Study Protocol

Reducing the Duration of Untreated Illness Among Youth in the Juvenile Justice System With Psychosis-Spectrum Disorders

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Specific Aims

According to the PAR-16-264 FOA, "approximately 100,000 adolescents and young adults in the United States experience a first episode of psychosis (FEP) every year." Among these individuals, a substantial proportion report having experienced clinically significant positive symptoms (e.g., hallucinations or delusions) prior to the age of 18, suggesting that adolescence may be a critical period for employing early intervention efforts. In this planning grant application, we focus on adolescents in contact with the juvenile justice system (JJS) because the literature indicates that 50-75% of youth in the JJS meet criteria for mental health disorders and most are not engaged in mental health services[1,2]. Among adolescents in the JJS, an estimated 3% have a psychotic illness[1], and it can be reasonably assumed that many more experience subthreshold psychotic-spectrum symptoms that may be indicative of risk. Evidence suggests that as many as 25% of those with FEP have their first contact with care through criminal justice agencies[3]. Among FEP individuals, duration of untreated psychosis (DUP), a negative prognostic factor, has been shown to be longer among those within the criminal justice system[3]. This suggests that youth with psychotic symptoms who end up in the JJS may not receive appropriate mental health care and may be more susceptible to the negative sequelae associated with prolonged DUP. Considering the early phase of illness, literature suggesting an association between longer DUP and a host of poor outcomes has led to efforts to identify individuals experiencing emerging psychosis-spectrum symptoms as early as possible[4–6]. Early identification facilitates initiation of empirically-supported intervention services such as those offered through Coordinated Specialty Care (CSC) programs. CSCs are becoming more widely available across the nation, yet access is often limited due to lack of awareness of these services in the mental health community as well as poor patient follow through with referrals to CSCs.

The current study will be conducted in the Rhode Island JJS in which all youth receive a mental health screen (Massachusetts Youth Screening Instrument – 2nd Ed; MAYSI -2). All youth *will also be screened with the Prodromal Questionnaire – Brief Version (PQ-B[7]).* If they screen in on either the MAYSI-2 or the PQ-B, they will be given referral information for CSC services by JJS staff. They will also be offered the opportunity to participate in the research assessment, regardless of whether they pursue the CSC referral, which involves the Structured Interview for Psychosis-risk Syndromes [SIPS] and other measures to thoroughly assess history of psychotic symptoms, comorbid difficulties, and mental health care engagement. A comparison sample of youth who do not screen positive on both the MAYSI-2 Thought Disturbance subscale *and PQ-B* will also be assessed with the SIPS to determine accuracy of the MAYSI-2 and *PQ-B* in the identification of psychosis-risk. During the first part (12 months) of the study, JJS staff will follow standard procedures in referring youth to the state CSC. In the second part of the study (also 12 months), JJS staff will be instructed in the enhanced referral/linkage to care protocol, including a "warm hand-off" where referrals will be put in direct and immediate contact with CSC staff CSC staff will also be trained in procedures to increase the likelihood of follow through with the referral to the CSC. The research team will conduct 3 month follow-up qualitative interviews and quantitative assessments regarding referral pathways, bottlenecks and gaps in care, youth psychiatric symptoms, and JJS contacts. The following specific aims, mapped to the **four stated goals of PAR 16- 264**, will be examined:

Aim 1A: Identify baseline rates of psychosis-spectrum disorders within the JJS by exploring the occurrence of psychotic disorders and psychosis-risk syndromes as identified through clinical interview with the SIPS**. 1B: Examine Duration of Illness (DUI)** for sub- **and DUP** for full- threshold psychosis, in the JJS population based on SIPS interview data.**1C**: **Examine the accuracy (i.e., sensitivity, specificity) of the MAYSI-2 and *PQ-B*** in identifying youth with psychosis-spectrum disorders, as defined by the SIPS.

Aim 2A: Examine whether an enhanced referral procedure results in higher rates of completed referrals to the CSC compared to standard referral procedures by comparing rates of completed referrals in Phase I, standard care, versus Phase II, when an enhanced referral/linkage to care procedure is instituted in JJS. **2B: Identify implementation and service level factors that promote/hinder linkage to the CSC** by assessing feasibility, as determined by penetration (i.e. number of JJS personnel trained, and consistency in using the enhanced referral protocol) and acceptability (i.e., JJS staff perceived roles in screening and referral). Barriers and facilitators to linkage to CSC services will be examined as will equity of the linkage across gender, race, and ethnicity. Efficiency will be rated by the number of text message and phone contacts necessary to complete the referral to the CSC. These data will improve understanding of service level factors that influence implementation of these procedures, with implications for both a future trial and real world practice.

Aim 3A: Investigate client level factors, including attitudes about CSC referrals and the rates of treatment initiation/retention in CSC services. This data, collected at the 3 month follow-up, will also allow examination of the effects of the intervention on DUP as well as treatment barriers and motivation for treatment. **3B:**

Investigate mental health indicators at follow-up including psychotic symptoms and other outcomes (i.e., symptoms, social/role functioning), as well as juvenile justice contacts. **Aim 3C. Investigate the relationship between service mechanisms (treatment linkage/attendance) and psychotic symptoms/DUP.**

Research Strategy

A. Background. Psychotic disorders are among the most costly and emotionally devastating mental health conditions. Psychosis typically emerges in late adolescence or young adulthood, a period of development when individuals are pursuing critical milestones in the formation of their identities and life goals[8]. The emergence of psychotic symptoms during adolescence can cause a great deal of distress and disruption, oftentimes leading to long-term illness and functional impairment, with poorer prognosis for those with earlier onset symptoms[9]. Those with psychosis-spectrum disorders have markedly increased rates of suicidal behaviors[10], and although severe violence is uncommon in this population, individuals in their first episode of psychosis are at high risk of committing violent acts and coming into contact with the legal system prior to receiving treatment[11]. Evidence supporting the benefits of psychosocial intervention in the early stages of psychosis has inspired ongoing efforts to identify individuals experiencing subthreshold symptoms and initiate appropriate services for symptom monitoring and/or treatment prior to the onset of full-threshold psychosis.

Prodromal psychosis. Although psychotic symptoms may emerge acutely within a "first episode" of psychosis, colloquially termed a "psychotic break," schizophrenia spectrum disorders are often insidious in nature, with positive symptoms initially emerging as low-level attenuated experiences that, over time, become increasingly distressing and impairing. This gradual onset of symptoms is not only associated with prolonged distress, but also poorer long-term outcomes. While the incubation period for psychotic symptoms varies greatly between individuals, many report a period of months to years during which psychotic-like experiences increase in frequency, intensity, and associated interference before they receive appropriate care. Insidious symptoms often go unrecognized for a host of reasons including confusion (among patients and individuals close to them), lack of insight, embarrassment, attempts to minimize the significance of or hide symptoms, and belief that symptoms will resolve on their own. Thus, psychosis-spectrum symptoms often progress, untreated, until acute level care is warranted, and onset characterized by gradual progression of symptoms is associated with longer duration of untreated psychosis (DUP[12]). Not surprisingly, longer DUP is associated with particularly poor clinical, functional, and cognitive outcomes, and the more broadly defined duration of untreated illness (DUI; which includes prodromal and full-threshold stages of illness) may be more strongly linked to psychosocial outcomes[13]. Overall, the DUI/DUP evidence suggests a need to recognize and treat early psychosis-spectrum symptoms to maximize recovery and minimize the personal and financial sequelae of illness[9].

Clinical high-risk states. Advances in understanding the prodromal stages of psychosis have led to the development of a relatively new diagnostic category, Attenuated Psychosis Syndrome (APS), that is now included in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). Individuals with APS are those determined to be at clinical high-risk (CHR) for psychosis based on their endorsement of subthreshold positive symptoms (i.e. delusions, paranoia, grandiosity, hallucinations, and disorganized communication/thoughts) that are distressing and interfering, yet lacking in intensity, frequency, or conviction necessary to meet a full-threshold psychosis diagnosis[14,15]. Individuals with APS have been shown to have a markedly high risk of developing future psychosis, as approximately 36% of those identified will transition to psychosis within three years[16]. Fortunately, treatment initiated among those determined to be at CHR, prior to psychosis onset, has the potential to alleviate severity, delay onset, and, in some cases, prevent the development of full-threshold symptoms[17]. Evidence showing positive outcomes associated with the initiation of treatment during the prodromal phase and proximal to the onset of psychosis calls for early identification initiatives aimed at recognizing potentially prodromal symptoms and related markers of early illness.

