

**Official title:** Optimizing Mealtime Care (OPTIMAL): Development and Pilot Testing of a Person-Centered Mealtime Care Intervention for Nursing Home Residents with Alzheimer's Disease and Related Dementias (ADRD).

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## Study protocol with statistical analysis plan

### Significance

People with advanced Alzheimer's Disease and Related Dementias (ADRD) commonly experience functional, cognitive, and behavioral symptoms that interfere with eating (mealtime difficulties),<sup>1-3</sup> resulting in low intake<sup>4-6</sup> and subsequent malnutrition and dehydration.<sup>7, 8</sup> Among people living with advanced ADRD in residential care settings (residents), 94% are at risk for malnutrition and 66.5% are already malnourished.<sup>7, 8</sup> Malnutrition further leads to increased infection, weight loss, decreased quality of life, and increased morbidity and mortality.<sup>7, 9</sup> Mealtime difficulties can be ameliorated by maximizing resident independence and use of evidence-based, person-centered care approaches,<sup>10-13</sup> so as to promote food intake<sup>11, 14</sup> and further maintain nutrition and hydration which are fundamental health needs among the aging population with ADRD.

Despite the increased risks and consequences of mealtime difficulties and inadequate intake, residents are not provided with optimal mealtime care.<sup>12, 15, 16</sup> Person-centered mealtime care (PCMC) is individually tailored to residents based on their preferences and levels of independence, in contrast to task-centered mealtime care (TCMC) that focuses on completion of tasks regardless of resident preferences and abilities.<sup>17-19</sup> The PCMC features individualized, resident-oriented care through adherence to four principles: 1) providing choices and acknowledging preferences, 2) showing respect, 3) supporting independence, and 4) promoting social interaction.<sup>10-12, 20</sup> Our preliminary studies show that positive staff engagement and social interaction with residents is associated with reduced mealtime difficulties and improved intake.<sup>10-12, 14</sup> While PCMC is highly recommended, PCMC strategies haven't been empirically tested using experimental designs.<sup>21-24</sup> A gap exists in creating effective individualized PCMC interventions to optimize mealtime care quality and resident outcomes.

### Objectives

This study developed and refined OPTIMAL, and evaluated its feasibility, fidelity, and usefulness. The specific aims are:

- 1. Develop, evaluate, and refine OPTIMAL intervention protocol and training materials.** We will integrate evidence from literature and our prior work to develop the intervention protocol and training materials, addressing resident mealtime difficulties, targeted PCMC strategies, and establishment of individualized PCMC plans. We will conduct separate focus group interviews of staff and family participants on the acceptability and appropriateness of the intervention protocol and training materials before pilot testing. Data obtained will be used to refine the intervention protocol and training materials before pilot testing.
- 2. Determine feasibility, fidelity, and usefulness of OPTIMAL.** Feasibility on participant identification, recruitment, consent, and retention will be evaluated descriptively. Fidelity will be assessed on a) delivery of treatment (staff attendance to training sessions), b) receipt of treatment (staff knowledge and self-efficacy post-training), and c) enactment of treatment skills (quality of staff engagement). We will conduct focus group interviews of staff to assess the usefulness of OPTIMAL after T3.
- 3. Describe resident outcomes (Exploratory).** We will measure and describe resident mealtime difficulties, eating performance, intake success rate, and body mass index using descriptive statistics over time for two treatment groups. Data obtained will inform estimates of effect sizes for a future larger-scale trial.

## Design

We used mixed methods (i.e., focus groups, a pilot single-group repeated measures) to refine and test OPTIMAL. We collected repeated measures at 3 time points: baseline (T1), immediately post intervention (6 weeks post baseline, T2), and 6-week post intervention (12 weeks post baseline, T3). At each time point, we assessed quality of staff engagement and resident outcomes including eating performance and BMI through collection and coding of videotaped observations of dyadic mealtime interaction (videos; Aim 2&3) over 6 meals in 2 consecutive days (2 breakfasts, 2 lunches, 2 dinners) for each staff-resident dyad. We used Cue Utilization and Engagement in Dementia (CUED) mealtime video coding scheme, an innovative, feasible, and reliable tool that our team has developed and validated, and assessed resident mealtime challenging behaviors including resistive behaviors and functional impairments and intake success rate using videos collected in this study.<sup>11, 25</sup>

