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Bipolar Disorder Center for Pennsylvanians: Implementing an Effectiveness Trial to Improve Treatment for At-Risk Patients

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Abstract

Objective—Adolescents, elderly persons, African Americans, and rural residents with bipolar disorder are less likely than their middle-aged, white, urban counterparts to be diagnosed, receive adequate treatment, remain in treatment once identified, and have positive outcomes. The Bipolar Disorder Center for Pennsylvanians (BDCP) study was designed to address these disparities. This report highlights the methods used to recruit, screen, and enroll a cohort of difficult-to-recruit individuals with bipolar disorder.

Methods—Study sites included three specialty clinics for bipolar disorder in a university setting and a rural behavioral health clinic. Study operations were standardized, and all study personnel were trained in study procedures. Several strategies were used for recruitment.

Results—It was possible to introduce the identical assessment and screening protocol in settings regardless of whether they had a history of implementing research protocols. This protocol was also able to be used across the age spectrum, in urban and rural areas, and in a racially diverse cohort of participants. Across the four sites 515 individuals with bipolar disorder were enrolled as a result of these methods (69 African Americans and 446 non–African Americans). Although clinical characteristics at study entry did not differ appreciably between African Americans and non–African Americans, the pathways into treatment differed significantly.

Conclusions—Rigorous recruitment and assessment procedures can be successfully introduced in different settings and with different patient cohorts, thus facilitating access to high-quality treatment for individuals who frequently do not receive appropriate care for bipolar disorder.

Bipolar disorder is one of the world's ten most disabling conditions, robbing persons with the disorder of years of healthy functioning. Although there do not appear to be disparities in who is at risk of bipolar disorder, there are marked disparities in who is likely to be diagnosed and treated. Once a diagnosis of bipolar disorder is made, there are equally marked disparities in treatment outcome (1). Young persons (2–5), elderly persons (6,7), African Americans (8,9), and rural residents (10,11) with bipolar disorder are less likely than their middle-aged, white, urban counterparts to be diagnosed, receive adequate treatment, remain in treatment once identified, and have positive outcomes if they remain in treatment.

In 2003 the Commonwealth of Pennsylvania funded an interdisciplinary group of investigators at the University of Pittsburgh and the DuBois Regional Medical Center (in rural western Pennsylvania) to develop the Bipolar Disorder Center for Pennsylvanians (BDCP) study (grant number ME-02385) whose procedures were designed to increase the probability of accurate diagnosis, increase adequacy of treatment, increase retention in treatment, and improve treatment outcomes for adolescents, elderly persons, residents of rural areas, and African-American individuals with bipolar disorder. In doing so, we, as members of this group, would facilitate increased access to high-quality treatment for individuals who frequently do not receive appropriate care for bipolar disorder. The study was designed to reproduce as closely as possible the quality of the most rigorous research protocol and at the same time avoid to the extent possible the rigidity and nongeneralizability of many such protocols.

Our goal was to address the health disparities in the treatment of bipolar disorder that are present at both ends of the life span (adolescents and elderly persons), for African American patients, and for individuals living in rural areas. There are several immediate challenges to reducing these disparities: younger, older, African American, and rural residents are frequently not diagnosed and treated or are misdiagnosed and not appropriately treated; once identified, patients in these subgroups are less likely to remain in treatment; and even if they remain in treatment, they are at high risk of poor clinical outcomes.

This report highlights the methods used to recruit, screen, and enroll a cohort of difficult-to-recruit individuals with bipolar disorder who are diverse with respect to age, race, and place of residence (urban versus rural). We discuss the methods we employed in order to implement a common treatment protocol across four different sites. We describe the procedures that were followed to ensure that all participants received appropriate and standardized diagnosis, clinical monitoring, and treatment, both for their bipolar disorder and for any comorbid medical conditions. We present the demographic and clinical characteristics of the 515 individuals with bipolar disorder who ultimately enrolled in the study. A future article will report on the longitudinal results, including study retention and outcomes.

Methods

Sites and training

Study sites included three specialty clinics for bipolar disorder (for adolescent, adult, and elderly patients, respectively) at the University of Pittsburgh and one behavioral health clinic at the DuBois Regional Medical Center (for adult patients).

Study operations were highly standardized, and all study personnel were extensively trained in the study procedures and provided with the appropriate tools to ensure the delivery of a structured and specialized treatment. The Pharmacotherapy Manual, the Enhanced Clinical Intervention Manual, the Study Procedures Manual, and the Data Handbook were developed as part of the grant to provide standardized references for study staff. These manuals were used in the daily clinical operations of the study.

