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EFFECTS OF DEPRESSION AND SOCIAL SUPPORT ON COMPREHENSION AND RECALL OF INFORMED CONSENT INFORMATION AMONG PARKINSON DISEASE PATIENTS AND THEIR CAREGIVERS*

ELLEN J. TENG, PH.D.,

VA HSR&D Houston Center of Excellence; Michael E. DeBakey Veterans Affairs Medical Center; VA South Central Mental Illness Research, Education, and Clinical Center; Baylor College of Medicine

NANCY J. PETERSEN, PH.D.,

VA HSR&D Houston Center of Excellence; Michael E. DeBakey Veterans Affairs Medical Center; Baylor College of Medicine

CHRISTINE HARTMAN, PH.D.,

VA HSR&D Houston Center of Excellence; Michael E. DeBakey Veterans Affairs Medical Center; Baylor College of Medicine

ELLEN MATTHIESEN, B.A.,

Michael E. DeBakey Veterans Affairs Medical Center; Baylor College of Medicine

MICHAEL KALLEN, PH.D.,

Baylor College of Medicine; The University of Texas M.D. Anderson Cancer Center

KARON F. COOK, PH.D., and

Michael E. DeBakey Veterans Affairs Medical Center; Baylor College of Medicine; Parkinson Disease Research, Education, and Clinical Center

MARVELLA E. FORD, PH.D.

Medical University of South Carolina

Abstract

Objective—Relatively little attention has focused on the impact of psychiatric conditions on human subjects' comprehension of consent information. The purpose of this randomized study was to determine whether depression affects comprehension and recall of informed consent information among persons with Parkinson's disease and their caregivers and to evaluate the effects of support on comprehension and recall during the consent process.

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Direct reprint requests to: Ellen J. Teng, Ph.D. Michael E. DeBakey VA Medical Center 116 MHCL 2002 Holcombe Blvd. Houston, TX 77030 eteng@bcm.edu.

Method—Comprehension and recall of information were assessed using a modified version of the Modified Quality of Informed Consent Questionnaire, taken 1 week and 1 month later, and scored using a consensus-based algorithm. Participants also completed the Center for Epidemiologic Studies Depression Scale. Data analyses were conducted on 129 patients and caregivers (*t*-tests, Fisher's exact test, and ANCOVAs).

Results—*T*-tests showed no significant differences in comprehension and recall between depressed and nondepressed participants at 1 week and 1 month. However, ANCOVA showed patients with a support person present had significantly higher comprehension and recall at 1 week but not at 1 month compared with controls. Caregivers present with a patient had lower comprehension/recall than those without a patient present ($p = 0.02$).

Conclusions—Having a support person present during the informed consent process helps depressed PD patients better retain information in the short term, but effects diminish over the long term. Implications for interventions will be discussed.

Keywords

informed consent; Parkinson disease; depression

INTRODUCTION

An important ethical concern in research in human populations is the need to obtain informed consent. Informed consent requires fulfilling three conditions [1]. First, potential participants must decide to participate of their own accord, free from coercion. Second, information about all aspects of the study, including potential risks, must be delineated in an understandable format. Third, to make informed decisions, potential participants must possess cognitive abilities sufficient for understanding the information presented and its implications. Although general guidelines exist for constructing consent forms (e.g., sixth grade reading level), writing style, language, and format are difficult variables to control. This variability highlights the importance of evaluating participants' understanding of the information, particularly in neurologically compromised individuals.

A number of disease processes can impact an individual's ability to make informed decisions. The impact of diminished cognitive ability in the context of informed consent has been studied in individuals with Alzheimer disease [2, 3]. To date, few studies have examined these issues in individuals who have Parkinson disease (PD). PD is associated not only with physical problems (e.g., tremors, postural instability, rigidity) but also psychological symptoms (e.g., depression) and cognitive (e.g., memory, attention) symptoms [8-11]. Both the psychological and cognitive symptoms associated with PD may impact the ability to give informed consent. Most literature to date has concentrated on the impact of diminished cognition, but cognition can be influenced by disorders such as depression [12]. Research shows that many depressed persons perform poorly on memory recall (immediate and delayed) and recognition tasks [13, 14]. In fact, recent studies examining neuropsychological functioning among PD patients found that those with depression showed significant cognitive dysfunction compared with those without depression, depressed persons without PD, and healthy control individuals [9, 15]. Research

further indicates that moderate levels of depression among PD patients can have a significant impact on cognition, whereas milder levels of depression have relatively little effect on cognitive processing [8, 16, 17]. Thus, severity of depression directly correlates with increasing degrees of cognitive impairment.

