

Sequenced Treatment Alternatives

STAR★D

to Relieve Depression

Patient Education Manual

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Overview of STAR☆D

At present, practitioners have a wide array of treatment options from which to choose when managing the care of patients with depression. These options include 20 Food and Drug Administration (FDA) approved antidepressant medications and 3 time-limited, scientifically tested psychotherapies. Even though a large number of treatment alternatives exist, no one treatment is effective for everyone, and many patients with depression do not experience a satisfactory clinical benefit from their initial treatment. In all, approximately 50% of patients benefit (i.e., have a response) from a standard first trial of an antidepressant medication. The remaining 50% (nonresponders to the initial treatment) must move on to the "next step" of treatment, in which patients receive some alternative to the initial failed trial. The most challenging task facing clinicians centers around choosing the next step once an initial treatment has not been effective.

STAR☆D aims to determine the most effective treatment strategies and specific treatment options for patients with major depressive disorder who do not benefit adequately (symptom remission) from initial treatment with an antidepressant medication. The treatment protocol aims to determine and to implement an adequate dose and duration of medication (or psychotherapy) at every stage following the initial failed trial. STAR☆D seeks to enroll 4,000 outpatients diagnosed with nonpsychotic, major depressive disorder. Thirteen Regional Centers across the United States will recruit these patients from primary and specialty care settings. Of these, it is expected that approximately 2,000 patients will not have a satisfactory response to the first antidepressant. Nonresponders as well as those who respond but who do not attain remission are eligible for seven different treatment options at the next treatment step (Level 2). These options also include one time-limited psychotherapy.

The patient and clinician will determine, from the treatment options available, which ones would be acceptable, beneficial, and medically safe. Patients will be randomized to one of all acceptable treatment options.

Patients who do not have a satisfactory therapeutic response to Level 2 treatment will be presented with four treatment options as a third step (Level 3). As in the previous level, patients will be randomly assigned to one of the acceptable options at Level 3. Consistent with Levels 2 and 3, at Level 4, two treatment options will be provided (using randomization) for patients who have not responded satisfactorily to the previous level of treatment.

STAR☆D will (1) compare the effectiveness of selected treatment options and, consequently, treatment sequences in reducing patients' symptoms and improving their function, and (2) define the costs and cost offsets of such care.

While both patients and clinicians will know of all the available treatment options, independent assessors, masked to treatment type, will evaluate research outcomes.



Research outcomes include measures of depressive and associated symptoms, work performance, functioning, quality of life, patient satisfaction, and service utilization.

Once patients' depressive symptoms have remitted, or at least responded, they will enter the 12-month follow-up. By including a follow-up phase, we will be able to determine the occurrence and timing of relapse associated with specific treatment strategies.

By recruiting a large, widely representative group of outpatients with major depressive disorder, STAR☆D will generate information that will be directly applicable to current practice. STAR☆D will develop and implement patient/family education materials, as well as practical guidelines for clinicians to follow when implementing evidence-based treatment steps in the care of depressed patients.

The National Coordinating Center for the study (University of Texas Southwestern Medical Center at Dallas) will oversee the implementation of the protocol at the 13 Regional Centers. Each Center will coordinate the care at 2–4 clinical settings or clinical sites where clinicians working in both private and public sectors providing either primary or specialty care will enroll and treat study participants. Key collaborating Special Regional Centers include Massachusetts General Hospital (Boston), University of Pittsburgh Medical Center and Western Psychiatric Institute and Clinic (Pittsburgh), University of Pittsburgh Epidemiology Data Center (Pittsburgh) and Columbia College of Physicians and Surgeons (New York).



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Introduction to the Patient Education Plan

Patient education is an essential element to the success of any treatment plan. The objective of a properly implemented patient education plan is improved knowledge about the diagnosis, the treatment options and monitoring of symptoms, and the side effects and outcomes. It will also assist with adherence to prescribed treatment, improved relationships between clinicians and patients, improved self-management of symptoms, and ultimately improved patient outcomes. STAR☆D includes an educational package that we anticipate will accomplish these objectives.

The STAR☆D Educational Package will address the following issues:

1. Introduction to the STAR☆D project:
 - ☆ Objectives of the project.
 - ☆ What will be expected of patients.

2. General information about Major Depressive Disorder (MDD):
 - ☆ Signs and symptoms of the disorder.
 - ☆ What causes MDD.
 - ☆ Available treatment options/alternatives.