Identifying individuals at risk for psychosis. Advances in understanding the prodromal stages of psychosis have led to the development of assessment tools aimed at identifying individuals at CHR for psychosis[14,15]. Interviews that focus on subthreshold positive symptoms that can be reliably rated and classified have been shown to identify individuals with a notably heightened risk for psychosis[16]. Unfortunately, these interview-based assessments are costly and require significant training and administration time. Given these hurdles, as well as the low base-rate of psychosis-risk, full interviews are not likely to be widely adopted for clinical use outside specialty psychosis clinics. Therefore, efficient and low-cost first-line screening methods may be more practical tools for identifying individuals who may benefit from thorough psychosis-risk assessment within community settings.

The use of brief psychosis-risk screening tools has the potential to conveniently identify individuals who may benefit from a thorough interview-based evaluation[7,18]. Several screening tools have been developed and validated among help-seeking clients in the context of psychosis-risk clinics[19], however, given constraints related to implementation of new, specialized measures within community settings, it is likely that a more feasible and acceptable approach to screening would include the use of key items within a broad measure of mental health concerns. Key-item screening is defined as the use of a limited number of specific items across

a wide range of clinical domains to, 1) assess risk, and 2) prompt further probing within specific areas of concern. If a client endorses a key item, the clinician follows up with additional questionnaires and/or clinical interviewing. Many non-specific mental health questionnaires have been developed to screen across multiple diagnostic categories, and success in the prediction of certain concerns (e.g., anxiety) has been demonstrated[20–24]. The validity of key items to screen for psychosis risk, however, has never been systematically examined as a means to facilitate more widely adopted intervention for early psychosis.

Youth in the Juvenile Justice System. One high risk group that receives relatively little attention in the literature with respect to identification and referral to treatment for psychotic symptoms is youth involved in Juvenile Justice (JJ). This study will focus specifically on court-involved, but non-incarcerated (CINI) juveniles, who comprise approximately two-thirds of the JJ population seen in the Juvenile Justice System (JJS). In Rhode Island, these youth, typically ranging in age from 11-18, have their first contact with the JJS in the Rhode Island Family Court (RIFC) Juvenile Intake Department (JID), a diversion based program for first-time offending youth. Most first-time offending, CINI juvenile offenders are diverted through monitoring (typically 90 days) by a juvenile intake coordinator who makes various referrals (e.g., substance abuse treatment, mental health evaluation) and closely monitors adherence with the caveat that intake requirements must be completed to avoid further JJ involvement (see letter of support from Chief Judge Michael Forte).

Linkage to treatment among JJ youth. In RI, the majority of youth (67%) who made their first contact with the JJS fell into the caution or warning range of at least one mental health subscale of the Massachusetts Youth Screening Instrument- Second Edition (MAYSI-2) with 40% flagging on at least 2 subscales[25]. For many youth, the JJS is the first point of contact for mental health support[26] and often their only access to these services[27]. CINI youth who endorse recent psychiatric symptoms on screening tools generally do not have immediate access to a medical or mental health provider for services[28,29]. For example, Burke and colleagues (2015) found that 74% of youth who made their first contact with the JJS had a psychiatric disorder, yet only 20% reported receipt of mental health services at follow-up assessments[30]. In another study, youth in the JJS had the lowest rates of mental health treatment utilization in a large sample of adolescents who received services in at least one public sector of care, e.g., alcohol and drug services, child welfare, etc[31]. Lack of access to needed mental health services among JJ youth[32], may increase risk for a range of future psychopathology, including psychotic symptoms. *Connecting JJ youth to care is a priority of this application.*

At the RIFC JID, evidenced-based screening measures, including the MAYSI-2, were implemented in 2014 to screen CINI youth for mental health and substance use issues. To date, 11% of these youth flag in the caution or warning range on the MAYSI-2 Thought Disturbance subscale[33]. Unless they are floridly psychotic and require emergency care, the overwhelming majority of these CINI youth return home with referral information to a community mental health clinic or, at best, a future mental health appointment with a poor rate (48-62%) of treatment uptake in the RI community[33]. The National Center for Mental Health and Juvenile Justice (NCMHJJ) Blueprint for Change goals include access to mental health treatment for all youth who endorse mental health symptoms indicating risk for a possible crisis or self-harm[34], a frequent concern of individuals with psychotic symptoms.

What prevents use of mental health services in JJ youth? Nationally, a commonly cited barrier to JJ involved youth receiving mental health care includes poor identification of mental health problems and referral to care. Mental health screenings are underutilized within the JJS and psychiatric disorders are often not detected[35]. For example, Hoeve et al. (2014) found that only 60% of youth with a psychiatric disorder received a treatment referral following probation or detention intake, with the lowest rates of referrals given to those with internalizing disorders[35]. In another study of substance using CINI youth, only 18% received referrals to JJ drug and alcohol services[36]. Of youth endorsing suicide ideation at the JID screening, 14% of youth were not referred to mental health services[37]. Minority and disadvantaged youth, who are overrepresented in the JJS, have particular problems with access to care[38–41]. In the Rhode Island JID, for example, white youth had 3.37 greater odds of being referred compared to black youth ($p < .01$) who endorsed a lifetime history of trauma.

In addition, when given referrals, CINI youth and their families often do not follow through with court recommendations and referrals, posing significant challenges for JJ staff in monitoring and enforcing juveniles' compliance with court orders. Factors related to nonadherence include living situation[42], poor family and social functioning[43], and social disadvantage[44]. Many adolescents and guardians may also exhibit low levels of motivation to change as a result of being court ordered to seek intervention[45,46]. *In this application's intervention protocol, we pay particular attention to educating caregivers about mental health treatment and improving access to care by linking families to appointments for specialized psychosis-spectrum care at the time of their positive screen at the JID.*

Early psychosis intervention through Coordinated Specialty Care. Given the rise in recognition of psychosis-risk syndromes and the promising benefits of early psychosocial care, specialized psychosis-spectrum intervention services are being established across the nation. Coordinated Specialty Care (CSC) intervention programs offer tailored services to clients with psychosis-spectrum disorders to help individuals effectively manage early symptoms and comorbid concerns (e.g., difficulties related to mood, anxiety, attention, and substance abuse), preserve functioning, and reduce the long-term impact of illness. As stated in

the FOA, "CSC treatment involves integrated, team-based care and typically features use of single antipsychotic medications, prescribed in low doses; family psychoeducation; supported employment and/or education; cognitive-behavioral therapy oriented to recovery; coordination with primary care services; and continuity of care across inpatient and outpatient treatment settings". Rhode Island has two CSC clinics funded by the 2014 SAMSHA set-aside in the Community Mental Health Block Grant Program grant to the state. In this research project, we will partner with the CSC based at the Kent Center, the mental health clinic based in Warwick, RI, which is the second largest city in the state and only a 15-minute drive for families that live in Providence, RI, where the largest JID is located. The CSC based in Warwick, called the Healthy Transitions program, uses a team approach to provide case management, family psychoeducation, individual and group therapy, coordination of mental health and primary care by a nurse clinician, psychiatry consultation, substance abuse specialty care, employment and education counseling, and wraparound case management. *The CSC accepts patients regardless of insurance status; schedules evaluations typically within 2 weeks; provides evening appointments and can be reached by public transportation. Families can be reimbursed for travel costs.* (See letter of support from Barbara Lamoureux, Program Director).

Model for dissemination and implementation. The manner in which best practice is implemented in JJ settings is important given challenges specific to the JJS. More than 60 dissemination and implementation (D&I) research models were identified in a D&I literature review[47]. The Conceptual Model of Implementation Research (CMIR)[48], developed from the mental health service field, is most consistent with the current study's goals to utilize strategies to introduce evidence-based practice within a specific setting, juvenile justice[48–50]. CMIR was chosen because of its focus on implementation research with mental health interventions across socio-ecological levels relevant to the court setting (e.g., system, organization, and individual levels). Successful implementation ensures feasibility, fidelity, context/population responsiveness, and sustainability[49].

