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I. BACKGROUND AND SIGNIFICANCE

a. Historical background

The Center for Disease Control and Prevention (CDC) estimates that there are currently 29 million people with diabetes and 86 million people with pre-diabetes in the U.S. One in 10 Americans has diabetes now, and, if current trends continue, 1 in 3 Americans will have diabetes by 2050. This chronic disease significantly impacts both quality of life and rapidly rising national healthcare costs. The estimated cost of diabetes in the U.S. in 2014 was $265 billion with $176 billion in direct medical costs and $89 billion is indirect medical costs (disability, work loss, premature mortality). Medical expenses for people with diabetes are 2.3 times higher than for people without diabetes.[1]

b. Previous clinical studies leading up to and supporting the proposed research

Food insecurity, defined as limited access to nutritious food due to cost[2], has been associated with increased prevalence of diabetes[3, 4], and worse diabetes control.[5, 6] Food insecurity may worsen diabetes by decreasing consumption of fresh fruits and vegetables and increasing consumption of inexpensive, calorie-dense food, and which in turn leads to greater Hemoglobin A1c, an indicator of hyperglycemia, over time[7].

c. Rationale behind the proposed research, and potential benefits to participants and/or society

Approximately 20% of diabetes patients report food insecurity, a number that increases to over 25% among those with the worst metabolic control.[5] The prevalence of food insecurity is also 20% in the MGH Population we surveyed (data not yet published). Hyperglycemia is particularly responsive to dietary changes,[8] yet few interventions have attempted to address food insecurity in diabetes care. Prior studies have examined the impact of the Supplemental Nutrition Assistance Program (SNAP, formerly the Food Stamp Program), but have not found important improvements in diabetes outcomes for participants[9]. This may be because neighborhood access to produce and other high quality food is low for many SNAP participants, or because making healthy food choices is difficult in resource-constrained environments. Additionally, recent sociological work has shown that expecting low-income women to cook healthy meals for their families induces a significant burden[10], and the burden of these expectations may drive less healthy food choices. Additionally, while significant time is needed for healthy food preparation[11], low-income patients often face limited leisure time, and multiple competing demands for both time and financial resources. Alternatively, direct provision of healthy foods was incidentally noted to improve diabetes outcomes in a prior randomized controlled trial[12], but this study was not conducted with the goal of addressing food insecurity.

In this study, we propose to test whether home delivery of freshly prepared meals specifically tailored to the needs of diabetes patients improves their dietary quality. We

hypothesize that the delivery of the meals will help them eat more healthily and improve the food security of participants. Secondary outcomes in this pilot study will be weight and metabolic control, along with psychological aspects of diabetes care.

This project aligns with MGH's Strategic Plan goal to address diabetes in the communities MGH serves. Further, this project will serve as an important test of the concept of 'Food as Medicine', the idea that we can improve management of chronic, diet-sensitive diseases by approaching the food people eat with the same rigor we apply to pharmaceutical studies.

II. SPECIFIC AIMS

a. Objectives and hypotheses to be tested in the research project

The goal of this pilot project is to demonstrate that enrolling MGH diabetes patients in the Community Servings nutritionally tailored meal delivery service is feasible and leads to dietary improvements that would be expected to offer clinical benefits in larger scale studies over longer timeframes. To maximize the knowledge gained from participation in this study, we will measure several self-reported, laboratory, and clinical outcomes, but the primary purpose of this study is to provide pilot data for a larger proposal.

Aim 1: To evaluate the effectiveness of receiving Community Servings meals on dietary quality for food insecure diabetes patients with severe hyperglycemia (HbA1c > 8.0%)

H1. Primary outcome. Healthy Eating Index 2010 (HEI) score: We hypothesize that the CS group will demonstrate greater improvements in dietary quality, as assessed by HEI score, at 12 weeks, compared with usual care. The sample size of 50 provides 80% power to detect a 5 point difference between the CS and usual care groups, assuming an 11 point standard deviation and accounting for a 10% drop-out rate.

H1b. Secondary exploratory outcomes. Medical outcomes: We hypothesize that compared with usual care, CS group participants will improve HbA1c, blood pressure, weight, and lipids from baseline at the end of the intervention.

