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Telephone-based Cognitive-Behavioral Therapy for Depression in Parkinson's disease

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Abstract

Background—Although face-to-face cognitive-behavioral therapy was found to be beneficial for the treatment of depression in Parkinson's disease (PD) in a recent randomized-controlled trial, access to care was identified as a critical issue that needs to be addressed in order to improve the management of this non-motor complication in PD. The purpose of this study was to examine the feasibility and effect of telephone-based cognitive-behavioral therapy for depression in Parkinson's disease.

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Methods—Twenty-one depressed people with Parkinson's disease participated in an NIH-sponsored uncontrolled pilot trial of telephone-based cognitive-behavioral therapy in an academic medical center from October 2009 to February 2011. The Hamilton Depression Rating Scale was the primary outcome. Treatment was provided to people with Parkinson's disease for 10 weeks, modified for delivery over the phone, and supplemented with 4 separate phone-based caregiver educational sessions. Assessments were completed at baseline and 5 (midpoint), 10 (end-of-treatment), and 14 weeks (follow-up) post-enrollment.

Results—Twenty (95%) people with Parkinson's disease completed the study treatment. Phone-based cognitive-behavioral therapy was associated with significant improvements in depression, anxiety, negative thoughts, and coping. Mean Hamilton Depression Rating Scale change from baseline to week 10 was 7.91 points ($P<.001$, Cohen's $d=1.21$).

Conclusions—Telephone-based cognitive-behavioral therapy may be a feasible and helpful approach for treating depression in Parkinson's disease and warrants further exploration in randomized-controlled trials. Results were comparable to those observed in the few in-person cognitive-behavioral treatment studies for depression in Parkinson's disease conducted to date.

Keywords

Parkinson's disease; depression; cognitive-behavioral therapy; telemedicine; treatment

Despite the high rate of depression observed in Parkinson's disease (PD)¹, few people with PD receive adequate treatment for this psychiatric comorbidity. Depression in PD (dPD) is frequently underreported by patients, as well as under-recognized and inadequately managed by health care providers^{2,3,4}. Challenges regarding the detection and treatment of dPD are of great clinical concern due to the significant disability and distress associated with this non-motor feature⁵. Studies have shown that depression may hasten physical and cognitive deterioration⁶, is associated with high rates of executive dysfunction, anxiety, sleep disturbance, pessimistic thoughts, and caregiver burden^{7,8,9,10}, and may negatively impact quality of life¹¹, coping¹² and social relationships¹³ in Parkinson's disease. Limited access to movement disorder specialists, geriatric psychiatrists, and evidence-based mental health care, such as cognitive-behavioral therapy (CBT), may be one factor implicated in the sub-optimal management of dPD¹⁴.

We have recently demonstrated that face-to-face CBT was superior to clinical monitoring for the treatment of dPD in a randomized-controlled trial¹⁵. Despite the success of this program (i.e., recruitment, retention, and outcomes), access to care was identified as a critical issue that needs to be addressed in order to improve the management of depression in Parkinson's disease. For example, demographic data indicated that the mean travel time to study visits was approximately one hour. Special transportation arrangements were needed for one-fifth of our randomized sample due to physical limitations. Geographic restrictions and physical disability were the main reasons for study exclusion after completion of the preliminary phone screen. It was also challenging to find appropriate referrals for individuals who did not qualify for participation and for those who wished to continue in this line of treatment after the study as there are very few psychologists or social workers with specialized training in both CBT and Parkinson's disease; necessary prerequisites to this type of work.

Telemedicine may represent a potential approach for overcoming such barriers to effective mental healthcare utilization in Parkinson's disease. Telemedicine employs telecommunications and information technologies (e.g., the Internet, telephone, videoconferencing) to examine, diagnose, treat, monitor and educate patients who are unable to present for an in-person visit¹⁶. The use of telemedicine to provide services to individuals

with chronic medical illnesses is a cost-effective strategy¹⁷ of growing interest and utility^{18,19}. For example, technology-based interventions aimed at treatment adherence, promotion of healthy behaviors, education, coping and support have demonstrated success in treating medical patients with diabetes, hypertension, and heart disease¹⁶. The provision of subspecialty medical care for people with PD in remote areas via videoconferencing has also been met with good results²⁰.

