Pilot and Feasibility Studies

STUDY PROTOCOL

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Tailoring registered dietitian and occupational therapy services for home-delivered meal recipients: feasibility study protocol for a randomized controlled trial

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Abstract

Background Home-delivered meal recipients often present with complex nutritional and functional needs that place them at elevated risk for health decline and potential institutionalization. To address these complex needs, clinical services—namely registered dietitian and occupational therapy services—may be warranted to reduce the risk of health decline and maximize outcomes of this vulnerable older adult population. Accordingly, this study will explore the feasibility of testing four different clinical service models with home-delivered meal recipients. In particular, this study will determine the feasibility of recruiting and retaining participants from one home-delivered meal provider, determine challenges and opportunities to improve data collection procedures, assess resources needed to conduct study activities, and identify if service models can be implemented as intended.

Methods This is a feasibility RCT with 1:1:1:1 allocation to four service arms: (a) meals only, (b) meals + registered dietitian services, (c) meals + occupational therapy services, or (d) meals + registered dietitian services + occupational therapy services. Study activities will be conducted in collaboration with one, large community-based agency in the Midwest United States. We will recruit 60 participants who meet the following inclusion criteria: is eligible to receive home-delivered meals funded through Title 3 of the Older Americans Act, has a self-reported diagnosis of diabetes and/or heart disease, is at risk for falling, and can store and reheat up to 14 frozen meals per week. Data collection will occur at baseline and at 3 months after informed consent to assess malnutrition risk, self-management of health conditions, and fall risk.

Discussion While tailored dietitian and occupational therapy services may be warranted to address the nutritional and functional needs of home-delivered meal recipients, the effect of these services on recipient outcomes has yet to be rigorously examined. This feasibility study will identify the degree to which our service models can be tested with one community-based agency and identify opportunities to improve study procedures prior to conducting a definitive, stage III randomized controlled trial.

Trial registration NCT06059404.

Keywords Aging, Community resources, Nutritional status, Functional status, Interdisciplinary research

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Introduction

Over 2 million older adults in the United States are homebound, and an additional 5 million have substantial difficulty leaving their home given health and functional limitations [1]. These limitations also increase older adults' susceptibility to health decline and institutionalization, thereby reducing their ability to remain living in their own homes and communities [2, 3]. Given the complex health needs of this vulnerable group, over 20,000 community-based organizations nationwide provide support services that are tailored to the health, safety, and social needs of older adults [4]. Though not an exhaustive list, services may include nutritional care, transportation assistance, housekeeping, simple home repairs, and personal care assistance to help delay or prevent the need for more advanced and costly care (e.g., nursing home placement) [5].

Home-delivered meal programs serve as one example of these support services and are well-known for providing nutritious meals to older adults who have difficulty affording, selecting, and preparing healthy foods [6, 7]. The benefits of home-delivered meals for older adults are vast and include enhanced dietary quality [8], reductions in reported falls [9], and decreased feelings of loneliness [10]. These benefits are particularly impactful given that home-delivered meal recipients typically present with health characteristics that increase their susceptibility to health complications. For instance, 90% of home-delivered meal recipients are living with at least one diet-related health condition, such as heart disease or diabetes [11]; 80% are living with at least one fall risk factor (e.g., mobility impairment; prior history of falling) [12]; and 50% experience perceived fair-poor health [13]. However, despite the established value of home-delivered meals, recipients' complex nutritional and health needs may not be sufficiently met through the provision of *standard* meal services alone. Given that the older adult population in the United States is expected to reach 82 million by 2050 [14], *enhanced* home-delivered meal services may be warranted to keep pace with recipients' growing health needs and promote their ability to age in their own homes—where the majority of older adults prefer to reside [15].

In response to the growing health needs of older adults, we propose that home-delivered meal services should be enhanced with clinical services that optimize recipients' health outcomes. This recommendation is predicated on two concepts. First, home-delivered meal service models are highly variable and include models that allow recipients to choose their own meal selections. Though this model preserves older adults' autonomy over their meal choices, some older adults—particularly those with diet-related health conditions—may need skilled nutritional guidance, as provided by a registered dietitian, to make meal selections that align with their health needs and dietary requirements [16, 17]. Second, we claim that the consumption of food is a complex activity of daily living and is influenced by several individual-level factors (e.g., motor skills, cognitive skills, sensation) and environment-level factors (e.g., safety in the kitchen, fall hazards in the dining areas) that can either hinder or promote one's ability to consume meals [18]. Accordingly, skilled services provided by occupational therapists—professionals who have expertise in the safe completion of activities of daily living in the home [19]—can be leveraged to support successful meal consumption. In combination, registered dietitian and occupational therapy services may enhance older adults' selection and consumption of home-delivered meals and arguably improve overall health outcomes.