H1c. Behavioral and psychosocial outcomes: Because meal provision will reduce stress related to procuring healthy meals, and free up household resources that would otherwise be spent on food, we hypothesize that compared with usual care, the CS groups will have greater improvements from baseline in patient-reported outcomes of diabetes distress and material need security.

Aim 2: To evaluate the feasibility of providing meals and patient experience with the CS program, particularly focusing on factors that determine acceptability, continuation, and scalability

We will use a mixed methods approach using participant structured interviews and surveys to assess engagement and satisfaction with the program, and participant interviews or focus groups to compare responders and non-responders. We will also collect quantitative indicators of feasibility and implementation such as percent of meals delivered and consumed, enrollment and persistence with the program, and logistical issues in order to plan for a future full-scale intervention.

Aim 3: To estimate the incremental cost per point increase of HEI of the CS group compared with usual care. The focus of our analysis will be identifying short-term costs and health effects that are relevant to accountable care organizations and insurers with the goal of informing the design of payment contracts that ensure the adoption of effective and efficient diabetes care.

III. SUBJECT SELECTION

a) Inclusion/exclusion criteria

Eligibility criteria for participation include:

- Diagnosis of type 2 diabetes
- Age 18 years or older
- HbA1c level >8.0%
- Report food insecurity as indicated by the 2-item USDA Food Security Survey Module[13]
- Willing to commit to random assignment to either receive CS meals immediately or as a waitlist control
- Stable health, with no severe medical comorbidities that might interfere with their ability to participate in the intervention, such as severe psychiatric illness or imminent hospitalization
- Be willing to keep a food diary
- Be willing to attend and complete a baseline, 12 week, and 24 week assessment at MGH
- Be able to understand and communicate effectively in English
- Have a primary care physician within the MGH practice based research network
- Live in an area where Community Servings can deliver meals
- Ability to store and prepare Community Servings meals

Exclusion criteria include:

- Must not be pregnant or planning pregnancy in the next year
- Currently enrolled in another diabetes study
- Receiving episodic treatments that may increase blood glucose levels (e.g. prednisone)
- Have a food allergy or intolerance that would preclude consumption of meals

b) Source of participants and recruitment methods

Participants will be recruited from MGH primary care practices. Participants can be identified by their primary care physician, nurse or nurse practitioner, dietician, or another clinician they have a relationship with. Patient registries will also be used to generate lists of potential participants for providers to review and identify eligible participants. We also have a small number of patients who have participated in a prior study on food insecurity and diabetes, and given permission to be re-contacted (Protocol number 2013P000552 PI: Deborah Wexler). These patients will start the recruitment process at Step 3, below.

From this potential pool, we will recruit using the following steps:

1) Conduct a manual electronic chart review using the primary care operations improvement diabetes registry to verify eligibility criteria and PCP linkage.

2) Obtain permission for initial contact from each potentially eligible patient's primary care physician (PCP) [see "PCP Patient Recruitment E-mail"]. After permission received, study staff will check to see if participant is in the process of being contacted or in the process of enrolling in another study (GRADE or REAL HEALTH) that is recruiting concurrently. If participant has already been contacted and is interested in GRADE or REAL HEALTH, we will not contact.

3) Send an introductory letter [see "Introductory Patient Letter"] to PCP-approved participants describing the study and procedures to opt out. This letter will include a phone number that participants can call to either decline further contact or to request that a study coordinator contact them.
4) If no answer is received after 2 weeks have passed, the potential research subject will be contacted by study staff to determine his/her willingness to participate.
5) If the subject is willing to participate, he/she will then undergo initial screening [see "Screening Phone Call Script"]. During this phone call, the study will be explained in further detail, subject questions will be answered, and an initial screening questionnaire to assess eligibility will be completed. Participants who remain eligible will be scheduled for an initial research visit and mailed an appointment reminder letter, food diary, and an informed consent form [see "Appointment Reminder" and "Informed Consent Form"] (described below "SUBJECT ENROLLMENT").
7) If the subject declines to participate, or does not wish to answer the questions at any point during the phone screening, he/she will be thanked for his/her time and the call will be ended.