At each site, the treatment team consisted of psychiatrists, psychologists, social workers, and in some cases, nurse clinicians. Psychiatrists were responsible for patients' pharmacotherapy while nonphysicians were responsible for their nonpharmacologic treatment and assessment. Staff at each site received a total of approximately ten days of combined research and treatment training by Pittsburgh research staff on site and in Pittsburgh. DuBios Regional Medical Center staff received training and underwent certification by raters from the Pittsburgh site who had been trained in how to use the Structured Clinical Interview for

DSM-IV (SCID). Clinicians from Pittsburgh and DuBois were trained by Dr. Frank and her colleagues in how to provide enhanced clinical intervention to patients with bipolar disorder across the life span (intervention described below). In addition, the Center of Minority Health of the University of Pittsburgh, Graduate School of Public Health, conducted a cultural competence enhancement program for all staff of the research study to promote improved understanding of the cultural commonalities and differences found in the patient population. A study site monitor visited each site periodically throughout the study to ensure adherence to study intake, screening, and treatment procedures.

Participant recruitment

Several strategies were implemented to accomplish the study goal of reducing health disparities related to bipolar disorder among patients at high risk of poor outcomes by nature of race, age, or place of residence. We developed and implemented a variety of approaches for community outreach. We launched a TV ad campaign of 30-second spots that aired over an eight-week period and targeted peak viewing times and specific programs known by the television stations to be popular among African Americans, adolescents, and elderly persons. A variety of informational and educational brochures were developed and provided to local community organizations specializing in mental health and social services and to college counseling centers. BDCP staff made regular visits to community organizations serving minority, adolescent, and elderly populations throughout the Pittsburgh area to meet with organization directors and provide information about bipolar disorder and the potential benefits of study participation for their clients. A team of BDCP staff members attended health fairs throughout the Pittsburgh area on a regular basis. Staff volunteers met with members of the community at these fairs, addressing questions about bipolar disorder and providing brochures with study specifics and general information pamphlets on bipolar disorder and depression. We also established connections with several colleagues and mental health facilities whose clinics were located in rural areas or in areas with a high number of African-American residents, such as the Western Psychiatric Institute and Clinic (WPIC) Hill Satellite Center. The study recruitment coordinator, the in-patient recruiter, and two of the study faculty were African Americans.

During the recruitment phase, 247 different locations were visited by a BDCP representative to provide pamphlets, presentations, education, or information about bipolar disorder and the BDCP study. Including the television spots, we estimate that over 9,000 people were exposed in some way to information about the BDCP study or bipolar disorder from this campaign alone. In addition to the recruitment campaign, staff members of the study's Clinical Coordinating Center sent a mass mailing of 1,345 informational flyers to residents in selected zip codes. We also developed a simple and informative PowerPoint program that could be presented by any BDCP staff member to community organizations, their staff, and clients. A user-friendly Web site was also developed to advertise the BDCP study, provide education about bipolar disorder, and link to other consumer-based and government resources related to bipolar disorder.

Participant enrollment and screening

The institutional review board at the University of Pittsburgh reviewed and approved all study procedures, and all participants gave written informed consent before participating in the study. The study inclusion criteria were age 12 years or older and a *DSM-IV* diagnosis of bipolar I disorder, bipolar II disorder, bipolar disorder not otherwise specified, or schizoaffective disorder bipolar type. The study exclusion criteria were incompetence to provide informed consent in the opinion of the investigator; mental retardation (IQ ≤70); current drug or alcohol dependence; organic mental disorder; unstable and severe medical illness or other medical contraindication to treatment with mood stabilizers, antidepressants,

or antipsychotic medications; and currently pregnant or breast-feeding. Participating sites offered enrollment into the BDCP study to all eligible patients seeking outpatient treatment.

As soon as a patient presented for evaluation at any site and met inclusion criteria, he or she was eligible to enroll in the study. Consenting patients participated in a research diagnostic interview using the SCID (12,13) for adults or the Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime Version (14) for children between the ages of 12 and 18 years. Patients also had a general physical examination including an electrocardiogram, urinalysis, thyroid examination, and blood studies; women were also given a pregnancy test. In addition, a complete assessment of mood state, comorbid psychiatric disorders, treatment history, social and role functioning, and care utilization was conducted.

All patients were randomly assigned to Specialized Care for Bipolar Disorder (SCBD) alone or to SCBD plus enhanced clinical intervention. Randomization was site specific, using a single permutated block randomization design stratified on site to ensure that equal numbers of participants were entered into each treatment arm for each site. Patients deemed well and relatively symptom free were seen for assessments once every two months, unless their clinical condition changed and they needed to be evaluated sooner. Participants experiencing acute bipolar symptoms (score of >3 on the Clinical Global Impressions Scale for Bipolar Disorder) were required to visit the clinic at least once every two weeks. When recovery from the episode occurred, patients continued to receive their assigned treatment for the duration of the treatment trial. All patients had a minimum treatment period of one year and a maximum treatment period of 44 months.