One intervention that could potentially serve as a buffer against the potential impact of depression on the informed consent process and have immediate positive effects for depressed individuals is the provision of social support during the informed consent process [18-20]. The construct of social support has been widely studied and found to positively affect health outcomes for people with a variety of physical [21, 22] and psychiatric difficulties, including depression [23-25]. Social support comes in many forms, including instrumental, emotional, and informational support [24-27]. Instrumental support is based on the extent to which individuals rely on others for help with daily activities (e.g., borrowing things from friends and neighbors, obtaining help with transportation). Emotional support involves communicating a sense of caring and understanding to others, which can help recipients derive comfort. Informational support involves providing help with obtaining and understanding information through the exchange of information. Based on research demonstrating the positive effects of social support [21-25], it is possible that informed consent social support can potentially have immediate positive effects on a depressed person's comprehension and recall of information of consent form information. That is, a social support person present with the potential research participant during the consent process cannot only be a source of reassurance but also facilitate a better understanding of information through the interchange of questions, thoughts, and concerns among the potential study participant, the support person, and the researcher.

The purpose of this study was to determine whether depression affects comprehension and recall of informed consent information among persons with PD and their caregivers and to evaluate the impact on comprehension and recall of informed consent information of having a social support caregiver present during the consent process. It was hypothesized that:

1. individuals with PD who are depressed will have lower comprehension and recall scores than non-depressed individuals with PD;
2. depressed caregivers will have lower comprehension and recall scores than non-depressed caregivers;
3. among patients with PD, those with a caregiver present during informed consent will have higher comprehension and recall scores than patients with no caregiver present; and
4. among caregivers, those who were present with a patient during the informed consent process will have higher comprehension and recall scores than caregivers who were not present with a patient.

METHODS

Participants

Participants ($N = 135$) were persons with PD ($n = 74$) and their caregivers ($n = 61$), seen at the Michael E. DeBakey Veterans Affairs Medical Center in the Parkinson Disease Research, Education, and Clinical Center (PADRECC) in Houston, Texas. Caregivers were defined as persons whom patients designated as providing them care. Most (90%) caregivers were spouses of patients, and the others were family members. These participants were part of a study examining the:

1. quality of life among PD patients; and
2. effects of social support on comprehension and recall of consent-form information.

Within the larger study, patients were invited to participate if a diagnosis of PD was indicated in their medical records. To control for the effects of cognitive impairment, persons with confirmed diagnoses of dementia, Alzheimer's disease, post-traumatic stress disorder (as severe symptoms of PTSD can affect concentration/memory), and/or acute psychosis were excluded from participation. This study was approved by the Institutional Review Board at Baylor College of Medicine and conducted with adequate understanding and written consent of participants.

Materials

Center for Epidemiologic Studies Depression Scale (CES-D) [28]—The CES-D is a self-report instrument widely used with the general population to screen for depressive symptomatology. It consists of 20 items designed to assess mood, somatic symptoms, and interpersonal and motor functioning during the past week. Responses are made using a 4-point Likert scale ranging from 0 to 3, which denotes the number of days per week a symptom was experienced. A score of 0 indicates that a symptom was rarely present (less than 1 day), and a score of 3 indicates that a symptom was present all the time (5-7 days). The total score ranges from 0 to 60 and is calculated by taking the sum of all items after accounting for items that are reverse coded. Interpretation guidelines specify that scores less than 15 indicate the absence of depression; scores of 15 to 21 indicate mild-to-moderate levels of depression; and a score of 22 or higher suggests that a clinically significant level of psychological distress is present, and that the individual likely meets criteria for a major depressive disorder.

The CES-D has been found to have high internal consistency across psychiatric and non-psychiatric populations (Cronbach's alphas ranging from .85 to .90) and adequate test-retest reliability ($r = .57$ for 2 to 8 weeks) [28]. It correlates highly with self-report and clinician ratings of depression severity [29] and is commonly used in PD and Alzheimer research [30, 31].

Modified Quality of Informed Consent Questionnaire (QuIC) [32]—The QuIC is a measure of objective understanding of consent-form information. The original instrument contains 17 items that assess various aspects related to the process of obtaining informed

consent as outlined by the U.S. Department of Health and Human Services [33]. Examples of some knowledge areas the QuIC evaluates include:

1. whether participants understand the purposes of the research;
2. the presence of foreseeable risks or discomforts to subjects; and
3. an understanding that participation is voluntary and that subjects may discontinue participation at any point without penalty.

