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Occupational therapy and registered dietitian services to reduce fall risk among home delivered meal clients: a randomized controlled feasibility trial

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Abstract

Background Older adults increasingly prefer to age in place, but health and safety risks often threaten this independence. Home delivered meals, a key service under the Older Americans Act, provide essential nutritional support to homebound older adults, the majority of whom are at elevated risk for fall-related morbidity and mortality. Given the complex health conditions of homebound older adults, we conducted a feasibility randomized controlled trial (RCT) to evaluate our methods for testing four different service models designed to help reduce fall risk among home delivered meal recipients: (1) meals alone; (2) meals + registered dietitian nutritionist (RDN) services; (3) meals + occupational therapy (OT) services; or (4) meals + RDN + OT services. Findings will inform protocol modifications for our definitive RCT to improve fall-related outcomes among this population.

Methods A four-arm, parallel-group feasibility RCT was conducted with one home delivered meal agency in the Midwest United States. Participants were eligible to participate if they were over 60 years old, were able to receive meals from our partner agency, had one diet-related health condition, and were at risk for falling. Feasibility outcomes included study eligibility, recruitment, retention, fidelity to RDN and OT services, and service acceptability.

Results Of 442 screened clients, 31% were eligible for participation, and 41% of eligible individuals were recruited ($N = 56$). Retention at three months was 79%. Fidelity rates were 84.5% for RDN services and 90.2% for OT services. Participants expressed high satisfaction with meal convenience and staff interactions but noted areas for improvement, including meal taste and inconsistent meal deliveries (e.g., timeliness; receiving correct meals).

Conclusions The study identified several barriers to scaling this trial, including restrictive eligibility criteria and recruitment challenges. Protocol modifications for the definitive trial include broader eligibility, expanded recruitment areas, and increased flexibility in meal selection. Randomization procedures will also be adjusted to account for participants from the same household. This feasibility trial demonstrates the potential for integrating RDN and OT services into home delivered meal programs to address recipients' fall-related needs.

Trial registration Clinicaltrials.gov; NCT06059404; 22/09/2023.

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Background

An overwhelming majority of older adults prefer to "age-in-place," defined as remaining in a community-based dwelling during one's later years in life [1]. However, the growth of the older adult population has brought to light several health and safety concerns that threaten the ability for older adults – particularly homebound older adults – to remain independent in their home environments [2, 3]. To mitigate these concerns, community-based agencies provide health and social services that optimize independence and reduce older adults' needs for more advanced and costly care (e.g., nursing home placement) [4, 5]. One example of these essential – and popular – services is *home delivered meals*. Authorized under the Older Americans Act of 1965, federally funded home delivered meal programs represent the largest nutritional support program for older individuals in the United States [6]. Meals are delivered to an older adult's home by paid or volunteer drivers who provide opportunities for social interaction and communicate any client concerns back to the meal agency.

Despite the well-established value that home delivered meals provide [7, 8], the health characteristics of home delivered meal recipients are becoming increasingly complex [9, 10]. For instance, nearly 90% of home delivered meal recipients are living with diet-related health conditions, such as cardiovascular disease, (e.g., hypertension; congestive heart failure), diabetes, and renal disease [11]. These conditions are often accompanied by metabolic changes, reductions in muscle mass, visual changes as a result of diabetic retinopathy, impairments in lower extremity sensation, and poor endurance to complete daily tasks (e.g., eating, cooking) [12, 13]. Of paramount concern is how these conditions also impact home delivered meal recipients' risk of falls – the leading cause of injury and disability among older adults [14]. While approximately 25% of the general older adult population experience falls annually [15], as high as 60% of older adults with diet-related health conditions report falling [13], suggesting that tailored clinical services are warranted to address the nutritional, physical, and functional needs of older adults with these conditions. Relatedly, 80% of home delivered meal recipients present with one or more personal fall risk factors (e.g., prior fall, use of assistive ambulatory device) [16], and as many as one-quarter are living in home environments that contain concerning fall hazards, such as uneven walking surfaces, broken flooring, and tripping obstacles in the kitchen and dining areas [17]. If proactively addressed by a skilled professional these fall risk concerns can be drastically reduced [18], resulting in improved safety and independence for older adults living at home.

