1. **Study Title: Advance Planning for Home Services for Seniors**
   Protocol Title: PLAN YOUR LIFESPAN Randomized Controlled Trial

2. **Version Date: 11/20/15**

3. **Northwestern University Principal Investigator's Name and Address:**

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4. **Study Description:**

Background/Rationale/Significance

Seniors over the age of 65 years represent 13.1% of the United States population, with a projected 36% increase to 55 million by the year 2020.[1,2] With advancing age, seniors experience an increased prevalence in memory loss, physical disability, and multiple chronic conditions (e.g., heart disease, emphysema, stroke, diabetes, cancers, hypertension, arthritis, osteoporosis, and macular degeneration).[3-7] A large fear among seniors is loss of independence and removal from their homes to be placed in a nursing home.[8-10]

As a whole, seniors play a much needed role in their communities. Seniors generally retire later today than ever before, and approximately 45% of all adults over the age of 65 volunteer annually.[11] Seniors who remain in their own homes tend to have greater satisfaction, less depression, and maintain their physical function better than seniors residing in assisted living or nursing homes.[12-16] Although remaining in the home is of utmost importance, many frail seniors teeter between safe living and personal endangerment.[17-19] Falls, illness, and worsening memory all jeopardize a senior's independence and ability to remain in his or her home.

Preliminary research by our team has shown that 63% of seniors had misconceptions about services that were offered in the home and in senior living communities (e.g., independent, assisted living). Adding to these misconceptions is the abundance of incorrect information that is propagated by hearsay and certain unsubstantiated websites.[20] Many seniors know people who have had negative experiences with paid caregiver support in their home, precluding them from pursuing these services.[21,22] Other seniors may not understand how to vet through home services and hire predatory home aids/caregivers who have criminal backgrounds.[23] Still other impoverish seniors may be struggling to pay for services that they could potentially obtain for free or at lower cost had they gone through a government supported agency on aging.[24-27] Navigating the home care system may seem overwhelming to many seniors and their caregivers.[28-30] Studies have shown that often seniors assume long-term care services are available but do not know how to access them (e.g., "I don't know who to talk to?").[31,32]

The PLAN YOUR LIFESPAN tool provides information that will help older Americans to "fill in the gaps" in their lives as necessary. An established plan would offer guidance toward obtaining those resources and professional services that would be useful to the senior. An effective plan would be dynamic and adaptable to the senior's changing health needs. Such a plan could range from safety proofing one's house to hiring a daytime caregiver. A tool dedicated to home services would help seniors determine which of the challenges they face in their homes may be overcome and determine an effective means by which these challenges may be overcome. The PLAN YOUR LIFESPAN tool could even help to eliminate unnecessary services. For example, the tool will allow seniors to identify their specific needs, which may range from having prepared meals delivered daily or having assistance picking things up at the grocery store.[33,34] The PLAN YOUR LIFESPAN tool may reduce resource requirements or ineffective care. It has the strong potential to decrease hospitalizations and days spent in a hospital (e.g., length of stay).[35]

Research has shown that rates of acute care admissions are higher for frail older people living with unmet versus met activity of daily living needs.[36,37] If a senior has adequate home support, (s)he may avoid being hospitalized.[38-41] Among hospitalized seniors, many wait while families look into and quickly arrange home care before they can be discharged.[42-44] With an advanced plan, families can follow the instructions and fulfill the senior's wishes for home care efficiently and without delaying the seniors' discharge from the hospital. Such improvements may, in turn, improve the overall quality of life that seniors experience in the home and enable them to remain in their homes safely for longer amounts of time than historically reported.

The Advanced Planning for Home Services for Seniors (APHS) study has three aims: (1) To develop, pilot test, and refine the PLAN YOUR LIFESPAN tool to assist seniors in making informed choices about issues in their health trajectory that influence their ability to remain in their own home, (2) to conduct a randomized, controlled trial of the PLAN YOUR LIFESPAN tool to determine the tool's influence on subject understanding of home care services, health trajectory, and other patient-centered outcomes compared with an attention control, and (3) to disseminate the PLAN YOUR LIFESPAN tool nationally through senior-focused organizations. After developing the PLAN YOUR LIFESPAN tool, we are now ready to pilot test the PLAN YOUR LIFESPAN tool as well as to conduct the proposed randomized, controlled trial.

