CLINICAL STUDY PROTOCOL

Protocol Title

Effect of Culturally Tailored Diabetes Education on Self-Management Behaviors of Adult Hispanic Males with Type 2 Diabetes Mellitus

Protocol Version

10/21/2025

version 3.0

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Revision#	Version Date	Summary of Changes	Consent Change (Y/N)
Original version 1.0	**TBD**	N/A	**N**
Version 2.0	**6/2/2025**	Informed consent, privacy & confidentiality, ethical considerations, data usage & storage all updated.	**N**
Version 3.0	**10/21/2025**	Protocol & consent revised to reflect addition of hybrid sessions.	**Y**

Summary

Study Title	Effect of Culturally Tailored Diabetes Education on Self-Management Behaviors of Adult Hispanic Males with Type 2 Diabetes
Study Design	Quasi-Experimental Quantitative Design
Primary Objective	To evaluate the effect of culturally tailored diabetes education on self-management behaviors of Hispanic males, aged 18-64, with type 2 diabetes mellitus (T2DM).
Secondary Objective	**N/A**
Research Intervention(s)	Five weeks of culturally tailored diabetes self-management education modeled after Association of Diabetes Care and Education Seven-item Framework (ADCES7).
Study Population	Adult Hispanic Males, aged 18-64 years diagnosed with Type 2 Diabetes Mellitus (T2DM)
Sample Size	Up to 98 based on power analysis and attrition rate

Study Duration for Participants	10 hours (Educational sessions: 120 minutes over 5 weeks)

1 – Introduction

Diabetes mellitus (DM) is a global public health concern. In the United States, adult Hispanic males are particularly vulnerable to type 2 diabetes mellitus and are more likely to develop complications and subsequently die from it, compared to non-Hispanic White males. Evidence suggests good self-management behaviors can potentially prevent disease-related complications and improve clinical outcomes. The American Diabetes Association and Association of Diabetes Care and Education Specialists have endorsed diabetes self-management education as a necessary component of care for all individuals living with the disease. However, adult Hispanic males with type 2 diabetes mellitus living in the Middle Atlantic Region of the U.S., especially those who are underserved, typically lack access to formal diabetes self-management education (DSME). Further, the majority have never participated in such educational activities (Au et al., 2021; New Jersey Department of Health, 2013; 2017; 2023). A large body of evidence suggests DSME can effectively improve self-management behaviors in diverse populations around the globe (Abraham et al., 2020; Dietz et al., 2022; ElGerges, 2020; Gehlawat et al., 2019; Hailu et al., 2019; Jiang et al., 2022; Leong et al., 2022; Oluchina, 2022; Riangkam et al., 2022; Tamiru et al., 2023; Yu et al., 2022; Zheng et al., 2019). However, this author identified a gap in the literature as to its effectiveness among adult Hispanic males. The purpose of the proposed study is to examine the effect of culturally tailored diabetes education on self-management behaviors of adult Hispanic males, aged 18-64 years, with type 2 diabetes mellitus living in the Middle Atlantic Region of the U.S. This study can shed more light on the effectiveness of community-based, culturally tailored diabetes educational activities in this vulnerable population and guide future efforts towards enhancing self-management.

2 – Background

2.1. Background/Literature Review

Diabetes mellitus is a global health problem and a major driver of disability and death worldwide (Global Burden of Diseases, Injuries, and Risk Factors Study [GBD] 2021 Diabetes Collaborators, 2023; International Diabetes Federation [IDF], 2021; Khan et al., 2020; World Health Organization [WHO], 2023). With over 500 million cases (roughly 6% of the world's population), DM has been labeled one of the most rapidly evolving public health crises of the Twenty-First Century. From 1990 to 2021, prevalence rose by over 90% globally, from 3.2% to 6.1%, and is expected to rise above 7.0% by 2030 (approximately 700 million cases. Internationally, more than six million deaths (1 every 5 seconds) were

attributed to DM or related complications in 2021 alone ([GBD] 2021 Diabetes Collaborators, 2023; IDF, 2021; Khan et al., 2020; U.S. Census Bureau, 2023; WHO, 2023).

The high cost of care associated with DM places great economic and financial constraints on individuals, families, healthcare systems, and society at large (American Diabetes Association [ADA 2023]; IDF, 2021). Globally, it is estimated that over $960 billion was spent on DM care in 2021 with projected spending to exceed $1 trillion by 2030 (IDF, 2021). Diabetes Mellitus is currently the costliest chronic medical problem in the U.S. with $1 in every $4 of healthcare costs being attributed to clinical management (ADA, 2023; Centers for Disease Control and Prevention [CDC], 2022a). The ADA (2023) estimates that persons diagnosed with DM in the U.S. spend more than twice of those without.

Serious complications can develop from DM, resulting in disability or even death (CDC, 2022c; IDF, 2021; WHO, 2023). Damage to major organs and lower extremities can occur (CDC, 2022c), including ischemic heart disease and stroke, the number one and two contributors to the global disease burden, respectively (GBD 2021 Diabetes Collaborators, 2023). In the U.S., the CDC (2022a) has estimated that persons with DM are two times more likely to develop heart disease and/or have a stroke, compared to those without.

