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SPECIFIC AIMS

Suicide is among the leading causes of death for adults with schizophrenia,[1-4] with risk estimates being over eight times greater than for the general population.[5] Epidemiological data indicate that 40-50% of adults diagnosed with schizophrenia experience suicidal thoughts,[6,7] 20-50% of which make suicide attempts,[8-10] and 4-13% die by suicide.[1,6,7] While suicide research prioritizes depression and hopelessness,[4,6,11,12] there is growing support for the role that symptoms of psychosis (e.g. hallucinations) play in risk.[4,10,13-15] Further, this high suicide rate continues to be a major public health concern given the paucity of evidence-based interventions to reduce suicidality in this population.[9] We propose to modify and evaluate the acceptability and preliminary effectiveness of Cognitive Behavioral Suicide Prevention for psychosis (CBSPp), a promising intervention requiring protocol and implementation modifications to increase its utility in community mental health (CMH).

A long-term goal of our research program is to reduce premature suicidal death among adults with schizophrenia. Our collaborative team developed and evaluated CBSPp,[11,16] one of few suicide interventions tailored for adults experiencing psychosis. CBSPp integrates aspects of validated theories of suicide, including: Schematic Appraisal Model of Suicide,[17] Cry of Pain,[18,19] and Cognitive Theory of Suicide.[20,21] Data show CBSPp improves global functioning and reduces depression, psychosis, suicidal ideation, and suicide attempt by targeting three cognitive components: information processing biases, appraisals, and schemas.[3,11,22]

While CBSPp yields promising results, the following innovations will be pursued given feedback from clients and providers: 1) modify and shorten treatment; 2) develop a hybrid technology-assisted provider training; and, 3) develop a between-session treatment website with treatment reinforcing videos. Further innovations will be informed by interviews with CMH stakeholders for protocol and delivery modification input.

Specific Aim 1: To modify CBSPp for clients with schizophrenia spectrum and other psychotic disorders (SSPD) receiving CMH services. We will develop the provider training, client engagement enhancers, and conduct in-depth qualitative interviews to evaluate CBSPp materials and delivery protocol with stakeholders, including ≈15 adults with SSPD and suicidal ideation and/or attempt (SI/A) within 3 months of screening and ≈10 CMH staff, providers, directors and leaders. Qualitative data will be analyzed and subsequently presented to a panel of scholarly experts in suicide, psychosis, intervention, and implementation science for input. A systematic process will guide CBSPp modifications, refinement of the provider training and client engagement enhancers, and an open pilot trial will be conducted with 8 clients and 2 providers. Open pilot findings and explorations of organizational impact of implementation will be discussed with the expert panel, followed by any additional modifications from feedback and lessons learned.

Specific Aim 2: To evaluate the feasibility and preliminary effectiveness of modified CBSPp in comparison to services-as-usual (SAU). Adults with SSPD and SI or SA within 1 year of screening (n=60) will be enrolled and randomized to CBSPp or SAU. A 4-wave design will include quantitative assessments at baseline (T1), mid-test (T2), post-test (T3), and follow-up (T4) with in-depth qualitative interviews at T3 for a random sample of adults in the CBSPp group (n=10). Providers (n=12) will be trained to deliver CBSPp and be assessed T1-T3 to evaluate the implementation process, including in-depth qualitative interviews at T3. We will monitor fidelity, acceptability, usability, and feasibility of the modified CBSPp.

Aim 2a: To assess whether modified CBSPp is associated with reductions in SI/A (primary outcome), symptoms of psychosis, depression, and emergency/hospital service use over time. Compared to SAU, the CBSPp group will experience significant reductions in SI/A (**H1**), symptoms of psychosis (**H2**), symptoms of depression (**H3**), and emergency/hospital service use (**H4**).

Aim 2b: To assess whether modified CBSPp is associated with clinical (hopelessness,

defeat, and entrapment) and cognitive improvements (information processing biases, appraisals, and schemas) over time. Compared to SAU, the CBSPp group will experience significant improvements in hopelessness (**H5**), defeat (**H6**), entrapment (**H7**), information processing biases (**H8**), appraisals (**H9**), and schemas (**H10**).

Exploratory Aims: To develop hypotheses for future trials, we will explore mechanisms for reducing SI/A and improving clinical and cognitive mechanisms (mediators) involved in risk for SI/A or differential response to CBSPp (moderators). We will also collect and explore preliminary implementation data of implementation barriers and facilitators, acceptability, and scalability.

Impact: This project is in response to RFA-MH-18-706, *Pilot Effectiveness Trials for Treatment, Preventative and Services Interventions,* and follows NIMH's strategic plan to develop ways to tailor existing and new interventions to optimize outcomes (3.2) and test interventions for effectiveness in community practice (3.3). Successful completion of this proposal will result in a novel intervention that improves cognitive processes related to suicide risk, psychosis and depression, and reduces SI/A. Our future research will build on this work to evaluate large-scale CBSPp effectiveness and implementation within multiple sites of CMH.

A. BACKGROUND

A.1 Suicide among Adults with Schizophrenia

Suicide is among the leading causes of death for adults with schizophrenia[1-4] with risk estimates over eight- fold greater as compared to the general population.[5] Moreover, 40-50% of adults with schizophrenia have suicidal thoughts,[6,7] of which 20-50% make suicide attempts,[8-10] and 4-13% end their life by suicide.[1,6,7] The high suicide rates among adults diagnosed with schizophrenia have received much attention,[9] yet, evidence-based treatments are highly limited and suicide continues to be a major public health problem.

A.2 Risk Factors for Suicide in Schizophrenia

The relationship between schizophrenia and suicide is quite complex as researchers continue to examine what makes an individual with schizophrenia at risk for ending his or her life. A history of suicidal behaviors (ideation and/or attempt) is the strongest predictor of future behaviors.[23-25] Additional risk factors for suicide include race/ethnicity, gender, education, and poverty. More specifically, risk is increased when an individual is single, male, white, socially isolated, unemployed, impulsive, has a history of depression, a family history of suicide, greater insight, treatment noncompliance, severe symptoms, and recent loss.[2,3,6,10,26,27]

Among adults with schizophrenia, 22%-75% experience depressive symptoms[28] including low mood and hopelessness, which are empirically demonstrated factors that increase risk for suicide.[3,4,6,12,29] While research has largely focused on depression and hopelessness,[3,4,6,12,29] there is growing support for the role that positive symptoms of psychosis play in suicide risk with data showing delusions and auditory hallucinations increase suicidal behavior.[4,10,13-15,29] Positive symptoms are furthermore shown to weaken social skills, increase avoidance of social contact, and impair development and maintenance of supports, which are known to be important protective factors in suicide risk.[3] The importance of risk and protective factors notwithstanding, it is critical to examine and understand mechanisms involved in suicidal ideation and attempt.

A.3 Mechanisms of Suicidal Ideation and Attempt

Williams' Cry of Pain (CoP)[18,19] theory of suicide is grounded within ecological explanations of stress and defeat with the belief that feelings of extreme and uncontrollable stress are important and necessary components contributing to mechanisms of suicide.[3,18,30,31] Components of CoP include: the presence of stressors, perception of stressors, cognitive biases, hopelessness, feelings of no rescue from others, and means for suicide. Beyond defeat, entrapment, and

hopelessness in CoP,[18,19] the Schematic Appraisals Model of Suicide (SAMS)[17] suggests positive self-appraisals provide a key source of resilience by buffering suicidal thoughts and behaviors.

As a modified version of CoP, the SAMS is one of few theoretical models of suicide risk that specifically considers symptoms of psychosis. It builds on components of CoP to provide a theoretical framework in which psychological mechanisms of suicidal thoughts and behaviors are better understood.[3,17] The SAMS specifies the following 3 mechanisms shown empirically to relate with suicidal thoughts and behaviors: information processing biases (biases in attention, memory, reasoning, and problem solving), appraisals (appraisals of the current situation, past, future, and self), and schemas (patterns of thoughts/behaviors which categorize information about the self, others, and world). Nodes representing suicidal thoughts associate with representations of sensations, cognitions, and emotions, including a link between suicide and forms of escape.[3]

A.4 Suicide Prevention-Focused Interventions and Schizophrenia

Despite a larger literature suggesting individuals with schizophrenia have a heightened risk for suicide,[9,11] there is a paucity of evidence-based interventions targeting suicide risk for this population. Cognitive behavioral therapy for psychosis (CBTp) has been widely used among individuals with schizophrenia yet has not been empirically shown to improve hopelessness, suicidal thoughts, or behaviors.[11,32] Our team recently developed and tested the first intervention designed for suicidal individuals with symptoms of psychosis, the Cognitive Behavioral Suicide Prevention for psychosis (CBSPp),[3] which is designed to identify and alter the cognitive processes involved in suicidal thoughts and behaviors (*see B.1 CBSPp*).[3] While CBSPp yields promising results (*see C.2 Preliminary Data*), the treatment involves 24 individual sessions. Several modifications will be pursued (length of treatment, provider training, and between-session engagement enhancers) given feedback from clients[22] and providers to improve its utility in community mental health (*see B.2 Need to Modify CBSPp*).

