

Study Title: Inpatient Cognitive-Behavioral Therapy to Reduce Suicide Risk Post-Discharge

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Specific Aims and Hypotheses

Objectives. Although inpatient treatment provides immediate stabilization and crisis management for suicidal patients, the risk of suicide post-discharge is substantial, with approximately one third of all suicides by individuals with mental disorders occurring in the 90 days following hospitalization.¹ These data highlight the importance of establishing an empirically-supported inpatient treatment for suicide prevention. Cognitive behavioral therapy (CBT) is a strong candidate, given that CBT reduces risk in suicidal outpatients.²⁻⁵ In addition, our team has completed an open trial, in which we 1) adapted the strongest outpatient CBT protocol⁶ for an inpatient setting, 2) demonstrated high levels of feasibility and acceptability, and 3) obtained preliminary estimates of efficacy. The objective here, which is the final step before dissemination, is to conduct a large-scale randomized controlled trial (RCT) comparing CBT (n = 100) to treatment as usual (TAU, n = 100) to firmly establish efficacy and collect pilot data on treatment implementation metrics. Our central hypothesis, based on strong outpatient data,⁷ is that inpatient CBT will reduce suicidal behavior, suicidal ideation/intent, and inpatient readmission over 6 months post-discharge, compared to TAU. The rationale for the proposed study is to inform best practices treatment for hospitalized suicidal patients by establishing for the first time, and ultimately disseminating, an empirically-validated inpatient treatment for suicide prevention. Such results are expected to have a significant positive impact, because of the high risk of suicidal behavior after discharge from inpatient treatment and the substantial public health burden it entails.

We plan to test our central hypotheses and, thereby, accomplish the objective of this application by pursuing the following primary specific aims:

Primary Aim 1. Determine the efficacy of inpatient CBT on suicidal behavior over a 6-month follow-up.

We predict that compared to patients receiving TAU, those receiving CBT will report lower rates of suicidal behavior over a 6-month follow-up. .

Primary Aim 2. Determine the efficacy of inpatient CBT on suicidal ideation/intent at post-treatment and over a 6-month follow-up. We predict that compared to patients receiving TAU, those receiving CBT will report lower severity of suicidal ideation at post-treatment, and over a 6-month follow-up.

Primary Aim 3. Determine the efficacy of inpatient CBT on readmission over 6-month follow-up. We predict that patients receiving CBT will report fewer inpatient readmissions over the follow-up period.

In addition to these primary specific aims, the scope of the proposed study will also allow us to pursue several secondary aims, as detailed below.

Secondary Aim 1. Determine the efficacy of inpatient CBT on suicide implicit associations at post-treatment and over a 6-month follow-up. We predict that compared to patients receiving TAU, those receiving CBT will report stronger associations between life and self words at post-treatment and over a 6-month follow-up.

Secondary Aim 2. Determine the extent to which substance use disorders moderate outcome. Given that CBT for suicide prevention is a transdiagnostic intervention, we expect that CBT will be efficacious for the diverse range of clinical presentations represented in an inpatient sample. However, some research suggests that the presence of substance use disorder (SUD) may adversely impact the efficacy of CBT.^{8,9} Thus, we will take care to address comorbid SUD in the current study by utilizing stratified block randomization to ensure equal group representation on this variable, and to explore the presence of SUD as a treatment moderator in the data analytic plan.

Secondary Aim 3. Explore additional psychopathological moderators of treatment outcome. Additional exploratory analyses will examine the moderating effect of the following psychiatric symptoms, which have been found to be associated with increased suicide risk and/or attenuated response to CBT: depression severity, impulsivity, hopelessness, distress tolerance, insomnia, and borderline personality traits.

Exploratory Aim 1. To collect pilot data on implementation metrics. To enhance future implementation research we will collect pilot data on implementation metrics such as treatment barriers and facilitators.

Project Description

A. Background and Significance. The proposed research has substantial potential to identify best means to prevent suicide in the most highly vulnerable population: inpatients admitted following a suicide attempt. Below, we describe the importance of treating this population, the importance of testing CBT in this group, and the scientific importance of testing moderators of treatment response.

