PROTOCOL TITLE:

Decision Making & Implementation of Aging-in-Place/LTC Plans among Older Adults

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1.0 Purpose of the study:

The purpose of this study is to better understand how older adult aging-in-place (AIP) decision making and implementation is impacted by age-related changes (e.g. cognition, function, chronic condition) and social influences. The specific aims of this study are:

Aim 1: Determine how decision making and planning for aging-in-place is impacted by older adults' age-related changes (e.g. function, cognition, multi-chronic conditions) and social influences (e.g. adult offspring, spouses, friends).
Aim 2. Examine contemplation of decision making, rates of existing service utilization, pre-existing attitudes and their potential for influence on older adult age-related changes and social influences in decision making for aging-in-place choices.
Exploratory Aim 3. Assess whether decision making and planning for aging-in-place translates into timely adoption and goal concordance for older adults and their surrogate/caregiver decision makers.

2.0 Background / Literature Review / Rationale for the study:

Remaining in one's own home is a priority for many older adults. Decision making and planning is critical to ensure successful aging-in-place. The most important decision that many adults navigate is how to balance age-related changes (e.g. worsening cognition, increasing disability) with their needs. Although a great number of seniors will need support, prior research has shown that seniors may dismiss planning for their home support needs outright (e.g. I plan to die in my sleep before I ever need help). The majority of seniors do not want to leave their home and yet very few people plan for their home-based needs that they will require to age-in-place safely. Through our previously PCORI-funded research, we developed a tool, PlanYourLifespan.org (PYL), which facilitates making decisions and planning to AIP. Through education about future health and home-based needs as well as access to these resources, older adults can make choices and share them with loved ones for their future needs. PYL was tested in a multi-site randomized controlled trial of 385 community-dwelling older adults with 3-month follow-up and found to be significantly efficacious in improving decision making behaviors towards aging-in-place options among older adults. With a 3-month follow-up, we were limited in determining how these decision making plans of older adults translated into goal concordance towards AIP. A gap exists in how decision making for AIP is impacted by older adults' age-related changes, social factors, and environments. How these plans translate into timely adoption as well as the impact that loved ones have on goal concordance has also been unexplored. This study aims to close these gaps in knowledge.

3.0 Inclusion and Exclusion Criteria:

We will be offering the opportunity to participate in this study to the approximately 700 older adults who are currently enrolled in the LitCog study (STU00026255).

Inclusion criteria:

1. Be an active participant in the LitCog Trial (e.g. completion of T4 stage)

2. ≥ 55 years old*
3. English speaking*
4. Currently use a computer or tablet with internet
   *Note: these are already inclusion criteria of the LitCog Trial therefore we will not be re-assessing these criterion for our study

Exclusion criteria:

1. Previous participation in the Advanced Planning for Home Services (PlanYourLifespan.org) research (STU00080333). **Note:** this will be assessed by the study team and not self-reported by participant to ensure accuracy.

4.0 Sample Size:

We plan on recruiting and enrolling a total 700 participants for this study. This sample size was determined given power calculations that will allow us to detect significance of our study outcomes.

5.0 Research Locations:

Participants will complete in-person research activities (written consent, baseline survey, intervention completion, and post-intervention survey) in research space available at the NMHC and Access Community Health Network (ACCESS) locations. Study follow-up surveys will take place over the phone.

ACCESS is a Public Health Service 330-funded network of community health centers, also known as Federally Qualified Health Centers (FQHCs). The LitCog study is linked to six ACCESS community health centers, however study participants will be able to complete the in-person study interview at only one of two ACCESS locations. Staff who are employed by ACCESS Community Health Network will not be involved in any aspect of recruitment, consent, data collection, and/or data analysis for this study. ACCESS will only provide space for the in-person interview (if needed) and all consent & data collection procedures will be done by NU personnel if a participant wants to do the first study visit at an ACCESS location. All required permissions and/or approvals will be obtained at each research location prior to project implementation and submitted to the IRB.

6.0 Multiple sites:

Northwestern Medicine Division of General Internal Medicine and Geriatrics (GIM-GER) at the Feinberg School of Medicine will take the lead in collecting and storing the study data captured across this study in Aims 1, 2, and 3. Protocols, consent documents, and all data collection instruments will be disseminated to all study staff to ensure that everyone has the most up to date versions.

7.0 Reliance Agreements/Single IRB:

N/A

8.0 Procedures Involved:

Currently enrolled LitCog study participants (STU00026255) who have completed either T4 or T5 of that study will be invited to participate in this new, longitudinal, observational study. Interested participants who meet the study criteria will schedule a time for the in-person interview which will occur in research space available at the NMHC or the ACCESS locations, whichever is preferred by the participant and available to the study.

