. Depression, Self-Care, and Medication Adherence in Type 2 Diabetes: Relationships across the full range of symptom severity. *Diabetes Care*. 2007;30(9):2222-2227. doi:10.1002/cncr.29075.Familial
3. Lerman I, Lozano L, Villa AR, et al. Psychosocial factors associated with poor diabetes self-care management in a specialized center in Mexico City. *Biomed Pharmacother*. 2004;58(10):566-570. doi:10.1016/j.biopha.2004.09.003
4. Ducat L, Rubenstein A, Philipson LH, Anderson BJ. A review of the mental health issues of diabetes conference. *Diabetes Care*. 2015;38(2):333-338. doi:10.2337/dc14-1383
5. Gonzalvo JD, Hamm J, Eaves S, et al. A Practical Approach to Mental Health for the Diabetes Educator. *AADE Pract*. 2019;7(2):29-44. doi:10.1177/2325160319826929
6. Zong J, Batalova J. Chinese Immigrants in the United States | migrationpolicy.org. Migration policy institute. http://www.migrationpolicy.org/article/chinese-immigrants-united-states. Published 2017. Accessed May 30, 2017.
7. Passel JS, Cohn D. U.S. Population Projections: 2005-2050 |. Pew Research Center. http://www.pewsocialtrends.org/2008/02/11/us-population-projections-2005-2050/. Published 2008. Accessed May 30, 2017.
8. Hoeffel EM, Rastogi S, Kim MO, Shahid H. The Asian Population: 2010 2010 Census Briefs. 2012. https://www.census.gov/prod/cen2010/briefs/c2010br-11.pdf. Accessed May 30, 2017.
9. McNeely MJ, Boyko EJ. Type 2 diabetes prevalence in Asian Americans: results of a national health survey. *Diabetes Care*. 2004;27(1):66-69. http://www.ncbi.nlm.nih.gov/pubmed/14693968. Accessed May 30, 2017.
10. Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and Trends in Diabetes

Among Adults in the United States, 1988-2012. *JAMA*. 2015;314(10):1021. doi:10.1001/jama.2015.10029

11. Islam NS, Wyatt LC, Kapadia SB, Rey MJ, Trinh-Shevrin C, Kwon SC. Diabetes and associated risk factors among Asian American subgroups in New York City. *Diabetes Care*. 2013;36(1):2013. doi:10.2337/dc12-1252
12. Thorpe LE, Upadhyay UD, Chamany S, et al. Prevalence and control of diabetes and impaired fasting glucose in New York City. *Diabetes Care*. 2009;32(1):57-62. doi:10.2337/dc08-0727
13. Rajpathak SN, Wylie-Rosett J. High prevalence of diabetes and impaired fasting glucose among chinese immigrants in New York City. *J Immigr Minor Heal*. 2011;13(1):181-183. doi:10.1007/s10903-010-9356-2
14. Ma RCW, Chan JCN. Type 2 diabetes in East Asians: similarities and differences with populations in Europe and the United States. *Ann N Y Acad Sci*. 2013;1281(1):64-91. doi:10.1111/nyas.12098
15. Brown AF, Gregg EW, Stevens MR, et al. Race, ethnicity, socioeconomic position, and quality of care for adults with diabetes enrolled in managed care: the Translating Research Into Action for Diabetes (TRIAD) study. *Diabetes Care*. 2005;28(12):2864-2870. doi:10.2337/DIACARE.28.12.2864
16. Herman WH, Dungan KM, Wolffenbuttel BHR, et al. Racial and ethnic differences in mean plasma glucose, hemoglobin A1c, and 1,5-anhydroglucitol in over 2000 patients with type 2 diabetes. *J Clin Endocrinol Metab*. 2009;94(5):1689-1694. doi:10.1210/jc.2008-1940
17. Xu Y, Pan W, Liu H. Self-management practices of Chinese Americans with type 2 diabetes. *Nurs Heal Sci*. 2010;12(2):228-234. doi:10.1111/j.1442-2018.2010.00524.x
18. Islam NS, Kwon SC, Wyatt LC, et al. Disparities in diabetes management in Asian Americans in New York City compared with other racial/ethnic minority groups. *Am J Public Health*. 2015;105:S443-S446. doi:10.2105/AJPH.2014.302523
19. Lanting LC, Joung IMA, Mackenbach JP, Lamberts SWJ, Bootsma AH. Ethnic differences in mortality, end-stage complications, and quality of care among diabetic patients: a review. *Diabetes Care*. 2005;28(9):2280-2288. http://www.ncbi.nlm.nih.gov/pubmed/16123507. Accessed May 30, 2017.
20. Tseng J, Halperin L, Ritholz MD, Hsu WC. Perceptions and management of psychosocial factors affecting type 2 diabetes mellitus in Chinese Americans. *J Diabetes Complications*. 2013;27(4):383-390. doi:10.1016/j.jdiacomp.2013.01.001
21. Chun KM, Chesla CA, Kwan CML. “So We Adapt Step by Step”: Acculturation experiences affecting diabetes management and perceived health for Chinese American immigrants. *Soc Sci Med*. 2011;72(2):256-264. doi:10.1016/j.socscimed.2010.11.010
22. Ho EY, Tran H, Chesla C a. Assessing the Cultural in Culturally Sensitive Printed Patient-Education Materials for Chinese Americans With Type 2 Diabetes. *Health Commun*. 2014;0236(February):37-41. doi:10.1080/10410236.2013.835216
23. Chesla CA, Chun KM. Accommodating type 2 diabetes in the Chinese American family. *Qual Health Res*. 2005;15(2):240-255. doi:10.1177/1049732304272050
24. King GL, Mcneely MJ, Thorpe LE, et al. Understanding and addressing unique needs of diabetes in Asian Americans, Native Hawaiians, and Pacific Islanders. *Diabetes Care*.

