Informed Consent for Participation in Research

Adapting Critical Time Intervention to Support Inpatient Medical Care Transitions

Sponsor: National Institute of Mental Health

Investigators:
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Key Elements

Purpose: The purpose of this study is to examine whether a service called Critical Time Intervention (or "CTI") can help patients with psychiatric and medical problems connect with community-based services and treatment providers after discharge from the hospital.

Voluntary: Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits that you already have.

Alternatives to Participation: There is no alternative treatment to this research study. If you decide not to participate, you will continue to receive your services as usual.

Procedures:

- This study spans 3 months
- After you sign consent you will complete research assessments with research staff
- If you are assigned to receive the intervention, you will be assigned a case manager who will meet with you in the community to help meet your needs, help you connect with outpatient medical and mental health providers, and help you engage with other community supports
- If you are assigned to usual care, you will receive the usual care provided by the hospital
- Regardless of your assignment, we will reach out to you to complete follow-up research assessments at 6 weeks and 12 weeks after you are discharged from the hospital
- You will receive $40 cash for the completion of each of the research assessments

Possible risks: The most common risk for you participating in this study is that you may become upset by discussing symptoms and functioning when completing the research assessments. In addition, you may find the intervention intrusive.

Possible benefits: Participation in this study may not directly benefit you. If you are assigned to receive the CTI services, you will receive a direct benefit of enhanced services to increase your connection to community supports and enhance follow-up with your outpatient providers.

Purpose and Overview

The purpose of this study is to examine whether a service called Critical Time Intervention (or "CTI") can help patients with psychiatric and medical problems connect with community-based services and treatment providers after discharge from the hospital. Each participant in the study will be assigned to one of two groups by chance. You will have a two out of three chance of being assigned to the CTI group and a one out of three chance of being assigned to continue with your usual care. The CTI intervention involves a care manager meeting with you in the hospital before you are discharged and discussing with you what your immediate and short-term needs are. They will develop a plan with you and will continue to meet with you in the community or at your home on an ongoing basis for the next three months to help meet your needs, help you connect with outpatient medical and mental health providers, and help you engage with other community supports. We do not yet know if CTI is more beneficial or effective than usual care.

The goal of CTI is to ensure that patients get timely and needed medical and psychiatric care after they leave the hospital, which should help to avoid a readmission. We are also interested in how CTI might help patients feel better, and whether they feel that overall medical and psychiatric care is helping. You are being asked to participate because you have Healthfirst insurance, you have a psychiatric illness and you were admitted for treatment of a medical condition to BronxCare Health System. The Healthfirst Medicaid insurance program is identifying people like you who are eligible to participate in this study.

We will also ask your permission to look at information about health care treatment and services you have received in the prior 12 months that Healthfirst, your insurance company, keeps in its records. Also, we will conduct brief research assessments at the beginning of the study and 6 and 12 weeks later which will ask you questions about your symptoms, your quality of life, and your feelings related to the medical and psychiatric care that you receive.

This study is funded by a grant from the National Institute of Mental Health.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits that you already have. A decision not to participate or withdraw your participation will not affect your current or future treatment at BronxCare Health System, New York State Psychiatric Institute, or with any of your community providers. It will also not affect your healthcare coverage through Healthfirst.

Procedures

Once you sign the consent form, the research assistant will conduct several research assessments with you, which will take approximately 60-90 minutes. You will then be randomly assigned to receive the CTI intervention or to receive usual care from the hospital. If you are assigned to the CTI intervention, the research assistant will then notify the CTI team who will meet with you in the hospital prior to your discharge to introduce themselves and discuss with you how they can best help you.

The CTI team consists of two care managers, a licensed clinical social worker who supervises them, and a nurse practitioner. Your case manager will meet with you in the community after you are discharged as often as needed over the course of 12 weeks. Some of the services your case manager can help you with include: scheduling and attending follow-up medical and psychiatric care visits, getting and (if needed) taking your

medications, problem solving around barriers to getting care and services, and making sure you get evaluated in a timely manner if you experience worsening medical or mental health symptoms.

Regardless of which group you are assigned to, at 6 and 12 weeks, the research assistant will contact you to schedule follow-up research assessments at a time and place that is convenient for you. This may include at a coffee shop or restaurant in your community that has a private, quiet area to talk. The research assessments take 45-60 minutes and you will be compensated for your time to complete each interview.

