NEW YORK STATE PSYCHIATRIC INSTITUTE

INSTITUTIONAL REVIEW BOARD

MEMORANDUM

May 02, 2022

TO: Michael Compton, MD

FROM: Dr. Edward Nunes, Co-Chair, IRB

Dr. Agnes Whitaker, Co-Chair, IRB

SUBJECT: EXPEDITED APPROVAL OF PROTOCOL AMENDMENT

The amendment to your protocol #7771 entitled: REDUCING DURATION OF UNTREATED PSYCHOSIS THROUGH EARLY DETECTION IN A LARGE JAIL SYSTEM **(In the HIPAA form, to remove "Rikers Island Jails" and add "Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research", as per the 4/29/2022 memorandum)** has been approved by the Psychiatric Institute - Columbia University Department of Psychiatry Institutional Review Board.

Please note that this does not change the IRB's cycle of review. A progress report and an application for continuing review will be required 2 months before the study's approval is due to expire: (4/21/2023).

Signed copy on file at IRB.
EN/AW/sc2432

Protocol Title:
Reducing Duration of Untreated Psychosis through Early Detection in a Large Jail System

Version Date:
05/02/2022

Protocol Number:
7771

First Approval:
05/13/2019

Expiration Date:
04/21/2023

Contact Principal Investigator:
Michael Compton, MD, MPH
Email: mtc2176@cumc.columbia.edu
Telephone: 404-375-9231

Co-Investigator(s):
Lisa Dixon, MD, MPH
Genevra Jones
Leah Pope, PHD

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 proposing an amendment only to an existing protocol

Department & Unaffiliated Personnel

Department

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

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.

Jason Tan de Bibiana, M.Sc.,Vera Institute of Justice
Amy Watson, Ph.D., University of Illinois at Chicago
Nev Jones, Ph.D., University of South Florida
Bipin Subedi, M.D., New York City Health and Hospital Corporation
Elizabeth Ford, M.D., Center for Alternative Sentencing and Employment Services (CASES)
Jessica Pollard, Ph.D., Yale University
Beth Broussard, M.P.H., C.H.E.S., Emory University

Amendment

Describe the change(s) being made
In the HIPAA form, we are requesting to change the entities to which we might disclose participants' health information. Specifically, we have removed "Rikers Island Jails" and added "Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research." See the uploaded HIPAA form for this update.
Provide the rationale for the change(s)
We will only use this HIPAA form when interviewing released detainees. Neither the participant nor us will have any contact with Rikers Island Jails because the participants have already been released from the jails.
Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects
This change will better protect participants' health information and protect them from any consequences resulting from disclosing health information to researchers or staff at Rikers Island Jails.
Comment on if the proposed change(s) require a modification to the Consent Form (CF)
The change does not require any modifications to the Consent Form.

Procedures

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

✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission
✓ Psychiatric Assessment

Population

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

✓ Prisoners
✓ Medically and Psychiatrically Healthy Subjects

✓ Adults
✓ Adults over 50
✓ Employees or Students
✓ Individuals with Psychosis

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
2

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract is currently funded
Source of Funding
Federal
Institute/Agency
National Institute of Mental Health
Grant Name
Reducing Duration of Untreated Psychosis through Early Detection in a Large Jail System
Grant Number
R34 MH117766
Select one of the following
Single Site
Business Office
CU
Does the grant/contract involve a subcontract?
Yes
Subcontracted?
To
Name institution(s)

University of Illinois at Chicago
Research Foundation for Mental Hygiene
University of South Florida

Funding Source #2

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract is currently funded
Source of Funding
Foundation
Sponsor
VAN AMERINGEN FOUNDATION
Select one of the following
Single Site
Business Office
RFMH
Does the grant/contract involve a subcontract?
Yes
Subcontracted?
To
Name institution(s)
Grant is awarded to RFMH and subcontracted to CU.

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
✓ Prison system

Hospitals,clinics and other healthcare facilities

Select from the list
or type in location(s)..
Bellevue Hospital Prison Ward and Elmhurst Hospital Prison Ward (both are operated by NYC Department of Correction)

Prison System(Includes Parole)

Type in location(s)
Rikers Island Jails (Anna M. Kross Center, Rose M. Singer Center, and Robert N. Davoren Complex)

Lay Summary of Proposed Research

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Persons with serious mental illnesses are overrepresented in jails. Criminal justice (CJ) involvement, including jail detention, is common among those with first-episode psychosis (FEP) and frequently precedes psychiatric treatment engagement. Yet, no documented interventions currently exist specifically to identify/ engage such individuals while in jail and connect them to Coordinated Specialty Care (CSC) in the community upon release. Expansion of CSC programs across the U.S. provides an opportunity for partnership with the CJ system—one that has the potential to reduce the duration of untreated psychosis (DUP) and thus improve outcomes. To detect FEP and reduce DUP among detainees in a large, urban jail, we propose to implement: (1) a "Targeted Educational Campaign" (TEC), and (2) a Specialized Early Engagement **Support Service** (SEE**SS**) in 3 jails on Rikers Island in New York City (NYC): Anna M. Kross Center (AMKC), Rose M. Singer Center (RMSC) and Robert N. Davoren Complex (RNDC). We expect the multi-media TEC to generate referrals to the Correctional Health Services (CHS), and to reduce our DUP-1 (psychosis onset to antipsychotic initiation). Then, the jail-based SEE**SS** (a Social Worker and Peer Specialist) will link those identified to community-based CSC (primarily OnTrackNY sites in NYC), thus reducing DUP-2 (psychosis onset to CSC enrollment). We will examine a set of hypothesized targets/mediators (the "how's"). These are key ingredients that underpin the intervention's ability to reduce DUP. The multi-media TEC will generate referrals to the CHS. How will it do that? By improving the behavioral capabilities, expectations, and self-efficacy (constructs from Social Cognitive Theory) of the Correction Officers trained. The SEE**SS** will then link detainees with FEP, using tenets of person-centered treatment and shared decision-making, and the Critical Time Intervention model, to community-based CSC. How will this occur? Through engagement of detainees while in jail, and telephonically (when possible) after release, which we will measure with measures of engagement. We will assess feasibility and acceptability to lay the groundwork for a multi-site, definitive effectiveness trial.

Background, Significance and Rationale

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Treatment delay, or longer DUP, is linked to poorer outcomes (e.g., greater symptom severity, less remission, poorer quality of life) in FEP patients [1-4]. Early intervention for psychosis, as exemplified by CSC, leads to improved outcomes, especially when DUP is shorter. The NIMH RAISE-ETP study found that young people who initiate treatment within 1.5 years of symptom onset remain in treatment longer and show improved quality of life and work/school functioning [5]. An international movement is underway to determine ways to reduce DUP; however, it has largely neglected those with FEP who have become entangled in the CJ system.

