

STAR*D: Studies Fact Sheet

STAR*D confirms what consumers and providers have known and advocated all along: *customized treatment works for depression.*

FAST FACTS:

Who sponsored this research study?

National Institutes of Mental Health

Number of participants: • 2,876

patients participated in Level 1 • 1,439

entered Level 2 • 376 entered Level 3 •

108 entered Level 4

Drugs used: • Citalopram (Celexa®) • Sertraline (Zoloft®) • Bupropion SR (Wellbutrin SR®) • Venlafaxine XR (Effexor XR®) • Buspirone (BuSpar®) • Mirtazapine (Remeron®) • Triiodothyronine (T3) (Cytomel®) • Nortriptyline (Pamelor, Aventyl®) • Tranylcypromine (Parnate®) • Lithium (Eskalith, Lithobid®)

Who participated? STAR*D included “real world” patients with depression, including those with more complicated medical histories commonly found in clinical practices. The average participant was: • Caucasian, • 41 years old, • had 13 years of education, • 64% were female & 36% were male.

Other participants included: • 18 percent were African American • 13

percent were Hispanic • 6 percent, other races

What is STAR*D?

- STAR*D (Sequenced Treatment Alternatives to Relieve Depression) is a \$35 million independent study sponsored by the National Institute of Mental Health (NIMH) that aims to help determine the effectiveness of various depression treatments.
- The results are intended to offer treatment guidelines to mental health care providers and the people they treat, with the goal of improving outcomes and the lives of each person.
- While most efficacy studies typically exclude patients with numerous complications or co-morbidities, STAR*D researchers sought to include hard to treat populations, including those with more complicated medical histories commonly found in clinical practice. The study evaluates treatments in real-life settings, such as clinics, primary care and providers' offices.

What did STAR*D Study?

STAR*D consists of four phases.

Phase 1

The goal of Phase 1 was to assess the effectiveness of treatments for individuals who have major depressive disorder in the "real world." The first phase was published in the January 2006 edition of the American Journal of Psychiatry.

Phase 2

The goal of Phase 2 was to determine the most effective next step treatments for the participants whose symptoms were not fully relieved (i.e., did not achieve remission) or could not tolerate initial treatment with Citalopram in Level 1. Phase 2 results were published in The New England Journal of Medicine on March 23, 2006.

Phase 3

The goal of Phase 3 was to assess which of two antidepressant medications, Nortriptyline or Mirtazapine, was most effective for treatment-resistant study participants (i.e., individuals who did not achieve remission of symptoms) to consecutive treatment trials in Phase 1 and Phase 2 of the STAR*D study. Phase 3 results were published in the American Journal of Psychiatry on July 1, 2006.

Phase 4

STAR*D researchers continue to evaluate the effectiveness of various depression treatments by reviewing antidepressant medications, talk therapies (e.g., cognitive behavioral therapy) and combinations of the two. The results of Phase 4, the final phase of the STAR*D study, will be reported in the Fall of 2006.

What Did STAR*D Find?

Phase 1 results:

- The STAR*D found that 28-33% of the 2,876 initial research participants with chronic depression experienced remission of symptoms after taking an antidepressant medication for 8-12 weeks.
- An additional 10-15% experienced at least some relief of symptoms. In total, antidepressants helped nearly half of the study participants.

Phase 2 results:

- Major depressive disorders often require more than one step of treatment to elicit a remission of symptoms.
- After unsuccessful treatment with an initial SSRI (Selective Serotonin Reuptake Inhibitor) approximately 25% of the Phase 2 participants experienced remission of symptoms after switching to another antidepressant. (Note: Therapies in Phase 2 were not limited to medications. For

example, cognitive therapy, alone or in addition to medication, was utilized as a treatment option. These results will be reported in Phase 4).

- Phase 2 confirmed that intolerance or failure to respond to an SSRI does not predict a lack of efficacy or intolerance of another SSRI. Any one of the medications in the study provided a reasonable second step option for individuals with depression.
- Adding a second antidepressant medication (also called augmentation) can help achieve symptom remission. Approximately 30% of those who chose to add a medication got better.

Phase 3 results:

- The use of successive antidepressant therapies resulted in only a modest remission rate (<20%) of symptoms for those with treatment resistant depression — even when the antidepressants administered varied greatly in their individual pharmacological properties.
- Between 8% and 20% of the patients with major depressive disorder enrolled in Phase 3 experienced remission of symptoms after trying a third antidepressant medication, following two previous consecutive treatment trials.

Phase 4 results will be released in Fall 2006.

Where Can I Find the Study?

- The American Journal of Psychiatry published the first phase of STAR*D research in its January 2006 edition. The full article can be found at <http://ajp.psychiatryonline.org/cgi/reprint/163/1/28> or <http://ajp.psychiatryonline.org/cgi/reprint/163/1/28.pdf>.
- The New England Journal of Medicine published the second phase. An abstract can be accessed at <http://content.nejm.org/cgi/content/short/354/12/1243>
- The American Journal of Psychiatry published the third phase of STAR*D on July 1, 2006. An abstract can be found [here](#)

Where Can I Find Additional Information?

Mental Health America www.mentalhealthamerica.net

Main Line: 703-684-7722

Press Office: 703-797-2588 or mediainfo@nmha.org

Toll-free Resource Center: 800-969-NMHA (6642)

The National Institute for Mental Health

<http://www.nimh.nih.gov/healthinformation/stard.cfm>