To support the nutritional, physical, and functional needs of home delivered meal recipients living with diet-related health conditions, we propose that tailored clinical services – particularly those provided by registered dietitian nutritionists (RDNs) and occupational therapists (OTs) – may attenuate fall risk and promote the ability for meal recipients to remain living in their own homes. Given that RDNs are experts in providing nutritional guidance, and OTs are experts in maximizing safety in the home environment, we claim that these are the ideal professionals to address the complex fall-related needs of the home delivered meal population.

While supplementing home delivered meals with skilled clinical services (e.g., RDN and OT services) seems like a practical approach to mitigate recipients' nutritional and safety needs [19, 20], the value of these services has yet to be empirically evaluated. Without such evidence, it is unlikely that meal agencies would attempt to add new, time- and resource-intensive services to their restrictive operating budgets. Accordingly, the present feasibility study serves as a first step towards testing the effect of RDN and OT services on meal recipients' fall-related outcomes. Below, we describe our methodological approaches and the feasibility outcomes that have informed revisions to our definitive randomized controlled trial study protocol.

Methods

Study design and setting

We conducted a four-arm, parallel-group randomized controlled feasibility trial in partnership with one home delivered meal agency in the Midwest United States (NCT06059404). The feasibility trial design was most appropriate given our interest in examining two understudied services in the home delivered meal setting – RDN and OT services. In our definitive trial, the four-arm design will also allow us to estimate the individual effect of meals, registered dietitian services, and occupational therapist services, *as well as* the combined effect of these services on fall-related outcomes.

Notably, our interests in this early investigative phase were primarily focused on evaluating the feasibility of our study methods. We were *not* focused on determining

estimates of RDN or OT effectiveness, nor were we interested in estimating the effect of home delivered meals on participant outcomes. Rather, we planned to use findings from this feasibility study to inform refinements to our definitive RCT study protocol and research procedures. All study activities described below are reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility trials [21] (Additional file 1).

The agency partner for this study typically provided home delivered meals to over 6,000 older adults each year and employed over 200 part- and full-time staff members. For the present study, meals were provided to homebound older adults who resided in the agency's primary service area, and the cost of meal services were covered by a combination of federal appropriations (e.g., Older Americans Act Nutrition Program), local tax levies, and private donations.

Participant eligibility

Participants were recruited from our partner agency in the six months between September 1, 2023 – February 29, 2024. Individuals who contacted our partner agency to begin meal services were automatically assessed for study eligibility by the lead outcome assessor via telephone. Inclusion criteria and exclusion criteria are listed below:

Inclusion criteria:

- The presence of one or more fall risk factors, as defined by the Centers for Disease Control and Prevention [22], given that such factors can be addressed by an occupational therapist
- A self-reported diagnosis of either cardiovascular disease or diabetes as these are diet-related conditions that often warrant registered dietitian services
- Age of 60 years or older
- Willing to receive the weekly-delivered Frozen Choice meal plan (versus the daily-delivered hot meal plan)
- The ability to store and reheat 14 frozen meals
- Met our partner agency's home delivered meal eligibility criteria (i.e., difficulty with safe and independent meal preparation; no regular access to a caregiver who can provide meals).

Exclusion criteria:

- Had received home delivered meals from our partner agency or other meal agency within the past 6 months
- Resided in a residential care or skilled nursing facility
- Had cognitive impairments that limited their ability to provide informed consent
- Were unable to communicate in English

Participants who were eligible and interested in study participation then scheduled an in-home visit with the lead outcome assessor within 14 days. During this in-home visit, the assessor reviewed the purpose of the study and potential study risks, obtained informed consent, provided participants with printed educational handouts (described below), and helped participants select frozen meals for their first week of meal deliveries.

Sample size

Given that this study was designed as a feasibility RCT, we did not conduct a power analysis to determine sample size. Rather, we used a combination of feasibility study recommendations [23] and expertise from our agency experts to determine the likelihood of recruiting participants over a 6-month time frame. Accordingly, we aimed to recruit 60 participants – or 15 participants per study arm. Recruitment activities were scheduled to occur between September 1, 2023—February 29, 2024 regardless of whether we reached our target sample size. The decision to cease recruitment was made to ensure the study team had sufficient time to develop and implement protocol modifications before the study entered its definitive RCT phase (August 1, 2024 – July 31, 2026).