Even with mounting evidence about the importance of early intervention, early detection programs have been concentrated mainly in mental health (e.g., inpatient psychiatric units), primary care (e.g., clinics), and educational settings (e.g., colleges) to date, and thus continue to miss a significant number of young people who do not traverse traditional pathways to care. Pathways for FEP patients are often delayed or bottlenecked by common sequelae of psychosis such as social withdrawal and loss of social support. Additionally, social factors like unemployment, residing in public housing, ethnic minority status, being

underinsured, and—central to our intervention—a history of being locked up, can postpone accessing care and lengthen DUP [6-8]. There is very little literature worldwide on this, but there is evidence that CJ involvement is common in many FEP samples prior to treatment engagement [9-13]. In the PI's study of 191 urban, disadvantaged, predominantly African American FEP patients—the only study that has examined the link between DUP and jail detention history—59% had a history of detention (primarily in jails for misdemeanors) prior to their first treatment and 37% had been detained at some point during their DUP [14]. Prior detention predicted a much longer DUP [14]. Further, national estimates show that 24% of people in jail have had psychotic symptoms in the past 12 months [15]. Large jails have become "public health outposts" in screening and, if appropriate, treating, large numbers of individuals who might not otherwise seek or be exposed to care in the community. Jails likely have an enriched population for the detection of FEP, and thus need to collaborate with community-based CSC.

The development and implementation of a TEC and SEET in **3** jails seeks to reduce DUP for detained young people with FEP through "supply side" approaches. The TEC will educate Correction Officers about early signs and referring to correctional health services (CHS) staff. The SEET will forge referral networks that fast-track the initiation of CSC upon release from jail. The SEET will be comprised of two people: one professional social worker and one peer worker. Dr. Genevra Jones, Co-Investigator, will serve as an expert in peer support theories. Dr. Jones will advise on all aspects of the training and supervision of the peer specialist. Four interrelated bodies of knowledge guide this work. Three guide our TEC + SEET intervention: (1) the Scandinavian Early Treatment and Intervention in Psychosis (TIPS) model, (2) person-centered treatment and shared decision-making, and (3) Critical Time Intervention; and one guides our selection of targets/mediators (and thus intervention development): (4) Social Cognitive Theory.

Our intervention is critically informed by the TIPS study in Scandinavia, the largest experimental study of early detection to date. TIPS successfully reduced median DUP in FEP patients from 15 weeks to 4.5 using two core strategies: intensive, multi-media public information campaigns, and easy-access, low-threshold mobile early detection teams [16]. A wide body of literature attests to the pivotal role education campaigns can play in improving professional and public recognition of early warning signs and symptoms of many disorders [17]. TIPS developed a mass media campaign to both enhance the public's knowledge of psychiatric disorders in general and early signs of psychosis in particular, and to reduce stigma associated with schizophrenia and psychiatry. Information was tailored to 3 target groups: the general public, general practitioners and healthcare workers, and teachers. Information was distributed systematically and repeatedly over several years. Notably, when a lack of funding interrupted the campaign for a period of time, the rate of referrals dropped (particularly from general practitioners) and DUP increased again, further showing the importance of information campaigns in reducing DUP [18]. The success of the TIPS campaign has led to efforts to replicate the approach in other places. In the US, the Specialized Treatment Early in Psychosis (STEP) clinic implemented the STEP-ED campaign that includes: public education, outreach to and academic detailing of professionals, and rapid access to the STEP clinic [19]. Our proposed intervention will take place in an urban jail setting rather than in the community; as such, it will focus on the same two interlocking strategies (TEC and SEET) used by TIPS to shorten DUP for people experiencing FEP, but tailored within the confines of the jail. The NYC jail system has over 55,000 admissions and roughly the same discharges each year, with high correctional staff turnover; a continuous and broad-reaching "Targeted Education Campaign" is essential to ensure the messaging works.

Studies show that person-centered communication (e.g., asking open-ended questions, involving patients in treatment decisions) has positive effects on satisfaction, treatment adherence, and health status [20-22]. Both the content of communication(e.g., creating space for the person's interpretations of illness) and the context of communication (e.g., clinicians' interpersonal behaviors, expectations about communication

style, use of simplified language) influence treatment initiation and participation [23]. Clinician communication behaviors, such as building rapport, using open-ended questions, and answering questions, are a key mechanism for engagement. Communication functions that are key to promoting improved health outcomes include: establishing and maintaining the provider-patient relationship, exchanging information, validating and responding to emotions, managing uncertainty, sharing in making treatment decisions, and enabling patient self-management. Some of the pathways through which effective communication may lead to better health outcomes include improved patient knowledge and shared understanding, improved access to care, improved therapeutic alliances, and improved patient agency [24]. Even though the health care provided in the jail system is not necessarily person-centered or oriented around shared decision-making, the work of the SEET—trained by the expert resources available at the Center for Practice Innovations and among the PI, Co-Investigators, and Consultants—will be framed by an approach that treats communication strategies as central to the future engagement of detainees in community-based CSC.

Our SEET will use a Critical Time Intervention (CTI) model to mobilize support for people with FEP during a period of transition from jail to the community. CTI was developed in the US in the 1990s based on the principles of case management and Assertive Community Treatment. CTI has been used with persons with mental illnesses, as well as those who are incarcerated. It has been evaluated extensively, with good evidence for its efficacy [25-26]. In a study of CTI among men with a serious mental illness who were leaving prison, CTI was effective at increasing engagement with services at 6 weeks; differences between the intervention and control group persisted through 6 months [27]. CTI will organize the activities of our SEET in that it is time-limited, focused, and designed to enhance support and engagement in services during critical periods of transition. Assertive outreach and ongoing engagement in jail, combined with brokering relationships with CSC leading up to and upon release (and telephonic support after release until CSC engagement) will ensure that individuals are adequately supported while detained and following their return to the community.

The jail-based TEC (and our targets/mediators) are also heavily influenced by Social Cognitive Theory and its concepts of behavioral capabilities (knowledge and skills), self-efficacy, and expectations. Social Cognitive Theory, developed by Bandura [28-29], posits that behavior is underpinned by personal (cognitive, affective, and biological), behavioral, and environmental factors that interact and influence each other bidirectionally. As applied to the field of health promotion, Social Cognitive Theory specifies a core set of determinants, the mechanisms through which they work, and the optimal ways of translating them into health practices. Five determinants are central: (1) behavioral capabilities—or knowledge and skills about health risks and benefits—that create the preconditions for change; (2) perceived self-efficacy about one's ability to successfully perform tasks; (3) expectations about the outcomes of certain actions or health habits; (4) personal goals for change; and (5) perceived facilitators and barriers to change [30]. As described in more detail below, the TEC is an intervention that will target Correction Officers' knowledge about the early symptoms of psychosis, and how to make a referral to the CHS, their self-efficacy to detect symptoms of psychosis and make referrals, and their expectations about their ability to be successful in making that referral (and for referrals to result in beneficial outcomes). All aspects of the TEC will be designed to improve behavioral capabilities, expectations, and self-efficacy. That is, regardless of the media (e.g., poster, flyer, brief roll-call training for Correction Officers), all TEC materials will target very specific knowledge and skills, increase expectations about the benefits of the SEET and CSC/OnTrackNY, and increase self-efficacy about one's ability to make a referral. Messaging will be specific, straight-forward, as simple as possible, and repetitive, so that we can effectively improve knowledge/skills, expectations, and self-efficacy in a focused way. These changes will ultimately influence rates of identifying detainees with undetected FEP and referral to CHS. Social Cognitive Theory, as well as everyday experience, suggests that

in order to successfully carry out a behavior, one must have the necessary knowledge/skills, the beliefs that what is expected to occur actually will occur, and the self-confidence to carry out that specific behavior. In targeting these mediators, our TEC will therefore have the greatest chances of generating referrals to the CHS (especially referrals of quietly psychotic young people who would have otherwise gone undetected and thus not referred to CHS).

