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Assessing the impact of medically tailored meals and medical nutrition therapy on type 2 diabetes: Protocol for Project MiNT

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7. Declaration of Competing Interest

The authors have no competing interests to disclose.

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abstract

Background: Research has shown that among people with type 2 diabetes mellitus, reduction in hemoglobin A1c (HbA1c) prevents long term complications. Medically tailored meals (MTM) and telehealth-delivered medical nutrition therapy (tele-MNT) are promising strategies for patient-centered diabetes care.

Objectives: Project MiNT will determine whether provision of MTM with and without the addition of telehealth-delivered medical nutrition therapy improves HbA1c and is cost effective for patients with type 2 diabetes mellitus.

Methods: Patients with poorly controlled type 2 diabetes mellitus (HbA1c >8%) will be recruited from Jefferson Health. Eligible patients will be randomized to one of three arms: 1) usual care, 2) 12 weeks of home-delivered MTM, or 3) MTM + 12 months of tele-MNT. All participants (n=600) will complete three follow-up assessments at 3, 6, and 12 months. The primary outcome is change in HbA1c at 6 months. Secondary outcomes include change in HbA1c at 3 and 12 months and cost-effectiveness of the intervention at 6 and 12 months.

Conclusion: Findings from Project MiNT will inform MTM coverage and financing decisions, how to structure services for scalability and system-wide integration, and the role of these services in reducing health disparities.

Keywords

Diabetes Mellitus; Medically Tailored Meals; Medical Nutrition Therapy; Telehealth; Hemoglobin A1c

1. Introduction

This pragmatic randomized control trial will determine whether provision of medically tailored meals with and without the addition of telehealth-delivered medical nutrition therapy improves hemoglobin A1c and is cost effective for patients with type 2 diabetes mellitus.

Diabetes mellitus (DM) impacts 30.3 million Americans, disproportionately affects minority populations [1], and is the 7th leading cause of death in the U.S [2]. National data from 2004 found that only 57% of patients with DM had adequate glycemic control [3], contributing to health disparities and greater use of unscheduled acute care services (e.g., emergency department (ED) utilization) [4–6]. Achieving glycemic control with medications and behavioral interventions is paramount to preventing the long term complications of DM. While medications are a mainstay of treatment, a focus on diet and nutrition contributes to glycemic control.

Medically tailored meals (MTM) are meals designed by a Registered Dietitian Nutritionist (RDN) to reflect appropriate dietary therapy according to evidence-based nutrition practice guidelines. They address medical diagnoses, symptoms, allergies, inability to chew or swallow, medication management, and side effects to ensure the best possible nutrition-related health outcomes. Pilot studies of MTM, including services provided by our local meal provider, demonstrated up to 50% fewer hospitalizations, reduced healthcare utilization and costs [7–9], and improved glycemic control for patients with poorly-controlled DM [7,10,11]. To date, however, no randomized control trials (RCT) have been conducted to assess the sustained impact of MTM on long-term patient outcomes for type 2 DM (T2DM).

Medical nutrition therapy (MNT) is offered as a component of diabetes self-management in many health systems and consists of individuals receiving nutrition education tailored to their unique medical needs, delivered by a RDN. While prior studies show the importance of MNT in improving DM control [12–14], patient utilization of MNT remains limited. In a study of 28,404 individuals with DM, only 9% had at least one nutrition visit within a 9-year period [12]. Individual studies of MNT delivered both in-person and via telemedicine (tele-MNT) have shown benefit for DM outcomes [15–18], yet data on the effectiveness of intensive MNT are lacking to demonstrate sustained impact of interventions.

We developed Project Meals and Nutrition Therapy (Project MiNT) to study the long term impact of MTM and MNT on outcomes for patients with T2DM. This is a pragmatic RCT funded by the National Institute of Diabetes and Digestive and Kidney Diseases (1R18DK118590). The primary outcome is change in Hemoglobin A1c (HbA1c) after 6 months of treatment with MTM and tele-MNT in patients with T2DM. Secondary outcomes include change in HbA1c at 3 and 12 months and cost effectiveness of the interventions at 6 and 12 months. We hypothesize that there will be a greater reduction in HbA1c in both treatment arms (MTM only or MTM + tele-MNT) as compared to usual care at both 3 and 6 months; however, at 12 months the effect will only be sustained in the MTM + tele-MNT arm. If successful, this study will provide robust evidence needed regarding the efficacy and cost-effectiveness of MTM and tele-MNT.

