

Development of Measures to Screen for Financial Hardship in Alzheimer's Disease and Dementia

PROTOCOL Version 2.0

Conducted by Investigators at Fred Hutchinson Cancer Center
and participating accrual sites.

Dates of Study: 08-01-24 to 07-31-2029

<p><u>Principal Investigator</u> Salene MW Jones, PhD, MA Fred Hutchinson Cancer Center 1100 Fairview Ave. North, M4-B402 Seattle, WA 98109 (206) 667-6976</p> <p><u>Fred Hutch Collaborators</u> Laura Panattoni, PhD</p> <p><u>Partnering Institutions</u> Erin Kent, PhD, University of North Carolina Laura Samuel, PhD and Katherine Ornstein, PhD Johns Hopkins University</p>	<p><u>Funding Agency Collaborators</u></p>
---	---

Table of Contents

Study Summary3

Background/Significance.....3

Objectives6

Subject Population and Inclusion/Exclusion Criteria6

Recruitment Methods.....7

The Consent Process9

Study Procedures10

Endpoints and Measures10

Statistics and Rationale for Number of Subjects11

Risks and Benefits16

Data Management and Confidentiality16

Use of Data17

Provisions to Monitor Data and Protect Privacy17

Qualifications to Conduct Research and Resources Available.....17

Study Timeline18

Appendix 1: Consent Forms18

Appendix 2: Interview Guide18

Appendix 3: Measures (Survey)18

Appendix 4: Recruitment Materials and Screening Scripts.....18

Study Summary

Alzheimer's Disease and related dementias (AD/ADRD) are common and debilitating conditions. Financial hardship, a multidimensional construct of financial strain, financial stress and asset depletion, is common in AD/ADRD due to exorbitant out-of-pocket spending such as for long-term care, lower work productivity and income for their caregivers that can last for decades after disease onset, and difficulty deciding between nursing home care or home-based care while negotiating insurance coverage. People from historically marginalized groups can experience a double disparity with fewer financial resources to manage AD/ADRD and a greater risk of AD/ADRD. Screening for financial hardship in AD/ADRD is key for addressing the needs of patients and caregivers but critical barriers include a lack of suitable screening measures. Current measures are very general and meant for people without chronic medical conditions or are specific to other diseases. To fill this gap, this study will create a suite of measures that can screen for financial hardship in people with AD/ADRD and their families and caregivers. The measures will include a set to assess caregiver burden; a set to assess patient hardship as reported by the caregiver for patients who cannot report for themselves; and a set of patient-reported measures for patients that are able to report for themselves. To create these financial hardship screening measures, the project will conduct the following aims. Aim 1- Develop financial hardship screening measures for Alzheimer's Disease and related dementias: Using interviews with both caregivers and people with AD/ADRD, key indicators of financial hardship that are unique to AD/ADRD and the point in the lifespan in which it occurs will be identified. The ways that social and caregiver network size affect financial hardship will also be explored. Using the interviews and previous measures, preliminary measures will be created and will be reviewed by experts and a patient and caregiver advisory board. Aim 2- Create item response theory-based screening measures for financial hardship measures in Alzheimer's Disease and related dementias: Large samples of people with AD/ADRD (n=1000) and caregivers (n=1000) will be surveyed and item response theory will be used to evaluate and revise the measures and create scoring algorithms. A sample of additional caregivers matched to primary caregivers (n=400) will also be recruited to evaluate interrater reliability of the measures. Aim 3- Evaluate the financial hardship measures across patient and caregiver populations: Using the sample from Aim 2 and item response theory, we will evaluate the financial hardship screening measures across the following groups to ensure they are unbiased and reflect true differences: race/ethnicity; patient comorbidities; stage of AD/ADRD; caregiver relationship; social network size; number of caregivers; financial support provided; and caregiver's own health status (disability, comorbidities). The resulting measures will improve identification of financial hardship in AD/ADRD.

Background/Significance

Alzheimer's Disease and related dementias (AD/ADRD) are common and debilitating conditions, with an overall prevalence rate between 10% and 15% and an annual incidence rate of 2.3%.^{1,2,20} While the primary symptoms of AD/ADRD are cognitive changes, functional decline and behavioral symptoms, an additional important sequela is financial hardship given several challenges that arise with AD/ADRD. These challenges include exorbitant out-of-pocket spending such as for long-term care,²¹ lower work productivity and income for their caregivers that can last for decades after disease onset,^{22,23} and difficulty deciding between nursing home care or home-based care while negotiating insurance coverage.^{24,25} Financial hardship is a multidimensional construct consisting of financial strain, financial stress and asset depletion.³⁻⁵ Financial strain is the lack of ability to afford and difficulty affording living costs. Financial stress is experienced as worry and distress about

finances that affect functioning. Asset depletion occurs when the caregiver and their recipient drain resources such as savings accounts and durable assets and these assets may include drawing support from additional family members or friends. Caregivers of people with AD/ADRD often manage finances for the patient and experience financial hardship themselves through employment disruption, difficulty caring for their own health and incurring debt to help pay for the patient’s healthcare and living costs. This can lead to financial hardship for both the person with AD/ADRD and their caregivers.