In addition to the primary recruitment method described above, we will welcome referrals from MGH Primary Care groups. We will leave pamphlets in the waiting rooms of the MGH Primary Care practices. We will also use the Broadcast MGH email system to seek study volunteers if necessary [see "Email Broadcast"]. If a study volunteer contacts the Broadcast MGH e-mail system or other posting, we will contact their PCP to make sure it is safe for him or her to participate.

IV. SUBJECT ENROLLMENT

a. Methods of enrollment for the clinical trial

Participants who call to express interest in the study, or are contacted in follow up to the introductory letter to determine interest in participation, will first have a phone or in-person screening interview to explain the study protocol, answer questions, determine eligibility and willingness to continue the screening process. Those who qualify according to the phone screen will be mailed the consent form to review. They will also receive a 1 week food diary to complete. Study volunteers will be asked to write down what they eat and the portion size, and bring this diary to the baseline visit, Research Visit 1 (RV1). Ability to keep this log predicts potential participants' readiness for dietary change and serves as an eligibility criterion for randomization.

In order to participate in this study, participants must complete at least 4 of the 7 days of the food diary. If a participant has not completed at least 4 of 7 days of the diary, then he or she will be offered a second chance to complete this behavioral task and will be rescheduled to complete Research Visit 1 (see below).

b. Procedure for obtaining informed consent

If a subject meets eligibility criteria for the study and expresses a desire to participate, a member of the research team will personally review the consent form and obtain written, informed consent from the subject. This process will occur at the beginning of the initial research visit before any study procedures are performed. At the time of informed consent, participants will receive an explanation of the randomization process so that they are aware that they may or may not be assigned to receive the CS meals immediately. We will make it clear that the study participants can choose to leave the study at any point without providing a reason. We will emphasize that participants declining to enroll and those leaving the study midway will not be jeopardizing their usual clinical care in any way. Before giving consent, every volunteer will be asked if they would like to discuss any further questions with the study investigators via telephone.

c. Treatment assignment and randomization

The proposed study is a controlled clinical trial comparing two arms: immediate receipt of CS meals for 12 weeks, and a wait list control group that receives usual care for the first 12 weeks. The study schema is shown in **Figure 1.** Participants will be randomly assigned to one of these arms at the end of Research Visit 1 following informed consent, and data will be collected and compared at baseline and Research Visits at 12 and 24 weeks, along with a telephone check-in after 2 weeks. Those receiving CS meals will receive 10 nutritionally tailored (created with guidance from a registered dietitian on staff at Community Servings to be in accord with dietary recommendations for diabetes patients) meals that are delivered frozen once weekly. Adherence to these meals is expected to lead to improvements in HEI 2010 score, HbA1c, blood pressure, and lipid levels and possibly weight.

Both groups will receive a balanced meal planning handout from choosemyplate.gov[see "Educational Handout"].

If participants have any questions about costs, we will arrange for them to speak with the study doctors and study staff and if necessary someone in Patient Financial Services about these costs.

V. STUDY PROCEDURES

1. Initial Research Visit (RV1). Research Visit 1 will last about 2 hours. Participants will need to fast from midnight until the morning of the visit and wait until after their blood samples are drawn to take any diabetes medications [see "Visit Instructions for Participants"]. The participants will be met by a member of the study team at MGH. At this meeting, informed consent will be obtained by study personnel. After enrolling in the study, participants will be asked to provide their contact information so they can be reached by the study staff throughout the study should they need to reschedule or remind participants about an appointment. Next, participants will be asked to provide a blood sample of 6 mL taken by trained staff. Blood pressure will be taken resting and will be measured in duplicate using an automated device. Height and weight will be measured to derive BMI values. Once blood samples, blood pressure and height and weight are taken, participants can take their diabetes medication(s) and will be provided a snack. Participants will then be asked to complete a packet of self-administered study questionnaires to evaluate diet, health behaviors, depression, literacy and numeracy, food

insecurity, health-related quality-of-life, and obtain demographic information via RedCap web interface at the diabetes research center[see "Baseline Questionnaires and "Dietary Assessment"]. Study staff will be available to assist with completion for participants of low literacy or with visual impairment that prevents self-completion.