2. Study Design

This clinical trial is registered and available at Clinicaltrials.gov (NCT04264572).

We are performing a three-arm, pragmatic RCT to study the effectiveness of MTM provision with and without tele-MNT on improving outcomes for a population of patients with T2DM, all with a baseline HbA1c>8% and a majority of whom are low income and African American. The study is being implemented at Jefferson Health and includes enrollment of patients from 2 hospitals both located in Philadelphia, PA: Thomas Jefferson University Hospital and Methodist Hospital. A total of 600 eligible participants are randomized into one of three groups: (1) Usual Care, (2) MTM, or (3) MTM + tele-MNT (Figure 1). Participants are engaged for a total of 12 months.

Participants are recruited during an ED visit or hospitalization at either hospital for any complaint. Research coordinators identify all patients in the ED or hospital who have

a glucose ≥ 250 or a HbA1c>8% in the past year for potential eligibility. Research coordinators then review the chart of each identified participant to further assess eligibility (Table 1). Eligible patients are approached in-person or via phone by a member of the study team to assess interest in study participation and confirm all eligibility criteria. Interested patients who meet eligibility criteria other than an HbA1c>8%, which may not yet have been assessed yet, are then consented for study participation and asked to complete baseline assessments.

All participants are required to complete written informed consent during the index encounter, which includes teach-back questions to confirm comprehension. The consent is signed either in-person or remotely using an e-consent form in REDCap (Research Electronic Data Capture, Vanderbilt University), with remote enrollment procedures implemented to allow for enrollment that incorporates COVID-19 precautions.

Enrolled participants with a HbA1c>8% are randomized in a 1:1:1 ratio using random permuted blocks stratified by HbA1c (>8 to 10 vs. >10) and hospital discharge site (inpatient vs ED) to 1 of 3 arms: 1) Usual Care; 2) MTM; or 3) MTM + tele-MNT. The size of any particular block is randomly selected and only known by the study biostatistician. This stratification approach was selected based on the hypothesis that the interventions may have differential effects based on how poorly controlled an individual's DM is at baseline, as well as the degree of acute decompensation of the patient at time of enrollment. A computer-generated list of random numbers is prepared in advance by the study biostatistician and loaded into the REDCap randomization tool to ensure research staff are blinded to assignment pre-randomization. All study procedures are approved by the Institutional Review Board (IRB) at Thomas Jefferson University. Study activities are regularly monitored by an external Data Safety Monitoring Board (DSMB) which meets every 6 months. Project MiNT is a nonblinded study, as it is not feasible to blind participants and research staff to assignment post enrollment. HbA1c is an objective outcome, and thus lack of blinding should not be a significant limitation.

3. Study Interventions

3.1 Usual Care

Participants in this arm receive usual services offered at Jefferson and other local health systems for patients with DM, which may include regular visits with a diabetes provider (primary care or endocrine) and standard American Diabetes Association (ADA) information pamphlets. Patients may be referred to 1) diabetes education classes and 2) nutrition counseling by dietitians and nurse practitioners by their provider. During routine office visits, providers reinforce messages about self-management and provide lists of local and national resources related to nutrition and diabetes self-management. For those referred to nutrition counseling, the standard of care at Jefferson is to begin with a single group MNT visit lasting from 60–90 minutes. Each patient's need for additional sessions and general time-frame for follow-up is individually determined following the group session, based on patient preference. Historically, only about 2% of the Jefferson population engages in these services, thus minimizing dilution of the effect of the tele-MNT. At the 6 and 12 month follow-up periods, the study team will ask participants about their participation in any

non-study individual or group nutrition counseling sessions. Participants who participate in MNT as part of usual care will still be included in study analyses.

3.2 MTM

Participants randomized to this arm receive MTM for 12 weeks. Meals are prepared and delivered by a local non-profit organization (MANNA) that has provided MTM for patients with chronic illnesses in Philadelphia and Southern New Jersey since 1990 [20]. Participants receive 21 complete, frozen meals delivered to their home each week. This includes 3 main meals per day and snacks, providing 45–60 grams of carbohydrates per meal for optimal glucose control based on ADA guidelines and 100% of overall nutritional requirements based on USDA guidelines. All participants receive MANNA's diabetes friendly meal modification and are able to choose up to 2 other modifications to fit their individual needs and preferences. MANNA offers 11 meal modifications to address medical conditions (kidney, diabetes/heart friendly) and other preferences (mechanically soft, GI friendly, elimination of certain foods). In addition, children and any senior dependents for whom the participant is the primary caregiver receive meals for the entire 12 weeks for no additional cost, to align with MANNA's standard of care services. The intervention duration is based primarily on current insurance policies, as we want to test a MTM timeframe that insurers would potentially consider reasonable as a covered benefit. Upon randomization to this group, a referral form is completed and sent to MANNA by the research team. MANNA staff establish a delivery time with participants, with a goal of delivering the first week of meals within two weeks of randomization. After the 12 weeks of delivered meals, participants continue with their usual diabetes care.

