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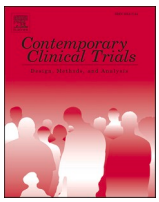

Home-delivered meals for people with dementia: Which model delays nursing home placement? - Protocol for a feasibility pilot

Kali S. Thomas [a,b,*], David M. Dosa [b,c], Alison Fisher [a], Emily Gadbois [a], Jill Harrison [a], Michelle Hilgeman [d,e,f], Emily A. Largent [g], Julie Lima [a], Katie McAuliff [a], Ellen McCreedy [a], Whitney Mills [a,b], Katherine A. Ornstein [h], Renee R. Shield [a], Marycela Barron [i], Shawna Callaghan [j], Kayla Clark [k], Chris Culak [k], Vinsen Faris [i], Anita E. Frankhauser [l], Sophie Huerta [i], Katherine Krause [k], Ileana Martinez [i], Amanda Mayer [j], Jacqueline Rodriguez [i], Lucy Theilheimer [j], William Truelove [i], Inga Wilson [k], Roee Gutman [a]

[a] Brown University School of Public Health, Providence, RI, USA
[b] Providence VA Medical Center, Providence, RI, USA
[c] Brown University, Providence, RI, USA
[d] Research & Development Service, Tuscaloosa VA Medical Center, Tuscaloosa, AL, USA
[e] Psychology Department, & Alabama Research Institute on Aging, The University of Alabama, Tuscaloosa, AL, USA
[f] Department of Medicine, Division of Gerontology, Geriatrics, & Palliative Care, The University of Alabama at Birmingham, Birmingham, AL, USA
[g] Perelman School of Medicine, University of Pennsylvania, Phildelphia, PA, USA
[h] Johns Hopkins School of Nursing, Baltimore, MD, USA
[i] Meals on Wheels San Antonio, TX, USA
[j] Meals on Wheels America, Arlington, VA, USA
[k] Visiting Nurse Association of Texas, Dallas, TX, USA
[l] Neighborly Care Network, Clearwater, FL, USA

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ABSTRACT

Background: Home-delivered meals promote food security, socialization, and independence among homebound older adults. However, it is unclear which of the two predominant modes of meal delivery, daily-delivered vs. drop-shipped, frozen meals, promotes community living for homebound older adults with dementia. Our objective is to present the protocol for a pilot multisite, two-arm, pragmatic feasibility trial comparing the effect of two modes of meal delivery on nursing home placement among people with dementia. We include justifications for individual randomization with different consent processes and waivers for specific elements of the trial.

Methods: 236 individuals with dementia on waiting lists at three Meals on Wheels programs' in Florida and Texas will be randomized to receive either: 1) meals delivered multiple times per week by a Meals on Wheels volunteer or paid driver who may socialize with and provide an informal wellness check or 2) frozen meals that are mailed to participants' homes every two weeks. We will evaluate and refine processes for recruitment and randomization; assess adherence to the intervention; identify common themes in participant experience; and test processes for linking participant data with Medicare records and nursing home assessment data. We will conduct exploratory analyses examining time to nursing home placement, the primary outcome for the larger trial.

Conclusion: This pilot will inform the follow-on large-scale, definitive pragmatic trial. In addition, the justifications for individual randomization with differing consent procedures for elements of a pragmatic trial provide a model for future trialists looking to develop ethical and feasible pragmatic studies enrolling people with dementia.

* Corresponding author at: Brown University School of Public Health, 21 S. Main Street, Providence, RI, 02912, USA.
E-mail address: kali_thomas@brown.edu (K.S. Thomas).

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1. Introduction

In 2019, 5.2 million older adults (7.1%) in the United States were food insecure [1]. Food insecurity, defined as a lack of consistent access to enough food for an active, healthy life [2] is associated with poor health and health outcomes and accounts for an estimated $130 billion annually in healthcare expenses [3]. People living with dementia are particularly vulnerable to food insecurity. The overwhelming majority (81%) of the 5.3 million Medicare beneficiaries with dementia live in the community, and an estimated 25–30% live alone [4]. Community-dwelling older adults with dementia have high rates of unmet care needs (e.g., assistance with eating, grocery shopping, preparing meals) [5,6], putting them at increased risk of nursing home placement [7].

