Northwell Health

RESEARCH PROTOCOL

Protocol Title:	**Patient and Caregiver-Centered Diabetes Telemanagement Program for Hispanic/Latino Patients**
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IRB Number:	19-0002
Sponsor:	Patient Centered Outcomes Research Institute (PCORI)

Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
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1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Over half of Hispanic/Latino (H/L) patients will develop types 2 diabetes (T2D) during their lifetime.[1] According to the Center of Disease Control (CDC), T2D is a leading cause of suffering and death due to cardiovascular disease, end-stage renal failure, blindness, non-traumatic lower limb amputations, hospitalizations, and poor QoL.[2] The risk of dying for people with T2D is twice that of those without T2D.[1] In the US, the prevalence in H/L males 65-74 is 31.1%; for H/L females, it is 32.6%.[3] Compared to non-H/L whites, the risk of diagnosed T2D is 66% higher among H/L.[4] The National Academy of Medicine (NAM) indicates that H/L experience a 50–100% higher illness burden and mortality from T2D than non-H/L whites and that T2D remains poorly managed.[4] The literature unequivocally shows that racial/ethnic minorities with T2D have poor access to healthcare and lower levels of T2D management.[9–12]

Diabetes Telehealth Management (DTM) improves important outcomes, such as glycemic management (GM) and quality of life (QoL). It is yet unknown whether these results generalize to Hispanic/Latino (H/L) disadvantaged populations with Type 2 Diabetes (T2D), primarily when utilizing community-based participatory research (CBPR)[26] approaches involving patients, caregivers, providers and other stakeholders in the process of adapting the intervention. The

proposed research has great potential to enhance evidence quality, empowering disadvantaged patients with T2D to make informed health decisions and improve outcomes. The study is designed to iteratively tailor DTM to the specific needs of the H/L patients, caregivers, and providers. It addresses several access issues consistently identified in disparities research and has the potential to improve adherence through increased engagement. Our goal is to compare DTM to comprehensive outpatient management (COM) on critical patient-centered outcomes. Both are based on 2018 American Diabetes Association (ADA) guidelinees.[25] We propose a multiphase mixed method,[27] CER RCT to:

Specific Aim 1: Assess usability of an evidence-based DTM intervention utilizing a CBPR approach[26] and adapt it to facilitate acceptability and feasibility in a population of H/L patients with T2D, and their caregivers and providers.

Specific Aim 2: Assess whether H/L patients receiving DTM attain significantly *improved* patient-centered outcomes compared to COM, through a CER RCT. *Expected outcomes* include *improved* diabetes QoL, GM, blood pressure (BP), cholesterol, medication adherence, and diabetes self-efficacy (SE), and *reduced* diabetes distress, problem areas in diabetes (PAID), inpatient utilization, unscheduled T2D physician visits and sick days.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Over half of Hispanic/Latino (H/L) patients will develop types 2 diabetes (T2D) during their lifetime.[1] According to the Center of Disease Control (CDC), T2D is a leading cause of suffering and death due to cardiovascular disease, end-stage renal failure, blindness, non-traumatic lower limb amputations, hospitalizations, and poor QoL.[2] The risk of dying for people with T2D is twice that of those without T2D.[1] In the US, the prevalence in H/L males 65-74 is 31.1%; for H/L females, it is 32.6%.[3] Compared to non-H/L whites, the risk of diagnosed T2D is 66% higher among H/L.[4] The National Academy of Medicine (NAM) indicates that H/L experience a 50–100% higher illness burden and mortality from T2D than non-H/L whites and that T2D remains poorly managed.[4] H/L patients with T2D have renal insufficiency rates 3 to 6 times greater than those of non-H/L white patients and

end-stage renal disease rates are 41% higher.[5–8] For H/L, the prevalence of diabetic retinopathy is 84% higher than that of non-H/L whites.[5,7] Compared to non-H/L whites, H/L Americans bear twice the risk of lower extremity amputation.[8] The literature unequivocally shows that racial/ethnic minorities with T2D have poor access to healthcare and lower levels of T2D management.[9–12]

Two 2016 systematic reviews, one based on 111 RCTs and another on 55 RCTs, both showed that DTM significantly improves GM; however, less than 25% of RCTs were conducted with ethnically diverse patients, which diminishes the external validity of the findings.[13–15] Polisena et al.'s meta-analysis of 26 studies also showed a positive effect on GM, noting that more research of higher methodological quality is required, and recommends including patients from diverse backgrounds to increase external validity and assess technology adaptation to optimize use among different populations.[16] Another meta-analysis which concluded that DTM improves GM, notes that studies *should utilize CBPR approaches* involving patients and caregivers to develop personalized interventions to enhance persistence in usage and treatment adherence.[17] Similarly, a 2017 overview of systematic reviews of mHealth T2D interventions found that they significantly reduce HbA1c when compared to COM.[18] However, few studies have examined mHealth technologies in patients from disparity populations or specifically tailored them to fit the cultural, linguistic, and other needs of underserved groups.[19] DTM programs have shown promise in improving GM in disparity populations.[20,21] The ADA recommends patient-centered management strategies for T2D,[22] but there has been no effort to date to specifically tailor a comprehensive, evidence-based DTM program to meet the needs of patients from H/L disparity populations. Interventions based on models that involve cultural, personal, caregiver and community factors and tailor care to patient preferences have been shown to have a higher probability of success.[23] Our research is germane to the NAM priority topics for CER, which recommends CER by comparing DTM and COM in managing chronic disease and enhancing medication adherence.[24] Although effective in the general population, we do not know how DTM should be tailored to the needs of H/L disparity patients. Our study seeks to fill critical knowledge gaps identified by meta-analyses, systematic reviews and the NAM, by directly comparing DTM to COM, an existing best practice based on 2018 ADA Standards of Medical Care in Diabetes.[25]

The proposed research has great potential to enhance evidence quality, empowering disadvantaged patients with T2D to make informed health decisions and improve outcomes. The study is designed to iteratively tailor DTM to the specific needs of the H/L patients, caregivers, and providers. It addresses several access issues consistently identified in disparities research and has the potential to improve adherence through increased engagement.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

Objectives:

Diabetes Telehealth Management (DTM) improves important outcomes, such as glycemic management (GM) and quality of life (QoL). It is yet unknown whether these results generalize to Hispanic/Latino (H/L) disadvantaged populations with Type 2 Diabetes (T2D), primarily when utilizing community-based participatory research (CBPR)[26] approaches involving patients, caregivers, providers and other stakeholders in the process of adapting the intervention. Our goal is to compare DTM to comprehensive outpatient management (COM) on critical patient-centered outcomes. Both are based on 2018 American Diabetes Association (ADA) guidelinees.[25] We propose a multiphase mixed method,[27] CER RCT to**:**

<u>Specific Aim 1:</u> Assess usability of an evidence-based DTM intervention utilizing a CBPR approach[26] and adapt it to facilitate acceptability and feasibility in a population of H/L patients with T2D, and their caregivers and providers.

<u>Specific Aim 2:</u> Assess whether H/L patients receiving DTM attain significantly *improved* patient-centered outcomes compared to COM, through a CER RCT. *Expected outcomes* include *improved* diabetes QoL, GM, blood pressure (BP), cholesterol, medication adherence, and diabetes self-efficacy (SE), and *reduced* diabetes distress, problem areas in diabetes (PAID), inpatient utilization, unscheduled T2D physician visits and sick days.

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

The specific population affected by the research is underserved T2D patients. Our estimated sample size is 200 patients (240, assuming a 10% attrition rate). We propose to study H/L patients with T2D, recruited from the Ambulatory Care Unit at LIJMC and the Division of General Internal Medicine Practice located in Queens NY, one of the most diverse populations in the world. We also propose to recruit at Southside Hospital. NUMC and Glen Cove Hospital as well as the Dolan Family

Health Center. We selected these sites because 1) clinic patient statistics meet our enrollment criteria, with 4,092 adults H/L patients with T2D (well over the 200 recruitment number required). 2) clinicians at these sites express enthusiasm for/commitment to the study and what it might mean for their H/L patients with T2D. These sites provide a real-world setting for implementation because LIJMC is where our target population of H/L disparity patients with T2D (many with limited English proficiency) receive their care (H/Ls comprise 27.5% of Queens' population).