Participants will then be randomly assigned to either immediate CS meals or usual care followed by CS meals after 12 weeks, and be assigned study ID numbers. Participants in both arms will receive a balanced meal planning handout from choosemyplate.gov[see "Educational Handout"].

Participants assigned to the CS meals will receive information about the receipt of the meals (scheduling, storage and preparation requirement). They will also provide contact information to be shared with Community Servings to facilitate delivery[see "Intake For Meal Delivery"]. Upon completion of the visit, participants will receive a parking voucher or a check in the mail for $10 to cover transportation, if applicable. They will also receive a set of diaries to fill out while receiving meals to document consumption of the meals, and to provide feedback regarding satisfaction with the program and suggestions for improvement. This can be filled out on paper.

Patients will discuss their case with a representative of community servings, who will go over procedures for receiving meals. The patient will be given a copy of Community Servings' Client Guidelines, and sign the Community Servings Client agreement. They will also be given a copy of this to keep [see "Community Servings Agreement and Guidelines"].

All clinical data and survey instrument responses will be entered into study databases using RedCap, either directly by participants or by study staff. Study staff and/or the principal investigator will quality check the data after entry.

While receiving meals, the participants will fill out diaries tracking food consumption and feedback [see "Meal Receipt Diary"]

2. Research Visit (RV2 and 3).
Research Visit 2-3 will last about 2 hours. Participants will be scheduled for a research visits 12 and 24 weeks after the initiation of the intervention with a $\pm$ 2 week visit window. They will receive an appointment reminder[see "Appointment Reminder"]. Participants will need to fast from midnight until the morning of the visit and wait until after their blood samples are drawn to take any diabetes medications [see "Visit Instructions for Participants"]. The participants will be met by a member of the study team. Participants will be asked to provide a blood sample of 6 mL taken by trained staff. Blood pressure will be taken resting and will be measured in duplicate using an automated device. Height and weight will be measured and then entered into the electronic medical record to derive BMI values. Once blood samples, blood pressure and height and weight are taken and processed as outlined above, participants may take their diabetes medication(s) and will be provided a snack. Then they will be asked to complete self-administered study questionnaires on paper or via RedCap as outlined above [see "Dietary Assessment" and "RV 2-3 Questionnaire"]. Any changes in medication doses for glycemic control, blood pressure and lipid management will be reviewed and confirmed by cross checking in electronic medical record. Participants assigned to usual care initially will, at RV2, receive

information about Community Servings meals and delivery, and provide contact information as the other group did in RV1

Research visits will be conducted by study staff who have received CITI certification in Human Subjects research and has been trained and will be funded by the study for this purpose.

Participant compensation. Study participants assigned to the immediate CS meals group will receive payment of $25 for completing follow up assessment at 24 weeks to promote retention for outcome assessment, as they will stop receiving meals at 12 weeks. Study participants assigned to the delayed CS meals group will receive payment of $25 for completing follow up assessment at 12 weeks to promote attendance, as they will have not yet received meals, and to ensure equal compensation for the groups.

Study outcomes/ data to be collected

AIM 1 Outcomes and Assessment Protocol

Measures at baseline and follow up assessments

1. ***Demographics and clinical history (completed at baseline only):*** Participants will report their race/ethnicity, educational attainment, household income, household size, prescription drug coverage, health literacy[14], country of birth, and age at which they were diagnosed with diabetes.
2. ***Dietary Assessment:*** The patients diet will be assessed from data provided using the Dietary Screener Questionnaire, which asks food frequency questions with a 1-month look back window. Supplementary dietary information will come from the initial 1 week food diary, and a total of seven 24-hour food recall assessments: 3 in-person assessment from each research visit, and 4 telephone assessments: one covering a weekday period and one covering a weekend period both on and off CS meals. This information will be collected using the ASA24 module.
3. ***Weight/BMI*** measured in light street clothes (without shoes) using a single calibrated scale at the diabetes research center. Height measured using a stadiometer.
4. ***Resting blood pressure*** measured using a calibrated sphygmomanometer with appropriate cuff sizes based on arm circumference. Average of 2 readings, first manual and second automated at 1 min intervals following a 5 min period of rest.
5. ***Laboratory:*** Hemoglobin A1c (HbA1c) and fasting lipids will be drawn on site and run as research assays at MGH laboratories.
6. ***Medications and doses*** prescribed for diabetes, blood pressure and lipid management will be captured by chart review at each outcome assessment.
7. ***Food Insecurity:*** The USDA's Food Security Survey module, well-validated, and widely used on national epidemiologic surveillance surveys such as NHANES and NHIS. We will use the 10 adult referenced items, modified to have a 1 month look back period.[2, 15]
8. ***Diabetes Distress:*** Diabetes distress scale (DDS), a validated 17-item questionnaire that measures diabetes distress across 4 domains: Emotional burden, regimen distress, physician related distress, and interpersonal distress.[16]
9. ***Depression:*** Measured using the Patient Health Questionnaire 8 (leaving out the question on suicidality as is common in research protocols[17]). MGH primary care practices are

