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Psychometric Properties of a Decisional Capacity Screening Tool for Individuals Contemplating Participation in Alzheimer's disease Research

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Abstract

Background—With the growing population of individuals affected by Alzheimer's disease (AD) and related disorders, there is a pressing demand for research on late life cognitive disorders. However, the high risk for decisional incapacity in this population necessitates the evaluation of capacity to consent to research participation, adding to the cost and complexity of the research process. The University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) was initially validated in a sample of persons with schizophrenia and healthy controls.

Objective—To assess the psychometric properties of the UBACC when used in a sample of individuals contemplating participation in research on AD.

Methods—The UBACC was administered to a convenience sample (n=132) consisting of individuals with mild to moderate cognitive impairment (n=52), their study partners (n= 52) and healthy older adults control subjects (n=30), as part of a broader study to evaluate perceived burden of research participation. Reliability tests, correlational analyses, and exploratory factor analytic methods were used to examine the psychometric properties of the instrument.

Results—UBACC scores were significantly associated with both global cognition (rs = .564, p < .001) and verbal fluency (rs = .511, P <.001), indicating concurrent validity with related constructs. The resulting factor structure differed from that reported by the developers in their initial testing. Items clustered almost entirely on one factor, and items reflecting the construct of

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understanding accounted for 32.12% of the total variance, with no evidence for distinct reasoning or appreciation scales.

Conclusion—The UBACC shows promise when used to screen for decisional capacity among those considering participation in AD research.

Keywords

Alzheimer's disease; decisional capacity; informed consent; instrumentation

Background

Decisional capacity is a requisite condition for the provision of informed consent to research. With origins in the field of bioethics, decisional capacity is widely viewed to be comprised of four elements: understanding, appreciation, reasoning and choice.[1] Research participants should comprehend that engaging in a research study is voluntary, may carry risk, is not intended as clinical care, may provide no benefit, and may be discontinued at any time without negative consequences. [2, 3]Furthermore, participants must be able to understand study procedures, apply that understanding to their own life circumstances in the context of their beliefs and values (a process typically referred to as appreciation), and arrive at a reasoned decision.

Decisional capacity is not fixed. Rather, the capacity to understand, appreciate, and reason is considered in relation to a particular decision and is recognized to be impacted by the complexity and risks associated with that decision.[4] Because the capacity to consent to research is study-specific and should not be solely based on a clinical diagnosis, regulatory bodies have adopted the language of populations at-risk for decisional incapacity to describe those for whom particular attention to decisional capacity is warranted.[5] When the potential for decisional incapacity is present, researchers are obligated to assess and make reasonable efforts to maximize a potential participant's understanding and appreciation of the protocol's purpose and procedures, duration, risks, benefits, alternatives, measures to ensure confidentiality, provisions in the event of injury, key study contact persons, voluntary nature of participation as well as the individual's ability to carry out the decision-making process.

Depending upon the degree of decisional impairment, an individual may be capable of providing consent to a low-risk study protocol, but have inadequate capacity to consent to one carrying higher risk. Furthermore, individuals with differing types of cognitive impairment appear to display different deficits with regard to the elements of decisional capacity. Although there is a great deal of variation within groups, research suggests that when compared with healthy control subjects, those with bipolar disorder and schizophrenia may be more likely to display impaired understanding and appreciation[6] while those with dementia may be more likely to struggle with understanding and reasoning.[7] The theory underlying decisional capacity suggests that, before an individual is provided with the opportunity to make a choice about research participation, these elements be assessed. Given the resources required to comprehensively assess decisional capacity in those at risk, a tool capable of reliably screening for capacity across various populations would be of

considerable utility. If screening reveals potential incapacity, more in-depth assessments like the MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR)[8] or a clinical interview can then be used to evaluate the potential participant.