Home-delivered meals, also known as "Meals on Wheels," promote food security, socialization, and independence among homebound older adults. Partially funded by Title III of the Older Americans Act, about 5000 programs served 880,000+ older adults in 2019, over half of whom lived alone, were over the age of 75, and indicated that the meals provided more than one-half of their total food for the day [8]). Evidence suggests that home-delivered meals affect the health and healthcare utilization of homebound, food insecure older adults, including those living with dementia [9–14].

Traditionally, "daily-delivered meals" have been provided to clients' homes by a volunteer or paid driver who may informally socialize with the client and report any concerns about clients' wellbeing to the meal program. However, less frequent deliveries of frozen meals (referred to as "drop-shipped meals") have emerged in recent years as a lower-cost alternative. In the latter model, participants are provided one to two weeks' worth of meals in one bulk delivery via postal courier. Prior research has found that 1) clients who received daily-delivered meals experienced fewer falls and less loneliness than do those who received frozen, drop-shipped meals; 2) drivers provide additional support to clients (e.g., meal set-up, general home assistance); 3) drivers report changes or concerns that they notice about their clients to programs for follow-up and assessment; and 4) the driver is the only person many clients see during the day [11,12,15]. However, it remains unknown whether the increased socialization, assistance, and identification of need afforded through the daily interaction with meal-delivery drivers results in reductions in healthcare utilization.

Healthcare entities (e.g., payers, integrated care organizations, providers) are increasingly interested in providing home-delivered meals to food insecure, functionally impaired older adults [2,16–18]. For example, in 2020, 49% of all Medicare Advantage (MA) plans offered a meal benefit to 9.4+ million enrollees [19]. These entities could benefit from

understanding what mode of 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 [7].

The primary aim of this study is to establish the feasibility of conducting a large, pragmatic definitive trial that compares the effects between daily-delivered and drop-shipped meals among people living with dementia. Consistent with a feasibility pilot [20], we will: evaluate and refine processes for recruitment and randomization; assess adherence to the intervention; identify critical themes in participant experience; and test assessment procedures, including linking participant data with Medicare records and nursing home assessment data. The secondary aim is to offer insights into trends in treatment effects observed between the two groups (i.e., daily-delivered meals vs. drop-shipped meals). To achieve this aim, we will conduct exploratory analyses examining time to nursing home placement, the primary outcome for the larger trial. In addition to describing the feasibility trial, this protocol includes justifications for individual randomization with different consent processes and waivers for specific elements of the trial.

2. Methods

This is a pilot multisite, two-arm, pragmatic feasibility trial conforming to the SPIRIT recommendations [21] for clinical trial protocols. The study will make use of a HIPAA waiver (45 CFR 164.512) and data use agreements (DUAs) with participating Meals on Wheels programs and the Centers for Medicare and Medicaid Services (CMS). The Brown University Institutional Review Board (IRB) reviewed and approved the study (approval #20082788), and it is registered with www.clinicaltrials.gov (NCT04850781). The full study protocol and statistical code will be made public through the Brown data repository (https://repository.library.brown.edu). The study flow is outlined in Fig. 1. The study will be conducted over approximately 12 months, with the first participant enrolled in April 2021.

2.1. Participants

Participants will be recruited from waiting lists at three Meals on Wheels programs, one in Florida and two in Texas (see Appendix for additional details about the programs). Potential participants must meet the following eligibility criteria: 1) on a waiting list for home-delivered meals at one of the three Meals on Wheels programs; 2) 66 years of age or older (to enable a one-year Medicare data lookback for all participants); 3) affirmative response to the question "Has a doctor or other health care professional told you that you suffer from memory loss, cognitive impairment, any type of dementia, or Alzheimer's disease?" on the program's routinely conducted eligibility assessment; and 4) reside in a Meals on Wheels program service area where it is possible to receive daily-delivered meals.

