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Effect of Medically Tailored Meals on Clinical Outcomes in Recently Hospitalized High-Risk Adults

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Background: Inability to adhere to nutritional recommendations is common and linked to worse outcomes in patients with nutrition-sensitive conditions.

Objectives: The purpose of this study is to evaluate whether medically tailored meals (MTMs) improve outcomes in recently discharged adults with nutrition-sensitive conditions compared with usual care.

Research Design: Remote pragmatic randomized trial.

Subjects: Adults with heart failure, diabetes, or chronic kidney disease being discharged home between April 27, 2020, and June 9, 2021, from 5 hospitals within an integrated health care delivery system.

Measures: Participants were prerandomized to 10 weeks of MTMs (with or without virtual nutritional counseling) compared with usual care. The primary outcome was all-cause hospitalization within 90 days after discharge. Exploratory outcomes included all-cause and cause-specific health care utilization and all-cause death within 90 days after discharge.

Results: A total of 1977 participants (MTMs: n = 993, with 497 assigned to also receive virtual nutritional counseling; usual care: n = 984) were enrolled. Compared with usual care, MTMs did not reduce all-cause hospitalization at 90 days after discharge [adjusted hazard ratio, aHR: 1.02, 95% confidence interval (CI), 0.86–1.21]. In exploratory analyses, MTMs were associated with lower mortality (aHR: 0.65, 95% CI, 0.43–0.98) and fewer hospitalizations for heart failure (aHR: 0.53, 95% CI, 0.33–0.88), but not for any emergency department visits (aHR: 0.95, 95% CI, 0.78–1.15) or diabetes-related hospitalizations (aHR: 0.75, 95% CI, 0.31–1.82). No additional benefit was observed with virtual nutritional counseling.

Conclusions: Provision of MTMs after discharge did not reduce risk of all-cause hospitalization in adults with nutrition-sensitive conditions. Additional large-scale randomized controlled trials are needed to definitively determine the impact of MTMs on survival and cause-specific health care utilization in at-risk individuals.

Key Words: medically tailored meals, clinical trial, heart failure, diabetes, chronic kidney disease

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The coronavirus disease (COVID-19) pandemic and associated public health responses (eg, shelter-in-place orders) and subsequent supply chain disruptions have acutely exacerbated pre-existing food insecurity and potentially contributed to worsening nonadherence to nutritional recommendations among at-risk individuals nationally.[1,2] Furthermore, older adults and those with multimorbidity are at higher risk for food insecurity, lower diet quality and associated worse health status, and excess resource utilization.[2–5]

These challenges, combined with the growing national burden of diet-related chronic diseases, have prompted efforts in collaboration with health care providers to develop food-based and nutrition-based interventions based on the hypothesis of "food is medicine."[6] Providing medically tailored meals (MTMs) at no or low cost is considered an intervention focused on high-risk patients with one or more complex chronic conditions who may have difficulty accessing or preparing nutritious food. Certain common conditions such as heart failure, diabetes, and chronic kidney disease are

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considered nutrition sensitive and associated with adverse clinical outcomes and reduced quality of life, but few randomized controlled trial (RCT) data exist about whether providing MTMs may translate to better clinical outcomes.[6,7] Although some states have conducted pilot programs of providing MTMs to low-income adults with heart failure[8] along with expanding Medicaid-covered benefits for MTMs in selected populations with chronic conditions in 2022,[9] there is a pressing need for more rigorous evidence to guide use of these resource-intensive services and especially in situations where patients may be more vulnerable such as being discharged home after an acute hospitalization.[10]

To address these knowledge gaps, we conducted a remote, decentralized pragmatic RCT of MTMs compared with usual care on postdischarge outcomes among high-risk hospitalized adults receiving care within an integrated health care delivery system during the COVID-19 pandemic.

METHODS

Trial Design and Oversight

The Kaiser Permanente Evaluation of Medically Tailored Meals in Adults With Chronic Medical Conditions at High Readmission Risk (KP NOURISH) study was a parallel-group, pragmatic RCT. The trial protocol (see Protocol, Supplemental Digital Content 1, http://links.lww.com/MLR/C499) and statistical analysis plan (see SAP, Supplemental Digital Content 2, http://links.lww.com/MLR/C500) were designed by the trial investigators. The Kaiser Permanente Northern California (KPNC) Institutional Review Board approved the trial, and all participants provided verbal informed consent. The funder was Kaiser Permanente (Oakland, CA).

The executive committee developed the protocol and statistical analysis plan, oversaw recruitment of participants, supervised data analysis, and provided interpretation of the results. The team based at the KPNC Division of Research was responsible for the data collection and storage. The authors made the decision to submit the manuscript for publication, assume full responsibility for accuracy and completeness of the data, and attest to the fidelity of the trial to the protocol (see Protocol, Supplemental Digital Content 1, http://links.lww.com/MLR/C499). The trial was retrospectively registered in ClinicalTrials.gov (NCT05166525) on December 8, 2021, and the authors confirm there were no changes to the protocol or SAP before or after participant enrollment began on April 27, 2020.