## Methods

**Development of OPTIMAL (Aim 1).** OPTIMAL is designed to teach staff to effectively manage mealtime difficulties and engage residents in eating to restore and maintain their highest level of function possible. We developed OPTIMAL following the four PCMC principles: 1) providing choices & acknowledging preferences (i.e., offering opportunities to make choices, providing and delivering food in ways personally acceptable and culturally appropriate), 2) supporting independence (i.e., providing appropriate technical, motivational, instrumental, and informational assistance based on residents' functional ability), 3) showing respect (i.e., honoring and valuing residents when assisting them), and 4) promoting social interactions (i.e., making connections with residents, creating/fostering a social environment with low stimuli and positive engagement).<sup>10-12, 20</sup> The use of these four PCMC principles in developing OPTIMAL is to manage *challenges that staff identified as the most significant barrier in providing optimal mealtime care in terms of assessing residents' preferences, interacting with residents, and modifying the over-stimulated environment.*<sup>12</sup> While receiving formal and informal training in Year 1-2 of the K23, the PI developed OPTIMAL by integrating evidence from literature and our prior work.<sup>10-14, 26-28</sup> Specifically, the PI has conducted a systematic review synthesizing evidence on common mealtime difficulties and targeted behavioral strategies for residents with ADRD by searching five health-related electronic databases (Pubmed, CINAHL, AgeLine, PsychINFO, Cochrane Library) between 1990 and 2016.<sup>27</sup> In this review, we have identified 98 unique mealtime difficulties categorized in four types of symptoms (behavioral, functional, cognitive, mixed), in which 48 mealtime difficulties are most commonly described and addressed by 260 unique behavioral multilevel strategies. The PI developed OPTIMAL intervention protocol and training materials following 3 steps: 1) updating evidence based on literature from 2017 forward; 2) integrating findings from the updated review, our preliminary studies (see 4C1), and our current R03 study that examines patterns of and temporal relationships between staff PCMC&TCMC behaviors and resident mealtime difficulties and intake (see 2A); and 3) synthesizing all the above evidence. The training materials will address three components of OPTIMAL: a) Why and What: rationale, benefits, and PCMC principles, b) How (basic): resident common mealtime difficulties and targeted behavioral multilevel PCMC strategies; and c) How (advanced): establishment of individualized PCMC plans based on assessments of common mealtime difficulties and use of targeted multilevel PCMC strategies.

**Evaluation and Refinement of OPTIMAL (Aim 1).** After the intervention protocol and training materials are developed, we conducted one focus group of NH stakeholders including leadership, staff, and families to prioritize the multiple mealtime difficulties identified from literature and to understand the acceptability of the OPTIMAL intervention following an interview guide. The focus

group was audio-recorded, and facilitated by the PI experienced in conducting focus group interviews. Data obtained were analyzed and used to refine the intervention protocol and training materials before pilot testing.

**Inclusion/Exclusion Criteria (Aim 2 and 3).** Participants including staff, residents, and families were recruited from nursing homes. Staff are eligible if they are 18 years old or above, English speaking, a permanent facility employee, provide informed consent, and provide direct mealtime care for a resident participant at least twice a week over the previous month. Families are eligible if they are 18 years old or above, English speaking, a family member of the resident who is living at the NH study site at the time of the study, having experiences of delivering mealtime care to their resident family members, and providing informed consent.

Residents are eligible if they: 1) are  $\geq 55$  years, 2) diagnosed as having ADRD based on medical records, 3) identified by NH staff as requiring mealtime assistance, and 4) having a legally authorized representative (LAR) providing informed written consent. Whether the resident needs mealtime assistance is based on medical record review as well as proxy report from the NH staff who has recently cared for the resident at mealtimes using the “feeding” item of the Katz ADL Index. Specifically, residents who need varied levels of assistance with feeding (limited, extensive, total assistance) are eligible, and those who get food from plate into mouth without help are excluded regardless of who prepares food. Residents will be excluded if they: 1) have a documented diagnosis of Parkinson’s disease, traumatic brain injury, or swallowing disorder, 2) do not eat orally (e.g., parenteral/IV feedings, use of feeding tubes), 3) unable to hear or see staff even with glasses and/or hearing aids (e.g., uncorrected visual or hearing impairment), or 4) stay in the NH study site for less than 12 weeks at the time of recruitment/consent/assent (e.g., terminally ill receiving hospice services, and/or receiving post-hospital skilled rehabilitation) that may not allow enough time for obtaining consent/assent, and scheduling days for video recording sessions across three time points (baseline, and 6- and 12-weeks post baseline).

