Supplement 1

CLINICAL STUDY PROTOCOL

Kaiser **P**erma**n**ente Evaluation **o**f Medically Tailored Meals in Ad**u**lts with Ch**r**onic Med**i**cal Condition**s** at **H**igh Readmission Risk (***KP NOURISH***)

Study Name:	***KP NOURISH***
Study Phase:	Phase III
Indication:	Heart failure, type 2 diabetes mellitus, chronic kidney disease
Funder:	Kaiser Permanente's National Shared Agenda Leadership Team, as part of the Bold Moves Food for Life Activation, Kaiser Permanente Community Health
Protocol Date and Version:	30 June 2021, Version 1.0
CONDUCT In accordance with the ethical principles that originate from the Declaration of Helsinki and that are consistent with International Council for Harmonization (ICH) guidelines on Good Clinical Practice (GCP) and regulatory requirements as applicable.	

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1 List of Abbreviations

Ceres = Ceres Community Project
CKD = chronic kidney disease
Covid-19 = COronaVIrus Disease 2019
DASH = Dietary Approaches to Stop Hypertension
DM = diabetes mellitus
DOR = Division of Research
ED = emergency department
EHR = electronic health record
eGFR = estimated glomerular filtration rate
GCP = good clinical practice
HIPAA = Health Insurance Portability and Accountability Act
ICD = International Classification of Diseases
ICH = International Conference on Harmonization
IRB = Institutional Review Board
KP = Kaiser Permanente
KPNC = Kaiser Permanente Northern California
MTMs = medically tailored meals
PCT = pragmatic clinical trial
PHI = protected health information
POH = Project Open Hand
RCT = randomized controlled trial
RDN = registered dietitian nutritionist
SAP = statistical analysis plan
SAS = statistical analysis system
SNF = skilled nursing facility
TZD = thiazolidinediones

2 Synopsis

Title	**K**aiser **P**erma**n**ente Evaluation of Medically tailored Meals in Ad**u**lts with Ch**r**onic Medi**c**al Condition**s** at **H**igh Readmission Risk
Brief Title	***KP NOURISH***
Clinical Phase	Phase III
Investigation Type	Interventional (Pragmatic)
Study Type	Prospective, virtual, remote, Electronic Health Record (EHR)-based, parallel-group, randomized, decentralized pragmatic clinical trial (PCT)
Purpose and Rationale	Adults with chronic conditions account for two-thirds of total U.S. health care expenses. Based on current trends, by 2023, chronic diseases will cost $4.2 trillion annually in treatment and lost economic output in the U.S. Addressing the social determinants of health can be an effective mechanism for reducing health care costs. Specifically, for adults with chronic illness, previous research has found a correlation between the delivery of certain types of social services and reductions in avoidable hospitalizations. Additionally, existing literature suggests that food insecurity or evidence of poor nutrition are common among individuals at the time of hospital discharge, and particularly among older adults and those with multimorbidity. These individuals may also experience other basic resource needs (inadequate or unsafe housing, transportation barriers, social isolation, etc.) that compound their difficulty in obtaining sufficient and/or nutritious food. Home-delivered meals may thus free up financial resources to address other social needs, reduce social isolation, and reduce transportation demands on the individual and their family. This is even more relevant in California given the impact of the ongoing novel coronavirus disease 2019 (Covid-19) pandemic and associated public health responses (e.g., statewide shelter in place orders enacted in early 2020) and supply chain difficulties, which have collectively introduced additional barriers to obtain healthy food, especially among at-risk individuals. Medically tailored meals (MTMs) provided for a limited time after hospital discharge may help achieve several desirable outcomes. Most directly, they may mitigate food insecurity, social isolation and nutritional deficits related to their nutrition-sensitive chronic medical condition. In turn, these effects may help vulnerable patients return to a more optimal nutritional status and clinical recovery more quickly after hospital discharge and improve patient and family satisfaction with care at home. The cost of MTMs may also offset use of acute care services (hospitalizations and emergency department [ED] visits) that could potentially be prevented after