Hispanic Americans have a greater than 50% chance of developing type 2 diabetes mellitus (T2DM), and at a much earlier age (CDC, 2022b). The U.S. Department of Health and Human Services Office of Minority Health (2021) has estimated that Hispanic males 18 years and over, were more likely to receive a diagnosis of T2DM, be admitted due to poorly controlled disease, develop visual problems, undergo amputations, or die prematurely from the disease or its complications, compared to non-Hispanic White males.

Diabetes is essentially a self-managed disease. Self-management behaviors are daily activities performed to reduce disease burden on overall health (ADA, 2023; Association of Diabetes Care and Education Specialists [ADCES], 2021; Powers et al., 2021). These include activities such as glucose monitoring, healthy eating, staying active, taking medication, and foot care. Self-management behaviors are typically carried out by individuals with support from family and loved ones. Diabetes educational activities that embody these concepts have been reported to enhance self-management, improve clinical outcomes, and delay onset of complications. Therefore, such activities have been endorsed as a critical aspect of care for all persons living with T2DM (ADA, 2023; ADCES, 2021; Powers et al., 2021).

When tailored to the culture of the target population, diabetes education can significantly improve self-management behaviors, increase knowledge, and improve outcomes, particularly among those with T2DM living in underserved communities (Brown et al., 2021; Gehlawat et al., 2019; Tamiru et al., 2023). Culturally tailored diabetes education has also been shown to decrease the cost of diabetes-related care, reduce emergency room visits, and

inpatient admissions (ADCES, 2021; CDC, 2019). However, little is known about its effect on adult Hispanic males living with the disease. Therefore, this study aims to evaluate the effect of culturally tailored diabetes education on self-management behaviors of adult Hispanic males, aged 18-64, with T2DM, living in the Middle Atlantic Region of the United States.

3 – Rationale, Objectives and Hypotheses

3.1. Study Rationale/Problem Statement/Research question or Study significance

Evidence shows that culturally tailored diabetes self management education can significantly improve DM outcomes, however, little is known about its impact among adult Hispanic males with T2DM, which this study aims to address.

3.2. Hypotheses

Research Hypotheses for the proposed study are as follows:

H_1 – Five weeks of culturally tailored diabetes education will have a statistically significant effect on **diet scores** of adult Hispanic males with T2DM post-intervention.

H_2 – Five weeks of culturally tailored diabetes education will have a statistically significant effect on **exercise scores** of adult Hispanic males with T2DM post-intervention.

H_3 _ Five weeks of culturally tailored diabetes education will have a statistically significant effect on **medication scores** of adult Hispanic males with T2DM post-intervention.

3.3. Primary Objective

To evaluate the effect of culturally tailored diabetes education on self-management behaviors of adult Hispanic males, 18-64, with T2DM.

3.4. Primary Outcome Variable

Title: Diabetes Self-Management (DSM) Behaviors

Description: DSM will be measured by self-reported data on diet, exercise, and medication adherence, utilizing scoring derived from the Spanish version of the Summary of Diabetes Self-Care Assessment (SDSCA-Sp) scale. SDSCA-Sp core items measure participants' DSM activities during the past seven days. In case of sickness during that period, participants are asked to respond based on the last seven days they were not sick.

Scoring: Scores will be calculated separately for each subscale of the instrument. Number of days per week an activity is performed, on a 0–7 scale, is recorded, with higher numbers corresponding to higher levels of self-care activity performance (Toobert et al., 2000; Vincent et al., 2008).

Primary Outcome Measure 1
Title: Healthy Eating
Description: Healthy eating behaviors will be measured by self-reported data on diet adherence utilizing scoring derived from the SDSCA-Sp scale.
Scoring: Items 1–5 relate to dietary behaviors, for example, "how many of the last seven days have you followed a healthful eating plan?" Diet will be scored using the mean number of days for items 1-5, using a reverse score for item 4 (Toobert et al., 2000; Vincent et al., 2008).

Primary Outcome Measure 2
Title: Staying Active
Description: Physical activity behaviors will be measured by self-reported data on exercise adherence utilizing scoring derived from the SDSCA-Sp scale.
Scoring: Items 6–7 pertain to exercise activity, for example, "on how many of the last seven days did you participate in at least 30 minutes of physical activity?" Exercise will be scored using the mean number of days for items 6 and 7.

Primary Outcome Measure 3
Title: Medication Use
Description: Medication use behaviors will be measured by self-reported data on medication adherence utilizing scoring derived from the SDSCA-Sp scale.
Scoring: Medication use will be scored using total number of days for item 12.

Timeframe: Self-reported data will be collected at Week 1 (baseline) and Week 5 (following implementation of educational sessions). The timeframe of instrument completion is 45-60 minutes.

3.5. Secondary Objective(s)

N/A

3.6. Secondary Outcome Variable(s)/Measure(s)

Secondary Outcome Measures
N/A

3.7. Exploratory objective(s)

N/A

3.8. Exploratory outcome variable(s)

N/A

Exploratory outcome measure 1
N/A

4 - Study Design

4.1 General Design

A one-group, pretest-posttest, quasi-experimental design (Gray et al., 2017) will be used for this study. This quantitative interventional design was chosen because the study will not have a control group and there will be no random assignment or random selection of participants. However, the independent variable of C-DSME will be manipulated and the outcome variable of DSM behaviors will be measured before and after the intervention for comparison (Gray et al., 2017). Participation in the research study is a requirement to participate in the educational sessions.