<u>Research Objectives/Aims</u>

Through partnerships with seniors, senior community groups, area agencies on aging, and homecare agencies, we plan to: pilot test and conduct a Randomized Controlled Trial of the PLAN YOUR LIFESPAN tool to determine subject understanding of home care services, health trajectory, and other patient-centered outcomes.

5. Research Methods

Study Design

Relevant Specific Aim and related hypotheses:

Specific Aim: Conduct a Randomized Controlled Trial of the PLAN YOUR LIFESPAN tool to determine subject understanding of home care services, advanced health planning, and other patient-centered outcomes.

H_1: Compared to participants in the attention control group and controlling for baseline assessments, participants receiving the PLAN YOUR LIFESPAN tool will show increased planning with regard to implementation/behavior, perception, and intention (measured via the Planning Assessment tool) one (efficacy) and three (effect retention) months after intervention.

H_2: Compared to participants in the attention control group and controlling for baseline assessments, participants receiving the PLAN YOUR LIFESPAN tool will show increased confidence in accessing home services (measured via the Confidence in Accessing Home Services tool) one (efficacy) and three (effect retention) months after intervention.

H_3: Compared to participants in the attention control group and controlling for baseline assessments, participants receiving the PLAN YOUR LIFESPAN tool will show increased understanding of home services (measured via the Understanding of Home Services tool) one (efficacy) and three (effect retention) months after intervention.

H_4: Compared to participants in the attention control group and controlling for baseline assessments, participants receiving the PLAN YOUR LIFESPAN tool will be more likely to report

communicating their preferences about issues related to lifespan planning to people who may need to make decisions for them (measured via the Communication about Lifespan Planning Questionnaire) one (efficacy) and three (effect retention) months after study intervention.

H_5: Compared to participants in the attention control group, participants randomized to the intervention arm will report overall satisfaction with the intervention/attention control (measured via the Satisfaction with Intervention tool).

Primary and secondary endpoints

The primary endpoint for this study is planning behavior score (ranging from 5-25 points) at the one-month follow-up time point as measured by the "Planning Implementation (Behavior)" assessment. Analyses will control for baseline planning behavior score.

Secondary endpoints include (Analyses will control for relevant baseline assessment scores where appropriate):

(a) Planning Implementation behavior score at three-month follow-up time point (to measure effect retention).

(b) Planning perception score at all follow-up time points as measured by the "Planning Perception" assessment.

(c) Change in individual planning intention item scores at all follow-up time points compared to baseline as measured by the "Planning Intention" assessment.

(d) Confidence score at all follow-up time points as measured by the "Confidence in Accessing Home Services" assessment.

(e) Knowledge of home services score at all follow-up time points as measured by "Understanding of Home Services" assessment.

(f) Percentage showing increased communication with family/Power of Attorney (POA) and health providers at one- and three-month follow-up time points in comparison to baseline as measured by "Communication about Lifespan Planning Questionnaire" assessment.

(g) Score of overall satisfaction with the intervention tool or attention control as measured by the "Satisfaction with Intervention Tool" assessment at all follow-up time points for the participants in the intervention arm.

Type/design of the study: We will conduct a two-armed (attention control and intervention), randomized controlled trial. Individuals will be randomly assigned to one of two interventions: attention control or PLAN YOUR LIFESPAN tool via a pre-generated central randomization list using equal (1:1) allocation and random permuted block design to ensure relatively equal allocation throughout the study. Our attention control group will control for the possibility that regular contact with the study team may improve outcomes in participants randomized to the intervention website. Participants randomized to the attention control group will go through an educational website on activities relevant to seniors, for 15-45 minutes. The educational website is sponsored by the National Institute on Aging and does not include information about advanced planning.

