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More than a Meal: Results from a Pilot Pragmatic Clinical Trial Evaluating Two Models of Home-Delivered Meals for Older Adults Living with Dementia



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Housekeeping

- All participants will be muted
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Learning Objectives

Upon completion of this presentation, you should be able to:

- Understand the steps taken to design a pilot pragmatic randomized control trial comparing two types of home-delivered meals among older adults living with dementia.
- Describe the feasibility of conducting this study, including recruitment, retention, and assessment procedures.
- Summarize the process for linking data to examine trends in treatment effects.

Acknowledgements

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 - 1R61AG070170-01

Background and Rationale

- Home-delivered meals, also known as “Meals on Wheels,” are designed to promote food security, socialization, and independence among homebound older adults.
- Evidence suggests home-delivered meals are associated with improved health and reductions of healthcare utilization among homebound, food insecure older adults.
- Because of this evidence, healthcare entities are increasingly contracting with meal providers to deliver food to their patients.

Study Question

- Which kind of meal delivery is most effective in supporting independent living – particularly among people with dementia, a growing population with unique care needs and increased risk for nursing home placement?

Two Models of Home-Delivered Meals



Objective

- Pilot Pragmatic Comparative Effectiveness Trial
- Primary Aim – Test Feasibility
 - Evaluate and refine processes for recruitment and randomization
 - Assess fidelity to the intervention
 - Test assessment procedures
- Secondary Aim – Offer insights into trends in treatment effects
 - Exploratory analysis examining time to nursing home placement

Design Considerations

- Engaged programs early in planning discussions
- Explored different designs
 - Randomize programs
 - Randomize routes
 - Randomize new clients
 - Randomize wait list



Established Enrollment Goals

- First two programs agreed to enroll 60 and 75-80 participants, each
- Obtained an administrative supplement and brought on another program who agreed to enroll 100 participants



Random Assignment

- Process
 - Meals on Wheels programs obtain information on initial intake – including self-reported dementia
 - Developed a process where programs would send us batches of 50 clients that met inclusion criteria:
 - On a waiting list for meals
 - 66 and older
 - “yes” response to the question “Has a doctor or other health care professional told you that you suffer from memory cognitive impairment, any type of dementia, or Alzheimer’s disease?”
 - Lived in daily service area

Random Assignment

- Research team stratified randomization (within program) and sent assignments back to the programs (n=325)
- Programs called and made assignments – that conversation determined “enrollment”
- Challenges
 - bad information
 - needs change
 - situations change

Waiver of Consent with Individual Randomization

- Worked closely with our IRB
- Five conditions for research with a waiver
 1. No greater than minimal risk
 2. Could not practicably be carried out without the waiver
 3. Could not practicably be carried out without using such information in an identifiable format
 4. Would not adversely affect the rights and welfare of the subjects
 5. Subjects or LARs would be provided with additional pertinent information after participation

Enrollment

- Exceeded target enrollment (n=243 participants)

	Frozen (n=115)	Daily (n=128)
65-74, n (%)	27 (23.5%)	36 (28.1%)
75-84, n (%)	46 (40.0%)	50 (39.1%)
85+, n (%)	42 (36.5%)	42 (32.8%)
Female, n (%)	78 (67.8%)	74 (57.8%)
White, n (%)	64 (55.7%)	64 (50.0%)
Black, n (%)	22 (19.1%)	21 (16.4%)
Latino or Hispanic Ethnicity, n (%)	25 (21.7%)	37 (28.9%)
Lives Alone, n (%)*	66 (57.4%)	53 (41.4%)

Monitoring Fidelity to the Intervention

- Site-level focus

Adherence subcategory	Intervention component	Guiding questions	Measurements	Data sources
Details of Content	The meal	Did the site provide meals that met nutritional standards of 1/3rd DRI per meal?	% of meals delivered with $\frac{1}{3}$ DRIs as outlined	Meeting minutes
	Model of meal service delivery	Did the intended model of meal delivery (e.g., face-to-face interaction that includes seeing/talking with the client, setting up meals for clients) change during the intervention?	By site, % of time during the intervention period that meals were delivered as planned (e.g., face to face with visual/audible confirmation of the participant wellness).	Program data Meeting minutes
Coverage	Randomized vs enrolled participants	At the site level, did enrolled participants differ from randomized participants?	By site, any significant differences in race, sex, gender, or age between enrolled and randomized participants.	Program data
	Intervention reach	How many enrolled participants actually received at least one meal	By site, rate of meal receipt among enrolled participants	Program data Meeting minutes
Frequency	Number of meals delivered	Did sites provide one meal per day for every weekday while enrolled?	Any site- driven change in the number of meals delivered per week.	Program data Meeting minutes
	Number of deliveries	Did the sites reduce the number of deliveries per week?	By site, any changes in number of meal deliveries made per week.	Program data Meeting minutes
Duration	Length of intervention	Did the sites deliver the intervention to participants for as long as they were intended to receive it?	Rate of participants who received the intervention for up to 180 days or until participant disenrollment	Program data