4.1.1 Study Duration

12-18 months

4.1.2 Participant Duration

10 hours over the course of 5 weeks

4.1.3 Number of Study Sites

Single site study - HMH JFK University Medical Center Plainfield Health Connections

4.2 Study Population

Adult Hispanic males, aged 18-64, diagnosed with type 2 diabetes mellitus

4.2.1. Number of Participants

98 participants, based on *a priori* power analysis and approximately 50% incompletion rate to counter attrition.

4.2.2. Eligibility Criteria

Inclusion Criteria:
The inclusion criteria will be:

1. **Age:** Adult Hispanic males 18-64 at time of study intervention.
2. **Diagnosis Codes:** Patients with self-reported diagnosis of T2DM without complex, co-morbid conditions such as severe kidney disease and terminal illnesses such as cancer.
3. **Payor:** N/A

4. **Procedure Codes:** N/A
5. **Medications:** N/A
6. **Test/Lab results:** N/A
7. **Study site:** HMH JFK University Medical Center Plainfield Health Connections
8. **Service:** Outpatient/Inpatient
9. **Date Range:** N/A
10. **Communication:** Subjects identified with a language barrier who agree to receive HMH medical interpreter services.

Exclusion Criteria:
The exclusion criteria will be:

1. **Age:** Hispanic adult males over the age of 65 years, children, adolescents, and females.
2. **Diagnosis Codes:** Hispanic males aged 18–64 with T2DM and complex, co-morbid conditions that can impair ability to perform self-care activities. This includes those with cancer and other terminal illnesses; severe cardiovascular and cerebrovascular diseases, such as congestive heart failure; severe kidney disease; physical disability; cognitive impairment; and major psychiatric disorders like schizophrenia.
3. **Payor:** N/A
4. **Procedure Codes:** N/A
5. **Communication:** Potential participants with an identified language barrier who refuse to receive HMH medical interpreter services.

4.2.3. Vulnerable Populations

- Minority individuals are considered as a vulnerable group when it comes to access to healthcare services (Aguayo-Mazzucato et al., 2019). The culturally tailored diabetic self management educational intervention will be applied to all participants meeting inclusion criteria.
- A certified medical Spanish interpreter (HMH certified) will be present during all participant encounters to ensure that information presented is language appropriate.
- Informed consent will be obtained from each participant at the time of recruitment; approximately 30-45 minutes will be given for questions.

4.3 Withdrawal Criteria

Participants may choose to withdraw from the study at any time.

- Study participants are required to participate in 80% of educational sessions. Failure to meet this threshold will result in study removal. Subjects may elect to withdraw from the study at any time. They will be directed to contact the study PI.
- The study PI will remove their identifiable information from study documentation. If they have completed the pre and post surveys, their de-identified data will remain in the study and will be used for analysis. If they have not completed the post-intervention survey, their data will not be used for analysis.
- An annotation will be made to the spreadsheet to indicate that the participant has withdrawn from the study.
- Participants who withdraw from the study will not be replaced. Sample size of 98 already accounts for possible attrition.
- In the event of participant withdrawal, collected data will be used in the study. Time of withdrawal and impact to study findings will be discussed in the results and study limitations. The same is reflected in the informed consent for all participants.

4.4. Study Procedures

Recruitment:

Convenience sampling strategy will be used to recruit participants for this study. Bilingual recruitment flyers will be distributed via JFK Family Medicine Center, Plainfield Health Connections, the Diabetes Center at JFK, a community-based family practice located in Plainfield, places of worship, and other community centers in the Middle Atlantic Region. Eligible participants will be invited to enroll in the study. Upon agreement to participate in this study, informed consent will be obtained electronically using REDCap or via paper-and-pencil format. Approximately 30 minutes will be given for questions and answers during the consent process.Efforts will be made to ensure participants know in advance that attending the educational program requires participation in the study.

Procedures:

1. The PI, a board-certified adult nurse practitioner with more than 10 years of experience in health education and caring for persons with T2DM, will be implementing the culturally tailored diabetes self-management education (C-DSME) intervention in this study, accompanied by a certified Spanish medical interpreter.
2. The intervention will be delivered to all participants in group sessions for five (5) consecutive weeks using a hybrid format (first and last sessions will be in person) in a private classroom at the HMH JFKUMC School of Nursing in Plainfield, on the same campus as Plainfield Health Connections. A Google Meet link will be shared each week as part of the class reminder texts via secure Twilio messaging using REDCap.
3. Each session will last approximately two (2) hours.
4. An electronic (via REDCap) or paper-and-pencil copy of the Spanish version (certified and validated) of the Summary of Diabetes Self-Care Activities survey

(Toobert et al., 2000; Vincent et al., 2008) will be completed by each participant during Week 1 ((pre-intervention) and again in Week 5 (post-intervention) for comparison.

