Reducing Burden in Care Partners of Community-Dwelling Persons With Dementia and Oropharyngeal Dysphagia

Study Protocol and Statistical Analysis Plan

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Northwell Health

RESEARCH PROTOCOL

Protocol Title:	Pilot RCT to determine the effect size estimates of WeCareToFeedDysphagia to reduce care-partner burden, and the feasibility of a full-scale RCT
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Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
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1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Oropharyngeal dysphagia (OD), a devastating syndrome that affects nearly 90% of hospitalized patients with Alzheimer's disease (AD) and AD-related dementias (AD/ADRD), is a significant predictor of care-partner burden. Upon hospital discharge, care partners of patients with AD/ADRD face dramatic and persistent OD-related unmet caregiving needs, which lead to higher care-partner burden.

Guided by a self-regulation theoretical framework, we propose a study to pilot test a **We**b-based **Care** Partner **To**ol for **Feed**ing in **Dysphagia** (WeCareToFeedDysphagia) to determine effect size estimates and feasibility of a future NIH Stage IV full-scale randomized controlled trial (RCT), to determine its effectiveness for reducing burden in care partners of community-dwelling persons with AD/ADRD, diagnosed with OD during hospitalization. The web tool uses written and video content, care-partner testimonials, frequently asked questions, and resource links to provide accurate information (e.g., dysphagia diets), set realistic expectations, identify/support feeding goals (Quality of Life, QoL, considerations), acknowledge/support care-partner feelings, and provide competencies/skills for OD management.

We will remotely recruit and randomize care partners (N=80) of hospitalized patients with AD/ADRD and OD to receive (via automated text messaging): enhanced condition (usual care by the patient's medical team and speech language pathologist (SLP) contact information from the study team, n=40) or the intervention (usual care by the patient's medical team and SLP contact information from the study team, + WeCareToFeedDysphagia, n=40). We will assess care partner reported outcomes at baseline, 1 month, and 3 months post post-hospital discharge. We define the go/no-go criteria for the full-scale RCT (R33) as meeting ≥3 of 6: 1) ≥40% consented; 2) ≤30% attrition; 3) ≥80% receive initial text; 4)

≥90% receive follow-up texts; 5) ≥60% access home page; and 6) ≥45% engage tool (≥2 pages).

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Oropharyngeal Dysphagia (OD) is a devastating syndrome that affects nearly 90% of Hospitalized Patients with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD).[1] OD, defined as difficulty in forming/moving bolus safely from the oral cavity to the esophagus, is a common syndrome, affecting 10%-33% of older adults.[2] Although OD is associated with many disease processes, it is particularly prevalent in persons with AD/ADRD. The prevalence of OD in AD/ADRD varies widely across settings, and has been found in nearly 90% of hospitalized patients with AD/ADRD. [1] Further, OD in hospitalized older adults with AD/ADRD has been associated with poor clinical outcomes, including aspiration, malnutrition, mortality, longer length of stay, higher costs, and severely compromised quality of life (QoL). [2-7] However, the consequences of OD are not limited to patients, as care partners experience substantial psychosocial ramifications. [8-14]

OD is an increasingly recognized predictor of care partner burden, which in turn, leads to poor patient and care partner health outcomes.[9,15] Providing care for persons with OD has associated high demands and significant disruptions to daily life, including, increased time spent thinking about and preparing meals; concerns over adequate nutrition, hydration, and risk of choking; and the need to provide significant social and emotional support for the person with OD. [10,12-14] Indeed, OD is a significant independent predictor of increased care-partner burden. [8-10] A 2018 systematic review found that burden (as measured by the Zarit Burden Interview scale, ZBI-22) was significantly higher in care partners of older adults with OD, compared to older adults without OD (38.9-moderate burden vs. 28.8-mild burden, $p<0.0001$).[10] Additionally, a 2020 cross-sectional study found that care partners of older adults with OD were 1.61 times more likely (when controlling for other factors known to influence burden) to experience burden, compared to care partners of older adults without OD; and 65% of care partners reported OD-related burden to be moderate to severe.[8] Care-partner burden leads to poor care partner health outcomes through an increased risk for: psychiatric morbidity (e.g., depression), health problems (e.g., coronary heart disease risk), and mortality.[15-20] In addition to their own health, care-partner burden is associated with poor outcomes for

community-dwelling dependent older adults, including mortality, hospitalization, and institutionalization, even after adjusting for potential confounders. [21] In persons with AD/ADRD, care-partner burden is an independent predictor of poor feeding behaviors, which is critical in the management of OD.[22] Therefore, it is essential to address care partner OD-related burden to improve health outcomes for both older adults with OD and their care partners.

Care partner OD-related burden is magnified in community-dwelling persons with AD/ADRD. Although caring for persons with AD/ADRD and OD is associated with care partner burden, no extant studies have accounted for OD-related burden in persons with AD/ADRD. [9] Yet, care partners of community-dwelling persons with AD/ADRD and OD are at an especially high risk of burden. The onset of OD in dementia is a late stage defining diagnosis that demands a significant increase in caregiving needs. Indeed, more patients with severe dementia (44%) aspirate, compared to those with moderate dementia (12.5%), and lower cognitive scores are associated with greater feeding assistance. [23] Further, the management of OD in persons with AD/ADRD is complex. Although, standard OD management focuses on the prescription of dysphagia diets (textured modified food and thickened liquids), care partners of persons with AD/ADRD must navigate increased caregiving needs, refusal of dysphagia diets, choking risk, dehydration/ malnutrition, QoL considerations that align with goal-concordant care, and dementia/OD progression. [24-26] Further, there is a lack of consensus regarding OD-related best practices in this population. [27-29] Thus, addressing OD-related burden in care partners of persons with AD/ADRD is critical for improving dementia care and care partner outcomes.

Care partner OD-related burden stems from dramatic and persistent unmet caregiving needs. Care partners of community-dwelling persons with OD must navigate the numerous complexities of OD management. Indeed, a 2021 scoping review found that care partners of persons with OD have wide-ranging caregiving needs, consisting of: informational (OD management options, dysphagia diet purchasing and preparation, and risks/benefit of dysphagia diets); physical (e.g., maintaining adequate nutrition/hydration, performing oral hygiene, and careful handfeeding); social (social support from healthcare professionals and other care partners); and psychological (coping with person's refusal to eat and frustration-feeling thirsty, coping with loss and acceptance of new normal). [30] Yet, the current standard of care strategies (compensatory-dysphagia diet, careful handfeeding, and rehabilitative-swallowing exercises) are either poorly communicated to care partners or fail to address important caregiving needs. [27-32] Further highlighting this point is our preliminary qualitative data which shows that upon hospital discharge, care partners of patients with AD/ADRD face dramatic and persistent unmet caregiving needs, including: A. little/inaccurate information on OD management and dysphagia diets; B. unrealistic expectations regarding dysphagia diet and aspiration risk; C. lack of identification of feeding goals and QoL preferences; D. poor coping with patient's refusal to eat, and frustration with dysphagia diets; and E. lack of competencies/skills (e.g., purchasing/making dysphagia food, oral

hygiene, and careful handfeeding). [30,33-37] Yet, there are currently no interventions to address OD-related caregiving needs, which leads to increased care-partner burden and poor outcomes.

