Randomization and Masking

The randomization code was kept in a locked file cabinet in the first author's office (RDD). Each patient assignment was individually concealed and not revealed until all baseline data had been completed and scored and the patient was deemed eligible for enrollment. Patients were randomized by RDD and notified of their assignment to group via telephone.

Efficacy of the Blinding

Information regarding the integrity of the blind (patient revealing assignment to treatment condition in the context of the clinical interview) and the blind raters' guess regarding group assignment was collected after each study evaluation. Patients broke the blind in 8% (N=19) of study interviews. In these cases, the interview (with unblinding information removed) was transcribed and presented to a second rater for coding. Therefore, all final score determinations were made by an independent evaluator with no knowledge of group assignment.

The kappa coefficient for the accuracy of the blind-raters' guesses regarding group assignment was .48. This reflects moderate accuracy in guessing, that is better than chance (P<.001). Importantly, the independent evaluator's treatment guess was unrelated to HAMD change over time (P=.62).