5. Assistance with survey completion will be available from the PI and medical interpreter as needed.
6. This C-DSME intervention will be modeled after the ADCES7 Framework, derived from national standards and consistent with current, evidence-based clinical practice guidelines for T2DM education in adults (ADA, 2022; ADCES, 2021; Powers et al., 2021). The main focus will be on three of the seven ADCES7 self-care behaviors, namely, (a) Healthy Eating, (b) Staying Active, and (c) Medication Use (ADCES, 2021).
7. Pertinent bilingual educational materials downloaded from the ADA and ADCES websites will be distributed to participants during weekly sessions. The C-DSME intervention will cover the following components and will be structured as follows:

Week	Educational Content/Intervention	Duration (in minutes)	Survey Administration
Week 1	Brief overview of T2DM; healthy coping; healthy eating - cultural beliefs about food.	60 minutes	60 minutes
Week 2	More in-depth discussion on healthy eating, including MyPlate method of meal planning for persons with T2DM; incorporation of fruits and vegetables in daily meals; consumption of whole grains, lean meats and other proteins; healthy fats and oils; healthy snacks and beverages.	120 minutes	N/A
Week 3:	Discussion will focus on physical activity and exercise; participants' beliefs and values regarding exercise will be explored; benefits of exercise will be discussed, and each participant will be encouraged to commit to a weekly exercise regimen in accordance with ADA and American Heart Association (AHA) guidelines.	120 minutes	N/A

Week	Educational Content/Intervention	Duration (in minutes)	Survey Administration
Week 4:	Participants' beliefs and values regarding medication use will be explored. Topics to be covered will include rationale for medication use; indications; dosage; frequency; adherence; herbs and supplement use; among others.	120 minutes	N/A
Week 5:	This interactive class will include discussions on self-monitoring, reducing risks, and problem solving. Participants will be given a chance to ask more questions, provide feedback, and interact with each other. They will also be invited to share what they have learned and how it can be applied to enhance their daily self-care practices.	60 minutes	60 minutes

Compensation:
Each participant will receive a $25 Visa card to offset transportation cost after participation in all 5 sessions.

4.4.1. Study discontinuation

N/A

4.4.2. Concomitant medication (if applicable)

N/A

4.5. Risks and Benefits

4.5.1. Risks

Eligible participants will be approached only after IRB approvals have been obtained. After the study is thoroughly explained, they will be invited to participate. Those who consent to participating will be included. An HMH-approved certified medical interpreter will be retained for the duration of the study to ensure information is delivered in a language-appropriate manner. The interpreter will receive four (4) hours of coaching prior to study initiation to enhance their understanding of study purpose and design.

To minimize the risk, albeit small, of breach of confidentiality, all hard copy data will be stored securely in a locked file cabinet in a private office at JFKUMC Plainfield Health Connections accessible only to the PI. Data will be stored on an HMH-issued, password-protected laptop accessible only to the PI, following which all hard copies will be destroyed. All participant data will be assigned a unique study ID that will be linked to their data throughout the study.
Participation in the survey and educational intervention is voluntary. Potential risks include breach of confidentiality and risk of disclosure of responses. The surveys will be coded. In any future published report based on findings from this study, the PI will ensure no information is included that could make it possible to identify individual participants. Other risks include potential discomfort with survey questions. Participants may skip any questions they do not feel comfortable answering.

4.5.2. Benefits

As a result of participation in this five-week C-DSME program, participants may gain increased knowledge, which can potentially lead to better self-management practices and subsequently, improved glycemic levels and overall clinical outcomes. Participation may also generate knowledge that can help determine the potential benefits of community-based C-DSME programs to adult Hispanic males living with T2DM.

Each participant will receive a $25 Visa card to offset the cost of transportation to the in-person sessions after participation in all 5 sessions.

5 – Methods

5.1. Screening

Only participants who meet elements of the inclusion criteria will be contacted for study participation.

5.2. Recruitment, Enrollment and Retention

Recruitment flyers (Appendix A) will be posted and distributed in high visibility areas at the JFKUMC Family Medicine and Diabetes Centers, through the Plainfield Health Connections program, and a community-based family practice located in Plainfield. Recruitment will also occur via community settings where members of the Hispanic/Latinx study population are largely represented. Physical settings may include places of worship, community centers, local community organizations, hospital and community based ambulatory care settings. Using convenience sampling strategies, the PI will contact eligible participants who express interest and are willing to participate, either in person or via telephone, with the assistance of the interpreter, and invite them to participate. Interested participants will also be able to contact the PI whose information will be shared through the recruitment flyer. Upon agreement to participate, consent will be obtained electronically through REDCap or via a

paper and pencil copy where applicable. Efforts will be made to ensure participants know in advance that attending the educational program requires participation in the study.

5.3. Study Intervention (including schedule of events and study visits)

The PI, a board-certified adult nurse practitioner with more than 10 years of experience in health education and providing care to persons with T2DM, will be implementing the C-DSME intervention in this study, accompanied by a certified Spanish medical interpreter. This educational intervention will be delivered in group sessions for five (5) consecutive weeks using a hybrid format (via Google Meet) and at the HMH JFKUMC School of Nursing classroom across from the Plainfield Health Connections office with each session lasting approximately two (2) hours (for a total of 10 hours over the five week period).
The Spanish version of the Summary of Diabetes Self-Care Activities survey (Appendix B) will be completed by each participant electronically (via REDCap) or via paper and pencil (with assistance from the PI and interpreter as needed) at the beginning of Week 1 (pre-intervention) and again at the end of Week 5 (post-intervention) for comparison.

This C-DSME intervention will be modeled after the ADCES7 Framework, derived from national standards and consistent with current, evidence-based clinical practice guidelines for T2DM education in adults (ADA, 2022; ADCES, 2021; Powers et al., 2021). The main focus will be on three of the seven ADCES7 self-care behaviors, namely, (a) Healthy Eating, (b) Staying Active, and (c) Medication Use (ADCES, 2021).