Web-based informational interventions are effective in improving disease-related self management skills and provide the necessary support for care partners of persons with AD/ADRD. Americans have become accustomed to receiving health information from the Internet. Most Internet users (72%) have looked online for health information within the past year. [38] Although many websites provide health information, such information is often inaccurate, sensational, and not tailored to specific conditions or populations. Yet, there are many advantages to developing and providing web-based solutions: A) care partners can consume the information at their own schedule and as often as they desire; B) information can be transmitted through multiple channels (personal computer, tablet); C) content can be augmented through videos, graphics, testimonials, and interactive activities; D) content can be tailored to specific time-points in the disease trajectory, and targeted to specific groups; and E) access transcends geographical barriers. Web based patient education has been shown to be effective in increasing disease-related knowledge and improving health behaviors and self-management skills.[39-43] For care partners of persons with AD/ADRD, web based access transcends the caregiving barriers that limit the ability of the care partner to leave the home and addresses unmet caregiving needs.

Theoretical Basis. The current proposal is informed by a comprehensive, self-regulatory framework, which recognizes the factors underlying effective cognitive and affective information processing.[44-47] The framework incorporates 5 self-regulation constructs, summarized by the Cognitive-Social Health Information Processing (C-SHIP) model, which consist of: A. disease-relevant interpretations; B. disease-relevant beliefs and expectations, including beliefs about one's own self-efficacy; C. disease-relevant goals and values; D. disease-relevant affective and emotional states; and E. disease-relevant self-regulatory competencies and skills for generating and maintaining goal-oriented health-protective behaviors. [44,47-55] The 5 conceptual constructs are directly translated into 5 key intervention objectives addressing the 4 domains of unmet needs (informational, physical, social, and psychological) that lead to OD-related burden, by increasing care partner self-efficacy in OD-related behavioral (cognitive) and stress (affective) management, which will reduce care-partner burden (primary outcome), raise QoL (secondary outcome), and improve patient outcomes (exploratory outcomes). Previous studies have demonstrated that care partners of persons with AD/ADRD can be supported through informational programs. [56,57] Thus, we will use the C-SHIP framework to guide the adaptation and evaluation of an easily administered Web-based Care Partner Tool for Feeding Dysphagia (WeCareToFeedDysphagia) to reduce burden for care partners of persons with AD/ADRD and OD.

Scientific Premise. Although previous interventions have targeted burden in care partners of persons with AD/ADRD, no extant studies have targeted OD-related

burden.[58-61] In addition, the extant literature on OD-related burden has focused on conditions such as head and neck cancer, Parkinson's disease, stroke, and neuromuscular disease.[30] There is a dearth of studies evaluating OD-related burden in care partners of persons with AD/ADRD. A 2022 systematic review found 17 relevant articles (16 cross-sectional, 1 longitudinal, and no RCTs) that demonstrate the high prevalence of OD-related care-partner burden.[9] The review concluded that there was an urgent need to better understand and address OD-related burden in care partners of older adults and specifically for distinct OD etiologies (e.g., AD/ADRD). A 2021 scoping review (15 studies, no RCTs, and none in AD/ADRD), evaluating the caregiving needs of persons with OD and their care partners, concluded that care partners face dramatic and persistent caregiving needs, and highlighted the critical need for larger and more focused studies to design and test interventions tailored to address OD-related care-partner needs.[30]

Thus, the proposed research is highly significant because if successful it will:

- Produce an easily administered, single-component, efficacious tool to reduce burden in care partners of persons with AD/ADRD and OD, which has the potential to improve care partner QoL.
- Improve dementia care for persons with OD by providing care partners with OD-related evidence-based informational content. This content can also be adapted to improve care for other populations that experience OD (e.g., head and neck cancer, Parkinson's disease, and stroke).

The proposed research is highly innovative for the following 3 reasons:

1. It is the first study that aims to reduce OD-Related burden by meeting the unmet caregiving needs of care partners of community-dwelling persons with AD/ADRD and OD. Most studies evaluating OD-related care-partner burden targeted conditions such as head and neck cancer.[30,62] However, care partners of community-dwelling persons with AD/ADRD and OD have dramatic and persistent unmet OD-related caregiving needs, resulting in higher burden and poor clinical outcomes. [23,30] Yet, no extant studies have targeted the unmet caregiving needs of care partners of persons with AD/ADRD to reduce OD-related care burden.
2. It is the first study to result in a centralized web-based informational care partner tool for managing OD in persons with AD/ADRD. There is currently no centralized, evidence-based informational resource to meet OD-related caregiving needs. Although many websites provide health information, such information is often inaccurate, incomplete, sensational, not tailored for specific conditions, and not user- friendly. WeCareToFeedDysphagia addresses these issues by creating: 1) evidence-based content that is based on a comprehensive literature review and an interprofessional expert panel 2) patient-centered content that is based on incorporating care-partner stakeholder input (Aim 1); and 3) user-friendly and practical content based on usability/acceptability testing (Aim 2). Further, a web-based platform maximizes intervention reach, and provides continuous access to intervention content, which is essential for care

partners of persons with AD/ADRD, who experience unique barriers to in-person participation (e.g., inability to leave the person with AD/ADRD alone).

3. It is the first study to use a comprehensive framework to standardize the design and evaluation of OD-related care partner burden research. A 2021 scoping review highlighted the lack of standardization in the design and evaluation of interventions to address OD-related care-partner burden, stating the need to integrate strong theoretical frameworks. [30] By adapting a validated and highly relevant framework (C-SHIP model), our study will be the first to standardize OD-related, care-partner burden research, allowing for future reproducibility and generalizability.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

The overall goal of this proposal is to reduce burden in care partners of community-dwelling persons with AD/ADRD and OD using a single-component, easily administered, intervention that addresses unmet OD-related caregiving needs. Guided by a self-regulation theoretical framework, WeCareToFeedDysphagia will use written and video content, care-partner testimonials, frequently asked questions, and resource links, to:

A. provide accurate information (e.g., dysphagia diets);
B. set realistic expectations;
C. identify/support feeding goals (QoL considerations);
D. acknowledge/support care-partner feelings; and
E. provide competencies/skills for OD management.

The goal of this study is to determine the effect size estimates of WeCareToFeedDysphagia to reduce care-partner burden, and the feasibility of a subsequent full-scale RCT. We believe that the study will meet or exceed the established feasibility (i.e. Go/No-Go) criterion to proceed with a large-scale trial to determine the effectiveness of the WeCareToFeedDysphagia web tool.

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

Northwell Health is the largest health system in New York State, encompassing 23 hospitals in Long Island, New York City, and Westchester County. We will recruit care partners of persons with AD/ADRD from 11 NWH hospitals that use the same electronic health record (EHR). These consist of 1 quaternary, 3 tertiary, and 7 community hospitals. The hospitals serve one of the most diverse urban counties in the country (Queens, NY). The 11 hospitals have a total of 75,619 medicine discharges per year. We have successfully developed and validated an electronic health record (EHR) tool for identifying hospitalized older adults with AD/ADRD and OD. Drs. Sinvani and Makhnevich worked closely with a data analyst to undertake an iterative process that consisted of a recurring loop of query refinement and data validation (manually reviewing randomly selected charts), followed by further query refinement, until they achieved validation of data integrity and harmonization. This will facilitate identification and recruitment of eligible care partners of patients with AD/ADRD and OD.

We created a database of hospitalized older adults with AD/ADRD, admitted across the 11 NWH hospitals for our currently funded NIA grant (1R03AG070662). The total number of hospitalized patients with AD/ADRD and OD, from 2017-2020, was: 2,757 in 2017 (average age 83.3, female 54.9%, and 62.4% white, 43.7% discharged home); 2,839 in 2018 (average age 82.7, female 55.5%, 66.2% white, and 43.7% discharged home); 2,809 in 2019 (average age 81.9, 53.8% female, 65.7% white, and 40.6% discharged home); and 2,779 in 2020 (average age 80.9, 54.4% female, 62.5% white, and 44.9% discharged home). Therefore, the average number of eligible care partners of patients with AD/ADRD and OD who are discharged home after hospitalization per year is 1,208. Based on our preliminary work demonstrating an average of 1,208 eligible patients per year and a consent rate of 50%, we will have ~600 eligible care partners/year, or ~11 care partners per week, that are willing to participate.