A.1. The Significance of Treating Suicidal Behavior in Psychiatric Inpatients. Suicide is one of the top 10 causes of death in the US, accounting for 1.6% of all deaths and 11% of deaths among individuals aged 25-44.¹⁰ Among individuals with depressive disorders, there is an 11% mortality rate from suicide.¹¹ The most significant risk factor for suicide is a history of suicide attempts,¹² present in 5% of the adult US population.¹³ The rate of completed suicide within 1 year is nearly 100 times higher among those who have engaged in suicidal behavior than among control subjects.¹⁴ Suicidal behavior, therefore, is the most promising target for reducing risk of completed suicide.

Most of what is known about the treatment of suicidal behavior comes from clinical trials conducted at the outpatient level of care. While these studies (see below) have been highly promising, it is not known whether their results extend to the highest-risk group: psychiatric inpatients who are admitted to hospital following a suicide attempt. Approximately one third of all suicides by individuals with mental disorders occur in the 90 days following hospitalization.¹ A review of nearly 2 million adult psychiatric inpatients found that the suicide rate in the 90 days after discharge for patients diagnosed with depressive disorders was 235.1 per 100,000 person-years, markedly higher than that in the US general population (14.2 per 100,000 person-years).¹⁵ A meta-analytic review found that the post-discharge rate of suicide was an alarming 2078 per 100,000 person-years among patients admitted with suicidal ideation or behavior.¹⁶ We therefore suggest that efforts to reduce rates of suicidal behavior are critical for inpatients that have attempted suicide.

A.2. The Significance of Using Cognitive-Behavioral Therapy for Suicidal Behavior. Cognitive behavioral therapy (CBT) is a brief, collaborative, and skills-based form of psychotherapy that is particularly well-suited to the prevention of suicide.⁶ A variety of CBT suicide prevention protocols have been tested, yielding a range of efficacy estimates.²⁻⁵ The CBT protocol used in the proposed study, developed by Rudd and colleagues,¹⁷ showed the strongest behavioral effect of the 6 RCTs of CBT that measured suicidal behavior outcomes (see Fig. 1).⁴ Thus, we have selected the CBT protocol with the strongest empirical support. In an RCT of outpatients, this protocol resulted in a significant reduction in suicide attempts over a 24-month follow-up assessment (hazard ratio = 0.38); those receiving CBT were 60% less likely to make a suicide attempt than were those receiving TAU (see Fig. 2).⁷

The Rudd et al.⁷ protocol emphasizes teaching skills for crisis management (i.e., crisis response plan), maintaining safety (e.g., means restriction counseling, survival/hope kit, reasons for living list) and emotion regulation (e.g., relaxation, mindfulness, sleep hygiene, cognitive therapy). The original protocol was designed to be delivered in 12 outpatient individual sessions on a weekly or biweekly basis. Prior to pilot testing, we recognized that such a protocol would not be feasible on an inpatient unit, given the brief length of stay. We will describe in section E our pilot work that involved paring down the protocol and switching to a daily, rather than weekly or biweekly, format. Importantly, the inpatient manual included the same conceptual framework and skill content as the outpatient version, but, given

Fig. 1. Effect sizes for CBT on suicidal behaviors in controlled trials (source: Mewton & Andrews, 2016)

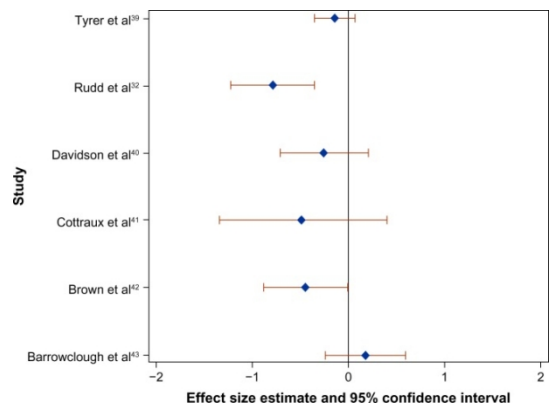
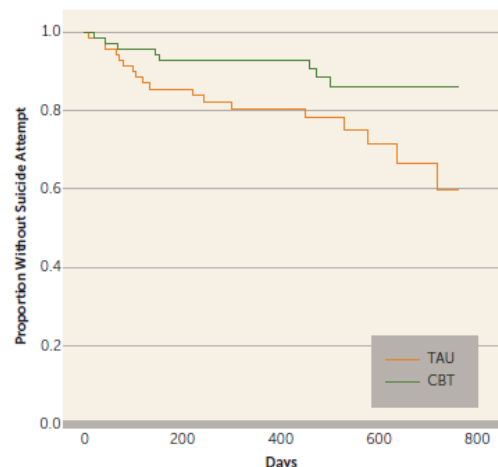