Pertinent bilingual educational materials downloaded from the ADA and ADCES websites will be distributed to participants during weekly sessions. The C-DSME intervention will cover the following components and will be structured as follows:

- **Weeks 1–2:** A brief overview of T2DM will be provided, followed by discussions on healthy coping, cultural beliefs about food; healthy eating, including MyPlate method of meal planning for persons with T2DM; incorporation of fruits and vegetables in daily meals; consumption of whole grains, lean meats and plant-based proteins; healthy fats and oils; healthy snacks and beverages.
    - Healthy snacks and water will be provided during classes.
    - Participants will receive culturally friendly recipes to try at home.
    - A compilation of local grocery stores carrying affordable, healthy foods will be distributed.
    - Sessions will be interactive and engaging, and will involve the use of visual aids, pictographs, and teaching aids to enhance learning.

- **Week 3:** Discussion will focus on physical activity and exercise; participants' beliefs and values regarding exercise will be explored; benefits of exercise will be discussed,

and each participant will be encouraged to commit to a weekly exercise regimen in accordance with ADA and AHA guidelines.

- **Week 4:** Participants' beliefs and values regarding medication use will be explored. Topics to be covered will include rationale for medication use; indications; dosage; frequency; adherence; herbs and supplement use; among others.

- **Week 5:** This interactive class will include discussions on effective self-monitoring, risk reduction, and problem solving. Further, participants will be given a chance to ask questions, provide feedback, and interact with each other. Participants will be invited to share what they have learned and how it can be applied to enhance their daily self-care practices and behaviors.

Methodological Rigor

For the proposed study, steps taken by the PI to enhance rigor are as follows:

- Prior to formulating the hypotheses, the PI thoroughly engaged with the current empirical and theoretical evidence related to DSME and T2DM. This was necessary to ensure congruency between hypotheses, literature review, and proposed methodology (Goodman et al., 2020).

- The existing body of evidence on DSME and T2DM was critically appraised and synthesized; the gap that emerged following this critical appraisal, which led to the proposed research study, was clearly identified (Goodman et al., 2020).

- *A priori* power analysis was completed to guide sample size determination (Cohen, 1992). This was done to control for the potential threat to statistical conclusion validity that can occur due to low statistical power, often associated with inadequate sample size selection (Gray et al., 2017).

- The Spanish version of the Summary of Diabetes Self-Care Activities (SDSCA-Sp) survey, the instrument of measure proposed for this study, is reliable and valid (Vincent et al, 2008), which can enhance statistical conclusion validity.

- The nonrandomized, one-group, pretest-posttest quasi-experimental design lacks a control group and randomization, which can pose a threat to internal validity of the study (Goodman et al., 2020). The pretest-posttest feature, which allows the sample to be their own control, can minimize this potential threat. Additionally, the proposed intervention will be implemented in a systematic and uniform manner, to further control for this threat (Flannelly et al., 2018).

- The proposed target population, setting, inclusion/exclusion criteria for sample selection, are clearly outlined for this research proposal. According to Goodman et al. (2020), clear presentation of information can potentially minimize threats to external validity.

- **Virtual Sessions**
    - Sessions will not be recorded
    - Participants may turn their cameras off if they choose (this will be announced at the beginning of each virtual session)
    - Participants may use an alternate pseudonym rather than their given name for privacy
    - Virtual link (via Google Meet) will be shared via text using Twilio messaging through REDCap along with weekly reminders

5.4. Assignment / Randomization (if applicable)

Convenience sampling will be used.

5.5. Section on Instruments (to include for all studies with a social behavioral intervention)

The SDSCA-Sp survey (Vincent et al., 2008) will be used as the instrument of measure in this study. The SDSCA, originally developed by Toobert et al. (2000), was selected for the proposed study because it has been established as a psychometrically sound instrument proven effective for assessing DSM behaviors in adults with T2DM in many settings across the globe for more than 20 years (Dietz et al., 2022; Gehlawat et al., 2019; Hailu et al., 2019; Zheng et al., 2019). Additionally, it is congruent with the purpose and desired outcomes of the proposed dissertation study.

The SDSCA is a brief, 11-item self-report questionnaire used to measure levels of self-management across different components of the DM regimen (Toobert et al., 2000). It is designated for use in research and practice in a variety of settings, including outpatient clinics and wellness centers, in-person or via the internet. It can be completed in paper and pencil or electronic formats, and in one-on-one or group-based scenarios (Toobert et al., 2000).

The SDSCA is recommended for use in clinical practice and research to assess DSM, which includes blood glucose self-monitoring, healthy eating, keeping active, and foot care, among others (Powers et al., 2021). Core aspects of DSM the SDSCA focuses on are general diet, exercise, blood glucose monitoring, foot care, and smoking (Toobert et al., 2000).

The SDSCA is a Likert-type instrument with five subscales (diet, exercise, blood glucose monitoring, foot care, and smoking) consisting of 11 core items and 14 extra items, all of

which are believed to have value in clinical practice and research. For ease of scoring and interpretation, all items on the scale are consistently scored using the metric “days per week” (Toobert et al., 2000).

