Expanded Methods Section

Sample

The patients were recruited as self-referrals from advertisements or by referrals from mental health professionals who worked in southern New Jersey. Most of the referrals were from local psychiatric hospitals, crisis centers, and other outpatient providers. All of patients who expressed interest in the study received an initial phone call during which they were asked a standard set of questions that addressed the study's inclusion and exclusion criteria. The inclusionary criteria included being 19 to 64 years of age, having a diagnosis of schizophrenia or schizoaffective disorder, currently experiencing psychotic symptoms, being on or willing to switch to a SGA, being able to speak English, and being capable of giving informed signed consent. With respect to the exclusionary criteria, a patient could not be currently abusing alcohol or substances, having current suicidal or homicidal ideation that might constitute a risk of causing harm to self or others, having unstable medical problems, not being able to acknowledge any symptoms about their mental health problems, being unwilling to take medication, being unwilling to switch to a SGA if currently on a FGA or clozapine, having level of mental retardation that might interfere with CBT, being unable to speak English, and having had more than three psychiatric

hospitalizations in the past year. If a patient met the inclusion criteria and expressed interest in the study, an initial appointment was scheduled in which the principal investigator (NAR) provided a detailed explanation of the study. The patient was given an opportunity to ask any questions that he or she might have. After all of the patient's questions were answered, he or she was asked to sign a consent form. A copy of the signed consent form was then given to the patient. NAR then informed the patient whether or not he or she had been randomly assigned to either the SGA+CBT or the SGA Only group. The study was approved by the medical school's institutional review board.

The principal investigator (NAR) then conducted a psychiatric evaluation in which the clinical version of SCID-IV was used to establish the patient's diagnoses. If the patient met the study's inclusion criteria, he or she was scheduled for a pretest (baseline) visit with the psychiatrist (DAR) who completed the clinical rating scales not only at pretest, but also 12 weeks later at posttest, and then three months later after the posttest evaluation. DAR was blind to which treatment group the patient had been assigned. The patients were administered the self-report scales during the pretest, posttest, and 3-month follow-up evaluations by the study's clinical coordinator or research assistant. Patients were reimbursed $25 for completing each of the three evaluations.

There were 36 patients who were eligible for the study (SuppF1). However, three (8%) had to be eliminated after their baseline evaluations indicated that they did not meet the criteria for inclusion in the study. Of the 33 patients who began the study, 18 (55%) were randomly assigned to receive treatment with an SGA and CBT (SGA+CBT), whereas 15 (45%) were randomly assigned to receive treatment with only an SGA (SGA Only). As SuppF1 shows, three patients in each treatment group dropped out of the study against medical advice (AMA), and two patients had to be terminated from the study for a significant adverse event (SAE), such hospitalization, or noncompliance with the study's treatment protocol, such as missing three or more consecutive appointments. Therefore, there were 14 patients in the SGA+CBT group and 15 patients in the SGA Only group who completed posttest evaluations (SuppF1).

There were no significant differences between the background characteristics of the four patients in each treatment group who did not complete treatment. Two out of the four patients who did not complete treatment in the combined group were men, whereas three out of the four patients who did not complete treatment in the SGA only group were men, $\varphi = -.25$, ns. With respect to ethnicity, there were two Caucasians in the combined group of noncompleters and four Caucasians in the medication only group of noncompleters, $\varphi = .21$, ns. Mann-

Whitney U tests also found that the mean ages, educational levels (years), ages of onset of metal illness (years), numbers of psychiatric hospitalizations, and DSM-IV Axis V global assessment of functioning (GAF) ratings for the four patients who did not complete treatment in both groups were comparable. The mean ranks with respect to age, educational level, age of onset of mental illness, number of hospitalizations, and GAF ratings for the SGA+CBT noncompleters were, respectively, 4.63, 5.13, 4.63, 4.00, and 4.50, and mean ranks with respect to age, educational level, age of onset of mental illness, number of hospitalizations, and GAF for the SGA Only noncompleters were, respectively, 4.38, 3.88, 4.38, 5.00, and 4.50. All of the Mann-Whitney U tests were calculated using the SPSS 17 exact statistics procedure for making comparisons between groups with small numbers of respondents. Therefore, it was concluded there was no significant background characteristic that differentiated the four SGA+CBT noncompleters and the four SGA Only noncompleters.

Supplemental Table SuppT1 presents the background and clinical characteristics of the 14 (56%) patients who completed posttest evaluations in the SGA+CBT group and the 11 (44%) patients who completed posttest evaluations in the SGA Only group. None of the characteristics significantly differentiated the two groups. Of the 25 patients who completed pre- and

posttest evaluations, 22 (88%) were diagnosed with a schizoaffective disorder, whereas three (12%) were diagnosed with paranoid schizophrenia. Nineteen (76%) of the 25 patients were also diagnosed with a comorbid psychiatric disorder. For the 19 patients with comorbid disorders, anxiety (84%) and alcohol and/or substance abuse disorders (42%) were most prevalent. It is important to note that the patients were prescribed various SGAs. For example at pretest, the numbers of patients who were prescribed risperidone, quetiapine, aripiprazole, olanzapine, ziprasidone, and paliperidone were, respectively, 5 (20%), 8 (32%), 3 (12%), 4 (16%), 4 (16&5, and 1 (4%). The daily dosages of these SGAs were converted into equivalent doses of chlorpromazine for comparative purposes. The mean pretest (baseline) equivalent doses of the SGAs were comparable for both treatment groups (SuppT1).