Responses consist of three options: “Disagree,” “Unsure,” and “Agree.” The QuIC has adequate test-retest reliability (intraclass correlation coefficient = 0.66). Originally developed for use in cancer clinical trials, it has applicability to other research programs.

In this study, comprehension and recall of consent information were assessed using a slightly modified version of the QuIC (Part A) that is more applicable to the study population and was administered over the telephone to participants. Items with a cancer-specific focus were reworded to reflect a more general research emphasis. A consensus-based scoring algorithm was developed to determine the correct response for each QuIC item. This process entailed four research-team members individually responding to items on the QuIC, based on information in the consent form. These individuals then met to discuss their responses until they attained 100% agreement regarding the correct answer for each QuIC item. This consensus-based scoring algorithm was used in determining the scores of QuIC questionnaires completed by participants. For each of the 17 items, an individual's response was compared with the response determined to be correct by the consensus approach. If the participant's response agreed with the consensus for an item, that item was coded as correct. For participants answering all 17 items, we summed the total number of items for each participant that were considered correct and divided by the total number of non-missing items for that participant (17). Only 5 individuals had missing items for 1 week, and 10 had missing items for 1 month; and they were thus excluded from the computation of QuIC scores at those time points. The score for each participant was calculated as the percentage of the 17 items for which his/her responses were correct. Thus, scores could potentially range from 0 to 100. The QuIC scores for the present sample at 1 week ranged from a minimum of 29.4% to a maximum of 82.4%. At 1 month, they ranged from 23.5% to 70.6%.

Design/Procedure

Description of the Larger Combined Study—As previously mentioned, the current study is derived from a larger study that examined quality of life among PD patients (PD study) and the effects of social support on comprehension and recall of consent-form information (Social Support study). Eligible participants included a total of 143 patients in the PADRECC clinic and their caregivers. All completed a questionnaire packet that included the CES-D. After enrollment into the study, patients and their caregivers were randomly assigned to one of two arms, using a block randomization procedure to ensure equal distribution of patient-caregiver pairs to both arms. Those assigned to the intervention arm were accompanied by their social support person (patient or caregiver), who completed the consent form in the same room as the participant. Participants randomized to the control

arm were asked to complete their consent forms in a room separate from the one in which their social support person completed his/her consent forms. One week later, trained interviewers, masked to the condition to which each participant was assigned, telephoned participants and used the QuIC to assess their comprehension and recall of consent-form information. This procedure was repeated 1 month after the consent form was signed.

Depressed vs. Non-Depressed Group Assignment—According to scoring guidelines for the CES-D [28], 13 participants reported the absence of depressive symptomatology (CES-D score < 15), 25 participants reported moderate levels of depressive symptomatology (CES-D score 15 to 21), and 91 participants reported severe levels of depressive symptomatology (CES-D score > 22). Because of unequal sample sizes in this distribution, participants were assigned to either the “depressed” or “non-depressed” group, using a median split of CES-D scores from the total sample. Separate analyses conducted on PD patients and their caregivers revealed that both groups reported a median CES-D score of 26. Thus, those whose CES-D score fell below 26 were assigned to the non-depressed group, and those with scores at or above 26 were assigned to the depressed group.

Participant Flow—Of the original 70 participants randomized to the intervention condition and 73 randomized to the control condition, 67 persons in the intervention and 69 persons in the control condition completed the QuIC at either the 1-week or 1-month time point. Because of missing data at both time points, six persons (five patients, one caregiver) were excluded from the analyses. No significant difference was found in the depression scores of these individuals compared with those of the remaining sample, based on the Wilcoxon test, $Z = 403.5$, $p = .96$. Thus, data analyses were conducted on a final sample of 69 patients and 60 caregivers (see Table 1 for demographic characteristics).

Data Analysis—Demographic characteristics for the intervention and control groups were compared, using the t -test for the continuous variable age and Fisher's exact test for the categorical variables of gender, race, ethnicity, education, income, and marital status. Variables found significant ($p < .05$) were included in subsequent multivariable analyses.

Using t -tests, we analyzed mean QuIC scores at the 1-week and 1-month time points to determine whether there were differences between participants classified as depressed vs. non-depressed. Comparisons were made separately for patients and caregivers at each time period. These analyses were repeated to compare the mean QuIC scores between participants with social support present when the informed consent form was signed and those without such support.