Despite the potential value dietetic and occupational therapy services may offer home-delivered meal recipients, the effect of these services on recipient outcomes has yet to be rigorously examined. As such, the purpose of this study is to determine the feasibility of conducting a randomized controlled trial that will test the effect of four different service models on home-delivered meal recipient outcomes: (1) meals alone, (2) meals + registered dietitian services, (3) meals + occupational therapy services, and (4) meals + registered dietitian services + occupational therapy services. Findings from this study will subsequently lay the foundation for a stage III efficacy trial. In alignment with key focus areas of feasibility studies [20], we aim to:

Determine the feasibility of recruiting and retaining participants from one community-based agency

Determine challenges and opportunities to improve data collection procedures

Assess the resources needed to implement services and study activities

Identify the extent to which services can be implemented as intended

Methods

Design

This study will test the feasibility of conducting a four-arm, randomized controlled trial in the community setting. This is a single-site study in that all participants will be recruited from one, large community-based agency located in the Midwest USA. Our partner agency will recruit participants from their standard database of new clients who either self-refer, are referred by family, or are referred by a healthcare provider (e.g., primary

care physician) to receive home-delivered meal services. This study follows procedures from protocol version 1.0 (September 1, 2023) approved by The Ohio State University (2023H0248) and registered with clinicaltrials.gov (NCT06059404; 9/22/2023). Study activities are reported in accordance with the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) statement [21] (Supplementary Table 1).

Setting

The community-based agency partner for this study provides federally-authorized, home-delivered meals to over 3000 older adults annually and employs over 200 part- and full-time staff members. Notably, agency staff led activities to secure funding for the present project and, with recruitment for this feasibility study underway, will take responsibility for managing study administration activities, adjusting workflow procedures to accommodate study needs, and are serving as essential members of the research team. Our research team is comprised of three co-Principal Investigators (co-PIs): one with a research background and an active faculty appointment and two who are in leadership positions at our partner agency. The responsibilities of these PIs will be divided accordingly: the "research PI" will lead and coordinate all research activities and ensure procedures are in compliance with the Institutional Review Board of record. One "agency PI" will coordinate data collection logistics and the delivery of meals while the other agency PI will coordinate the provision of dietitian and occupational therapy services. Given the complexity of our co-PIs' responsibilities, all PIs will meet weekly with our study coordinator to ensure research activities align with approved study procedures. Moreover, six staff members—three registered dietitians, two occupational therapists, and one case manager—have undergone all required research trainings and have established Individual Investigator Agreements to conduct the following critical study tasks: recruit eligible participants, obtain informed consent, securely collect data, implement clinical services, and disenroll participants upon study completion. Over 20 agency staff members were actively involved in this feasibility study's development which occurred between September 2022 and August 2023.

Randomization and blinding

After informed consent and baseline data are gathered, participants will be randomized (1:1:1:1) at the individual level into one of our four study arms using the REDCap (Research Electronic Data Capture) randomization feature [22]. To ensure balanced enrollment among 4 arms, we will follow clinical trial methodology guidance and [23] implement a stratified (living alone and living with others) block randomization scheme with a first block size of 16 patients followed by blocks of size 4. To avoid bias in data collection and analysis, the case manager and biostatisticians will be blinded to each participant's study arm assignment. Our partner agency's lead social worker—who will not have a role in data collection or service implementation—will be unblinded to arm assignment and will coordinate the delivery of services.

Participants

Participants will be community-dwelling older adults who meet our partner agency's standard home-delivered meal eligibility criteria. These criteria include (a) being unable to safely and independently leave the home and (b) having difficulty preparing meals at home. The inclusion and exclusion criteria for feasibility study participation are listed below. Given our prior work, we estimate that approximately 80% of our partner agency's client base will meet these criteria [12].

Inclusion criteria

- Self-reported diagnosis of one of the following diet-related diseases:
    - Cardiovascular disease (may include the following: hypertension, congestive heart failure, heart attack or myocardial infarction, peripheral artery disease, stent placement, coronary artery disease, coronary artery bypass graft)
    - Diabetes mellitus
- 60 years of age or older
- Responds "yes" to at least one of the following fall risk screening questions:
    - Do you currently use a cane, walker, or wheelchair?
    - Do you have a fear of falling?
    - Have you fallen in the past 12 months?
    - Do you ever feel unsteady when standing or walking?
- Has a working freezer to store up to 14 frozen meals/week
- Has a working microwave or oven to reheat meals
- Meets our partner agency's standard meal eligibility criteria:
    - Unable to safely and independently leave home
    - Has difficulty preparing meals at home