We will recruit a subsample of 2–4 participants at each program to pilot the interview recruitment procedures and interview guide. Inclusion criteria for the interviews are: 1) receiving meals, 2) English-speaking, and 3) ability to consent to an interview (described below). We will also recruit 6–12 caregivers of participants to pilot the recruitment procedures and a separate interview guide. Inclusion criteria for caregivers are: 1) identified by the participant as a caregiver; and 2) English-speaking.

2.1.1. Participant recruitment and randomization

Meals on Wheels programs will identify individuals who meet the inclusion criteria. The programs will send the list of eligible participants and an assigned study ID to the research team for randomization in a password-protected file via encrypted email. The research team will assign participants to either daily-delivered meals or drop-shipped meals with a 1:1 allocation in a stratified permuted-block randomization [22], where each block is of size six. The algorithm will be implemented in the R statistical software [23]. Randomization strata comprise the three programs. The research team will return the password-protected file with the Participant ID and the meal assignment to the program via an encrypted email.

After receiving the assignment list, the programs will call individuals to arrange their assigned meal delivery. Upon receiving this phone call, individuals are considered "enrolled." Participants who do not want their assigned meals can elect to return to their spot on the waiting list.

For the qualitative sub-study, the research team will recruit a random sample of participants for telephonic interviews approximately one month after they begin receiving meals. During interviews, participants will be asked to share contact information for caregivers who may be willing to be interviewed. Caregivers will be invited to participate in separate telephonic interviews.

2.2. Interventions

All participants randomized to drop-shipped meals will receive 10 frozen meals that are mailed via Fed-Ex to their home every two weeks from a Meals on Wheels program vendor, TRIO foods. All participants