Participants

All participants were enrolled within KPNC, an integrated health care delivery system currently providing comprehensive care to >4.5 million members at 21 medical centers and >260 offices. KPNC membership is highly representative of the statewide population in terms of age, sex, race/ethnicity, and socioeconomic status.[11]

Between April 27, 2020, and June 9, 2021, we identified adult (age ≥18 y) members hospitalized at 5 KPNC medical centers who had a documented history of heart failure[12] or diabetes[13] based on previously validated electronic health records (EHR)-based algorithms[14–16] using diagnosis codes, laboratory results and medications (see eTable 1, Supplemental Digital Content 3, http://links.lww.com/MLR/C501, for *International Classification of Diseases, Tenth Edition* diagnosis codes and specific criteria), or chronic kidney disease (defined as ≥2 preadmission estimated glomerular filtration rate[17] values between 30 and 45 mL/min/1.73 m^2, with the most recent value ≥30 mL/min/1.73 m^2).[18] Patients with a history of organ transplant, admitted from a skilled nursing facility or nursing home, homeless at admission, or whose home residence was outside the geographic area covered by the participating MTMs vendors were excluded. Potentially eligible participants were identified daily through the EHR, had their eligibility manually confirmed by study staff, and then prerandomized[19] before hospital discharge within each medical center using a SAS software-based randomization algorithm to be approached for receiving the MTMs intervention on top of usual care or usual care alone. Patients assigned to the MTMs intervention arm were further randomized after obtaining informed consent in a 1:1 ratio to be offered virtual nutritional counseling sessions in addition to MTMs. Patients with a planned discharge to home were subsequently contacted by phone while in the hospital to confirm eligibility and to obtain verbal consent.

Intervention

The intervention involved providing up to 10 weeks of MTMs that were initiated within 7 days after discharge. Meals were delivered to the participant and eligible household members by collaborating MTMs vendors, with 1 large meal per day per person. Nutritional recommendations were based on Food is Medicine Coalition standards that were supported by national guidelines and consistent with KPNC nutritional guidelines tailored to heart failure, diabetes, and chronic kidney disease (see eTable 2, Supplemental Digital Content 3, http://links.lww.com/MLR/C501).[20] Given how frequently diabetes and chronic kidney disease co-occur in patients with heart failure, MTMs prioritized nutritional standards for heart failure first, followed by those for diabetes and then for chronic kidney disease, if present. Although sodium restriction has been a key focus in patients with heart failure, there remains controversy about the optimal daily limit given the limited RCT data in the context of different types of heart failure, concomitant use of diuretics, and other factors.[21–26] Our MTMs targeted an average sodium intake of 2000–3000 mg/d that was further adjusted toward <2300 mg/d if diabetes or chronic kidney disease was present. In general, the remaining components (eg, percentage of total calories from saturated fat and daily protein, cholesterol, and fiber intake) of the MTMs followed the DASH diet, which emphasizes vegetables, whole grains, lower fat and saturated fat, and lean proteins.[27] Participants in the MTMs arm who were randomized to receive nutritional counseling were offered up to 3 virtual nutritional counseling sessions over 10 weeks provided by a registered dietician nutritionist, with content consistent with national and KPNC practice guidelines and educational resources. Participants enrolled at Kaiser Permanente Santa Clara, Oakland and San Francisco medical centers were provided MTMs and nutritional counseling by Project Open Hand (San Francisco, CA), and participants enrolled at

Kaiser Permanente Santa Rosa and San Rafael medical centers were provided MTMs and nutritional counseling by Ceres Community Project (Santa Rosa, CA).

Follow-up and Outcomes

All participants were followed through 90 days after hospital discharge. The primary outcome was all-cause hospitalization based on comprehensive EHR data. Secondary outcomes included hospitalization for heart failure, hospitalization for a diabetes-related complication, all-cause death, all-cause emergency department visits, and a composite of all-cause hospitalization, emergency department visit, and death. Hospitalizations attributed to heart failure or a diabetes-related complication were defined based on a primary discharge diagnosis using previously validated International Classification of Diseases, Tenth Edition codes (see eTable 1, Supplemental Digital Content 3, http://links.lww.com/MLR/C501).[28] Emergency department visits not leading to hospitalization were identified from EHR data. All network and out-of-network hospitalizations or emergency department visits were comprehensively captured through EHR and billing claims data. Investigators and study staff were blinded to utilization outcome assessment. We identified deaths in an inpatient or emergency department setting from EHR data and outpatient deaths by manual review of medical records and proxy reporting from follow-up calls conducted by study staff.