	discharge from the index hospitalization. Given the increasing consideration among health insurers about providing MTMs as a benefit of enrollment, and recent federal Center for Medicare and Medicaid Services' guidance allowing MTMs as a supplemental benefit in selected populations, there is a pressing need to generate robust evidence about the potential efficacy of MTMs to guide health policy and health care delivery system decision-making.
Study Design	This study is a remote, decentralized, randomized PCT. We will compare outcomes in 3 groups of recently hospitalized patients with a targeted, nutrition-sensitive chronic medical condition (i.e., heart failure, diabetes mellitus or chronic kidney disease): participants receiving MTMs alone, participants receiving MTMs with remotely delivered nutritional counseling, and patients receiving usual standard of care. Participants will be recruited from Kaiser Permanente (KP) Santa Rosa, Santa Clara, Oakland, San Francisco, and San Rafael Medical Centers. The Ceres Community Project (Ceres) will provide MTMs service to patients enrolled at KP Santa Rosa and San Rafael Medical Centers and Project Open Hand (POH) will provide MTMs service to patients enrolled at KP Santa Clara, Oakland and San Francisco Medical Centers.
Intervention	MTMs (with or without remotely delivered nutritional counseling) vs. usual care
Inclusion Criteria	1. Men and women age ≥18 years at admission to the index hospitalization 2. Hospitalized at KP Santa Rosa, Santa Clara, Oakland, San Francisco, or San Rafael Medical Centers 3. Kaiser Permanente Northern California (KPNC) membership at admission to the index hospitalization 4. Has a prior history of at least one of the following conditions: a. Heart failure (defined as ≥3 prior outpatient diagnoses or ≥1 inpatient principal discharge diagnosis or heart failure on current hospital problem list with a corresponding inpatient B-type natriuretic peptide value ≥100 pg/mL) b. Diabetes mellitus (defined as ≥1 principal inpatient discharge diagnosis within 5 years or ≥2 outpatient diagnoses, excluding optometry and ophthalmology diagnoses, within 5 years or ≥2 abnormal diabetes-related lab test results on separate days within 3 years or ≥1 prescription of a diabetes medication at any time, and not meeting the following exclusions: any diabetes indicator within 8 months before to 1 month after childbirth or a diabetes therapy prescription of metformin or a thiazolidinedione within 2 years after a diagnosis of a non-diabetes metabolic or fertility issue, with no other indication of diabetes.) c. Chronic kidney disease (defined as ≥2 outpatient

	estimated glomerular filtration rate [eGFR] values between 30-45 ml/min/1.73 m^2 within the prior 2 years and the most recent value ≥30 ml/min/1.73 m^2) 5. Able to speak English 6. Able to provide verbal informed consent
Exclusion Criteria	1. Inability to receive meals delivered to home residence 2. Inability to store or heat food 3. Requiring individual meal customization beyond MTMs
Primary Outcome	Occurrence of an acute hospitalization for any reasons within 90-days after discharge from the index hospitalization.
Secondary Outcomes	1. 90-day emergency department visit for any cause 2. 90-day death for any cause 3. Composite of 90-day readmission, emergency department visit, or death for any cause 4. 90-day readmission for heart failure 5. 90-day readmission for diabetes-related complication 6. 60-day readmission for any cause 7. 30-day readmission for any cause
Clinical Impact	KP is partnering with two community-based MTMs vendors to evaluate the effects of MTMs and remotely delivered nutritional counseling on various outcomes of patients with targeted nutrition-sensitive chronic medical conditions being discharged to home from KP Santa Rosa, Santa Clara, Oakland, San Francisco, and San Rafael Medical Centers in a randomized controlled trial (RCT) cohort. Due to the projected rise of Covid-19 in our patient population within KPNC and the urgency for optimizing care for our most at-risk members, there is a national KP effort to implement this study as quickly as possible.

3 Schedule of Assessments

	Screening	Consent	Follow-up	Closeout
Visit number	0	1	2	3
Day	0	1	Discharge + 70 Days	Discharge + 90 Days
Informed Consent		X		
Randomization	X			
Demographics	X	X		X
Medical History	X			X
Medications	X			X
Vital Signs	X			X
Laboratory Values	X			X
Baseline Assessment		X		
Post-Discharge Follow-Up Assessment			X	
MTMs/MTMs Plus Nutritional Counseling			X	
Study Close Out				X
Endpoints				X

Note: There are no in-person study visits, and all study visits will consist of a data pull by a study data analyst and/or a telephone or video encounter between a member of the study team (i.e., Study Coordinator) and the participant. Participants randomized to the MTMs (with or without remotely delivered nutritional counseling) received one week's worth of meals once a week for up to ten weeks. Participants randomized to MTMs with remotely delivered nutritional counseling also receive up to 3 virtual (i.e., by telephone or video) nutritional counseling sessions by a registered dietician nutritionist (RDN) between Week 1-2, Week 4-5, and Week 8-9 after hospital discharge.

4 Introduction

4.1 Chronic Conditions and Avoidable Hospitalizations

Adults with chronic conditions account for two-thirds of total U.S. health care expenses.[1] Based on current trends, by 2023, chronic diseases will cost $4.2 trillion annually in treatment and lost economic output in the U.S.[2] Addressing certain social determinants of health has been shown to be an effective mechanism for reducing health care costs and improving clinical outcomes in selected populations. Specifically, for individuals with chronic conditions, research has found a correlation between the delivery of social services and reductions in avoidable hospitalizations.[3-5] Additionally, substantial literature suggests that food insecurity or evidence of poor nutrition are common among individuals at the time of hospital discharge, and particularly among older adults and those with multimorbidity.[6-11]These individuals may also experience other basic resource needs (inadequate or unsafe housing, transportation barriers, social isolation, etc.) that compound their difficulty in obtaining sufficient or healthy food. Home-delivered meals may thus free up financial resources to address other social needs, reduce social isolation, and reduce transportation demands on the member and their family. This is even more relevant in California given the impact of the ongoing novel coronavirus disease 2019 (Covid-19) pandemic and associated public health responses (e.g., statewide shelter in place orders enacted in early 2020) and supply chain difficulties, which have collectively introduced additional barriers to obtain healthy food, especially among at-risk individuals.