Importantly, telephone-administered CBT may be a promising option for the treatment of depression in medical populations^{21,22,23,24}. Meta-analyses suggest that psychotherapy administered by telephone results in large pre-post treatment effect sizes, with attrition rates substantially lower than those observed for face-to-face psychotherapy²¹. In general, these phone-based approaches have involved individual work with the depressed person and targeted core CBT techniques such as behavioral activation, problem-solving, and cognitive restructuring.

For example, in a study of depressed patients in primary care, telephone-based CBT was found to be more effective than usual care (i.e., antidepressants) in the long-term treatment of depression²⁵. Another study of distressed rural caregivers to individuals with dementia indicated that CBT by phone was more effective in reducing psychological distress and burden than was routine education and support²⁶. Several randomized-controlled trials of telephone-administered treatments by Mohr and colleagues have also indicated that CBT is better than usual care and more effective than supportive emotion-focused therapy in alleviating depression associated with MS^{23,24,27}. To date, only one case report has examined the utility of phone-based CBT for depression and anxiety in PD²⁸. Given the neuropsychiatric complexity that defines dPD (as described above), further research is needed to determine if telephone-based approaches to treatment will be as helpful for this medical population as they are for other patient groups.

The purpose of the current NIH-sponsored pilot study was to examine the feasibility and effect of telephone-based cognitive-behavioral therapy for depression in Parkinson's disease. We hypothesized the following: 1) Telephone-based CBT for dPD will be associated with significant improvements in depression (*primary hypothesis*); 2) Telephone-based CBT will be associated with significant improvements in several well-documented correlates of dPD including anxiety, negative thoughts, quality life, coping, sleep, social support, and caregiver distress (*secondary hypotheses*); 3) High participant retention rates will be observed (*secondary hypothesis*); 4) Therapists will be able to competently adhere to the treatment protocol as delivered over the phone, based on established cognitive therapy adherence guidelines²⁹ (*secondary hypothesis*). Sample characteristics, feasibility data, treatment response rates, and preliminary estimates of effect size for this telephone-based intervention will be compared to those observed in this site's recent in-person randomized controlled trial of CBT for dPD¹⁵. Effect size estimates will also be used to power future randomized controlled trials and to inform further treatment development efforts for this medical group.

Method

Participants

Participants were recruited via physician referral from the Richard E. Heikkila Movement Disorders Clinic at Robert Wood Johnson Medical School and advertisements distributed to support groups affiliated with the American Parkinson's Disease Association from October 2009 through October 2010. The final follow-up occurred in February 2011. People with Parkinson's disease (PWP) enrolled in the study with a friend or family member (hereafter referred to as caregiver).

Eligibility requirements for study participation were similar to those employed in our previous face-to-face CBT trial¹⁵ and were determined as follows; PWP Inclusion Criteria: 1) Confirmed diagnosis of Parkinson's disease (by treating neurologist); 2) Primary Major Depressive Disorder, Dysthymia, or Depressive Disorder Not Otherwise Specified per the Structured Clinical Interview (SCID-I) for the Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV); 3) Clinical Global Impression (CGI)³⁰ Severity Scale 4 [at least moderately ill]; 4) age within the range of 35–85 years; 5) Stable medication regimen 6 weeks; PWP Exclusion Criteria: 1) A Modified Telephone Interview for Cognitive Status (TICS-M)³¹ score below 21 (which is equivalent to a MMSE 25); 2) Poor motor control (i.e., PD symptoms inadequately controlled by medications 50% of the day); 3) Suicidal plans or intent; 4) Unstable medical conditions (e.g., conditions such as diabetes or hypertension that are not adequately managed by medication); 5) Meeting DSM-IV Criteria for Bipolar, Psychotic Spectrum, or Substance Abuse Disorders; 6) Receiving CBT elsewhere. Caregivers were 25–85 years old, had daily contact with the PWP, scored 21 on the TICS and denied unstable medical or psychiatric conditions (based on clinical interview).

PWP continued to be followed by their personal healthcare team and were maintained on stable (6 weeks) medication regimens (including antidepressants, if applicable) for the duration of the study. Healthcare utilization and the use of prescription medications, as well as over-the-counter supplements, were monitored during the trial (i.e., participants were directly queried about any changes at each follow-up evaluation). PWP who required new or additional depression treatment were discontinued from the study and referred for appropriate follow-up care.