To assess the simultaneous effect of multiple factors on QuIC scores, an analysis of covariance was performed separately for the 1-week and 1-month scores. The model contained demographic variables found significant in the comparison of intervention and control patients, as well as depression status (whether the patient was depressed or not), intervention status (whether the patient was randomized to the intervention or control group), and the interaction of intervention and patient status. As discussed above, patients were classified as depressed if the CES-D score was above the median value. P values less

than .05 were considered significant. Partial η^2 was examined to assess the effect size of the independent variables.

RESULTS

There were 63 participants in the control group (34 patients; 29 caregivers), and 66 participants in the intervention group (35 patients; 31 caregivers). No statistically significant differences in age, gender, race, Hispanic ethnicity, or education were found between participants in the two groups (see Table 1). However, statistically significant differences were found between groups in income ($p = 0.01$) and marital status ($p = 0.03$). To control for these differences, income and marital status were used as covariates in the analysis. A variable indicating the participant's depression status was also included in the analysis.

No significant difference was found in depression scores between patients ($M = 26.7$, $SD = 7.47$) and their corresponding caregivers ($M = 24.1$, $SD = 7.31$), $t(56) = 1.52$, $p = 0.13$.

Hypotheses 1 and 2

The effect of depression on QuIC comprehension and recall scores was analyzed, using a series of independent t -tests (see Table 2). Although both depressed patients and caregivers (CES-D score greater or equal to the median score of 26 for all 129 participants) had lower comprehension and recall QuIC scores at 1 week and 1 month than non-depressed participants, differences were not statistically significant. The mean comprehension and recall scores of participants, based on depression and social support status, are shown in Tables 2 and 3.

Hypotheses 3 and 4

The effect of the intervention condition on QuIC comprehension and recall scores was first analyzed using t -tests to determine differences at the 1-week and 1-month time points in both PD patients and caregivers. The variables of depression, intervention status (social support present/absent), and participant status (patient/caregiver) were used as independent variables in two Analysis of Covariance (ANCOVA) models for which comprehension and recall QuIC scores at 1 week and 1 month were the dependent variables. Marital status and income were entered as covariates. As shown in Table 4, a significant interaction was present at both time points. Patients whose social support person (i.e., caregiver) was present during the consent process had significantly higher comprehension and recall QuIC scores at the 1-week time point ($p = 0.01$) but not at the 1-month time point ($p = 0.2$) compared with the control group (i.e., social support person absent condition). Conversely, although caregivers whose social support person (i.e., patient) was present during the consent process did not have significantly different comprehension and recall QuIC scores at the 1-week time point ($p = 0.55$) compared with the control condition, their QuIC scores were significantly lower at the 1-month time point ($p = 0.02$). Although the interaction term of intervention-by-patient status was statistically significant for comprehension and recall scores at both the 1-week and 1-month time points, effect sizes, as measured by the partial η^2 , were small at the 1-week (0.069) and 1-month (0.049) time points. No remaining independent variables in the model were statistically significant.

DISCUSSION

Findings from this study did not support hypotheses 1 and 2. That is, although depressed patients and caregivers on average scored lower on comprehension and recall 1 week and 1 month after receiving consent-form information compared with non-depressed individuals, results were not statistically significant.

In examining whether or not the presence of a social support person during consent helped depressed patients with PD understand and remember information presented, partial support was found for hypothesis 3. As hypothesized, compared with patients without a social support present, those with someone present during the consent process had better comprehension and recall 1 week later; however, differences between the two groups had diminished by the time patients were reassessed 1 month later. These findings are consistent with another study [26], which proposes that social support can serve as a buffer against psychological effects of depression, which often include cognitive difficulties. Although this study did not assess the effects of social support on psychological functioning, results examining cognitive functioning suggest that patients with PD may have experienced immediate benefits from having a caregiver present during consent (an unfamiliar and potentially stressful situation); these patients demonstrated better short-term understanding and recall of consent-form information. Since the positive cognitive effects of having social support present were not maintained over the long term for patients, incorporating a booster educational session might improve recall over extended periods. The value of booster sessions in enhancing the effects of an intervention has been demonstrated with various programs, such as marital therapy [34], alcohol rehabilitation [35], and anger management [36].