Data Analysis

Power Analysis. An *a priori* power analysis based on a medium effect size of .50 estimated that a total sample of 40 patients composed of 20 patients randomly assigned to the SGA+CBT group and 20 patients randomly assigned the SGA Only group would yield a power of 87% for detecting a significant ($p < .05$) adjusted mean difference between an outcome measure for both groups at posttest. However, the study was only able to

enroll 36 eligible patients by the end of three years when it was decided to stop the study for lack of funding.

Statistical Analyses. Because only six of the 11 SGA Only patients who had completed pre- and posttest evaluations had also completed 3-month follow-up evaluations as compared to 11 of the 14 SGA+CBT patients who had completed pre- and posttest evaluations and had also completed 3-month follow-up evaluations, it was considered inappropriate to conduct intent-to-treat analyses by carrying the last value for an outcome variable forward or using multiple imputation techniques for estimating missing values. Such approaches would be estimating missing follow-up values for approximately 54% of SGA Only group. Therefore, it was decided to calculate paired (correlated) *t* tests to determine whether an outcome measure had significantly changed between pre- and posttest for each treatment group. Analyses of covariance (ANCOVA) were then used to ascertain whether the adjusted posttest means of the outcome measures differed between the SGA+CBT and SGA Only groups. Because this was a pilot study, a Bonferroni adjustment was not used to control for the familywise error rates for the 14 paired t tests and seven ANCOVAS that were conducted, and Cohen's *d* statistic was used to estimate the magnitude of the effect size between the pre- and posttest mean differences and between the adjusted mean posttest differences of the SGA+CBT and SGA Only

groups. Because there were only six patients in the SGA Only group and 11 patients in the SGA+CBT group who completed 3-month follow-up evaluations, Wilcoxon Matched-Pairs Signed Ranks Tests were employed to compare the posttest and follow-up scores within each group.

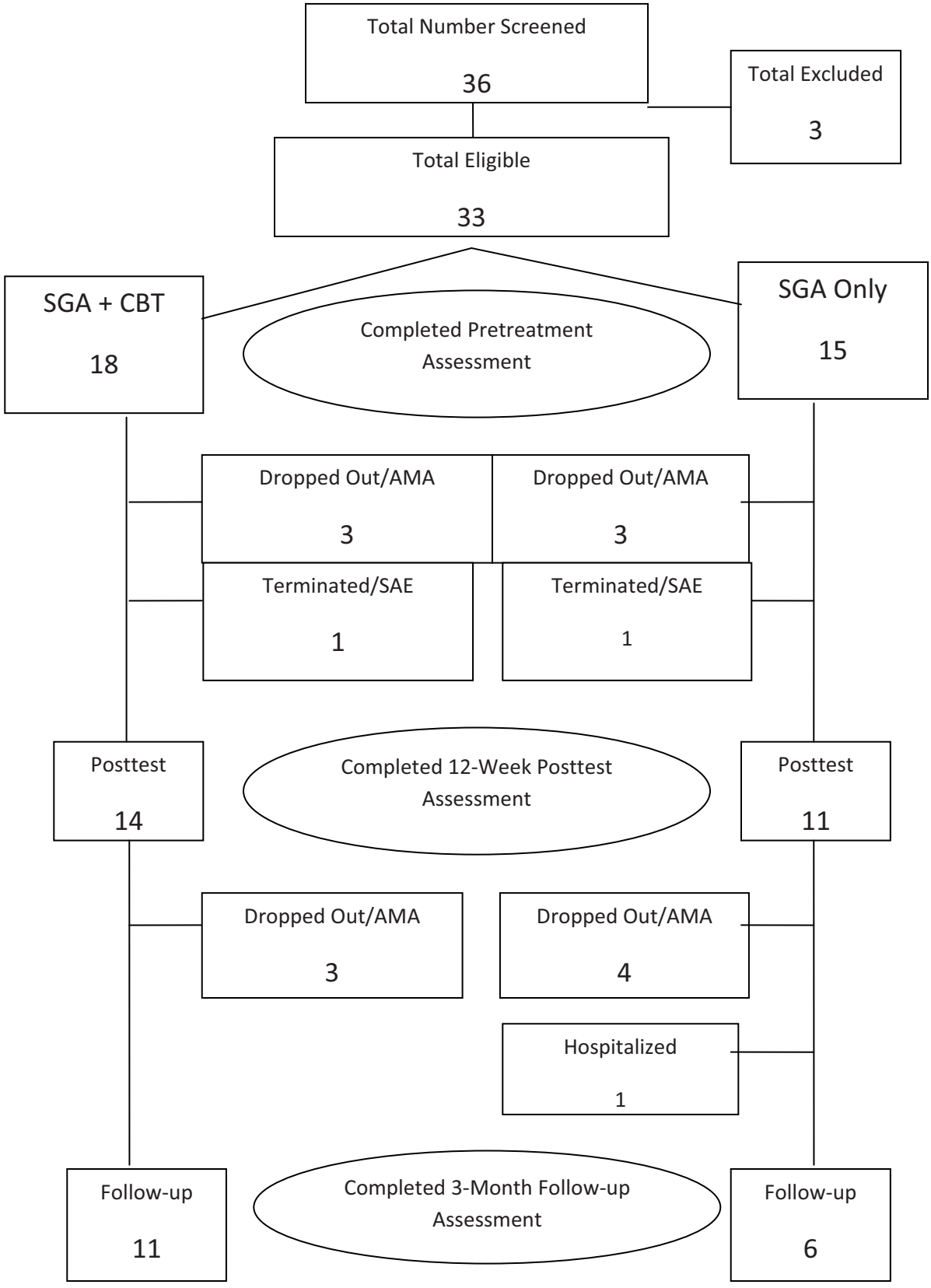
Total Number Screened
36
Total Excluded
3
Total Eligible
33
SGA + CBT
18
Completed Pretreatment Assessment
SGA Only
15
Dropped Out/AMA
3
Dropped Out/AMA
3
Terminated/SAE
1
Terminated/SAE
1
Posttest
14
Completed 12-Week Posttest Assessment
Posttest
11
Dropped Out/AMA
3
Dropped Out/AMA
4
Hospitalized
1
Follow-up
11
Completed 3-Month Follow-up Assessment
Follow-up
6