Study interventions: If randomized to receive the PLAN YOUR LIFESPAN tool, subjects will be introduced to the PLAN YOUR LIFESPAN tool and given instructions on how to use it. The PLAN YOUR LIFESPAN tool is a Web-based planning tool that provides information for seniors related to advanced health planning for home services in specific content areas of: hospitalizations, falls, Alzheimer's, dementia, as

well as communicating with others. The PLAN YOUR LIFESPAN tool is also interactive in that it allows participants to enter their information and share it with others to facilitate conversations and decision-making: http://tool.planyourlifespan.org/. Participants will navigate and complete the Web-based PLAN YOUR LIFESPAN tool. They will be allotted a minimum of 15 minutes and a maximum of 45 minutes to navigate the tool as part of the study. We anticipate that subjects may ask questions either relevant or irrelevant to the study while going through the website. RAs will be present to assist with questions as needed. RAs may guide subjects on navigation but will not be able to assist with decision making. Interactions with subjects while they proceed through the study intervention will be noted. After completing the PLAN YOUR LIFESPAN tool, the participant will be given the post-tool survey.

Participants in the attention control arm will navigate an electronic educational session via a National Institute on Aging at NIH Web site about physical activity and exercise as it is a topic of interest to seniors. A minimum of 15 minutes and a maximum of 45 minutes will be allotted for navigating the Web site. The Web site is interactive and comparable to the intervention tool: http://go4life.nia.nih.gov/get-started).

Pilot-testing Study Implementation: Prior to beginning data collection for the randomized, controlled study, we will conduct a pilot test to ensure that systems are working properly and to obtain feedback from participants. The pilot test will evaluate the success of the randomization process, confirm estimates of interview duration, and verify comprehension of the interview. Research Assistants will run through the research protocol with a total of 15 participants from the Chicago-based sites.

Expected duration of subject participation: The total duration of the study for each participant will be at least six months given the initial baseline, 1 and 3-month follow up. The additional follow-up will include those participants who have been enrolled in the study for at least 6 months and agree to participate in one additional study survey. We anticipate in-person study contact time for the subjects in the randomized, controlled trial to last approximately 60-110 minutes (note: range in contact time since participants can spend a minimum of 15 minutes on the Web-based tool and a maximum of 45 minutes). Phone study contact time for the subjects will last approximately 45 minutes. The screening interview conducted over the phone will last approximately 10-15 minutes and one- and three-month follow-up telephone calls will have an expected duration of an additional 15 minutes for each follow-up call, for an additional 45 minutes of contact time. The additional 6+month follow-up will take up to 20 minutes over the phone. Therefore, total expected study contact time of subject participation (in-person and phone) will range from 120-155 minutes.

Stopping rules or discontinuation criteria: N/A

Financial Compensation: Study participants will be compensated for their time with gift cards. After completing the in-person baseline survey, participants will receive a $50 gift card. Chicago-land participants will specifically receive a gift card to Target which can be used on-line or in-store while our more rural sites (e.g. Houston, TX and Fort Wayne, IN) will receive Walmart gift cards which can be used in-store or on-line. Participants will then receive an additional $25 gift card upon completion of each of the follow-up surveys at 1,3-months, and 6+ months after the in-person baseline interview. Gift cards will be mailed to participants. For example, a participant that completes all 4 study surveys; the in-person baseline, 1-month3-month, and 6+ month phone calls will receive a total of $125 in gift cards.