Fig. 2. Survival Curves for Time to First Suicide Attempt (source: Rudd et al., 2015)



expected short length of stay, the inpatient manual prioritized (i.e., included in the first three treatment sessions) the “core” crisis response plan, as well as skills most directly targeting suicide prevention (means restriction counseling, survival/hope kit, reasons for living list, and coping cards). We note that the crisis response plan has been independently validated as a stand-alone intervention for suicide prevention across a variety of treatment settings, including acute patients seen in the emergency department.¹⁸ The crisis response plan can be completed in one 30-min session, making it an ideal intervention for settings where time spent with the patient is extremely limited (such as the emergency department). Given that inpatient length of stay following a suicide attempt will typically be longer than a single day, we chose to investigate a CBT protocol which, as noted above, includes several key suicide prevention treatment components in addition to the crisis response plan. As the CBT protocol has now been validated in controlled research with outpatients and has been deemed feasible in an inpatient setting (See Section E), this proposed RCT will be the final empirical support needed before broad dissemination of the protocol within healthcare systems.

A.3. The Significance of Including and Examining Substance Use Disorder. Substance use disorders (SUDs) commonly co-occur with depression,¹⁹ and patients with SUDs are at particularly elevated risk for suicide attempts²⁰ (across studies, the relative risk ranges from 4.5-16.9).²¹ However, relatively little is known about the effect of CBT for suicidal behavior in patients with SUDs, as such patients are commonly excluded from clinical trials. Some evidence points to an attenuated response to CBT and pharmacotherapy for depression among substance-using patients.^{8,9} Of note, the outpatient CBT protocol was validated in a sample within which a substantial minority was diagnosed with SUD,⁷ suggesting that the protocol will be efficacious for these patients. However, the moderating effect of SUD on CBT for suicide prevention has not been established. To address this research question, we will include inpatients with SUD in the proposed study, and will examine whether the presence of a SUD is associated with diminished treatment response. We will use stratified block randomization to ensure that SUD is represented equally across the CBT and TAU groups (see Section F.5).

A.4. The Significance of Exploring Treatment Moderators. It is critical to identify those patients for whom the treatment is most and least effective. Though we predict a high level of success with the CBT protocol to be used here, no intervention is effective for all patients. By identifying those patients who are less likely to respond to the intervention, we will be able to better match patients to treatments and will stimulate the development of novel future treatments in which the intervention is modified or augmented to meet the needs of those groups who receive less benefit. Below, we describe several hypothesized treatment moderators.

A.4.1. Depression. Depression is a well-established risk factor for suicidal ideation,²² and higher depression severity is associated with greater suicide risk.²³ Further, there is some evidence that pre-treatment depression severity predicts less depressive symptom reduction in MDD,²⁴ greater risk of relapse²⁵⁻²⁹ and suicidal behavior in SUD,³⁰ and less improvement and lower remission rates in CBT for anxiety disorders.³¹ We will examine whether higher levels of depression are associated with attenuated treatment response for suicidal behaviors.

A.4.2. Impulsivity. There is growing evidence that those who attempt suicide have higher rates of impulsive behaviors,³²⁻³⁷ and impulsivity is associated with other known suicide risk factors (e.g., borderline personality disorder).³⁸ In outcome studies, greater impulsivity at intake is associated with poorer treatment outcomes for SUD,³⁹ eating disorders,⁴⁰⁻⁴² and impulse-control disorders.⁴³ We will attempt to extend previous work to examine the role of impulsivity on CBT treatment outcome for suicidal ideation and behavior.

A.4.3. Hopelessness. Trait hopelessness has been found to predict suicidal thoughts, attempts, and completions over periods up to 20 years.⁴⁴⁻⁴⁹ Results for state hopelessness are mixed, with some studies finding that state hopelessness is positively correlated with suicidal ideation,^{50,51} and others finding no relationship between state hopelessness and suicidal ideation.^{52,53} In treatment studies, greater pretreatment trait hopelessness was associated with less symptom reduction in inpatient⁵⁴ and outpatient CBT⁵⁵ for depression. Furthermore, hopelessness that is not responsive early in outpatient cognitive therapy for depression predicted worse treatment outcomes, suggesting the potential negative influence of state hopelessness.⁵⁶ We plan to extend previous findings to test whether trait and state hopelessness at pre-treatment are associated with poorer response to CBT for suicidal behavior.