The Institute of Health System Science has extensive experience recruiting and conducting fully remote studies. The study team will meet weekly to ensure that all persons assisting with the trial are adequately informed about their trail-related duties and functions.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Eligible care partners will be identified via 3 steps:

1) Using a previously developed EHR identification tool described in Section 5, a data analyst from QI will generate a list of potentially-eligible patients
2) a consenting coordinator will conduct a chart review of the QI-generated list to confirm eligibility described in Section 7, and
3) the consenting coordinator will call the care partner while the patient is still hospitalized, introduce the study, confirm patient and care partner eligibility, confirm that the patient is being discharged home, and offer study participation.

For care partners who are considered screen failures, the consenting coordinator will record demographic information, including the NIA-required Clinical Research Operations & Management System (CROMS) screen failure questionnaire (see Section 14).

A flyer with more information about the study will be given to potential participants that may be interested in consenting at a later time.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Inclusion Criteria:

- Self-identifies as the primary care partner of an older adult patient (patient age ≥ 65 years) with AD/ADRD and oropharyngeal dysphagia (OD) admitted to the Northwell medicine service
- Age ≥ 18 years
- Designated as the legally authorized representative (LAR) or health care proxy (HCP), or designated by the LAR or HCP to participate
- Proficient in English
- Has access to a device (e.g. smartphone, iPad, computer) capable of accessing a web browser

Exclusion Criteria

- Care partner of patient with a percutaneous feeding tube (i.e. PEG, PEJ used exclusively)
- Care partner of patient who will not be discharged to the home or community setting (e.g., home, assisted living, independent living)

- Care partner will not be involved with OD management (e.g. buying or making food, feeding, supervising) after hospital discharge

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

The study expects to screen up to 350 potential care partners for eligibility to enroll N=80 care partners into the study. Of the N=80 participants enrolled, N=40 will be randomized (blind allocation) to an enhanced control condition (usual care, with speech language pathologist [SLP] contact information) and the remaining N=40 will be randomized to the intervention condition (usual care, with SLP contact information + WeCareToFeedDysphagia). We anticipate at least N=60 (25% attrition) participants will complete research procedures.

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

Care partners will participate in the study remotely for a total of 3 months.

We anticipate enrollment to last approximately 1 year. The estimated date of study completion is July 2025.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

We define the feasibility of conducting a full-scale effectiveness trial as:

i. ≥40% of eligible care partners will be consented;
ii. Attrition rate will be ≤30% at Time Point 3 (care partner burden at 3 months);
iii. ≥80% of care partners will successfully receive the text message after enrollment (to be verified at the 1-week call with the RA);
iv. ≥90% of care partners will receive all follow-up text messages (1, 2, and 3 weeks);

v. ≥60% of care partners will access WeCareToFeedDysphagia (defined as reaching the home page); and
vi. ≥45% of care partners will engage (defined as viewing ≥ 2 pages) with WeCareToFeedDysphagia.

We will not proceed with the full-scale RCT to determine the effectiveness of WeCareToFeedDysphagia to reduce care partner burden if we do not meet at least 3 out of the 6 criteria outlined above.

11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

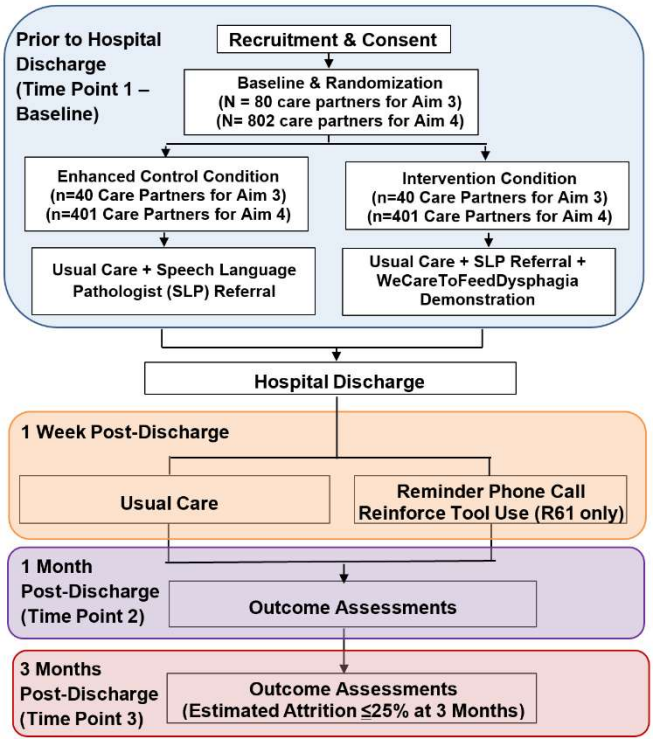
We will identify potentially eligible care partners by pre-screening the EHR and conducting a chart review. Using a previously developed EHR identification tool described in Section 5, a data analyst will generate a list of potentially-eligible patients and provide a link to the data file via a PHI-secured SharePoint site. A consenting coordinator will review these patient records to confirm potential eligibility using the inclusion and exclusion criteria described in Section 7. The consenting coordinator will contact the care partner, offer a study description, confirm interest in participation, evaluate care partner and patient eligibility, review the verbal HIPAA authorization and consent information and collect verbal consent from the care partner (for themselves and surrogate consent on behalf of the individual for whom they provide care). The consenting coordinator will then send the participant via text-message a link to a REDCap survey to document consent and authorization, and complete the Time Point 1 (baseline) measures. If the care partner prefers, Time Point 1 will occur virtually with the care partner using Microsoft Teams or Zoom. The consenting coordinator will reiterate the purpose of the research and answer any questions.

We will randomize (blind allocation) the care partner to either the enhanced condition (usual care, including speech language pathologist (SLP) contact information) or the intervention (usual care, including SLP contact information, + WeCareToFeedDysphagia). The study team will collect in the Time Point 1 measures, sociodemographic information, caregiving measures, as well as baseline

ZBI-22, CarerQol, CARES Part A and Part B, EdFED-Q, and QUALID via REDCap. In addition, the study team will collect relevant clinical data from the patient record (see Section 14 for a full list of variables collected via EHR and care partner survey).

Enhanced Control Condition (n=40)

In the enhanced control condition, following completion of baseline measures, the care partner will continue to receive usual care from the patient's medical team. The study team will provide information regarding contacting a speech language pathologist for further information regarding caring for someone with AD/ADRD and OD. The care partners will also receive information regarding contact for remaining study assessments (1 month and 3 months post-discharge).



Intervention Condition (N=40)

In the intervention condition, following completion of baseline measures, the care partner will continue to receive usual care from the patient's medical team, plus the study team will provide access to WeCareToFeedDysphagia. The study team will provide all participants a copy of the information sheet, the team's contact information, and a reminder that study personnel will contact them by phone 1 week post-discharge to assess tool use and answer any questions. The study team will provide unique usernames and passwords to participants in the intervention condition and instructions on how to access WeCareToFeedDysphagia from any smart device (e.g., smartphone) or computer. Care partners will receive a text message reminder about the WeCareToFeedDysphagia resource 1 week, 2 weeks, and 3 weeks after initial access is granted to the care giver.