Staff have all reviewed and been trained on methods for the study outlined in the protocol. There will be an initial kick off meeting to discuss the protocol in further detail. They have all completed CITI training and compliance for HIPPA data.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

To limit selection bias, and ensure true random selection, our Biostatistics Unit will randomly (using a random number generator) sample 400 patients from the 4,092 total patients.

Recruitment: The bilingual study RN, Multisite Patient Engagement Specialist or study coordinator will be responsible for recruitment at the various study sites. Given COVID-19 pandemic we will also be calling be patient over the phone to recruitment.

Recruitment for Data Collection: Eligible patients will be approached and called for consent (consent form 1) to have longitudinal data collected, including surveys at specified time points over the 12 months of their participation. Patients who are called will be give verbal consent. Next, bilingual study RN, Multisite Patient Engagement Specialist or study coordinator will obtain the randomization number from the Biostatistics Unit for the patient to determine if they were allocated to the DTM arm or COM arm. If the patient is randomized into the DTM arm, the recruiter will approach to obtain a second consent (consent form 2) to receive DTM. Verbal consent will be given for patients who are called for recruitment.
Informed consent will include a detailed but simple description, in patient's preferred language, of study risks/benefits.
Recruitment for DTM: Eligible patients will be approached or called for consent (consent 1) to have longitudinal data collected, including surveys at specified time

points over the 12 months from signing consent, in order to determine health outcomes. Next, the research coordinator will obtain the randomization number for the patient to determine if they were allocated to the DTM arm or COM arm. If the patient is randomized into the DTM arm, the coordinator will approach to obtain a second consent (consent 2) to receive DTM.

Informed consent for DTM will include a detailed description, in English and Spanish, of the risks and benefits of the study with user-friendly images of the equipment. If the patients decline to participate in DTM, they will continue to receive standard of care and still have surveys administered and data collected over time (as agreed to in consent 1). Based on intention to treat (ITT), they nevertheless will be analyzed as part of the DTM group.

For those patients randomized to DTM, the RN will explain to the patients that if they agree to participate, they will be asked to measure vital signs daily, receive weekly telehealth “visits” with the telehealth RN (with appropriate assurances regarding confidentiality), and receive reminders of their weekly visits. The experienced bilingual RN will be trained in the proper recruitment of patients to eliminate selection bias based on a standardized protocol. The research RN will also explain to the DTM patient that s/he will have a bilingual trainer meet them at their home and that they will receive training on how to properly use the equipment.

For those patients randomized to COM, the research RN will have monthly phone contacts to determine how the patient is doing, how many days during the week they have been sick, and whether they have been to an unscheduled doctors visit, the ED or hospital during the last month and how many days they have been sick. Lastly, in both groups, the enroller will let patients know that they will be asked to complete pre and post surveys. The enroller will be trained on the proposed enrollment practices to ensure objective, unbiased and systematic selection and recruitment of participants.

DTM patients will be asked if they prefer to involve their caregiver; if patients agree, caregivers will be provided with the caregiver app (Figure 3). The bilingual enroller will explain to DTM patients that they will provide DTM training at their home.

We propose to study H/L patients with T2D, recruited from the Ambulatory Care Unit at LIJMC and the Division of General Internal Medicine Practice located in Queens NY, one of the most diverse populations in the world. We also propose to recruit at Southside Hospital. NUMC and Glen Cove Hospital as well as the Dolan Family Health Center. We selected these sites because 1) clinic patient statistics meet our enrollment criteria, with 4,092 adults H/L patients with T2D (well over the

200 recruitment number required). 2) clinicians at these sites express enthusiasm for/commitment to the study and what it might mean for their H/L patients with T2D. These sites provide a real-world setting for implementation because LIJMC is where our target population of H/L disparity patients with T2D (many with limited English proficiency) receive their care (H/Ls comprise 27.5% of Queens' population).

Due to COVID-19 pandemic, we are also requesting patients be enrolled into the study via telephone by providing us with verbal consent. Surveys and questionnaires will be performed over the phone in the preferred language of the participant.

For patients reaching 6 month or 12 month follow-up during this time, interviews and surveys/questionnaires will also be collected over the phone.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

The specific population affected by the research is underserved T2D patients. Our research is designed to determine whether DTM improves important patient outcomes in H/L disparity patients.

Participant subgroups. The selection of our caregiver status subgroups (Y/N) is based on potential impact of having vs. not having a caregiver participate and discussions with stakeholders.

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria: 1) H/L patients with a diagnosis of T2D alone or in combination with other chronic conditions (e.g., heart disease); 2) age > 18 speak English or Spanish.
Caregivers age >18 taking care of a patient with T2D alone or in combination with other chronic conditions.
Providers who treat patients with T2D alone or in a combination with other chronic conditions

Exclusion criteria: 1) patient is not a H/L with a diagnosis of T2D; 2) age <18.
Identification of study participants: There are 4,092 H/L patients with T2D fitting our inclusion criteria.
Caregivers age <18 who do not take care of a patient with T2D or in combination with other chronic conditions
Providers who do not treat patients with T2D alone or in a combination with other chronic conditions.

Our goal is to enroll 224 (240, assuming a 10% attrition rate) patients/20-months. With a 50% acceptance rate (estimated on our previous enrollment experience), we will need to approach 400 total patients (or 20/month) to enroll 12 patients per month, easily reaching our goal of 224 participants over the 20-month accrual period.

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

For the pilot test in Aim 1, we will have 12 subjects. For the RCT in Aim 2, we will randomize 224 patients. We plan to consent 224 patients assuming there will be a 10% attrition rate.

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

Participants in the pilot study will be involved for 2 months. For one month they will pilot the equipment and in the 2nd month they will be involved in a focus group or semi-structured interviews. Participants in the RCT will participate in the trial for 12 months. See page 11 of the protocol for study timeline

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

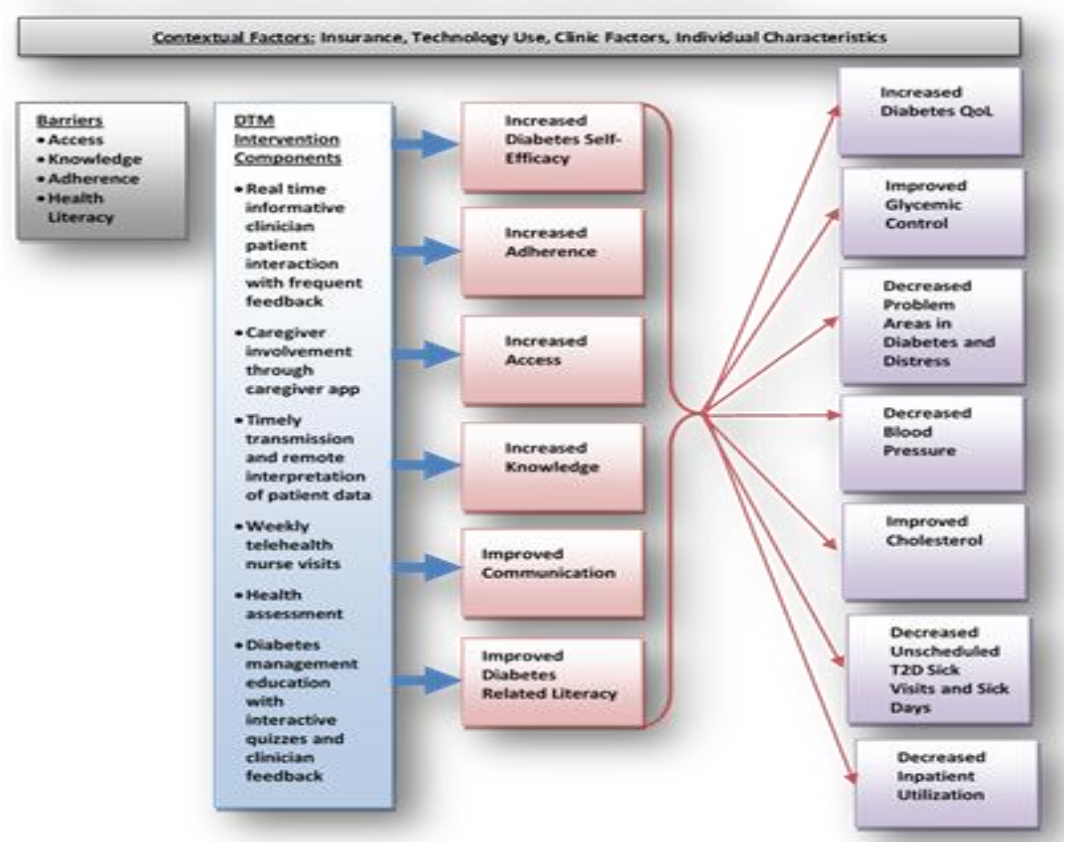
11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