The 11 core items measure participants’ DM self-care activities during the past seven days. In case of sickness during that period, participants are asked to respond based on the last seven days they were not sick (Toobert et al., 2000). Items 1–4 relate to dietary behaviors, for example, “how many of the last seven days have you followed a healthful eating plan?” Items 5–6 pertain to exercise activity, for example, “on how many of the last seven days did you participate in at least 30 minutes of physical activity?” Items 7–8 apply to blood sugar testing, for example, “on how many of the last seven days did you test your blood sugar?” Items 9–10 correspond to foot care activities, for example, “how many of the last seven days did you check your feet?” Item 11 focuses on smoking habits, for example, “have you smoked a cigarette in the past seven days?”
Scores are calculated separately for each of the five subscales. For items 1–10, number of days per week an activity is performed, on a 0–7 scale, is recorded, with higher numbers corresponding to higher levels of self-care activity performance (Toobert et al., 2000). General diet is scored using the mean number of days for core items 1 and 2. Specific diet is scored using the mean number of days for items 3 and 4, reversing item 4 (recommendation is to use individual items due to low inter-item correlations for this scale). Exercise is scored using the mean number of days for items 5 and 6. Blood glucose testing is scored using the mean number of days for items 7 and 8. Foot care is scored using the mean number of days for items 9 and 10. Smoking status is scored using item 11 (0 = non-smoker; 1= smoker) and number of cigarettes smoked per day (Toobert et al., 2000).

The additional 14 items constitute the expanded version of the SDSCA and are used when a particular question is of interest for clinical or research purposes (Toobert et al., 2000). Of note, there is little to no reliability or validity data for the additional items of the SDSCA. Six of the items address self-care recommendations and may help clarify patient understanding of self-management. For example, “which of the following medications for your diabetes has your doctor prescribed” specifically addresses medication use. In terms of scoring, none is required for items 1A–4A, and 12A–14A. Item 5A provides additional information on diet and is scored as the total number of days per week. Item 6A (total number of days per week), or items 7A and 8A (mean number of days per week) provide scores for medication use. Mean number of days per week for items 9A–11A, after reversing 10A and including items 9 and 10 from the brief version, provides scores on foot care (Toobert et al., 2000).

To complete the SDSCA, respondents are asked to circle how many days in the last seven days they performed a specific behavior pertaining to each of the subscales (Toobert et al., 2000). Response choices range from zero to seven, with higher scores indicating higher self-care activity performance.

The SDSCA-Sp has been established as easy to read at a sixth-grade readability level (Vincent et al., 2008). It has been previously used successfully in a study involving Mexican American adults with T2DM (Vincent et al., 2008). Regarding content validity, it is reported as being "exactly equivalent" to the original English version by Toobert et al. (2000) following expert translation and back translation. Additionally, the authors have noted that the SDSCA-Sp has high test-retest reliability (M = .84) and moderate internal consistency ([Cronbach's alpha, $\alpha = 0.72$]; Vincent et al., 2008), both of which speak to the quality of the instrument.

Pertinent demographic data that will be used to describe the sample (age, race/ethnicity, marital status, preferred language, health insurance status, educational level, and employment status) will be collected on each participant using a demographic form (Appendix C) during the first session. Demographic data and completed SDSCA-Sp questionnaires will be uploaded into an HMH-issued laptop computer for secure storage via an encrypted password known only to the PI. Once the information is uploaded, all paper forms will be destroyed to maintain confidentiality. Permission has been obtained to use surveys pertinent to this study.

5.6. Follow-up and end-of study (if applicable)

5.7. Statistical Method

5.7.1. Sample size calculation and justification

A priori power analysis was completed to guide sample size determination (Cohen, 1992). This was done to control for the potential threat to statistical conclusion validity that can occur due to low statistical power, often associated with inadequate sample size selection (Gray et al., 2017).

Based on published SDSCA data for diet and a calculated effect size of 0.41 (doi:10.1177/0145721712443292), an alpha of 0.05 and power of 0.80 for a paired two-sided test, a sample size of 49 is adequate. Assuming a 50% incompletion rate, a sample size of 98 would be able to detect a pre- and post-survey difference at 80% power ([R version 4.3.3; pwr.t.test]; Cohen, 1992; Choi & Rush, 2012; Kang, 2021; Plichta & Kelvin, 2013).

5.7.2. Statistical Analysis Plan

Efficacy Analyses

All continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. Discrete data will be summarized using n (non-missing sample size), median, minimum,

maximum, and interquartile range or semi-interquartile range. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. All summary tables will be annotated with the total population size relevant to that table/timepoint, including any missing observations. Note that sample sizes for individual variables may be different than for the complete case analyses as data in the summary tables may/ may not be present as compared to the complete case dataset.

Primary Efficacy Analysis

Primary outcome(s):

1) To determine the efficacy of DSME in the adult Hispanic male population on *healthy eating*.
    - Hypothesis: N/A
    - Variable: Eating questions (numeric: number of days)
    - Measurement: average number of days
    - Summary data: Mean and SD or median and min/max/SIQR will be calculated for numeric data, as appropriate. Results will be presented in a table, stratified by time.
    - Preliminary Model(s): Data will be modeled using linear regression, generating betas and 95% confidence intervals (PMID: 34325755). Variables included in the model will be the average number of days regressed on time (pre- and post-educational intervention). Results will be presented in a table. Models will be run as two-sided with significance levels set at 0.05. Assumptions for the model will be tested using visualizations, as appropriate.