6. Site Information
The study sites are as follows:

1. Northwestern Medical Faculty Foundation Geriatrics (NMFF) clinic; Chicago, IL
2. University of Chicago Outpatient Senior Health Center at South Shore; Chicago, IL
3. Lincoln Park Village; Chicago, IL
4. Skyline Village; Chicago, IL
5. Aging and In-Home Services of Northeast Indiana (AIHS); Fort Wayne, IN and surrounding counties
6. Aging in Place/Centre County; State College, PA (part of Village to Village Network)

Table 1. Names, responsibilities, and qualifications of those responsible for the conduct of the study, by site

Team Member	Institution	Expertise	Contribution/Responsibilities
Lee A Lindquist/PI	NMFF Geriatrics	Geriatrics, home caregivers, cognitive decline, health literacy	Study coordination/oversight of senior recruitment.
Huisingh-Scheetz/Co-I	University of Chicago Outpatient Senior Health Center at South Shore	Geriatrics, functional decline, social support of seniors	Assist with recruitment of seniors. Study coordination/oversight of senior recruitment and optimization of study design.
Phyllis Mitzen/Co-I	Skyline Village	Senior Citizen, Patient, Retired Social worker, Community Engagement	Study coordination/oversight of senior recruitment.
Dianne Campbell/Co-I	Lincoln Park Village	Senior Citizen, Patient, Community Engagement, Dissemination to Community groups	Study coordination/oversight of senior recruitment.
	Village to Village Network		
Chris Forcucci/ Co-I	AIHS	Area Agency on Aging, Home Nursing, Home Care Needs of Seniors, Community Engagement	Study coordination and oversight of Rural Indiana senior recruitment.

7. Village to Village Network sites
8. Mamie George Community Center, Houston, TX
9. Hyde Park Village, Chicago, IL

    a. Number of subjects to be enrolled: the total number of participants approved to participate in this study is 1110. The number of subject to be enrolled at each site is unable to be determined given the differences in size of the sites. We expect to recruit between 10-200 subjects at each site.

    b. Names, responsibilities, and qualifications of the individuals responsible for the conduct of the research study at each site:

    c. While Northwestern University and University of Chicago both have IRBs, the other sites do not. They have agreed to the process through their local boards and leadership as well as recognizing the Northwestern IRB.

7. Organizational Structure:

As this study is not high risk, there will not be a Data Safety Monitoring Board (DSMB). The Principal Investigator (PI), Dr. Lee Lindquist, will serve as the local study monitor. Project coordinators at Northwestern University will keep track of: number of subjects screened and enrolled (via enrollment table), subjects lost to follow-up, and quality of data collection and will share this information with the PI and other staff members during the weekly PLAN YOUR LIFESPAN project meeting.

All site Study Coordinators will ensure data entry and transmittal to the principle site (Chicago) on a weekly basis, and study staff at the principle site will review the study data on a weekly basis to ensure quality data collection. The Project Coordinators will also maintain weekly phone calls and

perform site-visits and continual training on an as needed basis with other site Research Assistants to monitor data collection and fidelity to study protocol.

8. **Project timeline:** Anticipated timeline for start-up of the study, completion of subject enrollment, data analysis and follow-up of subjects.

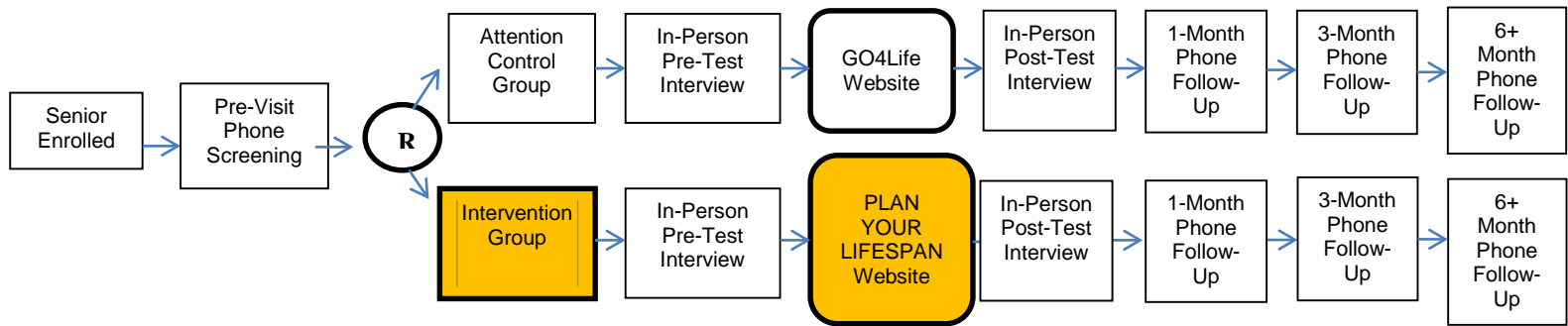Figure 1. Timeline of Randomized Controlled Trial for Study Subjects

