Advancing Understanding of Transportation Options (AUTO)

NCT04141891

12/3/2024

COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
CAMPUS BOX F-490 TELEPHONE: 303-724-1055 FAX: 303-724-0990

Protocol #: 19-0059
Project Title: Decision Making Among Older Adults: the AUTO Study
Principal Investigator: Marian Betz, MD, MPH
Version Date: 12/22/21

Hypotheses and Specific Aims:

This Stage II randomized, controlled, longitudinal trial seeks to assess the acceptability, feasibility, and effects of a driving decision aid use among geriatric patients and providers. This multi-site trial will (1) test the driving decision aid (DDA) in improving decision making and quality (knowledge, decision conflict, values concordance and behavior intent); and (2) determine its effects on specific subpopulations of older drivers (stratified for cognitive function, decisional capacity, and attitudinally readiness for a mobility transition). Our overarching hypotheses are that the DDA will help older adults make high-quality decisions, which will mitigate the negative psychosocial impacts of driving reduction, and that optimal DDA use will target certain populations and settings.

The challenge of how to support older adults making decisions about driving[1,2] gains urgency with the aging population, the increase in older adults with cognitive impairment,[3] and the fact that widespread use of driverless cars is likely distant.[4] Although informational websites[5] and self-assessment tools exist, a key knowledge gap remains: how to help older drivers actually make decisions about their driving in a way that is individualized and supports autonomy. In clinical medicine, decision aids[6] are used to increase patient knowledge and decision quality.[7] A web-accessible driving decision aid (DDA)[8] was iteratively developed (NIH Model Stage I)[9] to meet all international decision aid standards[10] and is now ready for efficacy testing (Stage II),[9] but questions remain. How do cognitive or emotional factors influence a decision aid's utility or timing for use? Should it be given to all older drivers at a certain age, or with certain conditions? Should there be pre-screening for a driver's cognitive state or readiness to consider changes? When and where should the DDA be used?

In this 5-year research project, our goals are to test how much the DDA improves outcomes in older drivers and to identify who benefits most from the DDA. We seek to facilitate optimal decision-making by identifying and leveraging cognitive, emotional and motivational factors.

Aim 1: In a multi-site, two-armed randomized trial of older drivers (n=300; ≥70 years) and family members, to test the effect of a web-based DDA as compared to control (web-based information only[5] on:

1a. Immediate decision quality (measured by the Decisional Conflict Scale), hypothesizing that more DDA participants will make high-quality decisions;

1b. Longitudinal psychosocial outcomes at 12 and 24 months, hypothesizing that DDA participants will have reduced prevalence of depressive symptoms and of decision regret but maintained life space

1c. Longitudinal driving behaviors (including reduction or cessation) at 12 and 24 months, hypothesizing that the DDA- although not intended to direct participants to continue or stop driving- will lead to changes.

Aim 2: Using data from Aim 1, to use stratified analyses to determine the DDA's effects in specific subpopulations, including:

2a. Older drivers with versus without cognitive impairment, hypothesizing that the DDA will improve decision quality more in cognitively intact drivers;

2b. Older drivers with maintained versus impaired decisional capacity, hypothesizing that the DDA will improve decision quality more in drivers with maintained decisional capacity;

2c. Older drivers who are attitudinally more ready versus less ready for a mobility transition, hypothesizing that the DDA will improve decision quality more in drivers who are ready for transition.

Aim 3: Through qualitative interviews and surveys with key stakeholders (older drivers, family members, healthcare providers, and experts in the field), to identify the desirable settings for DDA use, including:

3a. acceptability and suggestions for modifications or targeted use with subpopulations;

3b. preferred locations, such as clinical settings, community programs, or at home.

The proposed study will provide the groundwork for tailoring intervention delivery and preparing for its implementation.

Background and Significance:

"Driving retirement" is a critical life decision. As of 2015, there were over 25 million drivers aged ≥70 years, and 70% of adults aged ≥85 years still had a driver's license.[11] Driving is closely linked to well-being, and driving retirement can negatively impact independence and mental health.[12-18] A recognized national goal, therefore, is to help older drivers stay on the road as long as it is safe, as maintaining mobility and community involvement promotes health and longevity.[19-21] Safety remains a consideration since some older drivers are at increased risk of crashes[20,22,23] and fatal crash rates increase after age 75,[24] but generally older drivers pose a greater risk to themselves than to the community around them.[25,26] Precise estimation of an individual driver's risk remains difficult, as on-road testing is costly and not always available[27] and office-based assessment is often impractical[28,29] and not routine.[30] Thus, decisions about driving retirement typically involve some combination of the older driver, involved family members or trusted friends, and healthcare providers, depending on the individual's circumstances and preferences.

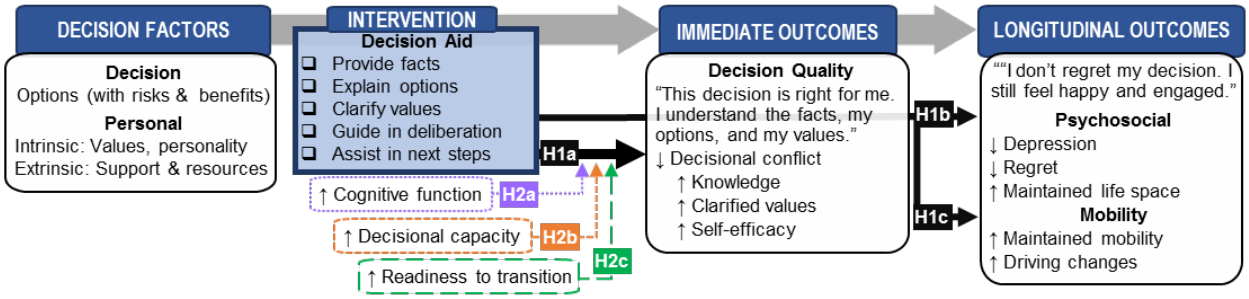
Decision-making is a multi-dimensional process. Decisions are affected by complex interactions between myriad internal and external factors, including cognitive ability, decisional capacity, emotions, personality, and environmental or pragmatic factors. Older drivers fear losing their

independence, being abandoned, or becoming a burden on others, while simultaneously fearing causing harm to others on the road,[31] and decisions about driving are complicated by financial and lifestyle considerations, such as alternative transportation options. The mechanisms of decision-making also change over an individual's life, and the process can be further complicated by attitudinal factors (e.g., emotional readiness for a major transition) and cognitive function. Understanding how key attitudinal and cognitive factors affect decisions about driving gains critical urgency with the aging population in the US who rely heavily on driving themselves.

Cognitive impairment complicates driving decisions. While physical conditions and medications can affect driving, Alzheimer's disease and other forms of progressive cognitive impairment have the strongest link to both driving risk and the need for eventual driving cessation.[22,32] Lack of insight, education, and/or recognition of cognitive impairment by spouses and families are all likely contributing factors. Given the estimate of almost 16 million older adults in the US with dementia by 2050,[33] the decision-making needs around driving for this group—and the transportation needs for our society—will be significant. This does not even factor in the large number of older adults with other acute or chronic medical conditions that also negatively impact cognition and driving, such as stroke, Parkinson's Disease, and visual impairment. The role of family members, trusted friends, and healthcare providers in supporting a driver through driving retirement gains additional importance in the context of cognitive impairment or concerns about decisional capacity.

Decision aids- based on evidence and theory- can help with difficult decisions. Decision aids are tools that facilitate decision-making and have been developed and used for medical issues from acne treatment to weight control,[6] but rarely (to date) for decisions about "life issues." A unifying, recommended model for decision aid development is the Ottawa Decision Support Framework (Figure 1),[34] which draws upon concepts from psychology, decision conflict, social support, and self-efficacy. The framework posits that decisional needs (e.g., knowledge, conflict/uncertainty, and values) affect decision quality, with the highest quality decision being one that is both informed and reflective of the individual's values. Decision quality, in turn, affects patient actions and, ultimately, impacts both health outcomes and patient's feelings about the decision. The overall assertion is that the highest quality decision will have the best outcome for the patient. Therefore, decision aids can enhance decision quality by addressing unmet decisional needs; specifically, decision aids facilitate complicated decisions by (a) identifying the decision to be made, (b) describing risks and benefits of various options, (c) assisting the patient in clarifying personal values, and (d) activating the patient for decision-making.[35,36] In a Cochrane review of 115 randomized trials (with 34,444 participants total), decision aids improved multiple decision outcomes, including knowledge, satisfaction, decisional conflict and regret, and communication.[7]

Figure 1. Theoretical framework of decision aid's immediate and long-term impact. Adapted from Ottawa Decision Support Framework



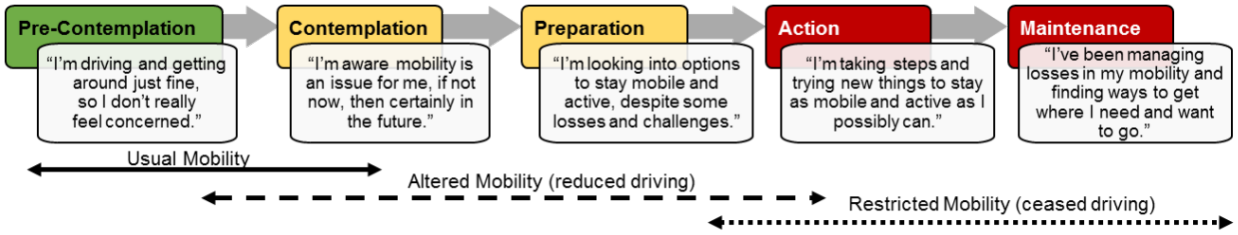
Older drivers need a tool to help their decision-making. Various guides and self-assessment tools exist to help older drivers and their families think about driving,[37-41] but what was missing was a tool to walk a driver through the process of deciding whether or not to stop driving. Decision aids have been developed for financial, long-term care, and end-of-life issues,[6] and a small pilot (n=12) found a paper-based driving decision aid (DDA) acceptable and useful,[42] although their tool is specific to individuals with dementia in Australia (which has different laws and systems of alternative transportation). Healthwise, a nonprofit organization that provides decision support tools and other services to enhance patient-centered decision making, released a DDA in 2015[8] for US drivers with or without dementia (Table 1). The tool was developed according to international decision aid standards,[10,43] is available online, and is easily accessible by 25% of clinicians in the United States. Unclear, however, is its effect on decision quality (i.e., satisfaction) or longer-term psychosocial outcomes, or which groups might benefit most from it (Figure 1).