currently using the PHQ2 and 9 for depression screening. Participants found to be severely depressed will be connected to mental health services.

10. ***Medication adherence*** will be measured at baseline, 12 and 24 weeks using the 5-item Medication Adherence Rating Scale (MARS).[18-20]
11. ***Cost-related medication underuse:*** measured using the 4 cost-related medication underuse items from MEPS/NHIS.[21]
12. ***Food/Medication trade-offs:*** 4 questions about trade-offs between affording food, medications, and meeting other basic needs
13. ***Simon Task and Consideration of Future Consequences:*** cognitive tests meant to measure the burden of food scarcity and possible improvement.[22, 23]

Patient-reported outcomes will be completed by participants in a quiet room at the time of outcome assessments. Outcomes assessors will be trained to review and administer these instruments and to help participants when necessary.

These questionnaires typically take about 40-50 minutes to complete.

Aim 2: Feasibility/Implementation and Patient experience analysis

In this pilot study, we will assess and evaluate the feasibility and implementation of the program, and patients' experience with the CS program, with a particular emphasis on scaling the intervention from a pilot study to one that can test changes in clinical outcomes. In order to do this, we will need to optimize both the patient experience and the implementation of the intervention. To obtain these key data, we will utilize a mixed methods approach that combines quantitative data regarding implementation, quantitative data regarding patient satisfaction, and qualitative data on the patient experience with the program.

We will track meal delivery and timeliness, along with any logistical issues that arise such as participants being unable to accept delivery. All intervention participants will receive a diary to track meal consumption and as an opportunity to provide feedback about the program. The qualitative portion of the study will consist of focus groups with a semi-structured interview follow-up. We anticipate conducting up to 4 focus groups with 4-8 participants, with up to 20 semi-structured interviews. Topics of discussion for the focus groups and interviews will be guided based on our experiences implementing the intervention, but are anticipated to include discussions of patient satisfaction and suggestions for improvement regarding the food (type, quantity, cultural background), service/meal delivery, coordination between Community Servings and MGH/health care providers, and ways to support diabetes management in addition to food provision, and include feedback on currently available resources with regard to language needs and cultural relevance.

AIM 3: To estimate the incremental cost per patient receiving CS meals, compared with those receiving usual care. Our approach will incorporate the costs and benefits of the intervention, including training and implementation costs, staff and participant time, and any savings from reduced medication use. We will also examine differences in numbers of visits and

hospitalization rates for all models as exploratory analyses. We will measure health utility to facilitate subsequent cost-effectiveness analysis comparing the care models.

Evaluation of implementation costs. The focus of our analysis will be identifying short-term costs and health effects that are relevant to ACOs and insurers with the goal of informing the design of payment contracts that align financial incentives ensuring the adoption of effective and efficient diabetes care. At the same time, we will collect a broad range of cost data, including costs that fall exclusively to participants, to build a foundation for future studies of long-term cost-effectiveness taking a societal perspective.

Primary data will be collected for the study arms. The main cost components include the **cost of services provided**, including cost of meals and delivery, medication utilization, health care utilization, and program materials, as well as the cost of personnel time to deliver the meals. To minimize respondent burden, we will collect most information on health care utilization and medications from the electronic medical record. However, we will ask patients about care received outside the MGH system that we would not otherwise have access to.