In this application, we will train front-line staff in the JID to implement an enhanced referral procedure to CSC when an adolescent has screened positive as potentially at risk for psychosis (based on their responses on the MAYSI-2 Thought Disorder subscale or *the Prodromal Questionnaire – Brief Version; PQ-B[7])* in order to develop a feasible, disseminable process of referral for appropriate mental health services. We will also test whether this enhanced referral process results in better linkage to care and improved outcomes compared to the baseline control condition. We will examine CMIR-specific implementation strategies, separate from the intervention strategies, with the goal of evaluating outcomes at the: implementation-level, such as the number of personnel trained and using screening and referral procedures for adolescents with psychosis-spectrum symptoms in the JJS; service-level, e.g., quality of the referral performed by CSC staff and the percentage of time treatment linkage is completed; and consumer (patient)-level, in particular, outpatient treatment attendance, and psychosis-spectrum symptoms. While the ultimate goal of implementation efforts is improving clinical outcomes, this model also provides an understanding of the mechanisms through which gains are conferred in order to improve both conceptual models of referral processes and the referral process itself.

SIGNFICANCE. The current study proposes a scalable intervention designed to increase identification and linkage to CSC for adolescents involved in the JJS who present with psychosis spectrum symptomatology. Juvenile courts, and the JJS broadly, are increasing the proactive screening of youth for mental health symptoms. However, there is an inevitable lag between screening and an outpatient mental health appointment which, in turn, is followed by generally poor uptake of outpatient treatment. This application's approach is consistent with FOA language, specifically the NIMH interest in "better signal detection of psychosis onset, or symptoms suggesting high clinical risk of psychosis, within …. criminal justice agencies," as well as "methods to achieve expeditious referral of persons with first episode psychosis (FEP), or those at high clinical risk of psychosis, to an appropriate specialty care treatment program". As specified in the FOA, this planning grant application will also: "identify a baseline rate of DUP", as well as explore the occurrence of psychosis-spectrum symptoms among high risk JJ youth, "identify bottlenecks and gaps in the pathway to CSC care", and "develop and pilot test feasible strategies for substantially reducing DUP". The scientific premise of this research is supported by the need to develop more effective screening and linkage to service strategies during a youth's contact with the JJS, the virtual absence of such studies in the literature, and its enhancement by use of a conceptual model for implementation. Our study will provide data on screening delivered by JJS staff and improved linkage to follow-up mental health care as the clinical services mechanism hypothesized to reduce the DUI/DUP. As requested in the FOA, we will also "provide evidence of the association between those targets", i.e. latency to treatment linkage and engagement in treatment, and "the outcomes of interest (e.g., DIU/DUP, symptoms, and functioning)". In exploratory analyses, we will also assess potential moderators that may inform which youth most benefit from this screening/referral intervention, including adolescent sex, gender, race, ethnicity, and socioeconomic status, as well as service level factors, i.e., fidelity of JID and CSC staff to the referral process. This research also has the potential to directly inform clinical practices in JJS settings and has significant implications for scalability and dissemination. Scientific rigor is maintained by ensuring fidelity to the brief screening/referral protocol, study retention procedures, blinding of research assessors, data analytic strategies including missing data procedures, which are described in detail in the approach section below. Additionally, relevant biological variables, specifically sex, are considered in the

experimental design. If the number of females is sufficiently large, we will report results separately by sex but do all primary hypothesis testing without sex stratification. We will also conduct analyses with boys alone because the sample will be largely boys.

B. INNOVATION: The proposed study is innovative in that it proposes a new approach to screening and referral with adolescents at high risk for or in the early stages of psychosis by: 1) using a protocol that is designed from the start to be readily disseminable to other JJS settings; 2) measuring moderators and mechanisms of action underlying the enhanced referral protocol; 3) examining the MAYSI-2/PQ-B as screens for psychosis risk; and 4) *examining gender identity, given that those who identify as transgendered have high rates of psychotic symptoms* [51] *but this question has not been examined in the juvenile justice population.*

C. APPROACH

Overview of study procedures. This study will be implemented as a roll-out trial, a commonly used approach in system-wide intervention designs[52,53]. During the JID intake process, all juveniles attend their appointment with a caregiver/legal guardian and complete the MAYSI-2[54] and PQ-B. Youth will be eligible to participate in the study if they flag on either the caution (2 items endorsed) or warning (3 or more items endorsed) cut-offs on the 5-item MAYSI-2 Thought Disturbance subscale, *or the cut-off score (> 6)* on t*he PQ-B. Using both measures will allow us to examine rates of false positives on the MAYSI-2, which is commonly used in juvenile justice settings, enhance identification of females at risk, which is a relative weakness of the MAYSI-2, but not the PQ-B, and collect data on the PQ-B with this population, adding to the database of this commonly used measure in NIMH-funded studies (Personal communication, PO Susan Azrin).*

JID intake workers will contact the research team when a youth screens in. As a back-up system, the JID workers turn in their MAYSI-2/*PQ-B* forms to the RIFC Mental Health Clinic (MHC) each day so the mental health team can determine if any further mental health evaluation is necessary for endorsement of any symptom. Co-Is Thompson and Kemp will be involved in this process so that if a youth who screened in on the Thought Disturbance subscale was not referred by the JID intake worker, they will be contacted by research staff if they signed the consent to contact form. Co-I Thompson, the Research Coordinator, or an RA, both of whom will have an office in the RIFC MHC on the same hallway as the JID, will consent/assent families. Research staff will be registered as court interns which will allow access to court records and the court calendar. Co-I Kemp, who also has an office in the MHC, will be the back-up for approaching families.

Because there are several research projects being conducted in the RIFC JID, Co-I Kemp has established a procedure whereby all families in the waiting room are approached by an RA and asked to sign a "consent to contact" form. If a parent signs this form, and the teen subsequently screens positive and qualifies for a study being conducted in RIFC after the JID intake worker administers the MAYSI-2/*PQ-B*, research staff will then meet separately with parent/caregiver and the juvenile to describe study procedures in detail and 1) obtain juvenile assent without parental presence (note: no juvenile will ever be sanctioned by the court for not agreeing or being unable to participate in the research study; see Human Subjects/RIFC Chief Judge Letter of Support), and 2) obtain written informed consent from the parent/caregiver. If the research team is unable to meet with the family while they are at their intake appointment, the family will be contacted by phone/text and an appointment, either at the RIFC or at the family home, to consent/assent the parent and teen, and conduct the baseline assessment. Consenting procedures will also include permission to access court records.

Intervention condition overview. The intervention will have two phases: 1) a Standard Care (baseline control) condition, followed by, 2) an Enhanced Referral/Linkage to Care condition. Because this is a roll-out trial, the two conditions will be compared using a non-randomized open trial design. **Design Consideration**: *We decided against randomization due to the following reasons: a) use of front line workers, as opposed to research staff specifically employed for the purposes of the research study, could result in contamination across the two study conditions; b) randomization would create the potential for therapist characteristics having a primary effect on referral outcomes; and c) JJS administrators and staff, at this site have expressed concerns that randomization is an unacceptable practice in the JJS because it results in the denial of what is assumed to be a superior service, the Enhanced Referral condition, to 50% of the youth.*

Families approached in **months 3 - 14** (n = 100; 12 months of recruitment) will be in the standard care, baseline control condition and receive standard court procedures, with one exception. If the youth screens positive on the Thought Disturbance subscale or PQ-B, the intake worker will be instructed to refer the family to the CSC, rather than their local mental health clinic.

During **months 6 – 17**, follow-up assessments of the standard care group will be completed and in **months 18 – 19**, JID intake workers will be trained in the Enhanced Referral/Linkage to Care protocol as will the CSC staff who receive the referral from JID intake workers.

Youth consented in **months 20 –31** (n= 100; 12 months of recruitment), will receive the Enhanced Referral/Linkage to Care protocol. Details regarding the content of this condition are described below.