A.4.4. Borderline Personality Disorder. Suicidal behavior is present in 69-80% of patients with borderline personality disorder (BPD).^{32,57-59} The moderating role of BPD in CBT for suicide has not yet been tested; however, previous work suggests that the presence of BPD at pre-treatment significantly predicts worse outcomes for depression, a known risk factor for suicide,^{24,50,60,61} and worse outcomes in a partial hospital sample.^{50,62} The current study will examine whether BPD traits moderate treatment outcome for suicidal thoughts and behaviors, thus warranting more specific intervention in inpatient settings.

A.4.5. Number of prior suicide attempts. History of previous suicide attempts has been identified as one of the best predictors of future suicide attempts, with two or more attempts conferring elevated risk of future suicidal behavior and suicide completion^{47,63-66} (e.g., weighted OR = 3.41).⁴⁴ Those with a history of multiple suicide attempts were more likely than single attempters to have higher anxiety, depression, SUD, hopelessness, and BPD symptoms, known risk factors for suicide.^{66,67} Further, data show a negative relationship between a history of a suicide attempt and treatment outcome;⁶⁸ however, the relationship between the number of previous suicide attempts and treatment outcome remains understudied. Given the high risk of those with a history of multiple attempts, the current study aims to examine if the number of previous suicide attempts moderates treatment outcomes.

A.4.6. Distress Tolerance. Patients with suicidal behavior have been characterized as having low distress tolerance.⁶⁹ Importantly, low distress tolerance may mediate the relationship between negative emotion and suicidality. We will examine the degree to which distress tolerance is associated with suicidality at pre-treatment, as well as the relationship between changes in distress tolerance and changes in suicidal thinking and behavior.

A.4.7. Insomnia. Insomnia is a well-established risk factor for depressive and anxiety disorders. Further, since 2010 alone, over 20 studies have demonstrated that insomnia is also associated with suicide risk.⁷⁰ This relationship could be explained by dysfunctional beliefs about sleep (e.g., hopelessness) as well as by the impaired executive function that can result from sleep loss. We will examine the relationship between insomnia and suicidal behavior at pre-treatment, and examine the potential moderating effects of insomnia on CBT response.

A.5. The Significance of Exploring Implicit Associations as an Outcome. Advances in the measurement of implicit cognition provide an opportunity to test whether automatic associations of self with death can provide a behavioral marker for suicide risk. Nock et al.⁷¹ measured *implicit associations*—the strength of a person's automatic association between mental representations of objects (concepts) in memory—about death/suicide in psychiatric ED patients. The *Implicit Association Test* (IAT, described in section F.2.6) is a brief computer-administered test that uses patients' reaction times when classifying semantic stimuli to assess automatic mental associations about life and death. Preliminary results from the IAT are impressive. Cross-sectionally, patients who had attempted suicide showed a significantly stronger implicit association between death and self than did patients who had not attempted suicide. Moreover, the implicit association of death with self was associated with an approximately 6-fold increase in the odds of making a suicide attempt in the next 6 months, exceeding the predictive validity of known risk factors (e.g., depression, suicide attempt history) and both patients' and clinicians' predictions.⁷¹

B. The Innovation of the Proposed Study. Our application of a well-validated treatment protocol to an acute inpatient population is innovative because of the unique characteristics of inpatients including short length of stay, severe levels of psychiatric distress, and very high risk of subsequent suicide attempts. Our modifications, which have proven effective in our pilot research (see section E), required us (with substantial consultation from Dr. Rudd) to focus the CBT protocol to those elements deemed most critical for acute care. Our exploration of multiple moderating factors will allow us to determine those patients for whom CBT is most effective. In addition, inclusion of the IAT as an outcome measure is innovative, as it moves the inquiry beyond traditional clinical variables and assessment methods.

