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Perceptions of Research Burden and Retention among Participants in ADRC Cohorts

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Abstract

Objectives: Alzheimer disease and related dementias (ADRD) clinical research is associated with significant participant burden. The Perceived Research Burden Assessment (PeRBA) measures participants' perceptions of logistical, psychological, and physical burdens. The purpose of this study was to assess PeRBA's psychometric properties, perceptual sources, and behavioral consequences with participants in a multi-site study of participant retention in longitudinal cohort studies of ADRD.

Design: Multi-center mixed methods

Setting: In-person or phone

Participants: 443 participants at 4 NIA-funded Alzheimer Disease Research Centers (ADRCs) were randomly selected and invited to participate if they were ≥45 years of age, enrolled in longitudinal studies, and had a Clinical Dementia Rating Scale global score ≤1.

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Author Contributions: S.L. Stark, J.H. Lingler, D.F. Edwards, and J.D. Grill formulated research questions and designed the study. R.M. Bollinger and M. Knox carried out the study. M. Gabel and D.W. Cobble analyzed the data. M. Gabel, R.M. Bollinger, M. Knox, D.W. Coble, J.D. Grill, D.F. Edwards, J.H. Lingler, and S.L. Stark wrote the article.

Conflicts of interest
None.

Measurements: Participants completed a 20-minute survey including the 21-item PeRBA about their research participation.

Results: PeRBA demonstrated high internal consistency and convergent and discriminant validity. PeRBA scores correlated with expected perceptual factors. Higher PeRBA scores were associated with lower attendance and higher dropout rates.

Conclusions: PeRBA can be used by researchers to identify participants who may feel overburdened and tailor approaches and strategies to support participants in longitudinal AD studies, maximizing participation and reducing dropout. Making efforts to increase participants' understanding of study procedures, and building and maintaining trust throughout the study, can contribute to reducing perceived burden and potentially increasing retention in longitudinal AD studies.

Keywords

Alzheimer disease; dementia; longitudinal studies; research design and methodology; psychogeriatrics

Introduction

Rapid progress has been made in research on Alzheimer disease (AD) and related disorders (ADRD) based, in large part, on longitudinal cohort studies. In particular, the increased understanding of ADRD as a spectrum disorder, characterized by distinct and progressive phases of biological and clinical progression, was made possible by longitudinal AD studies enrolling thousands of volunteers who underwent procedures such as cognitive assessments, blood draws, magnetic resonance imaging, positron emission tomography imaging, and lumbar puncture for cerebrospinal fluid protein analyses.[1]

The burden of participating in ADRD research includes the direct risks associated with research procedures but also the inconvenience of transportation to and from visits, the opportunity costs of ways one's time might otherwise be spent, and the emotional costs of contributing—which, for many participants, is out of a direct hope to contribute to discoveries that will lead to meaningful improvements to clinical care for diseases that afflict their families. Referred to as *research participant burden,* this phenomenon is subjective in nature and may be impacted by a range of factors including study design and procedures, as well as characteristics of study investigative staff and the participant (Figure 1).[2] Measuring this burden may be useful for both making choices about study design and monitoring participants during longitudinal studies to assess the risk for withdrawal/dropout.

The Perceived Research Burden Assessment (PeRBA) is a 21-item questionnaire designed to measure participants' perceptions of the logistical (e.g., time commitment), psychological (e.g., intrusiveness of interview questions), and physical (e.g., perceived risk of injury) burden associated with enrollment in ADRD research.[3] It is a flexible tool that consists of phrasing options for deployment before (e.g., "This study's visits might last too long") or after (e.g., "This study's visits last too long") an individual has enrolled in a study. A 26-item version is also available for assessment of family members'/study partners' perceptions of research burden.[3] The participant and study partner versions of PeRBA were initially

validated by assessing the anticipated burden of 3 hypothetical research studies using the pre-enrollment phrasing. This corresponds to the green box in Figure 1. While internal consistency was high and psychometric analyses demonstrated convergent and discriminant validity, PeRBA remains a relatively new tool that has not been validated as a measure of experienced (versus merely anticipated) research participant burden (Figure 1, blue box). Furthermore, PeRBA was initially examined in a convenience sample composed primarily of non-Hispanic White volunteers. Given the importance of recruiting and retaining racially and ethnically diverse samples in ADRD research internationally, there is a need to examine PeRBA in a larger, more generalizable sample.