Financial hardship in AD/ADRD can be particularly challenging for people from historically marginalized groups, such as racial and ethnic minoritized groups and those with disabilities, and may exacerbate chronic financial strain.⁶ As outlined in the National Institute on Aging’s Health Disparities Framework and the World Health Organization’s Social Determinants of Health Framework, fundamental factors such as race, ethnicity and disability status can predispose people to financial hardship due to institutional/structural racism, discrimination and lack of appropriate supports.^{6,26,27} As examples, the poverty rate is two or three times^{28,29} higher comparing either those with disabilities to those without or comparing those who are Black, Hispanic or Native American to those who are white and those who are Black have about one-tenth of the household wealth of those who are white.³⁰ People with AD/ADRD who are Black or Hispanic are also more likely to live with their adult children than people who are White and the adult children tend to provide caregiving.³¹ Importantly, these structural inequities create a double disparity with regard to AD/ADRD among those with limited financial resources; they are more likely to develop AD/ADRD but also have fewer resources to address AD/ADRD-related financial hardship.³²⁻³⁷ These health inequities highlight the need to ensure marginalized groups who experience AD/ADRD-related financial hardship are identified and provided appropriate financial aid.

Currently, suitable screening measures to identify financial hardship in AD/ADRD do not exist and this represents a **critical barrier** to addressing financial hardship and associated health inequities. Screening for financial hardship is a key part of health equity to ensure each patient and their family receive what they need to be as healthy as possible and many healthcare regulatory agencies are requiring some form of financial hardship screening.³⁸⁻⁴¹ Many well validated general measures of financial hardship exist^{7-13,42,43} as do some for specific clinical populations.¹⁴⁻¹⁶ However, these measures do not capture several unique aspects of AD/ADRD-related financial hardship. Financial management is often transferred to caregivers for people with AD/ADRD and this dynamic process is rarely captured in current financial hardship measures. Another unique aspect of financial hardship in AD/ADRD is the size and complexity of a patient’s network of caregivers involved in handling finances and paying bills.

Receiving financial support from family or friends may buffer against financial hardship most non-

Table 1: Measures that will be created as part of the proposed project

Set of Item banks	Person completing the measures	Person’s financial health being assessed	Financial Hardship Domains
1	Caregiver(s)	Caregiver	Financial stress; Financial strain; Asset depletion
2	Caregiver(s)	Person with AD/ADRD	Financial stress; Financial strain; Asset depletion
3	Person with AD/ADRD	Person with AD/ADRD	Financial function; Financial stress; Financial strain; Asset depletion

but

AD/ADRD measures do not account for level of financial support and larger social networks are not

necessarily protective.⁴⁴ Screening measures for each dimension of financial hardship are needed as some people with AD/ADRD and their caregivers may be able to cope but still experience financial stress and difficulty affording living costs.⁴⁵ The out-of-pocket costs from AD/ADRD can be high and long lasting, particularly due to the need to pay for in-home care to help manage daily activities and the need for the patient and caregiver to leave the labor force without the ability to return.

Current financial hardship screening measures would also present several logistical challenges for screening people with AD/ADRD and their caregivers for financial hardship. Many screeners are long (20+ items), putting an unnecessary burden on caregivers and patients and making clinic administration infeasible. Most current measures are also designed to be answered by the patient and have not been validated for use by caregivers to report on the patient's financial hardship. While patients with mild AD/ADRD might be able to report their own financial hardship, there is a persistent need for caregiver-reported measures of financial hardship for those with more severe disease as the caregiver and family members could report for the patient and are likely to experience hardship themselves.

Current Project

In response to RFA-AG-24-036 ("Measuring Financial Hardship Among People and Families Living with AD/ADRD"), the project will develop a measurement system that can screen for financial hardship in AD/ADRD across illness stages and variation in family involvement in care. The first measure will be a patient-reported measure of financial function, defined as how actively a patient is managing their finances. This also includes who may be managing finances for the patient. The next group of measures will include two sets of caregiver-reported outcome measures and one set of patient-reported measures to assess and screen for the three dimensions of financial hardship in AD/ADRD (Table 1). The financial function measure will help clinics identify whether the patient (set 3) or caregiver (set 2) should complete the financial hardship screening measure for the patient. The first set of caregiver-reported measures will assess the caregiver's own financial health as reported by the caregiver (set 1) and will be usable with multiple caregivers to capture financial hardship across members of families experiencing AD/ADRD. These measures will help identify caregivers who are themselves experiencing financial hardship and need extra support. The second set of caregiver-reported measures will assess the patient's financial health as reported by the caregiver (set 2). The second set of measures are often called observer-reported or informant-reported outcome measures and will be useful to screen people with AD/ADRD for financial hardship if the patient cannot report for themselves. The third set of measures (set 3) will assess the patient's financial health as reported by the patient for people with AD/ADRD who are able to report for themselves. Clinicians will be able to use the patient-reported measures to screen people with mild AD/ADRD who can report for themselves (set 3) and the caregiver-reported measures to screen people with AD/ADRD who cannot (set 2). Clinics with programs to assist caregivers can also use set 1 to screen caregivers. Patient and caregiver report do not always align with other data sources⁴⁶ and patients and caregivers might be reticent to share financial struggles unless directly asked.^{47,48} For this reason, we aim to create these ten measures to directly screen patients and caregivers for financial hardship.

We will use an innovative psychometric method, item response theory (IRT), to develop measures for each of the three financial hardship domains in each set and for the financial function measure for a total of ten measures. These measures, often called item banks, are collections of survey and questionnaire items that can be used in different combinations and administration methods. The measure development process will include interviews with caregivers of and people with AD/ADRD to identify indicators of financial hardship specific to AD/ADRD and the point in the lifespan in which it occurs. Feedback will be solicited from AD/ADRD experts on the initially

developed measures. We will then survey a large sample of people with AD/ADRD and caregivers of people with AD/ADRD to use IRT to create the final measures. We will survey multiple caregivers per patient and patient-caregiver pairs when possible to assess reliability across the item banks. Potential bias on the financial hardship measures will be assessed for the following factors: race, ethnicity, patient comorbidities, stage of AD/ADRD, pre-AD/ADRD socioeconomic status, caregiving relationship, size of social network, number of caregivers, financial support from the social network, and the caregiver's own health status. The result will be a suite of measures for screening for financial hardship in AD/ADRD that can be used across disease stage, caregiving relationships and different groups including historically marginalized populations.