Involvement of agency staff

Notably, agency staff were heavily involved in study activities and served as essential members of the research team. Two agency staff (LEB and MLR) served as project co-Principal Investigators with the lead author, and six staff members underwent required research training (e.g., Collaborative Institutional Training Initiative) [24] to complete informed consent, data collection, and intervention delivery activities. Agency staff met monthly with the full study team to discuss study progress and make modifications to feasibility study procedures, as indicated.

Randomization

After informed consent and baseline data were gathered, participants were 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 [25]. To ensure balanced enrollment among 4 arms, we implemented 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, our outcome assessor and

biostatisticians were blinded to each participant's study arm assignment.

Intervention arms

Arm 1 (meals only)

Participants randomized to Arm 1 received 14 frozen meals, delivered 1x/week, for 3-months. As required by the Older Americans Act, each meal met at least one-third of the dietary recommended intake requirements for older adults. Participants were provided with a menu of 40 standard meal options, were invited to select their own meals to be delivered each week, and were also provided with general nutrition education and fall prevention handouts.

Arm 2 (meals + registered dietitian services)

In addition to the weekly, frozen meals and educational handouts described for Arm 1, participants randomized to Arm 2 also received services from one of our agency's RDNs. Services were characterized by three core components: 1) a telephone-based nutrition assessment between the participant and dietitian, 2) assistance with frozen meal selections that were concordant with the participant's dietary needs, and 3) a follow-up phone-based encounter with the dietitian to address the participant's nutritional needs and satisfaction with meal selections.

Arm 3 (meals + occupational therapy services)

Participants in this arm received weekly frozen meals, educational handouts, and tailored services from one of our agency's occupational therapists. The four core components of occupational therapy services consisted of: 1) a phone-based screen related to the participants' fall risk and home safety needs, 2) a full in-home evaluation, 3) the development of a fall prevention intervention plan, and 4) an in-home OR phone-based (at the therapist's discretion) follow-up session to determine participants' satisfaction with fall prevention recommendations.

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

Participants in Arm 4 received frozen meals, educational handouts, and the combination of tailored dietitian and occupational therapy services as provided in Arms 2 and 3 (Table 1).

Data collection procedures

Self-reported demographic data, including age, gender, race, household composition, health conditions, mobility impairment status (yes/no), and marital status were drawn from our partner agency's electronic health record database. Additionally, we administered three standardized outcome measures, described below, to all enrolled participants at baseline and at 3-month follow-up. To assess fall risk, we used the Short Falls Efficacy Scale-International (FES-I) 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 [26]. The FES-I has excellent test–retest reliability (Cronbach's alpha = 0.92), and high scores indicate a greater concern with falling. The Mini Nutrition Assessment-Short Form (MNA-SF) is a 6-item instrument that measures older adults' malnutrition risk on a scale from 0–14 points [27]. Instrument items include those addressing food consumption, unintentional weight loss, mobility issues, acute illness, psychological function, and body mass index. The MNA-SF has been found to have both strong sensitivity (97.9%) and specificity (100%), and has a diagnostic accuracy of 98.7% for predicting malnutrition [28]. Lastly, four items from

Table 1 Description of services provided across Arms 1–4

	Arm 1 (Meals only)	Arm 2 (Meals + RDN services)	Arm 3 (Meals + OT services)	Arm 4 (Meals + RDN + OT services)
Up to 14 frozen meals, delivered weekly	X	X	X	X
Nutrition education handouts	X	X	X	X
Fall prevention education handouts	X	X	X	X
Nutrition assessment with RDN		X		X
RDN assistance with meal selection		X		X
Follow-up RDN encounter		X		X
Fall risk screen with OT			X	X
OT in-home safety evaluation			X	X
Fall prevention intervention plan			X	X
Follow-up OT encounter			X	X

RDN services registered dietitian nutritionist services, *OT services* occupational therapy services; follow-up encounters occurred 30-days after initial assessment/evaluation

the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire were used to assess dietary quality, particularly related to weekly intake of food items (e.g., How many of the last SEVEN DAYS have you eaten a healthy diet?) [29]. Psychometric assessments of the SCSCA have demonstrated that it has acceptable criterion validity ($r = -0.54–0.58$), test–retest reliability (mean $r = .40$), and internal consistency (mean $r = 0.47$) [30]. Our three outcome measures (FES-I, MNA-SF, SDSCA) were selected after extensive discussion with our meal agency partners and after piloting each measure to ensure they could be appropriately administered by agency staff who led data collection activities.