Participants in both the enhanced control condition and the intervention condition will receive text message link to complete repeat assessments of the ZBI-22, CarerQol, CARES Part A and Part B, EdFED-Q, and QUALID one month post-hospital discharge (Time Point 2) and 3 months post-hospital discharge (Time Point 3) via REDCap. For those care partners who are unable to complete the REDCap survey on their own, a member of the study team will set up a 30-minute

virtual (Microsoft Teams or Zoom) call to facilitate completion of the outcome assessments.

The study team will also collect patient-centered outcomes (defined in Section 14 below) at 1-month and 3-months post initial hospital discharge.

After care partners complete their Time Point 3 assessment, we will offer all care partners access to WeCareToFeedDysphagia.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

Go/No-Go for Future Large-Scale RCT

We define the feasibility of conducting a full-scale effectiveness trial as:

i. ≥40% of eligible care partners will be consented, calculated as care partners consented over those eligible and approached
ii. Attrition rate will be ≤30% at Time Point 3 (care partner burden at 3 months), calculated as non-completers of the assessments over consenters
iii. ≥80% of care partners will successfully receive the text message after enrollment, verified at the 1-week call with the research team;
iv. ≥90% of care partners will receive all follow-up text messages (1, 2, and 3 weeks), calculated via confirmation response in REDCap;
v. ≥60% of care partners will access WeCareToFeedDysphagia (defined as reaching the home page), calculated using Google Analytics data or confirmation response in REDCap; and
vi. ≥45% of care partners will engage (defined as viewing ≥ 2 pages) with WeCareToFeedDysphagia, calculated using Google Analytics data or confirmation response in REDCap

We will not proceed with the full-scale RCT to determine the effectiveness of WeCareToFeedDysphagia to reduce care partner burden if we do not meet at least 3 out of the 6 criteria outlined above.

Primary, Secondary, and Exploratory Outcomes

Although the effect size is not considered a go/no go criterion, this study is designed to support a pilot RCT that will inform the sample size calculations for the full-scale effectiveness trial. **We will obtain estimates of the ES on our primary outcome (care-partner burden at 3-months post-hospital discharge) among the 2 conditions.** We will summarize variables using descriptive statistics by study condition. Specifically, we will use mean and standard deviation for

continuous variables, and frequency and proportion for categorical variables. Our primary analysis will be to compute the ES between each pair of means on the measure of burden (our primary outcome) at the 3-month assessment. For example, we will compute the ES for Condition 1 versus Condition 2 as (Mean 1–Mean 2)/Standard Deviation. The ES will inform our sample size and power considerations for the future full-scale RCT.

Secondary Outcomes:

- Care partner burden at 1 month post-discharge
- Care-Related Quality of Life (CarerQol) at 1 month and 3 months post-discharge
- Percent tool engagement (Go/No-Go)
- Percent consented (Go/No-Go)
- Percent attrition at 1 month and 3 months post-discharge (Go/No-Go)

Exploratory Outcomes:

- Mediating measures:
  - CARES Part A at 1 month and 3 months post-discharge (mediating measures)
  - CARES Part B at 1 month and 3 months post-discharge (mediating measures)
  - Sociodemographics
  - Clinical data
  - Caregiving measures
- EdFED-Q at 1 month and 3 months post-discharge
- QUALID at 1 month and 3 months post-discharge
- Patient-centered outcomes at 1-month and 3 months post-discharge

Sample Size Considerations

Because this study is designed to inform the sample size calculations for a future full-scale efficacy RCT, we plan to enroll 10% of the projected sample size needed for the full-scale RCT (N=60 or 10% of 602, see Figure 2 and power calculation). To account for an attrition rate of 25% (based on patient mortality and care partner loss to follow-up) at 3 months, a total of N=80 or n=40 in each condition (enhanced control and intervention) is needed for the pilot RCT (increase from N=60 to N=80 based on 60 x 1.33-attrition calculation). To meet our 6-month recruitment goal of N=80, we will need to recruit ~4 care partners per week. Based on our preliminary work demonstrating an average of ~11 eligible care partners/week, we should have no issues reaching recruitment goals for this study.

Blind Allocation Procedures

Randomized allocation will be pre-generated via code and uploaded to a REDCap file accessible only to members of the Institute of Health System Science data team. The consenting coordinator will email a member of the data team for the next allocation prior to each individual consent.

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

Regular meetings will take place with the PI and other members of the study team to ensure protocol adherence and data accuracy. This protocol collects data from electronic health records (EHR) and self-reported surveys.

Both EHR and survey data will be collected and stored securely in coded format within REDCap, a Northwell-approved system for collecting and storing research data, including PHI. Only IRB-approved members of the study team will have access to the study REDCap.

Data Variables To-Be Collected:

Care Partner Burden
Post-hospital care partner burden will be assessed using the Zarit Burden Scale (ZBI-22) at 3 months. The ZBI-22 addresses personal strain, which is rated with 5 frequency-related response categories, scored 0 (never) to 4 (nearly always). The total score ranges between 0 and 88 (higher scores indicating higher burden). A score less than 21 has been suggested to indicate care-partner burden. We will measure care-partner burden at baseline, 1 month, and 3 months (long term) using technology. Outcome

measures will be captured through a REDCap link which will be sent to the care partner's smart phone/device.

Care-Related Quality of Life (CarerQol)
Post-Hospital Care-Partner Quality of Life will be measured using the Care-Related Qol-7D. The Care-Related Qol-7D measures well-being (CarerQol-VAS or visual analog scale) and subjective burden (CarerQol-7D). The CarerQol-VAS measures happiness, using endpoints between 'completely unhappy' (0) and 'completely happy' (10). Subjective burden is measured on 7 dimensions (fulfillment, relational problems, mental health, daily activities problems, physical health, and support), and rated as (i) no, (ii) some, and (iii) a lot. The weighted score ranges from 0-100 (worst to best caregiving situation). We will measure care-partner quality of life using technology. Outcome measures will be captured through a REDCap link which will be sent to the care partner's smart phone/device.

The Caregiver Analysis of Reported Experiences with Swallowing Disorders (CARES)
(CARES) is a 26-item survey (scored as "yes" or "no") divided across 2 subscales: Part A-Checklist of Behavioral Changes (10 items) and Part B-Measures of Subjective Caregiver Stress (16 items). Each part is scored separately (1 point for every "yes" response) out of 10 (Part A) and 16 points (Part B). Part A is scored with a maximum of 10 points and Part B is scored with a maximum of 16 points. Scores are continuous, with lower scores indicating more self-efficacy with behavioral (Part A) and stress (Part B) management. CARES Parts A and B will be administered at baseline, 1 month, and 3 months using technology. Outcome measures will be captured through a REDCap link which will be sent to the care partner's smart phone/device.

The Edinburgh Feeding Evaluation in Dementia Questionnaire (EdFED-Q)
The Edinburgh Feeding Evaluation in Dementia Questionnaire (EdFED-Q) is an 11-item instrument, which assesses eating and feeding problems in people with late-stage dementia (less than 5 minutes to complete). The care partner assigns a score (0 to 2, never, sometimes, or often occurring) to each item; higher scores (range 0 to 20) indicate greater feeding dysfunction. The EdFED-Q will be administered at baseline, 1 month and 3 months using technology. Outcome measures will be captured through a REDCap link which will be sent to the care partner's smart phone/device.

Quality of Life in Late-Stage Dementia Scale (QUALID)
The Quality of Life in Late-Stage Dementia Scale (QUALID), an 11-item, is a reliable and valid scale, administered to care partners for rating QoL in late-stage dementia. A 5-point scale is used to capture the frequency of each item (scores range from 11 to 55, low scores reflect a higher QoL). The QUALID will be administered at 1 month and 3 months using technology.