Psychosis and CBT. Cognitive behavioral therapy for psychosis (CBTp) has been widely used among individuals with schizophrenia and aims to improve symptoms and functioning despite challenging experiences of positive and negative symptoms.[20] CBTp incorporates cognitive and behavioral techniques to identify and address distressing psychotic symptoms and experiences, along with beliefs held about experiences, and work towards decreasing distress and improving quality of life. Data indicate CBSPp relates to improved positive and negative symptoms, functioning, and quality of life[32,121,174,175,176] with meta-analyses demonstrating the effectiveness of CBTp in practice.[32,177-181] Though there are demonstrations of effectiveness of CBTp among individuals with psychosis, empirical evidence has not examined outcomes of hopelessness, suicidal thoughts, or behaviors to date.[11,32]

Suicide prevention. Suicide prevention approaches often aim to target one of the following strategies: strengthen economic supports (e.g., housing), increase access and delivery of suicide-related care (e.g., mental health care), increase protective environments (e.g., means restrictions), bolster connectedness and support (e.g., professional, familial, and peer support), increase use of problem solving and coping skills (e.g., psychosocial treatment such as CBT and DBT), identify and address risk (e.g., psychosocial treatment such as CBT), and decrease/prevent potential for harm (e.g., postvention programs[182]). One psychosocial prevention approach, and relevant to the proposed application given its theoretical underpinnings, Cognitive behavioral therapy for suicide prevention (CBT-SP) is a psychotherapy used to reduce risk for suicide attempt among individuals with mental illness (Dr. Stanley is a consultant in the proposed project[183]). CBT-SP focuses on proximal risk factors and stressors (e.g., relationships), safety plan development, skill building, and psychoeducation. As a cognitive and behavioral approach, aspects of the treatment involve a focus on hope, awareness of thoughts and feelings, reasons for living, alternative ways of thinking and behaving, and distress tolerance. Data show support of CBT-SP improving suicide-related outcomes with a study by Brown and colleagues[184] indicating CBT-SP treatment (in 10

outpatient sessions) resulted in a 50% reduction in the likelihood of a suicide re-attempt among adults who initially presented in an emergency department after an attempt as compared to treatment as usual. Though there are demonstrations of CBT-SP effectiveness among individuals with mental illness, empirical evidence has not examined this intervention among individuals with psychosis.

Interventions to address suicide among individuals with psychosis. Suicide is among the leading causes of death for adults with schizophrenia[1-4] with risk estimates over eight- fold greater as compared to the general population.[5] Despite knowledge of this public health problem and evidence for the contributions of psychosis symptomatology in increased risk for suicide thoughts and behaviors,[4,14,29,185-189] effective evidence-based interventions aimed towards suicide prevention in this population are lacking.[9,11,190] Specifically, few controlled trials have been conducted investigating the effectiveness of psychosocial (i.e., nonpharmacological therapeutic interventions that address the psychological, social, personal, relational, or vocational problems associated with schizophrenia spectrum disorders) interventions for addressing suicide ideation, behavior, and death among participants with schizophrenia spectrum disorders.[190]

Tarrier and colleagues[16] conducted a systematic review and meta-analysis to examine cognitive-behavioral interventions to reduce suicidal behavior (suicide ideation, plan, attempt, or suicide death) among adolescents and adults in different diagnostic groups. A significant effect was found in 28 studies for cognitive-behavioral interventions in reducing suicidal thoughts and behavior; however, the majority of samples did not include participants with psychosis. Bornheimer and colleagues[190] recently conducted a systematic review and meta-analysis to evaluate the effectiveness of psychosocial interventions in reducing suicide ideation, plan, attempt, and death among individuals with psychotic symptoms. The psychosocial interventions examined in 11 studies, with 14 effect sizes (N=4,829 participants), had a significant impact on reducing suicide ideation, plan, attempt, and death in this population. In examinations of psychosocial treatment types, we observed that most participants received either a mixture of therapeutic (e.g., CBT) and supportive (e.g., case management) interventions (n=8) or therapeutic interventions (n=7), with cognitive and behavioral being most often delivered (n=4). Importantly, while cognitive and behavioral approached were used in 4 identified studies within this schizophrenia spectrum population, one used CBSPp (trial 1[3]) and the remainder indicated use of CBT tools and techniques without a manual. Not only did we note a variety of treatment modalities for suicidal intervention among participants with psychosis, we also observed a wide range in the number of sessions delivered to participants—6 weeks to 5 years—suggesting that the field is testing a variety of lengths of treatment.

B. RESEARCH DESIGN

We aim to modify, evaluate the feasibility and acceptability, and assess the preliminary effectiveness of a modified CBSPp administered to clients with SSPD and SI/A in CMH. By using the stage model of treatment development as a guiding framework,[55] we propose to: Aim 1) review qualitative data from stakeholders (clients, staff, providers, directors, and leaders of CMH) with input from an expert panel and an open pilot trial to guide modifications of CBSPp; and, Aim 2) conduct a feasibility and preliminary effectiveness trial of modified CBSPp.

B.1 Study Site

The study will take place at Washtenaw County Community Mental Health (WCCMH). WCCMH provides mental health services to adults with severe mental illness and developmental disability. They are the primary CMH provider in Washtenaw County, and represent a public mental health system encompassing the diversity of Michigan (race, ethnicity, socioeconomic status, organizational services, insurance/payment types). WCCMH offers a

breadth of programs including crisis residential services, case management, outpatient mental health, medication management, assertive community treatment, and more.

B.2 Study Participants and Procedures

Client participants. Includes adult clients 18 and older who have attended/engaged with any services offered at WCCMH within 6 months of contact, English-speaking, have at least a 6th grade reading level measured by the Wide Range Achievement Test 5 (WRAT-5), Schizophrenia spectrum or other psychotic disorder (SSPD) based upon The Mini International Neuropsychiatric Interview (MINI), and SI or SA within 1 year of screening based upon the Columbia-Suicide Severity Rating Scale (C-SSRS). Exclusions involve the following: requiring emergency care (e.g. imminent plan to harm self) as determined by trained research staff administering the Columbia-Suicide Severity Rating Scale (C-SSRS), or determined to not be appropriate for behavioral treatment according to own judgment in consultation with a treating clinician at the research site (WCCMH). Clients also must have the capacity (cognitive capacity) to participate and both case managers and providers delivering treatment will evaluate this. We expect the following time to complete study activities:

B.3 Recruitment, Screening, and Enrollment

Client participants. Designated WCCMH personnel will identify client participants who may meet criteria for study inclusion based upon DSM SSPD diagnosis and SI within or SA within 1 year of screening per CMH documentation. Such documentation is internal at CMH and could be considered as personnel assess if a client may meet criteria and suggest they be formally screened by the research team. Case managers will be notified if their client(s) meet criteria and will be prepared with instructions by the research team on how to present the study given clients' potential eligibility. Clients who are interested to learn more will be instructed to either: 1) reach out to research staff (RS) via phone, or, 2) give consent for the case manager to give the potential participant's contact information to RS so they can be contacted via phone and learn of next steps (eligibility, consent, enrollment, assessment). RS will begin this process while in the initial contact or schedule a meeting/conversation with clients who are interested in learning more about the at WCCMH (coordinating with an already scheduled appointment with a provider) either in-person at WCCMH or via zoom (virtually). In this meeting/conversation (phone or zoom), RS will describe the study and review the informed consent form so the client is prepared to view it on their own. At the end of this 'informational meeting,' the client will be given the link to provide informed consent on their own (via REDCap). If consent is obtained, the research team will see completion of consent in REDCap and follow up with the client via the contact information they provided in the consent form to schedule a screening assessment. Also, the research staff member will complete a post-consent form in REDCap to document their initial contact, explanation of study/consent form, and follow-up with client if consented to schedule screening assessment. The screening tool will be administered in the scheduled screening assessment to determine eligibility for enrollment. Screening will involve use of The Mini International Neuropsychiatric Interview (MINI)[148] to confirm a SSPD based upon criteria of the DSM-5.[149] A 1-year history of SI/A will be confirmed using the C-SSRS.[141] Lastly, the Wide Range Achievement Test 5 (WRAT-5)[150] will be administered to confirm at least a 6th grade reading level in English given use of CBSPp materials.

B.4 Procedures After Enrollment

Clients participating in the RCT of Aim 2 will:

1. Complete a 1.5-hour survey following screening/enrollment, including questions about personal characteristics, symptoms of psychosis, depression, suicide thoughts and suicide attempt.

2. Be randomized to either receive the treatment (CBSPp) or be in the SAU group (receive standard services at CMH already engaged with)
3. For CBSPp group only: Attend weekly one-on-one therapy sessions with a trained provider for up to 10 weeks. Our research staff will set this up and therapy sessions will either take place at Washtenaw County Community Mental health or virtually via Zoom. Therapy sessions will be focused on improving thoughts of suicide and preventing suicide attempt. All therapy sessions will be audio recorded so we can check that therapists are correctly giving this treatment.
4. Complete a 1.5-hour assessment approximately in 1-month, 3-months, and 5-months. Assessment surveys will be focused on experiences with symptoms of psychosis, depression, suicide thoughts and suicide attempt.
5. Use a treatment website that we will provide between therapy sessions with short videos to help you practice skills you will learn in treatment.
6. For CBSPp group only: A random selection of clients in the treatment group will attend a 30 minute interview with research staff at the end of the study which will be audio recorded and include questions about experiences in the study.