Table 1. Driving Decision Aid content

Section	Description
Get the Facts	Clarifies decision (whether to stop or continue driving, watching for warning signs) and presents basic facts about driving safety and aging.
Compare options	Explains what is involved in each option, including benefits and risks or side effects and stories from others.
Your Feelings	Helps individual rate, on scales, their feelings about reasons to stop or continue driving (concern about crashes, comfort with driving, concern from others, alternative transportation).
Your Decision	Encourages individual to rate, on a scale, if they are leaning towards stopping or continuing driving. This section also includes a quiz and printable summary.

Attitudinal readiness for driving retirement also affects decisions. The Transtheoretical Model[44,48] has been applied to the stages of transition involved with driving cessation, with the

Figure 2. Stages of driving retirement, in context of Transtheoretical Model
Yellow boxes (Contemplation & Preparation) may represent ideal stages for decision aid use



idea that drivers progress—albeit at different rates—from pre-contemplation (the older driver with no concerns or plans to stop) through maintenance (the former driver who has found usable alternative transportation; Figure 2). The Transtheoretical Model posits ambivalence is a natural consequence of considering changes to health behavior, with each stage representing definable activities along the continuum of readiness for change. The Assessment of Readiness for Mobility Transition (ARMT)[45,46] is a validated, attitudinal measure developed to help providers identify an older adult's openness to changes and loss of transportation-related mobility. Drivers with higher ARMT total scores are less prepared for and more resistant to discussing or using transportation alternatives because they believe mobility loss inevitably leads to loss of independence and becoming a burden to others. In contrast, drivers with lower ARMT total scores are more likely to openly and directly discuss mobility loss without the perceived risk to their self-identity. Ideally, the ARMT could guide ongoing, personalized mobility planning, as healthcare providers could tailor discussions by identifying an individual's stage along the spectrum.

Older drivers want time to prepare for changes- but discussions and decisions are often postponed. The Trans-theoretical Model posits (Figure 2), and prior work confirms, that older drivers want time to prepare for driving retirement.[31] In a qualitative meta-synthesis of existing studies, our team found: driving discussions are emotionally charged; context matters; providers are trusted and viewed as authority figures; communication should occur over a period of time rather than suddenly; and older adults desire agency in the decision to stop driving.[31] Unfortunately, in the real-world these difficult conversations are often delayed until a crash occurs or a new medical or social crisis develops, leaving little time for preparation[31] Engagement with healthcare providers is recommended for decisions about planning for future driving retirement,[22,31,47] but this has been difficult to operationalize in routine clinical practice because of system constraints,[28,29] leaving discussions in primary care to when significant safety concerns are already present and demand action.[28,48] In a review of electronic health records (EHR) from 240 patients' primary care encounters over a one-year period, we found documented conversations occurred with only 8-15% of older patients in general internal medicine clinics and 28% of those in a geriatric clinic.[30] Understanding the barriers and facilitators to decision aid use in clinical practice will be key for future research and real-world use. Given the estimated 17-year time lag from original research to implementation of evidence-based interventions into practice,[49] it is critical to consider dissemination & implementation (D&I) frameworks when developing, testing and refining interventions.

Study Team and Preliminary Studies:

Table 2: AUTO study team, by key expertise and key study roles

	Key Expertise			Key Roles		
	Older drivers	Decision making	Cognitive function	Trial design	Trial measures	Recruit-ment
M. Betz, MD, MPH (PI) - CU	●			●	●	● (CU)
C. DiGuiseppi, MD, PhD – CU	●			●	●	
C. Knoepke, PhD, MSW, LCSW- CU		●			●	
D. Matlock, MD, MPH – CU		●		●		
L. Hill, MD, MPH – UCSD	●					● (UCSD)
D. Han, PhD – USC			●		●	
N. Fowler, PhD – IU		●	●			● (IU)

Our multi-site, transdisciplinary research team has an established record of success in a broad range of topics related to older drivers and decision making. Table 2 represents the study team members' specific key areas of expertise and study responsibilities.

Decision research: Dr. Betz currently leads a team with Dr. Matlock to refine and test a decision aid on firearm storage in times of suicide risk (ED-AID, 17-2299), using a similar evaluation framework and measures to those proposed here. The team has completed development of the web-based tool and is testing it in a pilot randomized controlled trial (summer, 2018). Dr. Matlock, as Director of the UCD Program for Patient Centered Decisions, brings significant experience in the development, measurement, and implementation of decision aids [51, 52] and is PI on a hybrid effectiveness-implementation randomized trial of a decision aid for implantable cardioverter-defibrillators (NIH/NHLBI R01). Dr. Hill has experience in shared decision-making research with older drivers (through a program at the UCSD Memory Aging and Resiliency Clinic). Dr. Fowler is a decision scientist at the IU Center for Aging Research who focuses on older adults with ADRD and caregivers.

Clinical and epidemiological research with older adults: The team has significant relevant experience in trials and longitudinal studies with older adults, though none of their current projects overlap with this trial. Drs. Betz, DiGuiseppi, and Hill currently collaborate as Site PIs on the LongROAD study, an observational study of a cohort of 2990 healthy older drivers in five states that is currently in year 3 of longitudinal follow-up.[53] For the LongROAD study, they recruited 1200 drivers in Denver and San Diego in only 21 months. Through her NIA Beeson K23 project, Dr. Betz recruited 315 older drivers (65% participation) for an on-road test and one-month follow-up, with 90% overall retention. Dr. Fowler also has experience recruiting and following older adults and their family members, including as PI of a large trial (426 dyads; NIH/NIA R01) testing a decision aid for caregivers of women with ADRD.[54-57] Our study team also has experience in examining the emotional aspects of driving and mobility changes, including prior collaborations using the ARMT and qualitative studies of the views of older drivers and healthcare providers.[1, 15, 18, 19, 35]

Research with cognitively-impaired older adults: Dr. Fowler has extensive experience conducting quantitative and qualitative research with cognitively impaired older adults and their family members.[54-60] The focus of her work is on medical decision making for older adults with ADRD and early identification of ADRD in primary care. In her role as co-leader of the Outreach and Recruitment Core for the NIA funded Indiana Alzheimer Disease Center, she supports IU faculty who want to conduct research with persons with ADRD and their family members. Dr. Han is a board-certified clinical neuropsychologist who has published extensively on cognitive aging, MCI and ADRD[61-65] as well as cognitive impairment in the context of decision making in old age.[66, 67] He is the former recipient of an NIA Beeson K23 award on decision making in old age and current PI of an R01 (NIH/NIA) focused on the racial differences in decision making in old age.

Qualitative methods: Dr. Betz has extensive experience in qualitative methods, including interviews and focus groups with older adults and healthcare providers.[1, 15, 18, 19, 35] Dr. Matlock and Dr. Knoepke have also conducted significant qualitative work exploring decisional needs and cognitive biases surrounding implantable defibrillators,[68-70] left ventricular assist devices,[71-76] and advance care planning/hospice.[77-79]

Outcome Measures and Analysis:

Key measures in this trial (Table 3, additional details below) are tied directly to our theoretical framework (Figure 1) and assess DDA effects (Aim 1) and potentially differential subgroup effects (Aim 2).

Immediate outcomes: Our primary outcome will be the DDA's effect on decision quality, a fundamental element of the Ottawa Decision Support Framework[34] as a precursor to behavior change (Figure 1). A high quality decision is defined as an informed patient making a decision consistent with their values.[50,51]

-Decision Conflict: The Decisional Conflict Scale (DCS) measures internal conflict or ambivalence about the decision, with higher internal conflict (or ambivalence) indicating the decision is less in-line with personal values. The DCS is closely linked to overall decision quality and is a recommended primary outcome measure.[50-52] The DCS estimates decisional conflict through personal perceptions of issues such as uncertainty in choosing options, modifiable factors contributing to uncertainty, and effective decision-making (e.g., expressing satisfaction with the choice). The DCS is a 16-item scale (with Likert scale response options) that has high reliability and test-retest correlation (Cronbach's alpha coefficients > 0.78).[53] In prior work, the DCS has been shown to discriminate between known groups who make or delay decisions (effect size 0.4-0.8),[53] with lower scores indicating low decision conflict (and greater likelihood of implementing a decision). Scores <25 (out of 100 total) are associated with implementing decisions.[53]

-Values Concordance: We will use the "Values Clarity"[53] subscale of the DCS to examine specifically how much participants feel their decisions are in line with their values. Three DCS items are summed and multiplied by 8.33; scores range from 0 (extremely clear) to 100 (extremely unclear about personal values).

-Knowledge: Questions will assess concepts about driving presented in the DDA and control group website.

-Self-Efficacy: We will measure decision self-efficacy (one's self-confidence or belief in one's ability to make decisions) using the Decision Self-Efficacy Scale,[54] as decision aids can increase self-efficacy. Transformed scores range from 0 (extremely low) to 100 (extremely high self-efficacy).

Longitudinal outcomes: Key longitudinal outcomes, linked to our theoretical framework (Figure 1), are psychosocial and mobility-related.

-Depression: We will measure depression using the PROMIS 4-item scale, with higher scores indicating higher depression. All PROMIS scores are analyzed as standardized T-scores (mean=50, SD=10).[55]

-Decision regret: The Ottawa Decision Regret Scale. This validated measure correlates with decision satisfaction and conflict, and overall quality of life. Scored from 0-100, high scores represent higher regret.[56]

-Life space: Life space is a global measure of mobility and community engagement. The Life-Space Assessment instrument (UAB Study of Aging) is a validated tool assessing recent mobility and function.[57,58] Composite scores range from 0 (bedbound) to 120 (travel out of town

every day without assistance);[59] scores of ≤60 are correlated with lower levels of social participation and higher mortality.[60]

-Driving behaviors: We will assess driving frequency (days per week), avoidance in certain situations (e.g., night), driving cessation (none, partial, complete), and self-reported crashes (≥1 versus none).