Abundant evidence documents racial and ethnic disparities in access to mental health services [31-33]. While the underlying root causes of these disparities are complex—explained by patient-level, provider-level, and system-level factors—studies show that they persist even when controlling for differences in socioeconomics [32]. Racial and ethnic disparities also occur in pathways to care in FEP patients. Stigma remains a significant barrier to treatment and African Americans are more likely to experience negative routes to psychiatric care such as through the CJ system or involuntary hospitalizations [34-38]. Given that the population in the NYC jail system is 87% Black and Hispanic and that no specialized FEP treatment services currently exist within the jail system, our intervention has the potential to significantly improve treatment access for a population of young minorities with FEP who traditionally experience significant barriers to care.

Specific Aims and Hypotheses

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Aim A. Implement a Targeted Educational Campaign (TEC) within 3 jails at NYC's Rikers Island. The TEC is designed to lead to referrals of detainees (previously not detected as having potential mental health concerns) to Correctional Health Services (CHS) by Correction Officers. We expect that referral will occur via changes in scores on behavioral capability (knowledge/skills), expectations, and self-efficacy (among Correction Officers). Although this R34 feasibility study is meant to determine likely effect sizes rather than demonstrate statistical significance (which would be the goal of a subsequent, larger, multi-site study), using the data that we collect, we hypothesize that the number of referrals to CHS will be associated with: cumulative changes in Correction Officers' survey scores on behavioral capability, expectations, and self-efficacy.

Aim B. Implement a Specialized Early Engagement **Support Service** (SEE**SS**) in the same three jails. The SEET will increase the likelihood that referred individuals found to have first-episode psychosis enroll in CSC upon release. Although this R34 feasibility study is meant to determine likely effect sizes rather than demonstrate statistical significance, using the data that we collect, we hypothesize that the SEE**SS**'s extent of engagement and working alliance with referred individuals as measured by both client-related and clinician-related engagement and working alliance will be associated with likelihood of CSC engagement. This will be tested using logistic regression (modeling the odds of enrollment in CSC on measures of service engagement and working alliance. We will also consider several patient- level variables (age, gender, offense severity, duration detained, and symptom severity) as they all could potentially have an effect on enrollment in CSC

Aim C. Assess the acceptability and feasibility of the jail-based TEC and SEE**SS** in advance of a larger, multi-site, definitive trial. Regarding acceptability, we will conduct stakeholder interviews and focus groups with all relevant end-users of the new intervention (TEC+SEE**SS**). In terms of feasibility data in advance of a larger trial, metrics of interest will include, among others: (1) the number of detainees referred to the

SEE**SS**, (2) the number of those referred who have FEP, (3) the DUP for this sample, and (4) the proportion who later engage in CSC. Carefully evaluating acceptability and feasibility of the TEC and SEE**SS** will give us the information needed for a definitive effectiveness trial (for example, through a future R01).
Aim D. Prepare an intervention manual for broader deployment and further formal research. The intervention manual could be used by other diverse jails to carry out all aspects of the TEC and SEE**SS**.

Description of Subject Population

Sample #1

Specify subject population
Correction Officers
Number of completers required to accomplish study aims
540
Projected number of subjects who will be enrolled to obtain required number of completers
540
Age range of subject population
over 21

Sample #2

Specify subject population
Detainees
Number of completers required to accomplish study aims
20
Projected number of subjects who will be enrolled to obtain required number of completers
20
Age range of subject population
18-30

Sample #3

Specify subject population
Key Stakeholders
Number of completers required to accomplish study aims
28
Projected number of subjects who will be enrolled to obtain required number of completers
28
Age range of subject population
over 18

Gender, Racial and Ethnic Breakdown

Sample #1

Racial Categories	**Ethnic Categories**				
	Not Hispanic or Latino		**Hispanic or Latino**		**Total**
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	15	12	3	3	33
Asian	12	12	0	0	24
Native Hawaiian or Other Pacific Islander	12	9	0	0	21
Black or African American	102	87	21	27	237
White	69	66	18	18	171
More than One Race	27	24	0	3	54
Total	237	210	42	51	540

Sample # 2

Racial Categories	**Ethnic Categories**				
	Not Hispanic or Latino		**Hispanic or Latino**		**Total**
	Female	**Male**	**Female**	**Male**	
Black or African American	3	12	0	0	15
White	1	4	0	0	5
Total	4	16	0	0	20

Sample #3

Racial Categories	**Ethnic Categories**				
	Not Hispanic or Latino		**Hispanic or Latino**		**Total**
	Female	**Male**	**Female**	**Male**	
Black or African American	**10**	**8**	0	0	**18**
White	**6**	**1**	**2**	**1**	**10**
Total	**16**	**9**	**2**	**1**	**28**

Description of subject population

Sample #1: Correction Officers
The implementation of the Target Educational Campaign (TEC) will involve Correction Officers working at three jails: the Anna M. Kross Center (AMKC), the Rose M. Singer Center (RMSC), and the Robert N. Davoren Complex (RNDC), all located on Rikers Island in New York City. Correction Officers in these three jails will be approached to complete brief surveys. The study will need 540 completed surveys over the course of the three time points (180 surveys at each). Since identifying information is not being collected from the Correction Officers, it is possible that some of Correction Officers will participate more than once, meaning less than 540 Officers total will participate.

Sample #2: Detainees
Detainees receiving services from Correctional Health Staff for a first episode of psychosis will be referred as possible participants to the study.

Sample # 3: Stakeholders
We will conduct interviews with the following key groups of people: (1) SEESS staff (Social Worker and Peer Specialist); (2) Department of Correction Leadership; (3) Formerly detained individuals who participated in the project and who are now living in the community. We will also do focus groups with (1) Correction Officers; and (2) Correctional Health Service (CHS) staff.

Recruitment Procedures

Describe settings where recruitment will occur

Study 1: Surveys of Correction Officers

Recruitment of the study sample will take place in 3 jails on Rikers Island in New York City (NYC): Anna M. Kross Center (AMKC), Rose M. Singer Center (RMSC), and the Robert N. Davoren Complex (RNDC).