B.5.A Cognitive Behavioral Suicide Prevention for psychosis (CBSPp). Clients randomized to the treatment group (CBSPp) will attend 10 weekly individual therapy sessions with a trained provider in addition to standard WCCMH care (e.g. individual treatment, family services, case management, and medication management). Sessions will be audiotaped and providers will administer the C-SSRS[141] to asses for SI/A in each visit for risk management. Participants in the services as usual group (SAU) will receive SI/A screening as part of WCCMH's standard protocol.

Table 1. Cognitive components of CBSPp Mapped onto Tasks and Goals in Treatment

Cognitive Component	Task	Goal
Information processing biases	Attention to imagery and stimuli, guided relaxation, and broad-minded affective coping	Improve attentional control, positive affect, relaxation, and breathing **(Target: Information processing biases)**
Appraisals	Cognitive restricting to Identify implicit and explicit thoughts, challenging appraisals, and behavioral experiments	Shift negative appraisals **(Target: appraisals)**
Schemas	Guided imagery and systematic questions to promote the development of positive beliefs and improvements in self-esteem, and cognitive and affective responding.	Deactivate suicide schemas and adopt new beliefs and schemas of situations, the self, and future **(Target: schemas)**

Tarrier et al., 2013

CBSPp is structured to begin with an assessment phase followed by a treatment phase in which numerous techniques and strategies are used to address information processing biases, negative appraisals, and suicide schemas. Assessment phase sessions involve explorations of psychiatric symptoms, history of suicide ideation and attempt, family history of psychiatric illness, recent stressful life events, risk for suicide, recovery goals, protective factors, inhibitory factors, coping skills, social support and sense of defeat, entrapment, and hopelessness; all of which will inform the treatment delivery. Throughout assessment, the clinician begins to identify suicide-related information processing biases, appraisals, and schemas. After assessment, techniques and strategies are used in-session and assigned in homework to address information processing biases, negative appraisals, and suicide schemas. Exits from suicide schema occur as evidence of resilience and the cognitive processes involved in these exits are identified and reinforced in the treatment process.[3] While CBSPp is a promising intervention with encouraging preliminary data, it requires protocol and implementation modifications to increase its utility in community mental health settings.

B.5.B Services as usual (SAU). Standard outpatient care will serve as the comparison condition, allowing us to test effectiveness-based hypotheses (Aim 2a and 2b) comparing CBSPp to SAU.

As for management of suicide ideation and attempt in services-as-usual, current WCCMH practices involve safety assessment (which may result in referral for emergency services and/or hospitalization) and potential access to greater intensity of services, based upon psychiatric assessment and clinical judgment of providers. These changes in services may include more: 1) frequent psychiatry and/or therapy appointments; 2) outreach phone calls with peer support; and, 3) calls or visits with case managers for support, continued evaluation of risk, and crisis/safety planning).

B.5.C Engagement enhancers

Aim 2 Engagement enhancers for clients in treatment group. Engagement enhancement for clients in the CBSPp group include treatment boosting text messages each week, a link to watch a 1-2 minute video to boost treatment each week, and access to a treatment website with psychoeducation, supportive statements (similar to boosting text messages), and embedded weekly treatment videos.

B.5.D Assessment

Aim 2 Qualitative assessment. We will systematically evaluate the CBSPp treatment and its implementation in qualitative in depth interviews. A random subset of participants in the treatment group will be selected to participate in interviews (approximately 10-12) and 10 staff, directors, and leaders at CMH will be scheduled to attend an interview with research staff (30 min) and respond to questions about perceptions of the treatment, its implementation, and potential scalability in community mental health. The interview will be audio recorded for research purposes.

ASSESSMENT TIMING (T1-T4)

- **T1 (baseline assessment):** completed following consent for providers and following screener for clients (if eligible)
- **T2 (mid assessment):** completed 30 days after *baseline* for SAU client participants and 30 days after *treatment starts* for CBSPp client participants (intended to be around session 5 of treatment).
- **T3 (post assessment):** completed 90 days after *baseline* for SAU client participants and 90 days after *treatment starts* for CBSPp client participants (intended to be around session 10 of treatment).
- **T4 (follow up assessment):** completed 150 days after *baseline* for SAU client participants and 60 days after *treatment ends* for CBSPp client participants (intended to be 2 months after treatment is completed).
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Table 3: Measurement

Construct	Instrument(s)	Time	Reporter
Aim 2a: To assess whether modified CBSPp is associated with reductions in <u>SI/A (primary outcome)</u>, symptoms of psychosis, depression, and service use over time.			
Suicide ideation	Beck Scale for Suicide Ideation (BSI)[156]	T1,T2,T3,T4	CT
Suicide attempt	Columbia Suicide Severity Rating Scale (C-SSRS)	T1,T2,T3,T4	CT
Psychosis	Positive and Negative Syndrome Scale (PANSS)[158]	T1,T2,T3,T4	CT
Depression	Calgary Depression Rating Scale (CDRS)[159,160]	T1,T2,T3,T4	CT

Service use	Electronic medical records	T1,T2,T3,T4	PV
Aim 2b: To assess whether modified CBSPp is associated with clinical and cognitive improvements over time.			
Clinical			
Hopelessness	Beck Hopelessness Scale (BHS)[161]	T1,T2,T3,T4	CT
Defeat	Defeat Scale[162]	T1,T2,T3,T4	CT
Entrapment	Entrapment Scale[162]	T1,T2,T3,T4	CT
Key: T1 = baseline; T2= mid-test; T3= post-test; O= ongoing; CT= clients; PV= providers, RS= research staff **[a]Suicide ideation and attempt measures will yield a score on a continuous scale and will be additionally recoded into dichotomous variables to represent the incidence of ideation or attempt in analyses** **[b]Used in prior NIMH funded research projects of investigative team**			

B.7 Additional Procedural Information

b.7.a Service use tracking and diagnostic information. Service use will be tracked in an electronic medical record and designated staff of WCCMH will access this information and de-identify it for linkage with collected participant data in the study (from assessments). Participants will be linked to their study ID number in the process of de-identifying data for the research team. Clinical data that will be obtained from the participant's CMH medical record, as described in the consent, will include attendance and service use at CMH, frequency and nature of emergency room visit documentation, and frequency and nature of inpatient hospitalization documentation. More specifically, details of CMH services (frequency and duration of visits both scheduled and attended with therapist, psychiatrist, case manager, assertive community treatment team, and crisis residential service team) and community services (emergency room visits and inpatient hospitalizations) engaged in. In addition, diagnostic information will be collected from the electronic medical record within the past year (e.g., depressive disorder, diabetes, etc.)

B.7.b Provider CBSPp supervision. The PI and Dr. Himle (including consultation with Dr. Tarrier as needed) will supervise provider delivery of CBSPp through group videoconference (2-4 hours per month) and will be available as needed for clinical issues that may arise (see *Protection of Human Subjects*). Supervision will focus on CBSPp delivery, review of sessions, clinical care, fidelity, and implementation. Imbedded in supervision will also be identification and management of adverse events as a refresher to reinforce the study's safety protocol.

B.7.c Provider competence and CBSPp fidelity. Throughout the Aim 2 RCT, providers will self-rate fidelity using a checklist after each session. Also, 20% of audiotaped sessions will be randomly selected for rating. The fidelity rating scale has been developed and will be used.

B.7.d Feasibility. We will track the number of: 1) calls made and received with potential participants, 2) signed informed consents, and 3) eligible participants after screening. We will determine feasibility of CBSPp by: 1) session attendance, 2) CMH service use, and 3) fidelity ratings. An element of feasibility is the ability to recruit participants in the proposed timeframe.

B.7.e Retention, tracking, and attrition. Our research team has substantial experience in recruiting and tracking participants and providers in CMH clinics and we also have established a strong working relationship with WCCMH. Specific approaches include: 1) reminder calls one day prior to visits; 2) provider contact with clients who miss sessions/appointments to ascertain reasons for absence, barriers to attendance, and engage in troubleshooting efforts); 3) a

participant tracking system; and, 4) client participation will be encouraged through compensation for all assessments.

To mitigate risk to participants who drop out of the CMH system during their participation in the research, we will do the following:

1. CMH providers will be trained in client retention
2. If the participant contacts the study team, the study team will work with the participant to try and re-engage them with CMH
3. If the participant contacts the study team, the study team will work with CMH to re-establish contact with the subject.
4. If re-engagement isn't possible, the study team will work with CMH to provide alternate referral sources for the participant.

B.7.f Contamination. Providers will work exclusively with clients in the treatment (CBSPp) or comparison (SAU) groups at WCCMH in order to protect against contamination of CBSPp principles into the SAU group. We acknowledge that contamination can occur on various levels and will follow prevention recommendations of Magill and colleagues (2019). In particular, providers will be instructed throughout the hybrid-training and ongoing supervision not to talk about details of their clinical work with each other and we will use supervision and taping of sessions to monitor potential contamination. Also, clients will be periodically asked and reminded not to share contents of intervention with each other. If it is identified that contamination has occurred, our leadership team (PI and Co-Is) will investigate where contamination has occurred and discuss removal of certain provider(s) and/or client participant(s) from the study or analyses.