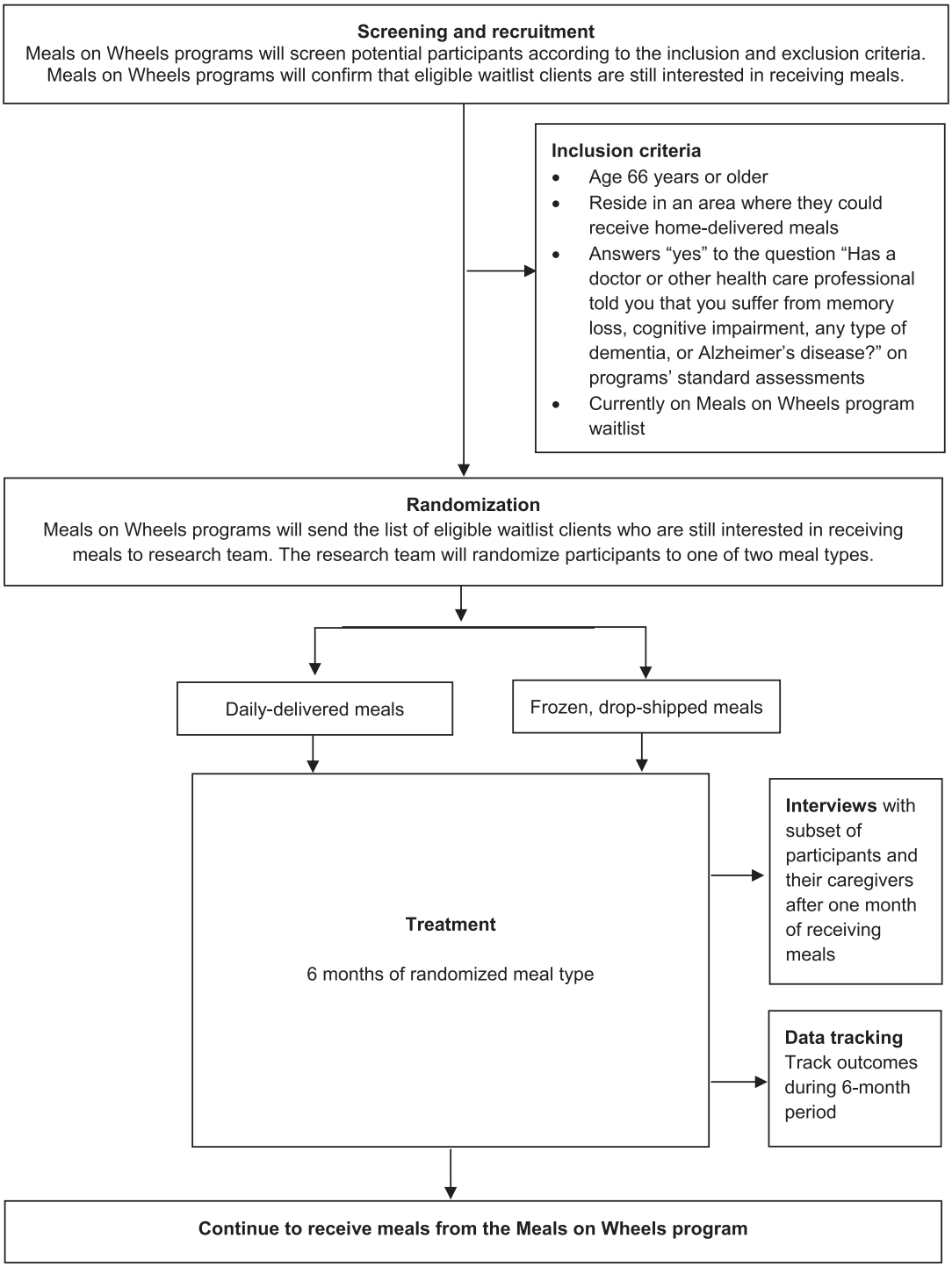

Fig. 1. Participant study flow.

randomized to daily-delivered meals will receive a hot or chilled lunch-time meal delivered to their homes, multiple times per week, by a Meals on Wheels program employee/volunteer who interacts with the client and provides an informal wellness check. All employees/volunteers are asked by programs to report any concerns. Meals in both arms meet the same nutritional standards (i.e., adhere to current Dietary Guidelines for Americans, [24] provide 1/3 of the Dietary Reference Intakes [25]). Study-funded meals will be provided for up to six months. After six months, participants will receive meals from the participating programs.

2.3. Sample size

Our target sample size is 236 participants. Based on our internal preliminary studies, we assume that the proportions of participants who would be admitted to nursing homes in 6 months is 11% and 13%, in the daily-delivered and drop-shipped meals arms, respectively. Under the Cox proportional hazard model and with a significance level of $\alpha = 0.05$, we would be able to detect a hazard ratio of 0.31 with 80% power [26]. For the larger pragmatic trial, we estimate that under these assumptions we would need to enroll 2100 participants to detect a hazard ratio as small as 0.7. For the qualitative interviews, we will recruit 6–12

participants (2–4 per program) and 6–12 caregivers.

2.4. Data and data collection

Consistent with the pragmatic design, this study utilizes waiting list eligibility assessments and service data (e.g., dates of meal delivery) routinely collected by Meals on Wheels programs. These data will be linked with Centers for Medicare and Medicaid Services (CMS) administrative data. CMS data that will be obtained through a study-specific DUA include the 2021–2022 Medicare Beneficiary Summary File and the 2021–2022 nursing home Minimum Data Set (MDS) [27].

Items from the programs' eligibility assessments that will be used for matching to the CMS data include last name, ZIP code, date of birth, sex, and social security number (SSN). Fidelity to the intervention is determined by dates of service and breaks in service as reported in the service data. Programs will share weekly updates and transfer data to the research team upon participant enrollment and at the end of the study period.

Six to twelve participants will be recruited for a 30-min phone interview using two different methods: 1) at two sites, we will pilot an "opt-in" approach by mailing letters and an informed consent document to a subset of participants inviting them to contact the research team if they are interested in participating; 2) at the third site, we will pilot an "opt-out" approach by mailing informed consent documents and letters describing the study and asking them to contact the research team via a self-addressed, stamped postcard, email, or telephone if they do not want to be contacted. If participants do not opt-out, the research team will make up to three recruitment attempts. Prior to phone interviews, we will review the informed consent form with participants to ensure they understand the purpose, procedure, risks, and benefits of the study.

We will also pilot the feasibility of recruiting 6–12 caregivers referred by participants for a 30-min phone interview using the contact information provided by the participant. We will mail caregivers an informed consent document and review it prior to conducting the interview.

