UT Southwestern Medical Center

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Scientific Sessions

# EFFECT OF MEDICALLY TAILORED MEALS AND PRODUCE BOXES ON OUTCOMES FOLLOWING HEART FAILURE HOSPITALIZATION

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American Heart Association.

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# PRESENTER DISCLOSURES

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**Ambarish Pandey reports the following:**

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# BACKGROUND

- 6M+ US adults with HF; >1M hospitalizations/year
- **~50% experience food insecurity** → malnutrition, readmission, mortality
- Food as Medicine approaches:
  - *Medically Tailored Meals* – fully prepared, ready-to-eat
  - *Medically Tailored Groceries* – healthy foods for home preparation
  - *Produce Prescriptions* – increased fruit/vegetable access
- Limited trials in post-discharge HF patients
- **Knowledge Gaps:**
  - Which Food as Medicine approach works best?
  - Can food supplementation incentivize care engagement?

# STUDY OBJECTIVES

Among patients following a HF hospitalization

- Assess the feasibility, acceptability, and appropriateness of food-as-medicine interventions in the post-discharge period.
- Determine the comparative effectiveness of medically tailored meals (MTM) vs. fresh produce (FP) supplementation vs. usual care with dietary counseling on outcomes.
- Evaluate whether conditioning food interventions to clinic attendance and medication adherence was more effective than unconditional delivery.

# STUDY DESIGN

- Open-label, two-center, factorial RCT in Dallas, TX (Apr 2024 – Jul 2025)
- American Heart Association Health Care by Food Initiative.
- Inclusion: Adults with HF within 14 days of discharge.
- Exclusion: End-stage HF.
- Randomization:1:1:1 to receive MTM, FP, or usual care with dietary counseling.
- Secondary 1:1 randomization to conditional vs. unconditional food supplementation
- The intervention duration was 90 days for all participants.

HF – heart failure, LVEF – left ventricular ejection fraction, MTM – medically-tailored meals, FP – fresh produce

# INTERVENTION DETAILS

**Food Intervention vs Usual Care:**

- Vendor: Season Health - Initial virtual RD consultation at days 0, 30, and 60
- *MTMs*: 14 fully prepared, refrigerated meals per week; ~650 mg of sodium
- *FP boxes*: Fresh fruits, vegetables, whole grains, dairy, eggs, olive oil, and pantry staples, along with recipes for nutritious meals.
- *Usual care*: Standardized dietary counseling

**Conditional vs Unconditional Delivery Intervention:**

- Conditional Delivery: Food provision linked to outpt appointments and Rx fills.
- Unconditional delivery of food supplementation