B.7.g Adverse events. WCCMH will have clinical staff available during the time of all scheduled screenings, assessments, and CBSPp sessions to assess mental health and risk of harm to self or others if needed during the study. Dr. Florence (WCCMH Medical Director), Dr. Bornheimer (PI), Dr. Himle (Co-I), Dr. King (Co-I), and Dr. Taylor (Co-I) will provide clinical oversight for emergent clinical issues that may arise. Further, mandated reporting will be carefully implemented, and all participants will be aware during consenting that clinical information indicating and acute risk for suicide will be shared with their respective provider.

B.7.h Client Participant Capacity (cognitive)

Client participants' capacity to consent will be assessed prior to participation as well as throughout the study by therapy providers and case managers. The following will be followed:

1. Case managers are trained on assessing client competency and correspond with treating psychiatrist per CMH protocol when competency is of concern.
2. If a potential participant is found not to be competent prior to participation (before consent and enrollment), the case manager will find other avenues of treatment within CMH.
3. Should a subject be found not to be competent after participation has begun, their participation in the research will end. Case managers will find other avenues of treatment within CMH which are appropriate for the client and their capacity. Ending participation in the study will have no impact on service delivery at CMH.

B.7.i DROPOUT. Any participant assigned to CBSPp who fails to attend at least 6 sessions will be coded as a non-completer, consistent with prior use of 60% completion cutoff within the research team's NIH funded CBT trials (Himle et al., 2019). Non-completers will be compared to completers on demographic and clinical characteristics, including suicidality to examine patterns predicting treatment non-completion. In addition, any participant who leaves treatment will be contacted in an attempt to collect the scheduled assessments. We

will also examine predictors of drop-out from the study for any participants who failed to provide assessment data for all four time-points versus those who provided all assessment data.

B.8 Client Incentives

Below describes payment for each of the 5 steps:

1. Screening assessment to determine eligibility: $30

If eligible:

2. Baseline survey assessment: $65
3. 1-month survey assessment: $50
4. 3-month survey assessment: $50
5. 5-months survey assessment: $55

If all 5 steps above are completed, the total amount a participant will receive is $250.

If a participant in the treatment group is selected and agree to the 30-minute interview with research staff at the end of the study (for those in the treatment group), they will get an additional $30 gift card or check ($280 total).

Clients randomized to treatment group: Maximum of $310 (see details above)

Clients randomized to SAU group: Maximum of $280 (see details above)

High Risk and Management

Risk status will be formally determined and recorded at the T1-T4 quantitative assessments. There will not be an assessment of suicide risk conducted by research staff during the treatment sessions for participants receiving CBSPp or SAU, as providers conduct a comprehensive risk assessment as part of standard clinical protocol. Steps are outlined below to assess for high risk, manage the high risk, and engage in the action plan if high risk is present.

Definition of High Risk
The following 4 questions must be asked to a client with potential of high risk. Clients will be categorized as *High Risk* if they meet <u>one or more</u> of the criteria listed below:

(1) Current active suicidal ideation with method or higher on the C-SSRS, defined as a "yes" to #3, 4, or 5 during the last week
(2) An actual, interrupted, or aborted suicide attempt since last assessment
(3) A verbal statement of clear suicidal intent or a plan to commit suicide
(4) Clinical judgment that combination of current risk factors places the participant at high risk

MANAGEMENT OF HIGH RISK STATUS

1. Procedures

If a client meets *High* Risk criteria during research staff contact (meeting one or more of the criteria above), the Action Plan will be followed and the Project Coordinators (Nick Brdar and Maura Campbell) and clinical supervisor (Dr. Bornheimer) will be notified.

If a client has been identified as *High Risk, (according to criteria specified)* the project staff member will ask the following additional questions. These questions will be helpful in determining next steps. Responses are recorded in the Risk Protection Action Plan Excel Sheet which will be regularly maintained and updated in the study Dropbox folder.

Additional questions to ask if potentially high-risk per the 4 initial questions above:

In the last week...
- Has the participant experienced suicidal ideation?
- Has the participant thought of a plan for how to kill self?
- Has there been alcohol or drug use?

And…
- Has the participant talked about their past week suicidal ideation or behaviors with a provider?
-How confident is the participant in keeping themselves safe today (0-10 scale, 10 being very safe)?
- Is the participant currently in treatment with a psychiatrist, psychologist or social worker? If yes, when was the most recent appointment and when is the next appointment?
- Does the participant have access to a firearm?

Script: "Do you have a firearm in your home or access to a firearm?" If Yes, "We have learned that the presence of a firearm in the home or the availability of a firearm is a risk factor for suicide. We strongly recommend that any firearm be removed from the home as soon as possible. Is there a friend or family member who could do this for you?"

-What protective factors does the participant have in place (contact with friends, pets, community)?

2. Action Plan

The study site (WCCMH) will have clinical staff available during the time of all scheduled screening, assessment, and CBSPp delivery to assess mental health and risk of harm to self or others if needed. Leadership team includes Dr. Florence (Medical Director of WCCMH), Dr. Bornheimer (PI), Dr. Himle (Co-I), Dr. Cheryl King (Co-I), Dr. Stephan Taylor (Co-I), Nick Brdar (coordinator), Maura Campbell (clinial coordinator), Katie Hoener (CMH director), Melisa Tasker (CMH director), and Krista DeWeese (CMH director). Leadership team will be involved in clinical issues requiring assessment of mental health and risk to harm self or others after RS evaluation, CBSPp sessions with providers, or interaction with site staff. If trained RS, providers, or site staff observe or assess a participant to be acutely symptomatic or having acute risk of harm to self or

others, then research staff will follow the following policies (informed by existing WCCMH procedures):

- Inform the participant you will need to consult with the supervising clinician and remain with them as you navigate the next steps. The participant can be told that this is a requirement of the study whenever there is a concern about a participant's level of risk and possibility of self-harm or suicide.
- Carry out the high-risk protocol (series of 4 questions above) to determine if there is potential high risk. If one of the 4 questions are yes, continue with additional high-risk questions that are italicized and document responses.
- Contact Nick Brdar (Project Coordinator) and report steps taken from the high-risk protocol.
- Contact Maura Campbell (clinical coordinator on site at WCCMH) if this is occurring at CMH in-person.
- If a coordinator (Nick or Maura) determines CMH staff should be consulted with to determine risk, contact any of the following: a) client's case manager or provider at CMH, or b) CMH director of the leadership team: Katie Hoener (CMH director), Melisa Tasker (CMH director), and Krista DeWeese (CMH director).
- Contact the clinical supervisor of the leadership team to discuss risk level and next steps (Dr. Bornheimer). Dr. Bornheimer will conduct a suicide risk assessment or psychosis symptom assessment if more information is needed to inform next steps. Dr. Bornheimer will also consult as needed with other members of the leadership team including CMH directors (especially if they have been involved as a prior step).
- The clinical supervisor will make a determination about risk level and appropriate next steps including need for follow-up evaluation, connecting with CMH crisis services (including the 24/7 mobile crisis team: 734-544-3050), or calling 911. The clinical supervisor will inform both coordinators and any involved research staff about this decision.
- If determined to be needed, the research staff or a leadership team member will call 911.
- In the case of acute suicidal ideation/intent, research staff must watch the participant until Police/Security/Ambulance arrives.
- If in person, call the WCCMH building security and inform them that Police and/or Ambulance was contacted. The security officer from the building will come to specific location within WCCMH, if needed. Security should arrive to facilitate within 10 minutes and help the research staff while Police and/or Ambulance arrive.
- A coordinator (Nick or Maura) will provide an oral report of the event and the clinical supervisor's recommendation to the police/security.
- Call ED to alert that a participant from the study is on the way and provide them with all necessary information.
- Follow-up with crisis team/on call resident to give information about the participant.
- Document use of the high-risk protocol in the Risk Protection Action Plan Excel Sheet (in Dropbox) regardless of the outcome. This means, we document every use of this protocol involving asking questions even if risk is determined to be low and the action plan doesn't unfold to consultations and linkage to care.

References

1. De Hert M, McKenzie K, Peuskens J. Risk factors for suicide in young people suffering from schizophrenia: a long-term follow-up study. *Schizophr Res.* 2001;47(2-3):127-134.

2. Lambert M, Naber D. Current Schizophrenia. *Current Schizophrenia*. London, UK: Springer Healthcare; 2012.

3. Tarrier N, Gooding P, Pratt D, Kelly J, Awenat Y, Maxwell J. *Cognitive behavioural prevention of suicide in psychosis: A treatment manual* New York: Routledge; 2013.

4. Bornheimer LA. Moderating effects of positive symptoms of psychosis in suicidal ideation among adults diagnosed with schizophrenia. *Schizophr Res.* 2016;176(2-3):364-370.

5. Jacob D, Baldessarini R, Conwell Y, et al. Practice guidelines for the assessment and treatment of patients with suicidal behaviors. *American Journal of Psychiatry.* 2003;160.

6. Montross LP, Zisook S, Kasckow J. Suicide among patients with schizophrenia: a consideration of risk and protective factors. *Ann Clin Psychiatry.* 2005;17(3):173-182.

