

3. How long will I be in the study?

The study includes 3 to 4 months of therapy and follow-up assessments at 4, 8, and 12 months. If you are in outpatient treatment then you will be in the study for 1 year. If you are in residential treatment, then you will be in the study for approximately 1 year after the completion of the residential treatment.

4. What will I have to do during the study?

You will not have to do much more than if you decide not to take part in the study.

- Attend your BSFT or Standard Treatment sessions for 3 to 4 months.
- Fill our questionnaires and give urine and breath samples at certain times.
- Return for study follow-up visits.
- Contact the clinic if you have any problems between visits.

5. What happens at study follow-up assessments?

Assessment visits include questions about:

- Your health and how you are feeling.
- Drugs you are taking.
- How you are doing in your life (family/social, legal, employment, etc.).

Study visits take 2-3 hours for you and 1- 1 1/2 hours for your parents/guardians. Information about attendance and the therapy (called “tracking measures”) is collected at more regular intervals in sessions that take about 10 minutes each.

6. What will I get for taking part in the study?

The therapies used in this study are designed to help you reach your recovery goals. Information from this study may help others in the future. For family participation at the assessment visits, your parent(s)/guardian(s) will receive \$25 for the first assessment, \$35 for the second assessment, \$45 for the third assessment, \$55 for the fourth

assessment, and \$10 for brief tracking measures. The total payment for a participant may be up to \$170. All payments are made directly to the parent(s)/guardian(s) participating in the assessment. You will receive movie passes for performing every monthly drug use test.

For More Information

For more information on the CTN, visit the NIDA website at www.drugabuse.gov.

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government-sponsored clinical trials. You may log on to www.Clinicaltrials.gov to learn about ongoing or new trials for all types of health-related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

National Institute on Drug Abuse
Center for Clinical Trials Network
6001 Executive Boulevard, MSC 9557
Bethesda, Maryland 20892-9557

Telephone: (301) 443-6697
Fax: (301) 443-2317

Clinical Trials Network



Brief Strategic Family Therapy for Adolescent Drug Abusers

A research study
involving the family

Should I sign up?

Introduction

You have taken the first step in seeking help with your parents and the law. And you want to make the best of it. By agreeing to join this research study, you will help therapists find out how to best help other adolescents like yourself.

Description of the Study

Drug abuse is one of the most pressing problems facing teenagers in the United States. However, treatments such as Brief Strategic Family Therapy (BSFT) have been shown to dramatically impact drug use and related problems in young people. BSFT is a therapy that includes members of the family in the recovery process. In past studies, BSFT has proven to be effective in reducing adolescent drug use and other problems by improving the way in which family members relate and communicate with each other.

The primary goal of this study is to examine the effectiveness of BSFT in the treatment of 12-17 year old drug abusers. The study looks at changes in drug use, problem behaviors, sexually risky behaviors, positive activities, involvement of family members, and family functioning.

If you join the study, you will be assigned to get either:

- 12 to 16 sessions of BSFT over a 4-month period, plus up to 8 “booster” sessions, or
- Standard Treatment for a minimum of 3 to 4 months, plus booster sessions as required. Standard Treatment will vary depending on the regular activities at the agency.

Treatment in both conditions is provided in a setting such as a clinic, your home, or your school.

If You Decide To Join

Your participation in this study is completely voluntary. You are encouraged to ask as many questions as you want to help you decide if you want to join the study. If you choose not to take part, your treatment will not be affected in any way. If you do decide to participate, this is what you can expect:

1. After the study is fully described to you, you will be asked for your written assent (agreement) and your family will be asked for written consent (permission) to participate.
2. If you are in outpatient treatment, you will be asked for baseline information in the first 2 weeks after the consent/assent process. Then you will be randomly selected to go into either BSFT or Standard Therapy (e.g., by the flip of a coin). This means that you cannot choose which therapy you will get. If you decide to join this study—you must be willing to accept either type of therapy.
3. If you are in residential treatment, the baseline assessment will be done in the first 2 weeks of your treatment. Several weeks before you leave residential treatment, a second assessment of substance use will be done. You will then be randomly selected to either BSFT or Standard Therapy. You and your family members will be asked again for consent or assent.
4. After assigned to treatment, you will be asked about your drug use and tested for drugs in urine and in your breath monthly. You will be asked to complete assessments similar to the baseline assessment 4, 8, and 12 months after you start therapy. Other information regarding the therapy, such as attendance, will also be collected at regular intervals.

5. All of the information that you give us, including urine test results, will be kept confidential. The staff will explain the details of confidentiality to you.

Questions About the Study

The answers to these questions may help you decide if you would like to participate in the study.

1. *Who can participate?*

Participants must be between 12 and 17 years old and have used illicit drugs other than alcohol or tobacco in the 30 days before the first assessment. Those in outpatient treatment must live with formal or informal “family.” Those in residential treatment must be expected to be discharged to live with their family. The family must live in the same geographical area as the treatment program. Other considerations:

- Special considerations apply for those who have considered suicide or who have current or pending legal charges.
- Adolescents in foster care cannot participate.

2. *Who is considered family?*

Family includes anyone who serves in the legal or traditional role of family members. All family members are encouraged to participate in the therapy. However, the consent of a biological parent or a legal guardian is required before you can participate.