Assessments

Both interventions involved the same frequency of assessments and treatment through all episodes and phases of the illness during the intervention period. Exposure to pharmacologic treatment was documented by using pharmacokinetic assessments and adherence monitoring. The outcomes of interest included retention in treatment, suicidality, and a range of treatment benefits, including health-related quality of life, employment status, treatment satisfaction, medication adherence, utilization of lower levels of intervention (that is, outpatient versus partial or inpatient care), and reduced substance use, medical morbidity, and mortality. A physical exam was repeated annually.

We developed a comprehensive, structured clinical interview, the bipolar disorder visit form (BDVF), that psychiatrists used at each visit to assess the presence of the *DSM-IV* criteria symptoms of bipolar disorder in the week before the visit to the clinic, the presence of physical symptoms and medication side effects, the current mental status, and the level of information provided to the patients in terms of risks and benefits of the treatment and general strategies to improve their safety. The form also recorded the score on the Clinical Global Impression (CGI) scale and the score on the Global Assessment of Functioning. The data from the BDVF were used to automatically produce the clinical note that became part of the documentation for the patient's medical chart. A self-report version of the BDVF was developed for the patient to complete before each visit with the psychiatrist to enable a more rapid and thorough evaluation.

The total number of assessments administered at any given visit varied according to the time point in the study. The total respondent burden ranged from approximately three hours for the initial evaluation to 30 minutes for follow-up assessments.

As noted above, all study participants also received a complete medical evaluation at entry to the study and annually (more frequently when clinically indicated), which included a

general physical examination and an electrocardiogram. Laboratory studies included urinalysis and the following blood tests: complete blood count and differential, plasma electrolytes, creatinine, blood urea nitrogen, serum calcium, alkaline phosphatase, serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, total proteins, fasting glucose, lipoprotein profile, thyroxine, free thyroxine index, and thyroid-stimulating hormone. Urine drug screens (including amphetamines, barbiturates, benzodiazepines, cocaine, opiates, phencyclidine, tetrahydrocannabinol, methamphetamine, and propoxyphene) were completed at screening and at anytime deemed necessary during the protocol. With respect to our goal of including participants who often receive no or substandard care for bipolar disorder, the initial assessment as well as all psychiatric visits and the primary study medications were provided at no cost to study participants.

Treatment procedures

SCBD—This type of care was based on the expert consensus guidelines (15) and the algorithms developed by the Texas Medication Algorithm Project (TMAP) (16). Clinicians also had access to the recent practice guidelines established by the American Psychiatric Association for the treatment of bipolar disorder (17). Treatment was delivered by site psychiatrists trained in Pittsburgh by Dr. Fagiolini and colleagues. Patients were treated pharmacologically following specific algorithmic guidelines for the treatment of mania, mixed states, or depression. All study participants were treated with a mood stabilizer (that is, either lithium or divalproex) according to predefined algorithms. Participants undergoing a major depressive episode also received sertraline or lamotrigine, whereas participants with psychotic symptoms received adjunctive aripiprazole or olanzapine. Lorazepam was also permitted as needed (up to 4 mg per day) for marked anxiety, sleeplessness, or agitation. When lorazepam was not an appropriate clinical choice, gabapentin was used (up to 3,200 mg per day). Participants who did not respond to or tolerate the medications above were offered alternative standard of care medications.

Enhanced clinical intervention—Enhanced clinical intervention consisted of the same pharmacologic treatment provided by a psychiatrist as in SCBD, with the addition of an intensive clinical management program provided by a nurse clinician (18). This team approach to disease management was drawn primarily from two sources: a randomized trial evaluating systematic care for bipolar disorder as developed by Simon and colleagues (19) and our previous federally funded research study on bipolar disorder (grant number MH029618) (20). This system of education and clinical management is consistent with best practices and associated with excellent treatment adherence and markedly improved clinical outcomes (21). Our clinical management protocol and manualized strategies for enhanced clinical intervention are based on the philosophy that fully informed patients and their family members are in the best position to aid in the management of this illness. This approach consists of ten key components: education about the mood disorder itself, education about medications used to treat the disorder, education about basic sleep hygiene and social rhythm therapy, education regarding the use of rescue medication, careful review of symptoms, a careful review of side effects, medical and behavioral management of side effects, discussion of early warning signs of impending episodes, 24-hour on-call service, and support. Our experience has been that training in this simple but effective paradigm is enthusiastically accepted and can be accomplished efficiently. To make these clinical modules more useful and broadly exportable to community mental health treatment sites, we enlisted the help of our community partners to adapt them for use with the special populations of adolescents, elderly persons, and African Americans.