4.2 Rationale for MTMs After Hospitalization

Medically tailored meals (MTMs) provided for a limited time after hospital discharge may help achieve several desirable outcomes. Most directly, they may mitigate food insecurity, social isolation and nutritional deficits related to their nutrition-sensitive chronic medical condition. In turn, these effects may help vulnerable patients return to a more optimal nutritional status and clinical recovery more quickly after hospital discharge and improve patient and family satisfaction with care at home. The cost of MTMs may also offset use of acute care services (hospitalizations and emergency department [ED] visits) that could potentially be prevented after discharge from the index hospitalization. Given the increasing consideration among health insurers about providing MTMs as a benefit of enrollment, and recent federal Center for Medicare and Medicaid Services' guidance allowing MTMs as a supplemental benefit in selected populations, there is a pressing need to generate robust evidence about the potential efficacy of MTMs to guide health policy and health care delivery system decision-making.

4.3 Objectives for KP NOURISH Pragmatic Clinical Trial

To date, no definitive randomized controlled trials have assessed the impact of in-home MTMs or other supplemental food services on health care-related outcomes in at-risk adults recently discharged from the hospital. Two small randomized trials[12, 13] and several lower-quality studies[14, 15] reported outcomes of home-delivered meal programs after hospital discharge. In a Spanish study,[12] an intensive nutritional intervention in patients with acute heart failure and anthropometrically-confirmed malnutrition was

associated with lower all-cause mortality and fewer heart failure-related readmissions. In another pilot study of 66 patients with acute heart failure, 4 weeks of home-delivered, MTMs produced a clinically meaningful but not statistically significant reduction in heart failure rehospitalizations (11% vs. 27%, p = 0.06).[13] Other previously published studies have included small sample sizes and/or used studies designs that could not appropriately control for potential confounders or selection bias.

Although MTMs may be beneficial even in individuals who are able to afford and prepare nutritious meals, individuals with food insecurity may derive particular benefit. Accumulating data suggest that food insecurity may be prevalent among certain segments of the KP membership.[16] Furthermore, the current Covid-19 pandemic has put additional, substantial strain on local and county services (e.g., food banks) that have been trying to address the growing food insecurity situation in Northern California.

Thus, there is a sound clinical rationale for assessing the efficacy of MTMs in high-risk KP members. Existing preliminary evidence from other health care delivery systems suggest that MTMs interventions may improve nutritional, social, clinical and system-level health outcomes. However, more definitive evidence is needed about MTMs given the broad implications for patients, families, insurers and health care delivery systems. In addition, rigorous data are needed about whether a specific duration of MTMs with or without additional nutritional counseling can influence clinical and patient-centered outcomes, as well as whether the number of MTMs per week matter or if a particular subset of patients are most likely to benefit from MTMs services.

5 Aims and Endpoints

The KP NOURISH Study has four overall Specific Aims:

Aim 1 (Primary): To determine if MTMs provided for up to 10 weeks after hospital discharge for patients with pre-existing heart failure, diabetes mellitus or chronic kidney disease will reduce the risk of all-cause readmissions at 90 days after discharge.

> Hypothesis 1: Patients receiving MTMs will have lower all-cause readmission rates at 90 days compared with patients who are receiving only usual care.

Aim 2 (Secondary): To determine if MTMs provided for up to 10 weeks after hospital discharge for patients with heart failure, diabetes mellitus or chronic kidney disease will reduce the risks of 90-day admissions for heart failure, admissions for diabetes-related complications, all-cause emergency department visits, all-cause death, and a composite of all-cause health care utilization and death.

> Hypothesis 2: Patients receiving MTMs will have better clinical outcomes compared with patients who are receiving only usual care.

Aim 3 (Secondary): To determine if MTMs provided for up to 10 weeks after hospital discharge for patients with heart failure, diabetes mellitus or chronic kidney disease will experience improved selected patient-reported outcomes (i.e., self-efficacy, social isolation, patient satisfaction, and perceived caring) at 10 weeks post-discharge.

> Hypothesis 3: Patients receiving MTMs will have better patient-reported outcomes compared with patients who receiving only usual care.

Aim 4 (Secondary): To determine if MTMs provided for up to 10 weeks with additional remotely delivered nutritional counseling after hospital discharge for patients with heart failure, diabetes mellitus or chronic kidney disease will experience improved all-cause and cause-specific clinical outcomes at 90-days post-discharge as well as selected patient-reported outcomes (i.e., self-efficacy, social isolation, patient satisfaction, and perceived caring) at 10-weeks post-discharge.