Table 2. Process Measures & Outcomes, by Time Point & Condition

Process Measures & Outcomes	Pre-Baseline (Phone)		Baseline (In-Person)		Immediately Post-Tool (In-Person)		1 month (Phone)		3 month (Phone)		6+ month (Phone)	
	I	A/C	I	A/C	I	A/C	I	A/C	I	A/C	I	A/C
Recruitment Phone Script	x											
Informed Consent			x									x
Planning Assessment			x		x		x		x		x	
Understanding of Home Services			x		x		x		x			
Confidence in Accessing Home Services			x		x		x		x		x	
Communication About Living Preferences			x				x		x		x	
Satisfaction with Intervention Tool					x	x	x	x	x	x	x	x
Current Utilization of Services			x									
Physical Function Assessment (IADLs)			x									
Co-Morbidities			x									
Social Support (LSNS-6)			x									
Health Literacy (REALM-SF)			x									
Self-Efficacy (General Self Efficacy)			x									
Sociodemographics			x									

Table 3. Overall Project Timeline

	YEAR 1				YEAR 2*				YEAR 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Development of PLAN YOUR LIFESPAN Tool				▓								
Pilot Testing Results and Finalized PLAN YOUR LIFESPAN Tool Deliverable Submitted to PCORI						▓						
Randomized Controlled Trial												
Refine Protocol						▓						
Obtain IRB approval*						▓						
Further Training of Research Assistants						▓						
Enrollment of Subjects							▓	▓	▓			
Follow-up of Subjects							▓	▓	▓			
Data Entry and Analysis								▓	▓	▓		
Results of PLAN YOUR LIFESPAN Tool RCT Deliverable Submitted to PCORI										▓		

*At the time of IRB submission

9. **Education:** All three Research Assistants collecting data will be trained to use Research Electronic Data Capture (REDCap) which will serve as the data collection tool[45]. Collaborating site Research Assistants will also receive extensive training on the study protocol, how to administer study instruments, as well as how to collect quality data. Practice interviews among the Research Assistants will also be conducted in conjunction with the study PI and co-Investigators to run through the protocol and obtain feedback. In addition to in-person training before the start of study recruitment, all Research Assistants will have continual training and feedback on data collection via in-person meetings, weekly phone calls, and electronic correspondence. The pilot-testing of the trial will also present an opportunity for additional training on data collection and protocol as well as study processes.

10. **Inclusion/Exclusion Criteria:**

Inclusion criteria:
  o Adults age 65 and older
  o English-speaking
  o Score ≥ 4 questions correctly on the Brief Cognitive Screen

Exclusion criteria:
  o Less than age 65
  o Non English-speaking
  o Participated in PLAN YOUR LIFESPAN tool focus groups or pilot study*
  o Score < 4 questions correctly on the Brief Cognitive Screen

*Note that the inclusion/exclusion criteria for the pilot study will be identical to those listed here with the exception of this exclusion criterion.

11. **Sample Protocol and Informed Consent Documents:** Key stakeholders from each collaborating site were actively engaged in drafting the components of the initial protocol to ensure representation and approval. As changes are made to protocol, this information will be shared with them via bi-weekly phone meetings, email correspondence as well as in-person meetings. Informed consent documents

will be distributed to each collaborating site for their review and approval by their IRB/ethics committee for input.

First, a phone script introducing the study and administering the brief screener will be administered. If they are eligible, then they will be scheduled for the in-person study interview. Therefore, if a participant is deemed ineligible based on the phone script, they will not receive information about the in-person study survey. Informed consent will be administered to all participants during the in-person baseline interview.