Statistical Analysis

Analyses were conducted using SAS, version 9.4 (Cary, NC). Assuming a conservative rate of 10 per 100 person-years for 90-day readmission for any cause in the usual care group, we determined a priori that 2000 enrolled participants (1000 receiving MTMs, 1000 receiving usual care) would provide 80% power for a minimally detectable hazard ratio of 0.68 with a 2-sided α of 0.05, corresponding to an estimated 32% relative reduction in risk of any hospitalization with MTMs. All analyses were conducted based on the intention-to-treat principle. We compared baseline characteristics by group using standardized differences. We also compared characteristics between participants who enrolled and those who refused participation (see eTable 3, Supplemental Digital Content 3, http://links.lww.com/MLR/C501).[28] For all outcomes, we calculated cumulative incidence curves and estimated cause-specific hazard ratios and 95% confidence intervals (CIs) from Cox proportional hazards models that adjusted[29] for medical center, predicted readmission risk score,[30] multimorbidity burden,[31] and active COVID-19 infection. Missing values of covariates included in models were imputed with the median value from the overall sample. Exploratory analyses of hospitalizations for heart failure and hospitalizations for a diabetes-related complication were performed in participants with known heart failure and diabetes, respectively. To account for potential competing risk of death, we performed Fine-Gray subdistribution hazard models for all utilization outcomes.[32] Finally, in an exploratory analysis to evaluate the incremental effect of virtual nutritional counseling among those receiving MTMs, we calculated cause-specific hazard ratios and 95% CIs for outcomes comparing MTMs plus virtual nutritional counseling with MTMs alone. Given our prespecified hypotheses, no adjustments for multiple comparisons were made.

RESULTS

Patients

Overall, between April 27, 2020, and June 9, 2021, 2445 prerandomized hospitalized patients were approached, with participation refusal in 298 (23%) of those assigned to MTMs and 147 (13%) of those assigned to usual care, resulting in the target 1000 participants enrolled in each arm (Fig. 1). Comparison of characteristics between enrolled participants and those who refused are described in eTable 3, Supplemental Digital Content 3, http://links.lww.com/MLR/C501. Among enrolled participants, 23 patients who died before hospital discharge (7 in the MTMs group, 16 in the usual care group) were subsequently excluded, leading to a final analytic sample of 1977 participants.

Overall, mean (SD) age was 68.4 (14.6) years, 45.2% were women, 11.5% were Black, 13.8% were Asian or Pacific Islander, and 16.5% were Hispanic. Heart failure was present in 32.4%, diabetes in 68.8%, and chronic kidney disease in 44.9% of participants. In addition, 9.2% had active COVID-19 infection at enrollment. Baseline characteristics were similar between groups, although predicted readmission risk and multimorbidity burden were higher in those assigned to MTMs compared with those assigned to usual care (Table 1). Participants in the MTMs group received a mean (SD) 6.9 (4.1) weeks of meals, with 53.5% receiving all 10 weeks of meals. Of note, those who received more than 5 weeks of meals were younger, less likely to be White or to have Medicare insurance, had lower median annual household income, lower predicted readmission risk and comorbidity burden, lower mean index hospitalization length of stay, and higher mean body mass index compared with those who received ≤ 5 weeks of meals (see eTable 4, Supplemental Digital Content 3, http://links.lww.com/MLR/C501).

Primary Outcome

No participants were lost to follow-up. Readmission for any cause at 90-days post discharge occurred in 270 (27.2%) participants receiving MTMs and in 242 (24.6%) receiving usual care (risk difference: 2.6%, 95% CI, −1.3% to 6.5%) (Fig. 2A, Table 2). After adjustment for predicted readmission risk score, multimorbidity burden, and COVID-19 status, the cause-specific hazard ratio for MTMs compared with usual care was 1.02 (95% CI, 0.86–1.21), and the subdistribution hazard ratio accounting for competing risk of death was 1.02 (95% CI, 0.86–1.22) (Table 2).

Secondary Outcomes and Other Prespecified Analyses

Among participants with heart failure, 316 received MTMs and 325 received usual care (see eTable 5, Supplemental Digital Content 3, http://links.lww.com/MLR/C501). After adjustment for predicted readmission risk score, multimorbidity burden, and COVID-19 status, receipt of MTMs was associated with a lower 90-day risk of hospitalization for heart failure [adjusted hazard ratio (aHR): 0.52, 95% CI, 0.32–0.86] (Fig. 2B, Table 2). Among participants with diabetes, 671 received MTMs and 689