The qualitative interview guides are informed by the Medical Research Council's Process Evaluation Framework [28] and include questions focused on implementation (e.g., participants' interaction, if any, with the driver/mail carrier who delivers their meals), mechanisms of impact (e.g., participants' experiences receiving, preparing, eating meals); and outcomes (e.g., participants' satisfaction with the meal services). The Telephone Interview for Cognitive Status (TICS-M) will be used to assess participants' cognitive status [29]. The caregiver interview guide will also include about caregiving responsibilities and how the meals have impacted caregivers' lives.

Multiple security measures are in place to ensure the integrity and confidentiality of the data. For example, all research staff involved in the study received training in the protection of human subjects. All data management and analyses will be conducted by the Brown Center for Gerontology & Healthcare Research, leveraging its administration and computing infrastructure. Any files or output containing identifiable information are treated as confidential data. Additionally, participant information is saved on a secure server, only accessible to research staff.

2.5. Statistical methods

2.5.1. Feasibility for a full-scale pragmatic clinical trial

To understand recruitment and retention rates, we will examine the frequencies that randomized individuals on waiting lists are contacted and enrolled in the study, begin and discontinue meals, die, and are admitted to a nursing home. To understand fidelity, we will calculate the length of service and any breaks in service reported by the programs. We will compare characteristics of participants by program, by intervention arm, and outcome states (i.e., enrolled full 6 months; discontinued meals; admitted to a nursing home, died). We will also assess the feasibility of recruiting participants and caregivers for interviews and identify common themes in participant experience.

We will assess the ability to link information routinely collected by the programs with Medicare enrollment records for our outcomes analysis. We will compare the linkage rate using two methods 1) linking on SSN; 2) linking on last name, date of birth, sex, and ZIP code.

2.5.2. Primary outcome analysis

The primary outcome is the number of days from the date of randomization to nursing home admission. Using the 2021 and 2022 MDS data, we will monitor for nursing home placement up to180 days from each participant's date of randomization. Participants who die or reach the end of the follow-up period without being admitted to a nursing home will be censored. We do not expect deaths to differ by condition. We will use an intention to treat approach and compare the modes of delivery using the Cox proportional hazards model [30]. In randomized experiments, the distribution of all the covariates should be similar on average. However, because there are many covariates (e.g., age, living situation, functional impairment, diagnoses), one may expect that some will suffer from slight imbalances. To address imbalances and obtain more efficient estimates, we will adjust for these variables. Formally, let $h(t) = h_0(t) \times exp(\gamma W_i + \beta' X_i)$ be the hazard function, where t is the time to nursing home admission, X_i is a set of baseline covariates for participant i, W_i is an indicator for daily-delivered meals for participant i, $h_0(t)$ is the baseline hazard, β is a set of unknown parameters and γ is the conditional hazard ratio between daily-delivered and drop-shipped, frozen meals. Standard errors will be obtained using bootstrap procedures [31].

2.5.3. Data monitoring

Because this trial has no known or anticipated risks, no formal data monitoring committee is required. An independent Safety Officer will monitor participant safety, study risks and benefits, scientific integrity, participant recruitment, and ethical conduct of the study, in accordance with our Data Safety Monitoring Plan. No serious adverse events are expected. Potential adverse events that could occur during the qualitative interviews include mild distress, negative emotional reactions, or confusion in response to being interviewed by phone; though, these are not expected. In the event that an adverse event occurs, it will be reported to the NIA Program Officer, the Safety Officer, and the IRB within 48 h. Participant deaths, even if not related to the study, will be reported within 24 h of becoming aware of the event.

2.6. Unique design features of the pilot pragmatic trial - consent

Written informed consent is a standard regulatory and ethical requirement in research. Obtaining written consent often challenges the pragmatic nature of trials and careful considerations are needed in the study design process to increase pragmatism while protecting individuals living with dementia participating in research [32]. To guide other researchers interested in pragmatic trials with special populations, we offer an approach and rationale for pursuing different consent processes for specific elements of the trial (i.e., waivers of informed consent for enrollment, randomization, and data sharing; a waiver of documentation of consent for phone interviews).