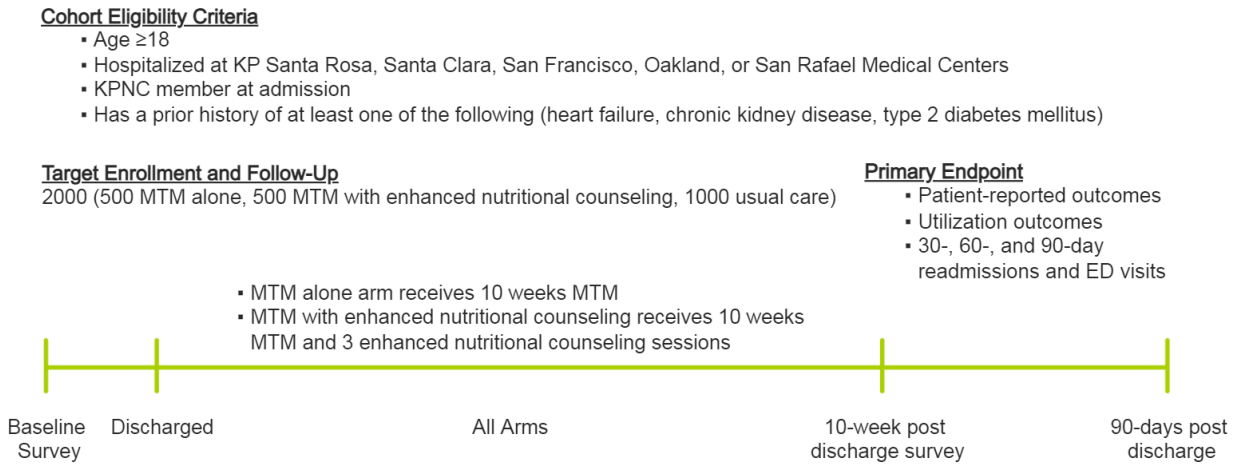
> Hypothesis 4: Patients receiving MTMs with remotely delivered nutritional counseling will have lower 90-days risks of adverse clinical outcomes and better patient-reported outcomes at 10-weeks post-discharge than patients receiving MTMs alone.

6 Study Design

*The **KP NOURISH Study*** is a virtual, remote, decentralized, EHR-based, parallel-group, randomized PCT. Participants with a targeted nutrition-sensitive chronic medical condition (i.e., heart failure, diabetes mellitus or chronic kidney disease) hospitalized at one of five medical centers (KP Santa Rosa, Santa Clara, Oakland, San Francisco, and San Rafael) will be identified and pre-randomized to 1 of 3 groups: receiving MTMs alone, MTMs with remotely delivered nutritional counseling, and patients receiving usual standard of care after hospital discharge. For the study, Ceres will provide MTMs and virtual nutritional counseling service to patients enrolled at KP Santa Rosa and San Rafael Medical Centers and POH will provide MTMs and virtual nutritional counseling service to patients enrolled at KP Santa Clara, Oakland, and San Francisco Medical Centers.

Figure 6-1 summarizes the study design, intervention and baseline and follow-up measurements.

Figure 6-1. KP NOURISH Study Design.



Participants at the KP Santa Rosa, Santa Clara, Oakland, San Francisco, and San Rafael Medical Centers will be identified daily from EHR data and electronically screened for inclusion criteria using KPNC EHR and associated data systems. After identification, participants will be pre-randomized to intervention or usual care arms using a SAS statistical software randomization program, and a list of initially eligible patients will be uploaded to a KPNC DOR-hosted web application to which only KPNC DOR research staff will have access. After confirming eligibility through manual review of the EHR, KPNC DOR research staff will then call the participant by phone in their hospital room and inquire about their interest in learning about the KP NOURISH Study. If interested, KPNC DOR research staff will review the procedures that the participant would be asked to complete and review verbal consent. Participants providing verbal consent to participate in the study will also be asked for verbal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Authorization. Participants providing verbal consent and HIPAA Privacy Rule Authorization will then complete the baseline study visit during the enrollment phone call, which includes questions about sociodemographic characteristics, selected patient reported outcomes, contact information, and ability to receive MTMs (if randomized to receive MTMs). Additionally, following enrollment, KPNC DOR research staff will email the participant thanking them for agreeing to participate in the study and to provide contact information for the study team and for the KPNC Institutional Review Board (IRB) if they have any questions after completing the baseline study visit. This email will also include a study flyer with additional details about their participation in the study. Participants requesting a study mailing will also be mailed the thank you letter and study flyer to their home residence.

After completion of the baseline study visit, KPNC DOR research staff will monitor the participant's discharge status on a daily basis, and upon discharge notify the MTMs service provider (Ceres or POH) to begin delivery service for up to 10 weeks for participants assigned to MTMs alone or and to MTMs with remotely delivered nutritional counseling groups. Participants assigned to the usual care group will be passively

monitored post-discharge and will receive care as directed by their usual treating physicians—these participants will not receive MTMs or remotely delivered nutritional counseling through Ceres or POH. Participants in the usual care group will only be asked to complete a 10-minute survey by phone at 10-weeks after hospital discharge. Participants eligible for and assigned to MTMs but unable to receive meals at home will also be followed passively and asked to complete a 10-minute follow-up survey at 10-weeks after hospital discharge.

Participants receiving MTMs will receive a call from the MTMs service provider to set up their meal delivery schedule, discuss optimal delivery location for their residence type, and initiate MTMs delivery within the target window of 7 days after discharge. MTMs are meals customized for the optimal health of the participant's specific nutrition-sensitive chronic medical condition (e.g., heart failure, diabetes mellitus or chronic kidney disease). The meals provided by Ceres or POH will all follow Food is Medicine™ Coalition nutritional standards (http://www.fimcoalition.org/s/Nutriton-Standards_2_04_2021-docx-6lxx.pdf) as well as current KPNC nutritional guidelines, and will be delivered to the participant's home residence for 10 weeks (1 large meal per day).