7. Simms J, McCormack V, Anderson R, Mulholland C. Correlates of self-harm behaviour in acutely ill patients with schizophrenia. *Psychol Psychother.* 2007;80(Pt 1):39-49.

8. Harkavy-Friedman JM, Restifo K, Malaspina D, et al. Suicidal behavior in schizophrenia: characteristics of individuals who had and had not attempted suicide. *Am J Psychiatry.* 1999;156(8):1276-1278.

9. Pompili M, Amador XF, Girardi P, et al. Suicide risk in schizophrenia: learning from the past to change the future. *Ann Gen Psychiatry.* 2007;6:10.

10. Siris SG. Suicide and schizophrenia. *J Psychopharmacol.* 2001;15(2):127-135.

11. Tarrier N, Kelly J, Maqsood S, et al. *The cognitive behavioural prevention of suicide in psychosis: a clinical trial.* Vol 156. 2014/05/24 ed2014.

12. Walsh E, Harvey K, White I, Higgitt A, Fraser J, Murray R. Suicidal behaviour in psychosis: prevalence and predictors from a randomised controlled trial of case management: report from the UK700 trial. *Br J Psychiatry.* 2001;178:255-260.

13. Taylor PJ, Gooding PA, Wood AM, Johnson J, Pratt D, Tarrier N. Defeat and entrapment in schizophrenia: the relationship with suicidal ideation and positive psychotic symptoms. *Psychiatry Res.* 2010;178(2):244-248.

14. Hor K, Taylor M. Suicide and schizophrenia: a systematic review of rates and risk factors. *J Psychopharmacol.* 2010;24(4 Suppl):81-90.

15. Kaplan KJ, Harrow M. Positive and negative symptoms as risk factors for later suicidal activity in schizophrenics versus depressives. *Suicide and Life-Threatening Behavior.* 1996;26(2):105-121.

16. Tarrier N, Taylor R. Schizophrenia and other psychotic disorders. *Clinical handbook of psychological disorders: A step-by-step treatment manual.* 2008;4.

17. Johnson J, Gooding P, Tarrier N. Suicide risk in schizophrenia: explanatory models and clinical implications, The Schematic Appraisal Model of Suicide (SAMS). *Psychol Psychother.* 2008;81(Pt 1):55-77.

18. Williams JMG, Crane C, Barnhofer T, Duggan DS. *Psychology and suicidal behaviour: Elaborating the entrapment model.* Oxford: Oxford University Press; 2005.

19. Williams JMG, Williams M. *Cry of pain: Understanding suicide and self-harm.* Penguin Group USA; 1997.

20. Beck AT, Alford BA. *Depression: Causes and treatment.* University of Pennsylvania Press; 2009.

21. Wenzel A, Brown GK, Beck AT. *Cognitive therapy for suicidal patients: Scientific and clinical applications.* American Psychological Association; 2009.

22. Pratt D, Tarrier N, Dunn G, et al. Cognitive-behavioural suicide prevention for male prisoners: a pilot randomized controlled trial. *Psychol Med.* 2015;45(16):3441-3451.

23. Bunney W, Kleinman A, Pellmar T, Goldsmith S. *Reducing suicide: A national imperative.* National Academies Press; 2002.

24. Joiner TE, Jr., Conwell Y, Fitzpatrick KK, et al. Four studies on how past and current suicidality relate even when "everything but the kitchen sink" is covaried. *J Abnorm Psychol.* 2005;114(2):291-303.

25. Nock MK. *Suicide: Global perspectives from the WHO world mental health surveys.* Cambridge University Press; 2012.

26. Hawton K, Sutton L, Haw C, Sinclair J, Deeks JJ. Schizophrenia and suicide: systematic review of risk factors. *Br J Psychiatry.* 2005;187:9-20.

27. Radomsky ED, Haas GL, Mann JJ, Sweeney JA. Suicidal behavior in patients with schizophrenia and other psychotic disorders. *Am J Psychiatry.* 1999;156(10):1590-1595.

28. Birchwood M, Jackson C. *Schizophrenia.* Philadelphia, PA: Psychology Press; 2011.

29. Bornheimer LA, Jaccard J. Symptoms of Depression, Positive Symptoms of Psychosis, and Suicidal Ideation Among Adults Diagnosed With Schizophrenia Within the Clinical Antipsychotic Trials of Intervention Effectiveness. *Arch Suicide Res.* 2017;21(4):633-645.

30. Gilbert P. Evolution and depression: issues and implications. *Psychol Med.* 2006;36(3):287-297.

31. Gilbert P. Evolutionary approaches to psychopathology: The role of natural defences. *Australian and New Zealand Journal of Psychiatry.* 2001;35(1):17-27.

32. Wykes T, Steel C, Everitt B, Tarrier N. Cognitive behavior therapy for schizophrenia: effect sizes, clinical models, and methodological rigor. *Schizophr Bull.* 2008;34(3):523-537.

33. Haddock G, Davies L, Evans E, et al. Investigating the feasibility and acceptability of a cognitive behavioural suicide prevention therapy for people in acute psychiatric wards (the 'INSITE' trial): study protocol for a randomised controlled trial. *Trials.* 2016;17:79.

34. Lora A, Kohn R, Levav I, McBain R, Morris J, Saxena S. Service availability and utilization and treatment gap for schizophrenic disorders: a survey in 50 low- and middle-income countries. *Bull World Health Organ.* 2012;90(1):47-54, 54A-54B.

35. Bellamy JL, Bledsoe SE, Traube DE. The Current State of Evidence-Based Practice in Social Work: A Review of the Literature and Qualitative Analysis of Expert Interviews. *J Evid Based Soc Work.* 2006;3(1):23-48.

36. Morse G, Salyers MP, Rollins AL, Monroe-DeVita M, Pfahler C. Burnout in mental health services: a review of the problem and its remediation. *Adm Policy Ment Health.* 2012;39(5):341-352.

37. Fairburn CG, Cooper Z. Therapist competence, therapy quality, and therapist training. *Behaviour Research and Therapy.* 2011;49:373-378.

38. Kobak KA, Craske MG, Rose RD, Wolitzky-Taylor K. Web-based therapist training on cognitive behavior therapy for anxiety disorders: a pilot study *Psychotherapy* 2013;50:235-247.

39. Gardner H. *Multiple intelligences: The theory in practice.* New York: Basic Books; 1993.

40. Sholomskas DE, Carroll KM. One small step for manuals: Computer-assisted training in twelve-step facilitation. *Journal of Studies on Alcohol.* 2006;67:939-945.

41. Dimeff LA, Koerner K, Woodcock EA, et al. Which training method works best? A randomized controlled trial comparing three methods of training clinicians in dialectical behavior therapy skills. *Behaviour Research and Therapy.* 2009;47:921-930.

42. Kobak K, Lipsitz JD, Williams JB, Engelhardt N, Bellew KM. A new approach to rater training and certification in a multi-center clinical trial. *Journal of Clinical Psychopharmacology.* 2005;25:407-412.

43. Kobak KA, Engelhardt N, Lipsitz JD. Enriched rater training using Internet based technologies: A comparison to traditional rater training in a multi-site depression trial. *Journal of Psychiatric Research.* 2006;40:192-199.

44. Kazantzis N, Deane FP, Ronan KR, L'Abate L. *Using homework assignments in cognitive behavior therapy.* Routledge; 2005.

45. Kazantzis N, Deane FP. Psychologists' use of homework assignments in clinical practice. *Professional Psychology: Research and Practice.* 1999;30(6):581.

46. Kazantzis N, Lampropoulos GK, Deane FP. A national survey of practicing psychologists' use and attitudes toward homework in psychotherapy. *J Consult Clin Psychol.* 2005;73(4):742-748.

47. Kazantzis N, Ronan KR. Can between-session (homework) activities be considered a common factor in psychotherapy? *Journal of Psychotherapy Integration.* 2006;16(2):115.

48. Helbig-Lang S, Fehm L. Problems with homework in CBT: Rare exception or rather frequent? *Behavioural and Cognitive Psychotherapy.* 2004;32(3).

49. Gaynor ST, Lawrence PS, Nelson-Gray RO. Measuring homework compliance in cognitive-behavioral therapy for adolescent depression: review, preliminary findings, and implications for theory and practice. *Behav Modif.* 2006;30(5):647-672.

50. Leahy RL. Improving homework compliance in the treatment of generalized anxiety disorder. *J Clin Psychol.* 2002;58(5):499-511.

51. Garland A, Scott J. Using homework in therapy for depression. *J Clin Psychol.* 2002;58(5):489-498.

52. Bru L, Solholm R, Idsoe T. Participants' expereinces of an early cognitive behavioral intervention for adolescents with symptoms of depression. *Emotional and Behavioural Difficulties.* 2013;18(1).

53. Williams C, Squires G. The session bridging worksheet: Impact on outcomes, homework adherence and participants' experience. *Cognitive Behaviour Therapist.* 2014;7.

54. Tompkins MA. Guidelines for enhancing homework compliance. *J Clin Psychol.* 2002;58(5):565-576.

55. Rounsaville BJ, Carroll KM, Onken LS. A stage model of behavioral therapies research: Getting started and moving on from stage I. *Clinical Psychology: Science and Practice.* 2001;8(2):133-142.