Exclusion criteria

- Already receiving home-delivered meals from our partner agency or other meal agency (within the past 6 months)
- Residing in residential care or a skilled nursing facility
- Has cognitive impairments that limit the ability to provide informed consent
- Unable to speak and/or understand English

Recruitment

We will leverage the standard workflow processes of our partner agency to recruit our sample. Potential participants will contact our partner agency to initiate their home-delivered meal services. The home-delivered meal case manager will then screen potential participants via telephone for eligibility and determine their interest in the study. If interested and eligible, the case manager will schedule an in-home visit where the study will be explained in detail and consent and baseline data will be obtained electronically in REDCap. Figure 1 depicts the

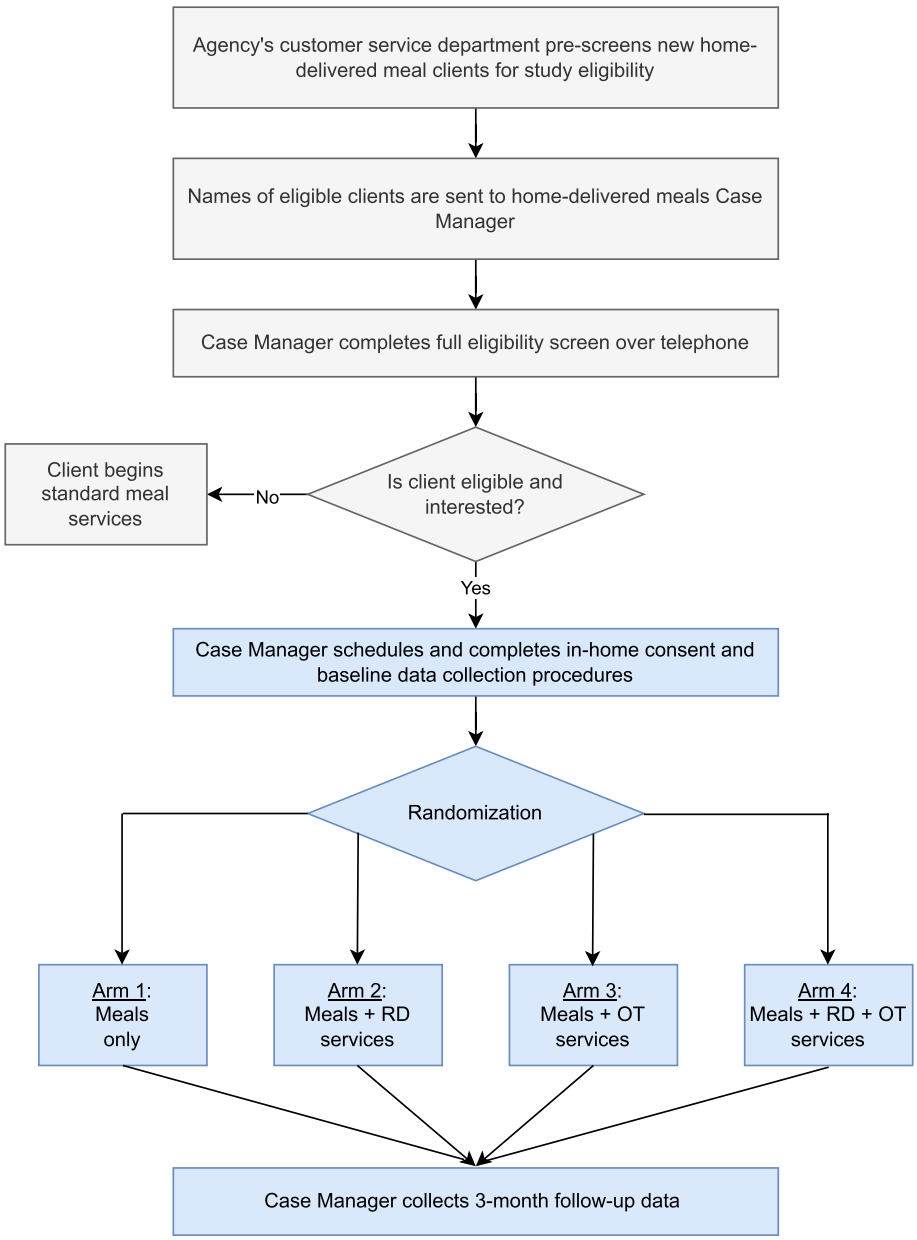

Fig. 1 Participant recruitment and randomization process

recruitment process that leverages our partner agency's existing workflow and infrastructure.