C. Qualifications, Experience, and Productivity of the Applicant. The applicant, David Tolin, Ph.D., is an accomplished treatment outcome researcher with particular expertise in clinical trials of CBT. Dr. Tolin is the founder and director of the Anxiety Disorders Center/Center for Cognitive Behavioral Therapy at the Institute of Living, and an Adjunct Professor of Psychiatry at Yale University School of Medicine. Dr. Tolin has obtained

over \$5M of funding to support his research from organizations including the National Institute of Mental Health and the Donaghue Medical Research Foundation. He has amassed a publication record which includes over 180 peer-reviewed journal articles. As outlined in section E, Dr. Tolin was PI on a pilot open trial, conducted in support of the present proposal, investigating CBT for suicide prevention in adults who had made a suicide attempt.

Dr. Tolin's effort on the current proposal will be further supported by a strong investigative team including co-investigator Gretchen Diefenbach, Ph.D., and consultants M. David Rudd, Ph.D. and Ralitza Gueorguieva, Ph.D. Dr. Diefenbach has collaborated with Dr. Tolin for the past 17 years. She has extensive experience with CBT treatment manual development and took the lead role in revising the manual for use in the pilot study (see section E). Dr. Rudd is an expert in CBT for suicide prevention and was a co-author of the original CBT manual.⁶ He trained staff at the IOL in the treatment and provided ongoing consultations into the clinical application of the manual as well as study methodology. He will continue to play a similar consulting role during the proposed RCT. Dr. Gueorguieva has collaborated with Dr. Tolin on multiple clinical trials. Her expertise is in data analytic strategies for repeated measures designs. Dr. Gueorguieva will consult on data analytic strategies (e.g., power estimates) as well as conduct multi-level modeling statistical analyses.

D. Research Facilities. This study will be conducted at the Institute of Living (IOL). The IOL is one of the oldest psychiatric hospitals in the nation and is currently the largest psychiatric hospital in Hartford HealthCare (HHC), the largest health care system in Connecticut. HHC is a fully integrated health system which includes a tertiary-care teaching hospital, an acute-care community teaching hospital, an acute-care hospital and trauma center, three community hospitals, a large multispecialty physician group, a regional home care system, an array of senior care services, a large physical therapy and rehabilitation network, and the state's most extensive behavioral health network, comprised of three psychiatric and substance abuse treatment facilities, including the IOL. The IOL offers both inpatient and ambulatory services, thus providing continuity across levels of care. The IOL offers a large inpatient division, including child/adolescent, adult, and geriatric services, and hosts approximately 3,800 admissions annually. The adult inpatient division specifically is comprised of two 24-bed units. Further, the IOL is committed to the Zero Suicide Academy Initiative, which was developed by the Suicide Prevention Resource Center and the National Action Alliance for Suicide Prevention to improve the assessment and treatment of suicide. The Zero Suicide Academy Team meets monthly with staff across clinical areas and disciplines at the IOL. The IOL has implemented training in the Chronological Assessment of Suicide Events (C.A.S.E.), C-SSRS, and mental health first aid. The Zero Suicide Initiative is now being adapted across the behavioral health network of HHC.

E. Prior Related Work. In this section, we describe our pilot study, conducted this year at the IOL. The aims of this study were to refine the CBT manual⁶ for an inpatient setting, to pilot our assessment and treatment strategy, and to collect preliminary data on the feasibility, acceptability, and clinical efficacy of the protocol.

E.1. Participants. Six participants were enrolled in the study. Participants were all women, with a mean age of 34 (SD = 15.36, range = 18-58). A third of the sample self-identified as a member of a racial/ethnic minority group. Inclusion criteria were adults (age 18-65 inclusive) who made a suicide attempt within one week of hospital admission. Admission was defined as admission to either the medical floor (in cases where medical stabilization was required) or to the psychiatric inpatient unit (in cases where medical stabilization was not required). Suicide attempt was defined as self-directed behavior that deliberately resulted in injury or the potential for injury for which there was evidence, whether explicit or implicit, of intent to die. Participants were excluded if they were not fluent in English, when the inpatient treatment plan included electroconvulsive therapy, current SUD, or active mania; history of schizophrenia spectrum disorder, mental retardation, or organic brain illness; or any other psychiatric or medical condition that in the investigator's opinion would preclude informed consent or participation in the trial. We note that although we excluded participants with SUD in the pilot study, these patients will be included in the proposed RCT (see Section A.3 for rationale).