3.3 MTM + tele-MNT

Participants in this arm receive MTM services exactly as described above, as well as tele-MNT over a period of 12 months. All video visits are conducted synchronously between participant and the study RDN using the MyChart application [21]. Participants receive technology support as needed from Jefferson telehealth support staff for setting up MyChart and initiating a telehealth visit. The tele-MNT intervention is designed based on evidence-based recommendations for MNT and informed by social cognitive theory. Based on Academy of Nutrition and Dietetics recommendations, each participant's MNT includes the following core features: nutrition assessment, intervention, care coordination, monitoring and evaluation [12]. Sessions also include motivational interviewing to help participants overcome challenges related to their individual food choices and understand how choices affect their blood glucose values. In the first three months, sessions focus on supporting individuals who are not selecting, preparing, or purchasing their own meals, as participants will be receiving MANNA meals during this time. As the end of MTM services approaches, the intervention shifts to focus on how to transition from MTM to self-directed healthy eating. The curriculum includes a set of core features and covers a list of specific evidence-based topics [12,13,22], while also being individualized to address the needs and preferences of each participant (Table 2) [22].

The visit schedule includes bi-monthly one-on-one visits that make up 315 minutes of direct patient time in the first 6 months. Each month, one visit focuses on education delivery while

the other visit checks-in on participant progress. Visits may last 15–60 minutes. In months 7–12, participants are invited to attend a monthly, 60-minute group session via Zoom with a set, rotating topic to reinforce topics discussed in individual sessions (Table 3).

4. Assessment Protocol

Data collection occurs at four different time points throughout the study: baseline, 3 months, 6 months, and 12 months (Table 4). All baseline assessments are conducted prior to randomization. Assessments may be administered in-person or over the phone at all time points.

4.1 Primary Measure – HbA1c

Participants' HbA1c is assessed using non-fasting blood samples collected at assessment points (baseline, 3 months, 6 months, 12 months).

4.2 Secondary Measures

4.2.1 Healthcare Costs—The initial protocol was to receive participant health care utilization from the Healthshare Exchange of Southeast Pennsylvania (HSX) [23], the regional health information exchange. HSX captures electronic health records for outpatient care, emergency department care, inpatient care, post-acute care and prescription drugs. More granular detail was needed than could be obtained through HSX, so the protocol was modified to obtain Jefferson billing and claims data for this measure.

4.2.2 Health Utility and Quality-adjusted Life—Preference-based health related quality of life is measured using the EQ-5D-5L, which assesses 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, on a scale from 1–5 [24]. EQ-5D-5L responses will be converted into a health utility using validated values sets developed by the EuroQol Research Foundation. An area under the curve approach will be applied to calculate participants' quality-adjusted life year (QALY) during the trial [25].

4.2.3 Intervention Costs—The costs of delivering usual care are obtained from administrative data within the Jefferson Health system. The cost of medically-tailored meals is derived from MANNA's per meal cost. Cost of delivering tele-MNT is obtained from data logs which capture time preparing and delivering sessions.

4.2.4 Adherence to Refills and Medications—The Adherence to Refills and Medications Scale for people with T2DM (ARMS-D) is used to assess participants' self-reported adherence to diabetes medications [26]. The survey consists of 14 questions on a 4-point scale to assess frequency of medication-related activities.

4.2.5 Diabetes Self-Care—Self-care is measured using The Summary of Diabetes Self-Care Activities (SDSCA) [27], made up of 11 questions, all scored on a 7-point scale. The SDSCA assess five regimen areas: General Diet, Specific Diet, Exercise, Blood-Glucose Testing, Foot Care, and Smoking Status. Scores are calculated for each of the five regimen areas by finding the mean number of days each task was performed within each regimen.