To assess PeRBA's psychometric properties in a diverse research cohort and after having participated in research (Figure 1, blue box), we administered the post-enrollment version of PeRBA to participants in a multi-site study of participant retention in longitudinal cohort studies of ADRD. We also evaluated whether the posited perceptual factors (Figure 1, orange box) influence perceptions of experienced burden (Figure 1, orange arrow), and whether the perceived experienced burden affects participation (Figure 1, blue arrow).

Methods

Participants

We recruited research participants from active cohorts at 4 NIA-funded Alzheimer Disease Research Centers (ADRCs) across the United States: Knight ADRC at Washington University in St. Louis, Missouri (Knight ADRC); University of Pittsburgh ADRC in Pittsburgh, Pennsylvania (PITT ADRC); University of Wisconsin in Madison, Wisconsin ADRC (Wisconsin ADRC); and University of California–Irvine ADRC in Irvine, California (UCI ADRC). Individuals who were at least 45 years of age, were currently enrolled in longitudinal studies, and had a Clinical Dementia Rating (CDR®) global score of ≤1 at their most recent clinical assessment were invited to participate. Exclusion criteria included residence in an institutional setting and/or residence outside of the geographic area of one of the participating ADRCs.

Participants from each ADRC were randomly selected and invited to participate either in person or via phone between ADRC visits. If interested, participants and study partners provided written or verbal informed consent. As a function of their participation in the ADRC cohort study, participants self-reported their race and ethnicity as separate constructs. For the purpose of this study, we considered mutually exclusive categories of race and ethnicity (Hispanic ethnicity, non-Hispanic White, non-Hispanic African American or Black, or non-Hispanic Asian American).

The study was approved by the Institutional Review Boards at all 4 sites.

Study Procedures

This study consisted of a 20-minute survey about facilitators and barriers to retention in longitudinal research. Trained and certified raters administered surveys in person or via phone. Participants were offered a $5 gift card for participation. Demographic information

for this sample was analyzed using the National Alzheimer's Coordinating Center (NACC) Uniform Data Set.[4,5]

Measures

Our survey included the PeRBA items as well as a battery of questions about participants' perceived facilitators and barriers to study participation. Survey items were ranked on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree), unless otherwise noted. The final survey consisted of 57 closed-ended and 2 open-ended questions. The survey questions are available in the appendix. For the purposes of this paper, we will focus on the results of the PeRBA assessment. Results about facilitators and barriers to study participation are published elsewhere.[6]

We generated 2 metrics of participation: (1) attendance rates based on the number of ADRC study visits each participant attended divided by the number of study visits scheduled as of January 21, 2021, and (2) whether the participant had dropped out of the study. The analysis of attendance rates included only participants (N = 377) with 2 or more possible visits and included a control variable for the total number of possible visits. This ensured that the number of possible visits did not confound the analysis. For instance, the most committed participants may exhibit both relatively high attendance rates and relatively large numbers of visits. We defined dropouts (N = 11) as participants who, as of October 18, 2020, were defined in the NACC database as no longer receiving follow-ups and who had not died or been removed from the study. Those who dropped out had much lower average attendance (59%) prior to dropout than those who had not dropped out (93%). Also, these analyses included controls for the participants' ADRC sites. This means that the estimated effects were based on comparisons of participants within study sites, not across sites.

Statistical Analyses

Survey data were entered directly into the web-based data collection tool Research Electronic Data Capture (REDCap)[7], which provides secure data entry with real-time validation. REDCap servers are housed in a firewall-protected, limited-access data center managed by the Washington University Division of Biostatistics. Quality control programs were used to verify identification, evaluate consistency, and monitor recruitment and retention. Standardized procedures were used for secure data transfer. Response frequencies were computed for each item. Data analyses were conducted in STATA 15.1 (StataCorp LLC).

We performed a principal component factor analysis to estimate and explain the latent structure of the responses to the PeRBA items, and we used regression scoring to generate factor scores on the latent PeRBA dimension. Linear regression analysis of the factor scores was by ordinary least squares (OLS) with robust (Huber/White/sandwich) standard errors. Attendance rates were analyzed using the 'fracreg' (fractional logistic regression) procedure, which is appropriate for proportions. Dropouts were analyzed using the 'firthlogit' procedure (Firth logistic regression), which is designed for rare binary events.