At the in-person study visit, participants will provide written informed consent using procedures approved by the Institutional Review Board of Northwestern University. Research staff will then administer a baseline study survey. Next, research staff will introduce subjects to the intervention, the PlanYourLifespan.org website, and provide instructions on its use. Research staff will be present to assist with questions as needed on navigation but will not assist with decision making or any content-related questions. A minimum of 15 minutes and a maximum of 45 minutes will be allotted for navigating the website. After completing the time allotted on PlanYourLifespan.org, subjects will administer an immediate post-test survey.

There will be a total of 8 follow-up surveys. Research staff will contact participants to complete a follow-up survey one month after the in-person interview, and then every six months thereafter. Follow-up surveys will be administered over the phone by research staff.

A maximum of five phone calls and two voice mail messages will be left for study participants. If after five phone call attempts have been made and the participant is not able to be reached, they will be considered 'unable to reach' for that time-point. Study coordinators will continue to reach out to study participants for the subsequent follow-up surveys. All follow-up phone surveys will have a target completion of at most 4 weeks from the scheduled follow-up interval.

The anticipated duration of this study is 42 months, or 3.5 years, from the time of consent to the completion of the final, follow-up study survey. Study participants will not be engaged in the study during that entire period.

Time (months)	**0**	**1**	**6**	**12**	**18**	**24**	**30**	**36**	**42**
Survey Modality	In-person pre and post-test	Phone	Phone	Phone	Phone	Phone	Phone	Phone	Phone

The in-person meeting which will include the written consent (10 mins), baseline survey (30 mins), navigation of PlanYourLifespan.org (min: 15 minutes, max: 45 minutes), and

completion of the post-intervention survey (15 mins) is expected to take between 70 minutes and 100 minutes of the subject's in-person time. Each follow-up survey is expected to take 15 minutes to complete, and with 8 planned follow-up surveys, they may collectively take participants up to 120 minutes, or approximately 2 hours to complete. These 15-minute follow-up surveys will be spaced out over 6-month periods. Therefore the total time of participation if all study components are completed is estimated to be between 190 – 220 minutes (approximately 3-3.5 hours).

Study data will come from multiple sources and includes (1) self-reported data by the study participant, (2) data that has been previously collected from the study participants from their participation in the LitCog study (e.g. cognition data), and (3) retrieving data from the participant's electronic health record. All of the electronic health records data we plan to analyze from this study will already be collected for the LitCog study. No additional electronic health records data will be accessed for this study.

We will collect a wide range of measurements such as process outcomes, cognition variables, functional and health variables, and social/environmental variables. Additionally we will collect sociodemographic variables, such as race and ethnicity, an assessment of PlanYourLifespan.org, and timing and goal concordance. The table below illustrates the measures/data that will be collected in this study. Data collection materials for each time point are submitted with this application.

	MEASURES	DETAILS	LITCOG Collected
PROCESS OUTCOMES			
Previous Health Experiences: Self & Others	Participant's past health experiences with self, others.	Non-validated binary & open-ended questions.	
Contemplation: Hospitalizations	Participant's thoughts about issues related to hospitalizations	Non-validated, Likert scale. Modified ACP questions.	
Decision-Making: Hospitalizations	Decision making specifically related to hospitalizations	Non-validated, open-ended	
Healthcare Utilization	Hospitalization + Rehabilitation; Emergency Department Visit; Urgent care visits (RUI); Medical Supplies (RUI); Physical therapy/occupational therapy (RUI); Long Term Care Facility Use	individual items, Sano, 2006	X
Contemplation: AD & Memory Loss	Participant's thoughts about issues related to AD & memory loss.	Non-validated, Likert scale. Modified ACP questions.	
Decision-Making: AD & Memory Loss	Decision making specifically related to AD & memory loss. Primary Outcome at 36 Months.	Non-validated binary & open-ended questions	
Website Satisfaction Assessment	Perception of the PYL program, satisfaction, usage.	Likert Scale and non-validated binary questions	
AGE-RELATED CHANGES - COGNITIVE VARIABLES			
General Cognition	Mini-Mental State Exam	Folstein, 1975	X
Processing Speed	Digit Comparison	Salthouse, 1992	X
Working Memory	Size Judgement Span	Cherry, 1993	X
Inductive Reasoning	ETS Letter Sets	ETS, 1976	X
Long Term Memory	New York Paragraph	Kluger, 1999	X
Verbal Ability	AM-NART	Grober, 1991	X