4.2.6 Diabetes Self-Efficacy—Self-efficacy is measured using The Diabetes Self Efficacy Scale [28], made up of 8 questions, all scored on a 10-point Likert scale. Each questions asks about the respondent's confidence in performing an activity relative to diabetes. The score for the scale is the mean of the eight items.

4.2.7 Diabetes Treatment Satisfaction—Treatment satisfaction is measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQs) instrument [29]. The DTSQ is made up of 6 questions assessing treatment satisfaction and 2 items assessing perceived frequency of hyperglycemia and hypoglycemia. All items are scored on a 7-point Likert scale assessing either frequency or satisfaction.

4.2.8 Diabetes Quality of Life—Quality of life is measured using the Diabetes Quality of Life (DQoL) instrument [30], made up of 15 questions, all scored on a 5-point Likert scale assessing either frequency or satisfaction.

4.2.9 Dietary Assessment—Participant self-reported dietary habits are assessed using the DietID tool, powered by Diet Quality Photo Navigation [31]. As opposed to a detailed recall or log of food consumed, DietID uses images to establish dietary patterns and diet quality, resulting in a DietID quality score and a Healthy Eating Index score.

4.2.10 Readiness to Change—Readiness to change is measured using two questions based on motivational interviewing practices [32]. The two items assess readiness to make changes to manage diabetes and readiness to make changes to diet on an 11-point Likert scale.

4.3.11 Food Insecurity—Food insecurity is measured using a brief, two-question screener based on the 18-item U.S. Household Food Security Survey (HFSS). The two-item assessment has been validated for use as a screening tool in healthcare settings [33]. A response of "often true" or "sometimes true" to either question identifies a household at risk for food insecurity.

4.2.11 Weight—Weight is measured using study-specific calibrated scales, in bare feet, at baseline assessment (Etekcity Digital Body Scale). Built-in hospital bed scales or weight recorded in the EMR may be used if participants are unable to stand on scale. Follow-up weight measures may be captured using participants' personal scales, or measurements recorded in the EMR.

4.3 Fidelity and Satisfaction

Process evaluation measures allow for a better understanding of intervention fidelity and participant satisfaction, which inform continuous quality improvement. MTM fidelity is being assessed by the number of deliveries each participant receives in the 12-week period, as well as using participant self-reported information regarding intake of MANNA meals as well as other supplemental food. Meal delivery information is tracked by the meal provider and shared with the study team on a monthly basis. At the 3 month follow-up, participants who received meals are asked about their satisfaction with the meals and to assess how frequently they strayed from the study-provided meals. Similarly, tele-MNT visit

participation is tracked using an EMR-based platform and dietitian attendance tracking. At the 6 month follow-up, participants who completed tele-MNT visits are asked about their satisfaction with the sessions. Participant feedback that does not change the study design will be considered for ongoing program strengthening.

5. Analysis Plan

5.1 Sample Size & Power

Power was calculated to detect a difference in mean change of 0.5 in our primary endpoint of HbA1c for MTM compared to usual care, as well as MTM + tele-MNT compared to usual care, at 6 months. An absolute change of 0.5 was determine as the minimal clinically important difference in HbA1c based on 1) clinical guidelines indicating a change in HbA1c of 0.5 is clinically significant [34–36] and 2) the fact that numerous studies have powered for this outcome [37,38]. Statisticians fixed the two-sided type 1 error rate α to be 0.05. Since othe trial is multi-armed and two primary hypotheses are being tested, Bonferroni multiple comparison adjustment is performed to control the familywise error rate, which equates to using a smaller value for α (0.025) in the power calculations. The standard deviation of change in HbA1c over a 6-month period ranges from 0.9 to 1.5 in the literature [39,40]. Assumptions include a SD of 1.4 for our calculation and that 20% of participants either drop out or will not provide data on the primary outcome, based on observed rates in the literature [41]. A sample of 200 randomized participants (160 with complete data for analysis) per arm provides greater than 80% power to detect a difference in mean changes of 0.5.

5.2 Primary Analysis

The primary objective of this trial is to assess the effectiveness of MTM compared to usual care, and of MTM + tele-MNT compared to usual care, in reducing HbA1c at 6 months. Mixed effects linear regression will be used to model the repeated, longitudinal measurements of HbA1c. Fixed effects in the model will be randomization assignment (usual care, MTM, and MTM + tele-MNT), time (baseline vs 3 months vs 6 months vs 12 months) and time by randomization interaction. The randomization stratification variables will be included as covariates. Additional baseline covariates (BMI, prior health utilization, age, sex, self-efficacy, self-care, quality of life, treatment satisfaction, medication adherence, family support, and food insecurity) will also be included if bivariate associations with HbA1c are significant at the $p < 0.2$ level. A compound symmetric or first-order auto-regressive correlation structure will be assumed to account for correlation among repeated measurements.