2) To determine the efficacy of DSME in the adult Hispanic male population on *staying active*.
    - Hypothesis: N/A
    - Variable: Activity questions (numeric: number of days)
    - Measurement: average number of days
    - Summary data: Mean and SD or median and min/max/SIQR will be calculated for numeric data, as appropriate. Results will be presented in a table, stratified by time.
    - Preliminary Model(s): Data will be modeled using linear regression, generating betas and 95% confidence intervals (PMID: 34325755). Variables included in the model will be the average number of days regressed on time (pre- and post-educational intervention). Results will be presented in a table. Models will be run as two-sided with significance levels set at 0.05. Assumptions for the model will be tested using visualizations, as appropriate.

3) To determine the efficacy of DSME in the adult Hispanic male population on *medication compliance*.
    - Hypothesis: N/A
    - Variable: Medication questions (numeric: number of days)
    - Measurement: Total number of days
    - Summary data: Mean and SD or median and min/max/SIQR will be calculated

for numeric data, as appropriate. Results will be presented in a table, stratified by time.

- Preliminary Model(s): Data will be modeled using linear regression, generating betas and 95% confidence intervals (PMID: 34325755). Variables included in the model will be the number of days regressed on time (pre- and post-educational intervention). Results will be presented in a table. Models will be run as two-sided with significance levels set at 0.05. Assumptions for the model will be tested using visualizations, as appropriate.

6 - Trial Administration

6.1. Ethical Considerations - Institutional Review Board (IRB) Review

The study will be conducted according to the Declaration of Helsinki, IRB, and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

In line with the above regulations, study approvals will be sought from the IRBs of HMH and Wilkes University. Eligible patients will be approached only after approvals have been obtained. Only after the study is thoroughly explained will they be invited to participate. Those who consent to participating will be included. An HMH-approved medical interpreter will be retained for the duration of the study to ensure information is delivered in a language appropriate manner. The interpreter will receive four hours of coaching prior to study initiation to enhance their understanding of study purpose and design. Participants will be made aware that study participation is completely voluntary.
Participants' phone numbers will be stored in a separate instrument in REDCap from the survey data. Each subject will maintain the same unique ID throughout the study.
Demographic data that will be collected will include participants' age, race/ethnicity, preferred language, marital status, employment status, educational level, and health insurance status.

6.2. Institutional Review Board (IRB) Review (list the IRB of record)

The final study and data collection tools will be approved by the IRB at HMH. Approval will be received in writing before any study activities are initiated. Any changes to the study design will be formally documented in modifications and will be approved by the IRB prior to implementation.

6.3. Privacy and Confidentiality

A unique study ID will be assigned to each participant. The study ID will be included in the data collection tools and analysis software while the list with direct identifiers and ID numbers is stored separately in a private, password protected computer and locked cabinet in an office accessible only to the PI. If results of the study are published, individual names or other identifying information will not be used. Once hard copy data has been electronically transcribed, they will be destroyed.

6.4. Informed Consent

Eligible individuals who agree to participate in the study will be consented at the time of recruitment. The PI will read or have participants read the Consent Form in their preferred language (Appendix D) and ask if participants have questions. The consent form will provide: 1) an explanation of the purpose of the study; 2) an explanation of benefits and risks to participation; 3) an assurance of confidentiality; and 4) an assurance of participant's right to choose not to participate or to terminate participation at any time during study implementation. Participants will be advised that participation is completely voluntary. Efforts will be made to ensure participants know in advance that attending the educational program requires participation in the study.

Once consent has been obtained, each participant will be assigned a unique study ID to protect their identity and ensure confidentiality throughout the study. Phone numbers will be collected so the PI can send reminders to participants 24 hours prior to each class via approved Twilio text messaging through REDCap. Participants' phone numbers will be stored in a separate instrument in REDCap from the survey data. Each subject will maintain the same unique ID throughout the study. Demographic data that will be collected will include participants' age, race/ethnicity, preferred language, marital status, health insurance status, educational level, and employment status.

6.5. Data Management and Sharing Plan

6.5.1. Data Sources

Demographic data forms will be completed prospectively during Week 1 of the study. Additionally, each participant will complete the SDSCA-Sp survey during Weeks 1 and 5 either via paper and pencil, or electronic using REDCap.

6.5.2 Data Type

Data on DSM behaviors will be collected using a paper and pencil copy or electronic version of the SDSCA-Sp during Weeks 1 and 5. Hard copy data will be subsequently transcribed into an HMH-issued, password-protected laptop accessible only to the PI. Following this, all hard copies will be destroyed by the PI.

6.5.3 Estimated Amount

Demographic and DSM data will be collected for all 98 participants. The former will be collected during Week 1 and the latter, during Weeks 1 and 5.

6.5.4 Data Storage

Data will be coded and a unique ID assigned to each subject and maintained throughout the study using secure HMH REDCap database. The paper version of the informed consent forms, demographic forms, and SDSCA-Sp surveys, will be stored in a locked file cabinet at

the Plainfield Health Connections office accessible only to the PI after data is entered into REDCap. Data will be stored on an HMH-issued laptop accessible only to the PI. All hard copies will be subsequently destroyed following transcription. Coded data will be stored electronically and analyzed on the HMH-issued, password-protected laptop.

6.5.5 Scientific data that will be shared and means of transmission

De-identified data will be shared as part of the PI's dissertation report with Wilkes University. Data will be shared over secure email.