Outcome measures will be captured through a REDCap link which will be sent to the care partner's smart phone/device.

Sociodemographics
The sociodemographic questions will consist of patient's and care partner's age, gender, race or ethnicity, income, and education.

Clinical Data
Clinical data will consist of patient diagnoses (clinical and psychiatric comorbidities); patient's level of cognitive impairment (Clinical Dementia Rating Scale, CDRS), and patient's OD severity (recommendation of dysphagia diet types or non-dysphagia diet types).

Caregiving Measures
Caregiving measures will consist of the relationship between care partner and patient; time since assuming the care partner role; number of other care partners; overall number of caregiving responsibilities (e.g., financial, physical, medical); OD-related caregiving responsibilities (e.g., purchasing and preparing food, feeding); and other factors of caregiver burden such as clinical and psychiatric comorbidities.

Patient-Centered Outcomes
Patients will be assessed for outcomes including 1) acute care visits (emergency department visits and hospital readmissions; differentiating between aspiration and non-aspiration related complaints); 2) dehydration (requiring intravenous or subcutaneous fluid administration); 3) nutritional intake (weight loss greater than 3 kg, 1-3 kg, and no weight loss; derived from the Mini Nutritional Assessment, MNA); 4) behavioral and psychological symptoms of dementia (BPSD, Neuropsychiatric Inventory Questionnaire, NPI-Q).

National Institutes on Aging Clinical Research Operations & Management System (CROMS) Screening and Enrollment Questionnaires
The funding agency of this study requires the collection of standardized demographic information from all funded clinical trial aims and enrollment to facilitate early interventions to help with enrollment challenges, particularly among underrepresented populations. Participants will have the ability to select "prefer not to answer" to any of the items listed. Variables collected include age, sex, gender, sexual orientation, race, ethnicity, patient's cognitive status, education level, household income, occupation category, marital status, living situation, primary language spoken, insurance status, zip code, and dates associated with screening, enrollment, and study participation

All data collected for this research will be maintained in its original and unaltered source data state indefinitely and stored within the Quantitative Intelligence Data

Lake, on a Microsoft Azure platform, which complies with all Northwell security standards and best practices for processing Protected Health Information (PHI). QI, as Honest Brokers, will have access to direct identifiers for linkage purposes and will retain the map/linkage between datasets in the event that data needs to be re-identified and/or for traceability purposes. Data collected for this study may be used for future research in coded format without additional consent pursuant to any conditions outlined within the consent form participants signed, and with appropriate IRB approval as required. Access to identifiable data is controlled and limited to IRB-approved individuals who have completed all required human subjects protection training.

This research is funded by the NIH; a Certificate of Confidentiality has been issued for this research. Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. In addition, per NIH requirement for Data Management and Sharing, scientific data generated as a result of this research will be shared broadly via OpenScience: https://cos.io/. The Open Science Framework is a free, open-source web application built to provide researchers with a free platform for data and materials sharing. There will be no identifiable data posted to this website. In addition, a description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law.

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*

- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis, and that each individual engaged in research is qualified to do so by virtue of education, training and experience to perform the delegated task.

This project proposes a non-systematic collection method of reported events to determine if an adverse event has occurred, and to determine next steps, if any, for reporting. Events reported by participants that meet the definition of an adverse event during the time frame specified in the protocol (e.g., from the start of intervention through the end of study procedures) will be collected in electronic format using REDCap.

Definitions

Definitions are from the January 2007 OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, OHRP Guidance.

Adverse Event (AE):

An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied. The Northwell Health IRB further defines AEs to encompass both physical and psychological harms.

Serious Adverse Event (SAE):

Any adverse event that:

- Results in death
- Is a life-threatening experience
- Hospitalization (for a person not already hospitalized)
- Prolongation of hospitalization (for a patient already hospitalized)
- Persistent or significant disability or incapacity
- Congenital anomaly and/or birth defects
- Event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

In this trial, we do not expect adverse events (serious or otherwise) to occur as part of care partner's participation in this research. We do not consider any patient-centered outcomes collected to require adverse event assessment.

Unanticipated Problem (UP):

Defined by DHHS 45 CFR part 46 as any incident, experience, or outcome that **meets all the following criteria:**

- unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related

documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population;
- related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

CLASSIFYING ADVERSE EVENTS

Should adverse events be reported, the severity, expectedness, and potential relatedness to the study intervention will be classified according to the below:

Severity

- **Mild**: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.
- **Moderate**: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities but are usually improved by simple therapeutic measures: moderate experiences may cause some interference with functioning.
- **Severe**: Events interrupt the participant's normal daily activities and generally, require systemic drug therapy or other treatment; they are usually incapacitating

Expectedness

AEs will be assessed as to whether they were expected to occur or unexpected, meaning not anticipated based on current knowledge found in the protocol. Categories are:

- **Unexpected** - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.
- **Expected** - event is known to be associated with the intervention or condition under study.

Relatedness

The event's potential relationship to the study intervention and/or participation is assessed according to the below:

- **Related:** An event is "related" if it is likely to have been caused by the research procedures.

- **Probably/Possibly Related:** An event is considered to be probably or possibly related to the intervention if there is a greater than 50% chance that the event was caused by the study procedures.
- **Unrelated**: The adverse event is clearly not related to the research - i.e., another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

REPORTING PROCESSES

All **adverse events that are serious** (SAE), **unexpected** (have not been defined as expected) and **related** to the research will be reported to the NIA Program Officer, the study's Data and Safety Monitoring Board (DSMB) chair, and the Northwell Health IRB within **48 hours** of the study's knowledge of the SAE, per NIA policy.

Unanticipated Problems (UP) that are determined by the Northwell Health IRB to meet the criteria of an Unanticipated Problem as defined above by will be reported to the NIA Program Officer and the study's Data and Safety Monitoring Board (DSMB) within **48 hours** of that determination. A report will be submitted to OHRP by the Northwell Health IRB as per 45 CFR 46(a)(4)(i), and according to the IRB's standard operating procedures for reportable events.

All other adverse events (events that meet the definition of an AE, but are not unanticipated problems or an unexpected, related SAE) will be reported to the study's DSMB **annually**, or at a frequency requested by NIA Program Officer and/or by the DSMB.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

Although this single-site study is considered minimal risk, the funding agency (NIA) has appointed a data safety and monitoring board. Please see the attached DSMB Charter for more information. The NIA-appointed DSMB will provide recommendations for study initiation to the study team and NIA electronically, via email, prior to the start of the research. Meetings of the DSMB will then be held regularly (e.g., every six to nine months) at the call of NIA or the DSMB Chair.

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Should a care partner choose to withdraw themselves and the patient from research, they will be instructed to contact the study team to withdraw. Participants will be contacted by a member of the research team confirming their study withdrawal, and to answer any questions they may have. All data up until the receipt date of participant contact for withdrawal will be included in the research study.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

The probability and magnitude of harm or discomfort anticipated from the care partner's participation in this research is not greater than those ordinarily encountered in daily life.

Potential risks associated with the intervention include:

- *Psychological risks:* Some of the assessment questions may be considered personal or may be upsetting to participants; such experiences are usually temporary. We will inform individuals they can skip any question they do not want to answer during the interview process and will provide linkage to care (counseling) should a care partner become distressed or uncomfortable during the interviews. In the event of high levels of distress, the participant will be referred to our NWH outpatient geriatrics faculty practice or our adult outpatient psychiatry service. The study team will facilitate this connection for all interested study participants. They may alternately be referred to the Alzheimer's Disease Caregiver Support Initiative and/or provided information on Alzheimer's Disease and Healthy Aging, Caregiving Support by the Centers for Disease Control and Prevention (CDC). Resources and support.
- *Privacy risks:* A potential risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Measures to mitigate risks to loss of privacy are detailed in Section 20.