Table 3. Key study measures. Shown in relation to measurement point (pre- or post- DDA or website

Participant, and analytic plan. ● = about self, ○ = as surrogate about older driver

Domain and Key Measures		Drivers			Family/friends			Analytic Plan		
		Enroll		F/u	Enroll		F/u			
		Pre	Post		Pre	Post			Hypoth.	Scoring
Immediate outcome										
Decision Conflict	Decisional Conflict Scale (DCS)	●	●	●	●	●	●	1° Outcome	1a, 2a, 2b, 2c	Score <25
Knowledge	Knowledge questionnaire	●	●	●		●	●	2° Outcome	1a	Descriptive (cat.)
Values concordance	DCS Values Clarity subscale	●	●	●	●	●	●	2° Outcome	1a	Descriptive (cat.)
Self-efficacy	Decision Self-Efficacy scale	●	●	●		●	●	2° Outcome	1a	Descriptive (contin.)
Longitudinal outcome										
Depression	PROMIS depression	●		●				2° Outcome Covariate	1b 1c	T-score >50 Descriptive (contin.)
Decision regret	Ottawa Decision Regret Scale			●			●	2° Outcome	1b	Descriptive (contin.)
Life space	Life-Space Assessment	●		●			○	2° Outcome	1b	Descriptive (contin.)
Driving behaviors	Amount; reduction or cessation	●		●			○	2° Outcome	1c	Descriptive (cat.)
Subgroups										
Cognitive screening	5 minute MoCA			●			●	Eligibility Covariate	--	Score ≥21
Cognitive function	BTACT, OTMT	●						Stratify	2a	Normal vs. impaired
Insight	Beck Cognitive Insight Scale	●		●				Stratify	2a	R-C index ≥3
Decisional capacity	SPACED	●		●				Stratify	2b	# correct answers
Attitudes about driving	ARMT	●		●				Stratify Covariate	2c 1c	Mean score ≥3.57

Domain and Key Measures		Drivers				Family/friends				Analytic Plan		
		Enroll		F/u		Enroll		F/u				
		Pre	Post			Pre	Post				Hypoth.	Scoring
Other covariates												
Demographics	E.g., age, gender, race/ethnicity, marital/home status, education, income, urban/rural	●		●		●		●		Covariate	all	Descriptive (cat.)
Physical health	Medical history, Activities of Daily Living, PROMIS global health	●		●				●		Covariate	all	Descriptive (cat.)
Mental health	PROMIS Emotional Support, Social Isolation; Perceived Stress Scale	●		●						Covariate	1b, 1c	Descriptive (cat.)
Personality	TIPI	●								Covariate	1c, 2c	Descriptive. (cat.)
Driving behaviors	Crashes, self-driving technologies	●		●				○		Covariate	1c	Descriptive (cat.)
Driving resources	Alternative transportation, support	●		●		●		●	○	Covariate	1c	Descriptive (cat.)
Driving education	Use of websites, courses, or other material driving or cessation	●		●		●		●		Covariate	1c	Descriptive (cat.)
Family questionnaire	Relationship to driver, co-reliance					●		●		Covariate	1a	Descriptive (cat.)
Life Events	Major Life Events			●				●	○	Covariate	all	Descriptive (cat.)
Coronavirus-related health	Coronavirus/COVID-19 Health/Exposure Status		●	●			●	●				

Subgroups: Analyses will include stratification by cognitive and attitudinal factors.

-Cognitive function: At baseline we will administer the Brief Test of Adult Cognition by Telephone,[61] which assesses episodic memory (word list recall immediate and delayed), Category verbal fluency, Backward digit span, 30-Second Counting task, Number series, Stop & GoSwitch Task, and Executive Functioning. We will augment the BTACT with the Oral Trail Making Test (OTMT).[62] Dr. Han will categorize participants' cognitive function as MCI, dementia or non-impaired based on the BTACT Composite and OTMT-B (z-score < -1.5 is impaired). [Note: initial study protocol included RBANS and TMT instead of BTACT and OTMT; see protocol version 10.14.19 for more details]

-Insight: The Beck Cognitive Insight Scale[63] comprises two sub-scales (self-reflectiveness and self-certainty); the composite "R-C index" (self-reflectiveness score minus self-certainty score) reflects overall cognitive insight. In one study each sub-scale and the R-C index were lower in

those with probable Alzheimer's disease compared to control.[64] We will use a conservative cut-off, with <3 categorized as low insight.[65]

-Decisional capacity: This construct is related to but distinct from cognitive ability.[66] We will use the Short Portable ACED (SPACED) to measure understanding, appreciation, comparative reasoning, and consequential reasoning. Each of these four criteria are scored a 0 for inadequate, 1 for marginal, and 2 for adequate. This produces as total range of 0 to 8. In the end, participants can be dichotomized as those with 0s versus others, median split, 8's versus others, etc. Scores can also be used as a continuous outcome measure in regression models..

-Attitudes about driving: The ARMT[46] measures affective and emotional aspects of present or future mobility changes associated with cessation. It has four subscales: anticipatory anxiety, perceived burden, avoidance, and adverse situation (i.e., the view that mobility loss is harmful to quality of life). Each of the 24 items is rated on a 1-5 Likert scale; high total average scores (mean >3.57) indicate low readiness to transition.[46]

Other covariates: Additional measures are for eligibility screening, key covariates, and exploratory analyses.

-Cognitive screening: We will use the 5-minute Montreal Cognitive Assessment [MoCA][69, 81] with a score <21 being an enrollment exclusion criterion due to the likelihood of poor driving ability and impaired decisional capacity. However, even individuals with MoCA scores ≥21 may have impaired decision-making capacity. If concerns arise during the consent process that the participant does not understand aspects of the study, the participant will not be enrolled in the study.

-Demographics: These will include basic demographic characteristics like age, gender, and residence (e.g., private residence vs senior apartment complex, alone vs with others, urban vs rural location).

-Physical and emotional health: These measures will include assistance for Activities of Daily Living (ADLs), medical comorbidities, and overall perceived health.[53, 106-108] Progressive medical conditions associated with reduced driving ability and increase risk of cessation (eligibility criterion, above) will be categorized by type (e.g., visual, cognitive or musculoskeletal) or particular diagnosis, depending on sample prevalence.

-Emotional health: We will also collect PROMIS measures of Emotional Support (4-item) and Social Isolation (4-item) and the 4-item Perceived Stress Scale.[109]

-Personality: As personality may relate to driving (e.g., enjoyment versus anxiety with driving) we will use the Ten-Item Personality Inventory (TIPI), a shortened questionnaire for personality dimensions.[110]

-Driving resources: Resources assessed will include access to and use of alternative transportation, interest in self-driving technologies, and emotional, financial or logistical support from others.

-Driving education: To assess possible control group contamination, at baseline and follow-up we will assess exposure to websites, videos, courses, or other educational resources about driving and driving cessation.

-Family member questionnaire: Questions will assess the relationship between the driver and family member, including frequency of contact and co-reliance for transportation (e.g., does older driver provide rides for family member's children, is family member available and willing to provide rides to older driver).

-Coronavirus/COVID-19 Health/Exposure Status (informed by the Coronavirus Health Impact Survey (CRISIS)): Questions will assess current impact of Coronavirus pandemic on physical and mental health, as well as other select domains (e.g., impact on important events, routine in-person activities, financial and living stability, etc).

Analysis for Aim 1: Analyses will be performed according to the principle of intention-to-treat, including all randomized drivers. Unless otherwise specified, hypothesis tests will be two-sided with alpha=.05, with 95% confidence intervals or p values reported. All canalyses will be performed using SAS/STAT® software. First, descriptive statistics will be computed for baseline patient characteristics, initially testing for differences between control and intervention groups (including for key covariates, Table 3.3). We will assess site effects by comparing demographic variables across the sites, using ANOVA for continuous measures and chi-square tests of proportions for categorical measures. If no statistically significant differences exist among sites, we will ignore site and formally test the differences in proportions or means as described below. If there are significant differences among sites, then (assuming enough events) we will use separate bivariate logistic regression models for each aim described below, with a fixed effect for site and with treatment arm as the main predictor. For longitudinal analyses, we will conduct logistic regression with unstructured correlation of generalized estimating equations (GEE) to account for the repeated observations for each participant. Statistical significance will be evaluated at one-sided p<.05 level. Analyses of the DDA's longitudinal effects may be vulnerable to bias, as control arm participants may be exposed to intervention arm messages through exposure to available materials or courses related to driving safety or cessation (e.g., websites, physician counseling, AARP courses). We will assess exposure to other sources of information through structured questions. To mitigate the impact of this potential bias, we will adjust measurements of contamination as applicable. In all analyses, validation of distributional and parameterization assumptions will be checked and data transformations (e.g. log-transformations) or alternative methods will be implemented as appropriate.

Aim 1a. Test the DDA's effect on immediate decision quality (measured by the Decisional Conflict Scale). Hypothesis 1a: More DDA participants will have high-quality (DCS<25) scores, compared to control, immediately after the intervention. Our primary outcome measure will be the proportion of participants with DCS score <25. We will perform multiple logistic regression to test the DDA's effect on decision quality. We are also interested in jointly modeling the proportion of family members with DCS score <25, so a bivariate logistic regression model will be used for analysis to allow assessment of marginal effects of the intervention on patients and family members separately while jointly accounting for the correlation between participants and family members, as well as their concordance/discordance in decision quality. In the small pilot trial of Australian drivers with dementia, mean DCS scores decreased from 22.5 to 7.5 (out of 100) after the DA;[42] should we find that DCS score distributions do not allow dichotomization based on the cut-point of 25, we will instead compare means between the groups. Missing data for the primary measure should be minimal, given that this will be obtained at enrollment. Additional analyses will include examining components of decision quality to identify changes in

measures like knowledge, values-concordance, or self-efficacy, as they may shed light on the mechanisms underlying decision-making about driving.

Family member data: In addition to the analysis under 1a, we will examine the degree of concordance (or discordance) within driver-family dyads on various measures, including current versus desired level of family involvement in driving retirement process (part of the driving questionnaire). To evaluate agreement we will look at the kappa coefficients at baseline and at follow-up points, as well as apply this class of repeated-measure concordance correlation coefficients. For longitudinal data, we will examine changes across the other time points (6, 12, 18, 24 months) using GEE after adjusting covariates.

Aim 1b. Test the DDA's longitudinal effect on psychosocial outcomes at 12 and 24 months. Hypothesis 1b: Participants in the DDA group will have reduced prevalence of depressive symptoms and of decision regret but maintained life space, at 12 and 24 months after enrollment, compared to control participants. We will use descriptive statistics, including proportions with 95% CIs or medians and interquartile ranges, for comparison between treatment groups. We will utilize GEE with a linear link, and a linear mixed model (LMM) with a random intercept, fixed effects and a linear link for each outcome. We will adjust for baseline characteristics (gender, age, education, etc.), driving behaviors and other variables. We will perform sensitivity analyses to examine the missing assumption under maximum likelihood.

Aim 1c. Test the DDA's longitudinal effect on driving behaviors at 12 and 24 months. Exploratory: The DDA does not provide specific recommendations as to whether the participant should stop driving or not. We will compare the proportion of participants who change their reported driving behaviors (reduce driving or cease altogether) over the follow-up period to examine whether the DDA appears to affect them. We will apply GEE with a logistic link, and a generalized LMM (GLMM) with a random intercept and a logistic link for each outcome. Also, we will adjust demographic variables and appropriate variables.

Secondary analyses: Secondary analyses by gender will be conducted, as we hypothesize there will be differences in behavior and outcomes based on gender, and the belief that the responses to DDA intervention may be heterogeneous between men and women. Aim 1a-1c will be considered gender analyses using logistic regression and GLMM. We will also examine the degree of concordance (or discordance) within driver-family dyads on various measures, including DCS and current versus desired level of family involvement in driving retirement process (part of the driving questionnaire). For longitudinal data, we will examine changes across time points (follow-up at 6, 12, 18, 24 months) and correlation between older driver and family member report.