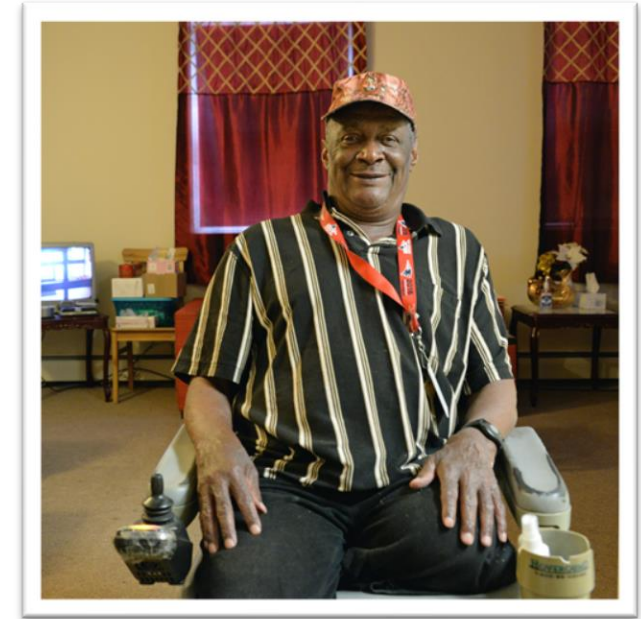
Fidelity - Findings

- All programs demonstrated sufficient fidelity to implementation of the intervention
- Main impact on fidelity was COVID safety measures

Adherence subcategory	Intervention component	Site 1	Site 2	Site 3
Details of Content	The meal	High (3)	High (3)	High (3)
	Model of meal service delivery	Low (1)	Low (1)	Low (1)
Coverage	Randomized versus enrolled participants	Moderate (2)	High (3)	High (3)
	Intervention reach	High (3)	High (3)	High (3)
Frequency	Number of meals delivered	High (3)	High (3)	High (3)
	Number of deliveries	High (3)	Low (1)	Low (1)
Duration	Length of intervention	High (3)	High (3)	High (3)
	Totals	18/21	17/21	17/21

Participant “Fidelity”

	Frozen (n=115)	Daily (n=128)
Completed 6 months with meals	63%	69%
Cancelled meals	30%	27%
Died	7%	4%