The study team will explain to participants that participation is voluntary and they are able to withdraw at any time without impacting the current or future care of the care partner or the patient at Northwell Health.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

Research-related injuries are not expected for this no greater than minimal risk study.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Care partner participants may benefit from content, tools, and resources provided via the WeCareToFeedDysphagia platform.

The current standard of care strategies (dysphagia diets and rehabilitative-swallowing exercises) are either poorly communicated to care partners or fail to address important caregiving needs, yet there are currently no interventions that address these unmet needs. Although many websites provide health information, such information is often inaccurate, sensational, and not tailored for specific conditions. Delivering intervention content via a web based platform maximizes reach for care partners of patients with AD/ADRD, who experience unique barriers to in-person participation, including the inability to leave the person with AD/ADRD alone.

The study team believes the risks of confidentiality loss are reasonable in relation to the proposed potential long-term benefits of directly addressing OD-related burden in care partners of persons with AD/ADRD, which is critical for improving dementia care and care partner outcomes

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

The researchers take the issue of privacy very seriously. Study information will be stored in a Northwell-approved database drive to store PHI (e.g. SharePoint and REDCap), and it will only be accessible to research staff listed on the approved IRB protocol. Names or other identifying information will not be shared with those outside the research team. Phone numbers and email will only be used for study-related communications. Any phone calls or emails will be sent to participants through the respective study site's secured server and calls made in a secured area.

Along with the organizational administrative, technical and physical safeguards and IRB approved measures, data privacy and security procedures will include:

(1) training staff on data sensitivity and protocols for safeguarding confidentiality;
(2) capturing and storing follow-up assessments in REDCap, a secure web-based HIPAA compliant application designed to support data capture for research studies; and
(3) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

Additionally, all personnel will be instructed in the ethics of electronic data access. Everything will follow the strict Health Care Information and Technology – Privacy and Security rules, regulations, policies and procedures, and protocols established at Northwell Health based on the industry standards. Application and data access will be controlled by appropriate authentication and authorization measures. It is the policy of the health system to use encryption safeguards on Sensitive and Highly Sensitive data as defined in the Data Classification Policy (900.12), such as ePHI, to ensure data authenticity and integrity where reasonable and appropriate, and in accordance with applicable laws and regulations.

We will establish and ensure that appropriate limits on the type and amount of information collected, used, and/or disclosed are in place. This will increase privacy protections and is essential to building trust in electronic exchange of individually identifiable health information because it minimizes potential misuse and abuse. Northwell Health's Information System Review and Audit Controls Policy (900.27) will allow us to maintain a comprehensive internal security control and audit program, and established procedures and record keeping activities to ensure proper legal, ethical and business practices. This will complement the user authentication process and acts as a deterrent to internal abuse by making users aware that audit trails, access reports, and security incident tracking reports are produced, reviewed and, where applicable, investigated. These internal security

controls may take various forms including regular information system activity review. These reviews incorporate logon monitoring, audit trails and logs, access reports, and manually produced security incident tracking reports for network and ePHI systems. It is the policy of health system to have departmental procedures (e.g., human resource, corporate security and information services) to grant, modify and revoke access, permissions and rights to health system networks, systems, applications, facilities and physical locations to staff based on their roles and responsibilities.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

WeCareToFeedDysphagia access will be provided to participants at no cost. Participants randomized to the enhanced control condition will receive access to the WeCareToFeedDysphagia platform at the conclusion of their study participation.

This study uses text messaging to deliver notifications, reminders, and surveys. Standard message and data rates from the participant's wireless carrier may apply to the study participant. Study participants will not be compensated for any costs related to data usage or sending or receiving text messages by the study or by members of the study team.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

Care partners will receive a $50 ClinCard after completion of Time Point 1 (baseline). Care partners will receive an additional $25 to their ClinCard after completion of both Time Points 2 (1-month post discharge) and 3 (3-months post discharge) up to $100 total.

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

A consenting coordinator will pre-screen patient records for potential participants via hospital visit information, age, race, ethnicity, gender, sex, history of dementia, OD diagnosis, and legally authorized representative (LAR) or health care proxy (HCP). For those eligible, the consenting coordinator will contact the LAR or HCP (who might be the same person or who might direct the research team to another care partner) to provide study information and offer the opportunity to participate. The EMR will be reviewed for contact information to speak with the LAR/HCP via phone. The research team member will verbally offer the LAR/HCP or other care partner information about the study, explain all aspects of study participation, and state that participation of the study is voluntary, that the care partner may opt out at any time, and that the decision to decline to participate or to opt out will not affect the patient's treatment.

After verbal consent and authorization, the consenting coordinator will send a text-message with a link to REDCap hosted econsent to document their consent and authorization to participate. After the form's submission, the consenting coordinator who undertook the consent process will review the form for completion and use the REDCap Locking and E-signature functions on the form to disable future changes to the form. The E-signature function will require the consenting coordinator to enter their Northwell credentials to authenticate the signature. The participant will be considered enrolled once the consent form has been reviewed for an acceptable signature and the consenting coordinator has E-signed the form.
A copy of the consent form including participant responses and documentation of the consenting coordinator's Locking & E-signature will be exported as a PDF from REDCap. PDF copies of signed consent forms will be made available to participants via a securely sent email using Northwell's encryption system. A copy of all signed forms will be stored in a HIPAA-secured, Northwell approved storage drive with protected access to only the PI and research personnel listed on the study protocol.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*

- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

N/A

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

The focus of this study is on care partners of patients. This study has designed all patient-related information (secondary participants) to be obtained through care partner and electronic medical records as to not disrupt the patient and their medical care. Care partners eligible for participation in this study care for patients that have baseline cognitive disruption and diminished or lack of capacity, e.g. e.g. progressive dementia with associated oropharyngeal dysphagia as documented in the medical record. Oropharyngeal dysphagia in patients with dementia is indicative of advanced disease and therefore the inability to understand and provide consent. Since no direct patient contact is required for data collection in this study, in order to reduce the burden of approaching patients with advanced dementia in the stressful hospital setting, it would be least disruptive for the

study team to forgo any direct communication with the patient and proceed to speak directly to the LAR. As such, we propose that the care partner of these secondary participants provide surrogate consent for collection of medical record information to assess secondary outcomes.

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

The study is committed to enrolling a racially and ethnically diverse population. This stage of study is focused on piloting the WeCareToFeedDysphagia platform for effect size estimates and feasibility to conduct a subsequent full-scale RCT. In the future, it will be especially important to obtain this feedback from individuals who are non-English speaking, and the intention once we document feasibility and proof of greater effectiveness over usual care methods through our project's forthcoming RCT, is to seek funding to build virtual delivery capabilities that are fit-for-purpose in research involving individuals who are non-native English speakers.

Having a platform capable of accurately displaying research requirements and study related material is especially important for speakers whose language involves characters that may not be easily displayed electronically or may introduce formatting errors. We aim to be transparent that further research is needed to assess feasibility in the same delivery with non-English speaking individuals. Injustice has no place in research with human subjects and undermines public trust in science, thus we are committed to enrolling a racially and ethnically diverse population in this protocol and for all research conducted by the Institute for Health System Science.

Towards that commitment, we anticipate that many participants interested in this current research project will represent racial and ethnic minority groups. Race and ethnicity (not just English proficiency) are strongly correlated with access to care, environmental exposures, income, employment, and other social determinants of health, which, by definition, affect health outcomes. We will collect information to help inform virtual research delivery and do not believe that focusing on English speaking participants in this study - those that may be from ethnically and racially diverse populations - will confirm pre-existing bias or will later negatively

impact equitable access, participant comprehensibility or research design applicability to the diverse populations that may be solicited for participation in future studies. We would be happy to further discuss considerations for equality in research and ways we as researchers and ethics professionals can address bias and structural injustices.