VI. BIOSTATISTICAL ANALYSIS

a. Specific data variables (e.g. data collection sheets)

A list of the variables collected via medical chart review, survey instruments (from screening interview, research visits, and cost estimates) are listed in the protocol appendix [see 'Data variables list'].

b. Study outcomes

All outcomes will be assessed at baseline (prior to randomization) and at 12 and 24 weeks. Primary study endpoints will be change in HEI 2010, with secondary outcomes being food quality, weight change, glycemia (HbA1c), blood pressure, and lipids and medication prescriptions (number, dose and cost) for these conditions as well as health behavior, depression, food insecurity, diabetes distress and quality-of-life, patient satisfaction, and cost.

c. Statistical methods

For all continuous outcomes (% weight loss, HbA1c, blood pressure, fasting lipid levels, self-efficacy, health related quality-of-life score, and satisfaction with care), we will compare changes from baseline among groups using a mixed effects model that includes group, follow-up period (12 weeks or 24 weeks), group and period interaction, and baseline HEI 2010 score. The follow-up period will be modeled as a categorical variable; average changes at each time point by treatment group as well as the overall change (with all follow-up visits included in the model) will be presented.

d. Power analysis

Aim 1:

Sample size/power calculation.

H1a. A difference of 5 points on HEI 2010 score is considered clinically meaningful. The standard deviation of HEI 2010 scores in national cohorts is 11.[24] Our aim is to detect a clinically meaningful difference of 5 points between the groups. Assuming a SD of 11, the study will need an effective sample size of 38 (19 per arm) to detect a 10-point difference with 80% power. We assume a conservative 25% dropout rate. The final sample size will be 50, 25 per arm.

Further analyses:
H1b and H1c. We hypothesize that participants the CS meals will maintain or improve food quality, HbA1c, blood pressure, and LDL, along with improvement in psychological factors such as diabetes distress, and material needs issues such as food insecurity. In this pilot study, we do not anticipate sufficient power to detect clinically meaningfully differences in these outcomes. Instead, we hope to generate data that will be used to inform the design of future interventions.

Aim 2:
We will analyze feasibility and implementation data using descriptive statistics. For quantitative patient experience outcomes we will compare groups if appropriate, but the study is not powered to perform statistical analyses for this aim. We will analyze qualitative results using thematic coding.

Aim 3:
We will estimate the cost of each treatment model. A formal cost-effectiveness or cost-utility analysis (cost per QALY saved) is beyond the scope of this project, but we will collect data that may be used for a future effort if the intervention is effective.

VII. RISKS AND DISCOMFORTS
The risks to the participants will be minor, and be limited to 1) blood drawing, 2) discomfort answering questions 3) risks of intervention 4) loss of confidentiality. We will address these sequentially.

Blood drawing will be minimal. Three blood draws (total 6 mL) will be taken, one at baseline and one each at 12 and 24 weeks. Results of these blood draws may also be used for usual care. Participants may experience a small amount of pain. Occasionally a bruise may be produced. There is also a small risk of infection, lightheadedness, and/or fainting. Fasting overnight will be required, however a snack will be offered after the blood draw.

Discomfort answering questions. Some participants may feel uncomfortable answering questions about their diabetes, health, nutrition and daily activity. Participants will be told that that they may skip over the questions in the questionnaires that they do not want to answer.

Risks of the intervention: The risk of this intervention, which simply provides food, is minimal. Community Servings will work with participants to avoid foods they might be allergic too, but it is possible they may be allergic to a food they do not know about.

Subject confidentiality will be protected. In order to protect the privacy of the participants, they will be assigned a coded, anonymous numerical identifier at enrollment. Study specific data (mostly from the survey instruments) will be linked to this anonymous coded identifier only, and will not be part of the medical record.

For study-specific data, the key will be stored in the MGH General Internal Medicine Office in a locked cabinet and in the principal investigator's password-protected hard drive. Only study personnel who have undergone appropriate human research training and signed standard confidentiality agreements will have access to these data. All subject-related documents will be

stored in locked file cabinets within locked offices. However, it cannot be guaranteed that a breach will not occur.