The plan begins with more general, basic information because many patients have had little exposure to this kind of information. Once the patient demonstrates an understanding of the initial educational material, more complex, in-depth information will be introduced.

The patient educator will explain the above issues using various direct and simple handouts and a video to explain the Level 2 treatment options. In addition, a monthly newsletter will be mailed to each study participant to reinforce the educational information patients have been presented with and to maintain high levels of interest and motivation.



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Introduction to STAR☆D

☆ *An Introduction to STAR☆D*

This introductory pamphlet is a basic overview of STAR☆D. It briefly explains the objectives of the project. It also includes what will be expected of the patient in the study. This pamphlet presents much of the information contained in the consent form.

General Information About Major Depressive Disorder

☆ *Major Depression Fact Sheet*

This is a glossy, two-sided, one-page document that provides general information about depression with a visual representation of the brain and neurotransmitters, as well as symptoms of the illness. The primary message of this sheet is that depression involves brain functioning, has specific symptoms associated with it, and that with treatment, patients do get better.

☆ *NIMH Depression Guide*

This booklet produced by the National Institute of Mental Health (NIMH) provides information about MDD including: symptoms of the illness, discussions of available treatment options, causes of depression, and resources for further information.

☆ *Depression: A Guide for Patients and Families (STAR☆D Depression Guide)*

This booklet produced by STAR☆D provides more in-depth information about depression and general information about the available treatments

Medication Information

☆ *Medication Fact Sheets*

These are one-page documents about specific medications, including information about medications and side effects. The purpose of these sheets is to educate the patient on the proper use of medications and possible side effects.

STAR☆D Video

☆ *What's Next? Treatment Options for Level 2*

This is a 15-minute video explaining to the patient the options available at Level 2. This video will help the patient make a more informed decision about acceptability of options. This is not intended to be a substitute for the Level 2 consent form.



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Patient Education Plan

Patients must be seen at weeks 0, 2, 4, 6, 9, and 12. The patient education will be initiated at the baseline visit for Level 1 and continue through Week 12 of treatment, regardless of level (i.e., if a patient moves to another level before Week 12).

As previously mentioned, the STAR☆D Education Plan begins with information that is simple and easy to understand and progresses to more complex information at subsequent visits as the patient demonstrates an understanding of the material provided. Because the rate at which each patient learns is different, the education plan guidelines allow for flexibility to accommodate the individual.

Each education session should begin by discussing the patient's symptoms and side effects and reviewing material from the previous visit, and end with questions about the materials presented in that session. The sessions are face-to-face with the patient (and family members, if possible).

Visits 1-3 (Weeks 0, 2, 4)

Objectives: At the end of the Week 4 visit, the patient should be able to:

- ☆ Demonstrate satisfactory comprehension of the project and what their role will entail.
- ☆ Identify at least one possible cause of depression.
- ☆ Identify key symptoms of depression.
- ☆ Indicate the name of the medication that has been prescribed and how to take the medication.
- ☆ Describe common side effects of the prescribed medication.
- ☆ Explain why it is important to follow the treatment plan.

Materials to be used for these objectives:

- *An Introduction to STAR☆D*
- *Major Depression Fact Sheet*
- *NIMH Depression Guide*
- *Medication Fact Sheet*



Week 0

Process: At week 0, the patient will have a great deal of information to process, so it is vital that adequate time is spent with the patient at this visit. This is the time to work on developing a rapport with the patient, and it should not be rushed. It is important to remember that patients come to the clinic with various cultural and ethnic backgrounds and may perceive mental illness and treatment differently than the "traditional Western" perspective.

Assess the knowledge base of the patient. If the patient is newly diagnosed, allow time for the patient to process the information provided and encourage questions. If the patient has been previously diagnosed, ask what they know about the illness and work from there. Whenever possible, and if the patient agrees, include family members.

The educator should explain the information in layman language, using the materials (*Major Depression Fact Sheet* and *Medication Fact Sheet*) and tying in the patient's individual symptoms and circumstances. The patient should understand that depression is a disease, like diabetes or high blood pressure, and has not been caused by something the patient has or has not done. (Depression is an illness, not a personal weakness or character flaw.) The educator should emphasize that depression can be treated as effectively as other illnesses.