Table 1 (Supplement)
Background Characteristics of Patients by Type of Treatment

Characteristic	SGA Only		SGA + CBT		
	N	%	*N*	%	φ
Categorical					
Sex					
Women	6	55	8	57	-.03
Men	5	45	6	43	
Caucasian					
Yes	10	91	10	71	-.24
No	1	9	4	29	
Never married					
Yes	6	55	7	50	-.05
No	5	45	7	50	
Principal Disorder					
Schizoaffective	10	91	12	86	-.08
Paranoid Schizophrenia	1	9	2	14	
Comorbid Anxiety Disorder (*N* =19)					
Yes	8	80	8	89	.12
No	2	20	1	11	

Table 1, continued

Characteristic	SGA Only		SGA + CBT		
	N	%	*N*	%	φ
Comorbid Alcohol and/or Drug Disorder (N = 19)					
Yes	4	40	4	44	.05
No	6	60	5	56	
Continuous					
	M	*SD*	*M*	*SD*	*t*(23)	*d*
Age (years)	42.27	10.74	38.71	11.69	.78	.31
Education (years)	12.45	2.16	13.21	2.58	.78	.31
Level of Functioning	46.46	12.86	42.14	4.69	1.14	.47
Age of onset (years)	18.18	5.64	20.00	10.21	.53	.21
Number of psychiatric Hospitalizations	2.73	2.10	3.79	3.64	.86	.35

Note. SGA = Second Generation Antipsychotic, SGA + CBT = Second Generation Antipsychotic and Cognitive Behavorial Therapy. None of the φ correlations or *t* tests is significant.

Table 2 (Supplement)
Analyses of Covariance for Outcome Measures

Outcome Measure	Type of Treatment	M_{adj}	M_{diff}	*MS*	*F*(1,22)	*d*
Clinical Ratings						
PSYRATS						
Auditory Hallucinations	SGA Only	13.89	.73	151.90	.02	.06
	CBT + SGA	13.16				
Delusions	SGA Only	13.37	3.59	19.84	4.00	.81
	CBT + SGA	9.78				
HRSD	SGA Only	19.98	2.11	75.77	.35	.24
	CBT + SGA	17.87				
HARS	SGA Only	13.15	.06	31.15	.00	.01
	CBT + SGA	13.09				

Table, continued

Outcome Measure	Type of Treatment	M_{adj}	M_{diff}	MS	$F(1,22)$	d
Self-Report Instruments						
BDI-II	SGA Only	18.77	.08	80.32	.00	.01
	CBT + SGA	18.69				
BAI	SGA Only	16.28	-.65	94.58	.03	-.07
	CBT + SGA	16.93				
BCIS	SGA Only	6.24	.65	36.09	.07	.11
	CBT + SGA	5.59				

Note. There were 11 patients in the SGA Only group and 14 patients in the CBT & SGA group. SGA = Second Generation Antipsychotic, CBT + SGA = Cognitive Behavioral Therapy and Second Generation Antipsychotic, HARS = Hamilton Psychiatric Rating Scale for Depression, HRSD = Hamilton Psychiatric Rating Scale for Anxiety, PSYRATS = Psychosis Symptom Rating Scales, BAI = Beck Anxiety Inventory, BDI-II = Beck Depression Inventory-II, BCIS = Beck Cognitive Insight Scale