56. Bornheimer LA. Suicidal Ideation in First-Episode Psychosis (FEP): Examination of Symptoms of Depression and Psychosis Among Individuals in an Early Phase of Treatment. *Suicide Life Threat Behav.* 2018.

57. Bornheimer LA, Acri M, Parchment T, McKay MM. Provider Attitudes, Organizational Readiness for Change, and Uptake of Research Supported Treatment. *Research on Social Work Practice.* 2017;0(0):1049731518770278.

58. Bornheimer LA, Acri MC, Gopalan G, McKay MM. Barriers to Service Utilization and Child Mental Health Treatment Attendance Among Poverty-Affected Families. *Psychiatr Serv.* 2018:appips201700317.

59. Bornheimer LA, Nguyen D. Suicide among individuals with schizophrenia: A risk factor model. *Social Work in Mental Health.* 2015;14(2).

60. Tarrier N. CBT for psychosis: effectiveness, diversity, dissemination, politics, the future and technology. *World Psychiatry.* 2014;13(3):256-257.

61. Tarrier N. Cognitive behavior therapy for schizophrenia and psychosis: current status and future directions. *Clin Schizophr Relat Psychoses.* 2010;4(3):176-184.

62. Tarrier N. Negative symptoms in schizophrenia: comments from a clinical psychology perspective. *Schizophr Bull.* 2006;32(2):231-233.

63. Tarrier N. Cognitive behaviour therapy for schizophrenia -- a review of development, evidence and implementation. *Psychother Psychosom.* 2005;74(3):136-144.

64. Tarrier N, Barrowclough C. Professional attitudes to psychiatric patients: a time for change and an end to medical paternalism. *Epidemiol Psichiatr Soc.* 2003;12(4):238-241.

65. Tarrier N, Barrowclough C, Andrews B, Gregg L. Risk of non-fatal suicide ideation and behaviour in recent onset schizophrenia--the influence of clinical, social, self-esteem and demographic factors. *Soc Psychiatry Psychiatr Epidemiol.* 2004;39(11):927-937.

66. Tarrier N, Barrowclough C, Ward J, Donaldson C, Burns A, Gregg L. Expressed emotion and attributions in the carers of patients with Alzheimer's disease: the effect on carer burden. *J Abnorm Psychol.* 2002;111(2):340-349.

67. Tarrier N, Gooding P, Gregg L, Johnson J, Drake R, Socrates Trial G. Suicide schema in schizophrenia: the effect of emotional reactivity, negative symptoms and schema elaboration. *Behav Res Ther.* 2007;45(9):2090-2097.

68. Tarrier N, Gregg L. Suicide risk in civilian PTSD patients--predictors of suicidal ideation, planning and attempts. *Soc Psychiatry Psychiatr Epidemiol.* 2004;39(8):655-661.

69. Tarrier N, Gregg L, Edwards J, Dunn K. The influence of pre-existing psychiatric illness on recovery in burn injury patients: the impact of psychosis and depression. *Burns.* 2005;31(1):45-49.

70. Tarrier N, Haddock G, Barrowclough C, Wykes T. Are all psychological treatments for psychosis equal? The need for CBT in the treatment of psychosis and not for psychodynamic psychotherapy. *Psychol Psychother.* 2002;75(Pt 4):365-374; discussion 375-369.

71. Tarrier N, Haddock G, Lewis S, Drake R, Gregg L, So CTG. Suicide behaviour over 18 months in recent onset schizophrenic patients: the effects of CBT. *Schizophr Res.* 2006;83(1):15-27.

72. Tarrier N, Khan S, Cater J, Picken A. The subjective consequences of suffering a first episode psychosis: trauma and suicide behaviour. *Soc Psychiatry Psychiatr Epidemiol.* 2007;42(1):29-35.

73. Tarrier N, Kinney C, McCarthy E, Humphreys L, Wittkowski A, Morris J. Two-year follow-up of cognitive--behavioral therapy and supportive counseling in the treatment of persistent symptoms in chronic schizophrenia. *J Consult Clin Psychol.* 2000;68(5):917-922.

74. Tarrier N, Lewis S, Haddock G, et al. Cognitive-behavioural therapy in first-episode and early schizophrenia. 18-month follow-up of a randomised controlled trial. *Br J Psychiatry.* 2004;184:231-239.

75. Tarrier N, Liversidge T, Gregg L. The acceptability and preference for the psychological treatment of PTSD. *Behav Res Ther.* 2006;44(11):1643-1656.

76. Tarrier N, Picken A. Co-morbid PTSD and suicidality in individuals with schizophrenia and substance and alcohol abuse. *Soc Psychiatry Psychiatr Epidemiol.* 2011;46(11):1079-1086.

77. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior: a systematic review and meta-analysis. *Behav Modif.* 2008;32(1):77-108.

78. Tarrier N, Wykes T. Is there evidence that cognitive behaviour therapy is an effective treatment for schizophrenia? A cautious or cautionary tale? *Behav Res Ther.* 2004;42(12):1377-1401.

79. Acri M, Hamovitch E, Mini M, Garay E, Connolly C, McKay M. Testing the 4Rs and 2Ss Multiple Family Group intervention: study protocol for a randomized controlled trial. *Trials.* 2017;18(1):588.

80. Gopalan G, Chacko A, Franco L, et al. Multiple Family Groups for Children with Disruptive Behavior Disorders: Child Outcomes at 6-Month Follow-Up. *J Child Fam Stud.* 2015;24(9):2721-2733.

81. Gopalan G, Goldstein L, Klingenstein K, Sicher C, Blake C, McKay MM. Engaging families into child mental health treatment: updates and special considerations. *J Can Acad Child Adolesc Psychiatry.* 2010;19(3):182-196.

82. Himle JA, Rassi S, Haghighatgou H, Krone KP, Nesse RM, Abelson J. Group behavioral therapy of obsessive-compulsive disorder: seven vs. twelve-week outcomes. *Depress Anxiety.* 2001;13(4):161-165.

83. Krone KP, Himle JA, Nesse RM. A standardized behavioral group treatment program for obsessive-compulsive disorder: preliminary outcomes. *Behav Res Ther.* 1991;29(6):627-631.

84. O'Mahen H, Himle JA, Fedock G, Henshaw E, Flynn H. A pilot randomized controlled trial of cognitive behavioral therapy for perinatal depression adapted for women with low incomes. *Depress Anxiety.* 2013;30(7):679-687.

85. Vogel PA, Solem S, Hagen K, et al. A pilot randomized controlled trial of videoconference-assisted treatment for obsessive-compulsive disorder. *Behav Res Ther.* 2014;63:162-168.

86. Taylor SF, Grove TB, Ellingrod VL, Tso IF. The Fragile Brain: Stress Vulnerability, Negative Affect and GABAergic Neurocircuits in Psychosis. *Schizophr Bull.* 2019.

87. Lynch S, McFarlane WR, Joly B, et al. Early Detection, Intervention and Prevention of Psychosis Program: Community Outreach and Early Identification at Six U.S. Sites. *Psychiatr Serv.* 2016;67(5):510-516.

88. McFarlane WR, Levin B, Travis L, et al. Clinical and functional outcomes after 2 years in the early detection and intervention for the prevention of psychosis multisite effectiveness trial. *Schizophr Bull.* 2015;41(1):30-43.

89. King CA, Jiang Q, Czyz EK, Kerr DC. Suicidal ideation of psychiatrically hospitalized adolescents has one-year predictive validity for suicide attempts in girls only. *J Abnorm Child Psychol.* 2014;42(3):467-477.

90. King CA, Gipson PY, Arango A, et al. LET's CONNECT community mentorship program for youths with peer social problems: Preliminary findings from a randomized effectiveness trial. *J Community Psychol.* 2018;46(7):885-902.

91. King CA, Czyz E, Gillespie BW. Youth-Nominated Support Team Intervention For Suicidal Adolescents And Mortality Outcomes-Reply. *JAMA Psychiatry.* 2019;76(7):765-766.

92. Taylor SF, Chen AC, Tso IF, Liberzon I, Welsh RC. Social appraisal in chronic psychosis: role of medial frontal and occipital networks. *J Psychiatr Res.* 2011;45(4):526-538.

93. Hammers D, Spurgeon E, Ryan K, et al. Validity of a brief computerized cognitive screening test in dementia. *J Geriatr Psychiatry Neurol.* 2012;25(2):89-99.

94. Hammers D, Spurgeon E, Ryan K, et al. Reliability of repeated cognitive assessment of dementia using a brief computerized battery. *Am J Alzheimers Dis Other Demen.* 2011;26(4):326-333.

95. Langenecker SA, Caveney AF, Giordani B, et al. The sensitivity and psychometric properties of a brief computer-based cognitive screening battery in a depression clinic. *Psychiatry Res.* 2007;152(2-3):143-154.

96. Maruff P, Werth J, Giordani B, Caveney AF, Feltner D, Snyder PJ. A statistical approach for classifying change in cognitive function in individuals following pharmacologic challenge: an example with alprazolam. *Psychopharmacology (Berl).* 2006;186(1):7-17.

