

FIGURE S1. Participant Flow Diagram: Switch rates during lithium monotherapy, sertraline monotherapy and lithium/sertraline combination therapy for the acute treatment of bipolar II depression: a randomized, double-blind comparison

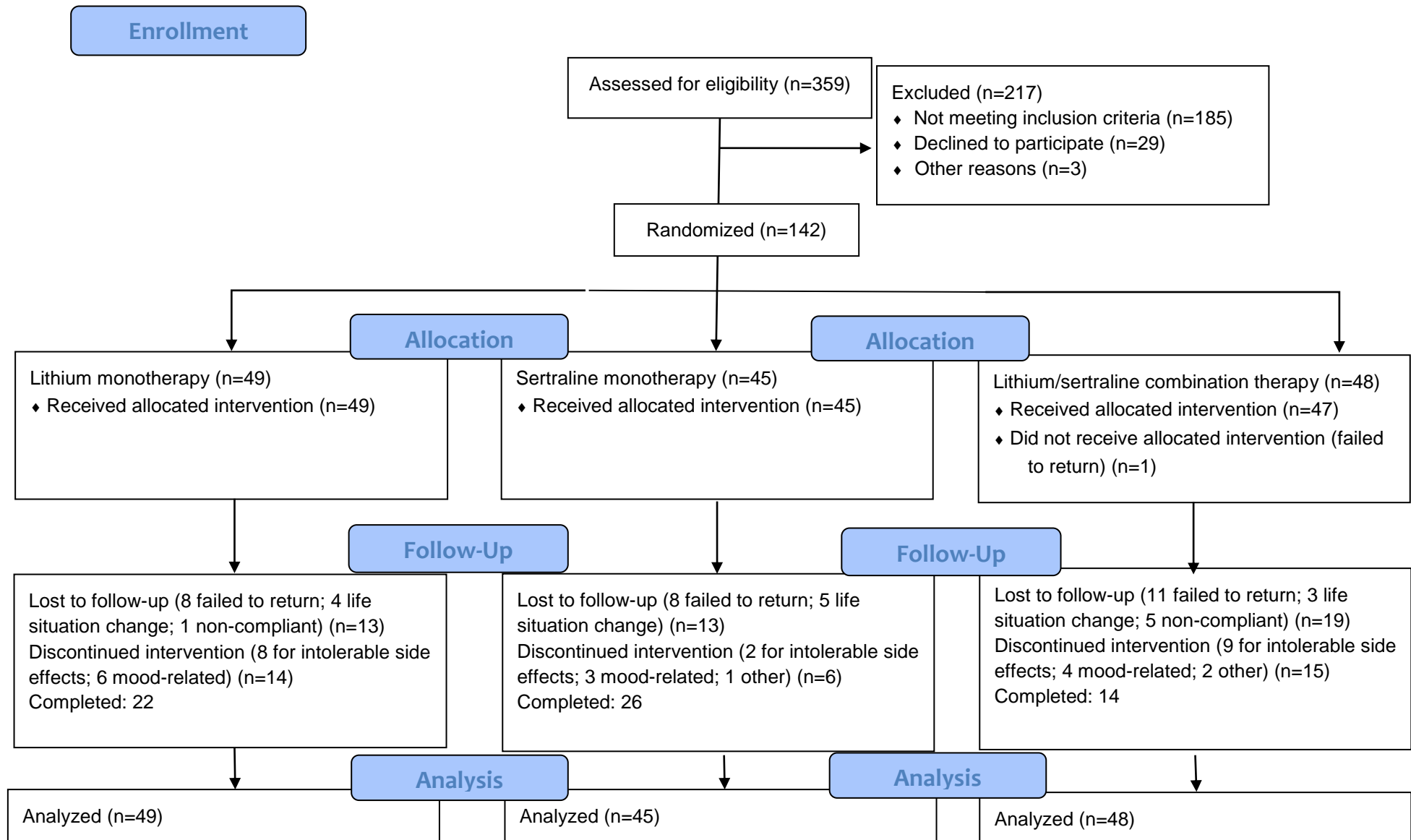


TABLE S1. Demographic and Clinical Variables by Site

	Total (N=142)		UCLA (N=51)		Palo Alto / UTSW (N=49)		UCCM (N=42)		P*
Demographic Variables	mean	± SD	mean	± SD	mean	± SD	mean	± SD	
Age (years)	38.6	11.8	39.8	11.3	39.8	13.3	35.8	10.4	0.182
	n	%	n	%	n	%	n	%	
Gender (female)	77	54.2	22	43.1	27	55.1	28	66.7	0.076
Ethnicity (Hispanic)	18	13.0	8	15.7	9	19.2	1	2.5	0.046
Race									0.003
Caucasian	97	68.3	28	54.9	33	67.4	36	85.7	
African American	18	12.7	11	21.6	3	6.1	4	9.5	
Mixed / Other	27	19.0	12	23.5	13	26.5	2	4.8	
Married / Cohabiting	48	33.8	13	25.5	16	32.7	19	45.2	0.131
Employed	62	43.7	23	45.1	22	44.9	17	40.5	0.884
Highest education attained									0.054
Some high school	4	2.8	1	2.0	0	0.0	3	7.1	
High school or GED	19	13.4	3	5.9	7	14.3	9	21.4	
< 4 year college degree	77	54.2	28	54.9	27	55.1	22	52.4	
4 year college degree	22	15.5	13	25.5	5	10.2	4	9.5	
Graduate/Pro- fessional school	20	14.1	6	11.8	10	20.4	4	9.5	
Clinical Variables	mean	± SD	mean	± SD	mean	± SD	mean	± SD	
Age of onset - depression (years)	16.9	9.5	17.2	9.7	17	10.4	16.5	8.5	0.948
Age of onset - hypomania (years)	20.1	8.8	20.3	7.6	20.1	10.9	19.9	8.0	0.972
Age at diagnosis (years)	30.5	11.9	30.4	11.5	33.6	12.8	27.4	10.9	0.052
Time since first symptoms (years)	23.5	12.4	23.8	12.1	25.9	12.4	20.4	10.0	0.110
Duration of illness (years since diagnosis)	8	8.7	9.4	9.2	5.9	7.4	8.4	8.9	0.134
Baseline IDS-C	32.9	8.4	32.5	7.2	34.3	10.5	31.6	6.9	0.276
Baseline Young Mania Rating Scale score	5.2	2.9	3.5	2.1	5.4	2.7	6.9	3.1	<0.001
Baseline CGI- bipolar depression severity	4.3	0.8	4.5	0.9	3.9	0.6	4.3	0.8	<0.001
	n	%	n	%	n	%	n	%	

Rapid Cycling	59	41.6	22	43.1	18	36.7	19	45.2	0.685
Dropped out of study									
Overall	80	56.3	24	47.1	32	66.0	24	57.1	0.392
Due to side effects**	19	23.75	7	29.2	10	31.3	2	8.33	0.100

* p values are from ANOVAs for continuous variables or Pearson chi-squared tests for categorical variables except for ethnicity, race, education and drop out due to side effects for which nonparametric tests were used due to small expected cell counts