We propose a multiphase mixed method,[27] CER RCT study to 1) assess DTM usability, focusing on patient/stakeholder input to adapt the intervention to facilitate acceptability and feasibility and 2) conduct a CER RCT to compare DTM to COM in H/L patients on critical patient-centered outcomes. DTM addresses many barriers facing T2D H/L disparity patients. DTM increases **Access**, as patients are seen at home, with less travel. **Knowledge**: T2D education, in English and Spanish, is a cornerstone of DTM, incorporating ADA educational modules to model successful T2D management behaviors and interactive quizzes to enhance education engagement (Figure 2 Bottom). The patient is actively involved in measuring vital signs daily and discussing how behavior affects results. **Adherence:** Culturally tailored DTM actively involves the patient in measuring vital signs and participating in tele-visits, resulting in higher treatment adherence. Our CAB discussions, focus groups, interviews, and previous literature strongly indicate that the proposed caregiver app (Figure 3) has real potential to increase patient engagement/adherence in a family-oriented population.[28,29] **Health literacy**: Tailored educational videos, quizzes and frequent interaction with the DTM nurse provide many opportunities to improve T2D health literacy. Previous studies show that T2D patients with low health literacy receiving tailored messaging are more likely to reach their HbA1c goal.[30] **Theoretical Framework.** Our methodology is well grounded in theory (Figure 1). The concept of self-efficacy (SE), stemming from social cognitive theory, is critical in chronic care management.[31] SE beliefs are patient thought patterns that influence health behavior, including whether particular behaviors are initiated, effort used and sustained while experiencing impediments to progress. Health behavior requires confidence in the ability to self-regulate using strategies such as goal setting, planning, and self-monitoring.[31] There are 4 ways to increase SE:[31,32] **1) Mastery experiences**, the strongest predictor of SE, relates to actual performance when successfully meeting a challenging task. Patients with T2D performing daily health behaviors and seeing progress experience mastery. **2) Vicarious modeling** (seeing others facing similar

challenges and reaching their goals) will be achieved by showing patients ADA educational modules of similar H/L patients attaining GM. **3) Social persuasion** (verbal encouragement) is provided by the RN and caregiver using DTM. **4) Physiological factors,** such as anxiety and distress, are experienced by patients when they fail to manage symptoms; the RN/caregiver can interpret this as temporary-not associated with overall success. The ADA recognizes SE as critical in improving T2D management and recommends SE assessment in interventions.[33–36] SE predicts improved GM and is particularly important in disparity patients, who must overcome many barriers to T2D management.[36–38]

Figure 1. Conceptual Model of Diabetes Telehealth Management



Comparators: **1. Intervention: Diabetes Telehealth Management (DTM),** based on the 2018 ADA Standards for T2D, uses smart devices to share information between patients, caregivers, and clinicians**.** DTM has 7 components that differentiate it from COM (Table 1): **1) real time informative clinician patient video interaction**; **2) frequent vital signs discussion; 3) frequent diabetes management discussion; 4) timely vital signs/physiological data transmission/interpretation** (e.g., GM, automatically transmitted and reviewed by the clinician daily); **5) a weekly "virtual" visit**, wherein clinicians can "re-check" vitals, and discuss prior week's data in relation to medication, nutrition, and exercise, further involving the patient in their care; **6) patient interactive educational videos and "teach back" quizzes**, reinforcing self-management strategies involving diet, exercise, medication adherence, and stress management. Quiz results are transmitted to telehealth RN who can address knowledge gaps, and **7) a caregiver app with supportive capability** (Figure 3). With patient permission, caregivers will be able to see vital signs data in real time remotely, enhancing engagement and treatment adherence. The caregiver app is based on interviews and focus groups with patients, caregivers, and our CAB and informed by the literature. As increasing numbers of patients with T2D live alone, integrating caregivers in DTM facilitates increased patient adherence to treatment.[39,40] Patients receive a smartphone/tablet (Figure 2, Top), and Bluetooth enabled peripherals (calibrated BP cuff and scales) facilitating easy measurement and transmission of vital signs to clinicians. We propose to use patient-centered management guidelines **based on the 2018 ADA Standards**[25] (See Appendix 2). The ADA recommends that caregivers providing support for older adults with T2D should be included in management discussions[35]. The DTM nurse will work closely with the physician, particularly when readings are outside normal range/medications require adjustment. DTM can help clinicians address patient health from indicators (e.g., BG, hypertension and depression).[41]

Table 1. Proposed Timing of Measures & Comparator Components: DTM and Com

Measures	DTM	COM
Diabetes Quality of Life	Months 1, 6	Months 1, 6
HbA1C (Primary Outcome Variable)	Months 1, 3, 6	Months 1,3, 6
Medication Adherence	Months 1,6	Months 1,6
Diabetes Management Self-Efficacy	Months 1,6	Months 1,6
Diabetes Distress	Months 1,6	Months 1,6
Problem Areas in Diabetes Questionnaire	Months 1,6	Months 1,6
Patient Engagement	Months 1,6	Months 1,6
Telehealth Satisfaction and Usefulness Questionnaire	Month 6	None
Medical Outcomes Study (MOS) Social Support Survey	Months 1,6	Months 1,6
Unscheduled T2D sick visits & number of sick days	Weekly	Monthly
Lipid profile	Months 1,3,6	Months 1, 3,6
Weight	Daily	Every 3 months
Blood pressure	Daily	Every 3 months
Glucose Levels	Daily/MD Advise	Daily/MD Advise
Inpatient Utilization	Daily	Every 3 months
Hypoglycemia Episodes (blood glucose <70)	Weekly	Every 3 months
Comparator Components	**DTM**	**COM**
Based on 2018 ADA Standards	Yes	Yes
Real time informative clinician patient video interaction with frequent feedback	Yes	No
Vital signs discussion	Weekly	Every 3 months
Diabetes management discussion	Weekly	Every 3 months
Timely transmission and remote interpretation of patient data	Yes	No
Telehealth nurse visit	Yes	No
Comprehensive health assessment	Yes	Yes
Diabetes management education with interactive quizzes and clinician feedback	Yes	No
Caregiver involvement through caregiver app	Yes	No

- **Figure 3. Caregiver**

Process Evaluation for Complex Intervention. We will assess health literacy, as measured by the *Short Assessment of Health Literacy–Spanish and English (SAHL–S&E),* at baseline and 6 months, and again at 12 months, to assess our **hypothesized causal pathways. Participants who reach 6 months or 12 month follow up during the COVID-19 pandemic, will have data on secondary outcomes collected via phone for both groups. Participants will give verbal consent for outcomes to be**

collected. Our proposed mediator is a continuous variable; we will conduct mediation analyses using PROC CAUSALMED in SAS.

Comparator: Comprehensive Outpatient Management (COM) is the most realistic evidence-based comparator, in that it is the most frequently recommended and used option for US T2D patients. COM, like DTM, is consistent with the 2018 ADA Standards which include, but are not limited to, past medical and family history, social history, medications, screening, physical examination, laboratory evaluation, etc.[25,42] We will measure adherence to these standards using a chart review checklist to assess issues of fidelity and differential adherence. Patients are instructed to monitor BG (within physician recommendations) BG monitoring will individualized throughout the study. Frequency of BG monitoring will vary depending on medication, A1c readings, sick days and stress levels, and have routine or "well" visits every 3 months. Patients can set appointments with a T2D educator. COM patients will receive monthly calls from the study RN to collect data. In the "real world," COM patients would not receive such calls; however, to maximize retention, this will favor our outcomes *toward the null hypothesis*, thereby increasing our confidence in intervention effects of DTM relative to COM. **Formal Study Protocol.** We have initiated formal protocol development. It will include our research objectives, design, outcomes, and detailed analytical methods. We will provide internationally standardized data dictionaries, final study protocol documents, data sheets, study population descriptions, covariates used in analyses, discussion guides and qualitative research coding information and any other original materials that facilitate study replication along with the first 12-month progress report, and within 3 months of the end of the funding period. We understand that PCORI reserves the right to share our materials with other researchers. If funded, our work will be available for evidence synthesis, at http://www.crd.york.ac.ok/prospero/ and our clinical trial will be registered at www.clinicaltrials.gov. **Stakeholder Engagement.** Consistent with PCORI's engagement rubric, **there are five ways in which patient/stakeholder input has been and will continue to be critical (See Figure 5: Stakeholder Engagement) 1. Community Advisory Board** will ensure that DTM and outcomes have relevance for patients and provide the study team with stakeholder perspectives, tailoring, implementation, and evaluating DTM. The CAB will lead the discussion on study outcomes, adaptation, usability, program satisfaction, and dissemination, and will review and approve the study protocol and resolve issues to ensure project success. For example, the CAB of our previous PCORI study identified a barrier ("fear of undocumented patient identification via weekly video visits") and strongly recommended that the study team develop appropriate enrollment process protocols. We will use a similar strategy for this current proposal. Engagement will depend on the issue at hand; stakeholders bring different skills to the CAB (e.g., community dissemination of study results may be led by our H/L CBO representative, as she has expertise in this area, particularly with NY H/L media). ***See Research Team and Environment for details on CAB stakeholders and their expertise***. Stakeholders bring different skills to the CAB (e.g., community dissemination of study results may be led by our community representatives and legislators, as they have expertise in this