Primary outcome: feasibility of study methods

Given that feasibility of our study methods was of primary interest for this study, we evaluated the following: participant eligibility, recruitment, retention, fidelity to RDN and OT services, and perceived acceptability of services. *Eligibility* was defined as the proportion of our agency's meal recipients who were screened by agency staff and met our inclusion criteria. *Recruitment* was the proportion of eligible recipients who agreed to enroll in our study; *retention* was considered the proportion of enrolled participants who completed the 3-month follow-up encounter with our outcome assessor. *Fidelity* was calculated by determining the number of core service components that were implemented by dietitians and occupational therapists compared to how many components we expected to be implemented (actual components ÷ expected components). All core components were documented as being completed (Yes/No) in REDCap by our RDN and OT clinicians after each participant encounter. Lastly, *acceptability* was measured qualitatively upon study completion and was defined as participants' perceived satisfaction with their frozen meal deliveries and/or their receipt of RDN and OT services. To understand acceptability, participants were asked two questions: 1) What did you like about the services you received during this study? and 2) What about our services could be improved? Responses were not audio recorded but were summarized by the outcome assessor and entered directly into REDCap.

Consistent with previously established feasibility progression criteria [31, 32], we applied the traffic light rating system to interpret our feasibility outcomes (Table 2). Outcomes rated as green (≥ 80%) indicated that related activities (e.g., application of eligibility criteria) could proceed to the definitive trial with minor or no modifications to the study protocol. Outcomes rated as yellow (60–79%) indicated that moderate adjustments to the study protocol were warranted whereas red outcomes (≤ 59%) suggested major protocol adjustments were necessary prior to initiating our definitive trial.

Analysis

For our primary outcome of feasibility, we used univariate statistics to evaluate our feasibility outcomes. We used the following approaches to descriptively analyze each of our feasibility outcomes: *eligibility* = number of clients who met eligibility criteria ÷ number of clients screened over 6-months; *recruitment* = the total number of participants 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; *fidelity* = 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. An independent assessor calculated fidelity using the core component data that clinicians documented in REDCap. To evaluate acceptability of services, three members of our research team, with experience in qualitative methods, used a rapid qualitative analysis approach to independently code participants' comments about their satisfaction with services and opportunities to improve meals and clinical service implementation. Team members met twice to discuss common codes and identify primary themes about the acceptability of services provided.

Table 2 Traffic light rating criteria for interpreting feasibility outcomes

Feasibility outcome	Description	Green	Yellow	Red
Eligibility	Proportion of clients screened who were eligible for our study	≥ 80%	60–79%	≤ 59%
Recruitment	Proportion of eligible clients who enrolled in the study	≥ 80%	60–79%	≤ 59%
Retention	Proportion of enrolled participants who completed 3-month follow-up	≥ 80%	60–79%	≤ 59%
Fidelity	Proportion of clinical services that were implemented as intended	≥ 80%	60–79%	≤ 59%
Acceptability	Perceived satisfaction with services delivered (e.g., frozen meals, clinical services)	Assessed qualitatively		

Criteria adapted from Hilton et al. [32]. Clinical services = registered dietitian nutritionist and/or occupational therapy services

Ethics

This study was conducted in accordance with The Ohio State University's Institutional Review Board and was approved on 8/25/2023. All participants provided informed consent electronically, and participants' data were securely entered and stored in REDCap by approved members of the research team.

Results

A total of 56 participants enrolled in our feasibility study, and baseline characteristics of our sample are presented in Table 3. There were slightly more participants who identified as being women compared to being men (50% versus 46.4%); 25.0% were between the ages of 65–69 years of age; 58.9% of our sample was White, and half of our participants lived alone. The most commonly reported health conditions were cardiovascular disease, arthritis, and diabetes.

Primary outcome: feasibility of study methods

Eligibility

Over the course of 6-months, our team assessed 442 older adults, newly interested in participating in home delivered meals, for study eligibility. Of these older adults, 137 (31.0%; major protocol modifications warranted) met our eligibility criteria for study participation. The primary exclusion criterion for participation was the absence of self-reported diabetes, cardiovascular disease, and/or a fall risk factor.