Results

Four hundred forty-three participants completed the survey across the 4 ADRCs. Demographic characteristics for participants by site and overall are included in Table 1. The majority of participants were female and CDR=0. On average, participants had been enrolled in the parent cohort studies for more than 5 years. Few differences were observed among the sites, with the exception of the racial and ethnic composition of the participants at each site and the relative proportions of participants who were CDR=0 vs. CDR >0.

The Latent Structure of Responses to the PeRBA Survey Items about Experienced Burden

Examination of the first three eigenvalues (7.87, 1.38, 0.74) indicates that variation in responses to these questions is best accounted for by a single latent dimension. Factor loadings for PeRBA items were all in the same direction, with agreement with one source of burden (e.g., distance to study site) associated with agreement with other aspects of research burden (Table 2). Cronbach alpha scores (Table 2) indicated that the single factor was internally consistent and thus a reliable measure of the latent construct—research burden. In a sensitivity analysis, both the factor structure and the construct validity were consistent across sites (Table 2). For the ensuing analysis, we generated factor scores for each study participant on this latent dimension, which ranges from low perceived burden to high perceived burden.

Perceptual Features and PeRBA

As expected from the conceptual model in Figure 1 (orange box), study participants with higher perceived burden were less likely to agree that they were getting what they wanted from the study, that they trusted medical researchers, and that they understood the study procedures compared to those with lower PeRBA scores (Table 3). The statistical models included a variety of controls to account for potential confounding factors. Participants who identified as Asian expressed higher PeRBA than participants who identified as African American, and those with CDR scores above 0 expressed higher PeRBA than those with a CDR score of 0.

PeRBA and Participation Rates

Most (75%) of the surveyed study participants with at least 2 expected visits had perfect attendance. The mean attendance rate was 92%. Table 4 reports fractional logistic regression results estimating the effect of perceived burden on attendance rates and Firth logistic regression results for the likelihood of dropout. Study participants' attendance was adversely affected by perceived burden as measured by PeRBA. As anticipated in the conceptual model (Figure 1, blue arrow), study participants with higher PeRBA scores had lower odds of having perfect attendance at study visits (OR = 0.71, 95% CI: 0.56–0.89) and a higher risk of dropping out (OR = 2.26, 95%CI: 1.08–4.72). Independent of perceived burden, self-identified African American participants had lower attendance rates than did self-identified white and Asian participants.

Discussion

We conducted a cross-validation study of the PeRBA in a random sample of regionally diverse research participants from 4 sites within the national ADRC network. Overall, our findings suggest that PeRBA is a psychometrically valid measure. Internal consistency of PeRBA is high, and factor analysis suggests that perceived research burden is a unidimensional latent construct for which one overall metric is appropriate. In addition to providing cross-validation, this study expands upon our team's early work with PeRBA in 2 important ways. Specifically, this study quantified perceptions of the burden experienced, not just anticipated, by ADRD research participants and represents the first effort to empirically test several key relationships delineated in our conceptual model (Figure 1).

Better Understanding Yields Less Perceived Burden

Consistent with our conceptual model, we found that PeRBA scores were positively associated with self-reported understanding of study procedures. This finding suggests that participants may better tolerate procedures that are perceived as clearly explained. While explanations of study procedures are routinely offered during informed consent, the longitudinal nature of ADRD cohort research warrants ongoing explanations of procedures, especially those that may be perceived as burdensome (e.g., lumbar puncture and neuropsychological testing). Yet, with the exception of articles on research test results disclosure, the literature on communicating with ADRD research participants focuses almost exclusively on pre-enrollment explanations of the research.[8] The ADRCs in this study invite participants to annual events to honor their contributions and share results, but more may be needed to communicate with participants. Our findings indicate that ensuring participants' understanding of ADRD research procedures not only is critical to fulfilling the ethical obligation of informed consent prior to enrollment, but also plays an important role in minimizing the perceived burden of ADRD study participation and maximizing participation and retention. Efforts to promote clear, ongoing communication about research procedures should be explored and, when comprehensive, will not only describe what a participant may expect during a specific procedure, but also explain how specific procedures are linked to the study's overall goals. One method to facilitate participant engagement is using an electronic consent experience. In a recent study, participants retained more information and preferred the electronic format compared to a typical paper consent.[9] This approach could be integrated into existing studies to enhance participants' understanding of research procedures and could potentially decrease participant (and investigator) burden. Retention strategies such as these have been identified as key to minimizing dropout and facilitating long-term participation.[10]

PeRBA scores were also negatively associated with reporting that one's own goals for research participation are being met. This is consistent with our conceptual model, which posits that research that is perceived as more beneficial will be perceived as less burdensome. While the present study focused on participants in observational research and did not directly measure the benefits of research participation, it is nevertheless reasonable to expect participants to view participation that meets their personal goals as beneficial.