Study arms

Arm 1 (meals only)

Participants randomized to receive "meals only" will receive up to 14 frozen meals, delivered 1×/week, for 3 months. As required through the Older Americans Act, each meal will meet at least one-third of the dietary recommended intakes, per national dietary guidelines, for older adults [24, 25]. Upon consent, participants will be provided with a menu of 40 standard meal options and instructions for how to select their meals and change weekly meal selections (if desired) by calling or emailing our partner agency directly. Participants in this arm will also receive nutrition education and fall prevention handouts. Nutrition education handouts will indicate which of our agency's meals are considered to be "heart-healthy" as well as "diabetic-friendly." Participants will have the autonomy to select their own meals according to their preferences and their ability to self-manage their own health conditions (e.g., diabetes, cardiovascular disease). Fall prevention education handouts will provide guidance on how to increase safety in the kitchen and dining areas and modify the home environment to eliminate fall risk hazards (Fig. 2).

Arm 2 (meals + registered dietitian services)

In addition to frozen meals and educational handouts, participants randomized to Arm 2 will have a telephone-based nutrition assessment completed by one of our partner agency's registered dietitians who will assign participants a nutrition diagnosis (e.g., overconsumption of carbohydrates) within 30 days of informed consent being obtained. During the same phone call, the registered dietitian will also assist participants with their frozen meal selections according to their dietary needs and encourage participants to contact the dietitian with follow-up questions or nutrition concerns via phone. Participants will be able to make weekly meal selection changes based on an approved menu of meals tailored (by the dietitian) to the health needs of the participant. Additionally, dietitians will initiate at least one follow-up phone call no later than 30 days after the nutrition assessment is completed (Fig. 3).

Arm 3 (meals + occupational therapy services)

Participants in this arm will receive frozen meals and educational handouts and will also be contacted (within 30 days of informed consent) by one of our partner agency's occupational therapists to complete a phone screen to determine their fall-related needs (e.g., home safety/fall risk hazards, need for durable medical equipment). Within 30 days after the phone screen, the occupational therapist will then complete an in-home assessment with the participant and provide any initial fall prevention interventions, equipment, activity programs, and education as indicated. Within 45 days of the in-home assessment/treatment encounter, the occupational therapist will complete an

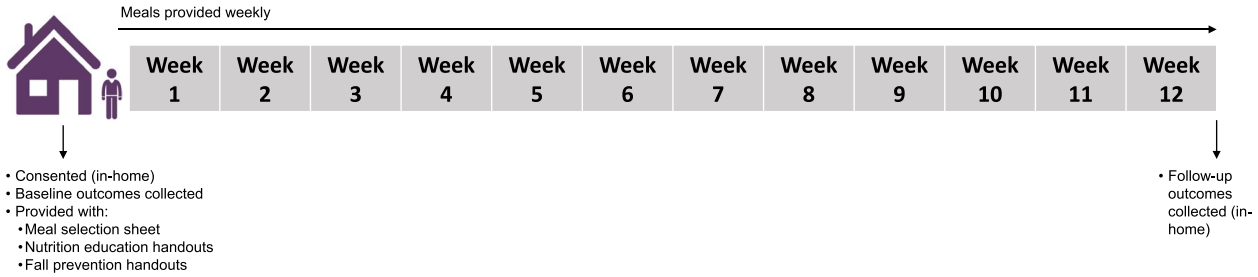

Fig. 2 Overview of study timeline for participants randomized to receive meals only

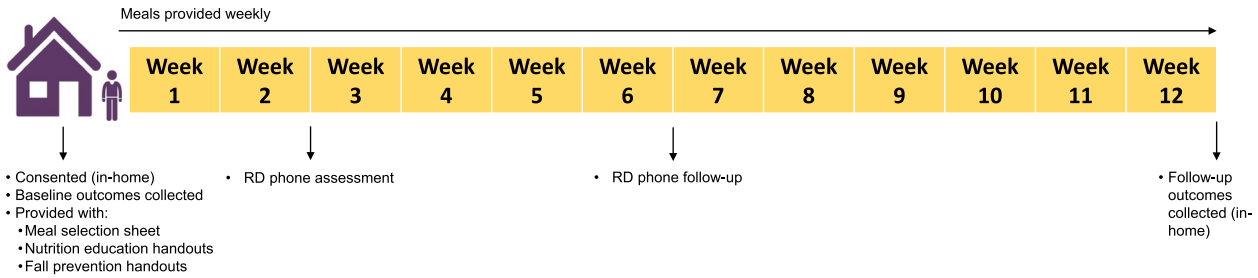

Fig. 3 Overview of study timeline for participants randomized to meals + registered dietitian services

in-home OR phone-based (at the therapist's discretion) follow-up session to determine participants' adherence to fall prevention recommendations. All participants randomized to this arm will also be encouraged to call their occupational therapist with questions or concerns over the 3-month study period (Fig. 4).