Explain to the patient that they will not likely notice an immediate reduction in symptoms and that antidepressants can take weeks to begin achieving a response. Stress the importance of and reasons for taking the medication as directed.

At the end of the education session, ask the patient questions relating to the material presented, and answer any questions the patient may have. Encourage the patient to read over the material at home and discuss it with family members (if possible).

Week 2

Process: Begin the session by asking about symptoms and side effects. Ask questions from the previous session to assess the patient's understanding of the material. This will indicate the readiness of the patient to go on to the newer material or if it is necessary to repeat the teaching from the first session.

☆ If the patient does not have a good grasp of the information from the previous visit, go over the *Major Depression Fact Sheet* again, determining areas of difficulty for the patient and focusing on those areas. Ask questions and encourage any questions that the patient may have.



- ☆ Introduce the *NIMH Depression Guide* to the patient. Go over the key sections of the booklet and encourage the patient to read it at home.
- ☆ Because medication information can be harder for patients to grasp, reiterate the information about the prescribed medication, using the *Medication Fact Sheet*. Again, emphasize the importance of taking the medication as directed.

At the end of the education session, ask the patient questions relating to the material presented and answer any questions that the patient may have.

Week 4

Process: Begin the session by discussing the patient's symptoms and side effects (if present). Ask questions from the previous sessions to assess the patient's understanding of the material.

- ☆ Review with the patient the *NIMH Depression Guide*.
- ☆ Go over the medication information, explaining the basic principles of mechanism of action.
- ☆ Because patients will sometimes quit taking their medication if the symptoms are improving, stress the importance of continuing to take their medication as directed.

At the end of the education session, ask the patient questions relating to the material presented and answer any questions that the patient may have.

Visits 4-6 (Weeks 6, 9, 12)

Objectives: At the end of the week 6 visit, the patient should be able to:

- ☆ Explain why it is important to follow the treatment plan.
- ☆ Demonstrate basic comprehension of MDD: symptoms, treatments, possible etiology.
- ☆ Indicate basic understanding of the mechanism of action of medication.



Materials used:

- *NIMH Depression Guide*
- *Depression: A Guide for Patients and Families (STAR☆D Depression Guide)*
- *Medication Fact Sheet* (for prescribed medication)

Mode: The education session should be presented one-on-one with the patient (and family members, if possible).

Week 6

Process: Begin the session by discussing the patient's symptoms and side effects (if present). Ask questions from the previous sessions to assess the patient's understanding of the material and answer any questions that the patient might have.

- ☆ Continue to review the previous materials if needed.
- ☆ If the patient has a good grasp of the information, introduce the *STAR☆D Depression Guide* to the patient. Go over the key sections of the brochure and encourage the patient to read at home.
- ☆ Again stress the importance of continuing to take their medication as directed.
- ☆ Ask patients if they have had any problems with taking the medicine as prescribed. If yes, help patients come up with a plan to overcome the obstacle(s) that get in the way of taking the medicine as prescribed.

Week 9

Process: Begin the session by discussing the patient's symptoms and side effects (if present). Assess the patient's understanding of the material presented in previous weeks.

- ☆ Introduce further information from the *STAR☆D Depression Guide*. Go over the key sections of the brochure and encourage the patient to read the brochure at home. This brochure contains extensive information about different treatments and medications. It also provides resources and suggested readings if the patient wants to further educate himself/herself about the disease.
- ☆ Continue to stress the importance of taking the medication as directed, regardless of the presence or absence of symptoms.



Week 12

Process: If the patient is moving to the follow-up phase, explain what to expect and what will be expected of the patient. Emphasize the importance of continuing on the medication/treatment as directed.

Additional Educational Tools

What's Next? Treatment Options for Level 2 (videotape)

If after an adequate amount of time a satisfactory response to the initial treatment has not been achieved, the patient will be offered the opportunity to advance to the next level. Patients advancing to Level 2 should view the 15-minute video that explains the different strategies/options available at Level 2. The patient will be asked about acceptability of different strategies at this point, and this educational video will assist the patient in making a more informed decision. After the patient has viewed the video, discuss the information with the patient and answer any questions that the patient may have.