Design Consideration: We considered enrolling an older sample because *we will likely identify a larger proportion of prodromal (CHR) rather than syndromal psychotic disorder youth in juvenile justice. Nonetheless, this application's approach is consistent with FOA language, specifically in "better signal detection of psychosis onset, or symptoms suggesting high clinical risk of psychosis, within …. criminal justice agencies," as well as*

"methods to achieve expeditious referral of persons with first episode psychosis (FEP), ***or those at high clinical risk of psychosis".*** *As specified in the FOA, this planning grant application will also: "explore the occurrence of psychosis-spectrum symptoms".*

We also considered having staff from the RIFC MHC perform a full evaluation before referring to the CSC but MHCs are not consistently associated with JJS nationwide so we opted for a procedure that would be generalizable to the JJS nationwide. Similarly, we considered having CSC staff meet the family at the JID but again felt this would not be a typical service delivery approach and consequently would affect eventual dissemination of our protocol.

Qualifications of research team. This application brings together clinical researchers with expertise in screening, brief intervention, and referral (**PI Spirito, Co-I Wolff**) and mental health in the JJS (**Co-I Kemp**). PI Spirito and Co-I Wolff have collaborated on 7 NIH treatment grants, primarily on adolescents with mood disorders and high levels of affect dysregulation. They are very experienced in conducting treatment trials with adolescents with major psychopathology[55] [39] , and just completed two studies (MH01783; AA020705). All of these studies have included an in-depth assessment of psychopathology. Co-I Wolff also works on the adolescent inpatient unit at Brown's child psychiatric hospital, Bradley Hospital, and routinely supervises treatment teams making differential diagnostic decisions regarding adolescents with psychotic symptoms. PI Spirito is currently conducting a screening/brief electronic intervention for substance misuse in juvenile justice with Co-I Kemp. **Co-I Thompson** brings experience in working with youth with psychosis-spectrum disorders. She has specific expertise in psychosis-risk assessment, having been trained by SIPS creators and worked as a graduate assistant for five years administering comprehensive diagnostic interviews including the SIPS to young people (aged 12-25) as part of the Maryland Early Intervention Program (funded through the Maryland Department of Health and Mental Hygiene, Behavioral Health Administration through the Center for Excellence on Early Intervention for Serious Mental Illness OPASS# 14-13717G/M00B4400241). Co-I Thompson also has experience in the development and administration of DUP interviews among young adults within an FEP clinic at the Maryland Psychiatric Research Center**. Co-I Yen** brings expertise in assessment and brief interventions with high risk adolescents, and has collaborated with PI Spirito on 6 NIMH and 2 private foundation grants. She is currently the PI on a brief intervention for psychosis and suicidality in adolescents/young adults *with patients recruited from an inpatient psychiatric unit* (AFSP grant SRG-0-158-14). She is also the Director of the Training and Assessment Unit at the Department of Psychiatry and Human Behavior at Brown University**. Co-I Kemp** collaborated on three prior NIH funded grants focused on youth involved in the JJS (HD080780; DA034538; DA035231). Currently, PI Spirito is the primary mentor on Co-I Kemp's Mentored Career Award (MH111606), focusing on suicidality among JJS involved youth**.** Co-I Kemp has received extensive training in qualitative research methods and interviewing. She is the Director of the RIFC MHC, which conducts forensic mental health evaluations with youth throughout the JJS continuum, including screening of adolescents with psychotic symptoms. She is very experienced in conducting research and examining clinical need with JJS involved youth. Co-I Kemp has worked extensively with the Chief Judge and Deputy Court Administrator, Kevin Richard, to implement research protocols within the court setting. She also oversees JID intake workers on screening youth for mental health and substance use issues with the MAYSI-2.

The assembled research team collectively brings expertise in the assessment of adolescents with a broad range of psychopathology, including psychosis-spectrum disorders, experience in conducting community-based research, and experience in improving assessment and referral within the juvenile justice system.

Participants. JJS offenders, ages 12- 17, will be eligible for enrollment with the following criteria: 1) legal guardian available to consent for juvenile's participation, and adolescent assents to participate; 2) juvenile is English speaking; parents may be Spanish-speaking because we will have Spanish-speaking research staff and interpreter services available; and 3) juvenile flags positive on the MAYSI-2 Thought Disturbance subscale or the PQ-B. Exclusion criteria include: 1) observable developmental delays that would interfere with obtaining assent and/or accurate assessment, and 2) juvenile meets hospital level of care for imminent risk due to severity of symptoms, in which case they will be transported to Emergency Department per existing JID procedures. In addition, we will collect a comparison sample (n = 70) meeting these same inclusion/exclusion criteria with the exception that they will screen negative on the MAYSI- 2 Thought Disturbance subscale and PQ-B. This subgroup will be used in analyses exploring the sensitivity/specificity of the MAYSI-2 Thought Disturbance subscale *and PQ-B.. The* MAYSI-2 is a 52-item self-report measure for ages 12-17 that screens for current MH symptoms. The Thought Disturbance Subscale consists of 5 items, 4 of which refer to altered perceptions of reality and the fifth to de-realization. The developers do not recommend use of the subscale with girls. *The PQ-B, a 21 item measure for both males and females, with an 8th grade reading level and takes 3-4 minutes to complete. In a sample of 141 adolescents and young adults referred for assessment to prodromal research centers, the instrument achieved specificity of 0.68 and sensitivity of 0.88 with regard to SIPS diagnoses using a cutoff distress score threshold of six or greater on the weighted distress measure. A recent review indicated sensitivity ranging from .70-.97 across different samples*[19].

Racial and ethnic minority considerations. Consistent with 2016 RIFC statistics, ethnic representation will be approximately 18% Hispanic and racial representation will be about 22% African American or Black

(and other) and 72% White. Consistent with US nationwide statistics, African American juveniles are disproportionately represented (22% of juvenile offenders, yet only 6% of the entire Rhode Island population). Approximately 9% of intake cases involve parents who speak only Spanish (see Facilities & Enrollment Table). Females are increasingly represented in the system (29% in 2016) and are disproportionately represented among status offenders (account for 46% of status offenses relative to 11% of violent offenses). We expect our sample to reflect these demographics, but we will over-sample girls if possible to lower the ratio of boys to girls.

Estimated sample size and retention rates. In 2016, the RIFC handled offenses for 2,634 juveniles of whom 764 (29%) were female and 2,581 (98%) who were in the 12-17 year old age range. The JID, for example, typically screens more than 900 juveniles per year and, of those youth who are screened, approximately 11% (N= 99) flag for thought disturbance. With a conservative enrollment rate of 70%, and 12 months of enrollment in both the baseline control (n = approximately 100 positive screens) and experimental intervention condition (n = approximately 100 positive screens), we would be able to meet our projected enrollment goals for both baseline standard care (n = 70) and enhanced referral (n=70) conditions. Using a conservative follow-up rate of 80% of the 140 enrolled and retained participants, approximately 55 families in both the baseline control and experimental condition are expected to complete the 3-month follow-up. In addition, we will recruit 70 youth in Phase I and Phase II who do not screen positive on the MAYSI-2 or *PQ-B* in order to conduct the sensitivity/specificity analyses. These projections are feasible given our excellent working relationship with the Rhode Island JJS including the RIFC and prior experience recruiting from the JID (see RIFC Chief Judge Letter of Support). Co-I Kemp collaborated on a 24-month longitudinal epidemiological study of first-time CINI offenders at the RIFC and she successfully recruited the entire sample of 400 first-time offending CINI youth (DA034538). Co-I Kemp is also currently recruiting at the RIFC JID for a baseline sample of suicidal CINI youth for her NIMH K23 Mentored Career Award. PI Spirito also successfully established a referral system from RIFC to two completed grants, NIAAA (AA017659) and NIDA (DA0029871) trials for youth with substance use-related court involvement.

Protection against attrition. To maximize participant retention, we will employ procedures routinely used in our studies to reinforce with JJS families the value of the follow-up portion of the study and to use all available resources to locate participants. Contact information will include the names and phone numbers of two friends/family members who can be contacted if staff is unable to reach the teen. We will also ask for the parent and teen cell phone numbers and emails. Contact information will also be updated periodically prior to the 3-month follow-up assessment. Participants will also be given refrigerator magnets and pens with the program's contact information as well as a card with the date for the follow-up assessment. Reminder postcards, text messages, and emails will be sent to participants. Telephone calls will also be made to participants. Weekly case review meetings will be held with the PI and Co-Is to review no-shows and plans discussed to complete contact with the participant. We have used these procedures with success in prior projects. Participants will be contacted 1 week prior to their follow-up appointment. In PI Spirito's NIAAA-funded study with CINI youth, retention rates were 94% at 3 months and 84% at 6 months

Compensation for participation. Families will be compensated $100 for each assessment ($50 each, for a parent and the teen, at baseline and 3-month follow-up).