97. Small L, Jackson J, Gopalan G, McKay MM. Meeting the complex needs of urban youth and their families through the 4Rs 2Ss Family Strengthening Program: The "real world" meets evidence-informed care. *Res Soc Work Pract.* 2015;25(4):433-445.

98. McKay MM, Gopalan G, Franco L, et al. A Collaboratively Designed Child Mental Health Service Model: Multiple Family Groups for Urban Children with Conduct Difficulties. *Res Soc Work Pract.* 2011;21(6):664-674.

99. Gopalan G, Dean-Assael K, Klingenstein K, Chacko A, McKay MM. Caregiver Depression and Youth Disruptive Behavior Difficulties. *Soc Work Ment Health.* 2011;9(1):56-70.

100. McKay MM, Gopalan G, Franco LM, et al. It Takes a Village to Deliver and Test Child and Family-Focused Services. *Res Soc Work Pract.* 2010;20(5):476-482.

101. Gopalan G, Cavaleri MA, Bannon WM, McKay MM. Correlates of Externalizing Behavior Symptoms Among Youth Within Two Impoverished, Urban Communities. *Child Youth Serv.* 2010;31(3-4):92-120.

102. Cavaleri MA, Bannon WM, Rodriguez J, McKay MM. The Protective Effect of Adult Mental Health Upon the Utilization of Racial Socialization Parenting Practices. *Soc Work Ment Health.* 2008;6(4):55-64.

103. McBride CK, Baptiste D, Traube D, et al. Family-Based HIV Preventive Intervention: Child Level Results from the CHAMP Family Program. *Soc Work Ment Health.* 2007;5(1&2):203-220.

104. Devoe ER, Dean K, Traube D, McKay MM. The SURVIVE Community Project: A Family-Based Intervention to Reduce the Impact of Violence Exposures in Urban Youth. *J Aggress Maltreat Trauma.* 2005;11(4):95-116.

105. Baptiste DR, Paikoff RL, McKay MM, Madison-Boyd S, Coleman D, Bell C. Collaborating with an urban community to develop an HIV and AIDS prevention program for black youth and families. *Behav Modif.* 2005;29(2):370-416.

106. McKay MM, Chasse KT, Paikoff R, et al. Family-level impact of the CHAMP Family Program: a community collaborative effort to support urban families and reduce youth HIV risk exposure. *Fam Process.* 2004;43(1):79-93.

107. McKay MM, Bannon WM, Jr. Engaging families in child mental health services. *Child Adolesc Psychiatr Clin N Am.* 2004;13(4):905-921, vii.

108. Bell CC, McKay MM. Constructing a children's mental health infrastructure using community psychiatry principles. *J Leg Med.* 2004;25(1):5-22.

109. McKay MM, Harrison ME, Gonzales J, Kim L, Quintana E. Multiple-family groups for urban children with conduct difficulties and their families. *Psychiatr Serv.* 2002;53(11):1467-1468.

110. Delahanty J, Ram R, Postrado L, Balis T, Green-Paden L, Dixon L. Differences in rates of depression in schizophrenia by race. *Schizophr Bull.* 2001;27(1):29-38.

111. Dixon L. What It Will Take to Make Coordinated Specialty Care Available to Anyone Experiencing Early Schizophrenia: Getting Over the Hump. *JAMA Psychiatry.* 2017;74(1):7-8.

112. Dixon L. Providing services to families of persons with schizophrenia: present and future. *J Ment Health Policy Econ.* 1999;2(1):3-8.

113. Dixon L. Dual diagnosis of substance abuse in schizophrenia: prevalence and impact on outcomes. *Schizophr Res.* 1999;35 Suppl:S93-100.

114. Dixon L, Adams C, Lucksted A. Update on family psychoeducation for schizophrenia. *Schizophr Bull.* 2000;26(1):5-20.

115. Dixon L, Green-Paden L, Delahanty J, Lucksted A, Postrado L, Hall J. Variables associated with disparities in treatment of patients with schizophrenia and comorbid mood and anxiety disorders. *Psychiatr Serv.* 2001;52(9):1216-1222.

116. Dixon L, Lyles A, Scott J, et al. Services to families of adults with schizophrenia: from treatment recommendations to dissemination. *Psychiatr Serv.* 1999;50(2):233-238.

117. Dixon L, Lyles A, Smith C, et al. Use and costs of ambulatory care services among Medicare enrollees with schizophrenia. *Psychiatr Serv.* 2001;52(6):786-792.

118. Dixon L, Postrado L, Delahanty J, Fischer PJ, Lehman A. The association of medical comorbidity in schizophrenia with poor physical and mental health. *J Nerv Ment Dis.* 1999;187(8):496-502.

119. Dixon L, Ramasamy S, Cardale K, et al. Long term patient reported swallowing function following chemoradiotherapy for oropharyngeal carcinoma. *Radiother Oncol.* 2018.

120. Dixon L, Weiden P, Delahanty J, et al. Prevalence and correlates of diabetes in national schizophrenia samples. *Schizophr Bull.* 2000;26(4):903-912.

121. Dixon LB, Dickerson F, Bellack AS, et al. The 2009 schizophrenia PORT psychosocial treatment recommendations and summary statements. *Schizophr Bull.* 2010;36(1):48-70.

122. Dixon LB, Goldman HH, Srihari VH, Kane JM. Transforming the Treatment of Schizophrenia in the United States: The RAISE Initiative. *Annu Rev Clin Psychol.* 2018;14:237-258.

123. Kreyenbuhl J, Buchanan RW, Dickerson FB, Dixon LB, Schizophrenia Patient Outcomes Research T. The Schizophrenia Patient Outcomes Research Team (PORT): updated treatment recommendations 2009. *Schizophr Bull.* 2010;36(1):94-103.

124. Lehman AF, Buchanan RW, Dickerson FB, et al. Evidence-based treatment for schizophrenia. *Psychiatr Clin North Am.* 2003;26(4):939-954.

125. Brodsky BS, Spruch-Feiner A, Stanley B. The Zero Suicide Model: Applying Evidence-Based Suicide Prevention Practices to Clinical Care. *Front Psychiatry.* 2018;9:33.

126. Interian A, Chesin M, Kline A, et al. Use of the Columbia-Suicide Severity Rating Scale (C-SSRS) to Classify Suicidal Behaviors. *Arch Suicide Res.* 2018;22(2):278-294.

127. Johns CA, Stanley M, Stanley B. Suicide in schizophrenia. *Ann N Y Acad Sci.* 1986;487:294-300.

128. Labouliere CD, Vasan P, Kramer A, et al. "Zero Suicide" - A model for reducing suicide in United States behavioral healthcare. *Suicidologi.* 2018;23(1):22-30.

129. Posner K, Brown GK, Stanley B, et al. The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *Am J Psychiatry.* 2011;168(12):1266-1277.

130. Stanley B. Ethical considerations in biological research on suicide. *Ann N Y Acad Sci.* 1986;487:42-46.

131. Stanley B, Brown G, Brent DA, et al. Cognitive-behavioral therapy for suicide prevention (CBT-SP): treatment model, feasibility, and acceptability. *J Am Acad Child Adolesc Psychiatry.* 2009;48(10):1005-1013.

132. Stanley B, Chaudhury SR, Chesin M, et al. An Emergency Department Intervention and Follow-Up to Reduce Suicide Risk in the VA: Acceptability and Effectiveness. *Psychiatr Serv.* 2016;67(6):680-683.

133. Stanley B, Gameroff MJ, Michalsen V, Mann JJ. Are suicide attempters who self-mutilate a unique population? *Am J Psychiatry.* 2001;158(3):427-432.

134. Stanley B, Green KL, Ghahramanlou-Holloway M, Brenner LA, Brown GK. The construct and measurement of suicide-related coping. *Psychiatry Res.* 2017;258:189-193.

135. Stanley B, Traskman-Bendz L, Stanley M. The suicide assessment scale: a scale evaluating change in suicidal behavior. *Psychopharmacol Bull.* 1986;22(1):200-205.

136. Stanley M, Stanley B. Postmortem evidence for serotonin's role in suicide. *J Clin Psychiatry.* 1990;51 Suppl:22-28; discussion 29-30.

137. Stanley M, Stanley B. Biochemical studies in suicide victims: current findings and future implications. *Suicide Life Threat Behav.* 1989;19(1):30-42.

138. Stanley M, Stanley B, Traskman-Bendz L, Mann JJ, Meyendorff E. Neurochemical findings in suicide completers and suicide attempters. *Suicide Life Threat Behav.* 1986;16(2):286-300.

139. Vitiello B, Brent DA, Greenhill LL, et al. Depressive symptoms and clinical status during the Treatment of Adolescent Suicide Attempters (TASA) Study. *J Am Acad Child Adolesc Psychiatry.* 2009;48(10):997-1004.

140. Murray LK, Tol W, Jordans M, et al. Dissemination and implementation of evidence based, mental health interventions in post conflict, low resource settings. *Intervention (Amstelveen).* 2014;12(Suppl 1):94-112.

141. Posner K, Brent D, Lucas C, et al. Columbia-suicide severity rating scale (C-SSRS). *New York, NY: Columbia University Medical Center.* 2008.

142. Michigan WC. Millage. 2019; https://www.washtenaw.org/2806/Millage.

143. Health WCCM. WCCMH CARES Team: Millage CCBHC Program Plan. 2019; https://www.cityofypsilanti.com/DocumentCenter/View/1916/CARES-Team-Presentation-32019-2-002.