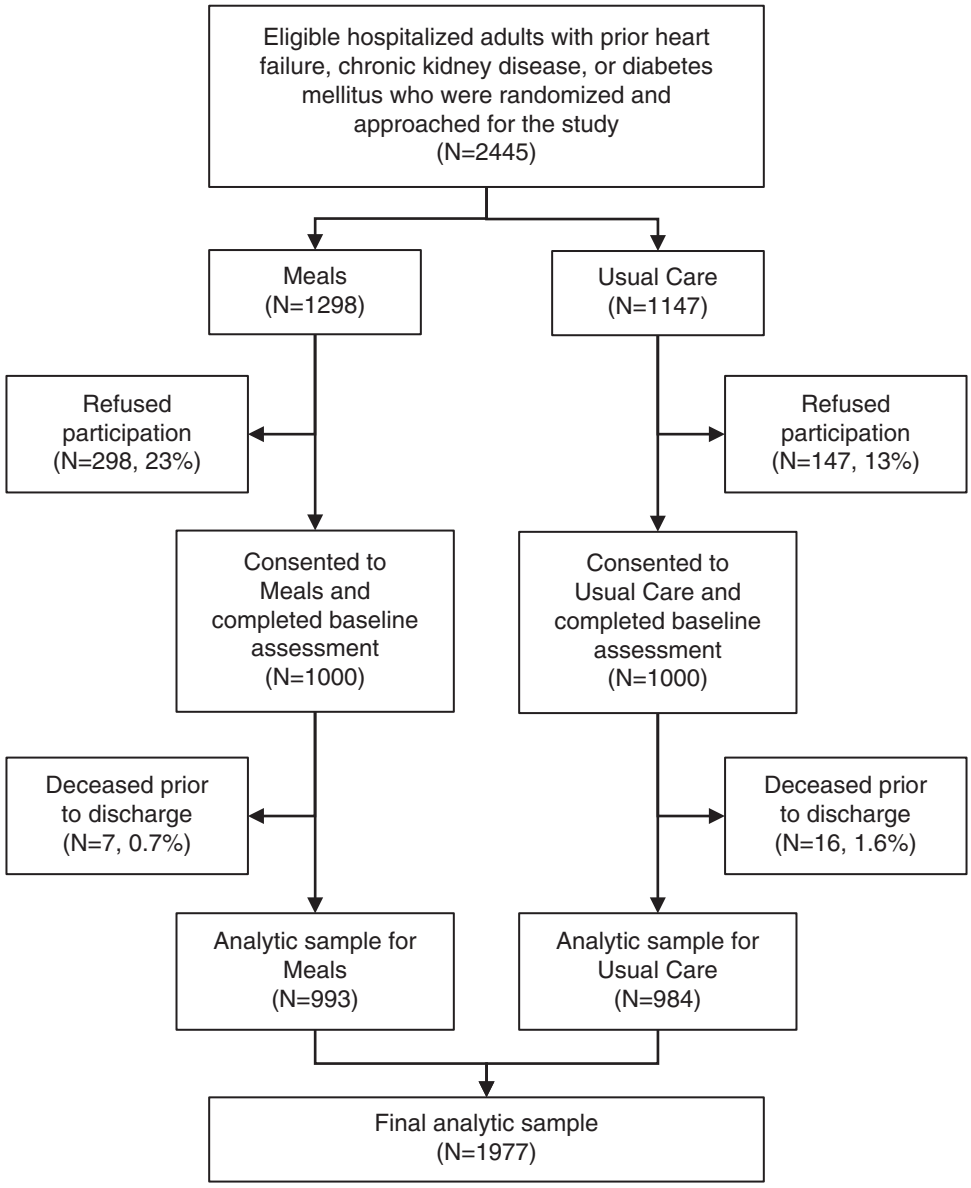

FIGURE 1. Randomization, enrollment, and treatment.

received usual care (see eTable 6, Supplemental Digital Content 3, http://links.lww.com/MLR/C501). Receipt of MTMs was not associated with 90-day risk of diabetes-related hospitalization (aHR: 0.64, 95% CI, 0.26–1.58) (Fig. 2C, Table 2).

No differences were seen between groups in all-cause emergency department visits, affecting 21.4% of participants receiving MTMs and 21.6% participants receiving usual care (aHR: 0.93, 95% CI, 0.77–1.13) (Fig. 2D, Table 2).

Fewer participants receiving MTMs died (4.1%) than participants receiving usual care (5.4%) (aHR: 0.64, 95% CI, 0.43–0.97) (Fig. 2E, Table 2). The 90-day incidence of the composite outcome of utilization and death was lower in participants receiving MTMs compared with those receiving usual care, but the difference was not statistically significant (aHR: 0.88, 95% CI, 0.77–1.02) (Fig. 2F, Table 2).

Among 993 participants receiving MTMs, 497 were randomized to receive additional virtual nutritional counseling. Of these, 57% completed at least 1 session and 16% completed all 3 sessions. Characteristics between those randomized to MTMs with nutritional counseling and those randomized to MTMs alone were similar (see eTable 7, Supplemental Digital Content 3, http://links.lww.com/MLR/C501). In multivariable analyses, there was no association between assignment to receive virtual nutritional counseling and 90-day utilization or death (see eTable 8, Supplemental Digital Content 3, http://links.lww.com/MLR/C501).