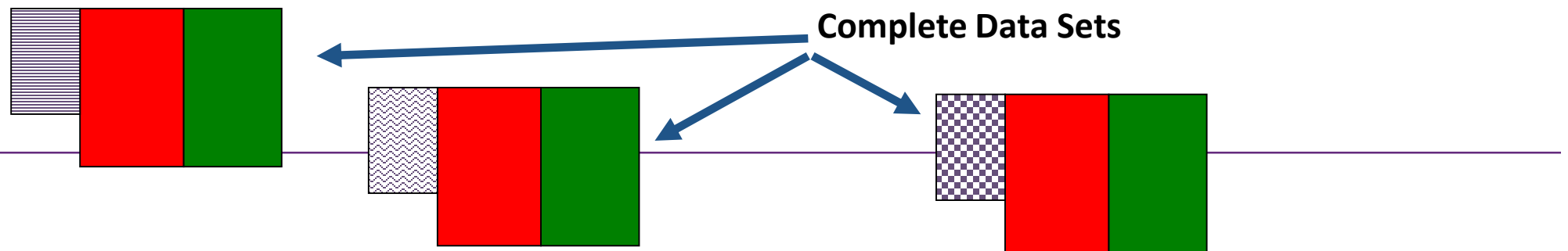
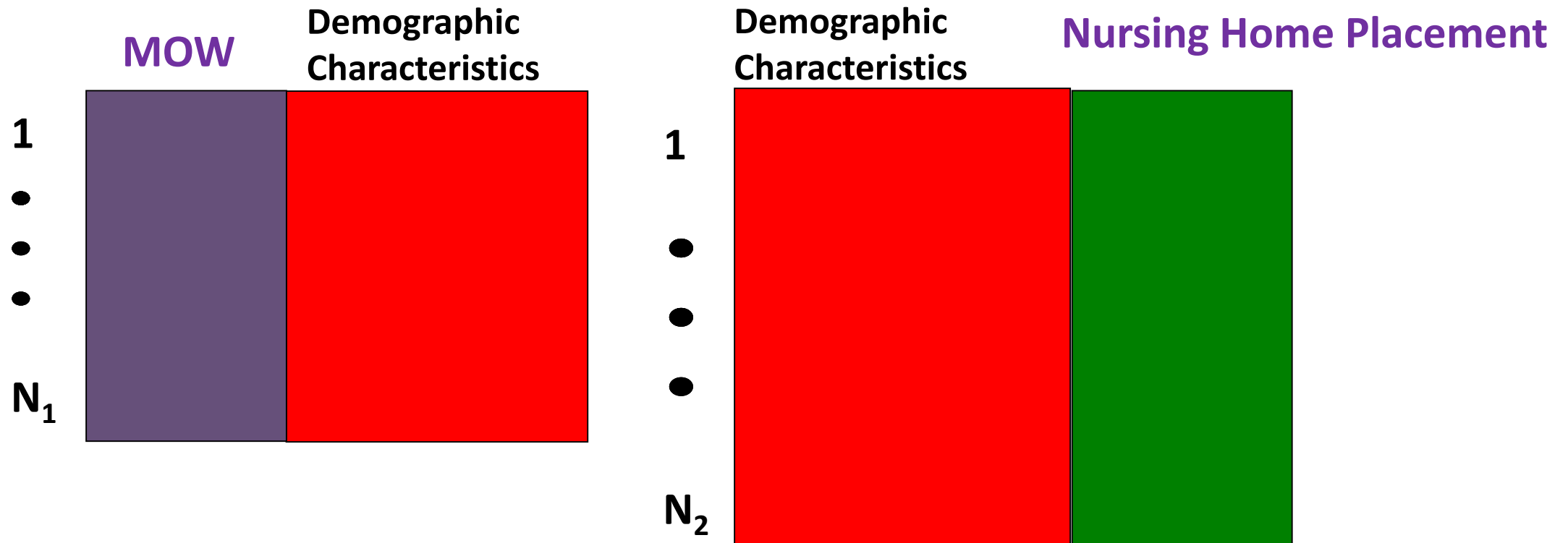
Linking Data to Measure Outcomes

Program Data -> Medicare Enrollment File ->

Nursing Home Minimum Data Set Admission Assessments

	All n=243	Frozen n=115	Daily n=128
File 1: Match on SSN	188 (77%)	82 (74%)	106 (83%)
File 2: Match on name + sex + DOB + ZIP	186 (76%)	93 (81%)	93 (73%)
Matched to different bene_id in each file	7 (3%)	5 (4%)	2 (2%)
Did not match to bene_id in either file	16 (6%)	10 (9%)	6 (5%)

Linking the 16 “Unmatched” Participants



With each dataset

- Examined differences by arm in proportions of people admitted to a nursing home at 6 months
- Estimated a Cox Regression
 - Time to nursing home placement
 - Adjusted for age, race gender, living alone
 - Censored for death

