

Data supplement

Table DS1 Treatment-emergent adverse events in $\geq 5\%$ of olanzapine group

Treatment-emergent adverse event	Placebo (<i>n</i> = 171)		Olanzapine (<i>n</i> = 343)		<i>P</i>
	<i>n</i>	%	<i>n</i>	%	
Patients with ≥ 1 treatment-emergent adverse event	93	54.4	239	69.7	<0.001
Somnolence	11	6.4	59	17.2	<0.001
Increased weight	6	3.5	59	17.2	<0.001
Increased appetite	4	2.3	46	13.4	<0.001
Sedation	4	2.3	29	8.5	0.007
Nasopharyngitis	6	3.5	24	7.0	0.161
Constipation	5	2.9	19	5.5	0.267
Dry mouth	6	3.5	18	5.2	0.507

Table DS2 Percentage change in weight and categorical changes in total cholesterol, triglycerides and glucose

	Placebo		Olanzapine		<i>P</i>
	<i>n</i>	Change, %	<i>n</i>	Change, %	
Patients with significant weight gain ($\geq 7\%$ body weight)	169	1.2	341	23.2	<0.001
Patients with categorical shifts in fasting cholesterol values					
Normal to borderline	92	8.7	181	27.1	<0.001
Normal to high	92	0.0	181	1.1	0.551
Borderline to high	46	4.3	112	22.3	0.005
Patients with categorical shifts in fasting low-density lipoprotein values					
Normal to borderline	47	25.5	120	40.8	0.075
Normal to high	47	0	120	0	
Borderline to high	93	2.2	176	5.1	0.340
Patients with categorical shifts in fasting high-density lipoprotein values					
Normal to low	123	4.9	261	10.0	0.114
Patients with categorical shifts in fasting triglyceride values					
Normal to borderline	112	15.2	219	17.4	0.644
Normal to high	112	3.6	219	11.0	0.022
Normal to extremely high	112	0.0	219	0.0	
Borderline to high	23	39.1	53	34.0	0.795
Borderline to extremely high	23	4.3	53	0.0	0.303
Patients with categorical shifts in fasting glucose values					
Normal to impaired	108	14.8	237	16.0	0.873
Impaired to high	46	0.0	81	8.6	0.048
Normal/impaired to high	154	0.0	318	3.5	0.019
Normal to high	108	0.0	237	1.7	0.314

Table DS3 Least squares (s.e.) change in weight and in total cholesterol, triglycerides and glucose

	Placebo			Olanzapine			<i>P</i>	
	<i>n</i>	Change		<i>n</i>	Change			
		Least-squares mean	s.e.		Least-squares mean	s.e.		
Weight gain, kg	169	-0.2	0.23	341	+2.4	0.18	<0.001	
Baseline to end-point change in fasting laboratory values								
Glucose, mg/dL	155	+0.9	0.9	321	+2.3	0.7	0.113	
Cholesterol, mg/dL	160	-1.5	2.3	330	+10.4	1.9	<0.001	
Triglycerides, mg/dL	160	+8.0	7.1	330	+30.1	5.3	0.003	
Low-density lipoprotein cholesterol	159	-0.09	0.05	329	+0.15	0.04	<0.001	
High-density lipoprotein cholesterol	160	+0.01	0.02	330	-0.03	0.02	0.093	

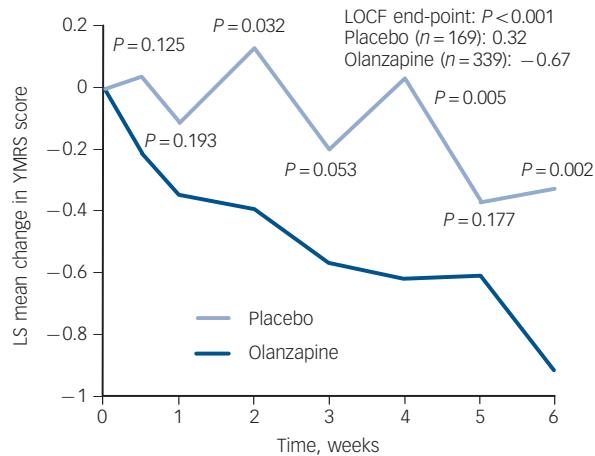


Fig. DS1 Observed case analysis of visit-wise change from baseline in least-squares (LS) mean Young Mania Rating Scale (YMRS) score. LOCF, last observation carried forward.

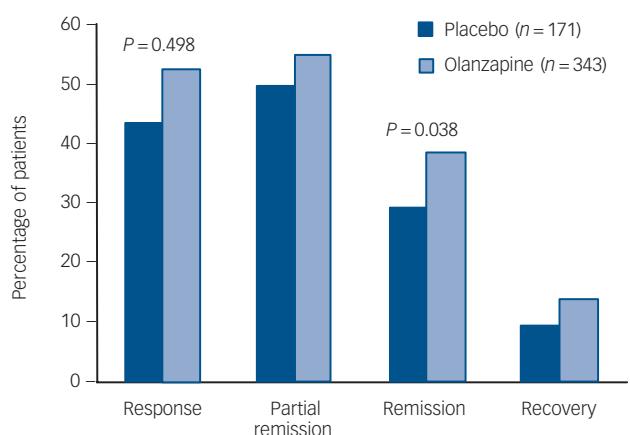


Fig. DS2 Response, remission and recovery rates.^a

a. Partial remission defined *a priori* as Montgomery–Åsberg Depression Rating Scale (MADRS) total score ≤ 12 ; remission defined *post hoc* as MADRS total score ≤ 8 .