Participants who are randomized to receive MTMs with remotely delivered nutritional counseling will also be contacted by a registered dietitian nutritionist (RDN) from the MTMs service provider (Ceres or POH). The RDN will aim to conduct a telephone or video visit during Week 1-2, Week 4-5, and Week 8-9 post-discharge, for a total of 3 remotely delivered nutrition counseling sessions (content described in Table 3 in Section 5: 10-Week Follow-up).

For participants receiving MTMs, after completion of 10-weeks and the last meal delivered, KPNC DOR research staff will contact the participant to complete a 10-week follow-up survey by phone on patient-reported outcomes and also mail a letter to participants thanking them for participating in the study. For participants randomized to the usual care arm, KPNC DOR research staff will contact the participant to complete a 10-week follow-up survey by phone on patient-reported outcomes and mail a letter thanking them for participating in the study as well as a $10 gift card.

KPNC DOR research staff will also collect data from the MTMs service providers (Ceres or POH) on process measures collected routinely through their service (e.g., meal delivery schedule, number of meals eaten, number of meals skipped). Our KPNC DOR research staff will also follow all identified participants through their EHR for 30-, 60-, and 90-day clinical outcomes. For participants receiving MTMs for their households, a sample of up to 30 patients will be contacted to ask for their interest in completing a 30-minute phone interview to ask about their experience receiving meals for their household in the KP NOURISH Study.

Enrollment will occur over a targeted 1-year timeframe, and all participants will be followed for at least 90 days after discharge from the index hospitalization. Clinical utilization outcomes will be passively and electronically assessed via the KPNC EHR, which includes hospitalizations and emergency department visits within and outside of KPNC facilities.

7 Study Population

The ***KP NOURISH Study*** will enroll a total of 2000 participants: 1000 participants will be randomized to MTMs (500 will be randomized to MTMs alone and 500 will be randomized to the MTMs with remotely delivered nutritional counseling) and 1000 participants will be randomized to usual care.

7.1 Inclusion Criteria

1.) Men and women age ≥18 years at the index admission
2.) Hospitalized at KP Santa Rosa, Santa Clara, Oakland, San Francisco, or San Rafael Medical Centers
3.) KPNC member at admission
4.) Has a prior history of at least one of the following potentially nutrition-sensitive chronic medical conditions:
    a. Heart failure (≥3 prior outpatient diagnoses or ≥1 inpatient principal discharge diagnosis, not including the index hospitalization)
    b. Diabetes (≥1 inpatient principal discharge diagnosis within 5 years or ≥2 outpatient diagnoses, excluding optometry and ophthalmology diagnoses, within 5 years or ≥2 abnormal lab test results on separate days within 3 years or ≥1 prescription of a diabetes medication at any time, and not meeting the following exclusions: any diabetes indicator within eight months before to one month after childbirth or a diabetes therapy prescription of metformin or a thiazolidinediones (TZD) within two years after a diagnosis of a non-DM metabolic or fertility issue, with no other indication of diabetes)
    c. Chronic kidney disease (≥2 outpatient eGFR values between 30-45 ml/min/1.73 m^2 within prior 2 years and the most recent pre-admission value ≥30 ml/min/1.73 m^2 using the CKD-EPI estimating equation)

7.2 Exclusion Criteria

1.) Primary home facility not KP Santa Rosa, Santa Clara, Oakland, San Francisco, or San Rafael Medical Centers
2.) Interpreter needed
3.) Admitted from skilled nursing facility/nursing home
4.) Homeless
5.) Residence outside MTMs provider delivery area
6.) Prior history of organ transplant

7.3 Electronic Screening

Patients at the KP Santa Rosa, Santa Clara, Oakland, San Francisco, and San Rafael Medical Centers will be identified daily for eligibility criteria using the KPNC EHR and associated data systems. A cron job scheduled on the KPNC DOR SAS grid server will execute a SAS statistical software program at 6:45 AM Monday through Friday that pulls relevant data from EHR databases, automatically applies the inclusion and exclusion criteria, randomizes patients to one of the three study arms, generates a unique study identifier, and outputs a file of all patients hospitalized at the participating KPNC hospital and their associated information needed for recruitment that is then automatically uploaded to web-based study tracking systems based at the KPNC DOR.

7.4 Randomization

This study will incorporate the concept of pre-randomization (i.e., prior to obtaining informed consent and administering the intervention) in order to streamline the study workflow consistent with the pragmatic trial design. Pre-randomization will be stratified by participating KPNC medical center (i.e. participants will be pre-randomized separately within each medical center).