Analysis for Aim 2: We will first test for interaction between DDA effect and each subgroup stratifying factor. We will then use separate stratified subgroup analyses to examine the effects of potential influential cognitive or affective factors on the effect of the DDA (using DCS score, the primary outcome from Aim 1a). As in Aim 1, we will first evaluate demographic characteristics and site effects; all comparisons within subgroups will be between DDA and control groups, using intention-to-treat analysis. The main analysis for each subgroup variable will be an unadjusted test of the intervention by subgroup variable interaction in a statistical model appropriate for the particular outcome (DCS score); specifically, separate multiple logistic models will include intervention group, subgroup, and an intervention-by-subgroup interaction as

factors. Potentially confounding variables (e.g., age, gender) will also be examined in separate multivariable logistic models for each sub-aims.

Aim 2a. Compare the effect of the DDA on decision quality in older drivers with versus without cognitive impairment. Hypothesis 2a: The impact of the DDA will be greater among those without cognitive impairment, as they are able to process the DDA's explanation of facts and options to facilitate a decision. We will examine interaction between cognitive function and the DDA's immediate effect on decision quality (DCS score) by dichotomizing cognitive function into impaired (comprising MCI and dementia) non-impaired. For our initial analyses, we will compare impaired versus non-impaired and run separate simple logistic regression models for each group to determine how cognitive function impacts the relationship between treatment group (DDA or control) and decision quality, as measured by DCS scores. For each cognitive function subgroup, the outcome variable of interest will be the dichotomized decision quality measure (DCS <25 versus DCS ≥25), and the intervention group status will be the independent variable. Should we have adequate sample size, we may examine the MCI and dementia subgroups independently.

Aim 2b. Compare the effect of the DDA on decision quality in older drivers with maintained versus impaired decisional capacity. Hypothesis 2b: The impact of the DDA will be greater among those with retained decisional capacity. Decisional capacity scores (range: 0-8) will be examined as a linear variable with controlling for confounding by cognitive function. We will examine the distribution of decisional capacity among the study's 300 participants to define subgroups; participants will be divided into 2-3 subgroups based on decisional capacity scores. As with cognitive impairment above, a simple logistic regression model will be run for each decisional capacity subgroup with dichotomized decision quality measure as the outcome of interest and intervention group status as the independent variable. Additionally, a non-stratified analysis can be conducted in which decisional capacity score is included as an additional independent variable model.

Aim 2c. Compare the effect of the DDA on decision quality in older drivers who are more versus less attitudinally ready for transitions. Hypothesis 2c: The impact of the DDA will be greater in those readier for mobility changes, as defined by lower ARMT scores, as they are "primed" for decision-making (Figures 3.1 and 3.2). We will follow methods similar to Aim 2a, using logistic regression to examine interaction between ARMT score and the DDA's effect on DCS scores by dichotomizing ARMT into high (mean>3.57) versus low/medium (mean 1-3.56). Depending on the distribution of ARMT scores in our sample, we may examine those with low ARMT scores (mean<2.3), as this group may be more open to mobility changes.[45]

Secondary analyses: Additional analyses will include dichotomizing groups based on insight into cognitive function, using the Beck Cognitive Insight Score and following procedures outlined in Aim 2a. We will also examine trajectories of attitudinal readiness to stop driving over time; this will be the first longitudinal study of ARMT scores, and we suspect scores will ultimately decrease (indicating greater readiness for driving retirement) but may first increase (as drivers cope with feeling threatened or worried about the transition). Employing an exploratory trajectory analysis to the data (rather than a recurrent cross-sectional approach) allows us to focus on changes over time for each individual. By following individual trajectories, we are likely to observe factors influencing individuals' decisions rather than have these factors obscured by focusing on recurrent cross-sections of the data. Data will be organized as time-ordered,

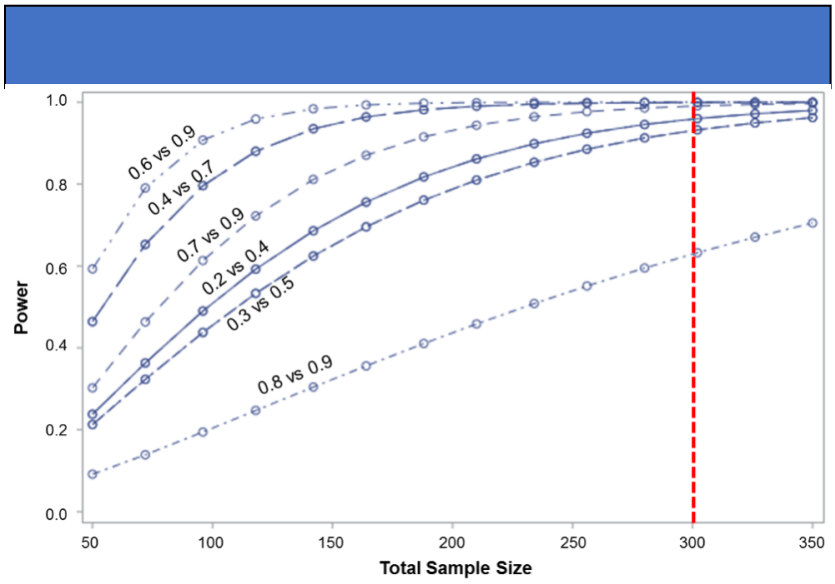
sequential matrices (one matrix per unit of analysis). Descriptive statistics for the ARMT scores will be summarized at each time point. In addition, study participants will be grouped into subcategories based on the type of trajectory (both shape and scale) being observed. Intervention group status and its effect on trajectory will be formally explored. Other variables of interest will be assessed in an exploratory manner. Additional secondary analyses will examine interactions between personality factors, ARMT, and the DDA. We will also explore the effect of gender, recognizing that women are more likely than men to self-regulate driving and to stop driving sooner.[70,71]

Analysis for Aim 3: In a mixed-method study with key stakeholders (drivers, family members, healthcare providers, and experts in the field), we will inform future DDA testing and eventual implementation.

Aim 3a. Explore acceptability of the DDA, including recommended modifications.

Aim 3b. Explore views on the ideal settings for DDA use (e.g., clinical setting versus community program). For these qualitative data, we will use a team-based, mixed inductive-deductive approach to review and code transcripts, identify dominant themes, compare themes across content areas, and then group these themes or create sub-themes. We will use "member-checking" to discuss final themes and theme organization with key informants.

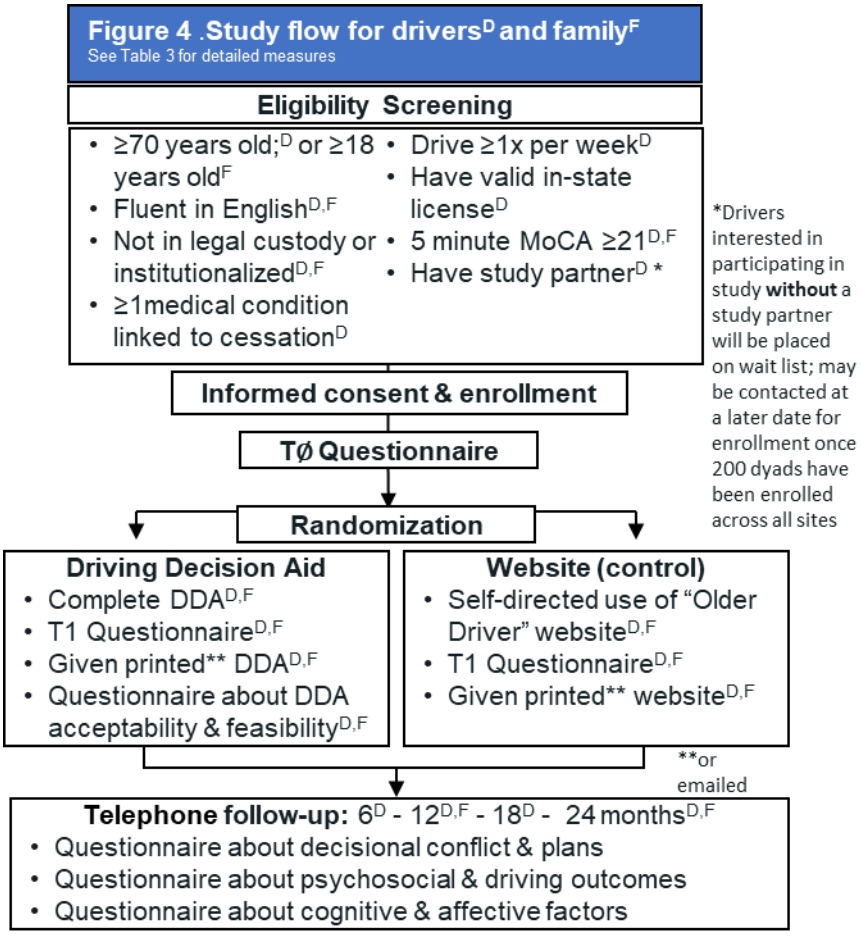
Figure 3.



Sample Size: Our target sample size for **Aim 1** (n=300 older drivers; 150 DDA and 150 control) was chosen to allow detection of a 20-40% difference between the DDA and control arms (depending on underlying proportions for each of the treatment arms) for the primary Aim 1a measure (DCS score <25; Figure 3.5) at a power of 90% and a 0.05 significance level, while allowing for 10% loss to follow-up. Our overall sample size also allows for stratified analyses (Aim 2). Estimates for the effect of the driving DDA on behavior among older drivers do not exist, so our assumption of a 20-40% difference is conservative (prior work with other DAs has found an effect size of 40-80% on DCS between groups[53]). For **Aim 2**, pilot work suggests estimates ~30% of participants will have cognitive impairment and 30% will have high ARMT scores (as described above). A stratified sample size of 90 should allow us to detect a 30% difference between the DDA and control groups, at 80% power (see Figure 3). For **Aim 3**, we estimate needing 15-20 interviews per stakeholder group (n=20 older drivers and family members/study partners; n=20 healthcare providers; n=20 experts in the field of older adult driving safety) to reach the "saturation point" (where additional interviews are unlikely to reveal

new themes) while allowing for adequate group diversity. Please note the older drivers and family members/study partners are all Aim 1 participants.

Description of Population to be Enrolled:



Eligible drivers: Eligible older drivers (n=300) must: be aged ≥ 70 years without severe cognitive impairment (5-minute MoCA ≥ 21).[72] Additional eligibility criteria are in Figure 4. We seek to enroll drivers more likely to be primed to consider driving retirement, so an additional eligibility criterion will be having at least one diagnosis of a progressive medical condition associated with reduced driving ability and increased risk of cessation (defined by the study team; preliminary list includes macular degeneration, Parkinson's disease, Alzheimer's disease, stroke-related paralysis or weakness, and syncope).