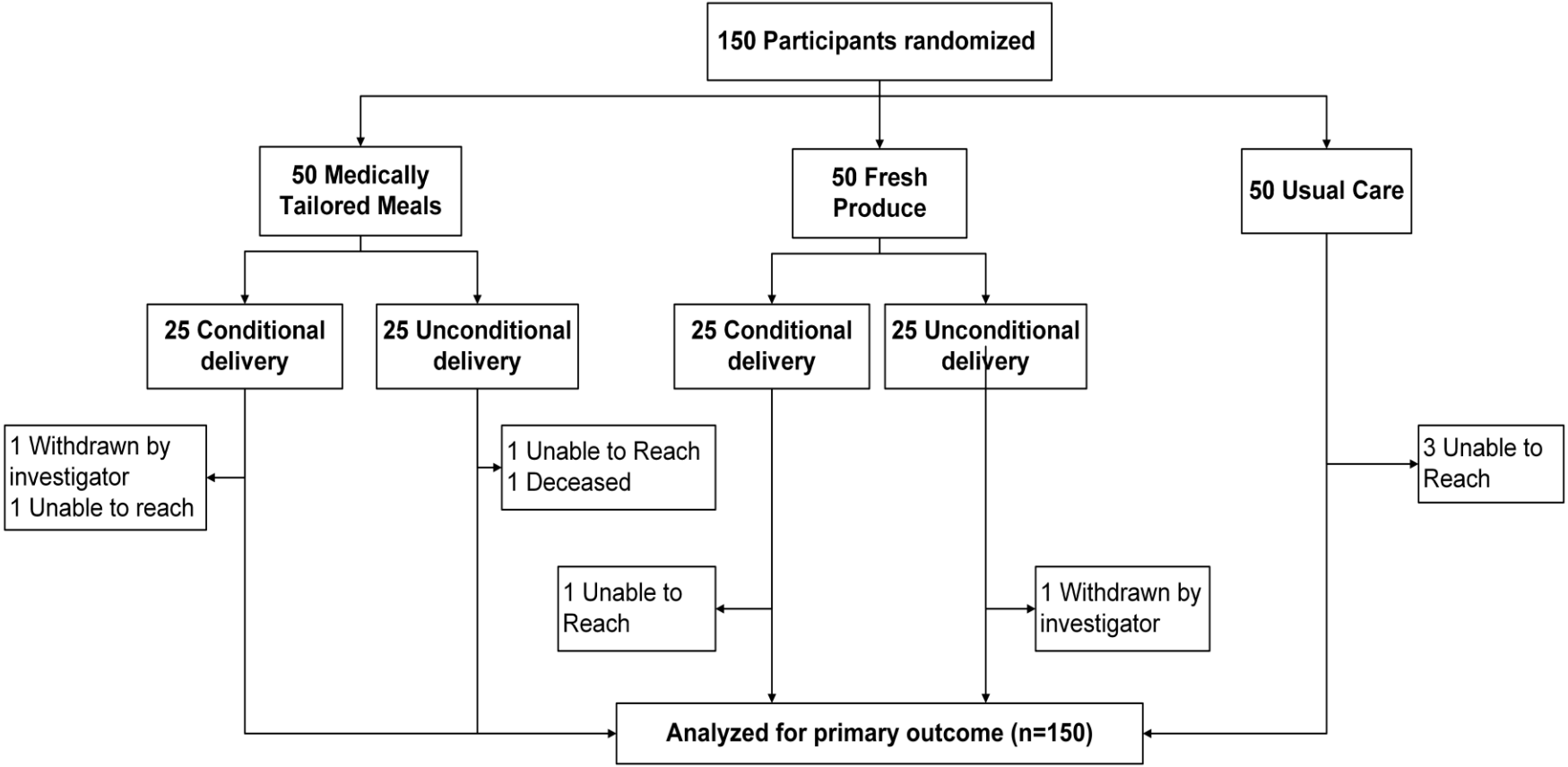
HF – heart failure, LVEF – left ventricular ejection fraction, MTM – medically-tailored meals, FP – fresh produce

# STUDY ENDPOINTS

- **Implementation outcomes:** Delivery success, self-reported food consumption, acceptability, participant experience
- **Primary Clinical Endpoint:** Composite of total hospitalizations or ED visits for HF
- **Secondary Endpoints:**
  - Hierarchical composite (win ratio): Death, HF events, QoL (KCCQ-CSS ≥10 pts)
  - Change in KCCQ-CSS
  - Odds of ≥10-point improvement in KCCQ-CSS

ED – Emergency Department; HF – heart failure; KCCQ-CSS – Kansas City Cardiomyopathy Questionnaire Clinical Summary Score