Recruitment

Of the 137 older adults who were eligible to participate, 68 were not interested in the study, and 13 were "too busy" to participate given other health-related appointments and ongoing medical complexities. Fifty-six participants, or 40.9% (major protocol modifications warranted) of eligible older adults, provided informed consent to be included in our study, completed baseline outcome measures with our assessment team, and were allocated to one of our four study arms.

Retention

A total of 44 participants completed their 3-month follow-up with our outcome assessor, yielding a retention rate of 78.6% (minor protocol modifications warranted). The most common reason participants did not complete their follow-up was due to the difficulty our assessment team had in reaching participants to schedule their follow-up visit (e.g., phone number out of order; unreturned voicemails). Three participants were not interested in providing follow-up data, two participants had been admitted to a care facility (e.g., skilled

Table 3 Characteristics of enrolled participants at baseline

Characteristics	N (%)
Gender	
Female	28 (50.0)
Male	26 (46.4)
Unknown	2 (3.6)
Age Range	
60–64	8 (14.3)
65–69	14 (25.0)
70–74	12 (21.4)
75–79	8 (14.3)
80–84	5 (8.9)
85–89	5 (8.9)
90–94	2 (3.6)
Unknown	2 (3.6)
Race	
White	33 (58.9)
African American	17 (30.4)
Other	2 (3.6)
Unknown	4 (7.1)
Household Composition	
Lives Alone	28 (50.0)
Lives with adult relative	4 (7.1)
Lives with non-relative	5 (8.9)
Lives with spouse	12 (21.4)
Lives with spouse and children	2 (3.6)
Other	2 (3.6)
Unknown	3 (5.4)
Marital Status	
Divorced	14 (25.0)
Married	14 (25.0)
Never married	14 (25.0)
Separated	2 (3.6)
Single	2 (3.6)
Widowed	5 (8.9)
Unknown	5 (8.9)
Mobility impairment (i.e., fall risk)	
Yes	49 (87.5)
No	4 (7.1)
Unknown	3 (5.4)
Health conditions	
Cardiovascular disease	46 (82.1)
Arthritis	33 (58.9)
Diabetes	24 (42.9)
COPD	8 (14.3)
Stroke	6 (10.7)
Memory issues	5 (8.9)
Orthopedic disorder	4 (7.1)
Renal disease	3 (5.4)
Cancer	2 (3.6)
Liver disease	2 (3.6)
Neurological disorder	2 (3.6)
Unknown health history	3 (5.4)

Baseline sample ($n = 56$)

nursing facility), and two had died during the study period. See Fig. 1 for our study flow diagram.

Fidelity

Twenty-eight participants were randomized to receive RDN services either in Arm 2 (meals + RDN services) or Arm 4 (meals + RDN + OT services). As such, we expected that 84 encounters (28 assessments; 28 meal selections, 28 follow-up calls) would be completed by our dietitians. Documentation data indicated that 71 of 84 encounters were completed, yielding a 84.5% fidelity rate. Missed RDN follow-up calls (i.e., no answer from participants) were the most common reason that reduced the fidelity rate. Relatedly, 28 participants were randomized to receive OT services either in Arm 3 or Arm 4, and we expected 112 completed OT encounters (28 phone screens, 28 in-home evaluations, 28 intervention plans provided, 28 follow-up encounters). Services documented by OTs indicated that 101 encounters were completed, resulting in a 90.2% fidelity rate (no protocol modifications warranted). Similar to RDN services, missed follow-up OT encounters contributed to reductions in the fidelity rate.

Acceptability

Open-ended comments from participants were manually recorded and analyzed to understand acceptability of services provided. Participants expressed satisfaction