Objectives

- Aim 1: Develop financial hardship screening measures for Alzheimer's Disease and related dementias
 - Aim 1a: Identify indicators of financial hardship in Alzheimer's Disease and related dementias.
 - Aim 1b: Refine item banks to measure financial hardship in Alzheimer's Disease and related dementias.
- Aim 2: Create item response theory-based screening measures for financial hardship in Alzheimer's Disease and related dementias.
- Aim 3: Evaluate the financial hardship measures across patient and caregiver populations.

Subject Population and Inclusion/Exclusion Criteria

Aim 1a: Eligibility criteria will include self-reported diagnosis of Alzheimer's disease or related dementia for patients OR self-reported status as a financial caregiver to a person with AD/ADRD. Additional eligibility criteria will be age 18 years or older; able to read and speak English or Spanish; able to provide informed consent; and located in the United States. We will recruit up to 60 participants for this aim.

Aim 1b: Eligibility criteria will be 18 years of age or older; able to read and speak English; able to provide informed consent; located in the United States; and self-identifying clinician who primarily treats people with AD/ADRD OR a scientist who primarily studies AD/ADRD. We will recruit up to 20 participants for this aim.

Aims 2 and 3: Eligibility criteria will be age 18 years of age or older; able to read and speak English or Spanish; able to provide informed consent; and either a financial caregiver to someone with AD/ADRD or told by a doctor that they have AD/ADRD. Caregivers will also be required to provide some amount of financial management or support for the person with AD/ADRD. We will recruit up to 1000 people with Alzheimer's Disease and up to 1400 caregivers for this aim.

Recruitment Methods

Aim 1a:

Participants will be recruited through advertisements on social media and news media, and notices in newsletters and flyers posted with organizations that work with people who have AD/ADRD and their families. Participants will also be recruited through ResearchMatch, which is an organization run by Vanderbilt University that connects researchers with potential participants.

Once a study is posted on ResearchMatch, potential participants receive a brief email describing the study and eligibility criteria and if they are interested, can release their contact information to the study team. Participants will also be recruited through purchased postal mail lists and will receive postcards and letters with information about the study.

Interested potential participants will see the study advertisement, email, postcard or letter, and then contact the study team directly or complete the online screening survey. Study staff will conduct a brief screening to ensure eligibility for potential participants who contact the team directly. Study staff will call potential participants who complete the online screening survey and confirm eligibility. For people with Alzheimer's disease or dementia, the eligibility screening will be conducted by a qualified study staff member who will use a guided cognitive assessment protocol (described below) to ensure the potential participant understands the questions. Dr. Jones will ensure that all study staff administering the cognitive assessment have completed appropriate trainings specific for the assessment tool and will train staff in the protocol and administration of the assessment.

People with AD/ADRD will be asked to complete one of the three English versions or the Spanish version of the Montreal Cognitive Assessment (MOCA) Blind/Telephone¹¹⁶ to ensure they will have the capacity to consent and understand the study questions. The MOCA Blind/Telephone version includes all the items from the standard MOCA except naming pictures and drawing tasks. As this study will recruit participants from all over the United States, we will not be able to complete the visual tasks (naming, drawing) for potential participants completing the screening by phone. Scores on the MOCA Blind/Telephone range from 0 to 22 with the typical cutoff (cutpoint) score below 19 signaling possible cognitive impairment. As we would expect people with AD/ADRD to score below 19, if a potential participant scores below 15 (score of 14 or lower) we will consider them ineligible for the study as they are unlikely to be able to provide informed consent and consistent information on financial hardship. This cutoff was chosen based on a systematic review of the sensitivity and specificity for MOCA cutoffs¹¹⁷ and cutoffs for mild impairment on the full MOCA.¹¹⁸ Dr. Jones is a clinical psychologist who has both training and experience using the MOCA and would be able to train study staff to administer the assessment with fidelity.

Aim 1b:

Participants for the survey of Alzheimer's disease and dementia experts will be recruited through the investigative team's networks and through identifying current experts in the social and behavioral aspects of Alzheimer's disease and dementia. The investigative team may also partner with professional organizations and place advertisements in professional publications to recruit experts. Potential participants will receive an email invitation from the study team to complete the survey. The email will contain a link to the online survey with the informed consent statement.

Aims 2 and 3:

We will initially start recruiting potential participants through address-based sampling. Using purchased postal mail lists, potential participants will receive a postcard in the mail with a brief description of the survey and a link and QR code to the eligibility screening survey. This will allow potential participants to access the survey when they have internet access and it is convenient for them (e.g., at a family member's home or library). Caregivers who screen eligible for the survey will then be taken to the consent form and survey. People with AD/ADRD who screen eligible will be asked to provide their name and contact information (phone number, email address) so study staff can conduct a cognitive screening to ensure they are likely able to provide informed consent and provide reliable information on the survey. The person with AD/ADRD will be administered one of

the MOCA Blind/Telephone versions over the phone and scores at or above 15 out of 22 will be considered eligible. The person with AD/ADRD will then be emailed either a link to the consent form and survey or mailed a hard copy of the consent form and survey, depending on their preference. The initial postcard will also include the study phone number and instructions that the potential participant can request a paper survey if they are eligible and would like to participate. Potential participants that call to request a paper survey will be screened for eligibility, including the cognitive screen for people with AD/ADRD, and mailed a paper survey with a business reply envelope. At least one reminder mailing will also be sent with instructions on how to complete the survey online and how to request a paper survey. Both people with AD/ADRD and caregivers will be asked to nominate either a caregiver or patient, respectively, to complete the corresponding version of the survey. Caregivers recruited through address-based sampling will also be asked to nominate a second and third caregiver, if applicable, of the person with AD/ADRD to also complete the survey. The second and third caregivers will be approached to complete the survey through the same methods as the first caregiver (online, paper) but may also be approached through phone calls if the first caregiver reports that may be acceptable to the other caregivers.