2.6.1. Waiver of individual informed consent to enroll participants, randomize participants to receive daily-delivered or drop-shipped meals, and link routinely collected data for analyses

We obtained a waiver of informed consent to enroll and randomize participants to meal type (daily-delivered vs. drop-shipped meals) as the intervention and analysis met the five criteria for a waiver described in 45 CFR 46.116(f)(3)(i-v):

(i) *The research involves no more than minimal risk to the subjects*. The study recruits from an existing waiting list and provides meals via the two predominant modes of meal delivery currently used by

home-delivered meals programs and contracted for by healthcare entities. The primary outcome analysis is through secondary data analysis of routinely collected administrative CMS data; therefore, no additional burden is placed on participants. Enrollment and receipt of meals puts these individuals at no greater risk than everyday life.

(ii) *The research could not practicably be carried out without the requested waiver or alteration.* The regulations regarding consent exceptions focus on whether a study is practicable if consent is required [33]. Although such judgments entail a degree of subjectivity, they commonly include considerations of whether approaches to consent would compromise scientific validity, for example, by introducing bias because of selective enrollment. Although individual consent is possible, requiring consent would introduce bias in two ways. First, while some individuals with dementia retain capacity to consent to research, restricting the study to only those able to provide consent (i.e., less-severe dementia) would limit the generalizability of our findings. Second, if we required consent and sought to include people who lacked capacity to consent, a legally authorized representative (LAR) would have to be identified. Most individuals with dementia living in the community do not have a LAR [34] and LAR rates are lowest among racial minorities and those with less education [35]. Meals on Wheels clients are more likely to be racial and ethnic minorities and low-income than the general population of older adults [10], and Meals on Wheels programs do not collect information about clients' LARs or surrogates; therefore, there is no mechanism for identifying LARs or consent surrogates for study participants. Thus, requiring consent would limit the generalizability, validity, and overall scientific value of the findings.

(iii) *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.* We are using routinely collected administrative data for analysis. We require the data in identifiable format to link programs' administrative data with CMS data. A waiver of consent is regularly obtained for analyses conducted using linked CMS data.

(iv) *The waiver or alteration will not adversely affect the rights and welfare of the subjects.* Participants are on waiting lists because the programs do not have funding to provide meals. Enrollment in the study offers participants an opportunity to receive meals sooner than they otherwise would. Additionally, participants have the opportunity to decline receipt of meals if they no longer want them or prefer not to receive their assigned meal-type without losing their place on the program's waiting list. Thus, participants are more likely to benefit from participation than not.

(v) *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.* Participants will be provided information about the study upon its completion through Meals on Wheels programs' newsletters and other client-facing materials. Contact information of who to call for additional information about the study will be included.

2.6.2. Waiver of documentation of informed consent for qualitative interviews with participants and caregivers

Detailed information about participants' experiences receiving, preparing, and eating meals is not available via administrative data; neither is information available about the impact of home-delivered meals on caregivers. While interviews make the study less pragmatic, they are necessary for understanding the context and mechanisms behind the effect of meals. We did not seek a waiver of consent for these interviews because the goal of qualitative research is to provide in-depth explanations and meanings, rather than generalizable findings [36] - thus, requiring consent for the interviews did not threaten the scientific validity of the research (i.e., they did not satisfy criteria two above). Instead, we obtained a waiver of documentation of informed consent for the subset of participants and caregivers taking part in qualitative interviews as described in 45 CFR 46.117(c)(ii): "The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." Consent would not normally be required for a telephone conversation of this nature, and it would not be practical to obtain signatures because the interviews are being conducted over the phone.

A trained research team member will assess the prospective participant's capacity to consent for the study interview. The team member will determine if all of the following standards are met: Did the individual "make a clear choice"? Did the individual show "understanding"? Did the individual show "reasoning/rational reasons"? Did the individual show an appreciation of the personal risks/benefits of participation in the study? This determination will be accomplished using a four-item study-specific consent checklist developed by the study team in accordance with best practices in ethics, law, and clinical assessment [37] and approved by the Brown IRB. Individuals who do not have adequate capacity to consent will be thanked for their time and willingness to speak with study staff, and the phone call will be ended in a way that preserves dignity (e.g., "Thank you for speaking with me today. That is all we have for now. Do you have any questions for me?").