E.2. Measures. Study measures were administered by an independent evaluator (IE) who was not involved in the patients' treatment. Diagnostic status was assessed using the Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Disorders (DIAMOND).⁷² Suicidal ideation and behavior was assessed using the Columbia Suicide Severity Rating Scale (C-SSRS).⁷³ Depressive symptoms were measured using the Structured Interview Guide for the Hamilton Rating Scale for Depression (SIGH-D).⁷⁴

Acceptability of treatment was assessed using the Client Satisfaction Questionnaire (CSQ).⁷⁵ Implicit associations were measured using the suicide IAT. For additional information about the measures, please see section F.2

E.3. Treatment. We adapted the treatment manual from Bryan and Rudd⁶ to align with the acute care and short lengths of stay of inpatient settings. As noted in Section A.2, the inpatient manual included the same conceptual framework and skill content as the outpatient version. However, to maximize efficiency we structured the treatment into two phases - Phase I Crisis Management and Phase II Emotion Regulation Skills Training. Phase I was comprised of three sessions which entailed psychoeducation about the CBT treatment model; developing an individualized case conceptualization, crisis response plan, survival kit, and coping cards; identifying reasons for living; and conducting means restriction counseling. Phase II was comprised of seven sessions of emotion regulation skills training which included sleep hygiene, relaxation, mindfulness, cognitive therapy, and activity planning. Given that discharge timelines were variable and many patients were discharged with little forewarning, relapse prevention was incorporated in whichever session was final and involved a review of the material covered to date. The treatment manual allowed for up to 10 sessions (depending on length of stay) to be administered once daily in a fixed session order.

E.4. Results

E.4.1. Treatment Acceptability. A high degree of treatment acceptability was evident as all patients who were identified as study eligible ($n = 8$) agreed to participate. Two participants were subsequently excluded after a current SUD was diagnosed. All patients who started treatment ($n = 6$) continued treatment until discharge and on average reported a high degree of satisfaction with the study intervention (Client Satisfaction Questionnaire [CSQ] total score $M = 3.49$, $SD = 0.73$). All but one participant completed the follow-up assessments.

E.4.2. Treatment Outcome. Participants completed 4 treatment sessions on average ($SD = 2.73$, range = 3-8). There was a large pre- to post-treatment treatment effect size (Cohen's $d' = 0.98$) for improvement in suicidal ideation (C-SSRS intensity subscale $t_5 = 2.40$, $p = .06$). Patients also reported a large ($d' = 1.33$) and statistically significant ($t_5 = 3.26$, $p = .023$) improvement in depression from pre-to-post treatment as assessed by the SIGH-D. Results from the IAT also indicated stronger associations between self and life words at post-treatment, compared to pre-treatment ($d' = 1.28$). There were no reported suicide attempts of any kind (i.e., aborted, interrupted, actual), no reported preparatory acts or behaviors, and no reported non-suicidal self-injury over follow-up. Two participants reported suicidal ideation over the follow-up period. One reported experiencing wishes to be dead (without actual thoughts of killing self) at the 3-month follow-up, and the other reported active suicidal ideation without intent to act at the 1-month follow-up and wishes to be dead (without actual thoughts of killing self) at the 2-month follow-up. When present, the intensity of suicidal ideation ranged from 10-13 on the C-SSRS during follow-up.

F. Methods for the Proposed Study

F.1. Participants. We will recruit 200 consecutive adult inpatients at the IOL. We will enroll participants with a recent (i.e., within one week of hospitalization) suicide attempt or who endorse current (i.e., listed as a reason for admission) suicidal ideation with plan (with or without details worked out and with or without intent) in addition to a history of at least one suicide attempt within the past 2 years. Other inclusion/exclusion criteria will be identical to those in our pilot study (see section E.1), with the exception that we will now include patients with a diagnosis of a SUD and schizophrenia spectrum disorders other than schizophrenia or schizoaffective disorder. In addition, in order to allow sufficient time for study completion, we will exclude participants if the attending anticipates discharging the patient within 4 business days of consult. In order to increase safety during the COVID-19 pandemic, participants will be excluded if they test positive for COVID-19. In addition, participants will be excluded if they are unwilling to wear a mask during in-person research procedures. We will systematically assess sexual orientation and gender identity.