# STUDY COHORT



# BASELINE CHARACTERISTICS

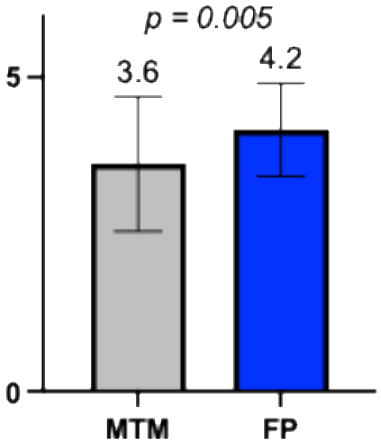
| Characteristic | Control (N=50) | FP (N=50) | MTM (N=50) |
|---|---|---|---|
| Age, years, median | 61 | 59 | 59 |
| Female sex, % | 40 | 46 | 32 |
| Black race, % | 46 | 36 | 44 |
| Food insecure, % | 54 | 48 | 56 |
| BMI, kg/m² | 33 | 32 | 30 |
| LVEF percentage | 40 | 36 | 30 |
| EF ≥50, % | 32 | 36 | 18 |
| eGFR, mL/min/1.73m² | 64 | 54 | 54 |
| Hypertension, % | 96 | 92 | 96 |
| Diabetes, % | 60 | 40 | 62 |
| Baseline KCCQ-CSS | 58 | 56 | 58 |

FP – fresh produce; MTM – medically tailored meals

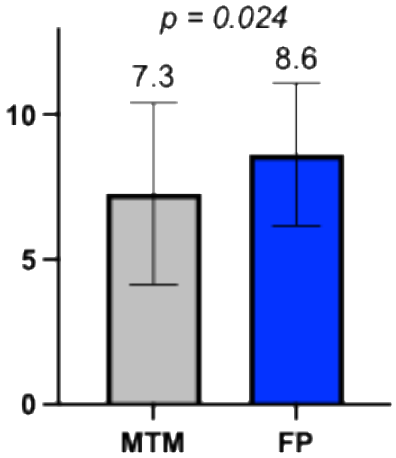
# FEASIBILITY AND IMPLEMENTATION

- 96% of participants completed the 90-day follow-up period, only 4% lost to follow-up
- Food delivery completion rates were high (93.6% overall)
- Participant-reported meal adherence, acceptability, and satisfaction were greater for FP vs MTM.