Health Literacy	Newest Vital Sign (NVS) Rapid Estimate of Literacy in Medicine (REALM)	Weiss, 2005, Davis, 1993	X
AGE- RELATED CHANGES – FUNCTIONAL and HEALTH VARIABLES			
Physical Function	PROMIS (Physical Function - Short Form 10a)	Cella, 2010	X
Psychological Factors	CHAI	Condon, 2016	X
Health Status	Chronic Conditions	individual items	X
	Depression (PROMIS Depression - Short Form 8b) Anxiety; PROMIS (Anxiety - Short Form 7a)	Cella, 2010[158]	X
Medication	Prescription Medications	chart review	X
	Number of Prescription Medications	individual item	X
Risk Behaviors	Smoking Status (Current, Former, Never),	individual item, BRFSS Block, 2000	X
Self-Manage Skills	Comprehensive Activities Scale (CHAS)	Curtis, 2015	X
SOCIAL and ENVIRONMENTAL VARIABLES			
Social Support	Lubben Social Network Scale; Social Support – Tangible;	Lubben 2006[159]; Woloshin, 1997	X
General Self-Efficacy	PROMIS: General Self-Efficacy		
Self-Efficacy for Managing Social Interactions	PROMIS: Self-Efficacy for Managing Social Interactions	PROMIS Short Form 4a	
Environmental Demands	Busyness and Routine Scale	Martin 2003	X
Prior Advanced Care Planning & Perception of Needs	Living Will, Power of Attorney	individual item	

Statistical Analyses

Statistical analyses will be carried out by the statistical analysts in SAS 9.4 PROC GLIMMIX. For **Aim 1** we will model the association between decision making and planning for aging-in-place (= outcome) and the predictors age-related changes (e.g. cognition, health literacy, multi-chronic conditions) and social influences (e.g. adult offspring, spouses) using generalized linear mixed-effects regression models (GLMM) over the time period of 0-36 months post-baseline. This model allows us to incorporate outcome variables that are continuous, dichotomous, and other types such as count, ordinal, and nominal variables. GLMM are well fit for modeling longitudinal data by allowing us to incorporate random effects, which account for repeated measurements on participants over multiple time points. Additionally, the model uses all available data; not requiring all participants to have complete data.

Structural Equation Modeling (SEM) will be performed to model relationships between cognitive function, health literacy, self-management skills, and aging-in-place outcomes (decision making, implementation, goal concordance) along with various mediating and/or moderating variables. SEM is an analytical technique in which a hypothetical model specifies the anticipated relationships between a series of constructs based on theory. Several statistical techniques (eg, confirmatory factor analysis, path analysis, regression) may also be seen as special cases of SEM methods. SEM follows 5 steps: 1) model specification, 2) model identification, 3) estimation of the model, 4) testing model fit, 5) re-specification, if needed. It is particularly useful when observed variables contain measurement error, are interdependent, and when potentially important explanatory variables (e.g. explicit resource knowledge, experiences) are not included in a model. Each of these cases applies to our models. In addition to allowing for comparisons of relative values of direct pathways within a model, SEM provides an explication of total effects of each factor on outcome variables by including information about indirect/direct effects of each exogenous and mediating variable on the outcomes. We predict that latent constructs of health literacy, self-management skills, and usage of PlanYourLifespan.org will mediate relationships between cognitive function and aging-in-place outcomes. In addition, treatment burden, social support, patient activation, and personality will moderate these associations. We are proposing to model change in these latent constructs over the 42 months in a multi-wave model. At each time point, we will model the mean level as well as the change (slope) in level of the latent variables. Growth curve parameters will be modeled similarly across all sets of constructs.

9.0 Incomplete Disclosure or Deception:

N/A

10.0 Recruitment Methods:

Participants who are currently enrolled in the LitCog observational study [R01AG03611, PI: Wolf], (STU00026255) and have completed either time point 4 (T4) or time point 5 (T5) of that study will be offered the opportunity to participate in this study. There are currently over 700 older adults who are currently enrolled in the LitCog study.

Research coordinators will reach out to LitCog study participants who have completed T4 by first mailing an introduction letter summarizing a new research study opportunity to their home address on file. LitCog T4 participants that have completed this time point within the past year will be prioritized for recruitment.

Approximately 7-10 days after the letters are mailed, a research coordinator will place a phone call to participants that did not opt out of being contacted for this new study upon receiving the letter. Research staff will 1) explain the study further; 2) confirm participant's study eligibility; and 3) arrange an appointment for the in-person study visit. If requested, transportation arrangements to the in-person interview will be made at this time.