Study 2: Clinical Interviews with Detainees Referred by Correction Health Services as having First Episode Psychosis.
Recruitment of the study sample will take place in 3 jails on Rikers Island in New York City (NYC): Anna M. Kross Center (AMKC), Rose M. Singer Center (RMSC), and the Robert N. Davoren Complex (RNDC). Additionally, since many patients with FEP get referred to Bellevue Hospital Prison Ward (for males) and Elmhurst Hospital Prison Ward (for females) for stabilization, we will be accepting referrals from those facilities as well.

Study 3:Interviews with Key Stakeholders to Assess Acceptability
Recruitment will take place in different settings, including the Anna M. Kross Center (AMKC), the Rose M. Singer Center (RMSC), the Robert N. Davoren Complex (RNDC) and community settings.

How and by whom will subjects be approached and/or recruited?

Study 1: Surveys of Correction Officers

Correction Officers in these three jails will be exposed to the Targeted Educational Campaign (TEC). Correction Officers will be approached and recruited during roll call and in the staff canteen where they take their meal breaks, or at a time/location agreed upon by the Department of Correction, to complete brief surveys to assess engagement of Target C at three different times: pre-exposure, after 6 months, and after 12 months from the beginning of the TEC. Jason Tan de Bibiana and Adria Zern, coordinated and supervised by Dr. Pope and Dr. Compton, will approach Correction Officers briefly presenting the study and asking for completion of the survey.

In the event that social distancing guidelines pertaining COVID-19 prevent the research team for going to the jails to survey the Officers at the 6 and 12-month follow-up time periods, we will coordinate with our study partners to administer the anonymous survey. The Deputy Wardens and/or Captains at the jails will introduce the survey during the daily roll-call meetings, and they will distribute the participant information document and survey to each Officer for their review. The Deputy Wardens and Captains will tell the Officers that the survey is voluntary and anonymous, but if they wish to complete it, they can put their completed survey in a container in the Officer's canteen or other communal space.

Study 2: Clinical Interviews with Detainees Referred by Correction Health Services as having First Episode Psychosis.
All subjects referred to the research team by CHS will initially meet with Jason Tan de Bibiana or Adria Zern, coordinated and supervised by Dr. Pope and Dr. Compton. The assessors will describe the study, and if the subject agrees and signs the informed consent, he/she will be assessed in a 90-minute clinical interview using standard materials already in use at OnTrackNY, as well as instruments to measure symptom onset and thus duration of untreated psychosis (DUP).
During times of social distancing related to COVID-19, Mr. Tan de Bibiana and Ms. Zern will do the interview process over phone or HIPAA-compliant video software, depending on the technical capacity of the Correctional Health Services clinic where the individual is located. Since interviewing over phone or video might make engaging with the individual more challenging, the 90-minute interview may be broken up over several phone or video calls.

Study 3: Interviews with Key Stakeholders to Assess Acceptability
For detainees that were engaged by SEE**SS**, after the individuals are released from jail, Jason Tan de Bibiana, coordinated and supervised by Dr. Pope and Dr. Compton, will recruit participants through telephone and/or email. All interviews will take place in the community **or via telephone or Zoom** and individuals will be remunerated $50 for taking part in an interview. For the focus groups Jason Tan de Bibiana will recruit participants from SEE**SS** staff, Correction Officers/leadership, Correctional Health Service staff through face-to-face contacts, word of mouth, and snowball sampling. Focus groups will take place during regular business hours and participants will not be remunerated (on-duty employees cannot be remunerated at these agencies).The eligibility criteria for interviews and for individuals to be members of focus groups will include: (1) age ≥18, and (2) willing to give consent.

How will the study be advertised/publicized?

N/A

Do you have ads/recruitment material requiring review at this time?
No
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
03962348

Concurrent Research Studies

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

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Correction Officers
Create or insert table to describe the inclusion criteria and methods to ascertain them

Inclusion Criteria	Methods to ascertain them
1) Exposure to the Targeted Educational Campaign	Staff Reports
2) Aged at least 21 years	

Create or insert table to describe the exclusion criteria and methods to ascertain them

Exclusion Criteria	Methods to ascertain them
Children under the age of 21	Staff Reports

Inclusion/Exclusion Criteria #2

Name the subject group/sub sample
Detainees Referred to the Specialized Early Engagement Team

Create or insert table to describe the inclusion criteria and methods to ascertain them

Inclusion Criteria	**Methods to ascertain them**
1) have been referred by Correctional Health Services as experiencing early-course or first-episode psychosis	Reports from Correctional Health Services
2) be between the ages of 18 and 30 years	Reports from Correctional Health Services
3) (a) have a Mini-Mental State Examination (MMSE) score of >23 **OR (b) for phone or video interviews, correct responses to first 5 orientation questions of MMSE**	(a) Administration of the MMSE **OR (b) Administration of first 5 questions of MMSE**
4) have the capacity to provide informed consent for the study.	Reports from Correctional Health Services Interaction with assessor
5) able to understand and speak English	Interaction with the assessor

Create or insert table to describe the exclusion criteria and methods to ascertain them

Exclusion Criteria	**Method to ascertain them**
Children under the age of 18 years	Reports from Correctional Health Services

Inclusion/Exclusion Criteria #3

Name the subject group/sub sample
Stakeholders
Create or insert table to describe the inclusion criteria and methods to ascertain them

Inclusion Criteria	Methods to ascertain them
1) age ≥18,	Individuals Reports
2) Willing to share contact information with the SEE**SS** or	Individuals

CSC program prior to or after release from jail in case of detainees	Reports
3) Willing and able to give informed consents	Individuals Reports

Create or insert table to describe the exclusion criteria and methods to ascertain them

Exclusion Criteria	Methods to ascertain them
Children under 18 years	Individuals Reports

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)
Yes
Waiver or alteration of consent
No
Waiver of documentation of consent
Yes
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

Jason Tan de Bibiana, and Adria Zern will obtain verbal consent from subject during the screening process, after identified as potentially eligible to participate in the study.

Describe Study Consent Procedures

Consent from Correction Officers

Correction Officers staff will receive an information sheet at the beginning of the questionnaire explaining the study, confidentiality, and possible risks and benefits. Continuing on to the questionnaire will imply that

the subject consents to take part to the study. The survey takes about 10 minutes. We will not be using a signed informed consent form so that this study can be anonymous in addition to being confidential.

Consent from Detainees

During the informed consent process, Jason Tan de Bibiana or Adria Zern will explain the study, confidentiality, and possible risks and benefits, and will answer all questions. Jason Tan de Bibiana and Adria Zern**,** who will be certified by NYSPI's IRB, will carry out the informed consent process with detainees. The PI will be available for assistance at any time and will closely supervise consent procedures. Participants will be provided with a thorough description of the risks, benefits, and alternatives to participating in the research project. The informed consent document will be read to detainees, and questions about any aspect of the research will be encouraged and answered. Jason Tan de Bibiana and Adria Zern will emphasize that participation is completely voluntary and will in no way affect their employment status, medical care, legal status, or benefits. During the informed consent process, all participants will be informed that they may withdraw from the study at any time without negative consequences to their employment status, medical care, legal status, or benefits. Upon completion of a thorough review of the Informed Consent Form, we will administer a 5-item true/false questionnaire to assess participants' understanding of the most crucial aspects of the Informed Consent Form. Only if the participant can verbalize understanding of the questions correctly will they be eligible to provide consent and move toward study participation. In case of incorrect answers, the assessor will explain again those portions of the Consent Form and will re-assess the understanding. Each individual has up to 3 attempts to respond correctly to all of the 5 questions.

