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Title: Cognitive Behavioral Suicide Prevention for Psychosis: Aim 1

Contents: Aim 1 Open Pilot Study Protocol and Statistical Analysis Plan (Approved for use by IRB on 12/10/2021)

Note: Any mention of Aim 1 stakeholder phase or Aim 2 RCT is informational

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/A within 3 months 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 T4 for a random sample of adults in the CBSPp group (n=10). Providers (n=8) will be trained to deliver CBSPp and be assessed T1-T4 to evaluate the implementation process, including in-depth qualitative interviews at T4. 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.

BACKGROUND

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.

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.

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]

RESEARCH DESIGN FOR AIM 1 OPEN PILOT (not including stakeholder phase or RCT)

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.

Study Participants and Procedures

Client participants. Includes adults 18 to 65 years of age clients 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 4 (WRAT-4), Schizophrenia spectrum or other psychotic disorder (SSPD) based upon The Mini International Neuropsychiatric Interview (MINI), and Suicidal ideation or attempt (SI/A) within 3 months of assessment 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:

- Clients in open trail of Aim 1: We expect the amount of time to be 20.5 hours total: 30 minute screener, weekly one-on-one therapy sessions with a trained provider for up to 10 weeks (10 hours maximum), use of treatment website with treatment reinforcing videos between treatment sessions during the 10 weeks of treatment (5 hours approximately), 1-hour surveys at 4 time-points (4 hours total), and an interview at the end of study (1 hour).

Recruitment, Screening, and Enrollment

Client participants. Designated WCCMH personnel will identify client participants who meet criteria for study inclusion based upon DSM SSPD diagnosis and endorsement of suicide ideation and/or attempt within 3 months per documentation of the C-SSRS. Case managers will be notified if their client(s) meet criteria and will be prepared with instructions by the research team (see scripts) 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 schedule an in-person meeting with clients who are interested in learning more about the at WCCMH (coordinating with an already scheduled appointment with a provider). In this meeting, RS will describe the study (see scripts) and review the informed consent form. If consent is obtained, the screening tool will be administered to determine eligibility for enrollment (approximately 15 minutes long). 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 3-month history of SI/A will be confirmed using the C-SSRS.[141] Lastly, the Wide Range Achievement Test 4 (WRAT-4)[150] will be administered to confirm at least a 6th grade reading level in English given use of CBSPp materials.

Procedures After Enrollment

Client participants in open trial of Aim 1. Clients participating in the open trial of Aim 1 will:

1. Complete a 1-hour survey following enrollment (not a separate visit), including questions about personal characteristics, symptoms of psychosis, depression, suicide thoughts and suicide attempt.
2. Attend weekly one-on-one therapy sessions with a trained provider for up to 10 weeks. Our research staff will set this and therapy sessions will take place at Washtenaw County Community Mental health at your convenience. 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.
3. Complete a 1-hour survey approximately in 1-month, 3-months, and 5-months. Surveys will be focused on experiences with symptoms of psychosis, depression, suicide thoughts and suicide attempt.
4. Use a treatment website that we will provide between therapy sessions with short videos to help you practice skills you will learn in treatment.
5. Attend a 1-hour interview with research staff at the end of the study which will be audio recorded and include questions about experiences in the study.

If client participants refuse to participate after determined to be eligible, enrolling in the study, being assigned to a provider, and/or starting study activities (surveys and/or treatment), they will be removed from the study and thanked for their time.

If a client participant leaves WCCMH services (e.g., moves, ends services, switches to different service provider) during the study, their participation in the study will end.

Client participant attendance will be tracked as one of our goals is to learn more about acceptability and feasibility of the intervention. While 10 sessions are what providers will be trained to deliver, clients may choose not to attend all sessions. It is important to note that

there will be no consequences for not attending sessions; participants can remain as active as they choose to be with treatment and survey completion.

If a provider leaves during the study and/or during the process of delivering CBSPp with a client participant, we will re-assign the client(s) to a different therapist who has been trained in CBSPp. If needed, we train additional providers in preparation for resuming treatment with client participants whose previous provider left.