Relapse prevention—At the point of recovery, patients entered the relapse prevention phase in which they were seen monthly for clinical visits and immediately (within 36 hours)

if a relapse was impending. Patients who experienced “roughening” (that is, subsyndromal symptomatic worsening) were seen at least every other week until recovering. Relapses included both depressive episodes and hypomanic or manic episodes. Patients who relapsed continued to receive algorithm-guided pharmacotherapy and remained in the randomized intervention to which they were originally assigned.

Incentives for participation—Although the required study medications were provided free of charge, many patients were on additional compounds that we deemed important to their health. We, therefore, provided a stipend of $80 every other month to help absorb patients’ copayments for nonstudy medications. Transportation to the Pittsburgh clinics was generally not a problem, because the clinics are centrally located on major public transit lines. If patients voiced concerns about the cost of parking or transportation, we provided parking vouchers. Taxi vouchers were provided to a small number of patients on an as-needed basis. There were no formal provisions for child care; however, patients knew that children were welcome in the clinic waiting area as long as there was an accompanying person to attend to them.

Statistical methods

The distribution of the baseline characteristics of the sample, including demographic, socioeconomic, clinical, and psychosocial measures, was analyzed overall, by study site, by gender, and by race. Descriptive statistics, including measures of central tendency (mean, median, and other percentiles) and dispersion (standard deviations and ranges), were computed for continuous data. Frequency distribution and percentage are presented for categorical data. Comparisons between African-American and non–African-American participants were performed with chi square analyses for categorical data and group t tests for continuous measures. Finally, a logistic model was done to examine the possible sociodemographic and clinical measures that might have accounted for the finding that there were racial differences in the number of suicide attempts. Having a lower household income, being male, having less education, not being married, and having comorbid anxiety disorder were examined, because these variables have been found to be strongly related to suicidality.

Results

Enrollment in the study began in November 2003 and ended on October 1, 2005. Enrolled participants were followed until the study ended in February 2007. A total of 626 individuals across the four study sites consented to be screened for participation. Of these, 515 individuals (82%) met inclusion criteria, enrolled in the BDCP study, and received regular clinical visits with a study psychiatrist. Table 1 shows the reasons that the 111 screened individuals did not enter the study.

The remaining data are presented for the 515 participants who enrolled in the study. Table 2 summarizes the referral sources of these patients and provides comparisons between referral sources of African-American participants and non–African-American participants. Although a substantial number of participants were referred by existing programs at WPIC, more than half of the study participants were referred from external sources. Table 3 summarizes data on site, age, gender, race, marital status, education, employment, and income. The three University of Pittsburgh sites accounted for 416 of the 515 total participants (54% in the adult clinic, 16% in the adolescent clinic, and 11% in the clinic for elderly persons), and the DuBois clinic accounted for 99 participants (19%). The mean ± SD age of the 515 participants was 40.2±17.5 years. A total of 295 participants (57%) belonged to populations at high risk of health disparities (adolescents, elderly persons, African Americans, or patients living in a rural area). Eighty-four participants (16%) were aged 12 to 18 years, and

41 participants (8%) were 65 years or older; 89 (17%) participants identified themselves as members of racial or ethnic minority groups: 69 (13%) were African American, 14 (3%) were biracial, three (1%) were Asian, two (<1%) were Pacific Islander, and one (<1%) was Native American. The 99 participants treated at the DuBois site all lived in a rural area.

Table 4 shows diagnostic and illness characteristics for the cohort. Two-thirds of the patients were diagnosed as having bipolar I disorder. The average age at onset of bipolar disorder was in the early twenties. Eighty-three percent of the sample had some lifetime comorbidity of other psychiatric illness. Almost 40% of the sample reported a history of attempted suicide. The mean CGI score for the sample was 2.5 (possible scores range from 1 to 7, with higher scores indicating more severe illness). Eighty percent of the sample had a mother, father, or sibling with a history of bipolar, unipolar, schizophrenic, or anxiety disorder. As Table 4 indicates, age at bipolar disorder onset was lower among African Americans than among non–African Americans; however, because African Americans were younger, there was no significant difference between the races for the duration of the illness. There was a trend (p=.06) for African-American participants to more frequently report a history of suicide attempt (49% versus 37%). In order to explore this finding further, a logistic model was performed. Household income (χ^2= 8.23, df=1, p=.004) and anxiety disorder (χ^2=3.88, df=1, p=.049) were found to be significant predictors of having made a suicide attempt; race was not a significant predictor.

Table 5 shows psychotropic medication status at entry to the study. Only 9% of the sample was not taking any medication at entry to the study, while 70% of the sample was taking two or more medications, and 50% was taking three or more medications. African Americans had fewer psychotropic medications than non–African-Americans (p=.004), mostly accounted for by fewer African-American participants taking lamotrigine, newer antidepressants, and hypnotics and anxiolytics.