For the extended 6+month follow-up survey, we will mail out a recruitment letter to enrolled study participants. They will have the option to "opt out" from participating in one more additional study phone survey at least 6-months after completing their baseline interview or to agree to complete this additional survey. Verbal consent will be administered to all participants that are interested in completing the additional 6+ month phone survey. Therefore, all participants enrolled in the study will have completed an in-person informed consent and some may additionally have a verbal consent form if they choose to complete the additional 6+ month survey which was later added on.

12. **Study Drugs:** N/A

13. **Study Devices:** N/A

14. **Case Report Forms:** All study sites will receive hard copies of clear, concise, case report forms (CRFs) and all relevant study documents for recording of required subject data. Subject study data include: eligibility, demographic and other baseline data, and all assessment data listed in Table 2. Research Electronic Data Capture (REDCap) will be used to develop electronic case report forms (eCRFs) as well as for study data collection.

15. **Data Transmission, Storage and Analysis:** Study data will be collected and managed using REDCap electronic data capture tools hosted at Northwestern University. REDCap is a secure, Web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Data Collection and Transmission: All three Research Assistants will have the same model computers and relevant training in REDCap software to be used for data collection and entry. All site study coordinators will ensure data entry and transmittal to the principle site (Chicago) on a weekly basis and study staff at the principle site will review the study data on a weekly basis to ensure quality data collection. Data files will be encrypted for security purposes). The study statistician and Dr. Lindquist (PI) will oversee the coordination of data collection between all study sites and provide feedback to each site to maintain harmonization.

Analysis:
This section outlines the general statistical analysis plan for this study; however, prior to export of data for any interim analyses, a formal stand-alone Statistical Analysis Plan (SAP) document will be finalized. The SAP will detail plans for handling data irregularities (e.g., outlying values, missing data) along with any exploratory analyses. Any modifications to the statistical analyses will be documented in an amendment to the SAP rather than the study protocol.

The primary endpoint for this study is planning behavior score (ranging from 5-25 points) at one month post-intervention/attention control as measured by the "Planning Implementation (Behavior)" assessment. Primary endpoint analyses will consist of an analysis of covariance (ANCOVA) comparing mean planning behavior score at one month post-intervention/attention control while controlling for baseline planning behavior score. All analyses will assume a type I error rate of 5%.

Additional, secondary analyses will compare baseline variables (current utilization of services, physical function assessment, co-morbidities, social support, health literacy, self-efficacy, and sociodemographics)

with outcome (one-at-a-time). Those found to have a significant association with outcome will be included in an overall maximal model for primary outcome. A backward stepwise model building procedure will be used to determine an overall parsimonious model for planning behavior score at one month.

Additional, exploratory analyses will consist of building a linear mixed model (LMM) for primary outcome with fixed intervention and covariate effects and random site, intercept, and slope (time) effects. A similar backward stepwise selection model building procedure will be used to construct a final mixed parsimonious model.

The following secondary endpoints will be analyzed similarly:

1. Planning behavior score at the three-month follow-up time point (in order to measure effect retention).

2. Planning perception score at all follow-up time points as measured by the "Planning Perception" assessment.

3. Confidence score at all follow-up time points as measured by the "Confidence in Accessing Home Services" assessment.

4. Knowledge of home services score at all follow-up time points as measured by "Understanding of Home Services" assessment.

5. Overall satisfaction with the intervention or attention control as measured by the "Satisfaction with Intervention Tool."

Individual items on the "Planning Intention" assessment tool will only be asked of participants who express lack of behavioral planning (i.e., a score of 1-3 on the corresponding item on the "Planning Behavior" assessment tool). Thus, a subset of the study data will be analyzed with respect to these items. Changes in scores between baseline and all follow-up time points for individual items on "Planning Intention" assessment will be analyzed via a series of Wilcoxon Rank-Sum tests.