The University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) [9] is a newly developed brief tool to screen for capacity to consent to research participation among those at risk for decisional incapacity. It was designed to meet the need for a short, efficient means of screening for potential decisional incapacity that could be conducted by research staff members with basic training, offering an alternative as a first line approach to using more comprehensive assessments, like the MacCAT-CR that require more training and administration time. The UBACC was first tested in a sample of 127 adults with schizophrenia and 30 healthy control subjects. Administration time averaged 5 minutes, very good inter-rater reliability scores were observed using trained bachelor's level research assistants, and concurrent validity with the MacArthur Competence Assessment Tool – Clinical Research (MacCATCR)[8] was demonstrated. Factor analysis by the developers revealed a 3-factor structure, with identified subscales for reasoning (1 item), appreciation (5 items) and understanding (4 items), which the authors related to the underlying theoretical framework for decisional capacity.

While the UBACC was psychometrically sound in a sample of individuals with schizophrenia and healthy controls, the reliability and validity of the UBAAC have not been examined in different populations. The UBACC's developers have suggested that the tool has application in multiple research settings. However, validity of measurement relies upon the population, and validity must be reconfirmed when a tool is used in a new or different population. Given the rising number of individuals affected by Alzheimer's disease and related disorders, their high risk for decisional incapacity, and the possibility of fluctuating levels of capacity, a valid, reliable tool which affords rapid assessment of capacity to consent for research participation is likely to be quite valuable. The purpose of the current study was to evaluate the internal consistency reliability and construct validity of the UBACC in a sample of older adults who are likely to face decisions about the possibility of participation in research on Alzheimer's disease and related disorders.

Methods

Procedure

The current study is a secondary analysis of data obtained from a sample of 134 subjects recruited from the University of Pittsburgh Alzheimer Disease Research Center (ADRC; NIA grant P50 AG05133; PI: Lopez) which included healthy controls, persons with mild cognitive impairment (MCI) or dementia (Mini Mental Status Exam[10] ≥16) and study partners of those persons with MCI or dementia. Within one year of recruitment to the parent study, all healthy controls and persons with MCI or dementia had undergone a comprehensive multidisciplinary evaluation including a physical exam, neurological assessment, psychiatric evaluation, cognitive testing and neuroimaging, the results of which were used to determine each individual's diagnostic classification by a consensus conference process applying standard diagnostic guidelines. A detailed description of ADRC enrollment criteria and diagnostic evaluation procedures has been previously published. [11] The parent

study, **P**erceived **R**esearch **B**urden **A**ssessment (PeRBA), involved the evaluation of measures of participant burden among those who might potentially participate in AD research.[12] ADRC participants were eligible for PeRBA if they: 1) had an ADRC consensus-based diagnosis of normal cognition, mild cognitive impairment [13, 14] Probable Alzheimer's disease[15], or other dementia, 2) had score of 16 or greater on the Mini-Mental Status Exam at their most recent ADRC visit [10], 3) were community-dwelling, 4) resided within 50 miles of the University of Pittsburgh; and 5) were willing to participate and, for those with a cognitive disorder, had a primary family member who was willing to participate as a study partner. Approval for the PeRBA study was obtained from the University of Pittsburgh, Institutional Review Board. The UBACC was utilized within the study protocol in order to determine if subjects likely understood hypothetical research scenarios well enough to complete the PeRBA assessment, which required meaningful deliberation about research participation and reflection on the potential burden of participation.

Also administered to participants were the Trust in Medical Researchers Scale[16] and four questions about social support adapted from the **R**esources for **E**nhancing **A**lzheimer's **C**aregiver **H**ealth **(**REACH) study.[17] Sociodemographic and clinical data were abstracted from the ADRC database and included age, gender, race, years of education, diagnosis (AD, non-AD dementia, MCI, or control), verbal fluency scores [15], and Mini Mental Status Exam (MMSE) Score.[10]

The PeRBA study used three hypothetical research vignettes developed for use in AD research,[18] each modified slightly to reflect current research practices. The vignettes described a low risk, a moderate risk, and a high risk research protocol and were independently presented to subjects in a counterbalanced order. For each vignette, participants were given a laminated cue card containing the text of the vignette and were allowed to refer to the card during administration of the UBACC questions. After the presentation of each vignette, the UBACC items were administered. The items are listed in the footnote of Table 3. The analyses of the current study were performed using data from the moderate risk vignette. The moderate risk vignette describes a hypothetical protocol for an investigational drug developed to treat memory problems and halt the progression of dementia.