Procedure

The study had the full approval of the UMDNJ-Robert Wood Johnson Medical School IRB. All study procedures took place over the phone. Interested parties contacted our office to receive information about the study (Figure 1). Consent forms were mailed to potential participants who wished to be formally evaluated for study eligibility. Study staff then reviewed the consent form page-by-page with the potential participant over the phone. After all questions were answered, the participant signed the consent form and mailed it back to the study team. An investigator and a witness then signed the consent form upon receipt. The screening appointment was scheduled once the study team was in possession of a fully executed copy of the consent form and a copy had been mailed to the potential participant. No study procedures (including the screening evaluation) took place prior to the full execution of the informed consent procedures.

During the screening appointment, psychiatric and medical history was obtained, inclusion/exclusion criteria were assessed, and baseline measures of primary and secondary outcomes were administered. Eligible candidates received 10 sessions of individually-administered phone-based CBT, which was augmented with up to four separate caregiver educational sessions. Outcome measures were re-administered 5, 10 and 14 weeks post-enrollment by research staff not directly involved with the participants' treatment.

The Hamilton Rating Scale for Depression (HAM-D 17)³² was the primary outcome. Scores on the HAM-D 17 range from 0–52 and a decrease in score reflects improvement. As recommended by an expert panel³³, an inclusive scoring approach was employed and all reported symptoms were counted towards HAM-D ratings, despite potential overlap with the physical aspects of PD (i.e., fatigue and psychomotor slowing). There is currently insufficient information available to establish definitive clinical cuts and severity ranges on the HAM-D-17 for depression in PD³⁴. However, the following categorization of depressive symptoms based on HAM-D-17 ratings has been proposed by the American Psychiatric

Association for other patient groups: 0–7 not depressed; 8–13 mild symptoms; 14–18 moderate symptoms; 19–22 severe symptoms; 23 very severe symptoms³⁵.

Secondary endpoints included severity of depression (Beck Depression Inventory; BDI³⁶), treatment response³⁷ [defined *a priori* as a score of *depression* much improved (2) or very much improved (1) on the Clinical Global Impression – Improvement Scale (CGI-I) or 50% reduction in the baseline HAM-D 17 score], anxiety (Hamilton Anxiety Rating Scale; HAM-A³⁸), negative thoughts (Inference Questionnaire; IQ³⁹), quality of life (social functioning, physical role limitations, and physical disability subscales of the Medical Outcomes Short Form; SF-36⁴⁰), coping (reframing and problem-focused subscales of the Brief Cope⁴¹), social support (Social Feedback Questionnaire; SFQ⁴²), sleep (Pittsburgh Sleep Quality Index; PSQI⁴³), and caregiver burden (Caregiver Distress Scale; CDS⁴⁴). Measures of therapist empathy and treatment helpfulness (Burns Empathy and Helpfulness Scales⁴⁵) were also obtained at week 10.

Telephone-based CBT Intervention—Phone-based CBT was provided by the first author (RDD), as well as 1 postdoctoral fellow, and 2 masters-level clinicians with background and training in CBT and health psychology. All study therapists treated at least 2 pilot PD patients, prior to their participation in the phone-based program. RDD reviewed audiotapes from study treatment sessions (based on training and supervision needs) and rated therapist skill and competence on the Cognitive Therapy Scale²⁹ (a well-validated treatment adherence tool) throughout the trial.

The core features of CBT for dPD have been described elsewhere¹⁵ and the same treatment protocol as previously detailed (including caregiver sessions) was employed in this telephone-based trial. In brief, PWP received 10 sessions (60–90 minutes each) of individually-administered CBT which was *delivered over the phone* and incorporated behavioral activation, recommendations to gradually increase exercise, thought monitoring and restructuring, relaxation training, worry control and sleep hygiene. Due to the high rates of anxiety symptomatology observed in dPD, anxiety management techniques were more heavily emphasized in this intervention, compared to traditional CBT protocols for depression.

Caregivers also had the option to receive up to four telephone-based educational sessions (30–60 minutes each), evenly dispersed throughout the course of the participants' treatment. Given the high rate of executive dysfunction in PD, the purpose of the caregiver sessions was to provide the care partner with the skills needed to facilitate the PWP's practice of CBT techniques (i.e., exercise, socializing, reframing thoughts) both between sessions and after treatment had ended. Caregivers were initially provided with background information regarding the psychiatric complications in PD and the cognitive-behavioral treatment model of depression. In later sessions, caregivers were trained to recognize the PWP's negative thoughts such as "I am rapidly deteriorating" and to help the PWP replace their negative thoughts with more balanced, accurate alternatives (i.e., "I am not rapidly deteriorating. The doctor said I am the same as I was six months ago and did not change my medication.").