TABLE 1. Characteristics of 1977 Participants Who Were Alive at Discharge From the Index Hospitalization

Variable	Medically Tailored Meals (N = 993)	Usual Care (N = 984)	Standardized Difference
Mean (SD) age (y)	68.2 (14.6)	68.5 (14.6)	0.02
Self-reported sex, n (%)	—	—	0.06
Men	516 (52.0)	567 (57.6)	
Women	477 (48.0)	416 (42.3)	
Nonbinary	0	1 (0.1)	
Self-reported race/ethnicity (not mutually exclusive), n (%)			
White	614 (61.8)	627 (63.7)	0.02
Black	119 (12.0)	109 (11.1)	0.01
Asian/Pacific Islander	134 (13.5)	138 (14.0)	0.01
American Indian/Alaska Native	25 (2.5)	19 (1.9)	0.02
Hispanic/Latino	185 (18.6)	142 (14.4)	0.06
Decline to state	4 (0.4)	5 (0.5)	0.01
Medicare insurance	668 (67.3)	662 (67.3)	0
Medicaid insurance	67 (6.7)	59 (6.0)	0.02
Median household income for census tract, dollars/year, mean (SD)	88,455 (34,923)	91,082 (37,782)	0.07
Median household income for census tract <$35,000/y, n (%)	31 (3.1)	31 (3.2)	0
Low educational attainment for census tract (>25% with less than high school education), n (%)	134 (13.5)	122 (12.4)	0.02
Neighborhood deprivation index, mean (SD)	–0.4 (0.8)	–0.5 (0.7)	0.05
Qualifying condition (not mutually exclusive), n (%)			
Heart failure	316 (31.8)	325 (33.0)	0.01
Diabetes mellitus	671 (67.6)	689 (70.0)	0.03
Chronic kidney disease	434 (43.7)	453 (46.0)	0.02
Index hospitalization characteristics			
Hospitalized with COVID-19, n (%)	71 (7.2)	111 (11.3)	0.07
Median (q1, q3) length of stay, days	4.0 (3.0, 6.0)	4.0 (3.0, 6.0)	0.03
Major discharge diagnosis category, n (%)	—	—	0.08
Circulatory	301 (30.3)	329 (33.4)	—
Infectious	164 (16.5)	170 (17.3)	—
Respiratory	128 (12.9)	140 (14.2)	—
Digestive	102 (10.3)	76 (7.7)	—
Musculoskeletal	48 (4.8)	53 (5.4)	—
Kidney/urinary	40 (4.0)	30 (3.0)	—
Endocrine/metabolic	39 (3.9)	36 (3.7)	—
Hepatobiliary	39 (3.9)	32 (3.3)	—
Pregnancy	35 (3.5)	24 (2.4)	—
Nervous system	33 (3.3)	26 (2.6)	—
Skin/breast	20 (2.0)	18 (1.8)	—
Other	44 (4.4)	50 (5.1)	—
Mean (SD) laboratory-based acute physiology score	68.4 (34.1)	65.7 (34.5)	0.08
Missing, n (%)	11 (1.1)	4 (0.4)	—
Mean (SD) predicted readmission risk score	15.7 (9.6)	14.7 (9.0)	0.11
Missing, n (%)	30 (3.0)	25 (2.5)	—
Mean (SD) comorbidity point score	44.9 (34.0)	40.1 (30.6)	0.15
Missing, n (%)	1 (0.1)	0	—
Other prior medical history, n (%)			
Acute myocardial infarction	73 (7.4)	63 (6.4)	0.02
Coronary artery bypass surgery	54 (5.4)	60 (6.1)	0.01
Percutaneous coronary intervention	93 (9.4)	94 (9.6)	0
Mitral or aortic valvular disease	138 (13.9)	139 (14.1)	0
Atrial fibrillation or flutter	254 (25.6)	251 (25.5)	0
Ventricular tachycardia or fibrillation	15 (1.5)	19 (1.9)	0.02
Ischemic stroke or transient ischemic attack	43 (4.3)	34 (3.5)	0.02
Venous thromboembolism	103 (10.4)	95 (9.7)	0.01
Hypertension	724 (72.9)	723 (73.5)	0.01
Dyslipidemia	844 (85.0)	837 (85.1)	0
Current smoker	67 (6.7)	61 (6.2)	0.04
Hospitalized bleed	67 (6.7)	44 (4.5)	0.05
Hyperthyroidism	41 (4.1)	32 (3.3)	0.02
Hypothyroidism	176 (17.7)	171 (17.4)	0
Chronic liver disease	102 (10.3)	87 (8.8)	0.02
Chronic lung disease	364 (36.7)	334 (33.9)	0.03
Diagnosed depression	241 (24.3)	197 (20.0)	0.05
Diagnosed dementia	12 (1.2)	26 (2.6)	0.05