Participants will also be recruited through ResearchMatch and partnerships with caregiving organizations. Potential participants from ResearchMatch will receive a brief email explaining the study and the eligibility criteria for the study. If interested, potential participants can then release their contact information to the study team through ResearchMatch. For potential participants recruited through caregiving organizations, they will either receive an email or letter about the study or see a notice about the study in the organizations' newsletters. Potential participants recruited through caregiving organizations and are interested will then contact the study team. The study team will then contact the potential participants and assess eligibility using the same methods as for address-based sampling.

Participants will also be recruited through Qualtrics survey panels. Dr. Jones has successfully recruited through Qualtrics panels before.^{114,115,176} Qualtrics is a survey and research company that maintains panels of over 100 million potential survey participants. The large survey panels will allow us to meet recruitment goals for each racial and ethnic group. Inclusion criteria will be: currently a caregiver to someone with Alzheimer's disease or dementia OR told by their doctor that they have AD/ADRD; 18 years of age or older; living in the United States; able to read English or Spanish; and able to provide informed consent. Qualtrics will invite potential survey participants to participate through their preferred method (email, text). Potential participants will answer a set of screening questions on age, caregiver status/diagnosis and location to ensure eligibility. People who report a diagnosis of AD/ADRD will complete an online version of the MOCA, Xpresso MOCA, to ensure ability to provide informed consent and participate. People that are eligible will then be invited to complete the survey. People who participate in Qualtrics survey panels receive perks for completing surveys including gift cards and frequent traveler points.

The Consent Process

Aim 1a:

Informed consent will be obtained from each interview participant. Due to the virtual nature of likely most of the interviews, the informed consent process will use both verbal and written methods. When potential participants contact the study team about participating in the interviews, study staff will explain the study, send the consent form by email or postal mail and review all relevant aspects of informed consent for those completing the study remotely (virtual, phone). Study staff will answer any questions about the study. If the person agrees to participate, documentation of informed consent will be noted in the study database. For participants coming to the Fred Hutch

campus and completing te interviews in-person, written informed consent will be obtained and documented with an ink signature. The PI (Jones) is a clinical psychologist and will train study staff to notice signs that participants may not be able to consent.

Aim 1b:

Informed consent will be obtained from each survey participant. Potential participants will complete the screening survey and then see an informed consent statement. They will be asked to read the statement and click a box noting that they have read and understood the informed consent statement. Participants will then be taken to the survey. Contact information for the study personnel will be provided so potential participants can contact the study team with any questions they may have.

Aims 2 and 3:

All elements of informed consent will be included with the survey and participants will be required to review it before they complete the survey. This will include potential risk of participation and actions the research team takes to minimize risks. Consent will be documented through the online survey and a waiver of documentation of informed consent will obtained from the institutional review board. Written, signed consent forms will be used for people completing paper surveys.

Study Procedures

Aim 1a:

Interviews will be conducted virtually, by phone or in-person. As we anticipate most participants will complete the interview by phone or virtually, both verbal informed consent and signed paper informed consent procedures will be used. If a patient and their caregiver are both participating in the interviews, each will be scheduled separately for the interview and will be asked to use a room where they can speak privately. A semi-structured interview guide will be developed by the investigative team (see Table 2). Participants will first be asked about their experience of financial hardship generally and then about each specific topic in Table 2. Participants will also be offered handouts on accessing financial support and mental healthcare. At the end of the interview, people with AD/ADRD will be asked if their caregiver may like to participate and caregivers will be asked if the person with AD/ADRD may like to participate. If the participant agrees, the other

Table 2: Interview Guide Outline

Interview Topics	
1.	Comparison of financial situation before vs. after AD/ADRD diagnosis for both person with AD/ADRD and their caregivers
2.	General financial hardship
3.	Specific financial hardship domains (financial stress, financial strain, asset depletion) a) Unique indicators for the age at which AD/ADRD usually occurs
4.	Factors that contributed to financial hardship
5.	Strategies that helped alleviate or mitigate the need
6.	How does financial hardship affect their financial well-being, emotional well-being and/or behaviors
7.	How has financial hardship influenced their decisions about care or limited options for care
8.	Financial function a) How are finances typically managed (who manages and what are the resources they use) b) How financial management was transferred from the patient to the caregiver, and any events or changes that triggered the transfer a. How the transfer process evolved over time c) When to ask the patient versus caregivers, or both
9.	How to account for multiple caregivers and social network size a) Number and composition of financial caregiving network and social network b) Change in financial caregiving network over time and disease stages c) How financial management works for the person with AD/ADRD across the caregivers d) How the caregiving and broader social networks have buffered against and/or exacerbated financial hardship including effects of network wealth a) Who is/are the best caregiver(s) to complete the screening measures

member of the dyad or family (caregiver, person with AD/ADRD) will be approached by email or phone to see if they would like to participate. Interviews will be recorded and transcribed. Spanish transcripts will be translated into English. Participants will receive a small incentive for participation.