LitCog study participants that have completed T5 will be introduced to the study in-person on the day they complete their Day 2 survey for that study. Participants will be given a study flyer with additional study and contact information. Participants that express interest in learning more about the study will then be contacted over the phone by a research coordinator within 7-10 days to 1) explain the study further; 2) confirm their study eligibility; and 3) arrange an appointment for the in-person study visit. If requested, transportation arrangements to the in-person interview will be made at this time.

A maximum of five phone calls and two voice mail messages will be left for potential study participants. If after five phone call attempts have been made and the participant is not able to be reached, they will be considered 'unable to reach'.

Written informed consent will be obtained in-person from all study participants immediately before commencing the interview. All recruitment material will include the study IRB and contact information for the study PI and study manager at Northwestern University.

11.0 Consent Process:

At the in-person study visit, subjects will provide written informed consent using procedures approved by the Institutional Review Board of Northwestern University. The research study coordinators will go over the informed consent with participants and answer any questions they may have. We anticipate the consent process to take approximately 10 minutes as all of the study participants have already consented and participated in at least one Northwestern IRB approved study (LitCog) and consequently will be somewhat familiar with the process.

In order to ensure that participants fully understand the study and procedures, an individual's consent capacity will be assessed by discussing the proposed study and then asking specific questions requiring descriptive answers. For example: *Can you tell me the purpose of this study? Do you have to be in this study? Can you tell me what will happen if you agree to take part in this study? How might this study help or not help you? What will happen if you decide not to be in the study?* If a participant correctly responds to these questions, they are deemed able to provide informed consent.

All participants will be given a copy of the signed consent form to keep for their records; the original will be kept on file at Northwestern University by the study team and also documented on the Study Tracker (formerly eNOTIS). Our study consent will require HIPAA Authorization given the electronic health record data collection and use of the LitCog data. The HIPAA Authorization language will be included in the consent form.

12.0 Financial Compensation:

Participants will be compensated for their time and participation. Participants will receive $100 in cash for completing all of the in-person interview activities. If a participant is only able to complete the in-person interview partially, they will be compensated in the

following manner: $25 for the pre-test survey, $50 for the PlanYourLifespan.org intervention completion, and $25 for the post-intervention survey. Participants who do not complete the intervention and/or the post-intervention survey will not be eligible for completion of the phone follow-up surveys and that will mark the end of their participation in the study.

Participants will also be compensated for the completion of the follow-up phone surveys. Participants will receive a $50 Target gift card for the completion of each follow-up phone survey. There will be a maximum of 8 follow-up phone surveys (month 1 – month 42), for a maximum total of $400 in Target gift cards during the follow-up period. Target gift cards will be used to compensate participants for the completion of phone follow-up surveys since the compensation will be mailed to study participants and we are unable to safely mail cash. The distribution of the financial compensation is specified below:

	Day of Intervention			**Follow-Up Survey Months**								**TOT**
	Baseline Survey	Intervention Completion	Post-PYL Survey	**1**	**6**	**12**	**18**	**24**	**30**	**36**	**42**	
Subject	$25	$50	$25	$50	$50	$50	$50	$50	$50	$50	$50	$500
Cash	x	x	x									$100
Gift Card				x	x	x	x	x	x	x	x	$400

Participants will only be compensated for the research activities they compete. Therefore, if a participant completes all three parts of the in-person interview, and all 8 follow-up surveys, they will receive a maximum compensation of $100 in cash and $400 in Target gift cards. If they miss any of the phone follow-up surveys, they will not receive a gift card for those surveys. If a participant withdraws from the study, they will only receive compensation for the surveys they complete.

Participants who communicate to study coordinators that they would like to participate in the study but need transportation to/from the in-person interview will be reimbursed for travel. Participants that take public transportation will be reimbursed $5 in cash. If a participant cannot access public transportation, they may be offered assistance by the study coordinators, depending on how far the participant lives. The coordinators will help to arrange for transport using ground transportation such as an Uber Health Ride or a pre-paid cab via Curb. Participants that need wheelchair accessible vehicles and use PACE to get to/from the study will be reimbursed the cost of their PACE ride. The cost of this transportation will be incurred by the research study, not the study participant.

13.0 Audio/Video Recording/Photography

N/A

14.0 Potential Benefits to Participants:

Participants in this study may experience a direct benefit from being exposed to the intervention, PlanYourLifespan.org. As a result of being exposed to this resource,

participants may increase their knowledge of home-based resources and aging-in-place/long term care planning options.