Family Members: We also aim to enroll one "family member" (i.e., relative *or* close friend, but will be referenced as "family member" or "study partner") for each driver (n=up to 300), ideally someone who might be involved in decision-making about driving or in providing support for the transition to non-driving. Eligible family members/study partners (Figure 4) must not have severe cognitive impairment (5-minute MoCA ≥ 21) and can participate via telephone; eligible drivers can participate via telephone, as well. Based on prior experience, we expect to recruit at least 200 family members, allowing adequate power for planned analyses. To ensure this, we will allow ≤100 older adults to participate without family.

For Aim 3, Key stakeholders for engagement in this exploratory work will include the following. We will invite a subsample of older drivers and family members to participate in qualitative interviews after their Aim 1 trial participation is complete. A sample of healthcare providers at participating sites will be invited to participate. At each site, eligible providers will be physicians, physician assistants, nurse practitioners, social workers, and case managers working in the clinics from which drivers were recruited. Additionally, we will invite national experts in older driver research and policy, drawing upon suggestions and connections from the study team and

NIA officials. For example, we will invite leaders from organizations such as the NIA, American Geriatrics Society, AARP, and, National Highway Traffic Safety Administration. All Aim 3 participants will be 18 years of age or older.

Study Design and Research Method

We will use a multi-site, two-armed randomized controlled trial of older drivers (n=300; ≥70 years) from clinical settings, and one family member each (n=up to 300), with longitudinal follow-up. Our goals are to test how much the DDA improves outcomes and identify who benefits most from the DDA. Our evaluation of the DDA's efficacy (Aim 1) and its relative effect in subgroups (Aim 2) corresponds to Stage II in the NIH Stage Model for Behavioral Intervention Development.[9] Our findings from Aims 1 & 2 could identify necessary refinements (Stage I) and inform future efficacy, effectiveness or implementation trials.

Sites: For this multi-site trial, we plan to include clinics associated with three sites to provide geographic diversity, along with access to populations with racial and ethnic variability. We request that COMRIB serve as the single IRB for this research study, with other IRBs ceding oversight.

- **University of Colorado Health:** Participants will be recruited primarily from three clinics associated with University of Colorado Health.
  - UCHealth Senior's Clinic – Aurora, CO
  - UCHealth Internal Medicine Anschutz clinic – Aurora, CO
  - UCHealth Internal Medicine Lowry clinic – Denver, CO
- **University of California-San Diego**: Participants will be recruited primarily from five clinics and four practices associated with University of California – San Diego
  - UCSD The Shiley Eye Clinic – San Diego, CA
  - UCSD Neurological Institute – San Diego, CA
  - UCSD Memory Disorders Clinic – San Diego, CA
  - UCSD Senior Medicine Clinic – San Diego, CA
  - Memory Aging and Resiliency Clinic – San Diego, CA
  - UCSD Internal Medicine Practice – San Diego, CA (four practices)
- **Indiana University:** Participants will be recruited primarily from 29 primary care clinics associated with the Indiana University School of Medicine.
  - Indiana Health – Indianapolis, IN (20 clinics)
  - Eskenazi Health – Indianapolis, IN (9 clinics)
    - Eskenazi Health is not a part of Indiana University and will not be actively engaged in research. They will be participating as a recruitment site only.

Recruitment: We will follow methods used successfully in the LongROAD cohort study.[73] Research assistants (RAs) at each site will identify potentially-eligible older drivers by screening the electronic health records of clinic patients to identify patients aged ≥70 years with at least one relevant medical diagnosis.

Table 4. Medical Conditions that May Impact Driving[80]

Medical Condition	Specific Examples
Diseases/conditions affecting vision	Diabetic retinopathy Macular degeneration Glaucoma

	Retinitis pigmentosa Field cuts Low visual acuity even after correction
Cardiovascular disease, especially when associated with presyncope, syncope, or cognitive deficits	Unstable coronary syndrome Implantable defib. Congestive heart failure Hypertrophic obstructive cardiomyopathy Orthostatic hypotension Syncope or presyncope
Neurologic disease	Narcolepsy Dementia Multiple sclerosis Parkinson disease Brain injury Spinal cord injury Stroke Vertigo or dizziness Seizure
Psychiatric disease	Alcohol or other substance abuse
Metabolic disease	IDDM
Musculoskeletal disabilities	Arthritis and foot abnormalities
Respiratory disease	Chronic obstructive pulmonary disease Obstructive sleep apnea
Chronic renal failure	End Stage Renal Disease Hemodialysis
Insomnia	Sleep apnea Insomnia Restless leg syndrome

Potentially eligible drivers will receive an informational opt-out letter or email (as well as a recruitment flyer) describing the study goals and objectives, eligibility requirements, procedures, and duration. The opportunity to opt out of further contact by either email or telephone will be offered, as will information on who to contact to learn more about the study. All persons who do not opt out within 2 weeks, or have not already contacted study personnel, will be called by a Research Assistant (RA). A maximum of 3 calls per potential participant, at different times and on different days, will be implemented. A telephone message will be left after the first call and again after the final call, with contact information. Once a potential participant is reached by telephone, the RA will screen for eligibility (including consideration of driving retirement and the requirement of a score ≥21 on the telephone MoCA 5-minute protocol[69]), explain the study, and request verbal consent. Those who refuse verbal consent to participation will not be contacted again.

It is possible that older drivers may learn about the AUTO study independent of study team outreach, i.e., via self-referral (e.g., an AUTO participant may share information about the study and study team contact information with a friend or loved one that they think may be interested in participating). The study team will consider enrolling self-referred older drivers as a secondary recruitment method if rates of recruitment are lower than anticipated.

Enrollment, and Consent: Interested and eligible older adults will be scheduled for an initial enrollment visit (can take place in person or by phone) and asked to identify a family member or close friend ("study partner") for participation and to provide that person's contact information. We will contact that family member/friend to describe the study and assess eligibility and interest. For drivers and study partners who are enrolled in person (vs. by phone), the in-person enrollment session will include written informed consent including HIPAA authorization. For drivers and study partners who are remotely enrolled by phone, verbal consent will be obtained using a postcard consent script. Drivers will be asked to sign a separate form to allow the researchers to access their DMV driving records (the study team will access participants' driving and accident records for the past 12 months before enrollment and up to every 12 months after enrollment.) We will attempt to schedule the driver and his/her family member for the same enrollment appointment, but they can be done separately if necessary or if the family member, driver, or both are participating by telephone. The study team has requested a waiver of documentation of informed consent for study partners and drivers who elect to participate via telephone only (i.e., study partners and drivers who do not have any in person contact with the study team). In these cases, great care will be taken to ensure the study partners and drivers have a comprehensive understanding of the study and their rights as research participants. The study team will also provide these participants with a copy of the "post-card consent" document, via mail or email, that includes details about study participation. Randomization will occur after enrollment. Family members will be allocated to the same treatment arm as their older driver partner.

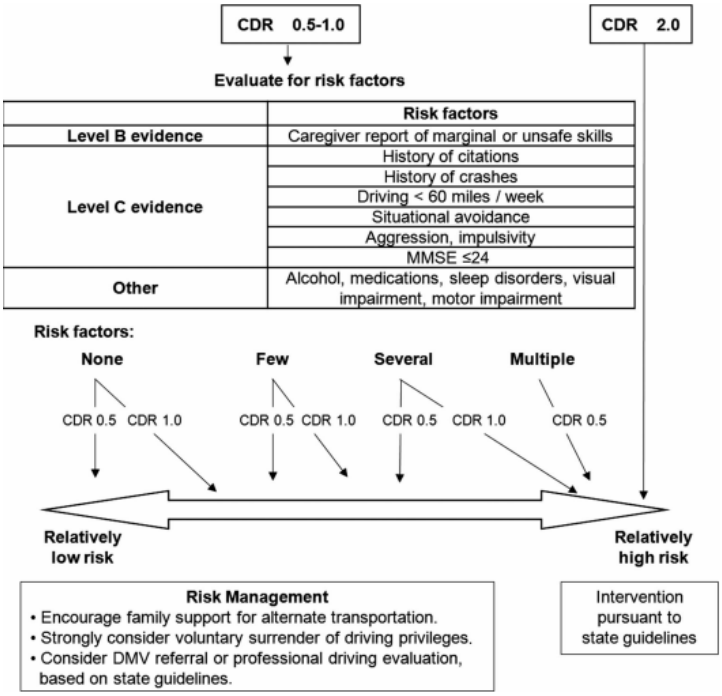
Randomization: At each site, enrolled drivers (with their family members) will be randomly assigned in equal numbers to the DDA or control arm (Figure 4). To reduce bias and aim for balance among arms, we will randomize patients in blocks with randomly varied block sizes of 4 and 6.[74,75] While RAs delivering the intervention to patients cannot be blinded to treatment, we will conceal allocation using a centralized, computer-generated list that RAs will access only after enrollment.[76] Other study staff, including a different RA (whenever possible) doing follow-up calls, will be blinded to study arm.

Baseline Measurements & Intervention: The driver and family member will be randomized to the same arm but will complete all study measures and interventions separately from each other. For each participant (including those enrolled in person as well as those enrolled remotely by phone), the RA will use a study tablet or laptop to administer the introductory questionnaire (Figure 4, Table 3). In the intervention arm, participants will then complete the web-based DDA; control group participants will be directed to the NIA "Older Drivers" website.[5] After completing the DDA or website review, all participants in both arms will answer questions about their knowledge, values, and plans related to driving cessation (Table 3). For family members, questions will generally be about the older driver, though there will be specific questions concerning their relationship, frequency of contact, and possible co-dependence for transportation. Whenever possible, participants will receive a printed handout of either their DDA results or the NIA webpage (for those enrolled in person) or will receive instruction from the RA about how to save an electronic copy of the DDA results or the NIA webpage (for those enrolled remotely by phone).

Identifying driving risk: At the request of the DSMB, the study team will use American Academy of Neurology (AAN) guidelines to identify drivers who are at moderate risk for being unsafe to drive (https://www.aan.com/PressRoom/home/GetDigitalAsset/8471). Per AAN

guidelines, “moderate risk” will be a Clinical Dementia Rating (CDR) of 0.5 with “few” to “several” risk factors, or a CDR of 1.0 with “no” or “few” risk factors”. AUTO uses the 5-minute MoCA, rather than the CDR or MMSE. MoCA scores of 18-25 suggest “mild” impairment while 10-17 suggest “moderate”. Drivers must score ≥21 on the 5-minute MoCA to be eligible, therefore, participants with “moderate” cognitive impairment (as defined by AAN guidelines) are not enrolled.