Aim 1b:

Potential participants will receive an email invitation from the study team, briefly explaining the study and providing a link to the survey. Interested people will click the survey link, review the informed consent statement and complete the survey. The survey will ask participants to review a definition of each domain of financial hardship and then rate the relevance of each item developed in Aim 1a with that domain based on who would be reporting (caregiver, patient) and who's outcome is measured (patient, caregiver). In the event of very long item banks being developed in Aim 1a, participants will only review a randomized portion of the items. Demographic and job characteristic information will also be collected. Participants will receive a small incentive for participation.

Aims 2 and 3:

Once participants screen as eligible, they will either be taken directly to the online survey or receive the survey and consent form in the mail. Participants completing the survey online will review the consent statement, indicate they have read it and then proceed to the online survey. Participants completing the survey by mail will sign the consent form, complete the survey and then return both in a business reply envelope. Each participant will receive a small incentive to thank them for completing the survey. Participants will also receive handouts on accessing financial support and mental healthcare.

Endpoints and Measures

Aim 1a:

There are no formal measures for this aim as the purpose of the aim is qualitative. The endpoint is development of indicators of financial hardship in AD/ADRD and a better understanding of the patient and caregiver experience.

Aim 1b:

Participants will be asked to rate the relevance of each item from the preliminary item bank to the corresponding financial hardship domain using a 4-point scale (Not relevant, Somewhat relevant, Quite relevant, Highly relevant).¹⁶¹ Qualitative feedback on the survey will be solicited through an open text field after each domain that asks for feedback on missing items or concepts for that domain as well as items that are misplaced and should be moved to a different financial hardship domain.

Aims 2 and 3:

Measures for Aims 2 and 3 will be developed based on the results of Aim 1. The measures will include each dimension of financial hardship (stress- psychological; strain- difficulty meeting needs; asset depletion) for the patient (both reported by the patient and by the caregiver) and the caregiver. There will also be a measure of financial function reported by the patient. Demographic and disease information will also be collected. Quality of life measures from the Patient-Reported Outcomes Measurement Information System, the Social Network Index, the Perceived Stress Scale and measures of pre-AD/ADRD socioeconomic status will also be included to validate the measures.

Statistics and Rationale for Number of Subjects

Aim 1a:

For the interviews, we will use an inductive analysis process. The post-doctoral fellow, the study coordinator and Dr. Jones will read the transcripts and develop a preliminary codebook. The codebook will be reviewed by the investigative team. The post-doctoral fellow and coordinator will then double-code 10% of the transcripts to ensure reliability. Disagreements will be resolved through consensus or review by the investigative team. The two coders will then code the remaining interview transcripts. Dr. Jones will then analyze the coded interviews in conjunction with the investigative team to identify key indicators of each financial hardship domain for both caregivers and patients and for both patient-reported and caregiver-reported measures. Analyses will be stratified by social network size, number of caregivers, financial support from the network, income levels and race/ethnicity to identify differences in the experience of financial hardship.

Results from the interviews will inform generation of new financial hardship items and revision of items from previous measures. We will include items from previous measures^{7-16,119-157} if permission is given to use the items in creating these new measures and if the investigative team deems the content relevant to those with AD/ADRD, the part in the lifecycle in which AD/ADRD usually occurs and to AD/ADRD caregivers. Items from previous measures will be revised to reflect the stage in the lifecycle at which AD/ADRD typically occurs and the advisory board will review the revised items. Based on the coding and analysis of the interviews, additional items will be generated either by using direct quotes or by generating item text that captures the content of what participants reported. For example, a caregiver participant might report that their loved one's cell phone was shut off because they forgot to pay the bill. An item on the caregiver (observer/informant) reported measure for the patient's financial health might then be "phone service interrupted because they forgot to pay bill." As another example, a patient might report feeling so anxious about paying for home care that they were jumping out of their seat. An item on the patient-reported measure for financial stress might then be "felt anxious about paying for home care." Items from the interviews and previous measures will be harmonized to have a consistent format including response options. Items will be generated and categorized into each financial hardship domain by the post-doctoral fellow and Dr. Jones and then reviewed by the entire investigative team with the results of the qualitative interviews. The caregiver and patient advisory board will provide feedback and revisions on items generated through this process.

Previous studies have suggested 15 interviews may be sufficient to achieve saturation^{158,159} and these sample sizes are standard for concept elicitation in measure development.¹⁶⁰ We will define saturation as no new items being identified for a financial hardship domain after coding an interview and saturation will be verified by all coders, then reviewed with the investigative team.

Aim 1b:

The quantitative portion of the survey will use the content validity index (CVI).^{161,162} Items will be retained if 78% of participants rated the item relevance as quite or highly relevant to that financial hardship domain, consistent with current guidelines for interpreting the CVI.¹⁶¹ The principal investigator and post-doctoral fellow will review the comments from the open text fields and draft new items based on the comments. The investigative team will review the revisions and amend any items that need to be reworded or moved to other domains. The advisory board of people with AD/ADRD and caregivers will review the feedback from experts and the investigative team's revisions. The advisory board will be asked to provide further feedback on the changes and any missing items. Based on the quantitative and qualitative data, the preliminary item banks will be

revised for testing in the larger survey (Aim 2). The final item bank will be translated into Spanish using recommended methods for measure translation.⁶¹

Aims 2 and 3:

Item response theory (IRT) is a family of statistical models for creating a quantitative score from self-reported and observer-reported data.^{179,180} IRT uses the logistic model to determine the severity (also called the threshold parameter) of each item from surveys and questionnaires and reflects content validity. IRT also accounts for the accuracy (also called the slope and reflecting reliability) for each item, weighting items with better accuracy higher than items with lower accuracy. This differs from traditional analyses that would simply weigh all items equally. IRT uses the construct itself, financial hardship in this case, to create the weights instead of relying on an outside outcome, allowing the severity and accuracy parameters to be used across settings and outcomes for clinical screening and research without additional validation.