7.5 Manual Eligibility Confirmation

After automated identification and randomization, a list of initially eligible patients will be uploaded to a KPNC DOR-hosted website that only KPNC DOR research staff will have access to for the purpose of this study. KPNC DOR research staff will complete manual review of patient EHR data to confirm study eligibility before contacting study participants. The additional exclusion criteria that were identified through manual review of EHR data includes:

1) Planned discharge to a skilled nursing facility, nursing home, rehabilitation facility, assisted living facility, board and care facility, or hospice facilities
2) Planned receipt of home hospice or comfort care services upon discharge
3) CKD progression to eGFR <30 mL/min/1.73 m^2 before discharge
4) Died during the index hospitalization
5) Inability to provide informed consent (e.g., due to acute delirium or dementia, substance use disorder, speech or hearing disability, significant language barrier)
6) Inability to receive meals (e.g., dietary restrictions, residence outside delivery areas by MTMs vendors, or already receiving meals from another meal service)
7) A study physician deemed not a suitable candidate due to severe multimorbidity or other life-limiting diagnoses

8 Follow-up

KPNC DOR research staff will check enrolled participants' bed status daily for discharge and track each participant's status in the Appian-based study online tracking system. KPNC DOR research staff will place a note in the Appian-based study online tracking system the date that participants are discharged from the hospital.

8.1 Follow-up in Usual Care Participants

Following discharge from the index hospitalization, participants randomized to the usual care arm are followed passively by KPNC DOR research staff through the KPNC EHR over the course of the next 10 weeks.

8.2 Intervention Follow-up

8.2.1 10-Week MTMs Delivery

After participants assigned to the MTMs alone or MTMs plus remotely delivered nutritional counseling arms are discharged, KPNC DOR research staff will create Excel files of the discharged participants' intake information and send it to Ceres and POH staff. Ceres and POH staff will contact patients and complete intake within 24 hours of patient discharge from the hospital.

During this initial phone call, Ceres and POH staff will use a structured approach to discuss:

- The participant's health needs
- The participant's current diet
- The MTMs program

Ceres and POH will also schedule the first MTMs delivery date and the weekly delivery times. Ceres and POH will target to deliver the first MTMs within 72 hours and no later than within 1 week of hospital discharge.

Over the course of the next 10 weeks, Ceres and POH delivery drivers will conduct wellness checks to briefly assess the well-being of the participant when they deliver weekly meals. Participants will also complete meal evaluations forms for the past week's meals.

Ceres and POH will document when they are unable to complete a delivery and communicate missed deliveries to the KPNC DOR research team to try to facilitate a successful delivery attempt.

Once the last MTMs delivery is made at the end of 10 weeks, Ceres and POH will inform the KPNC DOR research team and the date of the last meal delivered will be entered into the Appian-based study online tracking system.

8.2.2 Adjustment in MTMs

Compliance with study-provided MTMs will be encouraged by KPNC DOR research staff and meals vendors at each planned contact. Participants will be allowed to pause delivery of MTMs for up to two consecutive weeks as necessary (e.g., due to trips or buildup of MTMs at home). Participants can also request to receive as few as 4 meals per eligible household member per weekly home delivery.

8.2.3 Remotely Delivered Nutritional Counseling

For participants assigned to MTMs with remotely delivered nutritional counseling, Ceres and POH will also schedule the participant's first telephone or video visit with a RDN sometime during Week 1 or Week 2 post-discharge. The RDN will conduct their second telephone or video visit with the participant during Week 4 or Week 5 and have one last visit with the participant during Week 8 or Week 9 (see overview of nutrition education content described in Table 3 below).

Table 3. Nutritional education content by study visit and qualifying chronic condition for participants assigned to receive MTMs with remotely delivered nutritional counseling.

Nutrition Counseling Visit #	Completion window (post discharge)	Heart Failure	Type 2 Diabetes Mellitus	Chronic Kidney Disease
1	Week 1-2	▪ Review 10-week food plan ▪ Introduce education materials ▪ Review the Healthy Plate ▪ Review nutrition for heart failure ▪ Instruct on fluid restriction and teach volume concepts	▪ Overview of packet ▪ Managing diabetes overview ▪ Know your carbohydrates ▪ DASH diet basics/principles ▪ MyPlate ▪ MyPlate assessment	▪ Review 10-week food plan ▪ Introduce education materials ▪ Review MyPlate for CKD ▪ Review nutrition for CKD ▪ DASH diet meal plan
2	Week 4-5	▪ Check-in on goals ▪ Dietary approaches to stop hypertension (DASH) diet meal pattern ▪ Low sodium diet ▪ Label reading	▪ Blood glucose tests ▪ Hypoglycemia ▪ Hyperglycemia ▪ Diabetes goals and progress ▪ Diabetes true/false	▪ Check-in on goals ▪ Meal planning ▪ Reading a food label ▪ Sodium in processed foods

Nutrition Counseling Visit #	Completion window (post discharge)	Heart Failure	Type 2 Diabetes Mellitus	Chronic Kidney Disease
3	Week 8-9	▪ Evaluation of goals ▪ Kitchen basics ▪ Recipe reading and use ▪ Navigate Eat Fresh (if internet access) ▪ Provide written instruction for cooking and recipes ▪ Cooking skills ▪ Grocery shopping scavenger hunt (practice with food labels)	▪ Nutrition facts label ▪ Sugar shockers ▪ Cut out added sugars ▪ Rethink your drink + activity	▪ Review DASH diet education ▪ Check in/review meal planning ▪ Personalized recipes ▪ Fast food choices

8.3 10-Week Study Completion Interview

For patients assigned to the usual care arm, KPNC DOR research staff will contact patients at 10-weeks after discharge from the index hospitalization. During this phone call, KPNC DOR research staff will ask patients about measures of:

- Self-efficacy
- Social isolation
- Perceived caring related to diet (i.e., perception that current meals help create a caring environment that facilitates healing)

Once participants have completed this telephone- or video-based survey, the KPNC DOR research staff will thank them for their time and inform them that they will be receiving a thank you letter and a $10 gift card.

