Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)

The NIMH-funded Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) was a long-term outpatient study designed to find out which treatments, or combinations of treatments, were most effective for treating episodes of depression and mania and for preventing recurrent episodes in people with bipolar disorder. STEP-BD was the largest, federally-funded treatment study ever conducted for bipolar disorder. It was a long-term outpatient study that enrolled 4,360 participants from 22 sites over seven years (1998 to 2005).

How is the STEP-BD study different from other treatment studies of bipolar disorder?

STEP-BD differed from traditional bipolar disorder clinical trials in several important ways. Because the main goal of STEP-BD was to improve treatment and outcomes for all people with bipolar disorder, it was designed as a large-scale, public health study that included real-world patients contending with multiple mental and/or physical illnesses who were seeking care in their own communities. Most other clinical research studies excluded people with co-existing disorders, thus limiting those studies’ real-world applicability. In addition, STEP-BD was long-term. In most clinical trials, individuals are usually asked to participate for a relatively short period of time (e.g., 8-12 weeks), and receive only one of a few treatments being studied. In contrast, STEP-BD offered participants long-term continuity of care. Once enrolled, participants could receive care for as long as they were in the program — up to five years — and were monitored systematically, even when they were feeling well.

In addition, STEP-BD was different from typical clinical trials that tested one potential new treatment. It was a broad research program that included several different studies, each aimed at a different aspect of treatment for the illness. STEP-BD evaluated all the best-practice treatment options used for bipolar disorder: mood-stabilizing medications, antidepressants, atypical antipsychotics, and psychosocial interventions - or "talk" therapies - including Cognitive Behavioral Therapy, Family-focused Therapy, Interpersonal and Social Rhythm Therapy, and Collaborative Care (psychoeducation). There were two kinds of treatment "pathways" in STEP-BD, and participants had the opportunity to take part in both. The medications and psychosocial interventions provided in these pathways were considered among the best choices of treatment for bipolar disorder in everyday clinical practice.

In the "Best Practice Pathway," participants were followed by a STEP-BD certified doctor and all treatment choices were individualized. Everyone enrolled in STEP-BD could participate in this pathway. Participants and their doctors worked together to decide on the best treatment plans and changed those plans, if needed. Also, anyone who wished to stay on his or her current treatment (upon entering STEP-BD) could do so in this pathway. Adolescents and adults, age 15 years and older, participated in the Best Practice Pathway.

For adults age 18 and older, another way to participate was in the STEP-BD "Randomized Care Pathways." Depending on their symptoms, participants were offered treatment in one or more of these pathways during the course of the study. The participants remained on mood-stabilizing medication. However, because doctors were uncertain which of several treatment strategies worked best for bipolar disorder, another medication and/or talk therapy may have been added. Each Randomized Care Pathway involved a different set of these additional treatments. Unlike in the Best Practice Pathway, the participants in the Randomized Care Pathways were randomly assigned to treatments. Also, in some cases, neither the participant nor their doctor, were told which of the different medications was added. This was called a "double-blind" study and was done so that the medication effects could be evaluated objectively, without any unintended bias from knowing what had been assigned. Participants were not assigned medications that they had bad reactions to in the past, that they were strongly opposed to, or that their doctor felt was unsuitable for them. The
medication(s) participants were randomly assigned to (in the Randomized Care Pathways) were free of charge. There were other treatment options for participants if they did not respond well to the treatment assigned to them. Also, participants could return to the “Best Practice Pathway” at any time.

**What are the most important results of the STEP-BD study?**

Researchers are using the extensive data from STEP-BD to ask multiple, sharply focused research questions, such as how best to treat individuals with various expressions of the disorder (e.g., manic, mixed, or depressive episodes, rapid cycling, bipolar II vs. bipolar I disorder) and prevent recurrence. Other research questions include evaluating the special needs of women with the disorder, and evaluating treatment outcomes for those with co-occurring medical or mental illnesses. STEP-BD researchers also evaluated how treatments affect a person’s quality of life, such as social functioning and the ability to work; the cost-effectiveness of the combinations of treatments; and factors that affect a person’s continued use of each treatment. Therefore, many different findings have and will be published, as researchers analyze available data.