Using the UBACC requires the investigator to determine the protocol-specific responses that indicate clear or partial capability to consent to the study in question.[9] While Jeste and colleagues recommend developing a set of anticipated responses and scores in advance, the flexible nature of our pilot study allowed our team to record verbatim participants' responses to the UBACC items and to develop a scoring rubric based directly upon those responses. Blinded to the subject's status as a control, family member, or patient, our research team reviewed responses to the UBACC items for the first 34 subjects to develop study-specific criteria for capable and incapable responses. Responses were scored from 0 to 2, with a score of 0 reflecting a clearly incapable response, a score of 1 indicating a partially appropriate or uncertain response, and 2 reflecting a completely capable response (See Table 1). The rubric for scoring responses was developed by an inter-professional team that included a neuropsychologist, bioethicist, geriatric social worker and an advanced practice

nurse. Once the scoring rubric was established, trained, independent raters scored the subsequent subjects' responses; intraclass correlation coefficients (ICC) of the ratings were then calculated to assess inter-rater reliability for UBACC scoring. ICC was chosen as the method for assessing inter-rater reliability because multiple raters (3) were conducting the ratings and this approach takes into account variance between raters.[19] For UBACC ratings of responses based on the vignette used in the present analysis, ICC values ranged from 0.615 (for item 10) to 1.0 (for items 4 and 5), with ICC values exceeding 0.8 for 8 of the 10 items. Dual ratings were discontinued once inter-rater reliability was established, and all of the data for this analysis were based on scores assessed by a single rater. The cut-off score for potential decisional incapacity was set at <14 which was 2 standard deviations below the mean score of control participants.

Statistical Analysis

The sociodemographic characteristics of the sample were analyzed and descriptive statistics were generated, and subsequently the groups (patients, study partners, and healthy controls) were compared; one-way ANOVA tests were performed for continuous measures while percentages and χ^2 were calculated for categorical measures to determine if the groups differed significantly on sociodemographic characteristics. The normality of the sociodemographic data was assessed via visual inspection of boxplots and histograms and the Shapiro-Wilk test.

After the analysis of the sample demographics, the data were tested for influential multivariate outliers revealing two influential cases, which were removed from the dataset. Sample size adequacy was confirmed by calculating the Kaiser-Myer-Olkin (KMO) statistic; Bartlett's test of sphericity was used to assess for multicollinearity; and the inter-item correlation matrix was evaluated to determine the range of correlations.

Exploratory factor analysis (EFA) using principal axis factoring (PAF) with oblique rotation was used to determine how closely the UBACC's factor structure reflected the concepts as described in the underlying theory and observed in the original factor analysis. The recommended subjects-to-variable ratio for an adequate EFA sample size is at least five.[20, 21] With 10 variables in the current analysis, the sample size of 134 was more than sufficient to support an EFA.

The PAF method of factor analysis was chosen for the following reasons: 1) it is an appropriate choice for an instrument with an underlying theoretical framework; 2) it is the optimal method when the distribution of data is non-normal; and 3) PAF accounts for error variance by including only shared variance, thereby providing a more accurate picture of true variance than principal component analysis.[22] Based on prior studies that demonstrated correlation between factors on the UBACC, oblique rotation was performed because it is most appropriate for correlated factors.[23, 24]

Decisions regarding the number of components to retain were based on evaluation of the scree plot, eigenvalues greater than one, percentage of variance explained by the extracted components and the findings of prior psychometric testing. The threshold for item loading

was set at ≥ .32,[25] and items with more than one factor loading ≥ .32 were defined as cross-loading.[24]

Further testing of construct validity was performed with the evaluation of and discriminant validity. Concurrent validity was assessed by correlating UBACC total scores with MMSE scores, with the underlying expectation that capacity to consent would be strongly correlated with MMSE scores as a measure of global cognitive impairment. A strong correlation between the UBACC total scores and the MMSE scores would supply evidence that the two instruments were measuring related constructs, as would a strong positive association between the UBACC score and verbal fluency scores. Discriminant validity was tested by correlating UBACC total scores with total scores for the Trust in Medical Researchers (TMR) scale and four measures of social support adapted from the REACH study, each measured on a 6-point Likert scale. The TMR and social support scores were expected to be only weakly correlated with decisional capacity. A weak correlation would establish that the UBACC and the TMR and social support scores were measuring distinct constructs.