**Recruitment and Consent (Aim 2 and 3).** To enroll staff and families, we will adapt a standard consent protocol for NH dementia mealtime research developed based on our prior study.<sup>12</sup> To enroll residents, we will use a consent& assent protocol for research involving NH residents with dementia and their legally authorized representatives (LARs).<sup>29</sup> Briefly, proxy informed consent will be obtained from the eligible resident’s LAR, and assent from the resident afterwards. Detailed plan is described in the [PHS HSCTI, 2.5 Recruitment and Retention Plan](#).

**OPTIMAL intervention (Aim 2 and 3).** A research assistant (OPTIMAL interventionist) will be trained by the PI to facilitate and implement the OPTIMAL intervention. To assure sustainability of OPTIMAL care, we will identify a staff champion (a staff participant who is a lead nursing assistant or licensed practical nurse) in each NH to work with the OPTIMAL interventionist during the intervention period. The interventionist will train all staff participants to implement OPTIMAL through 3 phases: I) one training session, II) ongoing mentoring to establish/refine PCMC plans, and III) two biweekly facilitations of OPTIMAL care delivery. Phases will be implemented sequentially, although they will overlap in that, once initiated, they will continue throughout the intervention period.

In Phase I, all staff participants from one NH will attend an in-person 2-hour group training session led by the OPTIMAL interventionist in the format of didactic lectures, role modeling/playing, practicing with each other, and demonstration and application of skills in

individualized PCMC care planning. All staff participants will be provided with training materials to be developed by completion of Aim 1 (see 4C4). If a staff is not able to attend the group session, we will record reasons of no attendance and schedule a make-up individual training session led by the interventionist. By completion of the training session, staff participants are expected to be able to 1) assess common mealtime difficulties and describe the use of targeted PCMC strategies, and 2) develop PCMC plans to address observed mealtime difficulties with targeted strategies. Staff will complete a PCMC-related knowledge and self-efficacy test to be developed based on training materials pre- and post-training session. Adequate receipt of the OPTIMAL training is indicated by a total test score of  $\geq 75\%$  post-training.<sup>30, 31</sup> Individual staff with a total test score of  $<75\%$  post-training will attend booster training sessions (in group or individual format) until the individual staff receive a total test score of  $\geq 75\%$ .

The OPTIMAL interventionist will initiate Phase II, individualized PCMC planning, working closely with staff and resident participants. The interventionist will assess each resident's eating independence and mealtime difficulties as well as staff use of PCMC&TCMC strategies during the first week of the OPTIMAL intervention. After assessment, the interventionist will record major mealtime difficulties demonstrated by the resident, strategies used that do (not) work, and any barriers to implementing specific strategies. The interventionist will then develop a PCMC care plan for each resident by working with staff participants based on assessments of common mealtime difficulties. The primary goal is to engage residents to be actively involved in eating and initiate each intake attempt by themselves with minimum assistance using appropriate PCMC strategies. For example, a care plan for a resident demonstrating prolonged chewing may include offering food bites of smaller size, offering drinks frequently to flush food down, and giving short, simple verbal cues. Another example is that for a resident with difficulty using utensil properly, the care plan may include preloading utensils, offering finger food, and providing adaptive utensils. The interventionist will work with the staff participants to identify possible solutions to eliminate any barriers to implement specific PCMC strategies, the best places to store/locate the care plans, as well as the best way for staff participants to review residents' updated care plans in each NH.

After individualized PCMC care plans are established, Phase III, biweekly facilitations of OPTIMAL care, will be provided to each staff participant twice over 4 weeks by the OPTIMAL interventionist. The interventionist will coach staff participants in implementing care plans for resident participants. In each facilitation, the interventionist will observe each staff participant in providing care to a resident during one meal, and provide role modeling as well as feedback on how well the staff follows and implements the care plan. In this phase, individualized PCMC care plans will be updated continuously based on assessments of resident mealtime difficulties.