Inquiries about participants' personal goals for research participation can be incorporated into both study enrollment and participant retention protocols.

Higher Levels of Trust Yield Less Perceived Burden

As hypothesized in our conceptual model, we found that PeRBA scores were inversely associated with trust in researchers. This finding builds on numerous studies of the critical role of trust in recruitment to clinical research, suggesting that trust is not only requisite to enrollment, but likely has a broader impact on participants' overall research experiences once enrolled.[11–17] One implication of this finding is that research teams should explicitly strive to continue trust-building with participants throughout a study. Following through with commitments to participants, maintaining confidentiality, and providing timely compensation and return of research results (whether aggregate or individual[18]) are examples of ways that research teams can build and reinforce participants' trust in the researchers and ADRCs.

Lower Perceived Burden Yields Greater Research Participation

Retention is increasingly recognized as a significant issue in AD research. Clinical trials are moving toward earlier intervention in individuals without dementia and/or those with prodromal and preclinical ADRD but have been plagued with unacceptably high dropout rates.[19] In our sample, lower perceived burden was associated with higher attendance rates and lower likelihood of dropout. This finding suggests that strategies to reduce participant burden, such as eliminating unnecessary procedures, or perception of burden, such as concise and lay-friendly communication of the study purpose, should be developed and tested formally to increase compliance and follow-up.[10] Burden-lowering efforts may play a complementary role to activities that have traditionally been undertaken to demonstrate appreciation for research participants' contributions.[10]

Limitations

Several limitations of this study must be acknowledged. Our sample was randomly selected from active participants at four ADRCs and thus the generalizability of these results to other research contexts, including clinical trials, is unclear. The ADRC network, however, includes more than 30 centers and the remaining centers will benefit from this work on participant burden. The ADRC network is also increasing in size and the cohort study will likely continue for many years; so the value of these data will persist and increase.[20] And while the NACC cohort may be unique, the results may be applicable to other longitudinal studies, especially those in older populations and those with or at risk for neurodegenerative disease, though determining this generalizability will require more research. By design, we were limited to collecting data from participants whom we could reach for interviews; thus, those who withdrew their participation or refused further contact from ADRC personnel were not included. The relatively small number of dropouts observed in this study suggests that caution is warranted in drawing conclusions from our findings on dropouts. It is worth highlighting that the relationship between trust in research and perceived burden is likely to be bidirectional in nature, but the cross-sectional nature of our participant interviews constrained our ability to examine this possibility. Finally, while we were not able to enroll participants internationally, perceived burden is common to research populations.

The PeRBA is a standardized tool that can be deployed internationally to explore the generalizability of our findings.

Conclusions

These results may have several important implications for the burgeoning field of recruitment science.[21] PeRBA is a psychometrically valid measure that can be used to identify participants who may feel overburdened. Researchers can use these findings to tailor approaches and strategies to support participants and study partners, especially those who may be at risk for dropout or missed study visits. Moreover, PeRBA may be amenable to change. Our results indicate that researchers should make efforts to increase participants' understanding of study procedures, to build and maintain trust throughout the study, and to contribute to less perceived burden in order to increase participant retention. Future studies should aim to replicate these findings in more racially and ethnically diverse samples and within studies involving more complex research, including intervention trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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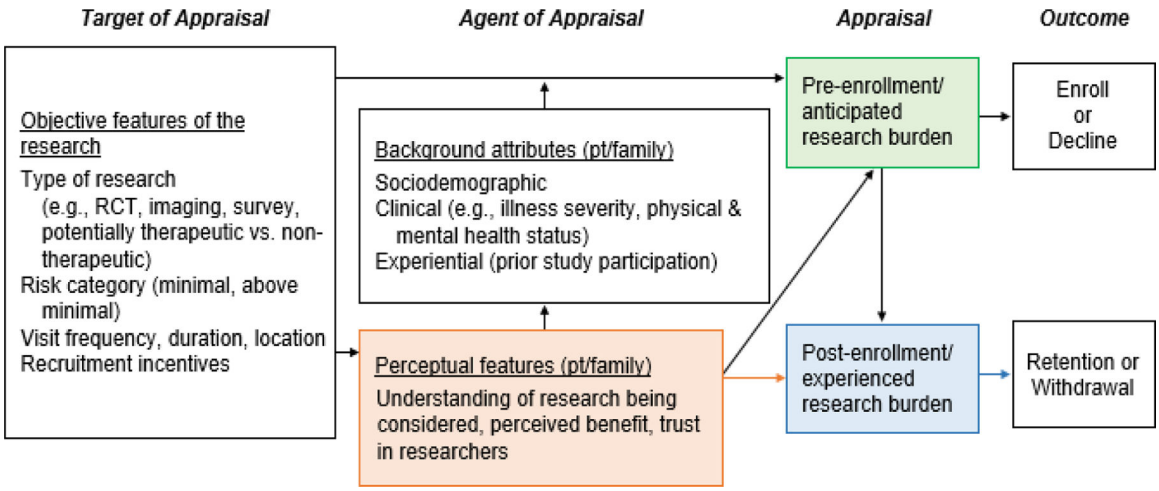