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS ☒ N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

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Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

)

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*

- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

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25. WAIVER OF HIPAA AUTHORIZATION ☐ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

Data will be collected from electronic health records. PHI is needed to determine eligibility of potential subjects, identifiers are necessary to contact the individual to discuss participation in the study. The use of protected health

information involves no more than a minimal risk to the privacy of individuals given our plan to protect the identifiers from improper use and disclosure and this written assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. The research EHR screening and chart review could not practicably be conducted without the waiver or without access to and use of the protected health information.

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☒ *Cognitively impaired*
- ☒ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☒ *NSLIJ Employees, residents, fellows, etc*
- ☒ *poor/uninsured*
- ☒ *Students*
- ☒ *Minorities*
- ☒ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

This research will not involve special vulnerable populations such as fetuses, neonates, children, prisoners, institutionalized individuals or other vulnerable populations. We are not targeting pregnant women, employees, minorities, students, the uninsured, or the elderly, however we will not exclude their participation in this research.

Potential participants will be educated about their rights as a research participant. Educational materials and informed consent will explain participation in this research study will not impact the quality of care received by a caregiver participant themself or those they provide care to at Northwell Health. Employee or student participation or non-participation in this study will have no bearing on an individual's position at Northwell Health (employment or school).

Any data collected from the medical record of cognitively impaired patients will be protected as per Section 14 of the protocol.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

N/A

28. REFERENCES/BIBLIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

1. Espinosa-Val MC, Martín-Martínez A, Graupera M, et al. Prevalence, risk factors, and complications of oropharyngeal dysphagia in older patients with dementia. Nutrients. 2020;12(3):863. PMCID: PMC7146553
2. Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in older adults. Mayo Clin Proc. 2021;96(2):488-497. PMID: 33549267
3. Makhnevich A., Marziliano A, Ahmad SE, et al. Factors and outcomes associated with dysphagia in hospitalized persons with dementia. J Am Med Dir Assoc. 2022;S1525-8610(21)01101-4. Online ahead of print. PMID: 35030318
4. Cabre M, Serra-Prat M, Palomera E, Almirall J, Pallares R, Clavé P. Prevalence and prognostic implications of dysphagia in elderly patients with pneumonia. Age Ageing. 2010;39(1):39-45. PMID: 19561160
5. Mateos-Nozal J, Montero-Errasquín B, García ES, Rodriguez ER, Cruz-Jentoft AJ. High prevalence of oropharyngeal dysphagia in acutely hospitalized patients aged 80 years and older. J Am Med Dir Assoc. 2020;21(12):2008-2011.PMID: 32499182
6. Paranji S, Paranji N, Wright S, Chandra S. A nationwide study of the impact of dysphagia on hospital outcomes among patients with dementia. Am J Alzheimers Dis Other Demen. 2017;32(1):5-11. PMID: 27821563
7. Banda KJ, Chu H, Chen R, et al. Prevalence of oropharyngeal dysphagia and risk of pneumonia, malnutrition, and mortality in adults aged 60 years and older: A meta-analysis. Gerontology. 2021;1-13. PMID: 34903688
8. Namasivayam-MacDonald AM, Shune SE. The influence of swallowing impairments as an independent risk factor for burden among caregivers of aging parents: A cross-sectional study. Geriatr Nurs. 2020;41(2):81-88. PMID: 31296403
9. Rangira D, Najeen H, Shune SE, Namasivayam-MacDonald A. Understanding burden in caregivers of adults with dysphagia: A systematic review. Am J Speech Lang Pathol. 2022;31(1):486-501. PMID: 34962832

10. Namasivayam-MacDonald AM, Shune SE. The burden of dysphagia on family caregivers of the elderly: A systematic review. Geriatrics (Basel). 2018;3(2):30. PMCID: PMC6319247
11. Johansson AEM, Johansson U. Relatives' experiences of family members' eating difficulties. Scand J Occup Ther. 2009;16(1):25-32. PMID: 18759159
12. Nund RL, Ward EC, Scarinci NA, Cartmill B, Kuipers P, Porceddu SV. Carers' experiences of dysphagia in people treated for head and neck cancer: A qualitative study. Dysphagia. 2014;29(4):450-458. PMID: 24844768
13. Nund RL, Scarinci NA, Cartmill B, Ward EC, Kuipers P, Porceddu SV. Third-party disability in carers of people with dysphagia following non-surgical management for head and neck cancer. Disabil Rehabil. 2016;38(5):462-471. PMID: 25981671
14. Patterson JM, Rapley T, Carding PN, Wilson JA, McColl E. Head and neck cancer and dysphagia; caring for carers. Psychooncology 2013;22(8):1815-1820. PMID: 23208850
15. Schulz R, Beach SR. Caregiving as a risk factor for mortality: The caregiver health effects study. JAMA. 1999;282(23):2215-2219. PMID: 10605972
16. Schulz R, Martire LM. Family caregiving of persons with dementia: prevalence, health effects, and support strategies. Am J Geriatr Psychiatry. 2004;12(3):240-249. PMID: 15126224
17. Gallicchio L, Siddiqi N, Langenberg P, Baumgarten M. Gender differences in burden and depression among informal caregivers of demented elders in the community. Int J Geriatr Psychiatry. 2002;17(2):154-163. PMID: 11813279
18. Kiecolt-Glaser JK, Marucha PT, Malarkey WB, Mercado AM, Glaser R. Slowing of wound healing by psychological stress. Lancet. 1995;346(8984):1194-1196. PMID: 7475659
19. Kiecolt-Glaser JK, Glaser R, Gravenstein S, Malarkey WB, Sheridan J. Chronic stress alters the immune response to influenza virus vaccine in older adults. Proc Natl Acad Sci USA.1996;93(7):3043-3047. PMCID: PMC39758
20. von Kanel R, Mausbach BT, Patterson TL, et al. Increased framingham coronary heart disease risk score in dementia caregivers relative to non-caregiving controls. Gerontology. 2008;54(3):131-137. PMID: 18204247
21. Kuzuya M, Enoki H, Hasegawa J, et al. Impact of caregiver burden on adverse health outcomes in community-dwelling dependent older care recipients. Am J Geriatr Psychiatry. 2011;19(4):382-391. PMID: 20808120
22. Riviere S, Gillette-Guyonnet S, Andrieu S, et al. Cognitive function and caregiver burden: Predictive factors for eating behaviour disorders in Alzheimer's disease. Int J Geriatr Psychiatry. 2022;17(10):950-955. PMID: 12325056
23. Kannayiram A, Bhanji RA, Kurian M. Evaluation and management of oropharyngeal dysphagia in different types of dementia: A systematic review. Arch Gerontol Geriatr. 2013;56(1):1-9. PMID: 22608838
24. Baijens LW, Clave P, Cras P, et al. European society for swallowing disorders–European union geriatric medicine society white paper: Oropharyngeal dysphagia as a geriatric syndrome. Clin Interv Aging. 2016;11:1403-1428. PMCID: PMC5063605