6.5.6 Scientific data to be published

The results of this study has the potential to inform DM care of the target population, improve DSM behaviors as well as clinical outcomes. As such, study results will be submitted for publication to a peer reviewed journal such as the Journal of the American Association of Nurse Practitioners and Diabetes Spectrum. Abstracts for podium or poster presentations will be submitted at local and national conferences. Findings will also be disseminated throughout Hackensack Meridian *Health*. No individually identifiable information will be used in any publication or presentation.

6.5.7 Record Retention

Electronic records will be retained in accordance with regulatory and organizational requirements, but for no less than six (6) years following the completion of the study. Disposal of records will be performed according to regulations in a manner such that identifiers cannot be linked back to the study data.

6.5.8 Data Quality Assurance

For the proposed study, potential threats to study validity, and measures to control them, are as follows:

- *A priori* power analysis was completed to guide sample size determination (Cohen, 1992). This was done to control for the potential threat to statistical conclusion validity that can occur due to low statistical power, often associated with inadequate sample size selection. Adequate sample size gives a study adequate power to detect true differences that exist between groups, thereby reducing the threat to statistical conclusion validity (Cohen, 1992).

- The SDSCA-Sp, the instrument of choice for the proposed study, is reliable and valid, thereby minimizing the threat to statistical conclusion validity (Goodman et al., 2020).

- The nonrandomized, one-group, pretest-posttest quasi-experimental design lacks a control group and randomization, which can pose a threat to internal validity of the study (Goodman et al., 2020). The pretest-posttest feature, which allows the sample to be their own control, can potentially minimize this potential threat (Flannelly et al., 2018).

- The proposed target population, as well as inclusion/exclusion criteria for sample selection, have been clearly outlined to potentially minimize threats to external validity.

6.5.9 Data Preservation, Access, and Associated Timelines*

This study will be registered on ClinicalTrials.gov in compliance with federal regulations and institutional policy. Aggregate results from this study will be posted on ClinicalTrials.gov within 365 days from the study's Primary Completion date. No individual participant data (IPD) will be made available or shared on ClinicalTrials.gov.

6.5.10 Related Tools, Software and/or Code*

N/A

6.5.11 Standards*

N/A

6.5.12 Access, Distribution, or Reuse Considerations*

N/A

6.6. Compensation for Research-Related Injury

N/A

6.7. Economic Burden to Subjects

Upon completion of 4 out of 5 sessions, participants will receive a $25 Visa card to offset the cost of transportation.

6.8. Credentials, Training

Beryl O'Donnell, MSN, RN, NP-C, the PI for this study, serves as director for the HMH JFKUMC Plainfield Health Connections (PHC) program, a family medicine clerkship faculty for Hackensack Meridian School of Medicine, and is a final year PhD in nursing student at Wilkes University in Pennsylvania. As the director for the PHC program, Ms. O'Donnell has been providing health education and care coordination services for underserved patients with chronic health problems including T2DM, for more than a decade. Additionally, she has served as a mentor for several capstone projects geared towards improving outcomes for underserved patients with T2DM. In preparation for this project, Ms. O'Donnell has forged strong relationships with JFKUMC Family Medicine Center, the HMH Latinx team member resource group, and is in the process of connecting with local Hispanic/Latinx churches and community centers. These alliances will make it possible to recruit and track participants over the course of the study. Although this PI is considered a novice researcher, her decade-long

experience educating this community and years of experience as a capstone mentor, has provided valuable insight into the importance of constructing a realistic research plan and timeline. Ms. O'Donnell has the training, knowledge, passion, and motivation to successfully carry out the proposed study.

6.9. Financing and Insurance

No external funding is required for this project.

6.10 Investigator(s)' financial and other relevant personal interests

The PI has no financial or personal interests to disclose. The PI's conflict of interest is on file with the Institutional Review Board of Hackensack Meridian *Health*.

7- Resources Available

7.1. Describe the resources available to conduct the research:

Administrative permission and support for this study have been granted by the Chief Nursing Officer at JFKUMC, leadership at JFK Family Medicine Center and the PhD Coordinator at Wilkes University. The proposal is currently pending approval from JFKUMC's Nursing Research Council. The PI will be conducting this study under the mentorship and guidance of an expert nurse scientist from the HMH Ann May Center for Nursing Research, dedicated to promoting clinical excellence through evidence-based nursing education and research. Biostatistician support and a world class library with 24/7 access to the best available and most recent clinical evidence and reference materials, are offered at HMH as additional resources in support of research studies. The PI will seek approval from Hackensack Meridian Health and Wilkes University Institutional Review Boards to ensure the rights of participants are protected in the proposed study. Recruitment flyer, demographic data form, and informed consent, will all be translated into Spanish by the HMH Language Services Center prior to use.

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Appendices

Appendix	Name
A	Recruitment Flyer
B	Summary of Diabetes Self-Care Activities Scale-Spanish Version (SDSCA-Sp)
C	Demographic Data Form
D	Research Participant Information and Consent Form
E	SDSCA
F	SDSCA General User Agreement
G	SDSCA Special User Agreement
H	Permission to Use the SDSCA-Sp
I	Permission to Use ADCES7 Framework
J	HMH JFKUMC Site Approval Letter
K	HMH JFKUMC NRC Approval Letter