Figure 1. Conceptual Model of Role of Perceived Participant Burden in Recruitment and Retention

Note: RCT = randomized controlled trial; pt = patient; "Family" refers to relatives or close friends who may share in decision-making.[22]

Table 1.

Demographic characteristics of participants by site and overall

	Participants				
	Knight ADRC (n = 111)	**Wisconsin ADRC (n = 112)**	**PITT ADRC (n = 110)**	**UCI ADRC (n = 110)**	**Total (N = 443)**
Age, Mean (SD)	68.0 (6.8)	63.1 (8.7)	67.3 (7.3)	70.7 (7.8)	67.3 (8.1)
Gender					
Female	61 (54%)	75 (67%)	63 (57%)	63 (57%)	262 (59%)
Male	51 (46%)	37 (33%)	47 (43%)	47 (43%)	182 (41%)
Race/Ethnicity, n (%)					
African American	25 (22%)	14 (12%)	8 (7%)	0 (0%)	47 (11%)
Asian	0 (0%)	0 (0%)	0 (0%)	41 (37%)	47 (9%)
White	87 (78%)	94 (84%)	101 (92%)	67 (61%)	349 (79%)
Other	0 (0%)	4 (4%)	1 (1%)	2 (2%)	7 (1%)
Hispanic, n (%)					
Yes	0 (0%)	0 (0%)	1 (1%)	6 (5%)	7 (2%)
No	112 (100%)	112 (100%)	109 (99%)	104 (95%)	437 (98%)
Years of Education, Mean (SD)	16.1 (2.6)	16.1 (2.8)	16.4 (2.5)	17.3 (2.3)	16.5 (2.6)
Area Deprivation Index, Mean (SD)	3.51 (2.77)	3.69 (2.68)	4.18 (2.78)	3.62 (4.06)	3.75 (3.12)
APOE4, n (%)					
Positive	47 (42%)	43 (38%)	38 (35%)	32 (29%)	160 (36%)
Negative	65 (58%)	68 (61%)	72 (65%)	59 (54%)	264 (59%)
Missing	0 (0%)	1 (1%)	0 (0%)	19 (17%)	20 (5%)
CDR, n (%)					
CDR = 0	90 (80%)	90 (80%)	51 (46%)	77 (70%)	310 (70%)
CDR > 0	22 (20%)	22 (20%)	59 (54%)	33 (30%)	134 (30%)
Years enrolled, Mean (SD)	7.01 (4.01)	4.27 (2.03)	4.85 (3.31)	4.48 (3.94)	5.08 (3.51)

Note: Area Deprivation Index is missing for 11 participants (3 at Knight ADRC; 5 at Wisconsin ADRC; 3 at PITT ADRC)

Table 2.