Cognitive Behavioral Suicide Prevention for psychosis (CBSPp). Clients in the Aim 1 Open Pilot Trial treatment group (CBSPp) will attend individual therapy sessions with a trained provider (10 weeks/10 sessions) 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. CBSPp was developed as a 24-week series of individual therapy sessions with a clinician in a structured protocol, and modified to be 10 weeks in Aim 1 of this study (stakeholder phase of Aim 1 prior to open pilot trial). Cognitive and behavioral techniques[3] are implemented systematically to address cognitive (information processing biases, appraisals, and schemas) components from the SAMS theoretical model (***see Table 1***).[17] The goal is to develop broad-minded attention, balanced appraisals, and alternative schemas about the self, world, and the future resulting in exit from suicide schemas. The three cognitive components of SAMS have been tested empirically, though not within a CBSPp trial.[11,22]

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.

Assessment

Aim 1 Open pilot trial Quantitative data. Clients will complete comprehensive assessments at baseline (**T1**), mid-test (midpoint of total CBSPp sessions; **T2**), post-test (endpoint of CBSPp sessions;**T3**), and follow-up (3 months after CBSPp session endpoint;**T4**). Measurement shown below in Table 3.

Table 3: Measurement (note: this is measurement for testing within Aim 2, though all measurement will be tested in Aim 1's open pilot trial)

Construct	Instrument(s)	Time	Reporter
Aim 2a: To assess whether modified CBSPp is associated with reductions in SI/A (primary outcome), symptoms of psychosis, depression, and service use over time.			
SI/A	Columbia Suicide Severity Rating Scale (CSSRS)[129]	T1,T2,T3,T4	CT, RS score
Psychosis	Positive and Negative Syndrome Scale (PANSS)[158]	T1,T2,T3,T4	CT, RS score
Depression	Calgary Depression Rating Scale (CDRS)[159,160]	T1,T2,T3,T4	CT, RS score
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
Social support	Quality of Life[163]	T1,T2,T3,T4	CT
Coping	Coping in Stressful Situations Inventory (CSSI)[164]	T1,T2,T3,T4	CT
Cognitive			
Information processing biases	Modified Stroop task[165,166]	T1,T2,T3,T4	CT
Appraisals	Resilience Appraisals Scale (RAS)[167] Reappraisal Subscale of Emotion Regulation Questionnaire (ERQ)[168]	T1,T2,T3,T4	CT
Schemas	Suicide Concept Sort Task (SCT)[155]	T1,T2,T3,T4	CT

Key: T1 = baseline; T2= mid-test; T3= post-test; O= ongoing; CT= clients; RS score = research staff score ratings as this is a clinical interview and not a self-report measure.

Aim 1 Open Pilot trial Qualitative assessment. We will systematically evaluate the modified CBSPp using in-depth face-to-face qualitative interviews with all clients in the open pilot trial. Topics will focus on: 1) perceptions about their experience receiving the treatment, feedback regarding treatment impact and observed mental health outcomes, experiences with the added engagement enhancers, and factors impacting possible sustainability of maintaining the treatment at community mental health over time.

Statistical Design and Analysis

Aim 1 open pilot quantitative data analysis. A focus of Aim 1's open pilot is to implement the CBSPp treatment and assessments in preparation for potential modifications prior to Aim 2. We will preliminarily explore outcomes (SI/A, symptoms of psychosis, depression, emergency/hospital service use, hopelessness, defeat, entrapment, information processing biases, appraisals, and schemas) in preparation for Aim 2. Given the open pilot is small in size (n=8 clients), we don't have power to detect changes over time in Aim 1. Therefore, quantitative data will be examined at the univariate and bivariate level for distributions and associations between variables. Measures of dispersion (mean, standard deviation, variance, range) and distribution (kurtosis, skewness) will be computed. Scatterplots will be generated to examine linearity and outliers for bivariate relationships using Chi-Square analysis (categorical variables), analysis of variance (ANOVA; scaled variables), and paired samples t-tests (continuous variables) in SPSS28.