For the primary outcome assessment, we will perform two linear contrasts, estimating the difference in the mean change from baseline in each intervention arm compared with the mean change from baseline in the control group, and test the null hypothesis that these differences equal zero. Both tests are performed at the alpha=0.025 level. To estimate the effect of actually receiving treatment, for the primary hypotheses related to the effectiveness of MTM compared to usual care, and of MTM + tele-MNT compared to usual care, in reducing HbA1c, we will implement an innovative approach specifically designed to

address the issue of noncompliance, called a contamination adjusted intent-to-treat (CA ITT) analysis [42]. Under this framework, the RCT is treated as an instrumental variable (IV), with treatment assignment as the instrument. The effect of treatment assignment on the outcome observed is adjusted by the percentage of assigned participants who ultimately receive the treatment. The CA ITT analysis can only be implemented if one has information on the treatment that an individual actually received.

5.3 Secondary and Exploratory Analyses

For any continuous endpoint measured in all groups, groups will be compared with respect to change from baseline to 3, 6, and 12 months using the same mixed effects model approach as for the primary endpoint. Exploratory analyses will consider whether the effect of treatment differs by the following variables: sex, race/ethnicity, baseline HbA1c, BMI, diabetes self-efficacy, medication adherence, and level of food insecurity. Separate mixed effect models will be fit for each potential effect modifier where the model is extended to allow for separate treatment effects by level of the modifier through the use of interaction terms.

5.4 Cost-effectiveness Analysis

Cost-effectiveness at 6 and 12 months will be evaluated from a healthcare payor perspective [43,44]. For each strategy (MTM, MTM + tele-MNT, and usual care), intervention costs, healthcare costs, and QALYs will be calculated. Strategies will be ranked in terms of increasing total cost (intervention + healthcare costs) and the least costly strategy will serve as the reference case. Next, incremental cost-effectiveness ratios (ICERs) will be calculated to determine the extra cost per QALY of a more expensive strategy compared to the adjacent less expensive strategy. In a secondary analysis, ICERs in which the unit of benefit is HbA1c will be calculated. In the secondary cost effectiveness analysis, the ICER will be interpreted as the cost to reduce HbA1c. Univariate and probabilistic sensitivity analyses will be conducted to examine uncertainty and conclusions.

5.5 Missing Data

While all effort will be made to collect follow-up data on all randomized participants, there will undoubtedly be missing data due to the patient population having one or more chronic illnesses, and some may die or be lost to follow up. To avoid biasing the results and wasting data, we will use an analytic approach for the primary outcome (mixed effect linear regression with maximum likelihood estimation) that produces unbiased estimates under the assumption that data are missing at random. For cost effectiveness analyses, we will receive Jefferson administrative data for all enrolled participants regardless of whether they are otherwise lost to follow up, thus facilitating capture of complete utilization data. Health utility data will be captured from patient surveys and we will use multiple imputation to estimate the health utility of patients that dropout.

6. Discussion

Patients with DM report needing better access to healthy food and nutrition education to manage their condition [45,46], and data suggest that provision of MTM and MNT improve

short term outcomes for patients with DM [7,10,11,15–18]. Yet uptake of these services is generally low, due to patient accessibility barriers and insurance coverage limitations. This is the first large RCT to rigorously assess the impact of MTM and MNT on outcomes for patients with diabetes over 12 months. Findings will have important implications for providing patient-centered cost-effective treatment options.

Project MiNT will assess the impact of MTM, with and without tele-MNT, for patients with T2DM. We hypothesize that there will be a greater reduction in HbA1c in both treatment arms as compared to usual care at both 3 and 6 months; however, at 12 months the effect will only be sustained in the MTM + tele-MNT arm. Sustained benefit will be due to continued participation in MNT. We also aim to assess the cost-effectiveness of each intervention arm, compared to usual care. Rigorous data incorporating formal cost effectiveness analyses are needed to support more widespread coverage of these nutrition interventions as routine benefits.