Several modifications were made to facilitate the telephone-based administration of CBT. Immediately following enrollment, each participant was provided with a session-by-session manual, which included the rationale for each treatment strategy incorporated into the program, practice examples regarding the application of each skill, and blank worksheets for in-session and between-session practice of CBT techniques (i.e., thought logs, activity scheduling). A supplemental packet of color-coded blank worksheets was also included for ease of reference (i.e., "thought logs" in green, "questioning automatic thoughts" worksheets in blue). PWP were instructed to read the manual prior to each session. Detailed summaries,

including completed copies of all CBT worksheets reviewed, were mailed to participants both after each session and at the end of treatment.

Overview of Statistical Analyses

Data was analyzed using SPSS Version 18. An intent-to-treat approach was employed in all analyses, which included all enrolled patients (N=21). Primary (HAM-D) and secondary outcomes were evaluated at baseline and weeks 5, 10, and 14 using mixed-models repeated measures analysis of variance with restricted maximum likelihood estimation. Assessment point (baseline, weeks 5, 10, and 14) was the fixed effect. The PWP was treated as a random effect. Compound symmetry was used to model the covariance structure for all analyses, as this model yielded the best fit for the data among all covariate structures examined. Given the number of secondary outcomes explored, a significance level of $p=.01$ was employed in all analyses to decrease the chance of Type I error.

The rate of treatment response was separately explored at end-of-treatment (week 10) and follow-up (week 14). Effect sizes are presented for all primary and secondary outcomes (Table 2). Planned contrasts to examine changes specific to a particular time point (i.e., week 10) were only conducted if the overall omnibus F test (Table 2) was significant. Least squared means are presented in the text and tables. Sample size was determined a priori based on past CBT pilot work in Parkinson's disease conducted by RDD⁴⁶. It was estimated that 20 patients were needed to obtain preliminary approximations of effect size to power a future randomized-controlled trial of this phone-based intervention.

Results

Characteristics of the Sample

Thirty-six PWP signed informed consent. Twenty-one PWP (13 female, 8 male) and their caregivers met eligibility criteria and enrolled in the trial (Figure 1). Twenty participants (95%) met DSM-IV criteria for Major Depressive Disorder, while 1 (5%) met DSM-IV criteria for Dysthymia. The mean age of PWP was 65.86 (SD=9.38) years, while the average duration of PD was 7.45 (SD=9.38) years. The mean stage (Hoehn and Yahr⁴⁷) of PD in the sample was 2.39 (SD=0.72), suggesting a bilateral presentation of symptoms (i.e., tremor, rigidity). The majority of participants were physically independent with mild to moderate impairment in activities of daily living. Seventeen participants (81%) were taking a stable dose of an antidepressant at baseline and reported adherence to their medication regimen throughout the study. See Table 1 for a complete breakdown of clinical and demographic information.

Primary Outcome

Telephone-based CBT was associated with significant improvements on the HAM-D 17 over the course of the trial $F(3, 57)=18.49$, $P<.001$. The mean HAM-D score at week 10 (end of treatment) was 13.38 [95% CI: 11.31–15.45]. Mean HAM-D change from baseline was 7.91 points ($P<.001$, Cohen's $d=1.21$; Table 2).

Secondary Outcomes

Notable gains were observed for depression severity [BDI; $F(3,53)=23.68$, $P<.001$], anxiety [$F(3,57)=15.59$, $P<.001$], negative thoughts [$F(3,55)=4.05$, $P=.01$], and coping [positive reframing; $F(3,53)=7.09$, $P<.001$] for participants in the phone-based CBT program. No significant effects were found on measures of quality of life, problem-focused coping, sleep, social support, or caregiver burden (Table 2).

Treatment Response

Sixty-two percent (N=13) of the sample met criteria for treatment response at week 10, with 52% (N=11) classified as responders at week 14.