**Percentages are out of the total number of dropouts

SD: Standard Deviation; IDS-C: Inventory of Depressive Symptoms, Clinician-Rated; CGI: Clinical Global Impressions; ANOVA: Analysis of Variance

please spell out acronyms in footnotes here and under every other table and figure

TABLE S2. Reasons for Early Study Discontinuation by Treatment Group

	Total (N=80)	Lithium (N=27)	Sertraline (N=19)	Combination (N=34)
Reason for Early Discontinuation	n	n	n	n
Lost to Follow-up	45	13	13	19
■ Failed to return	27	8	8	11
■ Change in life situation	12	4	5	3
■ Noncompliant	6	1	0	5
Side effects	19	8	2	9
Mood-Related	13	6	3	4
■ Lack of mood improvement (depression)	7	5	0	2
■ Hypomania	5	1	2	2
■ Mixed depression and hypomania	1	0	1	0
■ Mania	0	0	0	0
Other Reasons	3	0	1	2

TABLE S3. Rates of Baseline* and Treatment-Emergent Side Effects by Treatment Group

	TOTAL N=142	Lithium N=49	Sertraline N=45	Combo N=48	p**
Baseline Physical Symptoms	n (%)	n (%)	n (%)	n (%)	
Thirst	11 (7.8)	3 (6.1)	3 (6.7)	5 (10.4)	0.516
Tremor	2 (1.4)	1 (2.0)	1 (2.2)	0 (0.0)	0.997
Gastrointestinal	14 (9.9)	6 (12.2)	4 (8.9)	4 (8.3)	0.613
Urinary frequency	9 (6.3)	2 (4.1)	4 (8.9)	3 (6.3)	0.679
Sexual dysfunction	6 (4.2)	2 (4.1)	2 (4.4)	2 (4.2)	0.886
Central Nervous System	49 (34.5)	20 (40.8)	16 (35.6)	13 (27.1)	0.656
Any of the Above Symptoms	62 (43.7)	24 (49)	21 (46.7)	17 (35.4)	0.774
Treatment-Emergent Side Effects***					
Thirst	44 (31.0)	16 (32.7)	21 (46.7)	7 (14.6)	0.012
Tremor	28 (19.7)	9 (18.4)	6 (13.3)	13 (27.1)	0.101
Gastrointestinal	60 (42.3)	24 (49.0)	17 (37.8)	19 (39.6)	0.403
Urinary frequency	34 (23.9)	18 (36.7)	6 (13.3)	10 (20.8)	0.023
Sexual dysfunction	21 (14.8)	3 (6.1)	7 (15.6)	11 (22.9)	0.072
Central Nervous System	31 (21.8)	9 (18.4)	10 (22.2)	12 (25.0)	0.590
Any of the Above Side Effects	97 (68.3)	35 (71.4)	31 (68.9)	31 (64.6)	0.944

* Includes physical symptoms rated at baseline (pretreatment) as moderate or severe

** p values represent treatment effects after adjustment for rapid cycling status, baseline covariates and, for treatment-emergent side effects, time in study

*** A side effect was considered treatment-emergent if its rating was both worse than the participant's baseline physical symptoms rating in that category and reached a level of moderate to severe