**Data Collection Procedures (Aim 1, 2, 3; Table 1).** In each NH, immediately after written consents of staff and family participants are obtained, separate focus groups for staff and families will be scheduled and conducted (see 4C4b, Aim 1), and participants' characteristics will be collected using a demographic survey (4C7) before T1. Residents will be recruited with written assents/consents from residents and their LARs. Resident characteristics will be collected by reviewing medical records. Feasibility data about identification, recruitment, consent, and retention of all participants will be gathered throughout the study (see 4C8a, Aim 2). A trained research videographer will schedule a 1-day practice recording session for each resident participant using a mini handheld digital video recorder. Adequate quality recordings for behavioral analyses have been obtained with a mini digital camera in prior research.<sup>32, 33</sup> After the practice session, the videographer will schedule a 2-day formal recording session for each resident participant at baseline (T1), and at 6- (T2) and 12-week post baseline (T3), respectively (Aim 2&3). We will videotape mealtime only in the scheduled days of all recording sessions. Staff participants will complete a knowledge & self-efficacy test pre- and post- OPTIMAL training

sessions (Aim 2). At each time point, in addition to mealtime video recording, a trained data collector will collect body mass index (BMI) of each resident, and complete observational measures on quality of staff engagement and resident eating performance for each of the 6 meals in 2 days in the NH (Aim 2&3). After T3, we will conduct one focus group in each NH (Aim 3), lasting 50-60 minutes, audio-recorded, and facilitated by the PI experienced in focus group interviews.

**Table 1. Data Collection Timeline**

<b>Aim s</b>	<b>Data/Variables</b>	<b>Recruitment</b>	<b>T 1</b>	<b>Pre- &amp;post-training</b>	<b>T 2</b>	<b>T 3</b>	<b>Post T3</b>
1,2,3	Consent & sample characteristics	X					
1	Acceptability of OPTIMAL	X					
2	Feasibility of OPTIMAL	X	X	X	X	X	X
	Fidelity of OPTIMAL		X	X	X	X	
	Usefulness of OPTIMAL						X
3	Resident mealtime difficulties, eating performance, intake success rate, BMI		X		X	X	

**Sample Characteristics (Aim 1, 2, 3).** Resident characteristics include age, gender, race, ethnicity, education, dementia stage. Staff and families characteristics include age, gender, race, ethnicity, education, job title (staff only), and length of caregiving.

### **Feasibility, Fidelity, and Usefulness Data (Aim 2)**

**Feasibility of OPTIMAL.** Descriptive data on identification, recruitment, consent, and retention of staff, resident, and family participants will be gathered to assess intervention feasibility<sup>34-36</sup> (see Appendix 5). In addition to the number of participants screened and eligible for the study, the recruiter will track reasons for those unwilling to participate in the study, and whether that is specifically related to video recording and/or OPTIMAL intervention. We will record the number of participants deemed not eligible and reasons for ineligibility as a basis for planning future trials of OPTIMAL. The length of time it takes to obtain assents/consents from residents, staff, families, and LARs, as well as the number of families and LARs who don't mail back their written consent within expected time period (i.e., 2 weeks after they receive blank consent forms by mail) will be tracked. Families/LARs will be contacted to determine barriers to return of consents and how processes could be changed to facilitate timely return of consent. We will track the number of residents and staff requiring rescheduling of video recording sessions and the reasons for rescheduling. We will track the number of resident and staff participants who withdraw at various time points (e.g., before, during, and after T1, T2, and T3), and those who withdraw will be contacted to determine reasons for withdrawal and how process could be changed to facilitate retention.

**Fidelity of OPTIMAL.** We will assess three aspects of fidelity<sup>37</sup>: 1) delivery of treatment, tracking staff attendance at the group or individual training sessions using a checklist, 2) receipt of treatment, indicated by a total test score of  $\geq 75\%$  on the staff PCMC-related knowledge & self-efficacy test post-training with or without booster sessions (we will track the number of group or individual booster sessions offered in each NH), and 3) enactment of treatment skills, including quality of staff engagement assessed by the 19-item Mealtime Engagement Scale<sup>38</sup> developed

by the PI with evidence of reliability and validity (each item is scored on 0-3, total score range: 0-57, higher score = higher quality of engagement).

**Usefulness of OPTIMAL.** Staff perceived usefulness of the OPTIMAL intervention (OPTIMAL group) or OPTIMAL training session (education control group) will be assessed using semi-structured focus group interviews. Open-ended questions focus on experiences in delivering OPTIMAL care, use of PCMC-related strategies, strategies that do (not) work, and suggestions of refinement for OPTIMAL (see Appendix 7).

### **Resident outcomes (Aim 3)**

**Resident mealtime difficulties.** We will code videos using CUED that has codes for resident mealtime difficulties grouped into three types: 1) chewing and swallowing difficulties represented by 4 behaviors (e.g., holds food in mouth), 2) functional impairment represented by 5 behaviors (e.g., difficulty using utensil), and 3) resistiveness to care represented by 6 behaviors (e.g., doesn't open mouth). Coded data will be used to calculate the number of resident mealtime difficulties by type in each videotaped meal.