Arm 4 (meals + registered dietitian + occupational therapy services)

Participants in this arm will receive frozen meals and the same nutrition education and fall prevention handouts as provided in Arms 1–3. Additionally, participants will receive the combination of dietitian and occupational therapy services as provided in Arms 2 and 3 and have the same autonomy to make their own weekly meal selections from a tailored list provided by the dietitian (Fig. 5).

Outcomes

Given that feasibility is of primary interest for this study, we will evaluate feasibility outcomes that pertain to the following: recruitment and retention of 60 participants over 9 months (6 months of active recruitment, 3-month wash-out period), data collection with outcome measures that will be used in our definitive trial, resources needed to perform study activities and clinical services, and the extent to which clinical services can be implemented as intended. Consistent with the feasibility progression criteria set forth by Hilton et al. [26], we will apply the traffic light rating system to interpret our feasibility outcomes.

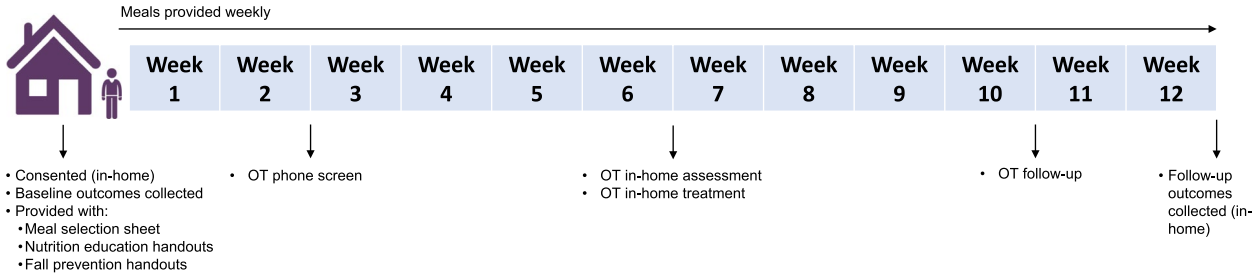

Fig. 4 Overview of study timeline for participants randomized to meals + occupational therapy services

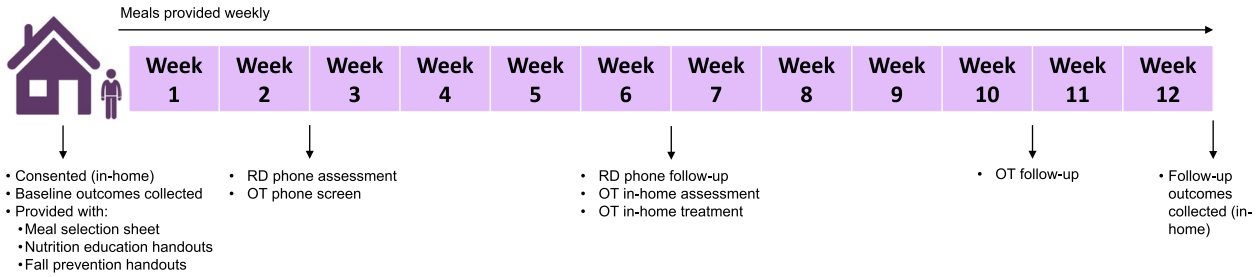

Fig. 5 Overview of study timeline for participants randomized to meals + registered dietitian services + occupational therapy services

Table 1 Traffic light rating criteria for interpreting feasibility outcomes

Feasibility outcome	Description	Green	Yellow	Red
Recruitment and retention	Recruitment: Proportion of participants recruited over 6-months compared to our target sample ($n=60$)	≥ 80%	60–79%	≤ 59%
	Retention: Proportion of participants who stay enrolled in the entire 3-month study period	≥ 80%	60–79%	≤ 59%
Outcome measure data collection	Proportion of data that passes data quality inspections (i.e., is not flagged as suspicious)	≥ 80%	60–79%	≤ 59%
Resources	Proportion of actual expenses (clinician wages, travel costs for in-home visits) that are concordant with budgeted expenses	≥ 80%	60–79%	≤ 59%
Services implemented as intended	For clinicians: Proportion of clinical services that are implemented as intended	≥ 80%	60–79%	≤ 59%
	For participants: Proportion of participants who received all planned clinical service encounters	≥ 80%	60–79%	≤ 59%

Criteria adapted from Hilton et al. [26]. Clinical services = registered dietitian and/or occupational therapy services

These criteria are presented in Table 1 and are described in detail below. Outcomes that are rated as green (≥ 80%) indicate that related activities (e.g., application of inclusion criteria; data collection procedures) can proceed to the definitive trial with minor or no modification to the study protocol. Outcomes rated as yellow (60–79%) indicate that moderate adjustments to the study protocol are warranted, whereas red outcomes (≤ 59%) suggest major protocol adjustments are necessary prior to initiating the definitive trial.