For any participants who are interviewed over video/phone and through which verbal consent is obtained, the research team will add a dated note to their research file stating that the consent discussion occurred and the participant verbally consented. The research staff who obtained the verbal consent will sign the note. When reading the consent form to the participants, the research staff will explain that the HIPAA-compliance of the video software offers the same privacy as discussions with their care providers or clinicians. Since private rooms will be scheduled ahead of the interview time, privacy should not be a concern, but the participants will be asked during the consent discussion if they are comfortable with the level of privacy they have in order to proceed. Their response to their feelings about the privacy will be documented in their research file along with the attestation that verbal consent was obtained. They will be encouraged to tell the research team if they feel like they don't have enough privacy at any time during the interview. If they don't feel comfortable with the level of privacy at any time, the interview will be stopped.

Consent from Stakeholders (Individuals engaged by the SEE**SS**, SEE**SS** staff, Correction Officers, Correctional Health Services staff, and criminal justice professionals)
During the informed consent process, the Jason Tan de Bibiana will explain the study, confidentiality, and possible risks and benefits, and will answer all questions. Dr. Pope and the PI will be available for assistance at any time and will closely supervise consent procedures. Participants will be provided with a thorough description of the risks, benefits, and alternatives to participating in the research project. Questions about any aspect of the research will be encouraged and answered. Jason Tan de Bibiana will emphasize that participation is completely voluntary and will in no way affect their employment status, medical care, legal status, or benefits. During the informed consent process, all participants will be informed that they may

withdraw from the study at any time without negative consequences to their employment status, medical care, legal status, or benefits.

The risk of travel for in-person visits during covid-19 will be discussed during the consent discussion. A consent procedure note will also be provided to participants who need to travel for the study: "You should exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public an avoiding crowds. It is important for you to stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. If you have any questions about how you will travel for appointments, or do not feel safe traveling, please let us know, and know that you can call to reschedule visits."

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

Waiver of Consent for use of Protected Health Information

What records do you wish to review?
Prior to obtaining informed consent, the only protected health information we seek to obtain is related to the referral process for detainees from Correctional Health Services (CHS). In order to refer the individuals, CHS will need to tell the research team the individuals' diagnoses, name, and age to determine eligibility.
What information are you seeking access to?
Individuals' age, name, and diagnoses. The information that we collect will not increase or change.
Describe your plan to protect identifiers from improper use and disclosure
We will not need to use any health information linked to identifiers after data collection is complete. If a potential participant declines to participate, his or her identifying information will be shredded in a secure location by research staff.
Describe your plan to destroy the identifiers as soon as possible consistent with the conduct of the research, or provide a health or research justification for retaining the identifiers or explain how retention is required by law
Identifiers will be shredded and destroyed if the patient does not meet criteria for admission to the study or does not provide consent to participate.
Explain why the research could not be practicably carried out without the information (for which you are requesting access)
We would be unable to verify the eligibility of potential participants who have been referred to the study without access to protected health information (e.g., diagnosis, age and name). Once this basic information is obtained, the research assessors will then talk to the patient (if the patient has given verbal consent to the treating clinician) to do a more intensive screening that covers all of the study's eligibility criteria. Once it is determined that the participant meets eligibility criteria, the informed consent process will begin before any additional information is collected.
Explain why the research cannot be practicably carried out without the waiver
It is not feasible to meet with every patient from CHS to obtain consent/authorization, especially given the difficulty of traveling to Rikers Island and accessing the facilities.

Explain how/if subjects will be provided with additional pertinent information after participation
Subjects will only be provided with additional information after participation if they give consent to be contacted again. If they do not give informed consent, they will not be contacted.

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?
Yes
Is breach of confidentiality the main study risk?
No
Describe the study component(s) for which waiver of documentation is requested.

Survey of Correction Officers
We will not be collecting any identifiable information from survey participants (Correction Officers); the surveys will be anonymous. Our plan to use a "Participant Information Document" (rather than signed Informed Consent Form) will allow us to not collect name and signature.

Clinical Interviews with Detainees
During times when it is not possible to conduct interviews in-person because of COVID-19, we will obtain verbal consent over phone call or video software, rather than having the individual sign the informed consent form. We will still read the informed consent form to the individual and will conduct the consent form questionnaire. The only change is that, at the end of the consent process, the individual will provide verbal consent to participating, rather than signing the document. The research team will add a dated note to their research file stating that the consent discussion occurred and the participant verbally consented. The research staff who obtained the verbal consent will sign the note.

Key Stakeholder Interviews and Focus Groups
We will obtain verbal consent from individuals agreeing to participate in interviews or focus groups for Study 3, whether they are in person or conducted over the phone or Zoom. A member of the research team will go through the consent process. At the end, the individual will provide verbal consent to participating, rather than signing the document. The research staff who obtained the verbal consent will sign the form.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Compton, Michael, MD
Pope, Leah, PHD
Type in the name(s) not found in the above list

Jason Tan de Bibiana, M.Sc., completed NIH's "Protecting Human Research Participants Online Training" on 09/06/2018. Certification Number: 2912938.

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

Study Procedures

Describe the procedures required for this study

Study 1: Surveys of Correction Officers

We will collect pre-Targeted Educational Campaign (TEC) and during-TEC (at 6 months and 12 months) survey data, which will be used to test engagement of Target C: changes in mean scores for behavioral capability, expectations, and self-efficacy, which are three key constructs from Social Cognitive Theory. The brief (10-minute) survey will assess knowledge and skills (behavioral capability), expectations, and self-efficacy. It will be offered to any staff in the jail, regardless of whether they have received an in-person (e.g., in roll call) training, since the various types of TEC materials are hypothesized to influence behavior, expectations, and self-efficacy.

Study 2: Clinical Interviews with Detainees Referred by Correctional Health Services as having First Episode Psychosis.

Jason Tan de Bibiana or Adria Zern will conduct a 90-minute interview with detainees referred by Correctional Health Services as having first-episode psychosis. After completing the screening process and having received informed consent, the assessors will complete the sociodemographic assessment and a substance use survey. The assessors will do the Structured Clinical Interview for the Positive and Negative Syndrome Scale (SCI-PANSS) to better understand the participants' symptoms. The assessors will also rigorously measure age at onset of psychosis, and thus duration of untreated psychosis (DUP), based on Dr. Compton's expertise in this area. DUP will be operationalized as duration in weeks from onset of hallucinations/delusions to initiation of an antipsychotic medication (DUP-1), as well as duration in weeks from onset to enrollment in CSC (DUP-2). During the second year of the project, when the Specialized Early Engagement **Support Service** (SEE**SS**) is implemented, the assessor will meet with the participant again after a week to measure the level of engagement of the individual with the SEE**SS**. For all interview participants, we will ask them if they would like to be interviewed again within two months of their release from jail. For individuals who engaged with the SEE**SS**, this will accomplish the aims of Study 3. If the individuals did not engage with the SEE**SS**, we will ask them basic questions about the treatment they've engaged with since being released.