2012;35(5):1181-1188. doi:10.2337/dc12-0210

25. Perez-Escamilla R, Damio G, Chhabra J, et al. Impact of a Community Health Workers – Led Structured Program on Blood Glucose Control Among Latinos With Type 2 Diabetes : The DIALBEST Trial. *Diabetes Care*. 2015;38:197-205. doi:10.2337/dc14-0327

26. Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care*. 2012;35(11):2393-2401. doi:10.2337/dc12-1707

27. Peyrot M, Rubin RR, Funnell MM, Siminerio LM. Access to Diabetes Self-management Education. *Diabetes Educ*. 2009;35(2):246-263. doi:10.1177/0145721708329546

28. Hsu WC, Cheung S, Ong E, et al. Identification of linguistic barriers to diabetes knowledge and glycemic control in Chinese Americans with diabetes. *Diabetes Care*. 2006;29(2):415-416. doi:10.1142/S0129054106003905

29. Chun KM, Chesla CA. Cultural issues in disease management for chinese americans with type 2 diabetes. *Psychol Health*. 2004;19(6):767-785. doi:10.1080/08870440410001722958

30. Ho EY, Chesla C a, Chun KM. Health communication with Chinese Americans about type 2 diabetes. *Diabetes Educ*. 2012;38(1):67-76. doi:10.1177/0145721711428774

31. Katigbak C, Zuo S, Chan P. Chinese immigrants' views on exercise and using technology to enhance physical activity. *Innov Aging*. 2017;1(suppl_1):404-405. doi:10.1093/geroni/igx004.1459

32. Juliana Reyes. Immigrants use mobile technology more than overall U.S. population, local study finds - Technical.ly Philly. https://technical.ly/philly/2013/01/28/immigrants-use-mobile-technology-more-than-overall-u-s-population-local-study-finds/. Published 2013. Accessed September 20, 2017.

33. Hu L, Islam N, Langford A, Sevick MA. Mobile Technology for Health Management in Chinese Americans: Preliminary Findings from 2014 HINTS Data. In: Poster presentation at the 3rd Annual NYU Health Disparity Symposium; 2017.

34. Free C, Phillips G, Galli L, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. *PLoS Med*. 2013;10(1):e1001362. doi:10.1371/journal.pmed.1001362

35. de Jongh T, Gurol-Urganci I, Vodopivec-Jamsek V, Car J, Atun R. Mobile phone messaging for facilitating self-management of long-term illnesses. *Cochrane database Syst Rev*. 2012;12(12):CD007459. doi:10.1002/14651858.CD007459.pub2.Copyright

36. Free C, Phillips G, Felix L, Galli L, Patel V, Edwards P. The effectiveness of M-health technologies for improving health and health services: a systematic review protocol. *BMC Res Notes*. 2010;3(1):250. doi:10.1186/1756-0500-3-250

37. Fortmann AL, Gallo LC, Garcia MI, et al. Dulce Digital: An mHealth SMS-Based Intervention Improves Glycemic Control in Hispanics With Type 2 Diabetes. *Diabetes Care*. 2017;40(10):1349-1355. doi:10.2337/dc17-0230

38. Nundy S, Dick JJ, Chou C-H, Nocon RS, Chin MH, Peek ME. Mobile Phone Diabetes Project Led To Improved Glycemic Control And Net Savings For Chicago Plan Participants. *Health Aff*. 2014;33(2):265-272. doi:10.1377/hlthaff.2013.0589

39. Dick JJ, Nundy S, Solomon MC, Bishop KN, Chin MH, Peek ME. Feasibility and usability of a text message-based program for diabetes self-management in an urban African-

American population. *J Diabetes Sci Technol*. 2011;5(5):1246-1254. doi:10.1177/193229681100500534

40. Lyles CR, Ratanawongsa N, Bolen SD, Samal L. mHealth and Health Information Technology Tools for Diverse Patients with Diabetes. *J Diabetes Res*. 2017;2017:1-3. doi:10.1155/2017/1704917

41. National Institute on Minority Health and Health Disparities. NIMHD Research Framework. https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html. Published 2017. Accessed September 20, 2021.