Aim 1 open pilot qualitative data analysis. Qualitative in-depth interviews data were transcribed and coded using Dedoose. Transcripts were independently coded by two research assistants (RAs) in preparation for codebook development using an open coding technique to generate themes across qualitative questions (Saldana, 2016). Grounded theory methods were utilized for analysis (Charmaz, 2014). The PI met with both RAs to discuss emerging themes after a first round of coding and agreed upon a final codebook. Both RAs completed a second round of coding using the final codebook and the PI resolved any disagreements to achieve inter-coder consistency. Themes were ultimately organized into a final framework and the following strategies for rigor (Padgett, 2016) were included in the study: 1) triangulation, specifically analytic triangulation (more than one coder), 2) audit trail, and 3) member checking with stakeholder participants (i.e., in provider, peer, and client meetings).

Additional Procedural Information

Service use tracking. 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.

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.

Provider competence and CBSPp fidelity. Throughout the open pilot, providers will self-rate fidelity using a checklist after each session. Also, 20% of audiotaped sessions will be randomly selected for blind rating by two established experts currently assessing CBT fidelity within Dr. Himle's NIMH-funded projects.

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.

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.

Risk 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 licensed clinicians conduct a comprehensive risk assessment as part of standard clinical protocol.

Definition of High Risk
Clients will be categorized as *High Risk* if they meet one or more 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 Risk Status

1. Procedures
If a client meets *High* Risk criteria during research staff contact, the Action Plan will be followed and the senior on-call clinician will be notified.

If a client has been identified as *High Risk, (according to criteria specified)* the project staff member asks the following additional questions. These questions will be helpful in determining next steps. Responses are recorded in an Action Plan form.

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?
- Does the participant have access to a firearm?
- 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?

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. Dr. Florence (Medical Director of WCCMH) and Dr. Bornheimer (PI), with input

and support as needed by Dr. Himle (Co-I), Dr. Cheryl King (Co-I), and Dr. Stephan Taylor (Co-I), will be involved in all 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 they will follow the following policies (informed by existing WCCMH procedures):

- Alert the Project Coordinator (provide with relevant information).
- Alert Dr. Florence (Medical Director of WCCMH), Dr. Bornheimer (PI), and Dr. Himle (Co-I) about the problem (provide demographics and relevant medical information such as suicidal, homicidal ideation/intent, diagnosis, presenting acute symptoms, medical condition). Drs. Bornheimer and Himle will consult with Drs. King and Taylor (Co-I) as needed.
- If expressing suicidal ideation with a plan and/or reporting a recent attempt, Dr. Florence (Medical Director of WCCMH), Dr. Bornheimer (PI), and Dr. Himle (Co-I), or trained RS will administer the C-SSRS (see above description in *A.1.a Inclusion and Exclusion Criteria*). Dr. Florence will lead the decision-making of who will administer the C-SSRS in a given situation.
- If escalation in symptoms not including suicidal ideation and/or attempt, Dr. Florence (Medical Director of WCCMH), Dr. Bornheimer (PI), and Dr. Himle (Co-I), or trained RS will administer the 18-item Brief Psychiatric Rating Scale (BPRS). Dr. Florence will lead the decision-making of who will administer the C-SSRS. A rating of 4 on the BPRS reflects functional impairment for: hostility, excitement, grandiosity, tension, mannerisms & posturing, motor retardation, uncooperativeness, blunted affect, blunted affect, conceptual disorganization, and disorientation; and a rating of 5 on the BPRS reflects functional impairment for: somatic concern, anxiety, depressive mood, guilt feelings, suspiciousness, hallucinatory behavior, and unusual thought content.
- Contact the primary treating WCCMH mental health provider (e.g., psychiatrist) via page or phone number (provided during consent) to be in touch with Dr. Florence.
- Pending recommendation from WCCMH provider in conjunction with Dr. Florence. If recommended to proceed to make appointment with provider or go immediately to an Emergency Department (ED), discuss the issue with all relevant RS and participant as well.
- Call 911.
- In the case of an involuntary hospitalization/ED evaluation, call Police (RS should go with police since “Petition” is required).
- In the case of a voluntary hospitalization/ED evaluation, call Ambulance to escort the participant.
- In the case of acute suicidal ideation/intent, a research team member must watch the participant until Police/Security/Ambulance arrives.
- 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 RS while Police and/or Ambulance arrive.
- The Research Coordinator needs to provide some documentation from the PI to give to the police/security regarding the PI’s recommendation.
- 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.

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