We examined the cohort for gender differences and found that women were more likely than men to have diagnoses of bipolar II disorder and schizoaffective disorder bipolar type (113 of 315 women, or 36%, versus 56 of 200 men, or 28%; χ^2=10.20, df=3, p=.017). Women had less education (χ^2=13.17, df=4, p=.010) and lower personal income (χ^2=18.19, df=7, p= .011). Women were more depressed than men (t=2.29, df=509, p=.022) and were more likely to have mothers with a history of psychiatric disorders (164 of 284 women, or 58%, versus 77 of 180 men, or 43%; χ^2=9.89, df=1, p= .002), siblings with a history of psychiatric disorders (162 of 281 women, or 58%, versus 67 of 173 men, or 39%; χ^2=15.34, df=1, p=.001), and more family history of psychiatric disorders (253 of 298 women, or 85%, versus 131 of 185 men, or 71%; χ^2=13.90, df=1, p=.001). Women were more likely than men to have comorbid anxiety disorders (159 of 273 women, or 58%, versus 70 of 157 men, or 45%; χ^2=7.47, df=1, p=.006) and eating disorders (63 of 273 women, or 23%, versus 15 of 157 men, or 10%; χ^2=12.28, df=1, p= .001). A greater proportion of men than women had never been married (126 of 314 women, or 40%, versus 100 of 197 men, or 51%; χ^2=9.29, df=3, p=.026) and had substance abuse diagnoses (132 of 273 women, or 48%, versus 94 of 157 men, or 60%; χ^2=5.31, df=1, p=.021). Finally, in this study the participation of African Americans was higher among women than among men (52 of 315 women, or 17%, versus 17 of 200 men, or 9%; χ^2=8.48, df=2, p=.014).

Discussion

In the BDCP study we demonstrated that it is feasible to implement, in settings other than intensive research environments, extensive intake and screening procedures for patients with bipolar disorder that approach the quality of a rigorous research protocol. It was possible to recruit a cohort of patients who were diverse in terms of age and race and to implement the

same protocol in various settings regardless of whether there was a history of routinely conducting research protocols and in urban as well as rural mental health provider agencies.

The patients in this study had baseline characteristics similar to those reported by patients in other large clinical studies of bipolar disorder. In our study, 61% of the participants were female, similar to several other recently published large studies, which found rates from 55% to 70% (19,22–26). The BDCP participants' mean age at onset of bipolar disorder was 20.8 years, which matches nationwide epidemiologic studies, such as the Epidemiologic Catchment Area study, the National Comorbidity Survey replication, and other studies, all of which found a mean age at onset between 19.8 and 22.9 years (22,24,25,27–29).

Because one of the aims of the BDCP study was to collect data on bipolar disorder among patients across the life span, different age groups are well represented in our sample. Eight percent of the patients in the study were 65 years or older, a rate higher than reported in other large studies, which range from .2% in the TMAP study (26) to 5.4% in the Stanley Foundation Bipolar Treatment Outcome Network (SFBN) study (25), yet consistent with the relative proportion of such elderly persons within the general population (9.7%) (30).

In the BDCP study we also made efforts to recruit a significant proportion of African-American participants, resulting in their constituting 13% of our total sample. Specific enrollment efforts in the BDCP study led to the proportion of African Americans in our study being higher than the proportion of African Americans in the Pittsburgh metropolitan statistical area (MSA) (8.1%), the area of western Pennsylvania served by WPIC where three of the study sites were located. Of note, the BDCP study recruited more than twice the proportion of African-American patients recruited in our earlier Maintenance Therapies in Bipolar Disorder study despite the fact that the BDCP study included a site in the DuBois area, where the percentage of African Americans in the general population is .3% (31). Other large studies reported variable rates of persons from racial or ethnic minority groups, from 37.5% in the TMAP study, conducted in an area with a high percentage of Latinos, to approximately 3% of African Americans reported in the Systematic Treatment Enhancement Program for Bipolar Disorder study (STEP-BD) and in the SFBN study.

It is worth noting that clinical characteristics, such as bipolar subtype, onset state, and lifetime comorbidity, differed very little between African Americans and non–African Americans in the BDCP study. However, the pathway into treatment differed significantly for African-American participants, who were referred more often from inpatient care, community presentations, and media outlets, compared with non–African-American participants. This difference may be attributable to the fact that we made planned, concerted efforts to do community outreach in African-American communities in the Pittsburgh MSA. In addition, to ensure continuity of care for inpatients with bipolar disorder once they were discharged, a study team member visited the inpatient units daily to discuss the BDCP study with patients, their family members, and inpatient staff. In addition, before study entry the African Americans in this sample were generally receiving less intensive treatment.

Forty-four percent of our BDCP sample had never been married, whereas other clinical studies reported a 30% to 35% rate (22–26). Twenty-one percent of our sample was separated or divorced, which is similar to the rates found in other studies of bipolar disorder and is as expected from a population with bipolar disorder, which displays the highest rates of separation and divorce among those with psychiatric disorders (32).