As recommended by DSMB, we will identify participants with a MoCA score of 21-25 as having possible mild cognitive impairment. For those participants, we will review any additional AAN driving risk factors (see table below).



Drivers with MoCA scores of 21-25 and ≥3 risk factors will be identified as “moderate risk” for the purposes of these safety checks. For participants identified as having moderate risk, we will perform an ad hoc review. We will report these findings to the DSMB at the regularly scheduled intervals unless there is an AE/SAE as previously described.

For participants meeting these thresholds, we will recommend a driving evaluation and provide the participant with information from ADED (Association for Driver Rehabilitation Specialists) about local resources. We will request participants share the subsequent driving evaluation results, although participants may remain in the study if they decline either the evaluation or data sharing. Any participant who receives a recommendation for a driving evaluation will be noted in the study database so we can later perform sensitivity analyses to see if that recommendation (or the evaluation, if obtained) affects the observed efficacy of the study intervention (driving decision aid).

Longitudinal follow-up: Participants will be contacted for telephone follow-up at pre-specified intervals (6, 12, 18, and 24 months after initial visit for drivers; 12 and 24 months after initial visit for study partners). Participants will be contacted via phone call, text message, or email (depending on participants’ preference) to schedule the follow-up interviews. For these follow-up interviews, the RA will contact the participant at the participant’s preferred phone number at a mutually-convenient time. Trained RAs across sites will follow COMIRB policies regarding contacting participants for follow up. Per suggested guidelines, participants will be contacted at least three times, but no more than 10 contact attempts will be made. Additionally, staff will attempt to reach the participant at different times of the day, leave a brief message on second attempt followed by a more detailed message on third (for participants who elect to receive reminders by phone call), and will reach out by email and/or text message as needed/as

preferred. Follow-up questionnaires will be administered via phone by RA unless the participant strongly prefers to complete an in-person interview. During follow up, participants will repeat all psychosocial and decisional measures. The study team will access participants' driving records for the past 12 months before enrollment and again up to every 12 months after enrollment.

Aim 3 Recruitment: For providers, study recruitment will include flyers posted in staff work areas and up to 3 emails to eligible providers, asking interested providers to contact study staff for further description of the study and scheduling of an interview. For experts, we will send up to 3 emails and describe the study in greater detail to interested respondents. For the older drivers and family members/study partners, at the end of the 24 month interview we will ask participants if they are interested in being contacted with information about the interview opportunity. Study staff will follow-up with these interested participants via phone or email, depending on the participant's preference.

Measures: Measures (Table 3.4) will be assessed through structured questionnaires and semi-structured qualitative interviews. Areas of focus will include recommended modifications to the DDA itself, the preferred setting for use (e.g., primary care clinic, older driver educational program, at home), and the recommended target audience (e.g., all drivers certain conditions or ages, family members). When possible, we will use existing scales (e.g., Ottawa Acceptability Scale) and Consolidated Framework for Implementation Research (CFIR) interview guides.

Table 3.4: Domains, constructs, and measures

CFIR Domain	Selected CFIR Constructs	Measures	Drivers	Family	Providers	Experts
Intervention	Adaptability; Design Complexity	Recommended edits	•	•	•	•
	Cost	Feasibility of use	•	•	•	
		Costs for D&I				•
Inner Setting	Site	Recommended setting for use	•	•	•	•
Outer Setting	Patient needs	Description; barriers & facilitators	•	•	•	•
	External policies and incentives	External strategies affecting use			•	•
Characteristics of Individuals	Beliefs about intervention	Attitudes (including acceptability)	•	•	•	•
Process	Planning; Engaging	As needed for setting			•	•

Data collection: Structured questionnaires will be administered to trial participants as well as to participating providers and experts. We will conduct semi-structured interviews with a subsample of trial participants, as well as providers and experts, to provide deeper understanding of the perspectives of key stakeholders concerning future D&I of the DDA, and, more broadly, decision support tools for older adults. Interviews will follow an interview guide, last 30-60 minutes, and be digitally recorded. They will be held via telephone or video conference depending on participants' preference.

Incentives: As incentive to participate, older drivers will be provided with $50 for the enrollment interview and $15 for each of four phone calls; family members or friends will receive $25 for the enrollment visit (as it is shorter than the drivers') and $15 for each of two follow-up calls. For Aim 3, participants will receive a $25 gift card for their participation in the qualitative interview/survey. Method of compensation will include but not be limited to the following: gift card, money order, check. Compensation will be provided after completion of study activities, i.e., after the enrollment interview and after each follow-up study interview. Additional activities

to maximize longitudinal retention can include: annual birthday phone calls or emails; phone call or email reminders prior to appointments; and a study website with site contact information. We may also consider other low-cost items like annual holiday greeting cards or study magnets.

Data Management: The RAs at each site will enter the enrollment and contact information, initial question responses, and telephone follow-up responses into a secure research database (REDCap, Research Electronic Data Capture) maintained by the Colorado Clinical & Translational Sciences Institute. RAs at each site will be able to see only their site's data, and limited study team members (e.g., PI, biostatistician, and analyst) will be able to see data from all sites. We will register the trial on clinicaltrials.gov and follow CONSORT guidelines.[77,78] For Aim 3, questionnaire responses will be entered into a secure REDCap database by the participant or RA. All interviews will be digitally recorded and transcribed. Qualitative data will be analyzed using Dedoose, an online platform for team-based qualitative analyses with project-specific data encryption.

Data Safety Monitoring Plan:

The Principal Investigator (Dr. Betz) will be responsible for the ongoing oversight, review, and reporting of adverse events related to the study. Dr. Betz will personally review each potential adverse event to determine the course of action, including reporting to appropriate groups, offices, or agencies, or identifying a need for making protocol changes.

A Data Safety and Monitoring Board (DSMB) will also be created to meet NIH requirements for monitoring of clinical trials. Members of the DSMB will be selected based on their expertise in biostatistics, gerontology, and clinical trials. They will be selected from institutions and research groups to minimize conflict of interests with the study's investigators.

In the event that a conflict of interest within the IDMC is identified, it will be disclosed to COMIRB. The DSMB will also provide recommendations to the PI on how to resolve the conflict of interest, which will then be reported to NIA and COMIRB. If a resolution cannot be found, a new member will be appointed to the DSMB.

The first task of the DSMB will be to approve the DSMB charter, which outlines procedures including meeting frequency. The DSMB will meet twice yearly or as-needed, such as in the event of a SAE. Any DSMB recommendations to amend the protocol will be reviewed and approved by Colorado Multiple Institutional Review Board (COMIRB) before implementation of proposed changes. The DSMB will review and evaluate study progress, data quality, risks and benefits, and other factors that will influence the overall study outcomes, safety, and feasibility during biannual meetings. Data reviewed by the DSMB will identify participants by their study ID only. If confidentiality is lost, the appropriate actions will be taken based on institutional policies. The DMSB will review data and make recommendations on any concerns or adverse events related to the study. These recommendations include altering or stopping with respect to safety concern for participants. Although not expected in this study, any serious adverse events will be reported to COMIRB, the DSMB, and NIA within 48 hours.

The DSMB will deliver an annual report to NIA, unless a report is requested more frequently. This report will include information on the safety and progress of the study. This report will include a summary of any AEs or SAEs and provide recommendations about whether the study should be continued, modified, or terminated.

Adverse Events and Serious Adverse Events: Adverse and serious adverse events will be defined based on guidance from Colorado Multiple Institutional Review Board and the NIH. An Adverse Event (AE) is any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable or definite). A serious adverse event (SAE) includes any untoward medical occurrence that at any dose results in death or the immediate risk of death, hospitalization or prolonging of an existing hospitalization, persistent or significant disability/incapacity or a congenital anomaly/birth defect (NIH guide-6/11/99).

The DSMB will review any unexpected events that may occur with study participants to determine whether the event is considered an adverse event, and if the event is study related. Research staff will alert the Site PI and Dr. Betz to any potential AE or SAE, who will assist with arranging any needed services for the participant. Within 48 hours of discovery of a SAE, it will be reported to COMIRB, and within one week to the DSMB and study's assigned project officer. Within two weeks of an AE being discovered, it will be reported to COMIRB, the project officer, and DSMB. In all cases, the PI, under advice of COMIRB, will determine what further, assessment, follow-up or action is required for an AE or SAE. A summary of SAEs that occurred during the study year will be part of the annual progress report that is submitted to both COMIRB and NIA. If it is unclear if an event meets criteria for a SAE by definition, the PI will refer it to the DSMB to determine if it meets SAE definition.

Description, Risks and Justification of Procedures

Risks to Human Subjects:

This is a minimal risk study. One risk of this study is loss of privacy due to breach of confidentiality. We will make every attempt to keep information private. Screening logs will not contain any identifying information. To ensure adequate protection of confidentiality, any age above 89 will be treated as an identifier and will be recorded as 89+ in screening logs. Data will be stored in a secure, password protected database on the University of Colorado server, (or equivalent institutional servers at other sites), with access limited to study personnel. Some participants may be uncomfortable discussing driving. They may choose not to answer certain questions. The research team will report any activities resulting in participant discomfort or injury to the IRB immediately.

Older adult drivers will be asked questions related to their driving behavior in addition to measures related to physical health, cognitive impairment, and decision-making capability. Mandatory reporting of potential driver impairment due to medical conditions varies by state. Of note, in this study we will not be assessing actual driving function, and no single question or cognitive test is accurate in identifying driving risk. Driving cessation itself comes with risks, so the study team will not automatically report drivers with particular MoCA scores. However, during the informed consent process, we will explain the study protocol related to participants who have clear visual, cognitive or functional deficits suggesting a driving safety concern, and individuals must agree to the protocol in order to enroll. In identifying potential impairment, research staff will draw upon evidence and impressions from responses as well as participant observation; examples might include a participant who is unable to remember the question just asked, who is disoriented to the purpose of the questions, who mentions a diagnosis of cognitive impairment/dementia or new difficulties with memory, who mentions new significant

physical limitations (including site, reflexes and strength), or who mentions problems with driving. In such cases, the research staff member would document the date and specific observations and review the issue with the Site PI. If the concerns are deemed relatively mild, the study team will provide the participant with information on community resources for driving assessment and rehabilitation and will recommend that they discuss their driving with their primary care provider. If the concerns are deemed more serious than "relatively mild," the study team would similarly provide information (including specific concerns) to the participant with the written recommendations that they talk with their primary care provider and/or have a driving safety evaluation and that they not drive until cleared. The informed consent form gives participants the option of allowing the research team to contact a primary care provider and/or another designee if the investigators' concerns about driving risks are more serious than "relatively mild." If consent was given, the study team would reach out to the designated person or people to express their concerns about the subjects' driving safety. Otherwise, additional survey responses will not be shared with anyone who is not involved with the study (including physicians, family members, or hospital or law enforcement authorities) unless specifically requested by the participant, this includes the co-enrolled family member or friend.