Internal consistency reliability for the UBACC was evaluated by calculating the Cronbach's α[26] for each subscale, indicating to what degree the items in each subscale measure a similar construct. According to DeVellis, an internal consistency of $\alpha = .70$ is considered acceptable for a scale.[27] All data analyses were performed using PASW (version 18.0., IBM SPSS, Inc., Chicago, IL).

Results

Initial screening of the data revealed two subjects with incomplete data and two subjects as influential outliers; the latter cases were examined in detail to better understand what made them outliers. The one participant, who had mild dementia, scored disproportionately low on language testing at his most recent ADRC visit. The second had only mild cognitive impairment on her most recent ADRC testing; however, her performance on the UBACC was erratic. For example, she had a perfect score on the item for therapeutic misconception, but a zero score on the item pertaining to voluntariness of research participation. These four subjects were removed from the sample prior to analysis. The final sample consisted of 130 subjects with complete data including 48 individuals with MCI or mild to moderate dementia, 52 study partners, and 30 healthy control subjects. Sociodemographic data for the sample (n=130) can be found in Table 2. The participant types (patient, family member, or control) were statistically different in age, gender, and racial composition, but they did not differ significantly on years of education. Of those in the patient group, 17 had a diagnosis of MCI while 31 had a diagnosis of dementia. Of those with dementia, 26 were diagnosed with early stage AD and 5 were diagnosed with other or unspecified dementias. Given the possibility that a frontotemporal dementia (FTD) presentation may bias our analysis, we reviewed the longitudinal ADRC data on those 5 cases. We found that 3 of those 5 individuals went on to receive diagnoses of atypical Alzheimer's disease (either atypical course or atypical presentation), 1 was diagnosed with vascular dementia, 1 with FTD, and 1 uncomplicated Alzheimer's disease (despite the uncertainty upon initial presentation). Further record review verified that the individual with FTD had scored above cut-offs on language tests at the ADRC assessment immediately preceding data collection for this study.

Table 3 displays the inter-item correlation matrix; correlations ranged from r =.004 (item 2 & item 5) to r =.604 (item 6 and item 7). Since none of the correlations exceeded r = .80, multicollinearity was not determined to be present.[23]

Table 4 reports the resultant factor loadings from the EFA. Using the cutoff criterion of .32 for an adequate factor loading, 3 factors appeared to be present. However, examination of the scree plot revealed only one item above the “elbow” or natural break between the steep slope and nearly flat slope, suggesting only one factor was present.[23, 27] The finding that the second and third factors each had only a single loading item, in conjunction with the scree plot provided further support for a one-factor solution.

Cronbach's α was used to evaluate the internal consistency reliability of the factors generated. Since only Factor 1 had more than one item loading on it, it was the only subscale for which Cronbach's α could be calculated. The result was α= .747, indicating an acceptable internal consistency reliability [24] Table 4.

Concurrent and discriminant validity were examined for the UBACC. To assess concurrent validity, a total score, based on the 8 UBACC items contained in the one-factor solution, was correlated with MMSE scores and with scores on a task of verbal fluency using the category animals.[28] Because the UBACC, MMSE, and verbal fluency results were non-normally distributed, Spearman's rho, a non-parametric correlational test was used. The results showed strong correlations, rs = .564, p < .001 and rs = .511, P <.001 for the MMSE and category fluency scores respectively .[29] Discriminant validity was evaluated by correlating 8-item UBACC total scores to both the Trust in Medical Researchers (TMR) total scores and the scores on four measures of social support used adapted from the REACH study. Correlation of the 8-item UBACC scores with TMR scores showed a low, negative correlation which was statistically significant (r_s= −.249, p= .006). However, correlations for each of the measures of social support were very close to zero, supporting discriminant validity among instruments measuring unrelated concepts.[29] A summary of concurrent and discriminant validity results are summarized in Table 5.