In the BDCP study two-thirds of the patients had bipolar I disorder, which is slightly below the rates reported in other studies (71% to 87%) (19,23–25). This lower rate of participants with bipolar I disorder is consistent with our effort to improve the diagnosis of bipolar II

disorder, which is more frequent than bipolar I disorder in the general population (30), albeit less frequently diagnosed in clinical settings.

Our patients reported considerable levels of psychiatric comorbidity, with a high rate of lifetime anxiety and substance use disorders (50% and 46%, respectively). Such findings are highly consistent with other large clinical studies reporting comorbid lifetime anxiety disorders at rates of 42% to 47.5% (23,25,33) and comorbid lifetime substance use disorders at rates of 40% to 43.7% (22,23,25). Finally, 39% of our patients reported a history of suicide attempts, which is slightly higher than the 31.8% found in the National Comorbidity Survey samples (34) and the 30% and 35.7% reported by the SFBN and STEP-BD studies, respectively. Similarly, both the Department of Veterans Affairs cooperative study and the Bipolar Disorder Case Registry reported rates of lifetime suicide attempts up to 65% within populations of patients with high unemployment and homelessness (24,27). Several differences in demographic characteristics, treatment history, and clinical characteristics were found between African-American and non–African-American patients (Tables 3, 4, and 5). For instance, African-American patients were less likely to be taking a psychotropic medication or an antidepressant at the time of study entry. Also, they tended to be more likely to report a history of suicide attempts ($p=.061$). However, in a logistic model of suicide attempts, household income and anxiety were strong predictors while African-American race was not, thus suggesting that socioeconomic status and comorbid anxiety have more of an influence than race on poorer outcomes among African-American patients.

Finally, African-American study participants were more likely to have been referred from inpatient services than their non–African-American counterparts. We suspect that this is because often African-American patients must reach a higher level of acuity before being willing to seek treatment for their bipolar disorder. This may have to do with the greater stigma associated with help seeking, particularly among African-American women, or with an inherent distrust of the medical establishment. Whatever the source of this difference, we found that with extensive community outreach, we were able to recruit the majority of the African Americans who participated in our study without their having to reach a level of symptom severity that required inpatient hospitalization.

One limitation to the interpretation of the results is that because the study intake criteria included individuals of all races, we felt that it was important to report on all people who participated in the study regardless of race, even though traditionally some studies compare African Americans to Caucasians. Therefore, the non–African-American group included 20 individuals who self-identified as Asian or American Indian, among other races. However, in the interest of completeness, we also compared the African-American group to the Caucasian group (for which we omitted the 20 individuals who were neither African American nor Caucasian) and still found no differences.

Another limitation to the study is that we cannot determine which of the procedures were most relevant to improved enrollment. Because the BDCP study was a research study supported by an outside agency, we had the funds to conduct extensive community outreach through in-person visits and presentations and through announcements of the availability of free treatment in various public media and to offer screening and treatment at no cost to participants. Reducing health disparities in terms of bipolar disorder treatment for patients in racial or ethnic minority groups, children and adolescents, and elderly persons may require this kind of community outreach because these patient subgroups are less likely to present voluntarily for treatment for a wide variety of reasons. Providing specialized bipolar disorder services that are of high quality undoubtedly helps with the retention of all patients, including these difficult-to-retain subpopulations. Although such efforts may not currently

occur in many community settings, our results suggest that when such efforts are made, they have the potential to bear fruit in terms of reducing health disparities.

Conclusions

Our sample of patients with bipolar disorder appears comparable to samples in other large recent studies of bipolar disorder. Furthermore, given that the design of the BDCP study was aimed at addressing the needs of patients across the life span and also the health needs of African Americans, our findings fit a broad range of individuals with bipolar disorder, with the different age classes and rates of African Americans mirroring their distribution within the U.S. general population. We demonstrated that highly rigorous intake, screening, diagnostic, and treatment procedures could be successfully implemented across different types of settings and within different cohorts of patients, thus facilitating increased access to high-quality treatment for individuals who do not frequently receive appropriate care for bipolar disorder. Future articles will report on a variety of outcome measures, including mediators and moderators of outcome, longitudinally from the point of randomization to the end point of the study.