If the assessors have any concerns about any possible suicidality or dangerousness, they will stop the assessment and inform a clinician within Correctional Health Services. Dr. Compton (PI) will also be notified right away before resuming the assessment to discuss the case and the clinician's response. In summoning a clinician (who will be readily available since the assessment is being done in the clinical area), the assessor will share this with the participant, in a manner such as: "Because I feel concerned about [your safety] based on what we have been discussing, I want to make sure that we talk to a mental health worker about it. We can talk to them together. I want to make sure that [you are safe] before we continue with the interview." The assessors will be trained that if at any point in the interview they have reason to believe that the participant has homicidality or the intention to harm a child, an elderly person, or anyone else, they are required to report it to both the clinical team and the PI.

While conducting phone or video interviews with participants, the same protocol will be in place. NYSPI Zoom for Healthcare will be used for the video/phone calls. The individuals will be in Correctional Health Services clinics or similar areas during the interview, so clinic or DOC staff will be readily available in the event that the individual requires immediate attention. Working with our partners, it was determined that the best space would be the discharge planning and competency evaluation rooms, which already have HIPAA-compliant video call capacity and offer privacy. It is standard practice for DOC Correction Officers to stand outside these rooms during the interviews, so they are able to intervene if there are any safety concerns. This same protocol will be followed for our clinical interviews. In addition to having the DOC staff member outside, the research team will have the phone number of a Correctional Health Services clinician who will be ready to step in if there are any technical issues or clinical concerns. The CHS staff members will help set up the video, just as they normally would for the discharge planning or competency evaluation calls.Additionally, the interview may be broken up over multiple phone or video calls to minimize participants' fatigue.

Study 3: Interviews with Key Stakeholders to Assess Acceptability
We will carefully assess acceptability to all end-users of the TEC and SEE**SS** by conducting interviews and focus groups that will be audio-recorded and then transcribed for qualitative analysis.

I attest to follow the COVID-19 Safety Guidelines for columbia Psychiatry and NYSPI Re-Entry outlined in the NYSPI Director's June 1st memo, which include but are not limited to:
Infection Control/PPE - Guidelines
Research participants will only come on-site if absolutely necessary for study procedures.
Research participants need to complete the online screening the day they come to the NYSPI building and must be met at one of the entrances by research/clinical staff in order to enter.
COVID/COVID-like symptoms of participants will be reported to the IRB via PRISM as an SAE.

You can upload charts or diagrams if any

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment

Study 1: Surveys of Correction Officers

Correction Officer Surveys: will measure three constructs from Social Cognitive Theory (behavioral capabilities (knowledge/skills), expectations, self-efficacy), as well as social distance stigma, while keeping the survey to approximately 10 minutes.

Study 2: Clinical Interviews with Detainees Referred by Correctional Health Services as having First Episode Psychosis

Screening Form with Mini Mental State Examination (MMSE) (attached) **Since some aspects of the MMSE include visual components or physical movements (i.e. folding a piece of paper), during phone or video assessments, only the first 5 questions of the MMSE on orientation will be read.**

Assessment Packet (attached), will be used to collect sociodemographic information, and history of previous arrests.

A slightly modified version of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) will be used to ascertain information about participants' substance use behaviors.

Structured Clinical Interview for the Positive and Negative Syndrome Scale (SCI-PANSS) will be conducted to better understand the severity of the participants' symptoms, which is necessary fundamental knowledge to be able to assess the dates required in the SOS below.

Symptom Onset in Schizophrenia (SOS) inventory SOS criteria will be used to determine when hallucinations and/or delusions met the threshold for psychosis. The interview-based date identifies the onset of symptoms, specifically when the severity of the symptom met clinical criteria, and the symptom occurred often enough to meet or exceed the required frequency.

Year 2: Working Alliance Inventory - Short Revised (WAI-SR): The clinician version is a 10-item measure and the client version is a 12-item measure. Items measure agreement on goals, tasks, and development of an effective bond between client and therapist. Clinicians and detainees will rate working alliance by measuring the relationship or alliance between client and therapist

Year 2: Service Engagement Scale (SES): Is a 14-item measure that asks clinicians about their client's availability (being available for arranged appointment),collaboration (participating in the management of illness), help seeking (seeking help when needed), and treatment adherence (client's attitude toward taking medication).

Year 2: Singh O'Brien Level of Engagement (SOLES): Is a 13-item client-rated scale measuring engagement with mental health services in people with psychosis.

Study 3: Interviews with Key Stakeholders to Assess Acceptability
Interviews and focus groups will be designed to answer the following two overarching research questions: (1) To what extent is the new intervention suitable and satisfying to users? and (2) What barriers and facilitators do users of the intervention report experiencing? Specific interview and focus group questions will be targeted to the specific stakeholder groups but will focus on content and mode of delivery,

satisfaction with the TEC and SEE**SS**, intent to continue using it, perceived demand, perceived appropriateness, and fit within the organizational culture of the jail and CSC programs.

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
No
Treatment to be provided at the end of the study
N/A

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period

Study 1: **Surveys of Correction Officers**

We do not foresee any risks for Correction Officers. Their participation is completely voluntary and the information collected will be confidential and anonymous, and will not be disclosed outside of the research team.

Study 2: Clinical Interviews with Detainees Referred by Correctional Health Services as having First Episode Psychosis.

Participants will be asked to notify the assessor of any physical or psychological discomfort during the interview. Additionally, the research assessors will be trained to identify for signs of distress. There is a risk that information about the patient may be disclosed to other people outside of the research study. Protections of confidentiality guard against this risk, thereby minimizing the risk of such disclosure. An important ethical concern that we will seriously attend to is the possibility that identified detainees could perceive coercion to participate. During the consent process, we will clearly explain that their decision to participate or not will not be reported to anyone at any correctional agencies or mental health facilities and will not impact their legal status or relationship with service providers in any way.

Study 3: **Interviews with Key Stakeholders to Assess Acceptability**
We do not foresee any risks to participants taking part in interviews or focus groups for this qualitative study. Their participation is completely voluntary and the information collected will be confidential and will not be disclosed outside of the research team.