Conclusion

The purpose of this study was to determine the internal consistency reliability and construct validity of the UBACC in a new population, that of individuals considering participation in research on Alzheimer's disease or a related disorder. Our results provided reliability and validity evidence for the UBACC as a screening tool for capacity to consent, or give proxy consent, to a moderate risk clinical trial for dementia. Scrutiny of the factor loadings and scree plot suggested that in this context the UBACC is measuring a single factor.

Our finding of a single factor structure consisting of eight items differs from that of the Jeste group who identified three factors upon psychometric testing of the UBACC in a schizophrenia sample. The strong internal consistency estimate generated by the eight item scale implied that the items were measuring a single construct. After an evaluation of the specific eight UBACC items that formed the unidimensional scale, a possible explanation of the one-factor solution emerged. The content of the eight UBACC items closely aligns with

the federal minimum standards for informed consent.[3] For example, item 1, “What is the purpose of the study that was described to you,” appears to capture the element of “an explanation of the purposes of the research”. And, item 7, “Please describe some of the risks or discomforts that people may experience if they participate in this study,” appears to capture “a description of any reasonably foreseeable risks or discomforts to the subject”. Since information like the purpose of the study and discomforts one might experience represent concrete facts regarding the nature of research, they correspond with the construct of understanding. Viewing the UBACC in this light, our finding that the items loaded almost exclusively on factor 1, labeled “understanding”, is reasonable.

Indeed, only two of the items appear, at face value, to address more abstract elements of research participation. Items 2 (“What makes you want to consider participating in this study?”) and 3 (“Do you believe this is primarily research or primarily treatment?”) were the two that addressed more abstract elements of research participation and required a respondent to manipulate information or apply information to herself or her situation. Keeping in mind that the UBACC is designed to function as a screening tool, it is fitting that the UBACC does not afford an individual the opportunity to substantively discuss information in relation to personal situations and engage in deliberation, as would be required for a formal determination of appreciation and reasoning. As Jeste and colleagues suggest, information derived by screening with the UBACC can be used to identify potential participants for whom a more detailed assessment of capacity is indicated.

In the case of our hypothetical clinical trial, 18 out of 130 UBACC respondents would have required more detailed assessment of capacity to consent. Of those, 14 individuals had a diagnosis of a dementia disorder and 4 were study partners. This pattern of results suggests that the UBACC is effective in identifying individuals who are likely to have decisional incapacity, yet the cutoff is conservative enough to identify a small number of false-positives for decisional incapacity. It is important to note that individuals with MMSE scores of 17 or lower were excluded from this study, as this degree of cognitive impairment has been consistently associated with decisional incapacity.[30] Our selection criteria for individuals with cognitive impairment focused specifically on those for whom decisional capacity has been shown to be variable[30] and for whom a screening tool may be most useful.

Limitations of this study include the hypothetical nature of the research study presented to participants and the limited ethnic diversity of the sample. It should also be noted that, although our three groups of participants are all likely to be in the position of contemplating participation in research on AD, there were differences in demographic characteristics across the three groups. It is unclear how these differences may have affected our analysis as the small sample size limited our ability to perform subgroup analyses. The one factor solution found in the current investigation should be verified in future studies using confirmatory techniques with a larger, more diverse sample. Another limitation of this study is that our dataset did not include an established measure of capacity to consent to research, which precluded analyses of convergent validity. While we were able to establish concurrent validity, meaning the presence of an expected correlation with a related construct (global cognition), we were unable to assess the UBACC's convergent validity which would require simultaneous measurement of the same construct (capacity to consent) with a different tool.

While our sample included individuals with a range of late life cognitive disorders, it should be noted that assessments like the UBACC rely upon receptive and expressive language abilities and may be inappropriate for use in populations with language-predominant clinical presentations such as primary progressive aphasia. Researchers who adopt the UBACC for use in research on AD should bear in mind that the tool appears to be primarily capturing the concept of understanding, focusing specifically on the elements of consent outlined in the Code of Federal Regulations.[3] It is also important to note that, in addition to identifying those who require a more detailed assessment of decisional capacity, the UBACC holds great potential for identifying individuals who would benefit from extra measures on the part of investigators to maximize their ability to provide meaningful informed consent to the study. Such measures may include providing study information in alternative forms, conveying information over multiple encounters, allowing extra time for deliberation, or use of a memory aid.