Referral Conditions

Phase I, months 3 – 14: Standard Care (baseline control) condition. In the Standard Care condition, if a teen has a positive screen on the MAYSI-2/*PQ-B screening battery*, JJS staff members determine whether there is need for further evaluation or concern of imminent risk. If there is concern for imminent risk, then the staff member contacts a clinician in the RIFC Mental Health Clinic for an emergency evaluation. If the teen is not at imminent risk, a referral to a community mental health clinic is arranged by the JJ intake worker. In this application, we will follow the same procedures, but if there is no imminent risk, the JID staff member will refer to the CSC rather than a community mental health clinic. *The CSC will evaluate the teen and offer services at the CSC if psychotic symptoms are a primary concern. CHR youth with other primary issues (e.g., trauma, substance use) are typically seen by other services in the mental health clinic which houses the CSC. All CHR youth who consent to the study will be seen for follow-up assessments and can be referred back to the CSC or mental health clinic to resume/initiate treatment if symptoms worsen. In the data analysis, we will record the percentage of youth referred to the CSC who are CHR/psychosis risk, as well as the services they receive and clinical outcome data at the 3 month follow-up assessment.* Data collected by Co-I Kemp indicates that 26% of the youth that present to JID report that they are already receiving mental health treatment. In such cases, the families will be referred back to their mental health provider with the recommendation to consult the CSC.

Phase II, months 20 – 31: Enhanced Referral/Linkage to Care condition. The Enhanced Referral/Linkage to Care condition follows the same steps as described in the Standard Care described above if there is imminent risk. If there is no imminent risk, the JJ intake worker contacts the CSC program directly for a "warm hand-off". The CSC intake worker will speak with the parent and arrange for an intake evaluation, either at the CSC clinic or at the family's home. For families that are already receiving mental health treatment, the JID intake worker will arrange the referral to the CSC for a consultation, at the CSC or family home. After the appointment is arranged, the JID intake worker reviews some psychoeducation material about the role of

mental health care in emotional/behavioral problems (see below).

In addition, the CSC clinician who takes the phone call will use a motivational interviewing style to encourage families to follow up with their scheduled appointment. This portion of the protocol is based on a module from PI Spirito/Co-I Wolff's protocol that was recently tested in two randomized controlled trials (MH01783; AA020705) that are nearing completion (see below).

Psychoeducation material. The JID intake worker will review a handout on common symptoms of emotional distress and how youth and parents benefit from seeking mental health services. More specifically, the document outlines how to recognize warning signs of emotional distress, and the importance of finding support for difficulties that interfere with functioning and quality of life. We decided to use a generic description of emotional problems, including some psychosis-like experiences as well as other common concerns, rather than a description of specific psychosis-spectrum symptoms, because we believe it is more consistent with the level of training of JID workers and avoids the premature implication of a psychotic disorder diagnosis. In addition, to ensure these procedures can be easily disseminated in the future if they appear useful, we kept this aspect of the protocol very straightforward. The JID Intake worker will just be asked to read through the handout with the parent and not required to learn any interview material about mental health care or psychosis-spectrum symptoms. The review of the psychoeducation material will be presented with the goal of enhancing the chances that the family will follow through with the CSC appointment.

Motivational interviewing prompts. Similar to the psychoeducation aspect of the protocol, the CSC clinician will not be required to learn any interview material but instead will have a sheet with the following prompts adapted from motivational interviewing protocols by Drs. Spirito and Wolff. The decision to keep this aspect of the protocol very structured was to ensure its eventual disseminability. Prompts include:

Do you think it is necessary for your child to be seen at the clinic?
May I share a few concerns I have?
Some teens who have thoughts such as [specify] often get worse as they get older. For many teens, it's only temporary and they start to feel better after they start talking to someone.
And for some teens there are medicines that can help with these thoughts quite a bit.
Getting help for these thoughts early is important so we really encourage parents to get it checked out.
How are you feeling about going to the clinic appointment?
What might get in the way of you being able to do that (i.e., transportation, insurance, time of day)?
Is there anything we can do to help make it easier for you to get to the appointment?
We can call you the day before or the morning of the appointment to remind you -- would you like that?

Follow-up reminders to set up a CSC appointment. Three and seven days after the referral to CSC, the JJ intake worker will text the teen's parent/caregiver to see if the family kept their appointment with the CSC. If not, the intake worker will text the parent the phone number for the CSC and will also ask permission to contact the CSC to further assist the family in setting up another appointment. JID workers can also choose to contact families by phone. A record of contacts will be recorded in order to examine feasibility, acceptability, and efficiency of these procedures.

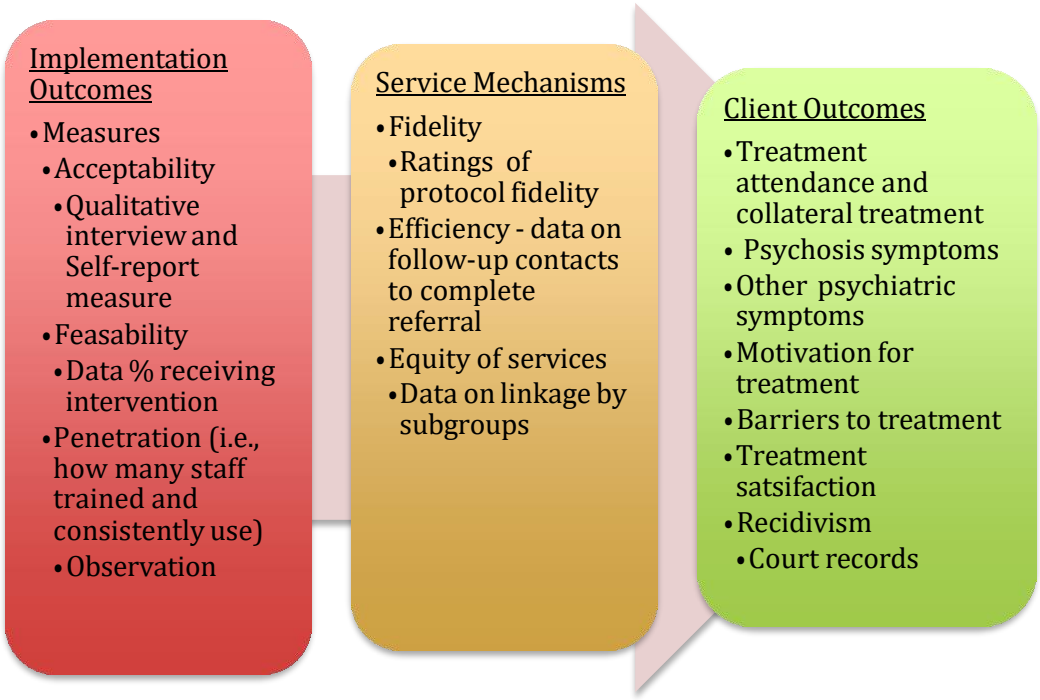
Training JID and CSC workers in Enhanced Referral protocol (months 18 -19). A one hour training in this protocol will be conducted to mimic the type of training that would occur in typical circumstances. For the JID intake workers, we will: 1) review the MAYSI-2 Thought Disturbance subscale *and PQ-B* and discuss why these symptoms might be potentially significant for these youth; 2) review the handout about symptoms of mental health problems in youth as well as the importance of a follow-up evaluation; 3) review the concept of the CSC and why a referral to the CSC would be potentially helpful to the adolescent; 4) review the need to arrange a referral to the CSC for a consult even if the youth is already receiving mental health care elsewhere; and 5) role play the "warm hand-off" procedures used when referring families to the CSC.