Caregivers who had a person (i.e., patient with PD) present during consent appeared to experience a negative effect on their ability to understand/recall this information later. Findings were not statistically significant at 1 week. However, at the 1-month assessment, caregivers with a support person present exhibited significantly poorer understanding and remembering of information than caregivers who were alone. These results may reflect the role of the caregiver, vis-à-vis the patient, which is to assist and attend to the needs of the patient. In fact, most caregivers were spouses of patients and thus very likely to be accustomed to caring for their partners. Moreover, given the type of physical and psychological difficulties patients with PD can experience, it is reasonable to presume that they would be less able (than caregivers) to provide the kind of social (e.g., instrumental, emotional, and informational) support [24-27] to their caregiver that could serve as a buffer against stress. Thus, one explanation for these findings is that patients may not be able to function effectively as support persons for their caregivers. Additionally, in sessions in which consent-form information is described/discussed, caregivers may be able to attend better to information when they are alone and do not have to be concerned with tending to the patient.

The findings from this study offer important insight into how the informed-consent process may be improved among PD patients who experience depression. One advantage is that it was inexpensive to conduct and has “real-world” application. However, because it was

based on archival data, several factors outside our control limit the interpretation and generalizability of findings. The main limitation was that cognitive functioning was not formally assessed among PD patients at baseline. Although patients were carefully screened for cognitive impairment via chart reviews before enrolling in the study, this research would be strengthened with direct assessments of cognitive abilities. Second, although this study is unique in examining the presence or absence of a patient or caregiver as a form of social support to the other person during the process of informed consent, support persons did not provide support in a standardized manner. Some caregivers may have provided varying amounts or types of social support. Though tightly controlling for such variables is an important consideration in research trials, there is often a trade-off when conducting effectiveness research. That is, it is equally important to find a practical intervention that can work in a real-world setting. Third, because this study was based on a convenience sample from a VA hospital, findings may not be representative of the general PD population. Fourth, participants were designated as depressed and non-depressed, using a median split to retain as many participants as possible, because of the small sample size and unequal distribution of their CES-D scores. This is not ideal, as it does not provide clean subsets of depressed versus non-depressed persons, which could have influenced our findings. Although the preferable approach would have been to use a strict cutoff score to compare depressed and non-depressed participants, the method we used effectively separated less depressed persons from those that were more depressed, as this was based directly on the number of symptoms endorsed.

Future studies would benefit from prospective recruitment of depressed versus non-depressed individuals, based on clinician assessments of depression. In addition, having participants complete measures of social support that assess the amount and form (i.e., instrumental, emotional, and/or informational) of social support received from the caregiver may clarify the nature of the relationships found in the present study. Though the current predominantly Caucasian sample includes only veterans and their caregivers, the generalizability of these findings to other populations in future studies could be increased by drawing from community samples and over-sampling various racial and ethnic groups. Although relatively little data are available regarding the prevalence of PD among Hispanic individuals [37], one study found equal PD prevalence rates among African Americans and Caucasians living in the same geographical location [38]. Thus, it is important to recruit individuals from diverse cultural backgrounds in this area of research, as emerging data indicate equally high prevalence rates of PD in these groups (i.e., African Americans) compared with Caucasians.

This study has several significant implications. First, all participants (regardless of the presence of depression or social support) recalled approximately 50% of consent-form information. Therefore, greater effort needs to be made toward improving consent-form information so that it is more understandable and easier to remember by persons with PD. Future studies may examine the utility of incorporating a booster educational session to increase information retention rates.

Second, although social support can be an adaptive psychological resource, findings from this study suggest that it may not always be enough by itself. This is particularly relevant for

caregivers, who seemed to derive no emotional or informational benefit from having the patient present during consent. Hence, these findings highlight the importance of providing additional interventions to persons caring for individuals with PD, such as offering social support groups or having caregivers identify their own support person to accompany them during the informed consent process. This is especially important with the greater reliance on informal caretaking for PD patients because of the continuing shift from providing institutional care to community care [39, 40].

CONCLUSION

Greater effort needs to be made to improve consent-form information to make it more understandable and easier to remember by persons with PD. Having a support person present during the informed consent process helps depressed PD patients better retain information in the short term, but effects diminish over the long term. It is also important to provide interventions for persons caring for individuals with PD.