Overall, the UBACC promises to be a highly useful screening tool for researchers studying patients with Alzheimer's disease and related disorders. The combination of relatively rapid administration and modest training requirements for administrators affords greater feasibility and cost savings to researchers. Its use can serve to facilitate better assessment of capacity and therefore enhance subject protection.

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References

1. Appelbaum PS, Roth LH. Competency to consent to research: A psychiatric overview. Archives of General Psychiatry. 1982; 39:951–958. [PubMed: 7103684]
2. Beauchamp, TL.; Childress, JF. Prinicples of Biomedical Ethics. Oxford University Press; New York, NY.: 2009.
3. Department of Health and Human Services. Title 45: Public Welfare Office of the Federal Register. National Archives and Records Administration; 2009. p. 128
4. Buchanan, AE.; Brock, DW. Deciding for Others: The Ethics of Surrogate Decision Making. Cambridge University Press; New York, NY.: 1989.
5. National Bioethics Advisory Commission. 1998–1999 Biennial Report National Bioethics Advisory Commission. Rockville, MD.: 1998.
6. Palmer B, Dunn L, Depp C, Eyler L, Jeste D. Decisional capacity to consent to research among patients with bipolar disorder: Comparison with schizophrenia patients and healthy subjects. Journal of Clinical Psychiatry. 2007; 68:689–696. [PubMed: 17503977]
7. Jefferson AL, Lambe S, Moser DJ, Byerly LK, Ozonoff A, Karlawish JH. Decisional Capacity for Research Participation in Individuals with Mild Cognitive Impairment. Journal of the American Geriatrics Society. 2008; 56:1236–1243. [PubMed: 18482298]
8. Appelbaum, PS.; Grisso, T. MacCAT-CR: MacArthur Competence Assessment Tool for Clinical Research. Professional Resource Press; Sarasota, FL.: 2001.