area, particularly with NY H/L media). Regarding dissemination of study findings, we will have a discussion led by the policy and finance stakeholders toward the end of the project period to address methods to disseminate study results. CAB members will use the knowledge generated through the research to make informed decisions about policies, programs, and practices and contribute to dissemination discussions, with particular expertise in H/L communities in Queens, NY. **2. in-depth semi-structured interviews** with patients have been a critical approach to shaping DTM thus far. Interviews with H/L disparity patients who have agreed to serve on our study team were conducted to identify and prioritize disease management barriers and facilitators encountered by H/L T2D disparity patients. Due to COVID-19 semi-structured interviews will be done over the phone. Phone interviews will last 45 minutes to an hour. Participants will give verbal consent to be audio recorded.

Caregivers are a vital part of the patient care. Research has shown that patients with caregivers are more likely to adhere to disease management practices. Caregivers will play a vital role in the study in the following ways.

a) ***Focus Groups****: at the start of the study during our CAB meetings we will be inviting a few caregivers in to assist us with developing the intervention for the Hispanic/Latino population. At this point we will be consenting caregiver participants with the focus group consent forms (see attached) including audio consent forms (see attached).*

b) ***Usability – pilot study:*** *We will also conduct a one month, in-home pilot study with 12 patient/caregiver dyads. Focus groups and structured interviews will be subsequently undertaken to obtain "in the home" user feedback regarding any barriers to implementation or usability suggestions to further adapt the intervention before the RCT commences.*

c) ***Use of the Caregiver App****: With patient permission, caregivers will be able to see vital signs data in real time remotely, enhancing engagement and treatment adherence. In this case the patient will consent that the caregiver may see their data- however, the caregiver will not require consent.*

d) ***Exit quality interviews:*** *Patients and caregivers in the DTM arm who complete the 6-month intervention or drop out of the CER RCT study will be asked to provide feedback on their experiences. The caregiver will not be consented to take part in the qualitative exit interviews, but will receive an information sheet that will detail what we will ask them.*

e) ***Caregiver usability app and engagement:*** *We will assess engagement as number of minutes/day spent on the smart device and number of minutes/each component of the app (e.g., educational videos).*

Our Community Advisory Board (CAB) consists of the study team, community members, health care practioners, health policy experts, subject matter experts, patient advisory committee and provider panel. Throughout this study, the CAB will be meeting 9 times, however, only three of those times we will be conducting focus groups. Our first CAB meeting will be a focus group (pre-pilot). During this time, the CAB will be broken down into three groups, each of which will participate in a focus group: 1. The Main CAB focus group, which will include all participants. After conducting the Main CAB focus group, the CAB will separate into two groups. 2. The Patient Advisory Comittee (PAC) Focus Group and 3) The Provider Focus Group. This CAB meeting will be to discuss adaptation to outcomes, intervention and study design. Participants will be consented to be in the Focus Groups and then consented to be audio recorded.

We will implement the recommendations from the CAB and then conduct a pilot study. After the pilot study, we will conduct our Third CAB meeting to discuss adaptations to outcomes, intervention and study design. See table below for further information:

Name	Description and Additional Information
1. CAB Focus Group # 1 (preliminary pre-pilot)	Focus groups with CAB to disucss adaptations to outcomes, intervention and study design.
a. PAC Focus Group (pre-pilot)	Focus group with PAC members to discuss adaptations to outcomes, intervention and study design
b. Provider Focus Groups (pre-pilot)	Provider focus group to tailor the intervention from the provider perspective
2. CAB focus group # 2 (pre-pilot)	Preliminary Adaptions combining CAB & PAC guidance presented to CAB. Provide summary of findings to PCORI.
a. PAC Focus Group (pre-pilot)	Focus group with PAC members to discuss adaptations to outcomes, intervention and study design
b. Provider Focus Groups (pre-pilot)	Provider focus group to tailor the intervention from the provider perspective
Patient/Caregiver Pilot Study	Recruit 12 patients and their caregivers to participate in pilot study, randomize to either DTM or COM
c. CAB Focus Group (post – pilot)	Conduct focus group with CAB to confirm adaptations to post-pilot study
a. Patient Focus Group (post – pilot)	Conduct focus group or structured interview with pilot patients PAC to confirm adaptations post-pilot
b. Provider Focus Group (post –pilot)	Conduct provider focus with providers to tailor the intervention from the provider perspective

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*

- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

Specific Aim 1: Assess usability of an evidence-based DTM intervention utilizing a CBPR approach[26] and adapt it to facilitate acceptability and feasibility in a population of H/L patients with T2D, and their caregivers and providers.

-

We will assess usability at Northwell's Usability Lab through the examination of qualitative and quantitative usability indicators. The ADAPT-ITT framework, developed by Winwood and DiClemente, and previously used by the PI to tailor a CHF telehealth intervention for disparity patients, will be used to engage stakeholders in adapting DTM.[43,44]

1a. Qualitative approach. We will assess indicators of usability to facilitate feasibility and acceptability in four stages. **1) We will analyze focus group sessions** of crucial CAB stakeholders (patients, caregivers, community partners and patient advocates, CBOs, healthcare practitioners, and disparities experts) using qualitative analytic methods. **2) We will conduct theater testing** of the evidence-based intervention (smart device, Bluetooth-enabled peripherals, and the caregiver app) with the CAB, provider panel, and PAC. **3) We will conduct a pilot and post-pilot focus groups or structured interviews** with 12 pilot study patient/caregiver dyads receiving DTM and our PAC, CAB, and provider panel. **4) We will conduct semi-structured exit interviews** of patients and caregivers in the DTM arm.

1ai. Pre-study acceptability/usability (stakeholder perspective). Qualitative methods (focus groups) will be used to tailor DTM to ensure patient and caregiver acceptability and feasibility from the CAB. The CAB will consist of individual patients with T2D, caregivers, and individual advocates within the community. Patient stakeholders in the CAB are demographically and geographically representative of the targeted outpatient population. We will conduct as many sessions as needed to reach data saturation. CAB members will be presented with the intervention (in English and Spanish) including its core components (non-adjustable components) as well as essential characteristics that can be adjusted. CAB members will be compensated $50 for their time plus transportation costs. Focus groups will occur before theater testing and the pilot study to ensure that we have incorporated all feedback. Based on previous experience, we have addressed some adaptation issues (e.g., Spanish translation in various dialects; having a fluent in Spanish study RN).

1aii.Theater testing. After the CAB completes the community needs assessment and reviews DTM components, DTM will be theater tested at Northwell's Usability Lab with the PAC, patients, and caregivers. The PAC will intentionally meet separately from the CAB to remove any influence from stakeholders (e.g., clinicians) that might be intimidating to patients. The PAC will theater test every screen, all patient and caregiver engagement activities (e.g., educational modules/videos), and smart device configurations (e.g., speed of speech and language translation) to ensure usability. Similarly, a provider-only focus group will be held to ensure that DTM is tailored to facilitate usability for providers.