Completing the research assessments is voluntary and not required for your participation in this study. If you are assigned to the CTI intervention, you may still receive the CTI services if you choose not to complete the research assessments, but you must agree to allow Healthfirst to share information from its records about treatment and service you receive during your time in the study as well as during the 12 months prior to the study.

Data Sharing

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

Risks and Inconveniences

The most common risk for you participating in this study is that you may become upset by discussing symptoms and functioning when completing the research assessments. The research staff will help you feel as comfortable as possible by making sure you can take breaks if needed and have as much time as needed. They can also reschedule if you are not feeling well. If you are participating in the CTI intervention and the care manager thinks your health has deteriorated or that you are otherwise in some imminent danger, the care manager will seek help and take whatever steps are needed to protect your safety. In addition, you may find the intervention

intrusive. You will be able to stop participation at any time and research staff will be able to help you cope with any emotional reactions, including a referral for evaluation and treatment if needed.

Benefits

Participation in this study may not directly benefit you. If you are assigned to receive the CTI services, you will receive a direct benefit of enhanced services to increase your connection to community supports and enhance follow-up with your outpatient providers.

Confidentiality

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. A coded number will be used to label your research records (assessment forms, digital files). This number will not be based on any information that could be used to identify you (for example, date of birth, initials). The master list linking names to code numbers of those individuals who provide written consent will be kept separately from the research files.

All research information will be kept in locked files and will be kept confidential to the extent permitted by law. Coded data will be entered into electronic databases that are protected with a password and stored in a secure locked office at Columbia University Medical Center. No identifying information will ever be transmitted electronically (through email). All computers used for research purposes are encrypted to protect all research records. As described under the Data Sharing section, de-identified information about your health and behavior will be submitted to the National Institute of Mental Health Data Archive. However, your private information with identifiers will not be used for future research studies or distributed to another investigator for future research studies.

There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot re-disclose this information without your consent. Records will only be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The investigators, Thomas Smith and Ketki Shah, will use and may share personal health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam, and laboratory test results. Some of these tests may have been done as part of your regular care. The investigator will use this information about you to complete this research.

By signing this authorization, you allow the investigator to use your personal health information to carry out and evaluate this study. You also allow the investigator to share your personal health information with the following:

- New York State Psychiatric Institute, Columbia University, BronxCare Health System, Healthfirst, the Bronx Lebanon Hospital Center Institutional Review Board

- Other regulatory agencies as required by law

Study Compensation

Compensation will be provided for your time and effort. You will be compensated $40 in the form of a cash card at the time of completion of each of the research assessments, for a total of $120.

In Case of Injury

Federal regulations require that we inform you about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

Please be aware that:

a. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital

b. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.

c. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University or by New York Presbyterian Hospital.

d. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Questions

Dr. Thomas Smith (Principal Investigator) will answer to the best of his ability any questions that you may have now or in the future about the research procedures. If you have any questions about the way the information will be used in the research study, please telephone Dr. Thomas Smith at 646-774-8442. He is the Principal Investigator and can tell you about the research. You may also write to him at 1051 Riverside Drive, New York, NY 10032.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Office at (646)774-7155 during regular office hours.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Print name: _____

Signed: _____

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name: _____
Person Designated to Obtain Consent

Signed: _____

Date: _____

You will be given a copy of this consent form to take with you.

*** Consent may only be obtained by persons named in the PSF as being authorized to obtain consent**.

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This study is funded by a grant from the National Institute of Mental Health.

Voluntary

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Risks and Inconveniences

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Study Compensation

Compensation will be provided for your time and effort. You will be compensated $40 in the form of a cash card at the time of completion of each of the research assessments, for a total of $120.

In Case of Injury

Federal regulations require that we inform you about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

Please be aware that:

a. If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.
b. No monetary compensation will be offered.
c. You are not waiving any of your legal rights by signing this informed consent document.
d. If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Questions

Dr. Thomas Smith (Principal Investigator) will answer to the best of his ability any questions that you may have now or in the future about the research procedures. If you have any questions about the way the information will be used in the research study, please telephone Dr. Thomas Smith at 646-774-8442. He is the Principal Investigator and can tell you about the research. You may also write to him at 1051 Riverside Drive, New York, NY 10032.

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