Evaluating recruitment and retention

In accordance with the CONSORT 2010 statement extension for pilot and feasibility studies [27], we will record the number of potential participants who are screened for eligibility, are invited to participate, provide informed consent, complete baseline outcome measures, are randomized into one of our four arms, receive allocated services, and complete outcome measures at the 3-month follow-up time point. Feasibility of recruitment will be determined by comparing the number of participants recruited within 6 months to our target sample size ($n = 60$). Retention will be calculated by comparing the number of participants who completed outcome measures at 3 months to the final number of participants enrolled in our study.

Evaluating outcome measure data collection

In preparation for our definitive trial, we will collect data to assess the risk of malnutrition, self-management of health conditions, and fall risk using the following outcome measures: the Mini Nutrition Assessment-Short Form [28], Summary of Diabetes/Heart Disease Self-Care Activities [29], and the Short Falls Efficacy Scale-International [30]. The *Mini Nutrition Assessment-Short Form* is a 6-item instrument that measures older adults' malnutrition risk on a scale from 0 to 14 points. Indicators of malnutrition are listed below:

- 12–14 points = normal nutritional status
- 8–11 points = at risk of malnutrition
- 0–7 points = malnourished

The 11 standardized items of the *Summary of Diabetes/Heart Disease Self-Care Activities* questionnaire will be used to assess 5 self-management health domains (scoring ranges in parentheses): diet (three items; score range, 0–21), physical activity (two items; score range, 0–14), blood sugar testing (one item; score range, 0–7), foot care (four items; score range, 0–28), and medication adherence (one item; score range, 0–7). There is a final, binary item related to smoking status (Yes = 1 No = 0). Of note, two questions on this questionnaire will be modified for participants who only report having heart disease and do not report having diabetes (thus, no monitoring of blood sugar is needed. Rather participants will be asked to report how often they monitor their blood pressure).

Fall risk will be assessed using the *Short Falls Efficacy Scale-International* which is a 7-item questionnaire with all items measured via a 1–4-point Likert scale to evaluate participants' level of concern about the possibility of falling. Scores can be interpreted as follows:

- 7–8 points = low concern
- 9–13 points = moderate concern
- 14–28 points = high concern

All outcome measure data will be entered into REDCap, and we have assigned thresholds with each REDCap data collection form to mitigate the risk of data entry errors. To further ensure data quality and integrity, we will run monthly reports taking a multi-pronged approach to assessing data quality in that: (a) we will first run reports to detect data which are likely incidentally omitted (i.e., one item in a form has missing data will be flagged whereas an entirely missing form would not be flagged) and (b) we will then run reports on newly entered data to detect large deviations from other values for the same variable and large deviations in patterns of association with other variables (i.e., abnormally high weight values collected at baseline on the Mini Nutrition Assessment-Short Form may trigger a flag to indicate that the weight value needs to be verified by the case manager). All reports containing flags will then be validated to ensure data quality and integrity.

Evaluating resources

To estimate resources needed for our future trial, our case manager, dietitians, and occupational therapists will document the approximate time duration of each participant encounter, equipment and printed materials provided to participants, and approximate travel costs (e.g., gas, mileage) associated with in-home visits. We will then compare staff member wage expenses, equipment and material costs, and travel costs to budgeted expenses to evaluate the feasibility of deploying these resources in our definitive trial.

Evaluating services implemented as intended

We want to ensure that our partner agency's registered dietitians and occupational therapists can implement their respective services as expected. Thus, during each encounter with participants, dietitians and occupational therapists will complete a fidelity checklist to identify which core components of services are being implemented consistently with all participants. The

core components of dietitian services include: client-centered assessment, nutrition diagnosis, meal selection assistance, blood sugar or blood pressure check-ins, and nutrition education. The core components of occupational therapy services include the following: phone screening, in-home assessment, fall risk diagnosis, fall prevention strategies, home environment modifications, and caregiver education. To evaluate if fidelity checklists were accurately completed by our dietitians and occupational therapists, we will select a random 10% of participants whose checklists our research team will review. We will then access participants' completed dietitian and/or occupational therapy documentation notes (standard agency practice) to confirm that the core components marked in each fidelity checklist were addressed during the clinical encounter. Importantly, we also want to determine the feasibility of implementing our recommended number of clinical encounters with each participant. Participants randomized to receive dietitian and/or occupational therapy services will be expected to receive at least two dietitian encounters (assessment encounter + follow-up encounter) and at least three occupational therapy encounters (phone screen, in-home assessment and treatment, follow-up encounter). Feasibility will be evaluated by calculating the proportion of participants who received the minimum number of encounters over the 3-month study enrollment period.