1aiii. Usability (pilot patient/caregiver/provider perspectives). We will also conduct a one month, in-home pilot study with 12patient/caregiver dyads. Focus groups or structured interviews will be subsequently undertaken to obtain "in the home" user feedback regarding any barriers to implementation or usability suggestions to further adapt the intervention before the RCT commences. The pilot for COM patients will assess the feasibility of extracting all measures identified in Table 2. Similarly, provider usability will be evaluated to ensure DTM is acceptable and feasible. Participants will be compensated $50 for their time/travel plus pre/post-test completion ($100). Discussion topics include (but are not limited to) the following: 1) patient and caregiver perceptions of the ease of the study implementation; 2) patient and caregiver perceptions of intervention usefulness; 3) patient and caregiver input on barriers/challenges to DTM implementation, including the impact of DTM on the caregiver/patient relationship; and 4) suggestions for improvements/adjustments.

Table 2.

Outcome Domain	Scale name or measurement method	Characteristics of scale/ test	Psychometric properties	Patient involvement in scale/test development
Patient satisfaction with telehealth program	Telehealth Satisfaction Questionnaire (TSQ) (modified from Yip et al)[76]	15 questions to assess patient satisfaction with the receipt of health-care via telemedicine.	There were three components with eigenvalues over 1.0, which together explained 68% of the total variance. These were: quality of care provided, similarity to face-to-face encounter and perception of the interaction.The internal consistency of the TSQ was 0.93, indicating strong correlations between the 15 items comprising the scale. Internal consistency above 0.7	Validated in 38 patients 40-70 yearswith .
Caregiver support	Rand modified Medical Outcomes Study (mMOS-SS) Social Support Survey scale (Short Form)[95]	8Items: emotional/ informational, tangible and affectionate, social support	Across populations, the internal reliability of the mMOS-SS measure was very good (Cronbach's alpha: Boston 0.88, UCLA 0.92, MOS 0.93, item-total correlations ≥0.67).	A total of 3,241 women with complete mMOS-SS and MOS-SS data (complete cases) from three individual study populations in the United States:
Diabetes QoL	Diabetes Quality of life Brief Clinical Inventory (Messina et al.,)	15 items measuring diabetes care behaviors and satisfaction with diabetes control	internal consistency (r = 0.78–0.92), test retest reliability (r = 0.78–0.92), and convergent validity for all four subscales for people with type 1 and type 2 diabetes.	498 respondents, 32% had type 1 diabetes, and 68% had type 2 diabetes, female (53%), and ages for respondents ranged from 21 to more than 80 years, with a median of 51 years.
HbA1c	Laboratory testing	Glucose control over 3 months	N/A	Standard laboratory test
Medication adherence	Adherence tp Refills and Medications Scale –Diabetes (ARMS-D) (Mayberry et al.,)	11 items assessing medication adherence in patients with T2D	Item-rest correlations ≥0.30 and Cronbach's α≥0.70	314 adult outpatients prescribed medications for type 2 diabetes and collected point-of-care HbA1C.
Diabetes management self-efficacy	Standford Diabetes Management Self-Efficacy Scale[80]	8 items measuring confidence in managing diabetes	One main factor (.828)	186 patients with diabetes. (α= .85) and a test-retest validity of .80
Hypoglycemia Episodes (blood glucose <70)	Fingerstick, or reported symptoms	Amount of glucose in the blood.	N/A	Standard laboratory test (In light of COVID-19, patients will have the option of LabFly or Point of Care testing (POC).
Blood glucose testing adherence	Number of times patient adheres to recommendations	BG testing is compared to physician recommendations.	N/A	N/A
Problem Areas in Diabetes	Problem Areas in Diabetes Questionnaire[82]	Problem areas that diabetics may experience.	PC identified a large emotional adjustment factor for total score.	256 volunteer diabetic outpatients
Patient Engagement	Patient Activation Measure[77,78]	Patient skill and confidence in managing health/care	Rasch person reliability .85 -.87. Cronbach's alpha was .87.	Validation study with a sample of 1,515 patients with chronic illnesses
Patient Distress	Diabetes Distress Scale (DDS 17)[45]	Problem areas/distress	Internal reliability was α = 0.87;	Validation with diverse patients
Health Literacy	Validation of Self-Reported Health Literacy Questions Among Diverse English and Spanish-Speaking Populations	Health literacy	The "confident with forms" question performed best for detecting inadequate (C-index = 0.82, (0.77-0.87)) and inadequate plus marginal HL (C index = 0.81, (0.76-0.86); p < 0.01 for differences from other	Of 296 participants, 48% were Spanish-speaking; 9% were White, non-Hispanic; 47% had inadequate HL and 12% had marginal HL.

			questions), and performed comparably to the summative scale. The "confident with forms" question and scale also performed best across language, race/ethnicity, educational attainment, and age	
Weight	Weight scale	Bluetooth enabled weight	N/A	N/A
Blood Pressure	Blood pressure cuff	Bluetooth enabled BP cuff	N/A	N/A
Lipid Profile	Laboratory testing	LDL, HDL, total cholesterol	N/A	Standard laboratory test
Inpatient utilization	Chart review and weekly/monthly phone calls	Hospitalization (Y/N); number of hospitalizations; cumulative length-of-stay	N/A	Patient-reported (with EHR review verification)
Unscheduled T2D sick visits and number of sick days n	Weekly video visits (DTM) and monthly phone calls (COM)	Patient ≤1 unscheduled sick visit; # of unscheduled T2D sick visits and days sick.	N/A	Patient-reported

* The study team will inform the Labfly members to have proper precautions when they coming to subjects' home to do the lab work.

1aiv. Exit qualitative interviews. Patients and caregivers in the DTM arm who complete the 6-month intervention or drop out of the CER RCT study will be asked to provide feedback on their experiences. Through semi-structured phone interviews conducted by experienced qualitative researchers and recruitment specialists (in English and Spanish), we will assess patient/caregiver perceptions regarding intervention usefulness, feasibility/usability and identify particularly essential components.

Qualitative procedure and analysis: Due to COVID_19 we will be conducting semi-structured phone interviews for each qualitative sub-aim, . Each focus group or structured interview will take about two hours and will be conducted in a private room at 600 Community Drive. All discussions will be guided by predetermined topics outlined in the interview guide (see Appendix 1), audio recorded (using two digital voice recorders) and professionally transcribed. Focus group and semi-structured interview transcripts will be analyzed according to Auerbach and Silverstein's grounded theory approach.[45] We will use NVivo software (QSR International, Inc.) for data storage/organization to improve procedure standardization and enhance completeness. Three researchers will conduct coding so that we can assess triangulation and achieve a broader and more complex understanding of the data. In the first phase, a team of coders (Dr. Williams, Dr. Kozikowski, and Dr. Patel) will independently read transcripts and highlight relevant text. They will describe their reasoning for coding a particular block of text by memo-ing to make explicit how they perceived, examined and developed their understanding of the data as well as its source in transcription. Concepts identified by at least two participants will be grouped into repeating ideas and categorized into themes to create an initial list of codes. In the second phase, the three coders will use this initial list to code each transcript and add new codes as needed. Coders will meet weekly discuss transcripts and resolve discrepancies between coded data. Codes will be compiled into themes and reviewed to ensure that quotations fit under the same code and to ensure accuracy. We will keep an audit trail throughout the coding process to document decision-making and support trustworthiness and dependability of the data.[46] Respondent validation will be implemented to improve accuracy, validity, and transferability. Participants will be shown an analysis summary and asked if it accurately represents their meanings/perspectives. Central themes will specify any necessary adaptation that should occur to increase the usability and acceptability of DTM.

1b. Quantitative approach. This adaptation phase involves an ongoing formative process evaluation of usability using quantitative methods so that adjustments can be made as DTM is implemented. Below is how we will operationalize usability measures. **The first two usability variables will be collected upon subject enrollment in the RCT:**

1bi. Rate of acceptability. To simulate the rate of DTM acceptability in the real outpatient environment, we propose to determine, among those who DO NOT consent to be part of the study, the proportion who state that their reason is related to the technology (as opposed to those who simply do not want to be part of a study). This will allow us to compute the "acceptability rate" (as opposed to "acceptance rate" below). Data from other studies most similar to the intervention proposed herein indicate that telehealth acceptability in a general population may be as high as 96%.[47] As acceptability may be different for the H/L disparity population, it is important to measure. Assuming the probability of acceptability in disparity populations is significantly lower (50% rather than 96%) and a total of 200 (240, assuming a 10% attrition rate) patients will need to be randomized (100 per arm) then, approximately 400 patients will need to be approached to yield 200 who consent to enroll. The actual acceptability rate will be calculated as X/200. Assuming the rate=50% and n=200, acceptability rate can be estimated to within +/- 7.1% using (95% CI for proportions).