3. Discussion

This manuscript describes the protocol for a pilot, pragmatic clinical trial that will compare the effects of two standard modes of providing home-delivered meals on time to nursing home placement for individuals with dementia. We highlight our rationale and justification for pursuing different consent processes within the same trial.

Prior research suggests that providing home-delivered meals has numerous benefits to clients [9,15,38]. While healthcare entities are increasingly contracting with organizations to provide home-delivered meals [16,18], there is limited evidence comparing the effectiveness of the two modes of meal delivery on prolonging the time that older adults living with dementia remain in the community. This pilot study will provide a signal of the potential efficacy of the intervention and provide important preliminary information on the treatment effect sizes necessary to proceed to a full-scale pragmatic clinical trial. This pilot study will evaluate whether the study design is feasible for recruitment, adherence to the intervention, extraction and transfer of data, and linkage of participant data with Medicare records and nursing home assessment data.

There are limitations to note. First, identification of dementia relies on the Meals on Wheels intake process, which is based on self-reported diagnoses by the client, caregiver, or person making the Meals on Wheels referral. While it is preferable to have a standardized clinical assessment of dementia for inclusion in the study, that is not pragmatic. Second, we are piloting two interview methods that are not based on random samples. Relatedly, interviewing by telephone allows us to target underrepresented groups; however, it might exclude others (e.g., hearing impaired, severe cognitive impairment). Finally, we have a limited ability to determine the mechanisms for any group differences we observe in the time to nursing home placement. We do, however, expect that the qualitative interviews will provide insight into these mechanisms and contexts.

The follow-on, large, definitive pragmatic trial that is directly informed by this pilot will provide evidence to help policymakers, healthcare entities, and meal providers identify the most effective mode of delivery for people living with dementia in need of in-home nutrition support. In addition to informing the follow-on study, this pilot will be useful to researchers conducting pragmatic clinical trials focused on people with dementia. Pragmatic clinical trials present a number of

ethical and regulatory challenges. For example, obtaining individual consent often reduces the pragmatism of the research; as such, random assignment is often done at the unit of care or "cluster" level in pragmatic clinical trials among people with dementia [29]. We present justification for the use of individual randomization with differing consent procedures for various elements of a pragmatic trial. The justifications laid out in this protocol provide a model for future trialists to work with their Human Subjects Protections office to develop ethical and feasible pragmatic studies enrolling people living with dementia focused on outcomes that matter most to them – like staying at home for as long as possible.

Declaration of interest

The authors declare no conflicts of interest.

Data availability

No data was used for the research described in the article.

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Appendix A. Additional information about the three participating sites

A.1. Neighborly Care Network

Neighborly Care Network, Nutrition Services, serves older adults residing in Pinellas County, Florida, an entirely urban area. In 2021, Neighborly Care Network served 2040 unique clients over 251,000 meals. 60% of clients were female, 76% of clients were white, 16% were black, (they do not report the number of Hispanic clients) and 28% were over the age of 85.

Website: https://neighborly.org/nutrition/

A.2. Meals on Wheels San Antonio

Meals on Wheels San Antonio serves older adults residing in Atascosa, Bandera, Bexar, Comal, Frio, Guadalupe, Karnes, Kendall, Medina, Uvalde, and Wilson, a mix of urban and rural locations. In 2021, Meals on Wheels San Antonio served 6610 unique clients and approximately 1,875,000 meals. 41.5% of clients were female, 43% of clients were white, 11% were black, 37% were Hispanic, and 23% were over the age of 85.

Website: https://www.mowsatx.org/

A.3. Visiting Nurse Association (VNA) of Texas Meals on Wheels

VNA of Texas Meals on Wheels serves older adults residing in Dallas County, an entirely urban area. In 2021, VNA of Texas Meals on Wheels served 6100 unique clients 1,143,434 meals. 62% of clients were female, 36% of clients were white, 50% were black, 12% were Hispanic, and 27% were over the age of 85.

Website: https://www.vnatexas.org/our-services/meals-on-wheels/

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