IRT uses the logistic statistical model. The severity and accuracy parameters for each item are estimated from large (400+) survey samples of responses to the items using maximum likelihood or estimation-maximization (EM) procedures. For Aim 2, we will use two IRT models. The first is the two-parameter logistic (2PL) model that estimates a single severity and single accuracy parameter for each item and is best suited to dichotomous, yes/no items such as “have you taken money out of savings due to your loved one’s Alzheimer’s disease or dementia.” The second IRT model is the graded response model (GRM) that estimates a single accuracy parameter and a set of severity parameters for items with three or more response options. Each severity parameter in the GRM corresponds to the level of financial hardship needed before a person will select the next highest response option. The GRM is best suited for items with ordinal response options such as never-rarely-sometimes-often-nearly always. For this study, we will use the Bock Aitkin EM method for estimating the severity and accuracy parameters in the 2PL and GRM models.¹⁸¹ We will examine the accuracy parameters for each item and eliminate items with low accuracy (<1).¹⁸² We will then use these parameters to create scores for each domain of financial hardship (Table 1) using a Bayes estimator.¹⁸³ The usual scale of measurement for IRT measures is a mean of 0 and standard deviation of 1.

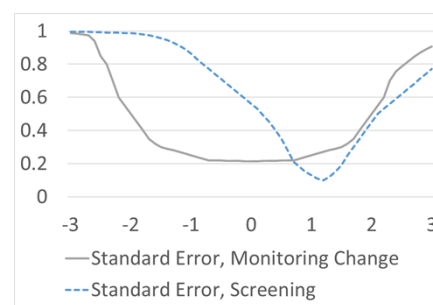


Figure 1: Example of standard error curves for item response theory analyses. Solid grey line is suitable for monitoring change over time and screening into multiple tiers. Dashed blue line is suitable for screening into two groups (high vs. low).

To further evaluate reliability for the financial hardship measures, we will examine the test (measure) error function, which is the inverse of the test information function created in IRT analyses.¹⁷ In IRT, reliability is not conceptualized as a single measure, but rather as varying at different levels of the construct. For example, a measure of financial stress may be more reliable for people with higher levels of financial hardship, but less reliable for people with high socioeconomic status and less financial hardship. For each of the financial hardship item banks, we will examine reliability (conversely, error) along the continuum of the construct by creating a test error curve (examples in Figure 1). The test error curve shows where the item banks are most accurate and informs use of the item banks. If the item banks have low error along a wide range of the continuum (two standard deviations below to two standard deviations above the mean, grey solid line, Figure 4), this would indicate that the item banks are suitable for monitoring changes in financial hardship or categorizing people into low, medium and high levels of hardship. If the item banks have much lower error in a specific point on the continuum (blue dashed line, Figure 4), this would indicate that the item banks are suitable for screening people for high and low levels of financial hardship. For

the financial function measure, we will examine the test error curve to determine cutoffs of high, moderate and low involvement of the person with AD/DRD in financial management. The high group would indicate the PRO financial hardship measures could be used for screening. Moderate involvement would suggest using both PROs and caregiver-reported ObsROs and low involvement would indicate use of only the caregiver-reported ObsROs for financial hardship screening. The root mean square error of approximation (RMSEA) will assess the overall fit of the IRT model.¹⁸⁴

The IRT scores will then be compared to health outcomes such as stress and quality of life to assess the construct validity of each financial hardship item bank. To evaluate the construct validity of the item banks, we will run a series of multiple linear regressions to assess the association of the financial hardship item bank scores with perceived stress and quality of life. We expect higher levels of financial hardship to be associated with higher levels of perceived stress and lower quality of life. Covariates will be age, gender, race/ethnicity group, and income, as these can influence level of financial hardship. A significant negative association between financial hardship and quality of life and a positive association between financial hardship and perceived stress will support the construct validity of the item banks.

An additional benefit of IRT analyses is the creation of short, pragmatic, standardized measures that can be used to screen patients. Measures for this purpose must be short (4 items or less) to reduce respondent burden. With IRT, severity and accuracy parameters can be compared and if two items have nearly identical parameters, this suggests the items are redundant and one could be eliminated while still covering the full breadth of the construct. This approach also means that users of the measure can choose different sets of items to use if their patient population has unique needs. We will examine the severity parameters and select two to three items from each item bank that help distinguish financial hardship at approximately 1.5 standard deviations above the mean and select these for initial short forms. Based on IRT analyses of previous social risk and financial hardship measures,¹⁸⁵ we hypothesize that error will be lowest between 1 and 2 standard deviations above the mean. Using 1.5 standard deviations would capture both people with very high levels of financial hardship that need immediate help but also people with moderate levels of financial hardship that could benefit from less intense intervention to prevent worse financial hardship. If the standard error curve suggests error is lowest at another point besides 1.5 standard deviations above the mean, the investigative team will then discuss using a different cutoff for positive versus negative screens and creating clinical interpretation guidelines. The advisory board of caregivers and people with AD/DRD will provide feedback on the selection of the items for the standardized screening short forms to ensure the selected items reflect what is important to caregivers and people with AD/DRD.