9. Jeste DV, Palmer BW, Appelbaum PS, Golshan S, Glorioso D, Dunn LB, Kim K, Meeks T, Kraemer HC. A new brief instrument for assessing decisional capacity for clinical research. Archives of General Psychiatry. 2007; 64:966–974. [PubMed: 17679641]
10. Folstein MF, Folstein SE, McHugh PR. “Mini-mental state”: A practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research. 1975; 12:189–198. [PubMed: 1202204]
11. Lopez OL, Becker JT, Klunk W, Saxton J, Hamilton RL, Kaufer DI, Sweet RA, Cidis Meltzer C, Wisniewski S, Kamboh MI, DeKosky ST. Research evaluation and diagnosis of probable Alzheimer's disease over the last two decades: I. Neurology. 2000; 55:1854–1862. [PubMed: 11134385]
12. Lingler JH, Schmidt KL, Gentry AL, Hu L, Terhorst LA. A New Measure of Research Participant Burden: Brief Report. Journal of Empirical Research on Human Research Ethics. 2014; 9:46–49. [PubMed: 26125079]
13. Petersen RC, Doody R, Kurz A, Mohs RC, Morris JC, Rabins PV, Ritchie K, Rossor M, Thal L, Winblad B. Current concepts in mild cognitive impairment. Arch Neurol. 2001; 58:1985–1992. [PubMed: 11735772]
14. Lopez OL, Jagust WJ, DeKosky ST, Becker JT, Fitzpatrick A, Dulberg C, Breitner J, Lyketsos C, Jones B, Kawas C, Carlson M, Kuller LH. Prevalence and classification of mild cognitive impairment in the Cardiovascular Health Study Cognition Study: part 1. Arch Neurol. 2003; 60:1385–1389. [PubMed: 14568808]
15. McKhann G, Drachman D, Folstein M, Katzman R, Price D, Stadlan EM. Clinical diagnosis of Alzheimer's disease: report of the NINCDS-ADRDA Work Group under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease. Neurology. 1984; 34:939–944. [PubMed: 6610841]
16. Hall MA, Camacho F, Lawlor JS, DePuy V, Sugarman J, Weinfurt K. Measuring Trust in Medical Researchers. Medical Care. 2006; 44:1048–1053. [PubMed: 17063137]
17. Haley WE, Gitlin LN, Wisniewski SR, Mahoney DF, Coon DW, Winter L, Corcoran M, Schinfeld S, Ory M. Well-being, appraisal, and coping in African-American and Caucasian dementia caregivers: findings from the REACH study. Aging & Mental Health. 2004; 8:316–329. [PubMed: 15370048]
18. Sachs GA, Stocking CB, Stern R, Cox DM, Hougham G, Sachs RS. Ethical aspects of dementia research: informed consent and proxy consent. Clinical Resarch. 1994; 42:403–412.
19. Shrout P, Fleiss J. Intraclass correlations: Uses in assessing rater reliability. Psychological Bulletin. 1997; 86:420–428. [PubMed: 18839484]
20. Hatcher, L. A step-by-step approach to using the SAS system for factor analysis and structural equation modeling. SAS Institute; Cary, NC.: 1995.
21. Bryant, FB.; Yarnold, PR. Principal components analysis and exploratory and confirmatory factor analysis. In: Grimm, LG.; Yarnold, PR., editors. Reading and Understanding Multivariate Statistics. American Psychological Association; Washington, DC.: 1994.
22. Harman, HH. Modern Factor Analysis. University of Chicago; Chicago, IL.: 1976.
23. Pett, M.; Lackey, N.; Sullivan, J. Making Sense of Factor Analysis: The Use of Factor Analysis for Instrument Development in Health Care Research. Sage; Thousand Oaks, CA.: 2003.
24. Costello AB, Osborne J. Best practices in exploratory factor analysis: four recommendations for getting the most from your analysis. Practical Assessment Research & Evaluation. 2005; 10:1–9.
25. Tabachnick, BG.; Fidell, LS. Using Multivarate Statistics. Pearson; Boston, MA.: 2007.
26. Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika. 1951; 16:297–344.
27. DeVellis, R. Scale Development: Theory and Applications. Sage; Newbury Park: 2003.
28. Borkowski J, Benton A, Spreen O. Word fluency and brain damage. Neuropsychologia. 1967; 5:135–140.
29. Carmines, EG.; Zeller, RA. Reliability and Validit Assessment. Sage; Thousand Oaks, CA.: 1979.

30. Kim SYH, Karlawish JHT, Caine ED. Current State of Research on Decision-Making Competence of Cognitively Impaired Elderly Persons. American Journal of Geriatric Psychiatry March/April. 2002; 10:151–165.

Table 1

Scoring for Selected UBACC Items

Selected UBACC items	**0** **Clearly incapable response**	**1** **Partially appropriate response**	**2** **Clearly capable response**
1. What is the purpose of the study just described to you?	Mention of treatment in a definite sense, or a vague, disoriented response	General response that study may help people or find a cure for dementia (without mention of experimental medication)	Must acknowledge testing a medication that may treat dementia
Example of participant response	“I would hope it would help the people who are in the process of finding out they have Alzheimer's”	“To find a cure or something that will delay AD”	“To see whether this experimental medication will actually improve memory”
3. Do you believe this is primarily research or primarily treatment?	Treatment or emphasis on treatment	Both in equal measure	Research or emphasis on research
Example of participant response	“I think this is more of treatment”	“Both”	“Research with possibility of treatment”
4. Do you have to be in this study if you do not want to be?	Yes	I don't know or other uncertainty	No
Example of participant response	[Not applicable]	“I think so...maybe”	“No”
6. If you participate in this study, what are some of the things you will be asked to do?	No procedures, incorrect procedures, or vague, disoriented response	1 procedure (either listed or reasonable to assume)	Any 2 or more procedures (either listed or reasonable to assume)
Example of participant response	“Be on trial, good or bad”	“It's gonna consume quite a bit of our time...intrusion...with all these visits...not sure if it's worth...she's gonna have to assume a high risk”	“Be asked to take experimental medicine, then come back for tests, memory tests and all that stuff”