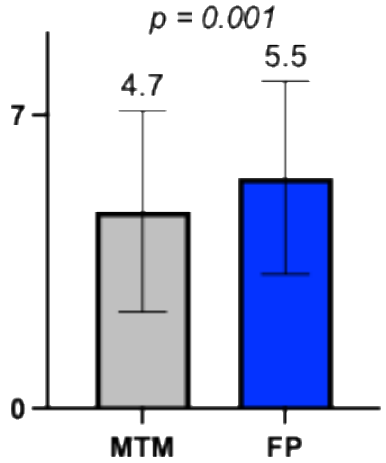
**FP had greater acceptability vs MTM**




**Net Promoter Score was higher in FP vs MTM**



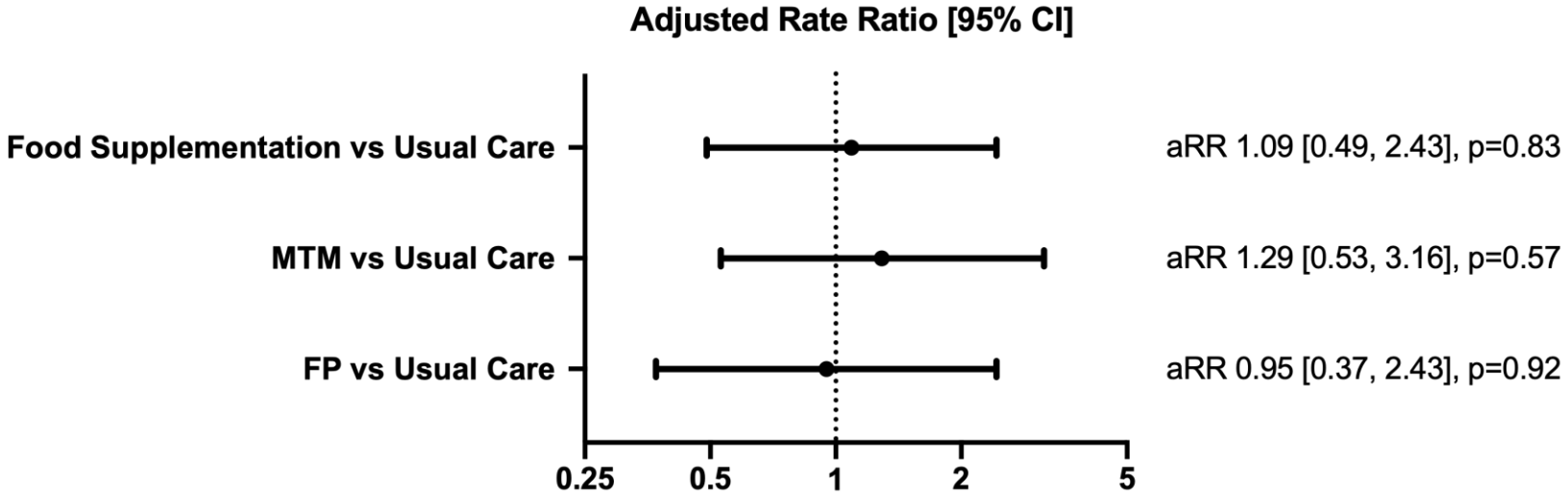

**Self-reported consumption per week greater in FP vs MTM**




MTM – medically-tailored meals, FP – fresh produce

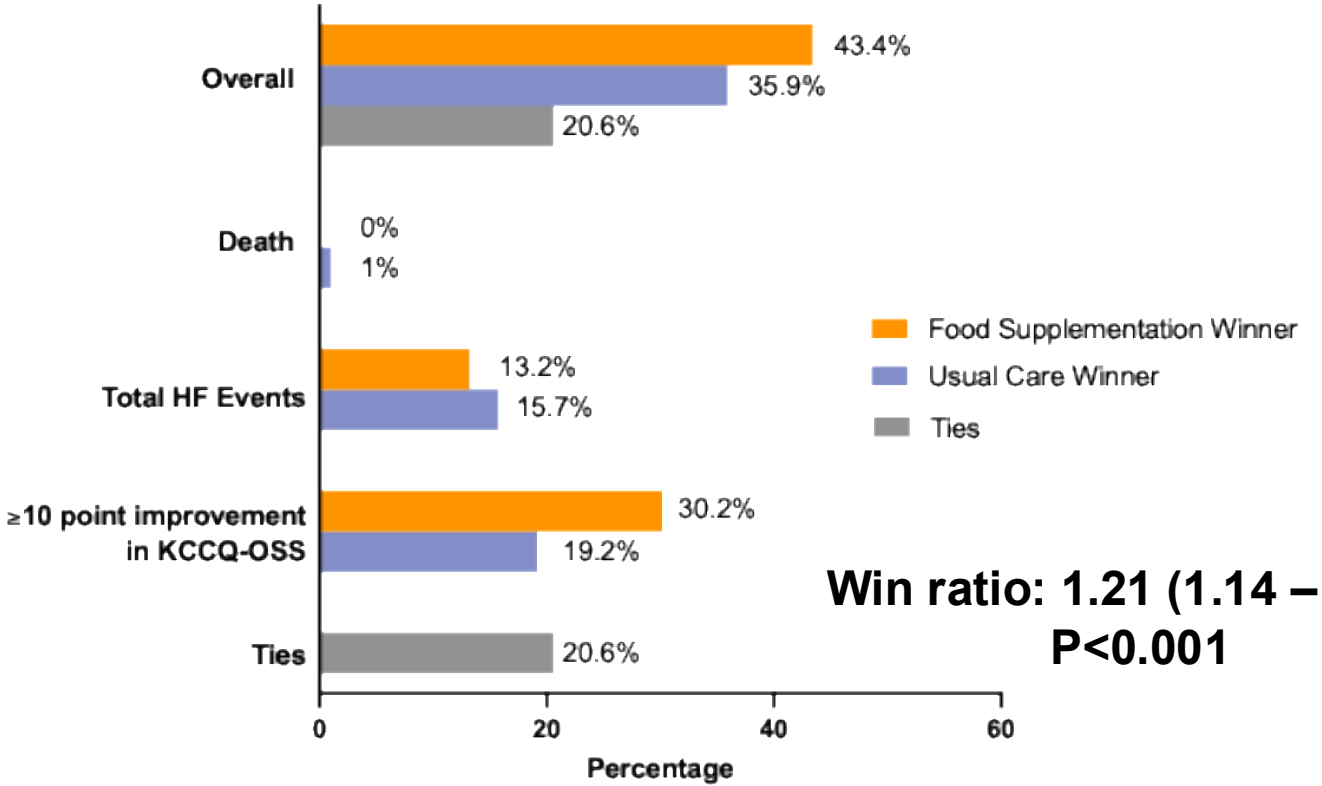
# PRIMARY ENDPOINT: HF HOSP OR ED VISITS