There will be no ongoing supervision of the JID intake worker because that would be the most likely situation in a typical JJS intake department. Instead, we will: 1) as part of routine staff meetings, the JID intake workers will be reminded about screening for mental health problems with the MAYSI-2/*PQ-B* and the referral procedures for youth flagging in on any problem, i.e. substance use, suicidal ideation, or thought disturbance; 2) have the JID intake workers complete procedural checklists at the end of the interview that prompt them to follow referral procedures (we have had success with improving procedures with this type of self-monitoring in two recently completed RCTs); 3) as part of the research procedure, in their daily review of MAYSI -2 *and PQ*-B forms, research staff will identify anyone who screened positive on these measures and check with the JID intake workers about whether they completed the self-monitoring checklist, reviewed the handout with the parents and made a direct referral to the CSC. This procedure serves as a feedback mechanism to JID staff and as a reminder to complete the referral protocol with youth.

Fidelity to the Enhanced Referral/Linkage to Care condition. We will have the CSC clinician, who will be employed by the research project but also work at the CSC, audiotape their conversation with the family in the enhanced referral phase of the study. The CSC clinician will use a hand-held audio recorder so that only the CSC clinician's portion of the conversation will be recorded. Fidelity will also be rated by interviewing the parent/caregiver at the baseline research assessment, which will typically occur within a week of the JID

appointment. Caregivers will be asked what the CSC intake worker said to them about scheduling a CSC appointment. The RA conducting the assessment will record verbatim the parent's responses. In both the clinician reported and parent reported data collection, fidelity will be rated by PI Spirito and Co-Is Wolff and Yen on a two-point scale (0= not satisfactory; 1= satisfactory). If there is disagreement, a consensus meeting will be held to resolve discrepancies in ratings.

Baseline and follow-up assessment. Families in both phases of the study will complete the same assessments at baseline and 3-month follow-up to gather data on treatment history, psychosis-spectrum symptoms, general psychiatric symptoms and functioning, as well as JJS contacts (see details below under Measures). In addition, at follow-up, we will interview families about barriers to treatment linkage and treatment satisfaction. The RA and Co-I Thompson will be blind as to whether the families were seen for follow-up CSC or mental health care until after the interviews are completed.



We will also interview JID intake workers and CSC staff to assess both services and implementation factors related to referral process and completion. The baseline and follow-up assessment battery were designed to minimize participant burden and to thoroughly assess psychosis-spectrum symptoms. The follow-up assessment will be scheduled 3-months post-referral to the CSC. The 3-month follow-up period will allow us to assess whether high risk youth engage in treatment with the CSC or other mental healthcare. Both baseline and follow up interviews will be conducted in-person and last approximately 1.5- 2 hours.

Co-I Thompson will administer the Structured Interview for Psychosis-risk Syndromes (SIPS), described below. She has received formal training and certification by SIPS developers to conduct the interviews, and she was trained to research quality reliability (ICC>.8) within her prior research team. She will administer all the SIPS interviews in order to maintain consistency across the two phases of the study as well as across participants. At baseline, when we will assess youth with both positive and negative screens, Co-I Thompson will be "blind" to whether youth have screened positive or negative. At follow-up, she will know that all youth have screened positive on the MAYSI-2 and *PQ-B*, but the RA and Co-I Thompson will instruct families not to disclose whether they followed through with the referral to the CSC or whether they have received any type of follow-up mental health care until after the assessment is completed.

Training in assessment. Training in the assessment protocol will occur during the first 2 months by Co-I Wolff, following procedures we used in other RCTs. Under Co-I Kemp's oversight, research staff conducting baseline assessments will also receive training on working in the JJS and on how to appropriately respond to logistical questions that participants' may have about the JJS. Co-I Kemp will oversee the baseline assessment and Co-I Wolff will oversee the follow-up assessment component of the protocol. If parents request it, the results of the evaluation will be shared with the CSC in both phases of the study.

Procedures for mental health deterioration/safety concerns. It is possible that some participants will report symptoms during their research assessment that may warrant additional mental health care. If any youth indicates serious psychotic symptoms or suicidal/homicidal thoughts, a safety plan will be established by Co-Thompson. Either Dr. Spirito, Wolff, Kemp, or Yen all licensed clinical psychologists, will be notified and review the safety plan. In all cases, if families are in treatment at the CSC, or a mental health clinic, a mutually agreeable plan will be derived with the CSC clinical team. In the event of an acute crisis, patient will be transferred to the Rhode Island Hospital (RIH) psychiatric Emergency Department, where all the PI and Co-Investigators Wolff and Kemp have staff appointments and clinical privileges (See **Human Subjects**).

Measures. The selection of measures was designed to be realistic for the court system with an emphasis on eventual implementation in a larger effectiveness trial. All assessments will be administered via laptops

using REDCap (Research Electronic Data Capture), a secure web-based application.[48] An advantage of computer-administered self-report assessments is that participants using this medium have been found to be more comfortable disclosing personally sensitive information and to be less likely influenced by social desirability in their responses[49]. Using REDCap instead of traditional pencil and paper measures will also save time and labor that would otherwise be required for data entry, double entry, and resolution of discrepancies. To ensure participant safety, all items will be reviewed by research staff before the end of the assessment in case there is a need to review responses with the youth or caregiver.

1. Background variables (obtained at baseline only).

Standard demographic variables including age, sex, race, ethnicity, and education will be assessed, including gender identity. Gender identity will be assessed using items listed in "Current Measures of Sexual Orientation and Gender Identity in Federal Surveys, August 2016". Specifically, we will ask "Do you currently describe yourself as male, female, or transgender?" If transgender, we will ask "Just to confirm, you were assigned [M or F] at birth and now describe yourself as [M or F], is that correct?" Legal history, as well item-level responses on the MAYSI-2 and *PQ-B*, will be obtained from JID records as part of the consent process. The collection of much of the data from legal records and existing JJ system procedures is an additional strength of this service-based application as it improves feasibility and the potential for scalability in the future.

2. CMIR implementation level measures

These data will be collected and measures will be administered to JID staff and administrators at the conclusion of Phase II of the project.

Feasibility will be defined as the percent of youth who screen positive on the MAYSI-2 Thought Disturbance subscale and/or *PQ-B* who receive the Enhanced Referral/Linkage to Care protocol in Phase II of the project. Follow-up rates of texting/phone calls will also be examined separately with respect to its feasibility.

Penetration will be measured by the percent of *personnel* who are trained to deliver the Enhanced Referral/Linkage to Care condition brief intervention.

Acceptability will be assessed using qualitative interviews with JJ staff related to their perceived roles in screening and using the Enhanced Referral/Linkage to Care protocol. In addition, the *Attitudes Toward Mental Health Screening*, a 15-item scale that assesses clinician's attitudes towards and self–efficacy in relation to screening and intervention[58], will be administered at baseline and follow-up. The measure has 4 subscales: positive attitudes, level of confidence, perceived barriers, and role congruence towards mental health screening. Staff rate each item on a five-point scale from "not at all" to "a very great extent".

3. CMIR service-level measures

Fidelity will be assessed using the rating procedure described above. Fidelity will also be considered a marker of the quality of treatment linkage in conjunction with the percent of referrals completed to the CSC.

Efficiency will be rated by the number of text message and phone contacts necessary to complete the referral to the CSC.

Equity will be measured by examining differences by sex/gender and racial/ethnic subgroups in the numbers of at-risk youth who receive the Enhanced Referral/Linkage to Care condition, fidelity/quality of the Enhanced Referral/Linkage to Care protocol, and actual completion of the referral to the CSC.

4. CMIR client (patient) level mechanisms

CSC services. These data will be collected from the CSC with signed, written consent of the parent, and assent for those adolescents under age 18.

Other non-CSC services. *The Child and Adolescent Services Assessment* [CASA[59]] is a parent-report instrument designed to assess at follow-up the use of mental health services for youth across 31 settings including inpatient, outpatient, and informal services. The measure has acceptable psychometric properties. Collateral[60] information on treatment attendance (attendance at first treatment appointment and total number of treatment sessions attended) will also be collected by contacting each juveniles' treatment provider at the 3-month follow-up. A release of information is requested at baseline, for both primary care physicians (PCP) and their mental health provider/agency, as part of the court intake process. The consent form will also contain language allowing the research team to collect this information from the youth's treatment providers.