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Table 1

Reasons for not entering the Bipolar Disorder Center for Pennsylvanians study among persons who consented to be screened for participation, by race

	Total (N=111)		African American (N=35)		Non–African American (N=76)	
Variable	**N**	**%**	**N**	**%**	**N**	**%**
Refused to participate in protocol	39	35	14	40	25	33
Did not meet entry criteria	32	29	7	20	25	33
Lost to follow-up	29	26	11	31	18	24
Change in diagnosis	4	4	1	3	3	4
Medical problems	4	4	2	6	2	3
Death	2	2	0	—	2	3
Relocation	1	1	0	—	1	1

Table 2

Source of referral to the Bipolar Disorder Center for Pennsylvanians study, by race

	Total (N=515)		African American (N=69)		Non–African American (N=446)	
Referral source[a]	**N**	**%**	**N**	**%**	**N**	**%**
Self-referral or word of mouth	67	13	6	9	61	14
Media	43	8	11	16	32	7
Community presentation	69	13	14	20	55	12
Inpatient service	23	5	9	13	14	3
Outpatient service	67	13	12	17	55	12
Other program	129	25	13	19	116	26
Private mental health practitioner	94	18	2	3	92	21
Other mental health service	10	2	1	2	9	2
Medical hospital	6	1	1	2	5	1
Private medical practitioner	6	1	0	—	6	1

[a] χ^2=36.31, df=9, p=.001 for the difference between African Americans and non–African Americans

Table 3

Demographic characteristics of participants at the time of entry to the Bipolar Disorder Center for Pennsylvanians study, by race

	Total (N=515)		African American (N=69)		Non–African American (N=446)		Difference between races		
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**	**Test statistic**	**df**	**p**
Age (M ± SD)	40.2±17.5		35.9±14.8		40.9±17.7		t=2.20	513	.028
Female	315	61	52	75	263	59	χ^2=6.76	1	.009
Study site							χ^2=21.11	3	.001
Adult clinic	276	54	52	75	224	50			
Adolescent clinic	84	16	11	16	73	16			
Elderly clinic	56	11	5	7	51	11			
DuBois clinic	99	19	1	1	98	22			
Marital status							χ^2=12.28	3	.006
Never married	226	44	42	61	184	41			
Married	158	31	10	14	148	33			
Separated or divorced	106	21	15	22	91	20			
Widowed	21	4	2	3	19	4			
Education							χ^2=10.82	4	.029
Less than high school	97	19	18	26	79	18			
High school or GED	88	17	9	13	79	18			
Some college	163	32	29	42	134	30			
College degree	100	19	10	14	90	20			
Graduate	64	12	3	4	61	14			
Employment status							χ^2=4.59	4	.33
Full- or part-time	176	34	22	32	154	35			
Disabled or leave of absence	107	21	18	26	89	20			
Unemployed	136	26	21	30	115	26			
Retired	36	7	2	3	34	8			
None reported	60	12	6	9	54	12			
Annual household income							χ^2=27.07	7	.001
<$10,000	94	18	25	36	69	15			
10,001–20,000	107	21	18	26	89	20			

	Total (N=515)		African American (N=69)		Non–African American (N=446)		Difference between races		
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**	**Test statistic**	**df**	**p**
20,001–30,000	67	13	11	16	56	13			
30,001–40,000	57	11	2	3	55	12			
40,001–50,000	43	8	4	6	39	9			
50,001–75,000	71	14	6	9	65	15			
75,001–100,000	30	6	1	1	29	7			
>$100,000	28	5	1	1	27	6			
Annual personal income							χ^2=7.80	7	.35
<$10,000	275	53	44	64	231	52			
10,001–20,000	98	19	11	16	87	20			
20,001–30,000	60	12	9	13	51	11			
30,001–40,000	25	5	2	3	23	5			
40,001–50,000	18	3	2	3	16	4			
50,001–75,000	19	4	0	—	19	4			
75,001–100,000	4	1	0	—	4	1			
>$100,000	9	2	0	—	9	2			
Sources of income[a]									
Wages	217	42	29	42	188	42	χ^2=.01	1	.99
Social Security Disability Insurance	94	18	13	19	81	18	χ^2=.02	1	.89
Social Security	48	9	3	4	45	10	χ^2=2.33	1	.13
Supplemental Security Income	47	9	12	17	35	8	χ^2=6.56	1	.010
Welfare	27	5	14	20	13	3	χ^2=36.3	1	.001
Unemployment	14	3	3	4	11	2	χ^2=.80	1	.37
Other	185	36	20	29	165	37	χ^2=1.67	1	.20

[a]Participants could report more than one source of income.

Table 4

Diagnostic and illness characteristics at the time of entry to the Bipolar Disorder Center for Pennsylvanians study, by race