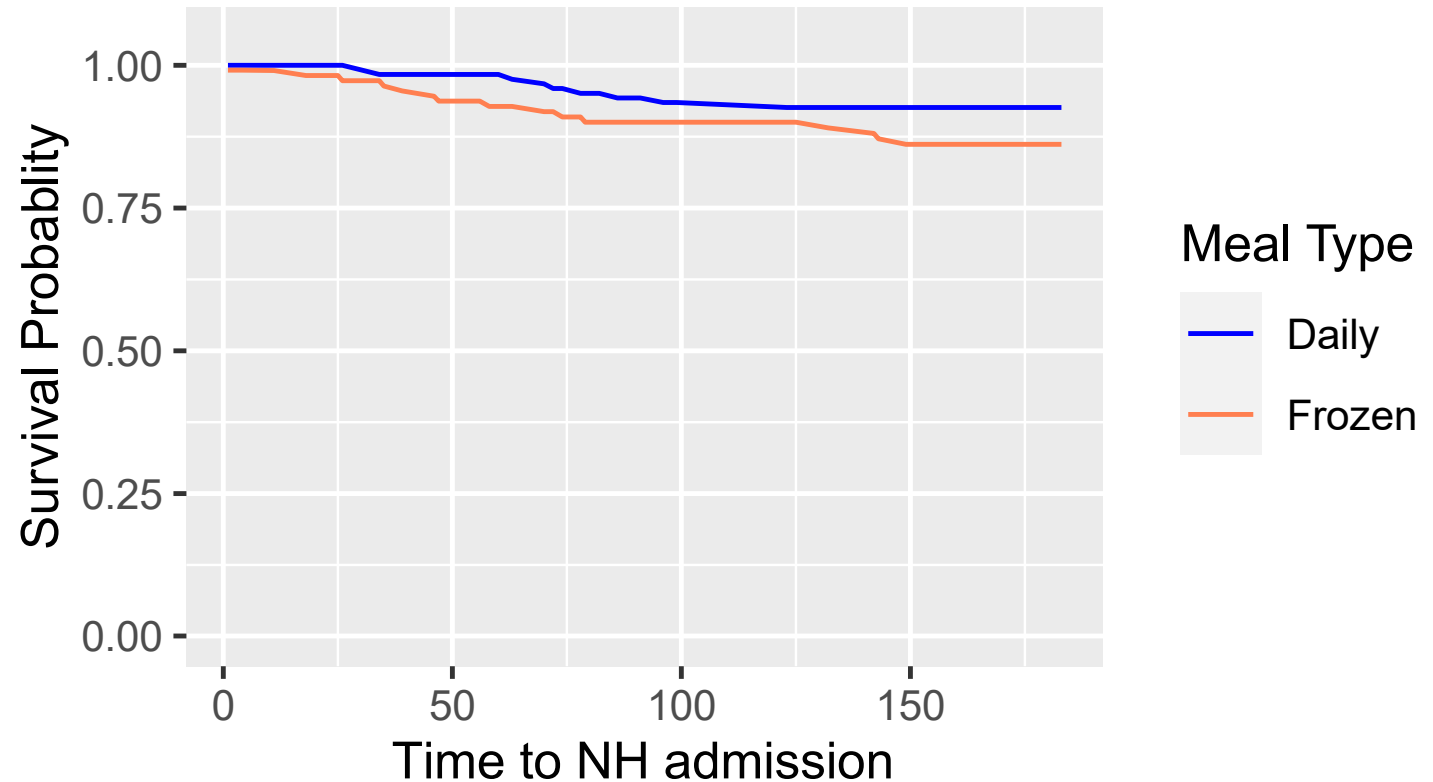
Multiple Imputation Combining Rule

- Using Bayesian model
 - Generate M samples $\Delta^{(1)}, \dots, \Delta^{(M)}$ from the posterior distribution $p(\beta, \Delta | Z_A, Z_B, X_A, Y_B)$
 - Estimate $\beta^{(m)}$ and its sampling variance $U^{(m)}$ assuming that $\Delta^{(m)}$ is the true linkage.
 - Point estimate $\hat{\beta} = M^{-1} \sum_{m=1}^M \beta^{(m)}$
 - Sampling variance

$$T = M^{-1} \sum_{m=1}^M U^{(m)} + \left(1 + \frac{1}{M}\right) M^{-1} \sum_{m=1}^M (\beta^{(m)} - \hat{\beta})^2$$

Findings

- At 6 months, 0.07 (95% CI 0.03, 0.12) beneficiaries in the daily arm were admitted to a nursing home
- 0.13 (95% 0.07,0.2) in the frozen meal arm were admitted to a nursing home.
- Resulted in -0.06 difference (95% CI -0.14,0.01) (p-value = 0.12).
- After adjustment for age, sex, race, and living arrangement, we have a log hazard ratio of -0.68 (95% CI -1.53,0.16; p-value = 0.11).



COVID Implications

- Fidelity to daily delivered meals compromised
- Primary outcome “rare-er” event