- Total number of HF hospitalizations or ED visit events over 3 months
  - 32 events overall (Food supplementation: 23 events vs. Usual care: 9 events)



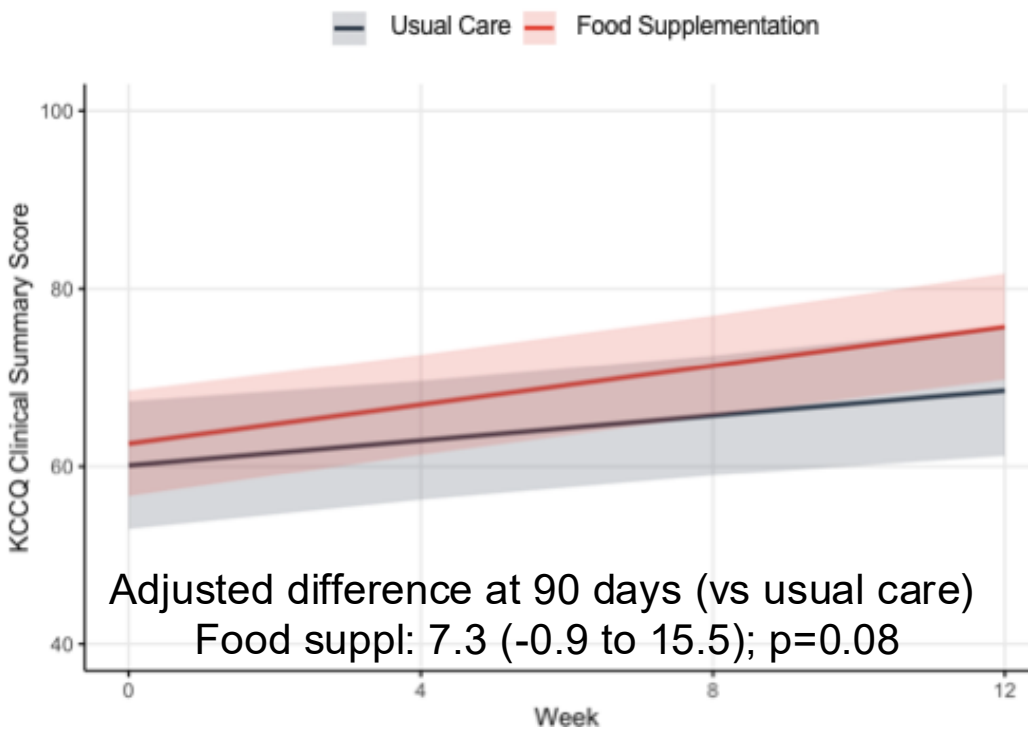

ED – emergency department; HF – heart failure; MTM – Medically Tailored Meals; FP – Fresh Produce, aRR – adjusted rate ratio