Treatment motivation *(self-report and parent/caregiver report).* The *Motivation for Youth's Treatment Scale*[61], an 8-item measure, will be used to assess the youth's motivation to engage in treatment at baseline and at follow-up. The total scale and two subscales (Problem Recognition and the Treatment Readiness) produce alpha coefficients of above .80.

Barriers to treatment. *The Barriers to Treatment Participation Scale*[62], a 44-item measure, will be completed at baseline and 3-month follow-up by caregivers to assess barriers that parents/caregivers experienced since intervention and the role those barriers may play in treatment engagement. Alpha coefficients range from 0.61 to 0.80.

Treatment satisfaction information will be gathered as part of the follow-up qualitative interview. Youth and caregivers will be interviewed about their satisfaction with the Enhanced Referral process as well as treatment at the 3-month follow-up.

5. CMIR client (patient) level outcomes

General psychopathology. *The Brief Problem Monitor* (BPM[63]) will be completed at baseline and 3 month follow-up by youth and caretakers to assess general psychopathology including items for rating Internalizing (INT), Attention (ATT), and Externalizing (EXT) problems. The items are drawn from the *Youth Self Report* (YSR) and the *Child Behavior Checklist for Ages 6-18* (CBCL[63]/6-18). The reliability and validity of these measures have been documented. Each item is rated 0 = not true, 1 = somewhat true, or 2 = very true. The BPM was chosen because it assesses behavior over various time periods whereas the CBCL/YSR are designed to assess behavior over a 6-month period.

The Mini International Neuropsychiatric Interview for Children and Adolescents (MINI-KID[64]) is a structured diagnostic interview used to characterize adolescents' past and current psychiatric diagnoses and can be completed in 20-30 minutes. Parents of adolescent participants will complete a collateral assessment of their child's past and current psychiatric diagnoses using the MINI-Kid-P collateral interview. Psychometric properties are acceptable and results in reliable and valid psychiatric diagnoses for children and adolescents.

Psychotic symptoms. *The Structured Interview for Psychosis-risk Syndromes* (SIPS[14]) is a semi-structured interview targeting interviewees' experiences of attenuated symptoms and other indicators of psychosis risk. The SIPS takes approximately 45-90 minutes to complete and assesses the presence of positive, negative, disorganized, and general symptoms. Respondents are determined to meet criteria for psychosis-spectrum disorders/syndromes based on their endorsement and description of five positive symptoms including odd or delusional thoughts, paranoia/suspiciousness, grandiosity, perceptual abnormalities, and disorganized communication. Factors such as the frequency and intensity of positive symptoms, along with the level of conviction (belief that the experience is real) and interference (i.e. associated distress or impairment), are used to determine whether individuals meet criteria for full-threshold psychosis or any of three risk syndromes. The SIPS is the most widely-used psychosis-risk assessment in North America; it has been used to identify individuals with significantly elevated risk for psychosis[16]. Additionally, the SIPS is designed to consider comorbid disorders that may better account for symptoms that could, in isolation, be conceptualized as psychosis-spectrum. The MINI will be completed prior to the SIPS so that comorbid diagnoses will be available. Elevations on the symptom scales of the BPM will also be available and will inform specific SIPS prompts to help with differential diagnosis considerations. In addition, in order to ensure collection of reliable and valid data from the SIPS, Co-I Thompson will audiotape interviews, with participant permission, and she will present the case to two of the Investigators on the study. Differential diagnoses will be discussed as well as whether symptoms might be better explained by other disorders.

In addition to rating current symptomatology at the date of interview, the SIPS is designed to track the emergence and progression of symptoms over time. For all positive symptoms that meet either risk or psychosis threshold, a timeline is established to retrospectively track when symptoms first reached clinical significance and the date when respondents would have first met risk or psychosis criteria. The SIPS is also designed to track symptom progression across assessment time points. At each assessment, the rater determines whether individuals meeting psychosis/risk criteria are best characterized as having progressing (i.e. worsening), persisting (i.e. stable), or remitting (i.e. partially or fully remitting) illness. This onset and trajectory information will be used to define the start of illness as well as to measure DUI and DUP.

Duration of Untreated Illness (DUI). DUI (including DUP) is defined as the time between the onset of symptoms and the initiation of adequate treatment. DUI will be measured using a combination of measures, specifically the SIPS to track positive symptom onset, the CASA to track adequate treatment, and a summary measure to calculate both DUI and DUP. Given that many DUP measures exist, no particular tools stand out as superior[65], and the specific tool used to measure DUP does not seem to have a significant impact on mean or median DUP[66], we will derive DUP in conjunction with established measures of symptoms and treatment. Using a validated measure of psychosis-spectrum symptoms, namely the SIPS, we will be able to create a thorough timeline of symptom onset and progression. Given the lack of consensus in the literature surrounding what constitutes adequate or effective treatment across psychosis and risk populations[67], two reasonable treatment variables will be included in the measurement of DUI and DUP: 1) date of first completed course of antipsychotics for one month or more, or 2) date of initiation of consistent psychosocial treatment (attending 4 or more sessions within 6 weeks), including psychosis-specific symptom monitoring and/or intervention[65–67]. Both of these variables will be captured by follow-up questions on items contained on the CASA, and the earlier of the two dates will be considered the date of adequate treatment provision. We will synthesize SIPS and treatment date in order to calculate DUP and DUI. The DUI summary form will be reviewed with parents to determine if the onset of psychosis symptoms aligns with their perspective of when symptoms emerged (to help account for lack of insight that may interfere with accurate reporting from youth), and clinical judgment will be used to navigate discrepancies and determine approximate DUI/DUP in the consensus meeting.

Functioning. *Global Functioning- Role and Social Scales* (GF-R and GF-S[68]) are clinician rated scales measuring functioning across two domains: role fulfillment and social integration/engagement. This set of scales was developed for the North American Prodrome Longitudinal Study (NAPLS[68–70]), a large multisite study investigating psychosis-risk, as a way to obtain consistent ratings across study sites. The measure was designed for individuals in the age range of highest risk for psychosis (i.e., ages 12-29), and it includes detailed

rating anchors based on developmentally appropriate activities and difficulties that may emerge in early stages of psychosis. Each GF scale includes 10 categories of functioning rated 1-10, with lower scores indicating more impairment. In addition to rating an individual's current level of functioning, the GF scales include ratings of the individual's highest and lowest rating within the past year (rated on the same scale, 1 to 10) to track changes in functioning across time. The GF scales are rated using information gathered through clinical evaluation (e.g., SIPS and MINI). In a recent study comparing the GF scales to similar functioning scales among help-seeking young people, Wilson and colleagues (2014) reported moderate to strong correlations between the measures. In addition to establishing adequate concurrent validity, this study looked at depression in relation to the GF scales and results suggested that the GF scales may successfully separate functioning from psychiatric symptom severity. This possibility, in addition to the brief and easily scored format of the GF scales, made the GF-R and GF-S appealing options for the current study.

Recidivism (collateral data from RIFC database). *Juveniles' recidivism rates* (e.g., new arrests), *description of related charges* (e.g., substance-related, property) and *time detained/incarcerated* (all tracked by the RIFC database) will be available.

Data Analysis Plan

Prior to conducting analyses for the project aims, a series of routine procedures will be conducted to ensure the data accuracy/adequacy. All forms will be checked for missing data. Descriptive statistics will be examined for distributional properties of the variables (e.g., normality, internal consistency). The data will be transformed to achieve normality if needed. Attrition/missing data: It is anticipated that less than 20% of subjects will not have follow-up. We will test for differential attrition across the standard care and experimental condition.

Sex as a biological variable. Our study does include specific a priori hypotheses about sex differences. However, we will tabulate our results separately by sex, although all hypothesis tests will use a unified sample.

For the qualitative analyses described below, stakeholder interviews will be audiotaped, transcribed, and entered into NVivo, a qualitative data management program. Co-I Kemp, who has received extensive training in qualitative methods, will develop coding process in collaboration with PI Spirito and Co-Is Wolff and Yen for qualitative information related to the systems-level factors and implementation process. These coding schemes will be used as a guide and adapted based on emergent themes from the data collected for the evaluation of the Enhanced Referral/Linkage to Care condition. The coherence between qualitative coding schemes and established quantitative measure subscales such as the Attitudes toward Mental Health Screening will allow for triangulation of the rich data captured by this process. As described below, we will examine interest in and acceptability of screening and referral in the JJS stakeholder's perspective, and barriers and facilitators of screening and referral, from both JJS staff and families perspectives.