(*Continued*)

TABLE 1. Characteristics of 1977 Participants Who Were Alive at Discharge From the Index Hospitalization (*continued*)

Variable	Medically Tailored Meals (N = 993)	Usual Care (N = 984)	Standardized Difference
Preadmission vital signs			
Body mass index, kg/m^2	31.9 (8.5)	32.0 (8.4)	0.02
Missing, n (%)	21 (2.1)	51 (5.2)	—
Systolic blood pressure (mm Hg)	126.5 (16.7)	128.6 (16.4)	0.13
Missing, n (%)	26 (2.6)	54 (5.5)	—
Inpatient laboratory values, mean (SD)			
Hemoglobin (g/dL)	11.3 (2.2)	11.5 (2.2)	0.12
Missing, n (%)	9 (0.9)	11 (1.1)	—
Serum creatinine (mg/dL)	1.0 (0.4)	1.0 (0.4)	0.03
Missing, n (%)	22 (2.2)	23 (2.3)	—
Blood urea nitrogen (mg/dL)	21.5 (12.4)	21.9 (12.2)	0.03
Missing, n (%)	36 (3.6)	36 (3.7)	—

COVID-19 indicates coronavirus disease.

Full model results for primary and secondary outcomes are shown in eTable 9, Supplemental Digital Content 3, http://links.lww.com/MLR/C501.

DISCUSSION

Among a large, ethnically diverse population of adults with heart failure, diabetes, or chronic kidney disease hospitalized during the COVID-19 pandemic and discharged to home, receipt of up to 10 weeks of MTMs did not affect the primary outcome of risk of any readmission during the 90 days after discharge compared with usual care. For exploratory outcomes, compared with those assigned to usual care, those assigned to receive MTMs experienced no significant difference in 90-day risk of an emergency department visit for any cause but did experience lower all-cause mortality. In additional exploratory subgroup analyses, compared with usual care, MTMs were linked to a lower risk of admission for heart failure in those with known heart failure, but there was no benefit observed with regard to the risk of a diabetes-related admission in those with diabetes. Finally, assignment to receive virtual nutritional counseling sessions in addition to MTMs did not incrementally impact subsequent 90-day resource utilization or survival.

Although the postdischarge period is recognized as a particularly vulnerable time for many patients with serious medical conditions that are exacerbated by nutritional challenges[10,33] and the ongoing pandemic, very limited RCT data exist about the value of MTMs in recently hospitalized adults.[6,34] In the Meals Enhancing Nutrition after Discharge pilot study, 21 older adults diagnosed with heart failure, myocardial infarction, chronic obstructive pulmonary disease, or pneumonia who were also considered at risk for malnutrition were randomly assigned to 3 meals per day for 10 days compared with an educational booklet.[35] Meals were based on general nutritional recommendations for older adults.[36,37] Although those randomized to meals had higher caloric intake during 45-day follow-up, there were nonsignificant differences in 30-day risk of readmission (27.7% in those receiving meals compared with 8.3% in those receiving education alone, $P = 0.59$), but this study was underpowered, had short follow-up, and differential loss to follow-up between groups.[35] We look forward to results from other randomized trials of MTMs in acutely ill patients, including 1 study evaluating 4 weeks of MTMs versus usual care in 30 adults hospitalized or treated in the emergency department for heart failure (NCT04289181), and another study assessing 2 versus 4 weeks of MTMs in 650 recently discharged adults with heart failure, diabetes, kidney disease, cancer, chronic obstructive pulmonary disease, or liver disease (NCT04351880). In this context, as multiple states and insurers implement or consider introducing MTMs-based programs in various populations, our study provides new insights about the expected outcomes of up to 10 weeks of MTMs after discharge in adults who have heart failure, diabetes, and/or chronic kidney disease.

The lower 90-day all-cause mortality in those assigned to MTMs compared with usual care was seen in all qualifying disease groups, but this was an exploratory outcome and warrants confirmation in larger adequately powered studies. We do note that the observed lower mortality was not explained by the avoidance of rehospitalizations or emergency department visits for any cause. The lower 90-day hospitalization risk for heart failure observed with MTMs in adults with known heart failure is consistent with prior observational studies suggesting potential benefits of MTMs in this population,[38,39] but these results should also be considered exploratory. Of note, a recently published international, open-label, RCT enrolling 806 adults with chronic heart failure found no difference in a composite endpoint of all-cause death or cardiovascular-related hospitalizations or ED visits between a low sodium diet (ie, <1500 mg/d) compared with usual care.[22–26] In contrast, the KP NOURISH study enrolled a higher acuity population (ie, after an index hospitalization) and incorporated a more comprehensive nutritional intervention permitting a higher average sodium intake (ie, 2000–3000 mg/d). This pragmatic approach may serve as a model for future studies specifically targeting patients with acute or chronic heart failure.