Once IRT-based item banks and short screening forms are developed as described above, screening can be conducted in a variety of ways. The first is using computerized adaptive testing (CAT). In CAT, patients or caregivers answer an initial question and receive different questions based on the level of financial hardship indicated by their answer to an initial question. Subsequent items are tailored to the estimated level of financial hardship from items already answered so people only answer questions relevant to their level of financial hardship. CAT is often more efficient than traditional statis measures.⁵⁰ A second method is to use the short forms created as part of Aim 2 or create a clinic-specific short form from the item banks and use the electronic health record or other computer program to use the severity and accuracy parameters to create IRT-based scores, similar to how PROMIS measures can be integrated into clinical practice and to how scores will be created for construct validity analyses in Aim 2. A third method is called sum score conversions.¹⁸⁶ With sum score conversions, answers to items on the short forms are summed similar to classical test theory measures and then the summed scores are transformed into IRT-based scores using a conversion table. Sum score conversion is not as precise as the other two methods but is an important option for

clinical practices that do not have information technology support and other computer resources to use CAT or scoring using accuracy and severity parameters. PROMIS has created sum score conversion tables^{57,187} and this has made the measures more accessible. As part of the Aim 2 analyses, we will create sum score conversion tables for each of the ten item banks and each standardized screening short form. Using IRT to create all three scoring methods for screening puts scores on a standardized, comparable metric. After successful completion of Aim 2, all three methods of scoring and using the financial hardship screening measures will be available for use.

To examine how assessing both caregivers and patients and number of caregivers may affect observer/informant report of patient financial hardship, we will examine interrater reliability of the three ObsRO item banks (caregiver-report of patient financial stress, financial strain, asset depletion, set 2) across caregivers and interrater reliability of the three ObsRO item banks (set 2) with the PRO item banks (set 3). The interrater analyses will be limited to the caregiver sample where multiple caregivers participated and to the subsample where both the patient and caregiver participated, respectively. The caregiver who is most involved in financial management for the patient will be defined as the index caregiver for these analyses. Agreement between the two or three caregivers on each item will be assessed using the prevalence and bias adjusted kappa.^{188,189} Kappas above 0.60 will indicate good agreement or interrater reliability. The overall scores on each financial hardship dimension will be compared between caregivers and between the caregiver and patient using the intraclass correlation with values above 0.70 indicating good interrater reliability. If interrater reliability is good, this would mean any caregiver managing the patient's finances could complete the ObsRO for the patient or that either the patient or caregiver could complete the screening. If interrater reliability is below the cutoffs, this would suggest that clinics should ask only the caregiver who is most involved in financial management to complete the screening of the patient's financial hardship.

We will use differential item functioning (DIF) analysis to ensure that the financial hardship item banks are not biased between racial and ethnic groups; by pre-AD/ADRD socioeconomic status; income; stage of AD/ADRD; comorbidities and disabilities for the patient and caregiver; social network size; caregiving relationship; and number of caregivers providing financial help and amount and type of financial help. Bias can sometimes hide true differences that are disparities and/or inequities. Differential item functioning analyses use the IRT models described above, but models and tests for statistically significant differences in the severity and accuracy parameters between groups.¹⁹² For example, DIF would model separate severity and accuracy parameters for those who are a spousal caregiver and those who are an adult child caregiver and then compare the parameters for statistically significant differences using the chi-square test. The top panel in Figure 2 shows what is called standardized DIF,¹⁷ where only the severity parameter differs. This means Group 1 needs more financial hardship before they will endorse the item and can give the illusion that there is no difference between groups when there actually is a disparity. The second panel of Figure 2 shows non-standardized DIF,¹⁷ where the accuracy (slope) parameter differs between groups. In the example, the item is more accurate and

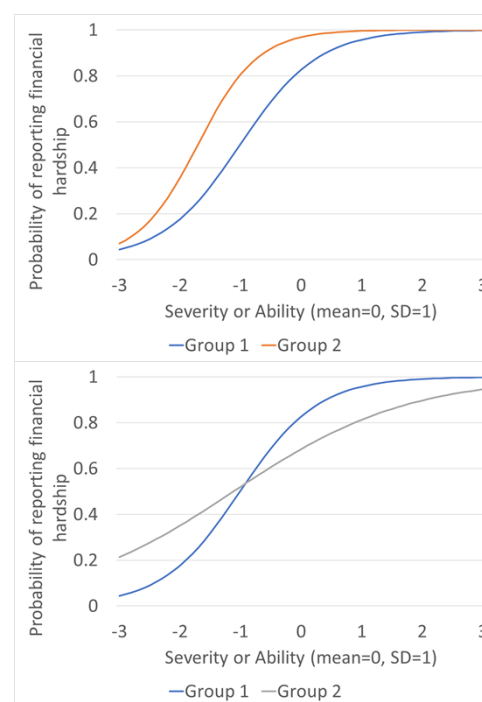


Figure 2: Item characteristic curves for dichotomous items testing for differential item functioning (bias).

reliable for Group 1 than for Group 2. DIF analyses compare multiple parameters across multiple items increasing the chance of a false positive for finding bias so a Type I (one) error correction will be used.¹⁹³⁻¹⁹⁵ If significant bias is found, we will calculate scores with and without adjustment for bias and then compare the scores using an intraclass correlation to quantify the effect size of the bias and determine whether bias is larger enough to be meaningful (i.e. intraclass correlations of <0.95).

In Aim 3 we will use DIF to test for bias on each of the three financial hardship dimensions and the financial function item bank. When there are three or more groups in a DIF analysis, comparisons can be made one of two ways. The first approach compares each group to a reference group similar to logistic regressions. The second approach compares all groups to each other. We plan to use the second approach for DIF analyses of bias by racial group and caregiver relationship as choosing a clear reference group would exclude other comparisons such as when the white group is chosen as a reference group and this excludes comparisons between racial minority groups. For both people with AD/ADRD and caregivers we will compare the following groups for DIF: each racial group (white, Black/African-American, Asian American, Native American, Pacific Islander) to every other racial group; people who are Hispanic or Latino/a to people who are not; gender identity; sex; 0-1 comorbidities versus 2 or more comorbidities; number of caregivers; financial help provided from social network; above versus below the median for Social Network Index score; above versus below median for income; and above versus below the median for pre-AD/ADRD social status.⁶ For caregivers, we will make additional comparisons between the following groups for DIF: 0-1 caregiver comorbidities versus 2 or more caregiver comorbidities; caregiver disability versus no reported caregiver disability; relationship to the patient (spouse, unmarried partner, adult child, other); and above versus below the median for pre-AD/ADRD social status. If specific items are significantly and meaningfully biased, those items will be eliminated or separate scoring algorithms will be created that corrects for the bias. We will bring results to our advisory board of people with AD/ADRD and caregivers for feedback on the most appropriate approaches to correcting for this bias and integrate their suggestions into the final item banks.