25. Vodanović D, Radošević T, Kolundžić Z. Dysphagia: An overlooked symptom and the role of a speech-language pathologist. Medica Jadertina. 2020;50(2):95-100.
26. Desai RV, Namasivayam-MacDonald A. Practice patterns of speech-language pathologists managing dysphagia in dementia: A cross-sectional survey in the United States. Perspect ASHA Spec Interest Groups. 2020;5(6):1631-1646.
27. American Speech-Language-Hearing Association. (n.d.). Adult Dysphagia. (Practice Portal). Accessed January 13, 2022 from www.asha.org/Practice-Portal/Clinical-Topics/Adult-Dysphagia/.
28. Wirth R, Dziewas R, Beck AM, et al. Oropharyngeal dysphagia in older persons - from pathophysiology to adequate intervention: A review and summary of an international expert meeting. Clin Interv Aging. 2016;11:189-208. PMCID: PMC4770066
29. Baijens LWJ, Clavé P, Cras P, et al. European society for swallowing disorders - European Union Geriatric Medicine Society white paper: Oropharyngeal dysphagia as a geriatric syndrome. Clin Interv Aging. 2016;11:1403-1428. PMCID: PMC5063605
30. Ninfa A, Crispiatico V, Pizzorni N, et al. The care needs of persons with oropharyngeal dysphagia and their informal caregivers: A scoping review. PloS One. 2021;16(9):e0257683. PMCID: PMC8460009
31. Howells SR, Cornwell PL, Ward EC, Kuipers P. Living with dysphagia in the community: Caregivers "do whatever it takes.". Dysphagia. 2021;36(1):108-19. PMID: 32333212
32. Bunn DK, Abdelhamid A, Copley M, et al. Effectiveness of interventions to indirectly support food and drink intake in people with dementia: Eating and Drinking Well IN dementiA (EDWINA) systematic review. BMC geriatrics. 2016;16(1):1-21. PMCID: PMC4855348
33. Barrado-Martín Y, Hatter L, Moore KJ, et al. Nutrition and hydration for people living with dementia near the end of life: A qualitative systematic review. J Adv Nurs. 2021;77(2):664-80. PMCID: PMC7898342
34. Choosing Wisely. Promoting conversations between providers and patients. Geriatrics - Feed patients with dementia by hand. Available at https://www.choosingwisely.org/clinician-lists/american-geriatrics-society-percutaneous-feeding-tubes-in-patients-with-dementia. Accessed January 9, 2022.
35. Gieniusz M, Sinvani L, Kozikowski A, et al. Percutaneous feeding tubes in individuals with advanced dementia: Are physicians "choosing wisely"? J Am Geriatr Soc. 2018;66(1):64-69. PMID: 28975616
36. O'Keeffe ST. Use of modified diets to prevent aspiration in oropharyngeal dysphagia: Is current practice justified?. BMC Geriatr. 2018;18(1): 1-10. PMCID: PMC6053717
37. Lazenby-Paterson T. Thickened liquids: do they still have a place in the dysphagia toolkit? Curr Opin Otrolaryngol Head Neck Surg. 2020;28(3):145-154. PMID: 32332203
38. Fox S, Duggan M. Health Online 2013: One in three American adults have gone online to figure out a medical condition. Pew Research Center. Available at

https://www.pewresearch.org/internet/2013/01/15/health-online-2013. Accessed January 26, 2022.
39. Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The effectiveness of web-based vs. non-web-based interventions: A meta-analysis of behavioral change outcomes. J Med Internet Res. 2004;6(4):e40. PMCID: PMC1550624
40. Krebs P, Prochaska JO, Rossi JS. A meta-analysis of computer-tailored interventions for health behavior change. Prev Med. 2010;51(3-4):214-221. PMCID: PMC2939185
41. Samoocha D, Bruinvels DJ, Elbers NA, Anema JR, van der Beek AJ. Effectiveness of web-based interventions on patient empowerment: A systematic review and meta-analysis. J Med Internet Res. 2010;12(2):e23. PMID: 20581001
42. Chi NC, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. J Telemed Telecare. 2015;21(1):37-44. PMID: 25475220
43. Fredericks S, Martorella G, Catallo C. A systematic review of web-based educational interventions. Clin Nurs Res. 2015;24(1):91-113. PMID: 2457196
44. Miller SM, Rodoletz M, Mangan CE, Schroeder CM, Sedlacek TV. Applications of the monitoring process model to coping with severe long-term medical threats. Health Psychol. 1996;15(3):216-225. PMID: 8698036
45. Carver CS, Scheier MF. Control theory: A useful conceptual framework for personality-social, clinical, and health psychology. Psychol Bull. 1982;92(1):111-135. PMID: 7134324
46. Carver CS, Scheier MF. (1998). On the self-regulation of behavior. United Kingdom: Cambridge University Press.
47. Leventhal H. Findings and theory in the study of fear communications. Adv Exp Soc Psychol.. 1970;5:119-186.
48. Janz NK, Becker MH. The health belief model: A decade later. Health Educ Q. 1984;11(1):1-47. PMID: 6392204
49. Bandura A. Human agency in social cognitive theory. Am Psychol. 1989;44(9):1175-1184. PMID: 2782727
50. Smith CA, Lazarus RS. (1999). Emotion and adaptation. In: LA Pervin (Ed.). Handbook of personality: Theory and research (pp. 609-637). New York, New York: Guilford.
51. Zajonc RB. Feeling and thinking: Preferences need no inferences. Am Psychol. 1980;35(2):151-175.
52. McCaul KD, Branstetter AD, O'Donnell SM, Jacobson K, Quinlan KB. A descriptive study of breast cancer worry. J Behav Med. 1998;21(6):565-579. PMID: 9891255
53. McCaul KD, Schroeder DM, Reid PA. Breast cancer worry and screening: Some prospective data. Health Psychol. 1996;15(6):430-433. PMID: 8973922
54. Diefenbach MA, Miller SM, Daly MB. Specific worry about breast cancer predicts mammography use in women at risk for breast and ovarian cancer. Health Psychol. 1998;18(5):532-536. PMID: 10519469
55. Slovic P, Fischhoff B, Lichtenstein S. Why Study Risk Perception? Risk Anal. 1982;2(2):83-93.

56. Thompson, CA., Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J. Systematic review of information and support interventions for caregivers of people with dementia. BMC Geriatr. 2007;7:18. PMCID: PMC1951962.
57. Vandepitte S, Noortgate NVD, Putman K, Verhaeghe S, Verdonck C, Annemans L. Effectiveness of respite care in supporting informal caregivers of persons with dementia: A systematic review. Int J Geriatr Psychiatry. 2016;31(12):1277-1288. PMID: 27245986
58. Hepburn KW, Tornatore J, Center B, Ostwald SW. Dementia family caregiver training: Affecting beliefs about caregiving and caregiver outcomes. J Am Geriatr Soc 2001;49(4):450-457. PMID: 11347790
59. de Rotrou J, Cantegreil I, Faucounau V, et al. Do patients diagnosed with Alzheimer's disease benefit from a psycho-educational programme for family caregivers? A randomised controlled study. Int J Geriatr Psychiatry. 2011;26(8):833-842.PMID: 20922772
60. Agüera-Ortiz L, Frank-Garcia A, Gil P, Moreno A, 5E Study Group. Clinical progression of moderate-to-severe Alzheimer's disease and caregiver burden: A 12-month multicenter prospective observational study. Int Psychogeriatrics. 2010;22(8): 1265-1279. PMID: 20849672
61. Jensen M, Agbata IN, Canavan M, McCarthy G. Effectiveness of educational interventions for informal caregivers of individuals with dementia residing in the community: Systematic review and meta-analysis of randomised controlled trials. Int J Geriatr Psychiatry. 2015;30(2): 130-143. PMID: 25354132
62. Shune SE, Namasivayam-MacDonald A. Dysphagia-related caregiver burden: Moving beyond the physiological impairment. Perspect ASHA Spec Interest Groups. 2020;5(5):1282-1289.