144. Guest G, MacQueen KM, Namey EE. *Applied Thematic Analysis.* Thousand Oaks, CA: Sage Publications, Inc.; 2012.

145. Lincoln Y, Guba E. Processing Naturally Obtained Data. *Naturalistic Inquiry*. London: Sage Publications; 1985:332-356.

146. Price RH, Lorion RP. Prevention programming as organizational reinvention: From research to implementation. *Prevention of mental disorders, alcohol, and other drug use in children and adolescents.* 1989:97-123.

147. CDC. Stats of the state of Michigan. 2018; https://www.cdc.gov/nchs/pressroom/states/michigan/michigan.htm. Accessed August, 2018.

148. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry.* 1998;59 Suppl 20:22-33;quiz 34-57.

149. American Psychiatric Association., American Psychiatric Association. DSM-5 Task Force. *Diagnostic and statistical manual of mental disorders : DSM-5.* 5th ed. Washington, D.C.: American Psychiatric Association; 2013.

150. Wilkinson GS, Robertson GJ. Wide range achievement test 4 (WRAT4). *Lutz, FL: Psychological Assessment Resources.* 2006.

151. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods.* 2006;18(1):59-82.

152. Bernard HR, Ryan GW. Text analysis: qualitative and quantitative methods. In: Bernard HR, ed. *Handbook of Methods in Cultural Anthropology*. Walnut Creek, CA: Altamira Press; 1998.

153. Kurasaki K. Intercoder reliability for validating conclusions drawn from open-ended interview data. *Field Methods.* 2000;12:179-194.

154. Young JE, Beck AT. Cognitive therapy scale: Rating manual.1980.

155. Pratt D, Gooding P, Johnson J, Taylor P, Tarrier N. Suicide schemas in non-affective psychosis: An empirical investigation. *Behav Res Ther.* 2010;48(12):1211-1220.

156. Beck AT, Kovacs M, Weissman A. Assessment of suicidal intention: the Scale for Suicide Ideation. *J Consult Clin Psychol.* 1979;47(2):343-352.

157. Osman A, Bagge CL, Gutierrez PM, Konick LC, Kopper BA, Barrios FX. The Suicidal Behaviors Questionnaire-Revised (SBQ-R): validation with clinical and nonclinical samples. *Assessment.* 2001;8(4):443-454.

158. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophr Bull.* 1987;13(2):261-276.

159. Addington D, Addington J, Maticka-Tyndale E. Assessing depression in schizophrenia: the Calgary Depression Scale. *Br J Psychiatry Suppl.* 1993(22):39-44.

160. Addington D, Addington J, Schissel B. A depression rating scale for schizophrenics. *Schizophr Res.* 1990;3(4):247-251.

161. Beck AT, Weissman A, Lester D, Trexler L. The measurement of pessimism: the hopelessness scale. *J Consult Clin Psychol.* 1974;42(6):861-865.

162. Gilbert P, Allan S. The role of defeat and entrapment (arrested flight) in depression: an exploration of an evolutionary view. *Psychol Med.* 1998;28(3):585-598.

163. Group W. Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychological medicine.* 1998;28(3):551-558.

164. Endler N, Parker, J. *Coping Inventory for Stressful Situations (CISS): Manual. .* Toronto: Multi-Health Systems; 1990.

165. Stroop JR. Studies of interference in serial verbal reactions. *Journal of experimental psychology.* 1935;18(6):643.

166. Cha CB, Najmi S, Park JM, Finn CT, Nock MK. Attentional bias toward suicide-related stimuli predicts suicidal behavior. *J Abnorm Psychol.* 2010;119(3):616-622.

167. Johnson J, Gooding PA, Wood AM, Tarrier N. Resilience as positive coping appraisals: Testing the schematic appraisals model of suicide (SAMS). *Behav Res Ther.* 2010;48(3):179-186.

168. Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. *J Pers Soc Psychol.* 2003;85(2):348-362.

169. Aarons GA. Mental health provider attitudes toward adoption of evidence-based practice: the Evidence-Based Practice Attitude Scale (EBPAS). *Ment Health Serv Res.* 2004;6(2):61-74.

170. West BT, Welch KB, Galecki AT, EBSCO. *Linear mixed models : a practical guide using statistical software.* Boca Raton: Chapman & Hall/CRC; 2007.

171. Little RJA, Rubin DB. *Statistical analysis with missing data.* 2nd ed. Hoboken, N.J.: Wiley; 2002.

172. Little RJ. Pattern-mixture models for multivariate incomplete data. *Journal of the American Statistical Association.* 1993;88:125-133.

173. Diggle P. *Analysis of longitudinal data.* 2nd ed. Oxford ; New York: Oxford University Press; 2002.

174. Burns AM, Erickson DH, Brenner CA. Cognitive-behavioral therapy for medication-resistant psychosis: a meta-analytic review. Psychiatric Services. 2014;65(7):874-80.

175. Turner DT, van der Gaag M, Karyotaki E, Cuijpers P. Psychological interventions for psychosis: a meta-analysis of comparative outcome studies. American Journal of Psychiatry. 2014;171(5):523-38.

176. Van der Gaag M, Valmaggia LR, Smit F. The effects of individually tailored formulation-based cognitive behavioural therapy in auditory hallucinations and delusions: a meta-analysis. Schizophrenia research. 2014;156(1):30-7.

177. Gould RA, Mueser KT, Bolton E, Mays V, Goff D. Cognitive therapy for psychosis in schizophrenia: an effect size analysis. Focus. 2004;48(1):335-101.

178. Jauhar S, McKenna PJ, Radua J, Fung E, Salvador R, Laws KR. Cognitive–behavioural therapy for the symptoms of schizophrenia: systematic review and meta-analysis with examination of potential bias. The British Journal of Psychiatry. 2014;204(1):20-9.

179. Pfammatter M, Brenner HD, Junghan UM, Tschacher W. The importance of cognitive processes for the integrative treatment of persons with schizophrenia. Schizophrenia bulletin. 2011;37(suppl_2):S1-4.

180. Pilling S, Bebbington P, Kuipers E, Garety P, Geddes J, Orbach G, Morgan C. Psychological treatments in schizophrenia: I. Meta-analysis of family intervention and cognitive behaviour therapy. Psychological medicine. 2002;32(5):763-82.

181. Zimmermann G, Favrod J, Trieu VH, Pomini V. The effect of cognitive behavioral treatment on the positive symptoms of schizophrenia spectrum disorders: a meta-analysis. Schizophrenia research. 2005;77(1):1-9.

182. Stone DM, Holland KM, Bartholow BN, Crosby AE, Davis SP, Wilkins N. Preventing suicide: A technical package of policies, programs, and practice. 2017.

183. Stanley B, Brown G, Brent DA, Wells K, Poling K, Curry J, Kennard BD, Wagner A, Cwik MF, Klomek AB, Goldstein T. Cognitive-behavioral therapy for suicide prevention (CBT-SP): treatment model, feasibility, and acceptability. Journal of the American Academy of Child & Adolescent Psychiatry. 2009;48(10):1005-13.

184. Brown GK, Ten Have T, Henriques GR, Xie SX, Hollander JE, Beck AT. Cognitive therapy for the prevention of suicide attempts: a randomized controlled trial. Jama. 2005;294(5):563-70.

185. DeVylder JE, Lukens EP, Link BG, Lieberman JA. Suicidal ideation and suicide attempts among adults with psychotic experiences: data from the collaborative psychiatric epidemiology surveys. JAMA psychiatry. 2015;72(3):219-25.

186. Meltzer HY, Alphs L, Green AI, Altamura AC, Anand R, Bertoldi A, Bourgeois M, Chouinard G, Islam MZ, Kane J, Krishnan R. Clozapine treatment for suicidality in schizophrenia: international suicide prevention trial (InterSePT). Archives of general psychiatry. 2003;60(1):82-91.

187. Powell J, Geddes J, Deeks J, Goldacre M, Hawton K. Suicide in psychiatric hospital in-patients: risk factors and their predictive power. The British Journal of Psychiatry. 2000;176(3):266-72.

188. Saha S, Scott JG, Johnston AK, Slade TN, Varghese D, Carter GL, McGrath JJ. The association between delusional-like experiences and suicidal thoughts and behaviour. Schizophrenia Research. 2011;132(2-3):197-202.189. Tiihonen J, Lönnqvist J, Wahlbeck K, Klaukka T, Tanskanen A, Haukka J. Antidepressants and the risk of suicide, attempted suicide, and overall mortality in a nationwide cohort. Archives of general psychiatry. 2006;63(12):1358-67.

189. Tiihonen J, Lönnqvist J, Wahlbeck K, Klaukka T, Tanskanen A, Haukka J. Antidepressants and the
risk of suicide, attempted suicide, and overall mortality in a nationwide cohort. Archives of general psychiatry. 2006;63(12):1358-67.

190. Bornheimer LA, Zhang A, Li J, Hiller M, Tarrier N. Effectiveness of suicide-focused psychosocial
interventions in psychosis: a systematic review and meta-analysis. Psychiatric services. 2020;71(8):829-38.