1bii. Rate of equipment acceptance: Of those randomized to DTM, the rate of "acceptance" will be the % of patients who accept the app and peripherals. We will randomize 200 patients (240, assuming a 10% attrition rate), to yield a maximum of 100 patients per arm/3 years, the maximum number that can be treated with DTM over 6 months. Assuming 90% of DTM patients will constitute the usability sample, DTM acceptance is estimated +/- 6% (95% CI for proportions). ITT analysis will include all patients randomized to DTM. **The following usability variables will be collected during and upon completion of RCT:**

1biii. Patient vital signs measurement adherence (BP, BG, weight). We propose 3 levels of adherence. "Minimal" is ≤ 45 measurements/180 days; "Moderate"= 46-90 measurements/180 days, and "High"=91-180/180 days. Only the first daily reading will count toward adherence. All measures will be prorated for patients who die/hospitalized during the study. With n=100, adherence rates can be estimated to, at worst, +/- 10% (95% CI).

1biv. Total number of telehealth visits completed: We will compute the proportion of scheduled visits kept; if a patient is followed for *w* weeks, there should be *w* scheduled visits. If the number of scheduled visits kept is denoted by *v*, then the proportion of scheduled visits kept = *v/w*. Visit participation rates will be averaged across patients; the mean rate will be computed, along with 95% CI. There is a maximum of 24 possible televisits over the 6-month study period.

1bv. Patient and caregiver usability measure: Usability will be measured with the Telemedicine Satisfaction and Usefulness Questionnaire[48] to elicit a total usability score dichotomized into satisfied/not satisfied. For satisfaction rates of 50%, 75%, and 90%, with a sample size of 100, the corresponding 95% CI will have precision of +/- 10%, 8.7%, and 6%.

1bvi. Caregiver app utilization (for patients with caregivers participating): We propose two levels of app utilization: "Low" is, at most, once a week app utilization for any 12/24 weeks. "High" is at least once a week app utilization for ≥ 13/24 weeks. We expect that at least 50% of patients will have caregivers that agree to participate; with this sample size, rates of adherence are estimated, at worst, +/- 14%, with a 95% CI.

1bvii. Patient and caregiver engagement. We will assess engagement as number of minutes/day spent on the smart device and number of minutes/each component of the app (e.g., educational videos). Patient engagement in both groups will be measured using the 13-item Patient Activation Measure (PAM).[49,50] With n=200, and an established SD=10[51] the standard error of the mean = .71, resulting in a 95% CI for the mean with precision of +/- 1.4.

Specific Aim 2: Assess whether H/L patients receiving DTM attain significantly *improved* patient-centered outcomes compared to COM, through a CER RCT. Expected outcomes include: *improved*

diabetes QoL, GM, BP, cholesterol, medication adherence, and diabetes SE, and *reduced* diabetes distress, PAID, inpatient utilization, unscheduled T2D physician visits and sick days.

Primary Analysis for Aim 2. Our primary outcome, the basis of our sample size calculation, is change in HbA1c for DTM relative to COM from **baseline to 180 days**. We will use the modified Zelen RCF method. For this continuous data, we will use mixed models repeated measures analysis of covariance (ANCOVA) (SAS 9.4; SAS Institute, Cary, NC) to compare the change in pre-post DTM HbA1c with the change in pre-post COM HbA1c, adjusting for caregiver status (Y,N). In keeping with ICH E9 statistical principles for clinical trials (V.7G) with a stratification variable, the interaction term for treatment x caregiver status will be included in the primary analysis, as well as main effects for treatment and caregiver status. Upon finding a significant treatment x caregiver interaction, treatment effects will be estimated separately for those with and without a caregiver (using ANCOVA for unequal slopes).

Secondary Analyses for Aim 2. Our secondary outcomes measure whether, relative to COM, the intervention: 1) **Decreases HbA1c over time** (baseline to 90 days to 180 days); 2) **Decreases hypoglycemia episodes** (BG<70) as measured by finger stick or reported symptoms; 3) **Increases adherence**, measured in 3 ways: **i.** Number of finger stick tests performed/6 month study period relative to physician recommendation. COM patients will receive a ReliOn Ultima glucometer which saves in memory up to 450 tests; to capture all finger stick tests (i.e., beyond 450), the research RN will reset the monitor every 90 days to allow for continued monitoring. For DTM subjects, the smart device will collect this data daily; **ii. ii.** Adherence to Refills and Medication in Diabetes (ARMS-D), validated in diverse populations;[52] 4) **Increases diabetes SE**, or confidence in managing 39;75 6) Decreases distress related to T2D using the validated 7) Decreases problem areas in diabetes (PAID scale,76 a 5-item validated measure of emotional functioning in diabetes); 8) Decreases weight, if physician recommended, from baseline-180, captured by a Bluetooth weight scale; 9) Improves cholesterol (total cholesterol/HDL ratio (e.g., from baseline to 90 days to 180 days); 10) Decreases BP, using a calibrated Bluetooth enabled BP cuff. Outcome 1 will be analyzed with mixed models repeated measures ANCOVA corresponding to days 0, 90 and 180. Outcome 2 will be analyzed using standard methods of Poisson regression (SAS PROC GENMOD, with corresponding to days 0, 90 and 180. Outcome 2 will be analyzed using standard methods of Poisson regression (SAS PROC GENMOD, with caregiver status as covariate and, adjusted for over dispersion, if indicated). Outcome 3i will utilize ANCOVA. Outcomes 3ii will utilize logistic regression. Outcomes 4-10 will be analyzed using ANCOVA models similar to the one used for the primary outcome. If necessary, appropriate data transformations will be made.

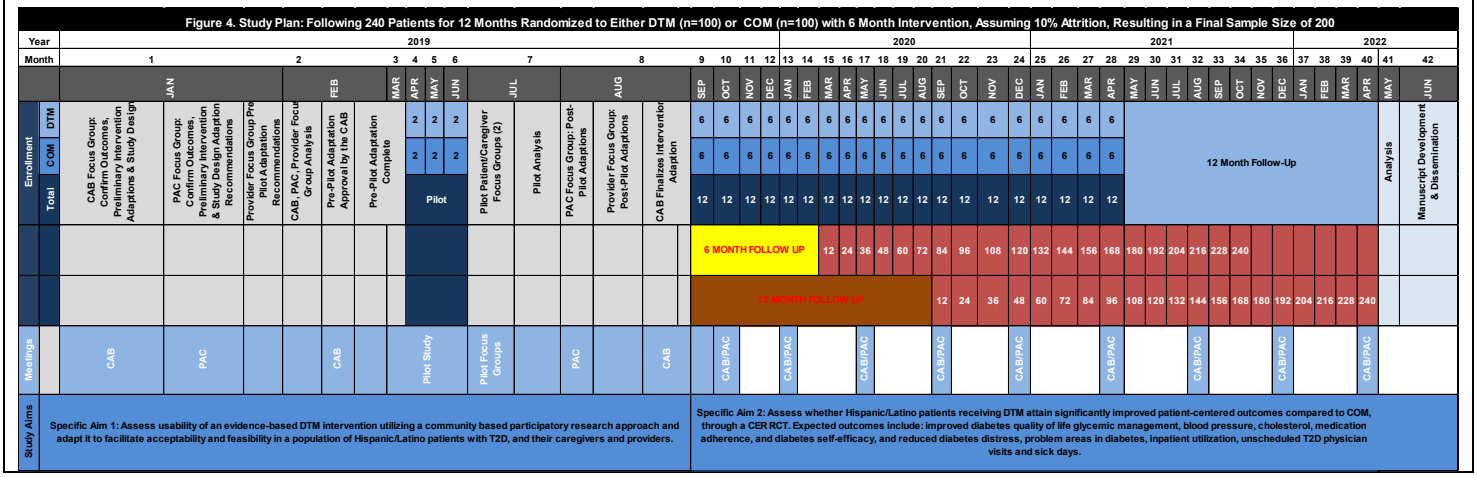
Tertiary analyses for Aim 2. Finally, we will measure whether, relative to the COM, patients in the DTM arm: **1) Experience less inpatient utilization** defined by *i. Hospitalization* (Y/N): whether each patient had at least 1 inpatient hospitalization; *ii. The number of hospitalizations* experienced by the patient; and *iii. Cumulative length-of-stay (inpatient days)* for each patient over the study period. **2) Experience less unscheduled T2D sick visits/days**, defined as **i**. Whether a subject has at least 1 unscheduled T2D sick clinic visit; and **ii.** Number of T2D unscheduled sick visits. **iii.** T2D sick days will be assessed monthly through self-report. Utilization outcomes (1-2) will be analyzed using Poisson regression to compare group rates. Despite discreteness of many of the scales cited above, the relatively large proposed sample size (100 per group), higher than what is necessary to detect differences, allows for the use of ANCOVA. All measures have documented validity evidence. Subgroup analysis will be exploratory, as no existing literature would support a particular effect size hypothesis. There are no plans for interim analyses or early stopping of the trial. Data