# WIN RATIO HIERARCHICAL COMPOSITE ENDPOINT

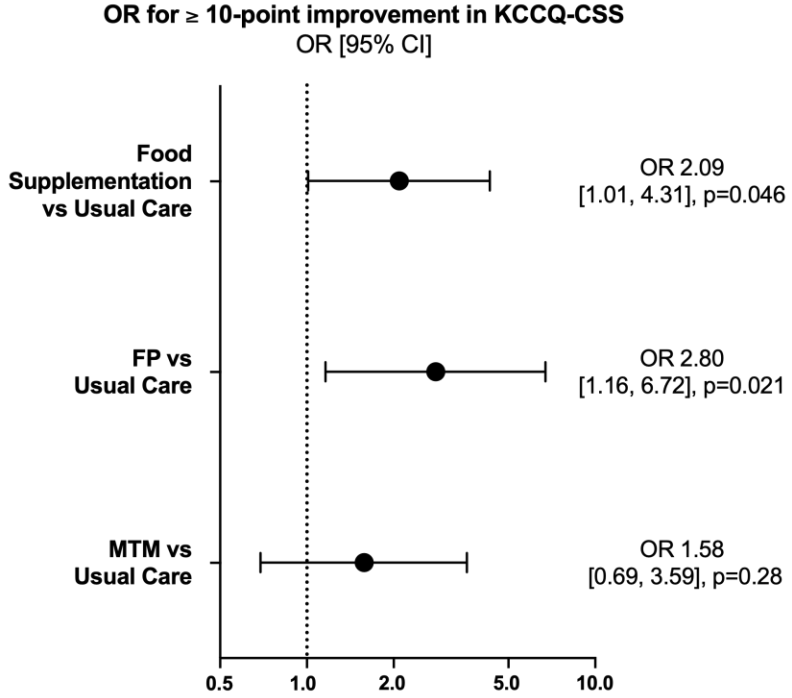



**Win ratio: 1.21 (1.14 – 1.29)**
**P<0.001**

# QUALITY OF LIFE BY KCCQ-CSS




Adjusted difference at 90 days (vs usual care)
Food suppl: 7.3 (-0.9 to 15.5); p=0.08



# CONDITIONAL VERSUS UNCONDITIONAL FOOD SUPPLEMENTATION

- **Primary:** aRR [95% CI]: 1.04 [0.43-2.48]; p=0.93
- **Hierarchical secondary outcome:** Win Ratio [95% CI]: 1.37 [1.25, 1.50], p<0.001
- **KCCQ-CSS at 90 days**: Adjusted difference [95% CI]: 9.6 [0.48, 18.71], p= 0.039
- **Odds of ≥ 10-point KCCQ-CSS improvement**
  - **Conditional vs unconditional:** 1.38 [0.58-3.25]; p=0.47
  - **Conditional delivery vs usual care:** 2.45 [1.04-5.79]; p=0.041
  - **Unconditional delivery vs usual care**: 1.57 [0.68-3.65]; p=0.29

# KEY FINDINGS AND CLINICAL IMPLICATIONS

**Among patients following HF hospitalization, food suppl. vs. usual care demonstrated:**

## FEASIBILITY & ACCEPTABILITY

- **High feasibility:** 96% completion rate with 93.6% delivery success
- **FP superior to MTM:** Better acceptability, satisfaction, and adherence

## IMPACT ON CLINICAL OUTCOMES

- **HF event rates:** no significant difference
- **Hierarchical Win ratio:** Favorable driven by QOL
  **Quality of life:** clinically meaningful improvement

## CONDITIONAL VS. UNCONDITIONAL DELIVERY

- **HF event rates:** No significant difference
- **Hierarchical Win ratio:** Favorable, driven by QOL
- **Quality of life:** Significantly greater KCCQ

## NEXT STEPS

- Larger, multicenter trials to evaluate clinical outcomes
- Focus on fresh produce interventions
- Longer-term food suppl intervention and f/u

# THANK YOU

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