VIII. POTENTIAL BENEFITS

a. Potential benefits to participating individuals

Participants will receive free, nutritionally tailored meals. Because food insecurity is an inclusion criterion, provision of these meals will increase access to healthy foods among food insecure diabetes patients. Based on prior nutritional work, it is possible that participants receiving the meals will lose weight and experience improvements in blood glucose control, blood pressure and lipid levels and reductions in some medications to treat these conditions.

b. Potential benefits to society

On a societal level, this proposal will be a step towards testing the idea of 'food as medicine' in the high-value clinical care of type 2 diabetes participants. Results will be shared through presentation at scientific meetings and manuscripts, and will inform future interventions of this type.

IX. MONITORING AND QUALITY ASSURANCE

a. Independent monitoring of source data

A Data Safety Monitoring Plan will be implemented. The PI will review the safety and progress of this study on a monthly basis. In addition, the PI will include results of the review in the annual progress reports submitted to the IRB. The annual report will include a list of adverse events. It will address: 1) whether adverse event rates are consistent with pre-study assumptions; 2) reason for dropouts from the study; 3) whether all participants met entry criteria; 4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and 5) conditions whereby the study might be terminated prematurely.

b. Safety monitoring

For this pilot, the study will employ a Data Safety Monitor who is an independent clinical investigator not affiliated with the study. The safety monitor will be charged with overseeing rates of recruitment, eligibility criteria, protocol adherence, and the tracking of patient safety. The data safety monitor will determine what, if any, safety stopping rules will be necessary. At a minimum, the monitor will meet with the PI (s) and co-investigators at 6, 12, and 24 weeks, and at study conclusion (should the study run long due to slower than anticipated recruitment) to evaluate the progress of the study and any safety concerns.

Study staff will document and log all adverse events for review by the PI. The Log will include the PI's evaluation of each event based on severity, whether it is related/unrelated to the study intervention, and if the event is anticipated/unanticipated. Based on that determination, the PI will follow the reporting requirements to the IRB within the required time frame. The Adverse Events Log will be provided to the DSM on a monthly basis.

Study staff will have each completed an IRB-required course in ethics and confidentiality in clinical research. Data will be largely electronic, stored on password protected Partners computers behind the partners firewall. Any data recorded on paper will be gathered in a subject

file that will be identified by number only, kept in a locked cabinet, and be made available only to authorized, trained study staff.

c. Adverse event reporting guidelines
Each subject is evaluated for any adverse events. Any event that is reported to either the PIs or the study staff by the subject or medical staff caring for the subject and which meets the criteria will be documented as such. Any event that is reported will then generate an adverse event report, which will be submitted to the IRB at the appropriate time. The report will include a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or the reporting of the event. Any severe, related, and/or unanticipated adverse event will be immediately reported to the IRB. All other adverse events will be reported in a timely fashion to the IRB per reporting guidelines depending on the severity of the event. All adverse events will be summarized annually and submitted to the IRB.

d. Data integrity
The research team will ensure that the documentation of all consent forms, questionnaires and diaries are adequate and accurate. Electronic data capture will be stored on RedCAP, the Partners Research Computing HIPAA and research-compliant electronic data capture system. The research team will also ensure that all paperwork is securely stored in locked drawers. Documents that include participants' PHI will be kept separately from documents that include the participants' study code.

The research team will maintain confidentiality of data. All study demographic and survey data will be entered by study staff to RedCap. Each participant will be given a coded ID. A master key of the coded IDs and participant MRNs will be kept in a secure and password protected file by the PI as well as within RedCap. Only study staff that requires access to the password protected file or RedCap will be given access to it.

Separation of subject names and identifiable health information from the data will be done through the use of unique identifiers. All information transferred via the Internet will be done using at least 128-bit SSL encryption. All email sent out of the Partners firewall will be sent through Send Secure if any medication or diagnoses are included. Virus and password-protected facilities will be provided for the research team. All mobile devices will be encrypted to the standard defined by the Partners Laptop and Portable device encryption policies.