For patients assigned to the MTMs alone arm or the MTMs plus remotely delivered nutritional counseling arm, KPNC DOR research staff will contact patients after Ceres and POH have delivered their last meals and informed the DOR research team of the completion of MTMs service. During this telephone- or video-based survey, DOR research staff will ask patients about measures of:

- Self-efficacy
- Self-reported levels of isolation
- Perceived caring (e.g., participating in a delivered MTMs program helps create a caring environment that facilitates healing)
- Satisfaction with MTMs vendor service

Participants assigned to the MTMs plus remotely delivered nutritional counseling arm will also be asked about their satisfaction with the nutritional counseling they received. Once participants have completed the survey, KPNC DOR research staff will thank them for their time and inform them that they will receive a thank you letter soon.

9 Discontinuation/Withdrawal

9.1 Discontinuation of Study Intervention

Participants may voluntarily discontinue receiving MTMs and/or remotely delivered nutritional counseling for any reason at any time. However, a member of the KPNC DOR research team will contact the participant before discontinuation to evaluate any issues related to the study meals or enhanced nutritional counseling and answer any questions before confirming their decision to discontinue study intervention.

9.2 Withdrawal from the Study

Participants may voluntarily withdraw consent to participate in the study for any reason at any point in time.

However, withdrawal of consent occurs only when all of the following criteria are met:

- The participant states they do not want to participate in the study any further
- The participant states they do not want any further follow-up visits (i.e., telephone encounters) or assessments
- The participant states they do not want any further study-related contacts

At the time a participant formally withdraws consent for study participation, a member of the KPNC DOR research staff will document the participant's decision and primary reason for study withdrawal in the Appian-based study online tracking system. If relevant, the study intervention will be discontinued and no further assessments conducted. Further attempts to contact the participant are not allowed.

9.3 Loss to Follow-up

For participant's whose status is unclear because they fail to complete study contacts without stating an intention to withdraw, the KPNC DOR research team will show due diligence by attempting to contact the participant, the participant's family and/or listed secondary contact(s), or KPNC primary treating physician. The KPNC DOR research team will also continue to monitor the participant's KPNC EHR data as agreed in the informed consent and will also document in the Appian-based study online tracking system all of the steps taken to contact the participant (i.e. dates of telephone calls, etc.). A participant should not be formally considered lost to follow-up until his/her scheduled end of study visit would have occurred. Outcome data for endpoint ascertainment should be available for all participants with active KPNC membership status.

9.4 Early Termination of the Study

The study may be terminated at the sole discretion of the Sponsor (i.e., KPNC DOR) for any reason, including medical or ethical reasons affecting the continued performance of the study, or the inability to effectively recruit participants. If this occurs, the Sponsor will notify the KPNC IRB, co-investigators, and any regulatory authorities, as appropriate.

9.5 Study End

End of Study will occur when the last participant discharged has 90-day clinical outcomes extracted, has withdrawn consent, or has died, whichever comes first.

10 Study Assessments and Procedures

10.1 Baseline Assessments and Follow-up

Patient demographic characteristics and baseline information on clinical characteristics will be automatically abstracted from the KPNC EHR by the study analyst after obtaining IRB approval but before pre-randomization. These data will include, but not be limited to, date of birth, sex, race/ethnicity, and relevant past medical history.

The study will be conducted between April 27, 2020 and September 29, 2021. End of Study will occur when the last enrolled participant discharged home has completed 90-day follow-up for clinical outcomes, has withdrawn consent, or has died, whichever comes first.

PROJECT YEAR	**2020**		**2021**	
Obtain IRB approvals				
Finalize protocol				
Identify and enroll participants				
Follow-up				
Data analyses				
Submit primary manuscript				
Project close-out				

Note: Each box represents a time interval of 6 months.

10.2 Primary Outcome

The primary outcome will be readmissions for any cause within 90 days after discharge from the index hospitalization. A readmission is defined as a non-elective hospitalization lasting >23 hours. All readmissions will be assessed passively using the KPNC EHR which comprehensively captures network and out-of-network hospitalizations.

