Protocol Title:
Adapting Critical Time Intervention to Support Inpatient Medical Care Transition

Version Date:
06/20/2019

Protocol Number:
7657

First Approval:
07/11/2018

Expiration Date:
06/17/2020

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Co-Investigator(s):
Mark Olfson, MD
Scott Stroup, MD, MPH
Leslie Marino, MD, MPH

Research Chief:
Lisa Dixon, MD, MPH

Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am submitting an annual continuation with modifications

Division & Personnel

Division

What Division/Department does the PI belong to?
Behavioral Health Services and Policy Research
Within the division/department, what Center or group are you affiliated with, if any?
N/A

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York

State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

Susan Beane, MD - Site PI
Ian Shaffer, MD
HealthFirst

Ketki Shah, MD - Site PI
Andreas Evdokas, MD
BronxCare Health System

Mary-Alice Dowd, MD - Site PI
Henry Chung, MD
Montefiore Medical Center

Daniel Herman, MSW, PhD - Co-I
Hunter College, City University of New York

Leo Cabassa, MD - Co-I
University of Washington

Amendment

Describe the change(s) being made

1. We are adding an additional field to the permission to contact form

2. We are submitting the data sharing document for IRB approval to share with NDS at NIMH

Provide the rationale for the change(s)

1. We need to collect the Medicaid ID number to link with HealthFirst data.

2. Required by NIMH as part of this study

Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects

1. None

2. None

Comment on if the proposed change(s) require a modification to the Consent Form (CF)

1. None

2. This process is already described in detail in the consent forms.

Application for Continuation of Research

Status

Current Status of Study:
Subject enrollment is ongoing.

Summary of Experiences to Date

Please provide a summary of scientific progress of the study and the experience of research participants, to date. This requirement is designed to allow for the investigator and the IRB to reassess the study's risks and benefits in terms of developments in the field, changing practice patterns, and new IRB policies and procedures.
The study was delayed 3 months in beginning recruitment due to logistical issues with partners. We have recently begun enrollment and are still on target to reach our goals. We have enrolled 3 subjects so far with no issues.

Funding

Have there been any changes in funding status since the prior approval?
No
Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?
Yes

Summary

Have there been any study findings, recent literature, or untoward events occuring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
No
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occured in the past year)?
No
Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?
Yes
Is the study covered by a certificate of confidentiality?
Yes

Certificate expiration date (mm/dd/yyyy)
04/30/2020

Overall Progress

Approved sample size
60
Total number of participants enrolled to date
3
Number of participants who have completed the study to date
0
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
No
Comments / additional information
We did not ultimately recruit any patients for the qualitative study as we were able to get enough information to adapt the model using other, non-research stakeholders.

Sample Demographics

Specify population
CTI feasability pilot
Total number of participants enrolled from this population to date
3
Gender, Racial and Ethnic Breakdown

Male: 3/3, 100%
Black: 2/3, 67%
Hispanic: 1/3, 33%

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
3
Number of participants currently enrolled
3
Did the investigator withdraw participants from the study?
No
Did participants decide to discontinue study involvement?
No

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Psychiatric Assessment
✓ Audio or Videotaping

Population

Indicate which of the following populations will be included in this research

✓ Medically Ill Subjects
✓ Adults
✓ Individuals with Psychosis
✓ Inpatients

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
No
Who is the PI of the grant/contract?
Stroup, Scott, MD
Select one of the following
The grant/contract is currently funded
Source of Funding
Federal
Institute/Agency
NIMH
Grant Name
Optimizing and Personalizing Interventions for Schizophrenia Across the Lifespan
Grant Number
1 P50 MH 115843 – 01
Select one of the following
Multicenter(NYSPI is the lead site)
Business Office

RFMH
Does the grant/contract involve a subcontract?
Yes
Subcontracted?
To
Name institution(s)

City University of New York at Hunter College

Healthfirst Management Services LLC

Columbia University

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
This protocol describes research conducted by the PI at other facilities/locations
Yes
✓ Hospital, clinics and other healthcare facilities

Hospitals,clinics and other healthcare facilities

Select from the list
or type in location(s)..