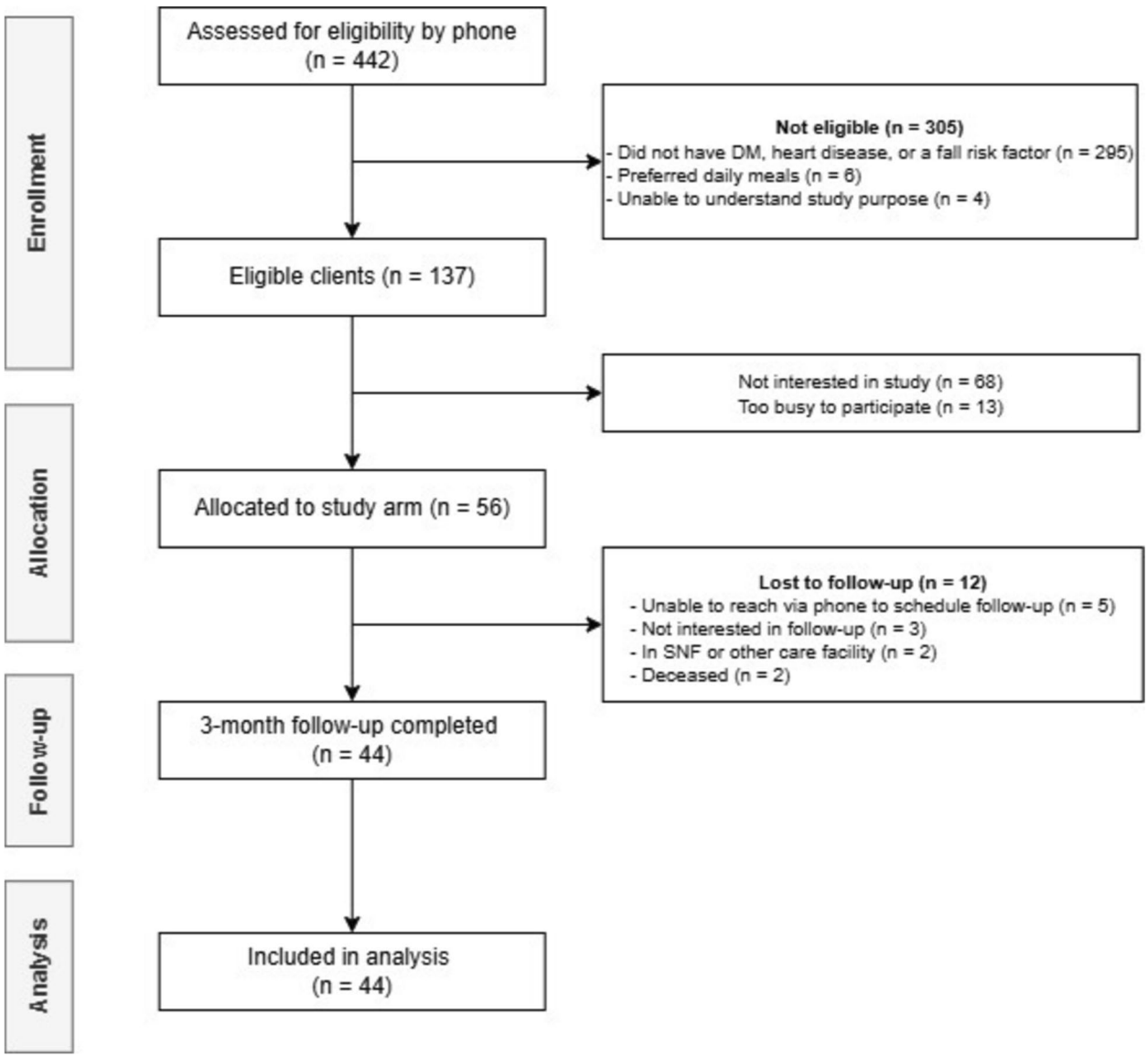

Fig. 1 Overview of participant recruitment and retention

with three main areas: 1) the convenience of meal preparation, 2) the positive interactions with staff members and drivers, and 3) meal variety. Participants noted that meals were "convenient and easy to prepare," that the agency hired "polite and caring drivers who provided meals when family was not available," and that meals had "a good variety of fruits and vegetables." Comments from participants also indicated two primary areas for improvement: 1) the taste and types of food items provided and 2) issues with meal deliveries. Some participants stated that "the taste could be improved for some meals" and that they experienced "inconsistent delivery times;" however, the majority of participants did not comment on areas for service improvement.

Discussion

The primary goal of the present study was to evaluate the feasibility of conducting a definitive, four-arm, randomized controlled trial that tests the effect of RDN and OT services on fall risk among home delivered meal recipients. We applied criteria set forth by Hilton et al. [32] to determine which of our study protocol procedures needed to be modified before proceeding with our definitive trial.