10.3 Secondary Clinical Outcomes

Secondary outcomes will include the following:

1.) 90-day emergency department visit for any cause
2.) 90-day death for any cause
3.) Composite of 90-day readmission, emergency department visit, or death for any cause
4.) 90-day readmission for heart failure
5.) 90-day readmission for diabetes-related complication
6.) 60-day readmission for any cause
7.) 30-day readmission for any cause

All utilization outcomes will be assessed passively using the KPNC EHR which comprehensively captures network and out-of-network hospitalizations or emergency department visits. Hospitalizations for heart failure and diabetes-related complications will be assessed using principal discharge ICD-10 diagnosis codes. Deaths will be assessed through a combination of EHR data and external state death certificate data and Social Security Administration vital status file information. In addition, participants' medical records will be manually reviewed by KPNC DOR research staff for participants whose vital status could not be confirmed through follow-up interviews or participant proxy reporting.

10.4 Secondary Patient-reported Outcomes

The following scales will be used for targeted patient-reported outcomes:

1.) Change in perceived social isolation (Likert 1-5 scale: Never, Rarely, Sometimes, Often, Always)
   a. I feel left out.
   b. I feel that people barely know me.
   c. I feel isolated from others.
   d. I feel that people are around me but not with me.
2.) Change in perceived self-efficacy (i.e., "How confident are you that you can stick with healthful foods?" Likert 1-10 scale: ranging from Not Confident to Completely Confident)
   a. Even if you need a long time to develop necessary routines?
   b. Even if you have to try several times to make it work?
   c. Even if you have to rethink your entire way of nutrition?
   d. Even if you have to make a detailed plan?
3.) Change in perceived caring (i.e., "My current meals help to create a caring environment that helps me heal": Likert 1-5 scale: Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree)

Responses to survey questions will be collected at baseline by phone and at the 10-week follow-up phone call conducted by KPNC DOR research staff.

11 Supporting Documentation and Operational Considerations

11.1 Ethical and Administrative Obligations

11.1.1 Regulatory and Ethical Considerations

This clinical study was designed and shall be implemented and reported in accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations, and with the ethical principles that originate from the Declaration of Helsinki. The protocol must be reviewed and approved by a properly constituted IRB (i.e., the KPNC IRB) before study start. Any amendments to the protocol will require KPNC IRB approval before

implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study patients.

11.1.2 Responsibilities of the Investigator and Good Clinical Practice

These include the following: providing written summaries of the status of the study to the KPNC IRB annually or more frequently in accordance with the requirements, policies, and procedures established by the KPNC IRB and notifying the KPNC IRB of serious adverse events (SAEs) or other significant safety findings as required by IRB procedures. Investigators also will provide careful oversight of the conduct of the study and adhere completely to requirements of ICH guidelines and the IRB for clinical studies (if applicable) and all other applicable local regulations.

11.2 Financial Disclosures

All members of the study team will provide the sponsor (i.e., KPNC DOR) with sufficient and accurate financial information as requested to allow the sponsor to address and disclose potential conflicts of interest.

11.3 Informed Consent Process

Eligible patients will be contacted by phone in their hospital room and asked about their interest in participation in the study during their index hospitalization. Due to Covid-19 restrictions, a waiver of written consent was granted by the KPNC IRB, and all patients interested in participating will be required to provide verbal informed consent. KPNC DOR research staff will explain the purpose of the study, the study procedures, and potential risks and benefits of participation also answer any questions the participant may have before confirming their interest in participating by providing verbal consent.

11.4 Data Collection and Management

11.4.1 Data Confidentiality

Participants will be assigned a unique, encrypted study identifier by the KPNC DOR research team.

Any participant records or datasets will contain the encrypted patient identifier only; patient names or any information which would make the patient identifiable will not be transferred outside of KPNC. Information about study patients will be kept confidential and managed under the applicable laws and regulations. Those regulations require a verbal authorization informing the participant of the following:

- What protected health information (PHI) will be collected from participants in this study
- Who will have access to that information and why.
- Who will use or disclose that information.
- The rights of a research participant to revoke their authorization for use of their PHI.

If a participant revokes authorization to collect or use PHI, the Principal Investigator, by regulation, retains the ability to use all information collected prior to the revocation of participant authorization.

Access to the data will be controlled by a sequence of individually-assigned user identification codes and passwords, made available only to authorized personnel who have completed prerequisite training.

11.4.2 Data Collection

Data pertinent to assessing the study objectives will be automatically abstracted from the EHR by a designated KPNC DOR research team member (i.e., study analyst). Automatic validation programs will check for data discrepancies and generate appropriate data queries to be confirmed or corrected before review of the data by the KPNC DOR research team. Prior to final database lock, the Principal Investigator must certify that the data entered are correct.

11.4.3 Database Management and Quality Control

Data management will be performed by the KPNC DOR research team. Data queries will be raised for any inconsistent, impossible, or missing data. Quality control procedures will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. When all data have been coded, validated and locked, a clean file will be declared. Any treatment revealing data may thereafter be added and the final database will be locked.

11.5 Dissemination of Clinical Study Data

The KPNC DOR research team assures that the key design elements of this protocol will be posted in a publicly accessible database such as clinicaltrials.gov. In addition, upon study completion and finalization of the study report the results of this trial will be either submitted for publication and/or posted in a publicly accessible database of clinical trial results.

In addition, upon study completion and finalization of the clinical study report, the results of this study may be submitted for publication in a peer-reviewed journal or presented at a scientific/biomedical conference.

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