We will use a two-sample test for binomial proportions to compare the percentage of participants showing an increase in communication with family/Power of Attorney (POA) and health providers (as measured by "Communication about Lifespan Planning Questionnaire" assessment) across arms at the one- and three-month follow-up time points. A backward stepwise selection approach similar to that above will be used to build an overall model for this outcome using a generalized linear (mixed) model with logit link.

Interim Analysis:
We will plan for a single interim analysis for primary outcome after enrollment and one-month follow-up of approximately half (300) of the target sample size. We will use an O'Brien-Fleming type alpha spending function[51], and if the calculated test statistic at the interim analysis surpasses the required threshold (associated with roughly 0.5% level of significance) according to the O'Brien-Fleming criterion, we will consider early termination of the study for overwhelming efficacy or harm (i.e., if the intervention appears to influence planning behavior in an overall overwhelming positive *or* overwhelming negative direction). Since we anticipate a single interim analysis, we will adjust final primary outcome analysis significance level to approximately 4.5% (note that the final adjustment will depend on the actual calculated type I error "spent" at the interim analysis such that the overall type I error rate remains at 5%).

Sample size considerations:
Without prior knowledge of the distributional properties of the primary outcome ("Planning Implementation Behavior" score, ranging from 5-25), we can use Cohen's *d* to estimate the detectable effect size given the predicted accrual[46]. With an overall recruitment goal of 600 subjects and an 85% retention rate (i.e., 510 study completers with 255 in each arm), we anticipate being able to detect a small to moderate effect size (0.25) with 80% power, assuming a 5% type I error rate.

16. Study Parameters:

We will use established thresholds to categorize some of the study parameters:
   a. Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF)[47]: scores range from 0-7.
   b. Lubben Social Network Scale-6[49] (LSNS-6): The LSNS-6 total score is an equally weighted sum of these six items. Scores range from 0 to 30.
   c. General Self-Efficacy[50]: 17-item survey, 5-point Likert scale.

We will also use a series of assessments we have created to measure the processes and outcomes we are seeking as there were no validated instruments available to use. We will use the following assessments:
   d. Planning Assessment: 15-item, 5-point Likert scale. Score ranges from 5-25.
   e. Understanding of Home Services: 6-item, multiple-choice survey.
   f. Confidence in Accessing Home Services: 5-item survey, 5-point Likert scale.
   g. Current Utilization of Services: 6-item survey with dichotomous and multiple response items.
   h. Communication About Living Preferences: 3-item, multiple choice and multiple response.
   i. Satisfaction with PLAN YOUR LIFESPAN tool: 10-item survey, 5-point Likert scale.
   j. Sociodemographics: 16-item survey with dichotomous, multiple response, and open-ended items.
   k. Comorbidities: 9-item dichotomous response items used to assess burden of disease in study participants.
   l. Modified Instrumental Activities of Daily Living Scale: 8-item scale measuring how much difficulty participants have doing various activities. Measured with 4-point Likert scale.

17. **Anticipated Benefits:** Subjects are not likely to have any direct benefit from being in this research study. Subject might experience the indirect benefit of being involved in research to help other seniors.

18. **Anticipated Risks:** Minimal risk. There is a slight risk that some of the questions might cause some emotional discomfort to subject. There is also a slight risk that the subject may get tired during the tasks. However, we do not expect subject to endure any physical or emotional risk beyond that of everyday life.

19. **Adverse Event Management:** While we do not anticipate any adverse events, they will be reported to the lead coordinating center by the Research Assistants and relayed to the Project Investigator.

20. **Central Data and Safety Monitoring Plan:** The entire research team including stakeholder representatives will meet by conference call at least bi-monthly and in-person monthly to discuss logistical issues, study recruitment, data collection and other issues pertaining to the study. Dr. Lindquist and the Project Coordinators will visit all sites regularly during all stages of the study. Weekly team meetings will take place in-person at the lead coordinating site and a weekly team meeting (Project Coordinators, Research Assistant, and PI) will take place over the phone with all collaborating study sites.

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