15.0 Risks to Participants:

There are minimal risks to participation in this study. Some participants may face emotional discomfort in answering questions and thinking about their aging-in-place and long term care plans. During the consent process, participants will be informed that they may choose not to answer any question(s) they do not feel comfortable answering. They will also be informed that their involvement in the study is voluntary and they may withdraw from the study at any time.

We anticipate there may be special circumstances where a participant would be withdrawn from the research without their consent by the person in charge of the research study. Possible reasons for removal include having a stroke or other medical event that may make it too difficult for the participant to respond to the interviewers' questions and participate in study tasks. We will inform the participant about any new information that may affect their health, welfare, or choice to stay in the research study.

16.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

All subjects participating in any aspects of the research will be informed about their rights as research subjects and written informed consent will be obtained. Participants have the opportunity to cease participation at any time. Information from participants will not be linked to their name and will be assigned a unique identification number. The research database will be password protected and accessible only to the research team and the Institutional Review Board. Information linking participants with their unique identifier will be kept on a separate password-protected desktop computer in a locked office within an Administrative Suite in the Division of General Internal Medicine and Geriatrics, Northwestern University. These methods are compliant with the "Standards for Privacy of Individual Identifiable Health Information" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The research database will be password protected and accessible only to the research team and the Institutional Review Board.

Information linking subjects' names and contact information with their unique identified will be kept in a separate password protected file. Copies of the consent forms will be kept in a locked cabinet only accessible by the research team and a hard copy will be given to participants at the in-person workshop. Demographics collected for this study do not include any identifiable information. When demographics data is entered into the database, a de-identified subject number will be used to identify research subjects. No individuals will be identified in any presentations or publications resulting from this research with results being shared in aggregate.

17.0 Data Monitoring Plan to Ensure the Safety of Participants:

We have opted to develop a Data Safety and Monitoring Plan (DSMP) for this study in order to ensure the safety of participants and the integrity of the study. Adverse events (AEs) will be monitored by research staff overseen by the principal investigator. Clinical data content will be the primary area to be monitored and not the statistical analysis. We will review data at any point that any patient harm occurs. Any necessary action will be taken; we will work with the NU IRB to determine what action and reporting will be necessary, depending on the AE. Corrective actions will be put into place if needed (e.g., if a protocol violation were to take place). All privacy violations, protocol violations, and AEs will be reported to and reviewed by the PI (Lindquist), the research team, the IRB, as well as the study sponsor, the NIA.

18.0 Data, and if applicable, Specimen Banking:

Study data will come from several sources. Participant self-reported data will be collected electronically using laptop computers to record participant responses. We will use Research Electronic Data Capture (REDCap) Surveys software to facilitate data entry. REDCap allows for straightforward electronic entry of responses and can generate output data files compatible with statistical programs. This is the data collection modality used in the LitCog study.

Data that has already been collected from study participants for the LitCog study, in addition to data from the Electronic Health Record, will be exported and merged with the REDCap file. The consent form for this study will ask participants to re-consent to allow for access to the LitCog electronic health record data.

All aggregate study analyses will be done using SAS software.

All research staff will have undergone training in maintaining patient confidentiality and will have completed Collaborative Institutional Training Initiative (CITI) training in Human Subjects Research.

19.0 Data Sharing:

Data collected from this study will be accessed by NU staff, namely the study PI, Co-I, research manager, and research assistants. The responses will be assigned a unique passcode and de-identified and any information published and/or shared will be done so in aggregate.

20.0 Qualifications of Research Team to Conduct the Research:

The research team is comprised of investigators from Northwestern University Feinberg School of Medicine, led by Dr. Lee Lindquist, a geriatrician with extensive expertise in older adults, caregivers of seniors, and outpatient safety. Co-Investigator, Dr. Wolf, is a health services researcher and cognitive/behavioral scientist with a focus in adult learning and cognition. Dr. Wolf is the PI of the NIA-funded cohort study, LitCog, investigating the association between cognitive function, health literacy, and performance on everyday health tasks among older adults. The study has over 10 years of longitudinal

data collected on a large, diverse cohort of older, community dwelling adults. The research manager has previous experience in patient centered outcomes research, data collection, analysis and consenting of participants. The research assistants have worked with the LitCog cohort for several years and are skilled in obtaining informed consent, data collection, and participant retention and long-term follow-up. The study team leadership will ensure that everyone on the team is made aware of research protocols and everyone will be kept up to date if any changes are needed.