REFERENCES

1. Alt-White AC. Obtaining "informed" consent from the elderly. *Western Journal of Nursing Research*. 1995; 17:700–705. [PubMed: 8597234]
2. Kim SYH, Cox C, Caine ED. Impaired decision-making ability in subjects with Alzheimer's disease and willingness to participate in research. *American Journal of Psychiatry*. 2002; 59:797–802. [PubMed: 11986134]
3. Pucci E, Belardinelli N, Borsetti G, Rodriguez D, Signorino M. Information and competency for consent to pharmacologic clinical trials in Alzheimer disease: An empirical analysis in patients and family caregivers. *Alzheimer Disease & Associated Disorders*. 2001; 15:146–154. [PubMed: 11522932]
4. McDonald WM, Rideard IH, DeLong MR. Prevalence, etiology, and treatment of depression in Parkinson's disease. *Biological Psychiatry*. 2003; 54:363–375. [PubMed: 12893111]
5. Jobges M, Heuschkel G, Pretzel C, Illhardt C, Renner C, Hummelsheim H. Repetitive training of compensatory steps: A therapeutic approach for postural instability in Parkinson's diseases. *Journal of Neurology, Neurosurgery and Psychiatry*. 2004; 75:1682–1687.
6. Louis ED, Tang MX, Schupf N, Mayeux R. Functional correlates and prevalence of mild Parkinsonian signs in a community population of older people. *Archives of Neurology*. 2005; 62:297–302. [PubMed: 15710859]
7. Walter BL, Vitek JL. Surgical treatment for Parkinson's disease. *Lancet Neurology*. 2004; 3:719–728.
8. Boller F, Marcie P, Starkstein S, Traykov L. Memory and depression in Parkinson's disease. *European Journal of Neurology*. 1998; 5:291–295. [PubMed: 10210845]
9. Norman S, Troster AI, Fields JA, Brooks R. Effects of depression and Parkinson's disease on cognitive functioning. *Journal of Neuropsychiatry and Clinical Neurosciences*. 2002; 14:31–36.
10. Slaughter JR, Slaughter KA, Nichols D, Holmes SE, Martens MP. Prevalence, clinical manifestations, etiology, and treatment of depression in Parkinson's disease. *Journal of Neuropsychiatry and Clinical Neurosciences*. 2001; 13:187–196. [PubMed: 11449025]
11. Troster, AI. Assessment of movement and demyelinating disorders.. In: Snyder, PJ.; Nussbaum, PD., editors. *Clinical neuropsychology: A pocket handbook for assessment*. American Psychological Association; Washington, DC: 1998. p. 266-303.
12. Montgomery C, Lydon A, Lloyd K. Psychological distress among cancer patients and informed consent. *Journal of Psychosomatic Research*. 1999; 46:241–245. [PubMed: 10193914]
13. Brand AN, Jolles J, Gispen-de Wied C. Recall and recognition memory deficits in depression. *Journal of Affective Disorders*. 1992; 25:77–86. [PubMed: 1624647]