BronxCare Health System

Montefiore Medical Center

Some research assessments may be conducted in the community

Uploaded Protocol Summary Form

Upload Document

Select file to upload.
Word PSF_v4.pdf

Lay Summary of Proposed Research

Lay Summary of Proposed Research
Critical Time Intervention (CTI) is a promising evidence-based time-limited intervention that mobilizes support for highly vulnerable individuals during transition periods, for example following discharge from a hospital inpatient unit. CTI facilitates community integration and continuity of care by helping patients develop enduring connections to their community and support systems during periods of transition. Our adaptation of the CTI model is a time-limited (3 month) targeted service coordination intervention and is delivered in two phases: 1) Bridging the transition to outpatient care, and 2) Facilitating ongoing engagement in community-based services. In the first phase, the CTI care manager maintains a high level of contact with both the participant and those involved in providing and supporting his/her treatment (doctor, therapist, family, etc). The care manager initially meets with the participant prior to discharge from the hospital, building rapport and appraising needs. After discharge the care manager maintains regular phone and in-person contact with the participant, visits him/her in his/her residence, continues assessment and care plan development, coordinates care with identified providers, and meets with people who support their treatment and well-being. In the second phase, the care manager continues assessment of the participant's treatment and service needs and ongoing collaboration with the participant to fine tune the various supports and treatments identified and implemented in the first phase. Priority is placed on strengthening their skills and sense of autonomy in managing service engagement and use. During each phase, CTI considers 7 target areas that are important to individual well-being, medical and psychiatric stability and treatment linkages: (a) Systems Engagement and Coordination; (b)Sus taining Motivation in Substance Abuse Treatment; (c) Medication Adherence; (d) Family Involvement/Social Network Support; (e) Housing and Income; (f) Integration of Medical Care; and (g) Practical Needs Assistance.

This pilot study will assess the feasibility and preliminary effectiveness of adapting CTI for adults with schizophrenia who have been medically admitted for the inpatient treatment of ambulatory care sensitive conditions (ACSCs) which are common health conditions, such as chronic obstructive pulmonary disease or short-term complications from diabetes mellitus, in which appropriate outpatient care should prevent or reduce the need for inpatient treatment. We will conduct the study at two large hospital centers in the Bronx (Montefiore Medical Center and BronxCare Health System and collaborate with Healthfirst, a NYC Medicaid Managed Care, to identify patients who are admitted to either of these hospitals and who meet study criteria. In the first phase we will conduct a qualitative study with eight hospital staff stakeholders and two patients with schizophrenia to help inform the adaptation of CTI to this population and intervention. **We will then conduct a 2-arm pilot study which will randomize 60 eligible inpatients to receive either: 1) treatment as usual (TAU) (N=20); or 2) CTI and TAU (N=40).** The primary outcome measure will be all-cause hospital readmissions at 7 and 30 days following discharge. Secondary outcomes will include follow-up with medical and mental health at 7 and 30 days following hospital discharge. **All consented subjects will receive 6 and 12-week assessments to evaluate secondary outcomes including satisfaction with CTI services (only those in CTI group), psychiatric symptoms, community function, and involvement in medical care decisions.**

Description of Subject Population

Sample #1

Specify subject population
CTI Feasibility pilot
Number of completers required to accomplish study aims
60
Projected number of subjects who will be enrolled to obtain required number of completers
75
Age range of subject population
21-64

Sample #2

Specify subject population
CTI Stakeholder interviews - Patients
Number of completers required to accomplish study aims
2
Projected number of subjects who will be enrolled to obtain required number of completers
2
Age range of subject population
21-64

Gender, Racial and Ethnic Breakdown

We expect that the gender, racial and ethnic breakdown for the patient samples (1, 2) will match the characteristics of individuals admitted to the hospitals meeting eligibility criteria as shown below.

Characteristics of admissions between Jan 2015 – June 2016 ACSC and Schizophrenia
Age, years, mean (SD) 50.8 (10.8)
Sex, % Male (54.0%)
Race
White, non-Hispanic (11.3%)
Black, non-Hispanic (47.2%)
Hispanic (32.4%)

Description of subject population

Sample 1: CTI Feasibility Pilot **(N=60)**

Newly admitted Healthfirst BCHS and MMC inpatients ages 21 to 64 years with ≥2 outpatient and ≥1 inpatient claims for schizophrenia during the past 12 months and an admitting ACSC diagnosis will be eligible to participate in the study.

Sample 2: Patient Stakeholder interviews (N=2)
Patient with a diagnosis of schizophrenia and co-morbid medical illness who are either admitted to the inpatient medical service, or who attend one of the outpatient psychiatry clinics at the participating hospitals

Recruitment Procedures

Describe settings where recruitment will occur
Recruitment will occur at each of the participating hospital sites.
How and by whom will subjects be approached and/or recruited?

CTI Patient Stakeholder Interviews
Patients eligible for qualitative interviews will be identified and informed of the study by hospital clinical staff familiar with the study's target population (patients with schizophrenia who have co-occurring medical conditions) and who have been admitted to the medical inpatient unit or attend the psychiatry outpatient clinic. Patients who are identified by hospital staff will sign a permission to be contacted form that will be faxed to the PI by hospital staff upon completion. Once identified, the study PI (Tom Smith), Co-PI (Leslie Marino), or RA (TBD) will contact the stakeholder to discuss the study and schedule a time to complete the interview.