Our study had several strengths. We conducted this large pragmatic RCT using a remote, decentralized approach involving multiple hospitals serving diverse populations, which allowed for greater inclusion, efficient recruitment, and implementation of the intervention during a pandemic. We

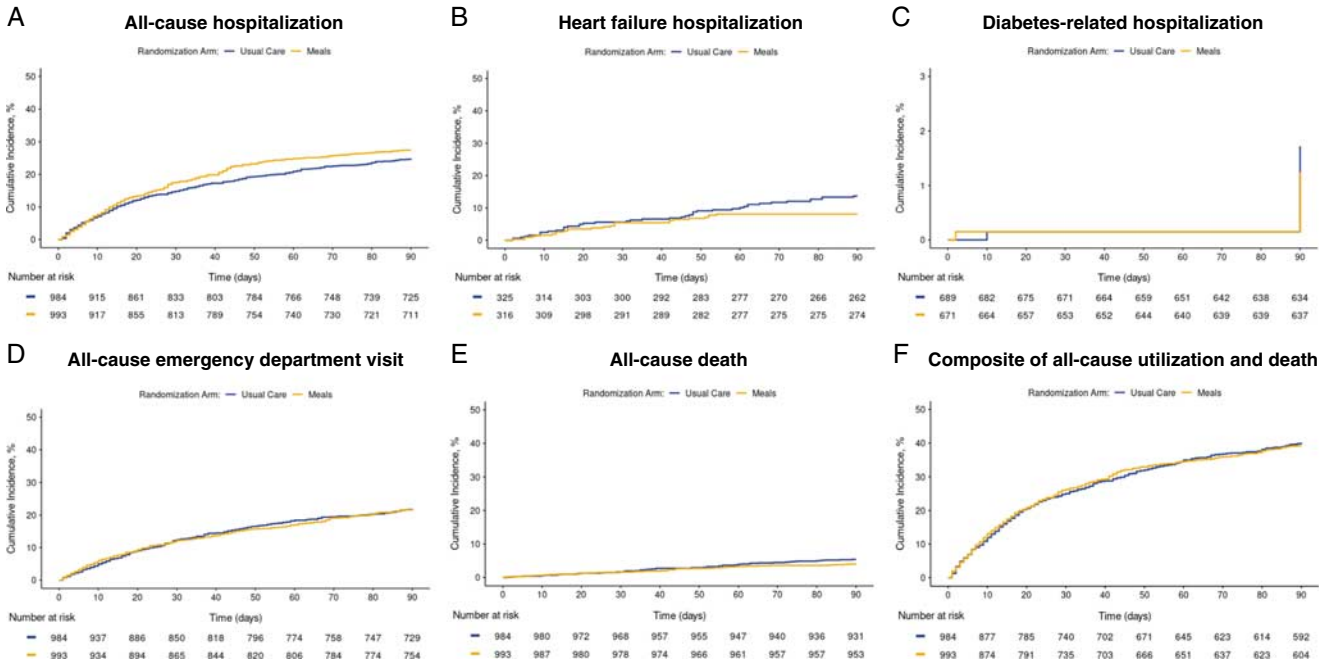

FIGURE 2. Cumulative incidence curves of primary and secondary outcomes.

leveraged a fully integrated EHR to facilitate participant identification, eligibility assessment, ascertain patient characteristics, and comprehensively identify outcomes. We studied patients with co-occurring chronic conditions that may be nutrition sensitive and evaluated a longer (ie, up to 10 wk) period of MTMs than previous studies compared with usual care (ie, involving primarily nutritional education alone). We also evaluated the incremental effect of virtual nutritional counseling on top of MTMs, along with studying clinically relevant outcomes of rehospitalization, emergency department visits, and mortality.