Feasibility of study methods

Our study was designed to assess the feasibility of the following: participant eligibility, recruitment, retention, fidelity to RDN and OT services, and acceptability of services delivered. Our assessment team screened a total of 442 older adults for study participation; however, only 31% met the study's inclusion criteria. This finding indicates that substantial revisions to our inclusion criteria are necessary to ensure a sufficient sample size can be recruited in our definitive trial. Additionally, among those who were eligible, only 41% consented to participate, highlighting the need for significant protocol modifications to enhance the study's appeal to potential participants. The most commonly reported reason for declining participation among eligible older adults was lack of interest followed by being too busy to engage in study activities.

A particularly promising outcome, however, was our study's retention rate. Of the 56 individuals enrolled, 44 participants (79%) completed the 3-month follow-up assessment. This high retention rate can likely be attributed to multiple retention strategies implemented by the assessment team, including consistent reminders (e.g., written reminders at baseline for follow-up appointments; up to three phone call reminders from the lead outcome assessor) and the ability to conduct *in-home* visits for participants who were otherwise difficult to reach via phone. The increased follow-up incentive ($25 gift card at baseline versus $50 gift card at follow-up) may have further contributed to this favorable retention rate.

Fidelity was also notably high, with 84.5% of RDN services and 90.2% of OT services delivered as expected. This suggests that RDNs and OTs were feasibly able to complete their initial encounters with participants; however, follow-up encounters were less consistent suggesting that additional strategies (e.g., written reminders, mailed reminders) may be warranted to further improve fidelity rates in our definitive trial. Furthermore, the acceptability of the meals and clinical services appeared favorable. Several participants found the convenience of frozen meals to be appealing and enjoyed their interactions with drivers and staff (e.g., clinicians, outcome assessors). However, minor suggestions for improvement were noted, primarily related to the taste of specific meal items.

Necessary changes to study methods for the definitive RCT

Findings from this feasibility study warranted major modifications to our methods in two primary areas: eligibility and recruitment. While our retention rate, clinician fidelity, and participants' perceived acceptability of services appeared sufficient, we also noted an opportunity to improve our protocol by modifying the randomization scheme for our full trial.

Eligibility

Only 31% of potential participants met our study's eligibility criteria, suggesting that our criteria were too strict and needed to be revised prior to initiating our definitive trial. As a result, we removed two criteria that seemed to be most prohibitive to recruiting a larger, representative study sample. First, we eliminated the requirement that all participants must have a diagnosis of either diabetes or cardiovascular disease. Despite our team's attempt to define diabetes and cardiovascular disease for participants (i.e., explaining to potential participants that these conditions may be colloquially known as "the sugar" or "high blood pressure"), our findings suggest that older adults are underreporting their health conditions to home delivered meal staff. Prior research linking national home delivered meal client data to their Medicare claims data indicated that 90% of meal clients are living with cardiovascular disease (e.g., hypertension), and almost half are living with diabetes [11]. Accordingly, our definitive trial will aim to recruit participants, regardless of their health conditions, given that meal clients likely have one or more diet-related health conditions but underreport these conditions when asked by our assessment team. Next, we also decided to remove the criterion about fall risk as we presume that all older adults in need of home delivered meals are at an increased risk of falling, and our

team's prior work estimated that 80% of meal clients present with one or more fall risk factors (e.g., prior fall; use of an assistive mobility device) [16]. With these criteria eliminated, our revised eligibility requirements for our full trial include: a) be eligible to receive home delivered meals from our partner agency, b) have the freezer space needed to store up to 14 frozen meals per week, and c) have the necessary appliances to reheat meals safely. Exclusion criteria underwent minor revisions and are as follows: a) has received home delivered meals from our partner agency within the past 40 days (the period of time after which a current client's meal plan "expires" if they do not make verbal or in-person contact with our partner agency), b) resides in a residential care or skilled nursing facility, c) has cognitive impairments that limit their ability to provide informed consent, or d) are unable to communicate in English. We also claim that these expanded eligibility criteria will make findings from our definitive RCT more generalizable to home delivered meal agencies nationwide.