CTI Feasibility Pilot Study
Healthfirst data system algorithms will identify patients eligible for the study. Healthfirst care managers will then contact the potential subject's treatment team to review the patient's appropriateness for research and if the team and if the team agrees the patient is appropriate, the care manager and treatment team will determine the most appropriate way to introduce the patient to the study. The care manager and/or clinical team will share the information sheet with the patient and ask the patient to sign a permission to contact form if they agree to be contacted by the research team to participate. This form will be faxed directly to the PI, at which time the research assistant will be sent to the hospital to discuss the study procedures and obtain consent.

How will the study be advertised/publicized?
Neither phase of the study will be advertised.
Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
Yes

Please provide the NCT Registration Number
NCT03637296

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
No

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
No
Waiver of documentation of consent
No
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process

CTI Patient Stakeholder Interviews
Once potential patient stakeholders have been identified by hospital staff, they will provide written permission to by contacted by research staff to complete the interviews. Research staff (either trained RA, or Dr. Marino) will speak with the patient by phone to arrange a time that is convenient for them to complete the interview.

CTI Feasibility Pilot Study
Prior to approaching prospective study participants, research staff or the Healthfirst care manager will ask a member of the clinical team whether the patient is a good candidate for the study and able to understand study procedures. We will not approach the patient if the treatment team does not feel that the patient would be appropriate for research. We will determine with the primary team the most appropriate way to contact the patient and discuss study participation. The individual who initially meets with the patient will introduce the study with an information sheet and ask for the patient's permission to invite a research assistant to discuss the study and consent process. Patient's documented permission and contact info will be faxed to the

study PI who will notify the research assistant. The research assistant will then go to the hospital and consent the patient. The CTI team will meet the patient 24 hours prior to discharge.

Describe Study Consent Procedures

CTI Patient Stakeholder Interviews
The interview will be conducted on-site at the hospital and consent will be reviewed and documented with the patient at that time. Consent will be obtained by either the trained RA, Dr. Smith or Dr. Marino.

CTI Feasibility Pilot Study
The trained bachelors level research assistant will approach the patient at the bedside in the hospital and will introduce themselves to the patient. They will ask the patient if this is a good time to discuss the study and with patient's permission, they will explain study procedures, risks, benefits, compensation, and confidentiality. They will ask the patient if they consent to participation and have patient sign consent document.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form
✓ Information Sheet

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Marino, Leslie, MD
Smith, Thomas, MD
Styke, Sarah
Type in the name(s) not found in the above list

Once patients are identified by Healthfirst staff, t**he project research assistant Sarah Styke** will be dispatched to the hospital to obtain consent.

For the stakeholder interviews, Dr. Marino and Dr. Smith may also obtain consent.

Independent Assessment of Capacity

You have indicated that your study involves subjects who MAY LACK capacity to consent.
Does this study require an independent assessment of capacity?

No

Methods to Protect Confidentiality

Will the study be conducted under a certificate of confidentiality?
Yes, we have already received a Certificate of Confidentiality

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.

Participants enrolled in the CTI feasibility pilot study will receive **$40** for each completed assessment (baseline, 6 weeks and 12 weeks post-discharge) for a potential total amount compensation equal to **$120**. They will receive the compensation in the form of a cash card at the time of the assessment, after it is completed.

Patients enrolled in the stakeholder interviews will received $25 for their time participating in the qualitative interview. will receive the compensation in the form of a cash card at the time of the interview, after it is completed.

Participant compensation represents support for their time and effort involved in participating in these research activities.

Uploads

Upload the entire grant application(s)
OPAL FINAL RESEARCH PROPOSAL.pdf
Upload copy(ies) of unbolded Consent Form(s)
Consent_Form_CTI feasibility pilot_unbolded_BXCare_v2.pdf
Consent_Form_CTI feasibility pilot_unbolded_Monte_v2.pdf
Upload copy(ies) of bolded Consent Form(s)
Consent_Form_CTI feasibility pilot_bolded_BXCare_v2.pdf
Consent_Form_CTI feasibility pilot_bolded_Monte_v2.pdf
Upload copy(ies) of unbolded Information Sheet(s)
Information sheet_v2.pdf
Upload copy(ies) of bolded Information Sheet(s)
Upload copy(ies) of recruitment materials/ads to be reviewed

Permission for contact_v3.pdf
Upload a copy of Certificate of Confidentiality
Upload copy(ies) of the HIPAA form
HIPAA (2).pdf
Upload any additional documents that may be related to this study
Data.RequestforUse_of_De-Identified_Data_Project2_5-8-19.pdf
IRB Response Memo 2019.06.06, 7657.CONT.appr_pend.en.060519 (3).pdf