This study will enroll older adults who potentially may experience mild to moderate levels of cognitive impairment, creating a potential risk for informed consent for study participation. Level of impairment will be measured through administration of the 5-minute MoCA during an initial phone screen; the participant must score ≥21 to be eligible to be scheduled for an enrollment visit. While completing the consent process during the initial study interview (in person or remotely, via phone), staff will ask a series of questions to determine understanding of study procedures. In the event there is cognitive concern, the participant will not be allowed to enroll in the study.

At each follow up for all drivers and study partners, a 5-minute MoCA will be repeated to determine current cognitive impairment. As all participants have completed informed consent at initial enrollment, potential diminished cognitive capacity does not limit the participant's right to continued participation in follow up calls. During consent at enrollment, participants will have reviewed study requirements, tasks, duration, and an explanation that all participants have the right to continue or withdraw as they wish. Therefore, cognitive impairment will not automatically withdraw a participant from the study. Further, this study poses minimal risk to the participant. In the event that severe cognitive impairment disrupts the research team's ability to collect follow up data from the participant, the study team may choose to discontinue all or specific portions of follow-up procedures.

Because of the study's affiliation with clinical sites, there is the potential risk of coercion. We will minimize this risk by being very clear that participation is completely voluntary, separate from their clinical care, and that a participant can withdraw from the study at any time. Additionally, we will make clear that the patient's clinical care will not be impacted by the decision to participate or not to participate. No clinicians or providers from the participating clinics will be involved in the consenting of patients. There will be no exchange of payment for study participant referrals.

This study will not involve pregnant women, human fetuses, neonates, children, or prisoners. Study participation will not interfere with clinical care. The study informed consent form will include a written description of all of these risks, including the potential for eventual driving

cessation due to study participation, and all of these risks will be discussed during the informed consent process. This study will not enroll older adults with severe cognitive impairment.

Adequacy of Protection against Risks

All staff participating in the project will complete compliance and human subjects research training. All recruitment materials will be submitted for approval by COMIRB. No one outside of the research team will know that a participant was involved in the study unless the participant discloses this him/herself. All research records and data will be kept in a locked file in the PI's and Site PIs' offices and/or in password-protected electronic files; recordings will be destroyed seven years after collection to further protect confidentiality.

An additional risk of this study is loss of privacy due to breach of confidentiality, although proven safeguards will be put in place to protect participant confidentiality as much as possible. Data will be entered electronically into REDCap, a COMIRB-preferred method of data storage. REDCap is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium which includes University of Colorado Denver and was initiated at Vanderbilt University. The database is hosted at the University of Colorado Denver Development and Informatics Service Center, which will be used as a central location for data processing and management.

Potential Benefits and Importance of the Knowledge to be Gained

All Aim 1 participants will be compensated for the enrollment session and for each telephone follow-up call (drivers: $50 for first interview and $15 per follow-up call; family members/friends: $25 for first interview and $15 per follow-up call). For Aim 3, participants will receive a $25 gift card for their participation in the qualitative interview/survey. The study is not designed to improve the health of study participants. However, some participants may benefit from the assessment tests by learning more about their health and functioning. The decision aid may help participants make more informed and value-concordant decisions about driving, which could enhance their health and mobility over subsequent years. Results of the study will contribute to helping older adults maintain safe mobility by extending the time period over which they can safely drive and to successfully transition to non-driving when it becomes necessary. Participants in the control website group are also receiving information, albeit in an unstructured way, and may benefit from that knowledge. The findings will expand the knowledge on factors that affect decision making, specifically to the important decision of driving cessation in older adults, which offers the potential to benefit the millions of older adult drivers in the US. The findings will also contribute to traffic safety and public health, by providing much-needed information for advancing the science and practice of safe mobility through a life-course perspective.

Potential Challenges and Strategies

In terms of feasibility, the study team is uniquely positioned to test the DDA, given the investigators' breadth and depth of complementary areas of expertise, as well as experience recruiting older adults for clinical trials and longitudinal studies. Regarding the choice of the Healthwise DDA, we recognize that the use of a commercial product (albeit from a nonprofit

organization) can, in some cases, complicate full dissemination. However, Healthwise decision aids are already widely available. The Healthwise DDA was developed according to and meets international standards[29] and is web-accessible and ready for efficacy testing, and Healthwise is excited for our team's study. Overall, we feel that the use of the Healthwise DDA for this study makes the most sense scientifically and with a view toward future widespread use. Regarding the choice of control, the NIA "Older Drivers" website best represents typical care, as it is an easily-accessible website that provides basic information about driving risk and driving cessation. However, the NIA website does not guide the individual through the decision, unlike the DDA being evaluated, making it an appropriate control for this study. We considered other websites (e.g., from AARP)[111, 112] but these include self-assessment tools, videos, and worksheets that make them more intensive than the DDA. Issues related to research with older drivers include variation in state laws for reporting of potentially unsafe drivers: among the study sites, such reporting is mandatory in California but optional in Colorado and Indiana. We will not be assessing actual driving ability. However, should study staff have strong concern that a participant may have high risk of crash, we will follow IRB and state regulations concerning safety reporting, having explained this during informed consent.

Another potential challenge is the development of semi-autonomous vehicles. With availability estimated to become widespread ≥10 years from now,[23] such technology does not negate the importance of research related to older driver self-regulation and driving retirement. However, in our study questionnaires we will assess use of, and interest in, such technologies. Finally, we anticipate being unable to enroll a family member for every participant, as many older adults are socially isolated. But exploration of the role of family members in decisions about driving—including their participation rate in the trial—is important. Our power calculations are based on older driver participation, so family participation should not affect overall DDA efficacy testing. However, to allow adequate power for family member analyses, as described above, we will ensure that at least 200 participants enrolled have a family member also enrolled.

Conducting research with cognitively-impaired participants poses certain challenges, but it is critically important. Cognitive impairment from Alzheimer's disease and other processes is associated with eventual driving impairment and the need for driving retirement, although the diagnosis of dementia alone does not mandate retirement.[32] Our team has experience recruiting cognitively-impaired older drivers for longitudinal research, and we will follow our standard practices to respect participant rights and safety while also being mindful of community safety. In the event there is cognitive concern, the participant will not be allowed to enroll in the study.. For potentially impaired drivers, we will follow state requirements for reporting to authorities or providers, with disclosure of these procedures during the consent process. It is important to note that we are not assessing driving function or crash risk, and no screens or cognitive tests adequately determine these. We chose measures for cognitive function and decisional capacity after careful consideration and discussion. We chose the 5 minute MoCA as the initial screening test (and telephone follow-up test) because of its various formats and common use in clinical practice, and the SPACED tool for its feasibility in real-world settings. Use of the BTACT and OTMT tests will allow categorization of participants into cognitive function subgroups, enabling a more refined analysis related to cognitive function. We considered the Assessment of Capacity for Everyday Decision-making,[79] but it requires identifying driving as its functional problem and could bias trial results.

Conclusions:

The proposed line of work described in this protocol combines innovative design, a uniquely-qualified team, and the potential for eventual widespread dissemination and impact. Our innovative application of the decision aid model to older driver decision making offers the possibility of facilitating decisions about driving retirement in a patient-centered, acceptable, feasible way, and consequentially it has the potential to reduce the negative psychosocial outcomes associated with driving retirement. Our study team is uniquely qualified to complete the proposed project, given its multidisciplinary expertise in relevant domains and its track record of enrollment of older drivers. There is a high potential for wide-spread dissemination in the future, given the large number of older drivers, the DDA's web format, already broad reach of Healthwise tools, and our inclusion of a range of stakeholder groups in evaluation. Understanding how, with whom, and when to use a driving decision aid has the potential to significantly improve the independence, health, and well-being of millions of older adults.

References:

1. Ross LA, Schmidt EL, Ball K. Interventions to maintain mobility: What works? Accid Anal Prev. 2012.

2. Ball K, Edwards JD, Ross LA, McGwin G, Jr. Cognitive training decreases motor vehicle collision involvement of older drivers. J Am Geriatr Soc. 2010;58(11):2107-2113.

3. 2017 Alzheimer's Disease Facts and Figures. 2017; http://www.alz.org/facts/.

4. Ure R. Autonomous vehicles may be further than regulators realize. 2017; http://thehill.com/blogs/pundits-blog/technology/347956-autonomous-vehicles-may-be-closer-than-regulators-realize.

5. Age Page: Older Drivers. 2014; http://www.nia.nih.gov/health/publication/older-drivers. Accessed June 10, 2014.

6. Alphabetical List of Decision Aids by Health Topic. 2015; https://decisionaid.ohri.ca/AZlist.html. Accessed July 30, 2015.

7. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014;1:CD001431.

8. Healthy Aging: Is It Time to Stop Driving? 2016; https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=zx3961. Accessed March 21, 2017.

9. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning Clinical Science. Clinical Psychological Science. 2013;2(1):22-34.

10. Decision Aid Summary (Healthy aging: Is it time to stop driving?). 2015; https://decisionaid.ohri.ca/AZsumm.php?ID=1342. Accessed March 21, 2017.

11. Distribution of licensed drivers - 2015- by sex and percentage in each age group and relation to population. 2016; https://www.fhwa.dot.gov/policyinformation/statistics/2015/dl20.cfm.

12. Freeman EE, Gange SJ, Munoz B, West SK. Driving status and risk of entry into long-term care in older adults. Am J Public Health. 2006;96(7):1254-1259.

13. Edwards JD, Perkins M, Ross LA, Reynolds SL. Driving status and three-year mortality among community-dwelling older adults. J Gerontol A Biol Sci Med Sci. 2009;64(2):300-305.

14. Foley DJ, Heimovitz HK, Guralnik JM, Brock DB. Driving life expectancy of persons aged 70 years and older in the United States. Am J Public Health. 2002;92(8):1284-1289.

15. Taylor BD, Tripodes S. The effects of driving cessation on the elderly with dementia and their caregivers. Accid Anal Prev. 2001;33(4):519-528.

16. Marottoli RA, de Leon CFM, Glass TA, Williams CS, Cooney LM, Jr., Berkman LF. Consequences of driving cessation: decreased out-of-home activity levels. J Gerontol B Psychol Sci Soc Sci. 2000;55(6):S334-340.

17. Ragland DR, Satariano WA, MacLeod KE. Driving cessation and increased depressive symptoms. J Gerontol A Biol Sci Med Sci. 2005;60(3):399-403.

18. Fonda SJ, Wallace RB, Herzog AR. Changes in driving patterns and worsening depressive symptoms among older adults. J Gerontol B Psychol Sci Soc Sci. 2001;56(6):S343-351.