Data collection

Baseline data will be collected from all consented participants during the first in-home visit completed by our case manager. Prior to initiating data collection, the case manager will be extensively trained on outcome measure administration through a combination of written materials, simulated experiences, and in-person demonstrations and observations with the co-PIs. Upon completion of training, our case manager will administer our three outcome measures (Mini Nutrition Assessment-Short Form, Summary of Diabetes/Heart Disease Self-Care Activities, and the Short Falls Efficacy Scale-International) to participants and electronically enter self-reported responses into REDCap using a secure, HIPAA-compliant tablet approved by our partner agency's technology department. Three months after the participant has been enrolled in the study, the case manager will complete a follow-up in-home visit and re-administer the same three outcome measures to each participant. Further, all participants at our partner agency are required to complete an initial eligibility assessment as part of standard practice for home-delivered meal services. During this assessment, the case manager will gather participant demographics as well as health history information that will be documented in ServTracker [31], the agency's primary electronic health record system. Table 2 depicts the time points at which each data source will be collected.

Table 2 Time points for data collection

Data source	Baseline	3-months
Participant demographics	X	
MNA-SF	X	X
SDSCA[a]	X	X
FES-I	X	X

Time points for data collection

MNA-SF Mini Nutrition Assessment-Short Form, *SDSCA* Summary of Diabetes/Heart Disease Self-Care Activities, *FES-I* Short Falls Efficacy Scale-International

[a] Two items of the SDSCA will be modified when administered to participants who only present with self-reported heart disease (not diabetes)

Sample size

We will recruit 60 participants who will be randomized into one of our four study arms (i.e., 15 participants per arm). This level of enrollment aligns with recommendations for feasibility studies in that our future trial will be designed to have 90% power and an alpha level of 0.05 to detect a medium effect size of 0.5 [32]. Further, for our feasibility outcomes of recruitment and retention, outcome measure data collection, resources, and implemented services listed in Table 1, we estimated precision with a 12.7% margin of error in the most conservative scenario with an estimated proportion near 50%. Proportions deviating from 50% in either direction would result in narrower confidence intervals.

Statistical methods

To facilitate the transfer of data in preparation for analysis, our partner agency established a Data Use Agreement with The Ohio State University. For our feasibility outcomes, we will use univariate statistics to calculate the following: *recruitment* = the total number who enrolled in the study ÷ the number of clients eligible clients; *retention* = number of enrolled participants who completed 3-month follow-up ÷ number of enrolled participants; *outcome measure data collection* = number of missing data points ÷ number of expected data points collected; *resources* = clinician wages + travel costs for in-home visits + equipment provided; and *fidelity* (i.e., services implemented as intended) = number of RDN and OT core components that were implemented (per clinician documentation) with each participant ÷ the number of core components that were expected to be implemented.

Descriptive statistics will also be provided for the entire sample and stratified by the 4 study arms. For continuous outcome measures, we will provide means (standard deviation) for normally distributed variables and medians

(interquartile range) for non-normally distributed variables. Although we will be collecting data using the outcome measures we plan to use in our definitive trial, we do not plan to examine the efficacy of any of our service models; however, our descriptive statistics may inform any protocol modifications that are warranted for the full trial.

Event reporting and trial oversight

Our study team will hold meetings twice a month to determine procedures for discontinuing services for participants who no longer want to be involved in the feasibility study but still want to receive standard home-delivered meal services. Event reporting will be reviewed during weekly meetings between the study Co-PIs and our clinical research specialist who will ensure that adverse events are properly documented in REDCap and reported to the IRB as needed. In addition to monitoring potential adverse events with our clinical research specialist, we will also participate in bi-monthly meetings with our funder—the Administration for Community Living, Department of Health and Human Services—who will monitor study progress, provide oversight to ensure study deliverables are met, and provide technical assistance to promote the success of study activities.