Our study also had limitations. The postrandomization refusal rate was higher among those assigned to MTMs, which could have introduced some selection bias, but few differences in baseline characteristics existed between groups. Furthermore, enrolled participants receiving MTMs were at higher predicted risk of adverse outcomes, which would tend to bias toward the null, and we additionally adjusted for short-term readmission risk, multimorbidity burden, and the presence of COVID-19 infection. Those receiving MTMs were provided one large meal per day, but information was unavailable on the number of meals and amount per meal that were actually consumed by participants, which may influence subsequent outcomes. Our study was underpowered to evaluate potential differences in subgroups of patients with heart failure by level of left ventricular ejection fraction, as well as across the range of severity of diabetes or chronic kidney disease. Despite offering the virtual nutritional counseling, only 57% of those assigned completed at least 1 of the target 3 sessions due to various reasons (eg, refusals, scheduling difficulties, feeling overwhelmed, etc.), which made it challenging to evaluate the possible incremental efficacy of nutritional counseling. The MTMs vendors followed similar nutritional standards but the specific types of cuisines and method (ie, refrigerated vs. fresh frozen) varied between vendors. We were also unable to determine the independent contribution of specific macronutrients or micronutrients on observed outcomes. The trial was conducted among insured adults receiving care within an integrated health care delivery framework, so results may not be fully generalizable to more fragmented care settings or uninsured populations. With regard to generalizability, those who agreed to participate in the study were younger, had longer index hospital length of stay, lower systolic blood pressure, and higher body mass index and blood urea nitrogen level than those who refused but were similar in other measured characteristics (eTable 3, Supplemental Digital Content 3, http://links.lww.com/MLR/C501). We also did not have information on all potentially relevant social determinants of health that may have influenced outcomes and the value of the intervention. Information on food insecurity, dietary quality, and complete cost information on components of the intervention were also unavailable. However, the intervention was specifically designed to be generalizable to other types of health systems and scalable based on its remote, decentralized approach and partnership with community MTMs vendors to deliver the intervention. Finally, we did not address the potential effects of MTMs with other potentially nutrition-sensitive conditions (eg, liver disease and cancer) or in lower-risk ambulatory patients, as well as varying duration and types of MTMs.

In conclusion, provision of up to 10 weeks of MTMs after hospital discharge did not affect 90-day postdischarge risk of being readmitted or being treated in the emergency department for any cause compared with usual care in adults with heart failure, diabetes, or chronic kidney disease. In exploratory analyses, MTMs were linked to lower all-cause

TABLE 2. Primary and Secondary Outcomes for Medically Tailored Meals Versus Usual Care

Outcome	No. Participants	No. Events	Risk (95% CI)	Risk Difference, % (95% CI)	Unadjusted Cause-specific Hazard Ratio (95% CI)	Adjusted Cause-specific Hazard Ratio (95% CI)	Adjusted Subdistribution Hazard Ratio (95% CI)
Primary outcome: all-cause hospitalization at 90 d postdischarge							
Medically tailored meals	993	270	27.1 (24.4, 30.1)	2.6 (−1.3, 6.5)	1.12 (0.95, 1.34)	1.02 (0.86, 1.21)	1.02 (0.86, 1.22)
Usual care	984	242	24.6 (21.9, 27.4)	—	—	—	—
Secondary outcomes at 90 d post discharge							
Hospitalization for heart failure							
Medically tailored meals	316	25	7.9 (5.2, 11.5)	−5.3 (−10.0, −0.6)	0.57 (0.35, 0.94)	0.52 (0.32, 0.86)	0.53 (0.32, 0.87)
Usual care	325	43	13.2 (9.7, 17.4)	—	—	—	—
Hospitalization related to diabetes							
Medically tailored meals	671	8	1.2 (0.5, 2.3)	−0.4 (−1.7, 0.8)	0.68 (0.27, 1.70)	0.64 (0.26, 1.58)	0.67 (0.27, 1.64)
Usual care	689	11	1.6 (0.8, 2.8)	—	—	—	—
Emergency department visit from any cause							
Medically tailored meals	993	212	21.4 (18.8, 24.0)	0.0 (−3.6, 3.6)	0.98 (0.81, 1.18)	0.93 (0.77, 1.13)	0.96 (0.80, 1.17)
Usual care	984	210	21.3 (18.8, 24.0)	—	—	—	—
Death from any cause							
Medically tailored meals	993	41	4.1 (3.0, 5.6)	−1.3 (−3.1, 0.6)	0.75 (0.50, 1.13)	0.64 (0.43, 0.97)	NA
Usual care	984	53	5.4 (4.1, 7.0)	—	—	—	—
Composite of all-cause death and utilization							
Medically tailored meals	993	389	39.2 (36.1, 42.3)	−1.0 (−5.3, 3.3)	0.97 (0.85, 1.12)	0.88 (0.77, 1.02)	NA
Usual care	984	395	40.1 (37.0, 43.3)	—	—	—	—

Hazard ratios are adjusted for predicted readmission risk score, multimorbidity burden, and active COVID-19 infection during the index hospitalization.
CI indicates confidence interval.

mortality in all groups and a lower risk of being hospitalized for heart failure in those with pre-existing heart failure as compared with usual care. There was no observed incremental benefit of virtual nutritional counseling above MTMs on 90-day outcomes. These findings can help inform health policy decisions about the expected clinical outcomes with provision of MTMs in high-risk hospitalized patients with selected nutrition-sensitive conditions. Our exploratory findings support the need for a larger evaluation of MTMs on risk of heart failure–related hospitalizations in adults with known heart failure, in addition to randomized trials exploring the impact of different durations and compositions of MTMs on clinical and patient-centered outcomes in at-risk adults who have been recently hospitalized.

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