transformations will be considered for all analyses. Subgroup analyses are outlined separately below. **Assess data source adequacy.** Given the RCT approach, it is unlikely that demographics will be misrepresented in treatment groups. Thus, confounding is highly unlikely. However, demographic variables such age, race/ethnicity, and insurance will be easy to measure through self-report, based on the success of an ongoing PCORI trial of telehealth-delivered CHF management (PI: Pekmezaris). These data will be a combination of self-report/medical record verification. The primary endpoint, HbA1c, is highly reliable as it is derived from a reputable, licensed laboratory. **Planned sensitivity analyses to determine the impact of key assumptions.** For all analyses, underlying assumptions will be evaluated using SAS diagnostic tools (PROC GENMOD, PROC MIXED, and PROC GLM). **Address missing data.** The best protection against missing data is to prevent it in the first place. To this end: 1) we have already partnered with the clinic directors to ensure that patient records will be available; 2) two separate team members, Patel and Williams, will track the completion of data weekly (checking each other's data), which will be reported at weekly research meetings; and 3) each team member will have clearly defined tasks and will regularly report on progress. **Prevention and monitoring of missing data on outcomes:** Participants in both arms will be contacted (DTM through video visit; COM monthly by phone). This will be a "check-in" contact to assess how patients are doing and whether they have interacted with the healthcare system (i.e., ED visits). The RN will make all patient contact. If a patient does not continue with the study, we will ask for the reason for discontinuance. We will ask permission to collect outcome data as scheduled. We believe that this will help obtain outcome data in the spirit of ITT. In addition, we will use our pilot study and focus groups or structured interviews to identify potential challenges to data collection that we can address a priori. During data collection researchers Dr (s) Patel and Williams will assess weekly capture of all outcomes. The database management system, managed by the Biostatistics Unit, includes features that report test and form completion. The study team will monitor data collection and troubleshoot during regular meetings. We will also minimize risk of incomplete data by making surveys as easy as possible for the patient, conducted in their home; we will also perform cognitive pretesting with our PAC and field test surveys with pilot patients. **Statistical methods to handle missing data.** We will use standard methods of multiple imputation. Since HbA1c will be measured 4 times (baseline, 3 months 6 months and 12 months) pre-HbA1c data will necessarily be available and 3 or 6-month data (theoretically) will not. Therefore, a monotone missing data structure will be used. The missing data mechanism will be assumed to be missing at random (MAR). Similar approaches will be used for secondary outcomes-continuous and binary. **Recording and reporting reasons for dropout and missing data, and account for all patients in reports.** We will use the CONSORT diagram method to describe/account for subjects who drop out or for whom outcome variables are missing.[53] Tables will reflect frequency/reasons for missing data. **Sensitivity of inferences to missing data methods and assumptions, and incorporation into interpretation.** A commonly used sensitivity analysis for the MAR assumption in multiple imputation is based on the pattern mixture model approach,[54,55] modeling distribution of responses as a mixture of observed responses and missing responses. **Goals of planned HTE analyses.** We will evaluate whether the treatment effect in H/L patients with a caregiver participating differs from those that do not by examining the treatment x caregiver status interaction term. Similarly, we will also evaluate whether the treatment effect in female H/L patients differs from male patients by examining the treatment x gender interaction term. It should be emphasized, however, given our resources, there may be insufficient power to detect such interactions. Therefore, these analyses will be exploratory. If feasible, we will also evaluate the treatment x SE interaction. **HTE analysis plan.** In keeping with ICH E9 statistical principles for clinical trials (V.7G), the interaction terms for treatment x caregiver status, and treatment x gender will be included in the primary analysis, as well as main effects for treatment, caregiver, and gender. We plan on exploratory subgroup analyses to explore differential effects of treatment on caregiver

and gender groups. Upon finding a significant treatment x caregiver interaction (or treatment x gender interaction), the effect of treatment on A1C will be estimated separately for caregiver status (Y/N) (likewise for gender). Estimate of treatment effects and their 95% CI will be constructed. **The basis for all HTE claims based on appropriate statistical contrasts among groups being compared.** The literature and discussions with our CAB indicate the importance of family in the H/L culture.[28,29] Given the different social/familial roles of women, we will also explore potential gender differences. We will also look at type of caregiver (paid/family) *and explore caregiver type in a post hoc analysis to better understand the effect of caregiving.* **HTE analysis plan to report all pre-specified analyses and, at minimum, the number of post-hoc analyses, including all subgroups and outcomes analyzed.** With the rich data set expected from this study, we will examine data patterns in an exploratory post-hoc way to identify potential trends not specified a priori. While we will use both exploratory and standard statistical approaches, p values, and associated CIs will be interpreted cautiously, as firm conclusions cannot be drawn. Post-hoc analyses will be adjusted for multiple testing. **Reporting plan to allow for assessments of the study's internal and external validity.** We will report trial results according to the CONSORT guidelines for reporting of RCTs, using the CONSORT 2010 checklist.[53] We will report the progression of patients through the study using the CONSORT flow diagram, showing numbers of patients at each study point (enrollment, allocation, follow-up), and reasons for attrition at each point. For reporting qualitative results, we will use the COREQ a 32-item checklist for interviews/focus groups.[56]

SECTION FIVE: SAMPLE SIZE JUSTIFICATION

Our estimated sample size is 224 patients (240, assuming a 10% attrition rate): 112/group, yielding 80% power to detect a 0.5% difference in the pre-post change in HbA1c (two-tailed t-test with α =.05) over 6 months. Our power calculation is based on Polisena et al.'s meta-analysis.[16] We computed a sample size-weighted median of the 12 standard deviations (SD) for HbA1c, yielding a value of 1.2%. If the SD of the pre-post 6-month *change* in HbA1c is 1.2% in each group, a 0.45% difference in this 6-month change yields a 0.42 effect size (ES). This ES is realistic, falling between 2 sets of reductions in the literature: the Diabetes Control and Complications Trial (1% decline in HbA1c reduced microvascular complications by 30%[57]) and RCTs/meta-analyses citing reductions of 0.3% as "clinically significant".[1–4] Our reduction of 0.45% falls between those limits, is clinically significant/meaningful, as patients can see improvements in their scores. In a systematic review of 13 RCTs (n=4,207) telehealth was associated with a clinically significant mean HbA1c decline of −0.44% compared to COM.[17] In medically underserved patients, telehealth led to a net improvement in HbA1c, cholesterol, and BP. Although our main power calculation refers to our primary outcome (HbA1c), power is still acceptably high for secondary variables (SE, distress or QoL) such that 112 patients/group will yield 80% power to detect an effect size of 0.4 SDs, using a simple t-test to sample size and power.