Describe procedures for minimizing risks

Study 1: Surveys of Correction Officers

Any risk of perceived coercion will be addressed by fully informing participants that their decision to participate is voluntary and will not be reported to anyone outside of the research team. We (or in the event that we cannot distribute the surveys due to social distancing, the Deputy Wardens and Captains) will explain that their decision will in no way impact their relationship with their employer or others. Risks to confidentiality also will be minimized. Participants' names and other potential identifiers will not be included in the dataset and each participant will be assigned a unique ID number. Surveys will be made anonymous by using a unique code created by the participant, as in Dr. Compton's prior survey-based research. For example, on the front page of the survey, respondents will be asked:
• What is the first letter of your middle name?
• What is the first letter of the street you live on?
• What is the last digit of the year you were born?
• What is the last two digits of your Social Security Number?
Doing so will create a unique identification code for each participant (e.g., JB223, TF189) to ensure anonymity, while allowing us to match any participants who complete a later survey (at 6 months or 12 months).

Study 2: Clinical Interviews with Detainees Referred by Correctional Health Services as having First Episode Psychosis.

The potential minor risks of physical or psychological distress will be protected against using measures taken to ensure that participants are comfortable during enrollment. If enrollment causes detectable distress, breaks will be given or enrollment will be postponed/rescheduled. Before beginning a phone or video interview (during times where social distancing guidelines are in place), the assessors will ensure they have the phone number of clinical staff currently in the clinic area, in case there is a need for a clinician to check in on the participant at any time. Any risk of perceived coercion will be addressed by fully informing participants that their decision to participate is voluntary and will not be reported to anyone outside of the research team. We will explain that their decision will in no way impact their relationship with mental health service providers or others. Risks to confidentiality also will be minimized. Consent forms with participants' signatures will be securely stored in a locked file cabinet in a locked research office in a secure building at the university. Participants' names and other potential identifiers will not be included in the dataset and each participant will be assigned a unique ID number. All initial screenings and interviews will be conducted in the same interview rooms or spaces that Correctional Health Services staff use for their meetings/counseling sessions with patients. Information pertaining to individual participants will only be released with their informed and written consent, except in unusual cases where withholding such information might pose a serious risk or danger to the participant or others. Publications and presentations will not report names, initials, or descriptors that could in any way violate confidentiality. These efforts to protect against potential risks are expected to be very effective, as they have been for our prior research.

Study 3: Interviews with Key Stakeholders to Assess Acceptability

Any risk of perceived coercion will be addressed by fully informing participants that their decision to participate is voluntary and will not be reported to anyone outside of the research team. We will explain that their decision will in no way impact their relationship with their employer or others.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

We will collect some identifiable information that will be used for the purpose of determining basic eligibility criteria, and we will carefully protect such information. All information collected will be confidential and will not be disclosed outside of the research team. We will keep all records private and confidential to the extent permitted by law.
All initial screenings and interviews will be conducted in the same private interview rooms/spaces used by Correctional Health Services staff for meetings and counseling sessions. Consent forms with participants' signatures will be securely stored in a locked file cabinet in a locked research office in a secure building. Subjects' name and other potential identifiers will not be included in the notes or dataset, and each participant in the study will be assigned a unique ID number. The only link between identifying information and the unique ID number will be the paper consent forms. Information pertaining to individual participants will only be released with their informed and written consent, except in unusual cases where withholding such information might pose a serious risk or danger to the participant or others. Publications and presentations will not report names, initials, or descriptors that could in any way violate confidentiality. These efforts to protect against potential risks are expected to be very effective, as they have been for our prior research.

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

Direct Benefits to Subjects

Direct Benefits to Subjects

There may be no definite direct benefits to individual participants of the proposed study. Given the minimal risks and potential benefits of the proposed research to participants and the significant potential benefit of knowledge gained, there is no evidence that the risk-benefit ratio would suggest changes to the research plan at the present time.

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.

Study 1 - Surveys of Correction Officers: there is no monetary compensation for this study, but officers will be offered a small piece of candy or a snack item as a thank you for participating.

Study 2 - Clinical Interviews with Detainees Referred by Correctional Health Services as having First Episode Psychosis: there is no compensation for this study

Study 3 - Interviews with Key Stakeholders to Assess Acceptability: Subjects who participate in interviews, who were previously engaged by the SEE**SS** while detained, will be compensated $50 for their time and effort. Other subjects who participate in focus groups (SEE**SS** staff, Correction Officers and leadership, and Correctional Health Service staff) will not be compensated (on-duty employees cannot be compensated at the agencies).

References

References
1. Marshall M, Lewis S, Lockwood A (2005) Association Between Duration of Untreated Psychosis and Outcome in Cohorts of First-Episode Patients: A Systematic Review. Archives of General Psychiatry 62:975-983.
2. Norman RMG, Lewis SW, Marshal M (2005) Duration of untreated psychosis and its relationship to clinical outcome. The British Journal of Psychiatry 187(48):s19-s23.
3. Perkins DO, Boteva GH, Lieberman JA (2005) Relationship Between Duration of Untreated Psychosis and Outcome in First-Episode Schizophrenia: A Critical Review and Meta-Analysis. The American Journal of Psychiatry 162(10):1785-1804.
4. Addington J, Van Mastrigt S, Addington D (2004) Duration of untreated psychosis: Impact on 2-year outcome. Psychological Medicine 34:277–84.
5. Gonzalez G, Goperlund E, Shern D (2016) Coordinated Specialty Care – First episode psychosis programs: Why specialty early intervention programs are a smart investment. Policy Brief. https://www.nasmhpd.org/sites/default/files/Policy_Brief-Coordinated_Specialty_Care_First_Episode_Psychosis_Programs.pdf
6. Singh SP, Grange T (2006) Measuring pathways to care in first-episode psychosis: A systematic review/ Schizophrenia Research 81:75-82.
7. Compton MT, Broussard B (2011) Conceptualizing the Multifaceted Determinants of the Duration of