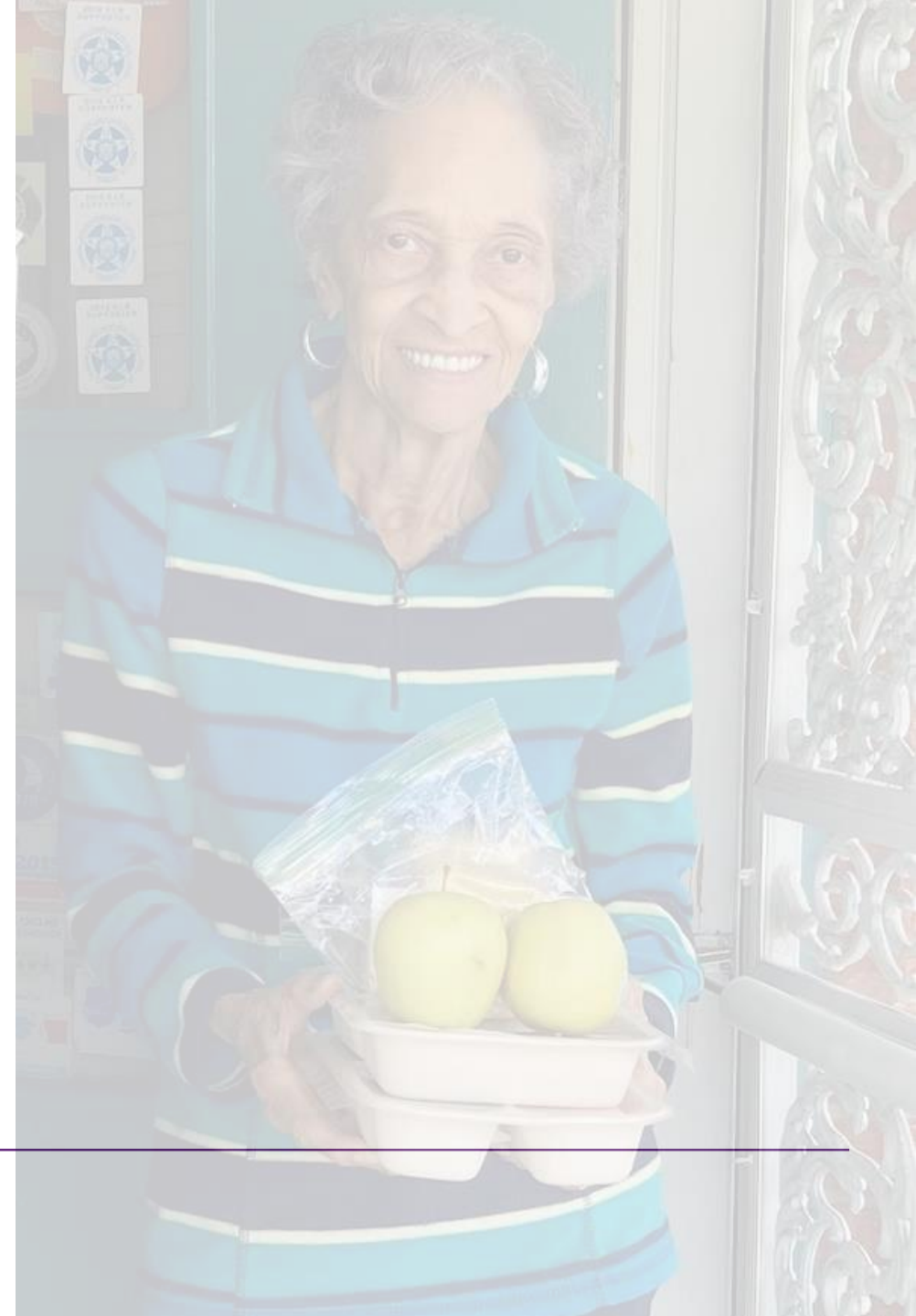
Ongoing Research

- Combining estimates from prior trial
- PCORI-funded comparative effectiveness trial among cognitively intact population
 - NCT05357261
 - <https://sites.brown.edu/deliveree/>



Next Steps

- Verifying “self-reported dementia”
- Scaling up to larger, definitive trial
 - Challenge – waiting lists
- Evaluating impact on caregivers



Additional Resources

- Thomas KS, Dosa DM, Fisher A, Gadbois E, Harrison J, Hilgeman M, Largent EA, Lima J, McAuliff K, McCreedy E, Mills W, Ornstein KA, Shield RR, Barron M, Callaghan S, Clark K, Culak C, Faris V, Frankhauser AE, Huerta S, Krause K, Martinez I, Mayer A, Rodriguez J, Theilheimer L, Truelove W, Wilson I, Gutman R. Home-delivered meals for people with dementia: Which model delays nursing home placement? - Protocol for a feasibility pilot. *Contemporary Clinical Trials*. 2022 Oct;121:106897. doi: 10.1016/j.cct.2022.106897. Epub 2022 Aug 30. PMID: 36055581; PMCID: PMC9817376.
- Gadbois E, Bunker JN, Hilgeman M, Shield RR, McAuliff K, Mills W, Thomas KT. Feasibility of Conducting Qualitative Research with Persons Living with Dementia and their Caregivers during a Home-Delivered Meals Pilot Trial. *Pilot and Feasibility Studies* (In Press).



Thank you!

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Questions?

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