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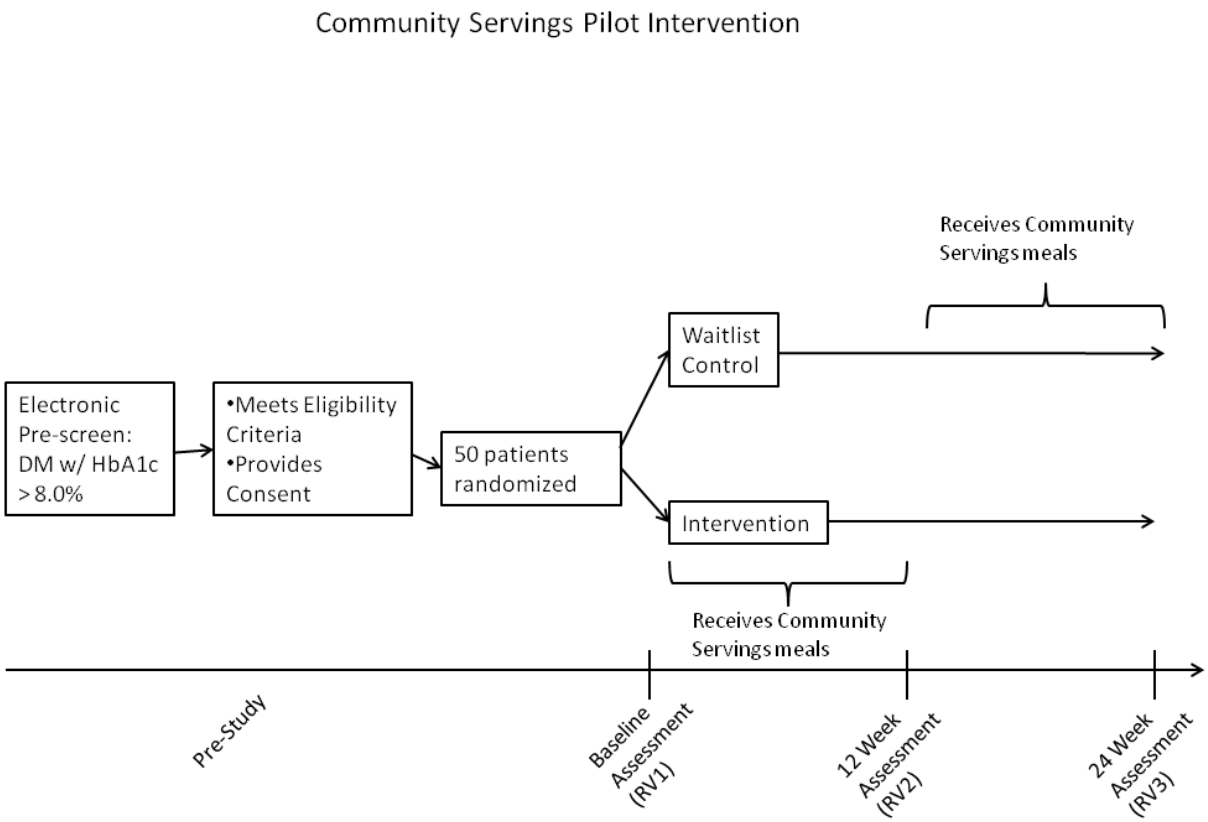
XI. STUDY SCHEMATIC



XII. APPENDICES

1. PCP Recruitment E-mail
2. Introductory Patient Letter
3. Screening Phone Call Script
4. Appointment Reminder
5. Informed Consent Form
6. Email Broadcast
7. Educational Handout
8. Visit Instructions for Participants
9. Intake for Meal Delivery
10. Baseline (RV1) Questionnaires
11. Dietary Assessments
12. Meal Receipt Diary
13. Follow up (RV2-3) Questionnaires
14. RV2-3 Appointment Reminder
15. Data Variables List
16. Community Servings Agreement and Guidelines

Data Variables List (to be collected/confirmed from electronic medical record)

1. Age and date of birth
2. Race/ethnicity
3. Gender
4. Education
5. Insurance
6. Height
7. Weight
8. Hba1c
9. Blood pressure
10. Lipids
11. Medications and doses
12. Co-morbidities
13. Visits
14. Billing charges
15. Questionnaire items
16. Dietary Assessment Items