19. Safe Mobility for Older People. 1999; http://www.nhtsa.dot.gov/people/injury/olddrive/safe/. Accessed October 2, 2008.

20. Classen S, Lopez ED, Winter S, Awadzi KD, Ferree N, Garvan CW. Population-based health promotion perspective for older driver safety: conceptual framework to intervention plan. Clin Interv Aging. 2007;2(4):677-693.

21. Older driver program five-year strategic plan: 2012-2017. 2010; http://www.nhtsa.gov/staticfiles/nti/pdf/811432.pdf.

22. Carr DB, Schwartzberg JG, Manning L, Sempek J. Physician's Guide to Assessing and Counseling Older Drivers, 2nd Edition. 2010; http://www.ama-assn.org/ama/pub/physician-resources/public-health/promoting-healthy-lifestyles/geriatric-health/older-driver-safety/assessing-counseling-older-drivers.shtml. Accessed June 17, 2010.

23. Q&As: Older drivers. 2010; http://www.iihs.org/research/qanda/older_people.html. Accessed April 15, 2011.

24. Older Adult Drivers. 2017; https://www.cdc.gov/motorvehiclesafety/older_adult_drivers/index.html. Accessed September 6, 2017.

25. Braver ER, Trempel RE. Are older drivers actually at higher risk of involvement in collisions resulting in deaths or non-fatal injuries among their passengers and other road users? Inj Prev. 2004;10(1):27-32.

26. Tefft BC. Risks older drivers pose to themselves and to other road users. J Safety Res. 2008;39(6):577-582.

27. Betz ME, Dickerson A, Coolman T, Schold Davis E, Jones J, Schwartz R. Driving rehabilitation programs for older drivers in the United States. Occup Ther Health Care. 2014;28(3):306-317.

28. Betz ME, Jones J, Carr DB. System facilitators and barriers to discussing older driver safety in primary care settings. Inj Prev. 2015.

29. Betz ME, Jones J, Genco E, et al. Perspectives on tiered older driver assessment in primary care settings. Gerontologist. 2014.

30. Betz ME, Kanani H, Juarez-Colunga E, Schwartz R. Discussions about driving between older adults and primary care providers. J Am Geriatr Soc. 2016;64(6):1318-1323.

31. Betz ME, Scott K, Jones J, Diguiseppi C. "Are you still driving?" Metasynthesis of patient preferences for communication with health care providers. Traffic Inj Prev. 2016;17(4):367-373.

32. Carr DB, Ott BR. The older adult driver with cognitive impairment: "It's a very frustrating life". JAMA. 2010;303(16):1632-1641.

33. Association As. 2016 Alzheimer's disease facts and figures. Alzheimer's & Dementia. 2016;12(4):459-509.

34. O'Connor AM. Ottawa Decision Support Framework to Address Decisional Conflict. 2006; https://decisionaid.ohri.ca/docs/develop/ODSF.pdf. Accessed October 7, 2015.

35. Matlock DD, Spatz ES. Design and testing of tools for shared decision making. Circ Cardiovasc Qual Outcomes. 2014;7(3):487-492.

36. Bhandari G, Hassanein K, Deaves R. Debiasing investors with decision support systems: An experimental investigation. Decision Support Systems. 2008;46(1):399-410.

37. Pomidor A. Clinician's guide to assessing and counseling older drivers (3rd edition). American Geriatrics Society and National Highway Traffic Safety Administration; 2016.

38. AAA Roadwise Review: A Tool to Help Seniors Drive Safely Longer. 2005; http://www.aaaexchange.com/MAIN/Default.asp?CategoryID=3&SubCategoryID=38&ContentID=315. Accessed November 25, 2008.

39. We Need to Talk. 2011; http://www.aarp.org/home-garden/transportation/we_need_to_talk/. Accessed December 15, 2011.

40. Pierson JL, Earles DR, Wood K. Brake response time after total knee arthroplasty: when is it safe for patients to drive? The Journal of arthroplasty. 2003;18(7):840-843.

41. Fitness-to-Drive Screening Measure. 2012; http://fitnesstodrive.phhp.ufl.edu/us/.

42. Carmody J, Potter J, Lewis K, Bhargava S, Traynor V, Iverson D. Development and pilot testing of a decision aid for drivers with dementia. BMC Med Inform Decis Mak. 2014;14:19.

43. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S2.

44. Glanz K, Rimer BK, Viswanath K. Health behavior and health education: theory, research, and practice. Jossey-Bass Publishers; 1997:60-84.

45. Meuser T, Berg-Weger ML. Assessment of readiness for mobility transition (ARMT): Application to the Trans-theoretical model (TTM). 2011; http://www.umsl.edu/mtci/PDFs/ARMT%20Manual%208-11.pdf.

46. Meuser TM, Berg-Weger M, Chibnall JT, Harmon AC, Stowe JD. Assessment of Readiness for Mobility Transition (ARMT) A Tool for Mobility Transition Counseling With Older Adults. J Appl Gerontol. 2013;32(4):484-507.

47. Carr DB, Meuser TM, Morris JC. Driving retirement: the role of the physician. CMAJ. 2006;175(6):601.

48. Betz ME, Jones J, Petroff E, Schwartz R. "I Wish We Could Normalize Driving Health:" A Qualitative Study of Clinician Discussions with Older Drivers. J Gen Intern Med. 2013;28 (12):1573-1580.

49. Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. Annu Rev Public Health. 2009;30:151-174.

50. Sepucha K, Ozanne E, Silvia K, Partridge A, Mulley AG, Jr. An approach to measuring the quality of breast cancer decisions. Patient Educ Couns. 2007;65(2):261-269.

51. Sepucha KR, Borkhoff CM, Lally J, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S12.

52. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ. 2006;333(7565):417.

53. O'Connor AM. User manual – Decisional Conflict Scale [updated 2010]. 1993; https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf. Accessed June 20, 2016.

54. O'Connor AM. Decision Self-Efficacy Scale. 1995; https://decisionaid.ohri.ca/docs/develop/Tools/Decision_SelfEfficacy.pdf.

55. PROMIS: Depression 2017; http://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Depression_Scoring_Manual_02222017.pdf.

56. O'Connor AM. Decision Regret Scale. 1996/2003; https://decisionaid.ohri.ca/docs/develop/User_manuals/UM_Regret_Scale.pdf. Accessed April 30, 2018.

57. Baker PS, Bodner EV, Allman RM. Measuring life-space mobility in community-dwelling older adults. J Am Geriatr Soc. 2003;51(11):1610-1614.

58. Peel C, Sawyer Baker P, Roth DL, Brown CJ, Brodner EV, Allman RM. Assessing mobility in older adults: The UAB study of aging life-space assessment. Phys Ther. 2005;85(10):1008-1119.

59. Stalvey BT, Owsley C, Sloane ME, Ball K. The Life Space Questionnaire: A measure of the extent of mobility of older adults. J Appl Gerontol. 1999;18(4):460-478.

60. Phillips J, Dal Grande E, Ritchie C, Abernethy AP, Currow DC. A population-based cross-sectional study that defined normative population data for the Life-Space Mobility Assessment-composite score. J Pain Symptom Manage. 2015;49(5):885-893.

61. Lachman M, Agrigoroaei S, Tun P, Weaver S. Monitoring Cognitive Functioning: Psychometric Properties of the Brief Test of Adult Cognition by Telephone (BTACT). Assessment. 2014;21(4):404-417.

62. Mrazik M, Millis S, Drane D. The Oral Trail Making Test: Effects of Age and Concurrent Validity. Archives of Clinical Neuropsychology. 2010;25:236-243.

63. Beck AT, Baruch E, Balter JM, Steer RA, Warman DM. A new instrument for measuring insight: the Beck Cognitive Insight Scale. Schizophr Res. 2004;68(2-3):319-329.

64. Degirmenci E, Degirmenci T, Duguncu Y, Yilmaz G. Cognitive insight in Alzheimer's disease. Am J Alzheimers Dis Other Demen. 2013;28(3):263-268.

65. Penney D, Sauve G, Malla A, Joober R, Lepage M. Toward developing clinical cutoff values for the Beck Cognitive Insight Scale. Schizophr Bull. 2018;44(suppl_1):S148-S149.

66. Han SD, Boyle PA, James BD, Yu L, Barnes LL, Bennett DA. Discrepancies between cognition and decision making in older adults. Aging Clin Exp Res. 2016;28(1):99-108.

67. Finucane ML, Gullion CM. Developing a tool for measuring the decision-making competence of older adults. Psychol Aging. 2010;25(2):271-288.

68. Finucane ML, Mertz CK, Slovic P, Schmidt ES. Task complexity and older adults' decision-making competence. Psychol Aging. 2005;20(1):71-84.

69. Wong A, Nyenhuis D, Black SE, et al. Montreal Cognitive Assessment 5-minute protocol is a brief, valid, reliable, and feasible cognitive screen for telephone administration. Stroke. 2015;46(4):1059-1064.

70. Choi M, Adams KB, Kahana E. Self-regulatory driving behaviors: gender and transportation support effects. J Women Aging. 2013;25(2):104-118.

71. Choi M, Mezuk B, Lohman MC, Edwards JD, Rebok GW. Gender and racial disparities in driving cessation among older adults. J Aging Health. 2013;25(8 Suppl):147S-162S.

72. Hollis AM, Duncanson H, Kapust LR, Xi PM, O'Connor MG. Validity of the mini-mental state examination and the montreal cognitive assessment in the prediction of driving test outcome. J Am Geriatr Soc. 2015;63(5):988-992.

73. Li G, Eby DW, Santos R, et al. Longitudinal Research on Aging Drivers (LongROAD): Study design and methods. Injury Epidemiology 2017;4(1):22.

74. Efird J. Blocked randomization with randomly selected block sizes. Int J Environ Res Public Health. 2011;8(1):15-20.

75. Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. The Lancet. 2002;359(9305):515-519.

76. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. The Lancet. 2002;359(9306):614-618.

77. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. PLoS Med. 2010;7(3):e1000251.

78. Eysenbach G, Group C-E. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011;13(4):e126.

79. Lai JM, Gill TM, Cooney LM, Bradley EH, Hawkins KA, Karlawish JH. Everyday decision-making ability in older persons with cognitive impairment. Am J Geriatr Psychiatry. 2008;16(8):693-696.

80. American Geriatrics Society & A. Pomidor, Ed. (2016, January). Clinician's guide to assessing

and counseling older drivers, 3rd edition. (Report No. DOT HS 812 228). Washington, DC:

National Highway Traffic Safety Administration. The American Geriatrics Society

retains the copyright.

81. Roalf Dr, Moore TM, Wolk DA, et al. Defining and validating a short form Montreal Cognitive Assesment (s-MoCA) for use in neurodegenerative disease. J Neurol Neurosurg Psychiatry. 2016;87(12):1303-1310.