14. Zakzanis KK, Leach L, Kaplan E. On the nature and pattern of neurocognitive function in major depressive disorder. *Neuropsychiatry, Neuropsychology and Behavioral Neurology*. 1998; 11:111–119.
15. Wertman E, Speedie L, Shemesh Z, Gilon D, Raphael M, Stessman J. Cognitive disturbances in Parkinsonian patients with depression. *Neuropsychiatry, Neuropsychology and Behavioral Neurology*. 1993; 6:31–37.
16. Starkstein, S.; Mayberg, HS. Depression in Parkinson disease.. In: Starkstein, SE.; Robinson, RG., editors. *Depression in neurologic disease*. Johns Hopkins University Press; Baltimore: 1993.
17. Troster AI, Stalp LD, Pado AM, Fields JA, Koller WC. Neuropsychological impairment in Parkinson's disease with and without depression. *Archives of Neurology*. 1995; 52:1164–1169. [PubMed: 7492290]
18. Mohr DC, Genain C. Social support as a buffer in the relationship between treatment for depression and T-cell production of interferon gamma in patients with multiple sclerosis. *Journal of Psychosomatic Research*. 2004; 57:155–158. [PubMed: 15465069]
19. Nasser EH, Overholser JC. Recovery from major depression: The role of support from family, friends, and spiritual beliefs. *Acta Psychiatrica Scandinavica*. 2005; 111:125–132. [PubMed: 15667431]
20. Stice E, Ragan J, Randall P. Prospective relations between social support and depression: Differential direction of effects for parent and peer support? *Journal of Abnormal Psychology*. 2004; 113:155–159. [PubMed: 14992668]
21. Hipkins J, Whitworth M, Tarrier N, Jayson G. Social support, anxiety and depression after chemotherapy for ovarian cancer: A prospective study. *British Journal of Health Psychology*. 2004; 9(Pt 4):569–581. [PubMed: 15509362]
22. Pedersen SS, van Domburg RT, Larsen ML. The effect of low social support on short-term prognosis in patients following a first myocardial infarction. *Scandinavian Journal of Psychology*. 2004; 45:313–318. [PubMed: 15281920]
23. Barefoot JC, Burg MM, Carney RM, Cornell CE, Czajkowski SM, Freedland KE, et al. Aspects of social support associated with depression at hospitalization and follow-up assessment among cardiac patients. *Journal of Cardiopulmonary Rehabilitation*. 2003; 23:404–412. [PubMed: 14646786]
24. Friedland J, Renwick R, McColl M. Coping and social support as determinants of quality of life in HIV/AIDS. *AIDS Care*. 1996; 8:15–31. [PubMed: 8664366]
25. Lin, N. Anonymous, Social support, life events, and depression. Orlando, FL: Academic Press, Inc.. 1986. *Conceptualizing social support.*; p. 17-31.
26. Cohen, S.; Syme, SL. Issues in the study and application of social support.. In: Cohen, S.; Syme, SL., editors. *Social support and health*. Academic Press, Inc.; Orlando, FL: 1985. p. 3-22.
27. Olstad R, Sexton H, Sogaard AJ. The Finnmark Study. A prospective population study of the social support buffer hypothesis, specific stressors and mental distress. *Social Psychiatry and Psychiatric Epidemiology*. 2001; 36:582–589. [PubMed: 11838829]
28. Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement*. 1977; 1:385–401.
29. Weissman MM, Sholomskas D, Pottenger M, Prusoff BA, Locke BZ. Assessing depressive symptoms in five psychiatric populations: A validation study. *American Journal of Epidemiology*. 1977; 106:203–214. [PubMed: 900119]
30. Hooker K, Manoogian-O'Dell M, Monahan DJ, Frazier LD, Shifren K. Does type of disease matter? Gender differences among Alzheimer's and Parkinson's disease spouse caregivers. *The Gerontologist*. 2000; 40:568–573. [PubMed: 11037935]
31. Lou JS, Kearns G, Oken B, Sexton G, Nutt J. Exacerbated physical fatigue and mental fatigue in Parkinson's disease. *Movement Disorders*. 2001; 16:190–196. [PubMed: 11295769]
32. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent: A new measure of understanding among research subjects. *Journal of the National Cancer Institute*. 2001; 93:139–147. [PubMed: 11208884]
33. U.S. Department of Health and Human Services. 45 Code of Federal Regulations 46. Federal Register. 1991; 56:28012.

34. Braukhaus C, Hahlweg K, Kroeger C, Groth T, Fehm-Wolfsdorf G. The effects of adding booster sessions to a prevention training program for committed couples. *Behavioural & Cognitive Psychotherapy*. 2003; 31:325–336.
35. Connors GJ, Walitzer KS. Reducing alcohol consumption among heavily drinking women: Evaluating the contributors of life-skills training and booster sessions. *Journal of Consulting and Clinical Psychology*. 2001; 69:447–456. [PubMed: 11495174]
36. Kellner MH, Bry BH, Colletti L. Teaching anger management skills to students with severe emotional or behavioral disorders. *Behavioral Disorders*. 2002; 27:400–407.
37. Young R. Update on Parkinson's disease. *American Family Physician*. 1999; 59:2155–2167, 2169-2170. [PubMed: 10221302]
38. Marder KS, Logroscino G, Alfaro B, Mejia H, Cote L, Mayeux R. Environmental risk factors for Parkinson's disease in a multi-ethnic urban community [Abstract]. *Neurology*. 1997; 48(3suppl 2):A334.
39. Han B, Haley WE. Family caregiving for patients with stroke. Review and analysis. *Stroke*. 1999; 30:1478–1485. [PubMed: 10390326]
40. Vrabec NJ. Literature review of social support and caregiver burden, 1980 to 1995. *Image – The Journal of Nursing Scholarship*. 1997; 29:383–388. [PubMed: 9433013]

Table 1

Demographic Characteristics of Participants in the Intervention vs. Control Groups