Feasibility Data

Twenty (95%) PWP completed all 10 treatment sessions (mean # sessions= 9.57, SD=1.96). The mean number of caregiver sessions attended was 2.19 (SD=1.69). On average, it took PWP 10.2 (SD=2.84) weeks to complete the treatment program. Therapists were able to competently adhere to the study protocol administered over the phone, as evidenced by a mean score of 49.77 (SD=7.46) on the Cognitive Therapy Scale [with a score 40 reflecting proficiency²⁹], based on the review of 87 treatment sessions. PWP also reported the perception of high levels of empathy from the study therapists (M=19.26, SD=1.52) and rated the phone treatment as very helpful (M=18.00, SD=2.11).

Comparison to Face-to-Face CBT

The within group effect size (Cohen's d) observed for telephone-based CBT was comparable to the within group effect observed for face-to-face CBT in our group's recent randomized-controlled trial¹⁵. Study completion rates, time needed to finish the study treatment program (i.e., number of weeks), and treatment response rates were similar across both trials. High levels of treatment adherence and therapist skill (Cognitive Therapy Scale scores 40 on more than 95% of treatment tapes assessed across both trials) were noted for both in-person and telephone-based CBT. Participants in the phone-based program reported less psychiatric and medical comorbidity, fewer past trials of antidepressant medications, and higher rates of current antidepressant medication use than participants enrolled in the face-to-face program. No significant difference emerged on any other baseline characteristic reported in Table 1 between participants in the telephone-based and in-person trials.

Discussion

This study examined the feasibility and effect of telephone-administered CBT for depression in PD. In contrast to previously described telephone-based CBT approaches for depression, this program incorporated a standardized, supplemental caregiver intervention and systematically integrated anxiety management modules into treatment in order to address the unique needs of the PD population. Results suggest that this modified psychosocial intervention may be a reasonable and helpful approach for the treatment of dPD and its clinical correlates. Telephone-administered CBT was associated with significant improvements in depression, anxiety, coping, and negative thoughts. Treatment gains were observed after 5 weeks of therapy and maintained throughout the one month follow-up period. More than half of this tele-health sample met criteria for treatment response at weeks 10 and 14 and the average HAM-D scores for the sample dropped from the severe to mild range³⁵, underscoring the clinical significance of the findings. Effect sizes were large for phone-based CBT on both clinician-administered (HAM-D- Cohen's d= 1.21) and self-report (BDI -Cohen's d= 1.13) measures of depression. However, no significant effects were found on measures of quality of life, sleep, social support, or caregiver burden.

With the exception of the lack of effect on quality of life (likely due to the large standard deviation on the measure and the small sample size), these findings mirror those from our recent randomized controlled trial of face-to-face CBT for dPD (HAM-D Cohen's d = 1.59, BDI Cohen's d = 1.10)¹⁵. These results were also comparable to the few additional in-person CBT pilot studies for dPD conducted to date^{46,48,49,50,51} and are consistent with the literature on phone-based psychotherapy for depression in other patient groups²¹. Importantly, this study provides preliminary evidence that the beneficial effects of telephone

psychotherapy observed in other chronic medical conditions are not attenuated by the neuropsychiatric complexity that is characteristic of the PD population.

Feasibility data pertaining to this tele-health approach for treating dPD also appears strong. The PD community expressed great interest in the phone-based intervention; the research team received approximately 6 inquiry calls for every one spot available for the study treatment. Excellent participant retention rates were observed. The high retention rate may be due to the flexible scheduling of study appointments, the comprehensive informed consent process employed, the team's past experience working with the PD population, the extensive modifications that were made to deliver CBT to PWP over the phone, the inclusion of caregivers in the treatment program, the strong need for evidence-based mental health treatment for PWP, and the lack of therapists in community-based settings with adequate knowledge of Parkinson's disease. Therapy was also completed in the timeframe specified by the protocol, and therapists were able to competently teach CBT skills over the phone. Notably, the non-specific components of the therapy process, such as patient perceptions of therapist empathy and helpfulness, were preserved in this phone-based approach. PWP gave study clinicians high ratings on attributes such as warmth, trustfulness, respect, understanding, and listening.