	Total			African American			Non–African American			Difference between races		
Characteristic	**Total N**	**N**	**%**	**Total N**	**N**	**%**	**Total N**	**N**	**%**	**Test statistic**	**df**	**p**
Bipolar disorder subtype										χ^2=9.18	3	.027
Bipolar I disorder	515	346	67	69	39	57	446	307	69			
Bipolar II disorder	515	101	20	69	15	22	446	86	19			
Bipolar disorder not otherwise specified	515	58	11	69	11	16	446	47	11			
Schizoaffective bipolar type	515	10	2	69	4	6	446	6	1			
Onset state										χ^2=2.93	4	.57
Depression	409	242	59	52	35	67	357	207	58			
Mania	409	76	19	52	10	19	357	66	18			
Depression and mania	409	57	14	52	4	8	357	53	15			
Hypomania	409	19	5	52	2	4	357	17	5			
Depression and hypomania	409	15	4	52	1	2	357	14	4			
Mood state at study entry										χ^2=18.92	5	.002
Euthymic	515	158	31	69	11	16	446	147	33			
Depressed	515	132	26	69	20	29	446	112	25			
Manic or hypomanic	515	43	8	69	6	9	446	37	8			
Mixed	515	59	11	69	8	12	446	51	11			
Recovering	515	93	18	69	23	33	446	70	16			
Other or unknown	515	30	6	69	1	1	446	29	7			
Lifetime comorbidity												
Any mental illness	515	426	83	69	58	84	446	368	83	χ^2=.10	1	.75
Attention-deficit hyperactivity disorder	515	35	7	69	7	10	446	28	6	χ^2=1.41	1	.24
Substance abuse or dependence	515	238	46	69	33	48	446	205	46	χ^2=.08	1	.77
Anxiety disorder	515	260	50	69	32	46	446	228	51	χ^2=.54	1	.46
Eating disorder	515	80	16	69	7	10	446	73	16	χ^2=1.76	1	.18
History of suicide attempt	499	194	39	67	33	49	432	161	37	χ^2=3.51	1	.061
Family history of mental illness												
Any family member	483	384	80	60	48	80	423	336	79	χ^2=.01	1	.92

	Total			African American			Non–African American			Difference between races		
Characteristic	**Total N**	**N**	**%**	**Total N**	**N**	**%**	**Total N**	**N**	**%**	**Test statistic**	**df**	**p**
Mother	464	241	52	53	34	64	411	207	50	χ^2=3.57	1	.059
Father	449	151	34	45	7	16	404	144	36	χ^2=7.32	1	.007
Sibling	454	229	50	54	33	61	400	196	49	χ^2=2.79	1	.095
Age at onset of bipolar disorder (M ± SD years)[a]	20.8±10.7			18.1±9.3			21.2±10.8			t=1.97	407	.049
Duration of illness (M ± SD years)	24.1±13.1			21.4±13.3			24.5±13.1			t=1.57	407	.12
CGI score (M ± SD)[b]												
Total	2.51±1.22			2.65±1.09			2.49±1.24			t=−.99	509	.32
Manic subscale	1.65±.97			1.74±.91			1.64±.98			t=−.73	506	.47
Depressed subscale	2.28±1.19			2.32±1.16			2.28±1.20			t=−.29	509	.77
QLESQ-14 score (M ± SD)[c]	45.4±10.2			45.1±10.2			45.5±10.3			t=.22	421	.82
GAF score (M ± SD)[d]	62.9±10.3			62.1±9.06			63.0±10.5			t=.64	504	.52

[a] Median age of 18 years for the total sample, 15 years for African Americans, and 18 years for non–African Americans

[b] Clinical Global Impression scale. Possible scores range from 1 to 7, with 1 indicating not ill and 7 indicating severely ill.

[c] 14-item Quality of Life Enjoyment and Satisfaction Questionnaire. Possible scores range from 14 to 70, with higher scores indicating better functioning.

[d] Global Assessment of Functioning scale. Possible scores range from 0 to 100, with higher scores indicating higher functioning. Participants were asked about their functioning in the past week.

Table 5

Psychotropic medication use by participants at the time of entry to the Bipolar Disorder Center for Pennsylvanians study, by race

	Total (N=515)		African American (N=69)		Non–African American (N=446)		Difference between races		
Variable	**N**	**%**	**N**	**%**	**N**	**%**	**χ^2**	**df**	**p**
Number of concurrent psychotropic medications							17.59	5	.004
0	47	9	11	16	36	8			
1	103	20	23	33	80	18			
2	120	23	14	20	106	24			
3	127	25	14	20	113	25			
4	64	12	4	6	60	13			
5 or more	53	10	3	4	50	11			
Current use of medication									
Classic mood stabilizer	278	54	33	48	245	55	1.21	1	.27
Lamotrigine	95	18	4	6	91	20	8.47	1	.004
Other anticonvulsant	70	14	5	7	65	15	2.73	1	.098
Second-generation neuroleptic	204	46	29	42	175	39	.20	1	.66
First-generation neuroleptic	8	2	1	1	7	2	.01	1	.94
Newer antidepressant	223	43	19	28	204	46	8.07	1	.005
Tricyclic antidepressant	12	2	1	1	11	2	.27	1	.60
Hypnotics and anxiolytic	173	34	12	17	161	36	9.37	1	.002
Stimulant	36	7	6	9	30	7	.36	1	.55