Although IRT models typically require a minimum of 400 to 500 responses to create item parameters based on simulation studies and general practice, we will recruit a larger sample of 1000 people with AD/ADRD and 1000 caregivers to ensure sufficient representation of people from racial and ethnic minority populations.^{57,190,191} Having enough participants from different subgroups is needed for differential item functioning analyses that will be conducted in Aim 3. Simulation studies have also suggested that measures with more items (30 to 240) can require sample sizes up to 1000. A sample size of 1000 will ensure accurate parameters if our item banks have more than 30 items.

Risks and Benefits

We anticipate this study will present minimal risk to participants. The most relevant risk for this study is breach of confidentiality. As outlined in Data Management and Confidentiality, we will take several precautions to ensure participant information remains private.

There are also potential risks for people with AD/ADRD participating due to the symptoms of the disease. While people with AD/ADRD will participate in this study, the study team will conduct an assessment to ensure they are able to understand study procedures and the risks of participation in this minimal risk study. The purpose of this study is also specifically to benefit people with AD/ADRD and their families/caregivers.

No direct benefits for participants are anticipated although they may find it beneficial to share their views on financial hardship of people with AD/ADRD and their caregivers. Results will be beneficial to scientists studying these diseases and their associated financial hardship, as the resulting item bank will allow harmonization between studies while still allowing customization for

specific study purposes. The resulting item banks will also create AD/ADRD financial hardship outcome measures that are more sensitive to change, improving power for future studies. The item banks will also be useful for tailoring clinical screening to each clinic and their patient population while providing a rigorously developed method of scoring AD/ADRD financial hardship. Qualitative results will also provide important context and understanding of the role of financial hardship in caring for people with AD/ADRD and supporting their caregivers.

Data Management and Confidentiality

We will use secure, HIPAA compliant virtual platforms for the interviews and keep all data and information in secure servers (firewalls, password protection). Survey data will be kept on secure online platforms and data will be downloaded only onto secure servers. Access to information will be limited to study staff and will be reviewed regularly. Transcripts will be deidentified and recordings will be deleted once the study is complete. Survey data will be deidentified when creating an analytic dataset and will be kept separately from information used to send incentives. We will also use unique identifiers for each participant and delete identifiable information once the study is complete.

Use of Data

Data will be used primarily to complete the three aims outline in Objectives. However, secondary data analyses may be conducted to further identify the causes and effects of financial hardship for people with AD/ADRD and their caregivers.

Provisions to Monitor Data and Protect Privacy

Only study with a reason to access the data or participant information will have access to study files. As outlined under Data Management and Confidentiality, we will only use secure virtual conference platforms and online data collection platforms to protect privacy. Any phone calls with participants will be conducted in a private office with the door closed. The PI will meet with study staff at least monthly to discuss any problems or concerns with the study procedures and participant experience.

Data for Aims 2 and 3 will be checked to ensure response quality. This includes checking for duplicate answers (participant completed survey twice), likely inattention (answering the most extreme option for each question, answering attention check questions incorrectly)^{177,178} and skipping most of the questions. Measures to assess for fraud will be used such as extremely fast completion times for online surveys or unlikely response patterns.

Qualifications to Conduct Research and Resources Available

The principal investigator is a clinical psychologist, behavioral and social scientist and psychometrician with over 15 years of experience in scientific research and over 80 peer-reviewed publications. She has previous experience with developing patient-reported outcome measures including a current project developing measures of financial hardship for people with cancer. Dr. Kent is a health services researcher and expert applying mixed methods (qualitative-quantitative) to studying caregiver lived experiences,⁸⁴⁻⁸⁷ including recent work redefining caregiving based on profiles of experience rather than care recipient health condition. Dr. Ornstein is an epidemiologist who studies dementia caregiving and the burden and cost of dementia. Dr. Samuel is a nurse

practitioner and expert in the experience of financial hardship and its effects on health among older adults. She has extensively studied the unique markers of health-related financial hardship among older adults and their families and the role of financial hardship in shaping disparities related to race, ethnicity and disability status using both qualitative and quantitative methods.^{24,25,36,44,45,94-102}

Study Timeline

Activity		Year 1				Year 2				Year 3				Year 4				Year 5			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Aim 1	Recruit advisory board and interview participants																				
	Conduct interviews																				
	Qualitative analysis and develop preliminary item banks																				
	Survey experts																				
	Finalize item banks																				
	Publication and dissemination																				
Aim 2	Survey caregivers and people with AD/ADRD, address-based																				
	Evaluate current samples																				
	Survey caregivers and people with AD/ADRD, survey panels																				
	IRT analyses, construct validity analyses, create short forms																				
	Publication and dissemination																				
Aim 3	DIF analyses																				
	Revision of the item banks if needed																				
	Publication and dissemination																				

Figure 6: Study Timeline

Appendix 1: Consent Forms

Appendix 2: Interview Guide

Appendix 3: Measures (Survey)

Appendix 4: Recruitment Materials and Screening Scripts