Untreated Psychosis. Current Psychiatry Reviews 7(1):1-11.
8. Broussard B, Kelley ME, Ramsay Wan C, Cristofaro SL, Crisafio A, Haggard PJ, Myers NL, Reed T, Compton MT (2013) Demographic, socio-environmental, and substance-related predictors of duration of untreated psychosis. Schizophrenia Research 148:93-98.
9. Marion-Veyron R, Lambert M, Cotton SM, Schimmelmann BG, Gravier B,McGorry PD, Conus P (2015) History of offending behavior in first episode psychosis patients: a marker of specific clinical needs and a call for early detection strategies among young offenders. Schizophrenia Research 161(2-3):163-168.
10. Munker R, Haastrum S, Joergensen T, Kramp P (2003) The Temporal Relationship between Schizophrenia and Crime Social Psychiatry and Psychiatric Epidemiology 38:347-353.
11. Wallace C, Mullen PE, Burgess P (2003) Criminal Offending in Schizophrenia Over a 25-Year Period Marked by Deinstitutionalization and Increasing Prevalence of Comorbid Substance Use Disorders. American Journal of Psychiatry 161:716-727.
12. Hodgins S, Calem M, Shimel R, Williams A, Harleston D, Morgan C, Dazzan P, Fearon P, Morgan K, Lappin J, Zanelli J, Reichenberg A, Jones P (2011) Criminal offending and distinguishing features of offenders among persons experiencing a first episode of psychosis," Early Intervention in Psychiatry 5:15-23.
13. Prince JD, Akincigil A, Bromet E (2007) Incarceration rates of persons with first-admission psychosis. Psychiatric Services 58(9):1173-1180.
14. Ramsay Wan C, Broussard B, Haggard P, Compton MT (2014) Criminal justice settings as possible sites for early detection of psychotic disorders and reducing treatment delay. Psychiatric Services 65:758–764.
15. James DJ, Glaze LE (2006) Mental health problems of prisoners and jail inmates. Bureau of Justice Statistics Special Report. NCJ 213600. Washington, DC: U.S. Department of Justice.
16. Joa I, Johannessen JO, Larsen TK, McGlashan TH (2008) Information Campaigns: The Experience in the Early Treatment and Intervention in Psychosis (TIPS) Study. Psychiatric Annals 38(8):512-520.
17. Grilli R, Ramsay C, Minozzi S (2002) Mass Media Interventions: effects on health services utilization. Cochrane Database of Systematic Reviews 1:CD000389.
18. Joa I, Johannessen JO, Auestad B, Friis S, Opjordsmoen S, Simonsen E, Vaglum P, McGlashan TH, Larsen TK (2007). Effects of referral patterns of reducing intensive informational campaigns about first-episode psychosis. Early Intervention in Psychiatry 1(4):340-345.
19. Srihari VH, Tek C, Pollard J, Zimmet S, Keat J, Cahill JD, Kucukgoncu S, Walsh BC, Li Gueorguieva R, Levine N, Mesholam-Gately RI, Friedman-Yakoobian M, Seidman L, Keshavan MS, McGlashan T, Woods SW (2014) Reducing the duration of untreated psychosis and its impact in the U.S.: the STEPED study. BMC Psychiatry 14:335-349.
20. Laplan SH, Greenfield S, Ware JE (1989) Assessing the effects of physician-patient interactions on the outcomes of chronic disease. Medical Care 27:S110–S127.
21. Stewart MA (1995) Effective physician-patient communication and health outcomes: a review. Canadian Medical Association Journal 152:1423-1433.
22. Kreyenbuhl J, Nossel IR, Dixon LB (2009) Disengagement from mental health treatment among individuals with schizophrenia and strategies for facilitating connections to care: A review of the literature. Schizophrenia Bulletin 35(4):696-703.
23. Aggarwal NK, Pieh MC, Dixon L, Guarnaccia P, Alegria M, Lewis-Fernandez R (2016) Clinician descriptions of communication strategies to improve treatment engagement by racial/ethnic minorities in mental health services: A systematic review. Patient Education and Counseling 99(2):198-209.
24. Duggan A, Street RL (X) Interpersonal communication in health and illness. In: Glanz K, Rimer BK,

Viswanath K (Eds) Health Behavior: Theory, Research, and Practice, 5th Edition. Wiley. 243–267.
25. Herman DB, Conover S, Gorroochurn P, Hinterland K, Hoepner L, Susser E (2011) Randomized trial of Critical Time Intervention to prevent homelessness after hospital discharge. Psychiatric Services, 62:713-719.
26. Jarrett M, Thornicroft G, Forrester A, Harty M, Senior J, King C, Huckle S, Parrott J, Dunn G, Shaw J (2012) Continuity of care for recently released prisoners with mental illness: a pilot randomized controlled trial testing the feasibility of a Critical Time Intervention. Epidemiology and Psychiatric Sciences, 21:187-193
27. Shaw J, Conover S, Herman D, Jarret M, Leese M, McCrone P, Murphy C, Senior J, Susser E, Thornicroft G, Wright N, Edge D, Emsley R, Lennox C, Williams A, Cust H, Hopkin G, Stevenson C (2017) Critical time intervention for Severely mentally ill Prisoners (CrISP) : a randomised controlled trial. Health Services and Delivery Research 5(8).
28. Bandura A (1986) Social foundations of thought and action: A social cognitive theory. Englewood Cliffs, NJ: Prentice-Hall.
29. Bandura A (1999) Social cognitive theory: An agentic perspective. Asian Journal of Social Psychology 2:21-41.
30. Bandura, A (2004). Health promotion by social cognitive means. Health education & behavior, 31(2), 143-164.
31. U.S. Department of Health and Human Services (2001) Mental Health: Culture, Race, and Ethnicity—A Supplement to Mental Health: A Report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services.
32. Smedley BD, Stith AY, Nelson AR (2003) Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington, DC: National Academies Press.
33. McGuire TG, Miranda J (2008) Racial and ethnic disparities in mental health care: Evidence and policy implications. Health Affairs 27(2):393-403.
34. Burnett R, Mallett R, Bhugra D, Hutchinson G, Der G, Leff J (1999) The first contact of patients with schizophrenia with psychiatric services: social factors and pathways to care in a multi-ethnic population. Psychological Medicine 29:475–483.
35. Morgan C, Mallett R, Hutchinson G, Leff J (2004) Negative pathways to psychiatric care and ethnicity: the bridge between social science and psychiatry. Social Science and Medicine 58:739–752.
36. Compton MT, Esterberg ML, Druss BG, Walker EF, Kaslow NJ (2006) A descriptive study of pathways to care among hospitalized urban African American first-episode schizophrenia-spectrum patients. Social Psychiatry and Psychiatric Epidemiology 41:566–573.
37. Archi S, Akhtar-Danesh N, Norman R, Malla A, Roy P, Zipursky RB (2010) Ethnic Diversity and Pathways to Care for a First Episode of Psychosis in Ontario. Schizophrenia Bulletin 36(4):688-701.
38. Franz L, Carter T, Leiner AS, Bergner E, Thompson NJ, Compton MT (2010) Stigma and treatment delay in first-episode psychosis: a grounded theory study. Early Intervention in Psychiatry 4(1):47-56.

Uploads

Upload copy(ies) of unbolded Consent Form(s)
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of unbolded Information Sheet(s)

Upload copy(ies) of bolded Information Sheet(s)
Upload a copy of Certificate of Confidentiality
Upload copy(ies) of the HIPAA form
hipaa form 4.29.22.pdf
Upload any additional documents that may be related to this study

New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: 7771 **Principal Investigator:** Michael T. Compton

Name of Study: Reducing Duration of Untreated Psychosis through Early Detection in a Large Jail System

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

☑ All information collected during the Research as told to you in the Informed Consent Form.
☑ Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
☐ Additional information may include:

2. **The Health Information listed above may be disclosed to:**

☐ Researchers and their staff at the following organizations involved with this Research:

☑ The Sponsor of the Research,
National Institute of Mental Health
and its agents and contractors (together, "Sponsor"); and
☑ Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
☐ Private laboratories and other persons and organizations that analyze your health information in connection with this study

☐ Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. **Please note that:**
   - You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

     Michael T. Compton, M.D., M.P.H., 1051 Riverside Drive, Box 100, New York, NY, 10032

   - While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. **This Authorization does not have an end date.**

6. **You will be given a copy of this form after you have signed it.**

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**