Recruitment

Of those participants who met the eligibility criteria for our feasibility study, only 41% opted to enroll, suggesting a need to increase the appeal of our study to older adults. As such, we plan to use three new strategies in our full trial. To make the frozen meal services more appealing, we will allow all our participants to receive snack items that accompany their weekly, frozen meal deliveries. It is from our study team's prior experiences that we recognized recipients appreciated these snack items, which will hopefully serve as an added incentive for participants. We also learned from our feasibility study that participants were not always able to consume all 14 meals provided to them each week. For our definitive trial, we will modify this requirement and allow participants to select how many meals – from the options of 7, 10, or 14 – they would like to receive. By allowing participants to customize the number of meals they receive, this will ideally contribute to the overall appeal of the study and further foster a sense of client-centeredness. Lastly, for our feasibility trial, we only recruited participants from our partner agency's largest county given its proximity to our agency's main office location. Going forward, we will expand recruitment to include our partner agency's full service area (five counties) in order to effectively recruit our target sample size.

Randomization scheme

Though not explicitly examined, our team used the present study as an opportunity to ensure that all randomization procedures could be implemented appropriately. All of our participants were *individually* randomized into one of our four study arms. However, upon analysis, we identified that several participants lived together (i.e., spouses; adult relatives) but were randomized to different study arms. Given that participants in the same household should receive the same services as to not risk contamination, we plan to randomize all participants at the *household level* for the full trial using minimal sufficient balance randomization (MSB). A novel approach of MSB will be employed to randomize household clusters using a 2×2 factorial design [33, 34]. The process will begin with a "burn-in" randomization phase, during which a subset of households ($n = 160$) will be allocated using stratified block randomization. Following this phase, the MSB method will be applied, leveraging test statistics and p-values to evaluate balance across key continuous and categorical covariates while maintaining randomness in treatment assignments.

Limitations

Though our pilot study provided our team with several lessons learned prior to our definitive trial, it is not without limitations. First, while our partner agency is one of the largest home delivered meal providers in the United States, our recruitment efforts were restricted only to those older adults who lived within the agency's primary service area. Thus, our study methods may not be as feasible in other geographic regions that are more expansive and necessitate greater travel and resource expenses. Additionally, our methods may not generalize to other agencies, especially agencies who serve a high proportion of non-English speaking clients as our eligible participants needed to be able to communicate in English. Further, our eligibility criteria required that participants have a diagnosis of cardiovascular disease or diabetes; however, all health history was provided to our assessment team via client self-report, which may have resulted in the underreporting of how many older adults were eligible for our study, though self-reporting of health conditions is the most common form of data collection in home delivered meal agencies in the United States. Lastly, our participant dropout rate may have biased our feasibility findings, particularly our findings that relate to acceptability of services.

Conclusions

This study provides evidence on the feasibility of conducting a four-arm, randomized controlled trial in partnership with one home delivered meal agency. Findings from this study have informed modifications to our definitive RCT study protocol where we expanded our eligibility criteria (e.g., removed criteria about diet-related health risk and fall risk factors), offered more appealing meal options (e.g., a range of 7–14 meals per

week), and are in the process of applying minimal sufficient balance randomization to enhance the methodological rigor of our definitive trial. We expect that results from our definitive trial will demonstrate the value of RDN and OT services for reducing fall risk among older adults, providing compelling evidence to indicate that these services warrant sufficient funding or insurance contracts to help provide services that keep older adults in their own homes and communities.

Abbreviations

ACL	Administration for Community Living
CDC	Centers for Disease Control and Prevention
CONSORT	Consolidated Standards of Reporting Trials
FES-I	Falls Efficacy Scale-International
MNA-SF	Mini Nutrition Assessment-Short Form
NIH	National Institutes of Health
OT	Occupational Therapy
RCT	Randomized Controlled Trial
RDN	Registered Dietitian Nutritionist
REDCap	Research Electronic Data Capture
SDSCA	Summary of Diabetes Self-Care Activities

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12877-025-06008-2.

Supplementary Material 1.

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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 data analyses; GH, KST, and MLH assisted with study design and manuscript development; LEB and MLR led development of agency procedures to support study implementation and assisted with study design; TSS ensured study activities were congruent with IRB approvals; 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 U.S. 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
The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This trial complied with the ethical rules stated in the Declaration of Helsinki. Informed consent was obtained from all study participants. Study activities were approved by the Institutional Review Board at The Ohio State University (#2023H0248).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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