The main limitations of this study include its small sample size and uncontrolled pilot design. Thus, in order to minimize rater bias, follow-up assessments were completed by study staff not directly involved with the participants' treatment (i.e., not the treating therapist). Given the lack of a comparison condition, the role of chance, non-specific treatment factors (i.e., time, therapeutic rapport), and caregiver participation cannot be ruled out as mechanisms of change. In addition, while depression has been linked to higher levels of functional impairment in PD^{4,6}, motor changes following treatment could not be evaluated given the absence of in-person assessment. The longer-term effects of the intervention are also unclear as the follow-up period was limited to one-month. Finally, results may not generalize to those with lower levels of education, significant cognitive impairment, more advanced stage PD, more severe depression, inadequate social supports (i.e., no caregiver), or no past history of psychiatric treatment. The generalization of these results to clinical practice at the current time may also be limited by insurance and reimbursement restrictions regarding tele-health interventions, as well as local licensing restrictions for mental health providers.

Multiple factors likely contribute to the sub-optimal management of dPD. Further research is needed to more clearly elucidate barriers to effective mental healthcare utilization in PD and the characteristics of patients who may derive optimal benefit from phone-based or other tele-health approaches. Interestingly, while the majority of subject characteristics assessed were similar across our in-person and phone-based trials (including disability measures), participants in the telephone-based intervention endorsed less medical and psychiatric comorbidity (despite comparable levels of depression severity). This could be an artifact of the small sample, may imply that patients are less likely to provide a complete medical history when an initial evaluation is completed over the phone vs. in-person, or may suggest that patients who are more complex in their presentation have a greater chance of being managed face-to-face by specialty-care providers.

In sum, results of this pilot study suggest that telephone-based CBT may be a feasible and beneficial option for depressed people with Parkinson's disease. This may be particularly encouraging for those individuals with PD who cannot access evidence-based mental healthcare in their local geographic area. Larger randomized-controlled trials are warranted to further evaluate the efficacy of this intervention and to identify specific mechanisms of change.

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Figure 1.
Flow of Participants through the Study

Table 1

Baseline Characteristics

	CBT (n = 21)	
Gender ^a		
<i>Male</i>	8	(38.1%)
<i>Female</i>	13	(61.9%)
Age ^b	65.86	(9.32)
Parkinson's Disease Duration (years)	7.45	(5.17)
Age of Parkinson's Disease Onset	58.67	(11.32%)
Depression Duration (years)	2.35	(5.42)
Primary DSM-IV Diagnosis		
<i>Major Depressive Disorder</i>	20	(95.2%)
<i>Dysthymia</i>	1	(4.8%)
<i>Depressive Disorder Not Otherwise Specified</i>	0	(0%)
Comorbid DSM-IV Anxiety Disorder	5	(23.8%)
Antidepressant Use²	17	(81%)
*Clinical Global Impression Scale – Severity^f	4.38	(0.50)
*17-Item Hamilton Depression Rating Scale Score^f	21.29	(6.48)
Beck Depression Inventory Score^f	22.62	(9.24)
Hamilton Anxiety Rating Scale Score^f	19.86	(5.79)
Telephone Interview for Cognitive Status	23.48	(2.40)
Hoehn & Yahr Parkinson's Disease Stage	2.39	(0.72)
Schwab & England Activities of Daily Living Scale (%)	76.0	(10.83)
Race		
<i>White</i>	20	(95.2%)
<i>Black</i>	1	(4.8%)
Ethnicity		
<i>Non-Hispanic</i>	21	(100%)
Marital Status		
<i>Married</i>	15	(71.4%)
<i>Divorced</i>	3	(14.3%)
<i>Widowed</i>	3	(14.3%)
<i>Never Married</i>	0	(0%)

CBT (n = 21)		
*Education		
<i>High School Diploma</i>	4	(19.0%)
<i>Some College</i>	0	(0%)
<i>College Degree</i>	8	(38.1%)
<i>Graduate Degree</i>	9	(42.9%)
Receiving Disability	4	(19%)
# Comorbid Medical Conditions	1.43	(1.47)
# Parkinson's Disease Medications	2	(1.14)
# Psychotropic Medications	1.33	(0.97)
# Total Medications	7.90	(4.35)
# Past Depression Med Trials	0.24	(0.70)
Deep Brain Stimulation	2	(9.5%)
*History of Supportive Psychotherapy	16	(76.2%)

^aN's and % are presented for categorical variables.

^bMeans and standard deviations are presented for continuous variables.

* Enrolled participants and screen fails were compared at baseline on all demographic and clinical variables listed, to check for group equivalence, with t or χ^2 tests as appropriate. A significant difference between enrolled participants and screen fails emerged on the noted variables. Specifically, screen fails experienced less severe depression, as indicated by the Hamilton Depression Rating Scale and Clinical Global Impression Scale, had lower levels of education, and were less likely to have a history of psychotherapy.