42. Lorig K, Ritter PL, Villa FJ, Armas J. Community-based peer-led diabetes self-management: A randomized trial. *Diabetes Educ*. 2009;35(4):641-651. doi:10.1177/0145721709335006

43. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care*. 2000;23(7):943-950. doi:10.2337/diacare.23.7.943

44. Ho EY, Pak S, Leung G, et al. Pilot cluster randomized controlled trial of integrative nutritional counseling versus standard diabetes self-management education for Chinese americans with type 2 diabetes. *Heal Equity*. 2020;4(1):410-420. doi:10.1089/heq.2020.0002

45. Panagiotakos DB, Pitsavos C, Stefanadis C. Dietary patterns: A Mediterranean diet score and its relation to clinical and biological markers of cardiovascular disease risk. *Nutr Metab Cardiovasc Dis*. 2006;16(8):559-568. doi:10.1016/j.numecd.2005.08.006

46. Craig C, Marshall A, Sjöström M, et al. International Physical Activity Questionnaire: 12-Country Reliability and Validity. *Med Sci Sport Exerc*. 2003;35(8):1381-1395. doi:10.1249/01.MSS.0000078924.61453.FB

47. International physical activity questionnaire. 2002. http://uacc.arizona.edu/sites/default/files/ipaq_english_telephone_short.pdf. Accessed August 23, 2017.

48. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385-396. doi:10.2307/2136404

49. Ezzati A, Jiang J, Katz MJ, Sliwinski MJ, Zimmerman ME, Lipton RB. Validation of the Perceived Stress Scale in a community sample of older adults. *Int J Geriatr Psychiatry*. 2014;29(6):645-652. doi:10.1002/gps.4049

50. Marin G, Sabogal F, Marin BV, Otero-Sabogal R, Perez-Stable EJ. Development of a Short Acculturation Scale for Hispanics: *http://dx.doi.org/101177/07399863870092005*. 2016;9(2):183-205. doi:10.1177/07399863870092005

51. Kim G, Sellbom M, Ford KL. Race/ethnicity and measurement equivalence of the Everyday Discrimination Scale. *Psychol Assess*. 2014;26(3):892-900. doi:10.1037/a0036431

52. Li C, Friedman B, Conwell Y, Fiscella K. Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people. *J Am Geriatr Soc*. 2007;55(4):596-602. doi:10.1111/j.1532-5415.2007.01103.x

53. Huang FY, Chung H, Kroenke K, Delucchi KL, Spitzer RL. Using the Patient Health Questionnaire-9 to measure depression among racially and ethnically diverse primary care patients. *J Gen Intern Med*. 2006;21(6):547-552. doi:10.1111/j.1525-

1497.2006.00409.x

54. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand*. 1983;67(6):361-370. doi:10.1111/J.1600-0447.1983.TB09716.X

55. Russell DW. UCLA Loneliness Scale (Version 3): reliability, validity, and factor structure. *J Pers Assess*. 1996;66(1):20-40. doi:10.1207/S15327752JPA6601_2

56. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med*. 1991;32(6):705-714. doi:10.1016/0277-9536(91)90150-B

57. Lubben J, Blozik E, Gillmann G, et al. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. *Gerontologist*. 2006;46(4):503-513. doi:10.1093/GERONT/46.4.503

58. Link, B. G. (1987). Perceived Devaluation-Discrimination Scale [Database record]. *APA PsycTests*. https://doi.org/10.1037/t16562-00059. Baer, R. A., Smith, G. T., Lykins, E., Button, D., Krietemeyer, J., Sauer, S., Walsh, E., Duggan, D. & Williams, J. M. G. (2008). Construct validity of the Five Facet Mindfulness Questionnaire in meditating and nonmeditating samples. Assessment, 15, 329–342. doi: 10.1177/1073191107313003600. Gu, J., Strauss, C., Crane, C., Barnhofer, T., Karl, A., Cavanagh, K., & Kuyken, W. (2016). Examining the factor structure of the 39-item and 15-item versions of the Five-Facet Mindfulness Questionnaire before and after MindfulnessBased Cognitive Therapy for people with recurrent depression. Psychological Assessment. doi: 10.1037/pas0000263

61. Fereday J, Muir-Cochrane E. Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development. *Int J Qual Methods*. 2006;5(1):80-92. doi:10.1177/160940690600500107

62. Burla L, Knierim B, Barth J, Liewald K, Duetz M, Abel T. From Text to Codings. *Nurs Res*. 2008;57(2):113-117. doi:10.1097/01.NNR.0000313482.33917.7d