Project MiNT has some important strengths to highlight. Project MiNT uses home-based interventions, which were designed to overcome patient accessibility and scheduling barriers. While this trial was designed before COVID-19, the importance of these interventions was highlighted with the onset of the pandemic. Provision of home delivered meals and the use of technology to conduct video-based nutrition therapy made it possible to continue all study activities despite widespread shutdown of in-person activities. Using existing Jefferson Health technology platforms and capabilities, all study activities including enrollment, consent, and interventions, can be completed remotely. In addition, it is a pragmatic trial, and thus these interventions have already been incorporated into the real world setting, supporting their ability to be continued upon trial completion if demonstrated to be cost effective.

While most insurance, including Medicare and Medicaid, do not systematically provide coverage of home-delivered MTM for most beneficiaries, several recent national changes support the potential for more widespread integration of MTM as a covered benefit. These include a report from the National Quality Forum focused on the importance of addressing food insecurity and housing instability [47], expansion by the Affordable Care Act of the ability of states to use waivers to cover the cost of home-delivered meals for Medicaid recipients [48], establishment of a bipartisan Food is Medicine working group by the House of Representatives focused on advancing policies to ensure access to MTM for chronically-ill people [49], and passage of the Chronic Care Act by Congress in 2018 which provides two potential reimbursement mechanisms to support covering both MTM and tele-MNT. If this trial demonstrates that MTM or MTM + tele-MNT improves T2DM outcomes in a cost-effective manner, regional payers have committed to consider expanding their coverage of these services based on study findings.

Sustainability of medically tailored nutrition services (food and education) will be crucial for improved health and well-being in the long-term. While temporary services, including medically tailored meals and nutrition education, may influence positive health outcomes over a set period of time, the ultimate goal is to support patients in becoming self-sufficient through increased knowledge and positive behavior change. Like traditional medical

management, nutrition needs and practices should be assessed regularly over time to support the ever-changing needs and situations of all patients.

As in all research, this study has limitations. We are only recruiting patients from Philadelphia and the surrounding areas, as they must live within the MANNA service area for study inclusion [19]. Although the population of patients with poorly-controlled T2DM at Jefferson is racially and ethnically diverse and includes a high proportion of low-income individuals, it is possible that findings will have limited generalizability to patient populations in other areas of the country. Due to the current abilities of the study team, we are only enrolling English-speaking participants. In addition, because we are offering a telemedicine intervention, we exclude patients who do not have a device that can support videoconferencing visits. While this limits the generalizability of our findings to a certain group of patients with poorly controlled diabetes with access to devices, in our experience we have found that only a small proportion, including low-income older adults, do not have access to a smartphone, tablet or computer that can support telemedicine (<10% according to internal Jefferson data). If we demonstrate cost effectiveness of these interventions, it is our hope that these findings, combined with results from other demonstration projects across the country, will provide sufficient data to support widespread policy change. Finally, we are unable to assess the impact of tele-MNT alone on outcomes for patients, and this may need future study if MTM + tele-MNT together is demonstrated to be effective.

Project MiNT's immediate goal is to provide patient-centered care, through food and education, to improve outcomes for patients with type 2 diabetes. The results of the study will add to the evidence-base for diabetes care while also reframing what medical care can look like. The study design, which utilizes existing health system infrastructure and local partnerships, is unique in its ability to promote sustainable, scalable, patient-centered care.

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Highlights:

- Glycemic control is paramount to preventing long term complications of diabetes
- Diet and nutrition education can contribute to long term glycemic control
- Medically tailored meals may improve outcomes and lower cost of care
- Tele-medical nutrition therapy may overcome barriers to patient engagement
- Opportunities exist to expand insurance coverage of meals and nutrition therapy