**Resident eating performance.** We will use the 9-item Level of Eating Independence scale (see appendix 8) to assess the ability of independence with eating and drinking activities during cycles of verbal prompts<sup>39</sup>. Each item is scored from 1 (total dependence) to 4 (total independence), with total score ranging from 9 to 36 (higher score = more independence). The inter-rater reliability was 0.96.<sup>39</sup>

**Resident intake success rate.** We will code videos using CUED to track whether the resident or staff initiates/completes each intake attempt, and whether there is a subsequent intake after each attempt. We will calculate resident intake success rate through dividing the number of intake attempts initiated/completed by the resident with subsequent intake by the total number of intake attempts coded during one meal.

**Resident Body Mass Index (BMI).** We will assess body weight in the early morning before breakfast with each individual resident dressing casual indoor clothes without shoes using the same digital body scale throughout the study. We will assess body weight twice in one early morning of each time point and calculate the average of the two assessments for BMI.

**Behavioral Coding Procedures for Videos.** All videos will be computer archived and coded second-by-second by trained coders using Noldus Observer® 14.0 following a standard CUED coding manual established by our team. Detailed training and coding procedures are described in PHS HSCTI, 4.4 Statistical Design and Power. Coded data on resident mealtime difficulties and intake process will be exported from Noldus Observer® to excel worksheets, and then imported to SAS 9.4<sup>40</sup> for us to calculate the number of mealtime difficulties, and intake success rate.

### **Statistical Analysis Plan.**

**Develop, evaluate, and refine OPTIMAL intervention protocol and training materials (Aim 1).** We developed OPTIMAL through systematic integration of four PCMC principles,<sup>10-12, 20</sup> our prior work on multilevel facilitators and barriers to *engaging residents in eating*, and our systematic review of mealtime difficulties and targeted behavioral strategies. We integrated evidence from literature and our prior work to develop the intervention protocol and training materials, addressing resident mealtime difficulties, targeted PCMC strategies, and establishment of individualized PCMC plans. We conducted focus group interviews of staff participants on the acceptability and appropriateness of the intervention protocol and training materials before pilot testing. Based on

staff overall comments, the OPTIMAL components were highly evaluated as timely and fit to the needs of care practice. Data obtained were used to refine the intervention protocol and training materials before pilot testing.

**Determine feasibility, fidelity, and usefulness of OPTIMAL (Aim 2).** We described feasibility data on participant identification, recruitment, consent and retention, including the number of and reasons for participants' ineligibility, unwillingness to participate, not consenting/assenting, not returning written consent within expected time period, and attrition/withdrawal. We used this information to refine study procedures for a future larger trial to facilitate recruitment and retention. We described treatment fidelity, including staff attendance at training sessions and staff PCMC-related knowledge scores pre- and post-training. Audio-recorded focus group interviews from staff (usefulness) were transcribed<sup>41</sup> and coded<sup>42</sup>. We extracted codes using open coding (using staff's own words)<sup>42, 43</sup> to address the usefulness and areas of refinement of OPTIMAL.

**Describe resident outcomes (Aim 3).** We described distributions of resident eating performance, mealtime challenging behaviors including resistive behaviors and functional impairments, intake success rate, and BMI using appropriate descriptive statistics (mean, median, mode, range, variance, SD, percentile and quartile ranks, n, %) over time. These data were used to inform estimates of effect sizes for sample size calculation in a future trial.

**Expected Outcomes and Impact for Future Trials.** *Using mixed methods, qualitative and quantitative data will be collected and analyzed to refine OPTIMAL intervention protocol, training materials, and study procedures, and to understand its feasibility, fidelity, and usefulness. Data obtained from this pilot trial will provide five critical pieces of information for a future larger efficacy trial. They are:* 1) refined OPTIMAL intervention protocol and training materials with preliminary evidence of feasibility, fidelity, and usefulness; 2) refined study procedures for recruitment, retention, data collection, and recording and behavioral coding of videos; 3) evidence of feasibility for a two-group parallel cluster RCT design with three repeated measures (baseline, 6- & 12-weeks post baseline); 4) effect size estimates of resident outcomes for sample size calculation; and 5) videotaped observations collected in this study to be used in future staff training sessions to illustrate OPTIMAL care skills.

**Limitations.** As a pilot RCT, a small sample of staff and residents from 4 NHs will be enrolled. This is a logical first step to develop and test a new behavioral intervention, prior to a large-scale efficacy trial.

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