Table 2

Sociodemographic Characteristics of the Sample

Characteristic	Overall	Patients	Family Members	Controls	*p-value**
n	130	48	52	30	
Age (years)					
Mean	72.77(34-91)	74.1(43-91)	69.88(40-88)	75.67(34-88)	.038
Median	74.0	74.0	71.0	77.5	
SD	10.91	10.04	11.53	10.28	
Sex (female)	60.8%	47.9%	67.3%	70.0%	.035
Primary Race					.012
White	86.9%	91.7%	92.3%	70.0%	
Black	13.1%	8.3%	7.7%	30.0%	
Years Education					
Mean	15.32(8-23)	15.40(8-22)	14.92(12-22)	15.90(12-23)	.342
Median	16.00	16.00	14.50	16.00	
SD	2.93	3.17	2.60	3.06	
Diagnostic Category					
MCI		17			
Dementia		31			

*p-values generated from one-way ANOVA procedures.

Table 3

Inter-Item Correlation Matrix for the 10 Item UBACC

Item*	1	2	3	4	5	6	7	8	9	10	$\bar{X}$	SD
1	1.000										1.32	.696
2	.091	1.000									1.76	.527
3	.154	.253	1.000								1.69	.647
4	.255	.057	−.050	1.000							1.88	.408
5	.137	.004	.214	.150	1.000						1.78	.488
6	.425	.272	.087	.366	.280	1.000					1.57	.660
7	.330	.280	.074	.406	.220	.604	1.000				1.66	.679
8	.275	.371	.052	.222	.249	.449	.516	1.000			1.75	.573
9	.188	.106	.112	.290	.089	.238	.298	.251	1.000		1.66	.679
10	.223	.157	.151	.181	.214	.252	.234	.215	.217	1.000	1.75	.573

1. What is the purpose of the study that was just described to you?

2. What makes you want to consider participation in this study?

3. Do you believe this is primarily research or primarily treatment?

4. Do you have to be in this study if you do not want to participate?

5. If you withdraw from this study, will you still be able to receive regular treatment?

6. If you participate in this study, what are some of the things you will be asked to do?

7. Please describe some of the risks or discomforts that people may experience if they participate in this study.

8. Please describe some of the possible benefits of this study.

9. Is it possible that being in this study will not have any benefit to you?

10. Who will pay for your medical care if you are injured as a direct result of participating in this study?

*Items

Table 4

Factor Structures and Percent Variance Explained for PeRBA UBACC Data

Factor Structure based on pattern matrix from PAF with promax rotation			
UBACC Item Number	**Factor 1**	**Factor 2**	**Factor 3**
1	**.517**	−.092	.128
2	.−.088	**.847**	.063
3	−.004	.100	**.729**
4	**.593**	−.143	−.102
5	**.381**	−.154	.258
6	**.727**	.058	−.004
7	**.723**	.125	−.088
8	**.485**	.284	−.053
9	**.408**	.−.033	.064
10	**.361**	−.020	.198
Total Variance Explained	**32.1%**	**12.2%**	**10.6%**
Cronbach's α	.747		

Table 5

Concurrent and Discriminant Validity

UBACC Total Score	MME	Social Support				Trust in Medical Researchers
		Overall Satisfaction[a]	Number of in Support Network[b]	Number of Close Friends[c]	Frequency of Contact with Close Friend[d]	TMR Total
	.564 * (p<.001)	.056 * (p=.537)	.077 * (p=.394)	.043 * (p=.635)	.146 * (p=.111)	−.249(p=.006)

[a] Overall, how satisfied have you been with the help you have received from friends, neighbors, or family members?

[b] How many relatives other than a caregiver do you see or hear from at least once a month?

[c] How many friends to you feel close to? That is, how many friends (not relatives) do you feel at ease with, and talk to about private matters, or can call on for help.

[d] Think about the friend (not including relatives) with whom you have the most contact. How often do you see or hear from that person?

* Spearman's Rho correlation coefficient