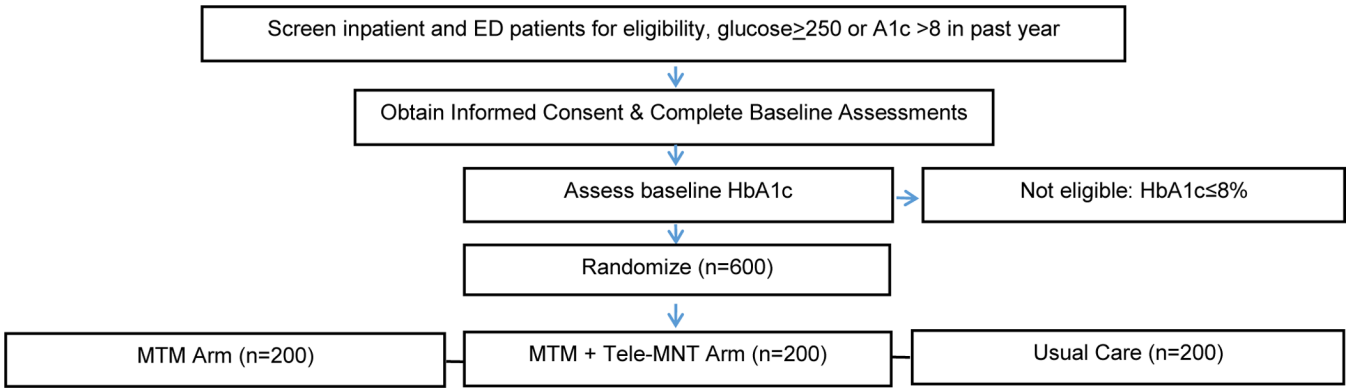

Figure 1.
Enrollment & Randomization Flow Chart

Table 1.

Participant Eligibility Criteria

Inclusion criteria	Exclusion criteria
• ≥ 18 years of age • Has Type 2 DM • HbA1c > 8% • Has DM provider (PCP or Endocrine) • Access to at least one device that can support video visits[a] • Access to an email address • Speaks English • Lives in MANNA meal delivery service area[19] • Access to a freezer to store meals and microwave or oven to reheat meals	• Has Type 1 DM • Unwilling to provide consent • Pregnant, planning to be pregnant, or currently breastfeeding • Life expectancy of ≤ 1 year • Does not eat by mouth • History of severe gastroparesis • Has psychiatric diagnosis other than depression or anxiety • Deaf or blind • In police custody • Currently receiving MTM • Life threatening food allergies • Active drug/alcohol abuse

[a]Includes smartphone, tablet, or Windows PC

Table 2.

Individual Tele-MNT Meeting Structure

Individual Visits (Months 1–6)	Length	Required?
Month 1, Visit 1: Nutrition Basics	35–60 minutes	Yes
Month 1, Visit 2: Check in	15–20 minutes	Yes
Month 2, Visit 1: Understanding Carbohydrates	35–60 minutes	Yes
Month 2, Visit 2: Check in	15–20 minutes	Yes
Month 3, Visit 1: Protein	35–60 minutes	Yes
Month 3, Visit 2: Check in	15–20 minutes	Yes
Month 4, Visit 1: Breakfast Ideas	35–60 minutes	Yes
Month 4, Visit 2: Check in	15–20 minutes	Yes
Month 5, Visit 1: Lunch and Snack Ideas	35–60 minutes	Yes
Month 5, Visit 2: Check in	15–20 minutes	Yes
Month 6, Visit 1: Meal Planning	35–60 minutes	Yes
Month 6, Visit 2: Check in	15–20 minutes	Yes

Table 3.

Group Tele-MNT Meeting Structure

Group Visits (Months 7–12)	Length	Required?
Basic Meal Planning	60 minutes	No
Physical Activity and Moving More	60 minutes	No
Eating Out and Special Occasions	60 minutes	No
More on Meal Planning	60 minutes	No
Making Good Food Choices	60 minutes	No
Importance of Consistent Sleep and Eating Patterns	60 minutes	No

Table 4.

Measures and Collection Schedule

Measure	Collection Schedule			
	Baseline	3-month	6-month	12-month
Demographics, family support	+			
Medical history/comorbidities	+	+	+	+
HbA1c (primary outcome)	+	+	+	+
Healthcare Costs	+		+	+
Health Utility & quality-adjusted life (EQ-5D-5L) [24]	+		+	+
Intervention Costs		+	+	+
Adherence to Refills and Medications Scale for Diabetes (ARMS-D) [26]	+		+	+
Diabetes Self-Care (SDSCA) [27]	+		+	+
Diabetes Self-Efficacy (Diabetes Self-Efficacy Scale) [28]	+		+	+
Diabetes Treatment Satisfaction (DTSQ) [29]	+	+	+	+
Diabetes Quality of Life (DQoL) [30]	+		+	+
Dietary Assessment (DietID) [31]	+	+	+	+
Readiness to Change	+	+	+	+
Food Insecurity (U.S. Household Food Security Survey: Two-Item Screener) [33]	+			+
Weight	+	+	+	+
Fidelity and Satisfaction		+	+	+