Aim 1: Identify baseline prevalence of psychotic disorders and psychosis-risk syndromes within the JJ system. We will calculate the percentage of youth who screen positive on the MAYSI-2 Thought Disturbance subscale *and/or PQ-B* over the 2-year period of the study. We will also calculate mean, median, and range of DUI/DUP in months, for both sub- and full- threshold psychosis. Correlations and regression techniques will be used to explore the relation between attenuated psychosis (both individual symptoms and syndromes) and co-occurring symptoms (BPM symptomatology; MINI symptoms and diagnoses). Prevalence estimates will make use of a weighted sample that takes into account the selection probability for SIPS evaluation given MAYSI-2 and *PQ-B* results, so that our results are generalizable back to the population of JJS youth. We will also examine the utility of the MAYSI-2 Thought Disturbance subscale and *PQ-B* as screeners for psychosis-spectrum syndromes and disorders by determining the criterion-related validity (e.g., sensitivity, specificity, positive and negative predictive value) of number of items endorsed for predicting psychosis risk, as confirmed by clinical interview with the SIPS, *as well as compare the two screens*. This analysis will also use the weighted data from the MAYSI-2 and *PQ- B* and SIPS evaluation sample, and logistic regression procedures.

Aim 2A: Examine whether an enhanced referral procedure results in higher proportion of completed referrals to the CSC compared to standard referral procedures by calculating the proportion of completed referrals in Phase I, standard care, versus Phase II, when an enhanced referral/linkage to care procedure is instituted in JJS. An 80% linkage will be considered a success, and reflects the expected linkage proportion in Phase II. The probability of linkage will be contrasted across phases using logistic regression procedures.

Aim 2B: Identify implementation and service level factors that promote/hinder linkage to the CSC. Feasibility and Penetration, the number and percentage of JID personnel trained and consistency (% of time) using the enhanced referral protocol will be calculated with descriptive statistics. A rate of 80% will be the benchmark. Efficiency will be rated by the number of text message and phone contacts necessary to complete the referral to the CSC. A benchmark of two contacts will be considered an indicator of efficiency. Equity of enhanced referral protocol fidelity and treatment linkage across gender, race, and ethnicity will be compared across Phase I (Standard Care) and Phase II (Enhanced Referral/Linkage to Care condition), as well as cross-sectionally in the Enhanced Referral/Linkage to Care condition only, using cross-tabulation approaches. Acceptability. JJS staff perceived roles in screening and referral will be reported in percentages based on qualitative interviews as well as by mean, median, and range of scores on the Attitudes toward Mental Health

Screening measure. A total of 80% of the JID personnel scoring within one standard deviation of the mean on this measure based on the literature will be the benchmark.

Aim 3A: Investigate client level factors at follow-up. Attitudes about CSC referrals. These analyses follow the qualitative interview procedure described above. Rates of treatment initiation/retention in CSC services or other mental health care. Percentages of CSC participation will be calculated with 80% set as the benchmark as will other types of mental health care as rated on the CASA. For those already in mental health care at the time of enrollment, percentages of consultation to the CSC will be calculated, as will the types of treatment received and frequency/intensity of the services. Treatment barriers and motivation. Scores on the *Motivation for Youth's Treatment Scale*[61] and *the Barriers to Treatment Participation Scale*[62] will be analyzed using a paired t-test to determine any changes in these measures from baseline to three month follow-up. Treatment Satisfaction. These analyses follow the qualitative interview procedure described above.

Aim 3B: Investigate mental health indicators at follow-up. Psychosis-spectrum symptoms will be assessed on the SIPS (which will also allow examination of the effects of the intervention on DUP, DUI, and functioning) and other clinical outcomes on the subscales of the BPM. The goal of this aim is to obtain a reasonably precise estimate of the standard deviation for the outcome variables, and pre-post correlations of outcome variables, which are essential statistics for powering a definitive trial. Following Leon and colleagues (2011)[71] and Kraemer and colleagues (2006)[72], our goal is not to obtain a preliminary estimate of the treatment effect size, but as per Teare and colleagues (2014)[73], the size of the pilot we propose is sufficient to obtain sufficiently precise estimates of key variance and covariance parameters necessary to design a definitive trial. Our approach will be to conduct an analysis consistent with the testing of the hypothesis that JJS youth enrolled in the Enhanced Referral/Linkage to Care condition will have fewer psychosis-spectrum symptoms and other clinical outcomes at 3 month follow-up relative to youth in the baseline control.

The main outcomes are individual and total symptom scores (reflecting intensity, interference, and conviction) as well as diagnosis (i.e., low-risk, high-risk, or psychosis) and illness trajectory (i.e. progression, persistence, and partial or full remission) from the SIPS. We will also examine treatment attendance, motivation for treatment, and treatment barrier reduction. The analysis framework will be linear regression, with psychosis-spectrum symptoms as the outcome and Enhanced Referral/Linkage to Care condition as the main predictor. In a randomized design, we would be certain that randomization introduced control for measured and unmeasured factors. In the baseline control design, we cannot be sure that secular trends might not cause different kinds of adolescents to become referred to JJ and/or influence their responses to questions about psychotic-like symptoms. For this reason, we will control for a select set of *a priori* identified confounding variables (sex, gender, race, ethnicity, and age), past history of psychosis-spectrum symptoms, and ongoing mental health treatment at the time of enrollment. The sign and standard error of the enhanced referral/linkage to care condition describes the magnitude and significance of the treatment effect at the threshold level of the screen[55]. For the purposes of this pilot, key outcome parameters are the standard deviation of the SIPS positive symptom scores, the pre-post correlation of the SIPS scores, and the overall R^2 in follow-up SIPS scores given pre-specified covariates. These parameters would be necessary to estimate the sample size requirements for a definitive trial.

Aim 3C. Relationship between service mechanisms (treatment linkage and attendance) and psychotic symptoms/DUP. Correlation and regression techniques will be used to examine how use of services over the 3-month study period is related to change in psychosis-spectrum symptoms as assessed by the SIPS as well as general symptomatology, as assessed by the BPM.

Exploratory analyses. In exploratory analyses, we will also assess potential moderators of the Enhanced Referral protocol effect. We are particularly interested in whether or not the effect of the Enhanced Referral protocol varies by sex, gender, race, ethnicity, and socioeconomic status, as well as service level factors, i.e., fidelity of JID and CSC staff to the referral process. These exploratory analyses will be accomplished by repeating our main analysis models, described above, but including main and interaction effects of selected potential moderators with study phase. Inference will be based on effect size statistics for interaction effects and used as hypothesis generating results for future studies.

Power: As mentioned above, per simulation studies conducted by Teare and colleagues (2014)[73], a total sample size of 60 is sufficient to obtain reasonably precise estimates of key design parameters necessary to power a definitive trial with continuous outcomes. Therefore, our total sample of 140 at baseline and 110 at 3 month follow-up should be sufficient to conduct a simulation study and determine power for a definitive trial.

Timeline: **Months 1 - 2**: Start-up; **Months 3- 14:** 12 months of baseline data collection on Standard Care condition (baseline control); **Months 6 - 17:** 3 month follow-up on Standard Care condition; **Months 18 - 19**: Training of JID intake workers in Enhanced Referral/Linkage to Care protocol; **Months 20 - 31**: 12 months of data collection on the Enhanced Referral/Linkage to Care condition; **Months 23 – 34**: 3 month follow-up on Enhanced Referral/Linkage to Care protocol; **Months 35 - 36**: Analyze data and prepare manuscript.

Future research. As stated in the FOA, this R34 planning grant proposes "the developmental work to be performed that enhances the probability of success in a larger study" and "develops and refines the research strategies to be utilized in the subsequent large-scale study….as well as close gaps in the pathway to specialty

FEP care". If successful, this planning grant will set the stage for a Type III Effectiveness-Implementation design to test this implementation strategy while also collecting data on the Enhanced Referral protocol's effect on linkage to CSC level care, DUP, and psychosis-spectrum symptoms.

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