1. Estimated number of potentially eligible participants (describe how number was determined [e.g., Electronic Health Record, claims data, clinic logs, administrative data, other]):	4092
2. Total number of study participants expected to be screened:	400
3. Total number of study participants expected to be eligible of those screened:	400
4. Target sample size (use same number stated in milestones):	200
5. If applicable, total number of practices or centers that will enroll participants:	2
6. Projected month first participant enrolled (month after project initiation):	1/2019
7. Projected month last participant enrolled (month after project initiation):	12/2021
8. Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	8 to 10
9. Estimated percentage of participant dropout:	10%

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

The investigators will use IRB-approved and HIPAA-compliant measures to maintain confidentiality, privacy and data security. Data privacy and security procedures will include: a) training staff on data sensitivity and protocols for safeguarding confidentiality; b) storing and processing sensitive hardcopy in a secured, centralized location; c) securing sensitive hardcopy in locked files when not in use; d) removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants; e) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed; f) using restricted logon

identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

RedCap and OneDrive are the only programs being used to restore research data

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

Adverse Events and Data and Safety Monitoring Plan
We do not expect any adverse events directly attributable to the intervention. Although discussions with our IRB indicate that the risk proposed by this intervention does not meet the requirements for establishing a Data Safety Monitoring Board (DSMB), we nonetheless will establish a DSMB to review aggregate data on a bi annually basis to review possible safety issues. Any adverse events will be reported immediately to the IRB.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

The patients and CAB members in the focus group or structured interviews may withdraw from the study at any time after giving consent. The study may discontinue at any time. Any actions that may follow such discontinuation of the study will have no impact upon patient care or employment.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

We do not anticipate any significant physical, psychological, or social risk to the study patients. All risks and benefits of participation will be explained to participants and included in the written consent forms. Participants will be at minimal risk and will be informed of their right to withdraw from the study at any time. All identifiable information will be maintained with strict confidentiality measures by the investigators.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

We do not anticipate any significant physical, psychological, or social risk to the study patients. All risks and benefits of participation will be explained to participants and included in the written consent forms. Participants will be at minimal risk and will be informed of their right to withdraw from the study at any time. All identifiable information will be maintained with strict confidentiality measures by the investigators.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Potential benefits of participants include **improved** QoL, glucose management, medication adherence, and diabetes SE, BP and cholesterol and significantly **reduced** diabetes distress, problem areas in diabetes, inpatient utilization (hospitalization) and number of unscheduled physician visits and sick days.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

The study coordinator, Multisite Patient Engagement Specialist, or bilingual study RN will initially contact patients by phone from the various study sites randomly selected from the list of patients who fit our inclusion criteria and invite them to participate in our study. Informed consent will include a detailed but simple description, in English or Spanish (based on preferred patient language), of the risks and benefits of the study with user-friendly images of the equipment.

Written, informed consent will be obtained prior to the participants taking part in any aspect of the study. Patients will be informed of the study's risk and benefits, and that their choice to participate or not will have no effect on their medical care. The study coordinator, Multisite Patient Engagement Specialist, or bilingual study RN will obtain informed consent after thoroughly explaining all aspects of participation, including the use of audio recording where relevant, assessing understanding, and answering any questions from potential participants. Participants will receive written consent forms detailing the study, what participation entails, potential risks and benefits, the voluntary nature of their participation, and contact information for the PI, Co-Is and Northwell/Feinstein IRB.

Patient contact information will be collected in secure electronic documents only accessible to the PI and study team. For the focus groups or structured interviews, which will be audio recorded, participants will give informed consent for participation and separate consent to be audiotaped.

We will also be obtaining the Certificate of Confidentiality from the NIH. Where necessary verbiage from this CoC is included in the consent forms.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

We do not anticipate any foreseeable costs that subjects might incur. All research procedures will be paid for by the research study. We do not anticipate that participants will have an additional health procedures other than that which they are already used too. Any injuries which incurred and not part of the research study will be billed and paid for by the participant's insurance.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

CAB members will be compensated $50 for their time plus transportation costs. Participants will be compensated $50 for their time/travel plus pre/post-test completion ($100).

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

The study coordinator, Multisite Patient Engagement Specialist, or bilingual study RN will initially contact patients by phone from the various study sites randomly selected from the list of patients who fit our inclusion criteria and invite them to participate in our study. Informed consent will include a detailed but simple description, in English or Spanish (based on preferred patient language), of the risks and benefits of the study with user-friendly images of the equipment.

Written, informed consent will be obtained prior to the participants taking part in any aspect of the study. Patients will be informed of the study's risk and benefits, and that their choice to participate or not will have no effect on their medical care. The study coordinator, Multisite Patient Engagement Specialist, or bilingual study RN will obtain informed consent after thoroughly explaining all aspects of participation, including the use of audio recording where relevant, assessing understanding, and answering any questions from potential participants. Participants will receive written consent forms detailing the study, what participation entails, potential risks and benefits, the voluntary nature of their participation, and contact information for the PI, Co-Is and Northwell/Feinstein IRB.

Patient contact information will be collected in secure electronic documents only accessible to the PI and study team. For the focus groups, which will be audio recorded, participants will give informed consent for participation and separate consent to be audiotaped. Subjects who signed consent for the pilot study and focus group, but will now participate in a structured phone interview instead of focus group, we are seeking a waiver of documentation of consent and HIPAA authorization. We will read the script approved by IRB to get the subjects' authorization. The subjects will be informed of the change over the phone and also asked for their authorization to be audio recorded before the interview begins.

With current COVID_19 pandemic, the team also requests waiver of documentation of HIPAA authorization, as the interview is minimal risk, the interviewees are not readily available in person (and are not expected to be in the near future), and it would be reasonably expected that the response rate to a mailed HIPAA authorization would be so low that the research would be impracticable to perform. The research could likewise not be performed without use of PHI, as the interviews will discuss patient health status and will be audio recorded.

In our main RCT study, for patients in the telemonitoring arm, the patient will be consenting that we can contact their caregiver. We will ask the patient whether or not they have a caregiver and if they will give the caregiver permission to see their daily vital signs during the study. At this point there will be verbal consent on the part of the patient that we may contact the caregiver, and the team member, who is consenting, will be indicating on the enrollment note that verbal consent was given by the patient. Once consent is given by the patient, we will provide the caregiver with an information sheet outlining what our study entails (see information sheet attached).

Our Research Nurse and Recruitment specialist are both fluent in Spanish. During the recruitment and consenting process, our research team will ask the patient what is their preferred language (either English or Spanish) for which they would like to be consented. All consent forms will be translated into Spanish.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

The consent form will be both in Spanish/English. The multisite recruitment specialists who are primarily recruiting for this study are both bilingual. Participants will be asked what is their preferred language of choice – Spanish or English. See recruitment procedures above.

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS ☐ N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

The caregiver will be provided with an information sheet. We are requesting a waiver of documented consent because the caregiver's only role is to provide information about the patient's care. The info sheet will have a phone number to answer questions about participation – see attached.

We are also requesting a waiver of elements of the consent process/form for Consent 1. We request that the first group of subjects are enrolled without a full description of the study procedures. It is impracticable to conduct this research if elements (disclosing the full purpose of the study and the randomization procedure) of informed consent are required because we believe if we tell people which arm they are in, the people who are randomized to the non-telehealth arm will not want to participate because the telehealth arm has advanced technology and is more convenient for the patient. This creates a

major barrier for the successful completion of the intervention and therefore, the study would not be feasible to complete without the Zelen consent process. The telehealth intervention involves no more than minimal risk. The waiver does not adversely affect the rights and welfare of the participants as they are still being asked to participate and being told the procedures that they will be involved in, at that point in the process.

In addition, we are requesting a waiver of elements of the consent process/form for witness signature. We request that in situations when recruiters are performing at home consenting, that a witness signature not be required if no witness is available at the time of consenting. At home consent occurs when the patient agrees to participate in the study, but does not have the time in the clinic to answer the surveys, complete the enrollment process and/or drop off equipment for participants in the DTM group. We are asking for a waiver on witness signature as it is not always practical to have a witness available for at home consenting. This creates a major barrier for the successful completion of the consenting process. The telehealth intervention involves no more than minimal risk. Both recruiters for this study are bilingual and have thoroughly been trained in consenting procedures and conducting consenting in an ethical manner and based on protocol procedures. As such, the waiver does not adversely affect the rights and welfare of the participants as they are still being asked to participate and be told the procedures that they will be involved in at that point in the consenting process.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

Participants will be giving verbal consent for this study. Verbal consent will be documented on the enrollment log. All staff who are recruiting participants are thoroughly trained in compliance and HIPAA rules and regulations for recruiting and ensuring participant confidentiality.

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

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25. WAIVER OF HIPAA AUTHORIZATION ☒ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine in, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☐ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☒ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

Minority populations: Individuals will be explained the full risks and benefits of taking part in the study. Additionally, participants will be told that all care will be taken to ensure their protection and confidentiality and only the Northwell Team will have access to their data. While results in the study will be published, all data is aggregated and their personal information will never be given out. The will not be asked any questions about their legal or immigrant status. We have obtained a Certificate of Confidentiality

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

For the Northwell sites, all study related files will be saved and shared between sites on a PHI drive on Northwell Health's servers. For external site, all study related files will be shared between sites on OneDrive data storage (a secure cloud sharing system provided by Northwell Health).

28. REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

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