Discussion

This study will establish the feasibility of testing our four service models in one home-delivered meal agency. Although the value of home-delivered meal services has been well-documented [7, 8, 10], the health needs of the growing older adult population are quite complex, warranting tailored clinical services to maximize health outcomes and preserve older adults' ability to remain living at home. Augmenting home-delivered meals with tailored registered dietitian and/or occupational therapist services may provide older adults with skilled nutritional guidance and home safety recommendations that can improve dietary quality and reduce fall risk among this vulnerable, community-dwelling population [19, 33].

By meeting the objectives of this feasibility study, our team will be able to determine the extent to which we can recruit and retain participants for our larger, definitive trial. We will also be able to identify challenges and solutions to collecting data, estimate resources and personnel needed to conduct study activities and provide clinical services, and ensure that dietitian and occupational therapy services can be implemented as intended. Accomplishing these objectives will be essential for enhancing our full, efficacy trial, especially given that there are few previously published studies that have tested similar service models or leveraged existing community-based agency infrastructures to support study activities.

Strengths

To our knowledge, this is the first feasibility study designed to examine the combination of registered dietitian and occupational therapy services with community-dwelling older adults. In addition to the innovative nature of this work, perhaps the most significant strength of this study is the collaborative manner in which our protocol was developed. Prior research has strongly emphasized the need for improved collaboration between academic researchers and community partners to enhance the implementation of experimental trials [34, 35]. As such, our team intentionally forged a reciprocal community-academic partnership in that the needs and interests of all team members—agency staff and researchers alike—were considered during the phases of protocol development. For instance, registered dietitian and occupational therapy services have been routinely offered to our agency's home-delivered meal recipients as part of standard practice for several years. To determine the efficacy of these services, both individually and in combination with one another, agency staff leveraged their existing partnerships with academic researchers to empirically test their service models with recipients. Relatedly, our researchers were eager to build the evidence base for models of care that promote older adults' safety and ability to remain living in their own homes and communities. Our team will continue to capitalize on these shared interests in improving the nutrition and functional status of older adults as we implement this feasibility study and refine the protocol for our future definitive trial.

Limitations

Despite the strengths of this community-based study, it is not without limitations. We recognize that the health conditions (e.g., cardiovascular disease, diabetes) collected from participants will be gathered through self-report, introducing the potential for under- or overreporting of conditions. However, obtaining such information through self-report is considered standard practice by home-delivered meal agencies across the United States. Further, while our partner agency has extensive experience coordinating and delivering meals to older adults, we do not have plans to monitor the extent to which meals, or other food items (e.g., snacks), are consumed on a week-by-week basis as dietary intake is not an outcome of interest for the definitive trial. Given that this study is being conducted in a community-based setting, we also cannot control for additional services participants may be receiving from sources outside of our partner agency, subsequentially influencing their willingness or ability to participate in our feasibility study. Lastly, while our partner agency is one of the largest home-delivered meal providers in the USA, findings from

this study may not generalize to other community-based agencies interested in conducting trials that test similar support service models for older adults. However, we anticipate that the demographic characteristics of our sample will mirror those of peer agencies in several geographic regions.

Conclusion

While registered dietitian and occupational therapy services have been shown to improve health outcomes among community-dwelling older adults [17, 19], they have yet to be examined in the context of home-delivered meal services. Studies that test the effect of these services on home-delivered meal recipient outcomes are needed to determine which combination of services yields the most optimal outcomes, should be replicated by other agencies, and may warrant potential reimbursement.

Abbreviations

SPIRIT	Standard Protocol Items Recommendations for Interventional Trials
Co-PIs	Co-Principal Investigator
IRB	Institutional Review Board
REDCap	Research Electronic Data Capture
RD	Registered Dietician
OT	Occupational Therapist
CONSORT	Consolidated Standards of Reporting Trials
HIPAA	Health Insurance Portability and Accountability Act
MNA-SF	Mini Nutrition Assessment-Short Form
SDSCA	Summary of Diabetes/Heart International
FES-I	Short Falls Efficacy Scale-International
U.S.	United States

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Authors' contributions

LJ led manuscript development and assisted with study design and conceptualization; SJ and JMH contributed to study design and led the creation of data collection forms and analysis plans; GH, KST, and MLH assisted with study design and manuscript development; TSS provided guidance on ethical and compliance requirements; LEB and MLR led development of agency procedures to support study implementation and assisted with study design; AD and KP led study conceptualization and administrative activities. All authors and LifeCare Alliance team members contributed to protocol development and approved the final version of this manuscript. The funder of this study, the US Administration for Community Living, Department of Health and Human Services, did not have any role in the aforementioned activities.

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Data availability

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Declarations

Ethics approval and consent to participate

Ethics approval for this study was granted by the Institutional Review Board at The Ohio State University (2023H0248). Written informed consent will be obtained from participants at the initial in-home visit.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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