¹Higher scores indicate more severe symptoms.

²The average length of time on the stabilized antidepressant regimen was 4.5 years.

Table 2

Outcome Means

CBT (n=21)					
PRIMARY OUTCOMES	Mean	(SD)	F	p-value ^d	Cohen's d
Hamilton Depression Rating Scale ^b	<i>Baseline</i>	21.29	(6.48)		
	<i>Midpoint</i>	15.33 ^{**}	(6.63)		
	<i>Endpoint</i>	13.38 ^{**}	(6.63)	18.49	<.001
	<i>Follow-up</i>	13.84 ^{**}	(6.77)		1.21
SECONDARY OUTCOMES					
Beck Depression Inventory ^b	<i>Baseline</i>	22.62	(9.24)		
	<i>Midpoint</i>	15.07 ^{**}	(9.55)		
	<i>Endpoint</i>	12.00 ^{**}	(9.57)	23.68	<.001
	<i>Follow-up</i>	11.89 ^{**}	(9.73)		1.13
Hamilton Anxiety Rating Scale ^b	<i>Baseline</i>	19.86	(5.79)		
	<i>Midpoint</i>	15.46 ^{**}	(5.91)		
	<i>Endpoint</i>	13.51 ^{**}	(5.91)	15.59	<.001
	<i>Follow-up</i>	14.07 ^{**}	(6.03)		1.09
Coping – Positive Reframing ^c	<i>Baseline</i>	3.85	(2.18)		
	<i>Midpoint</i>	5.01 [*]	(2.29)		
	<i>Endpoint</i>	5.78 ^{**}	(2.23)	7.09	<.001
	<i>Follow-up</i>	5.49 ^{**}	(2.29)		.88
Coping – Problem Focused ^c	<i>Baseline</i>	15.50	(5.79)		
	<i>Midpoint</i>	16.56	(6.06)		
	<i>Endpoint</i>	18.64	(5.94)	3.00	.04
	<i>Follow-up</i>	16.90	(6.06)		.54
Short-Form Health Survey – Social Functioning ^c	<i>Baseline</i>	54.17	(33.59)	1.93	.14
					.32

CBT (n=21)					
PRIMARY OUTCOMES	Mean	(SD)	F	p-value ^a	Cohen's d
<i>Midpoint</i>	64.45	(34.90)			
<i>Endpoint</i>	65.14	(34.94)			
<i>Follow-up</i>	66.51	(35.63)			
<i>Baseline</i>	50.92	(36.57)			
<i>Midpoint</i>	56.18	(37.02)	.86	.47	.01
<i>Endpoint</i>	50.45	(37.05)			
<i>Follow-up</i>	55.00	(37.84)			
<i>Baseline</i>	14.29	(41.36)			
<i>Midpoint</i>	20.69	(43.09)	.707	.55	.20
<i>Endpoint</i>	22.80	(43.16)			
<i>Follow-up</i>	13.95	(44.05)			
<i>Baseline</i>	5.67	(6.53)			
<i>Midpoint</i>	4.43	(7.06)	1.39	.26	.15
<i>Endpoint</i>	4.62	(6.95)			
<i>Follow-up</i>	3.54	(7.06)			
<i>Baseline</i>	14.00	(5.13)			
<i>Midpoint</i>	13.33	(5.33)	3.21	.03	.35
<i>Endpoint</i>	12.15	(5.34)			
<i>Follow-up</i>	11.43	(5.44)			
<i>Baseline</i>	7.33	(4.62)			
<i>Midpoint</i>	6.74	(4.83)	4.05	.01	.42
<i>Endpoint</i>	5.33 [*]	(4.83)			
<i>Follow-up</i>	4.28 [*]	(5.08)			
<i>Baseline</i>	20.76	(18.86)			
<i>Midpoint</i>	17.66	(19.41)	3.69	.02	.16
<i>Endpoint</i>	17.74	(19.41)			

CBT (n=21)					
PRIMARY OUTCOMES	Mean	(SD)	F	p-value ^a	Cohen's d
	Follow-up	14.35	(19.93)		

^asignificance level set at p .01

^blower scores reflect improvement

^chigher scores reflect improvement

* change significant from baseline at p .05

** change significant from baseline at p .001