Factor loadings of PeRBA items on first dimension

I agree that:	Knight ADRC (n = 110)	Wisconsin ADRC (n = 110)	PITT ADRC (n = 106)	UCI ADRC (n = 108)	Total (N = 434)
Study visits are too frequent	0.66	0.59	0.51	0.69	0.60
Study visits are too long	0.58	0.57	0.64	0.57	0.58
Study visits take away from time with family & friends	0.60	0.70	0.75	0.77	0.70
Research site is too far away	0.72	0.56	0.46	0.58	0.56
Inconvenient to get to research site	0.68	0.61	0.61	0.59	0.61
Inconvenient to park at research site	0.53	0.58	0.42	0.34	0.45
Study takes too much time away from my chores	0.71	0.70	0.78	0.81	0.75
Study takes too much time away from family member's job	0.70	0.71	0.62	0.74	0.70
Costs too much to get to research site	0.70	0.70	0.68	0.68	0.69
Researchers ask too many questions	0.69	0.69	0.76	0.80	0.73
Researchers ask questions that are too personal	0.69	0.69	0.77	0.79	0.73
Researchers contact me too often	0.70	0.68	0.76	0.82	0.74
Personal information might not be kept private	0.48	0.59	0.47	0.42	0.47
I became emotionally upset by study procedures	0.65	0.65	0.55	0.62	0.61
I have had second thoughts about my decision to participate	0.71	0.69	0.56	0.73	0.65
I regret my decision to participate	0.74	0.64	0.59	0.82	0.70
I worry that I may be harmed by procedures	0.52	0.65	0.68	0.43	0.55
I became fatigued from procedures	0.44	0.43	0.40	0.46	0.44
I experienced side effects from procedures	0.46	0.57	0.70	0.39	0.51
I experienced physical pain from procedures	0.34	0.48	0.64	0.39	0.44
My health got worse while participating in study	0.59	0.55	0.32	0.48	0.48
Cronbach alpha	*0.915*	*0.919*	*0.905*	*0.915*	*0.914*

Note. PeRBA = Perceived Research Burden Assessment, ADRC = Alzheimer Disease Research Center.

Table 3.

Perceptual features and perceived research burden (PeRBA)

	PeRBA score		
	Perceived benefit	**Trust in researchers**	**Understanding of research**
Accomplishing one's goals with study participation (1 strongly agree, 5 strongly disagree)	−0.46** (0.08)	—	—
How much do you trust medical researchers? (1 not at all, 5 a great deal)	—	−0.42** (0.07)	—
Understand why asked to participate in so many procedures (1 strongly agree, 5 strongly disagree)	—	—	−0.64** (0.09)
Male	0.06 (0.09)	0.09 (0.09)	−0.05 (0.08)
White	0.02 (0.15)	0.16 (0.15)	−0.05 (0.14)
Asian	0.75** (0.26)	0.88** (0.25)	0.62* (0.25)
Other race	0.39 (0.34)	0.15 (0.32)	0.35 (0.23)
Years of education	−0.02 (0.02)	−0.02 (0.02)	−0.02 (0.02)
Area Deprivation Index	−0.01 (0.01)	−0.01 (0.01)	−0.00 (0.01)
CDR score > 0 (0 if CDR = 0; 1 if CDR > 0)	0.18 (0.10)	0.16 (0.10)	0.23* (0.10)
Age	0.01 (0.01)	0.01 (0.01)	0.01 (0.01)
N	419	420	421
R^2	0.20	0.18	0.28

Note: The table reports OLS regression coefficients with robust standard errors. All models include controls for ADRC site.

* $p < .05$;

** $p < 0.01$, one-tailed test.

Table 4.

Behavioral consequences of PeRBA

	Attendance rate	Dropout
PeRBA score	−0.35** (0.12)	0.81* (0.38)
Male	0.14 (0.26)	−0.63 (0.75)
White	0.86* (0.39)	−1.20 (0.86)
Asian	1.93** (0.67)	−1.62 (2.50)
Other race	−0.23* (0.64)	−0.34 (1.68)
Years of education	0.05 (0.05)	0.03 (0.13)
Area Deprivation Index	−0.03 (0.04)	0.11 (0.08)
Age	−0.01 (0.02)	0.08 (0.04)
CDR score > 0 (0 if CDR = 0; 1 if CDR > 0)	−0.05 (0.28)	0.75 (0.73)
Number of possible visits	−0.02 (0.03)	-
N	357	421

Note. Log odds ratios are reported with standard errors in parentheses. All models included controls for ADRC site.

* $p < 0.05$,

** $p < 0.01$, one-tailed test.

The fractional logistic regression results for attendance rate include only participants with at least 2 scheduled study visits. Firth logistic regression was used to analyze dropouts.