Characteristics	Combined group (<i>n</i> = 129)	Control group (<i>n</i> = 63)	Intervention group (<i>n</i> = 66)	<i>p</i> -Value
Mean age (<i>SD</i>), in years	71.3 (8.4)	70.7 (7.3)	71.9 (9.4)	.43
Gender (%)				.60
Female	44.1	41.3	47.0	
Male	55.8	58.7	53.0	
Race (%)				.71
African American	4.6	6.4	3.0	
Caucasian	93.0	92.1	93.9	
Native American	1.5	1.6	1.5	
Other	0.7	0	1.5	
Ethnicity (%)				.76
Hispanic	8.5	9.5	7.6	
Non-Hispanic	91.4	90.5	92.4	
Education (%)				.19
H.S. diploma or less	27.1	27.0	27.3	
Some college/trade school	37.2	30.2	43.9	
College degree	35.6	42.9	28.8	
Income (%)				.01**
< \$19,999	30.2	31.2	31.8	
\$20,000-\$39,999	34.8	23.0	49.2	
\$40,000 or greater	31.0	45.9	19.1	
Marital status (%)				.03*
Single	6.9	1.6	12.1	
Married/partnered	93.0	98.4	87.9	

Notes: Includes participants with a non-missing depression score and either a 1-week or 1-month Quality of Informed Consent Questionnaire Score, *p*-values were obtained from the *t*-test for the continuous variable age and from the Fisher's Exact test for the categorical variables (gender, race, ethnicity, education, income, and marital status). H.S. = high school.

* *p* < .05

** *p* .01.

Table 2

Mean Comprehension and Recall QuIC Scores for Patients and Caregivers by Depression Status

	<i>n</i>	Depressed Mean (SD)	<i>n</i>	Non-depressed Mean (SD)	p-Value
Patients					
1 week	37	48.0 (7.3)	29	50.9 (8.1)	.1300
1 month	36	49.0 (9.1)	27	50.1 (7.4)	.6128
Caregivers					
1 week	27	51.4 (9.2)	31	52.4 (9.5)	.6995
1 month	26	52.0 (8.1)	31	51.9 (9.4)	.9614

Notes: *p*-Values were obtained from *t*-tests. Participants were designated as depressed if their CESD score was greater than or equal to the median score of 26 for all participants. QuIC = Quality of Informed Consent Questionnaire.

Table 3

Mean Comprehension and Recall QuIC Scores for Depressed Participants by Social Support Status

	<i>n</i>	Social support present Mean (SD)	<i>n</i>	Social support absent Mean (SD)	<i>p</i> -Value
Patients					
1 week	17	51.6 (4.9)	20	45.0 (7.7)	.0046**
1 month	18	51.0 (7.0)	18	47.1 (10.7)	.2011
Caregivers					
1 week	18	50.7 (9.7)	9	52.9 (8.3)	.5512
1 month	17	49.8 (8.9)	9	56.2 (4.3)	.0207*

Notes: *p*-Values were obtained from *t*-tests QuIC = Quality of Informed Consent Questionnaire.*
p < .05**
p < .01.

Table 4

Results of ANCOVA of QuIC Scores at 1 Week and 1 Month

1-Week QuIC score	<i>F</i>	<i>df</i>	<i>p</i> -Value	Partial η^2
Model				
Depression status	0.21	1	.6451	0.002
Intervention status	0.51	1	.4764	0.005
Patient status	2.58	1	.1113	0.022
Marital status	0.11	1	.7384	0.001
Income	1.73	2	.1825	0.030
Intervention by patient status	8.28	1	.0048 **	0.069
Error		112		
Total		120		

Intervention status by patient status, 1-week QuIC score	<i>n</i>	Adjusted mean ^a	Standard error
Intervention group			
Patient	33	51.7	1.9
Caregiver	28	49.7	2.0
Control group			
Patient	33	48.4	2.1
Caregiver	26	55.3	2.3

1-Month QuIC score	<i>F</i>	<i>df</i>	<i>p</i> -Value	Partial η^2
Model				
Depression status	0.00	1	.9801	0.000
Intervention status	1.18	1	.2805	0.011
Patient status	1.88	1	.1727	0.017
Marital status	0.67	1	.4152	0.006
Income	0.32	2	.7297	0.006
Intervention by patient status	5.60	1	.0198 *	0.049
Error		108		
Total		116		

Intervention status by patient status, 1-month QuIC score	<i>n</i>	Adjusted mean ^a	Standard error
Intervention group			
Patient	31	51.9	2.0
Caregiver	27	50.3	2.1
Control group			
Patient	32	50.0	2.4
Caregiver	26	56.0	2.4

^a Mean is adjusted for Intervention status, patient status, marital status, and income. ANCOVA = Analysis of Covariance; QuIC = Quality of Informed Consent Questionnaire

*
 $p < .05$

**
 $p < .01$.