F.1.1. Feasibility of Recruitment. During our pilot work, we conducted a search of electronic medical records for IOL inpatients admitted 3/16/18-7/10/18 and documented reasons for study exclusion. As shown in Fig. 3, the primary reason for exclusion was an absence of a clear suicide attempt. Other patients were excluded due to history of schizophrenia spectrum disorder, mental retardation, or organic brain illness, or early discharge before screening could be completed. Over this 4-month period, 47 patients appeared to meet the inclusion criteria for the proposed study (approximately 12 admissions per month). With this patient flow we will be able to reach our enrollment target even if we experience a more conservative eligible participant flow and/or acceptance rate than we had in our pilot study (we need an average of 9.52 participants per month to meet the proposed enrollment target).

F.2. Measures

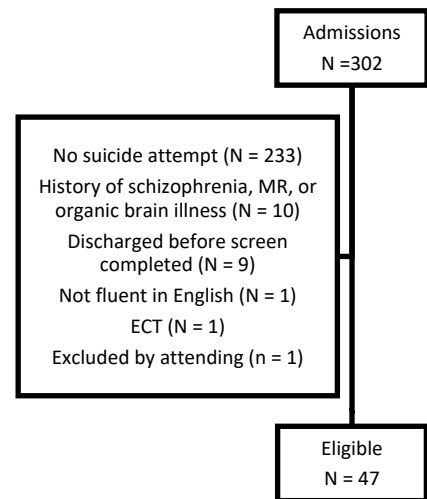
F.2.1. Diagnostic Measure. Diagnostic status will be assessed at pre-treatment using the Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Disorders (DIAMOND),⁷² a semi-structured interview for DSM-5 psychiatric disorders. The DIAMOND assesses for a wide range of DSM-5 disorders which will allow for determining diagnostic inclusion/exclusion criteria as well as characterization of the study sample. In addition to anxiety, mood, and obsessive-compulsive and related disorder, the DIAMOND assesses for substance use disorders, trauma- and stressor-related disorders, schizophrenia spectrum and other psychotic disorders, feeding and eating disorders, somatic symptom and related disorders, and a subset of neurodevelopmental disorders (tic disorders and attention deficit hyperactivity disorders). The DIAMOND shows very good to excellent ($\kappa = 0.68$) inter-rater reliability for depressive disorders, and very good ($\kappa = 0.65$) inter-rater reliability for SUDs. Similarly, test-retest reliability for the depressive disorders and SUDs is very good (both $\kappa = 0.76$).

F.2.2. Demographic Questionnaire. Demographic information including age, biological sex, race and ethnicity will be obtained from the medical record for all consented participants. Patients who are enrolled in the study will complete an expanded demographic questionnaire which will include questions about gender identity and sexual orientation.

F.2.3. Health Form. Diagnoses will be obtained from the medical record for all consented participants. In addition, patients who are enrolled in the study will complete a self-report indicating the presence of chronic medical conditions.

F.2.4. Suicidal Behavior. Suicidal behavior will be assessed using the Columbia Suicide Severity Rating Scale (C-SSRS), a widely used suicide assessment measure.⁷³ Several suicidal behaviors are assessed on the C-SSRS including the presence or absence of each of the following: suicide attempt, interrupted attempt, aborted attempt, and preparatory acts or behaviors. When an attempt is present, actual lethality is assessed on 6-point scale (0 = “no physical or very minor physical damage” to 5 = “death”). When actual lethality is rated as 0 then potential lethality is assessed on a 3-point scale (0 = “behavior not likely to result in injury” to 2 = “behavior likely to result in death despite medical care”). Presence or absence of non-suicidal self-injury is also assessed as these behaviors are associated with future suicide attempts.⁷⁶ The lifetime version of the C-SSRS will be administered at pre-treatment to assess both the total number of behaviors ever present as well as the number of behaviors present in “the past month.” At subsequent assessments the “since last visit” version will be administered with the timeframe for “since admission” at posttreatment, and “past month” at follow-up assessments. The behavior scales of the C-SSRS have demonstrated sensitivity to change across treatment, sensitivity and specificity in identifying lifetime actual and interrupted attempts⁷³, and predictive validity for identifying future suicidal behaviors and rehospitalization.^{77,78} Further, the C-SSRS behavior scales show moderate agreement with other measures of suicide risk.^{73,79,80} The C-SSRS has shown good inter-rater reliability for rating the number of lifetime attempts, interrupted attempts, aborted attempts, preparatory behaviors, and non-suicidal self-injury ($\kappa = 0.64$ to 0.81).^{81,82}

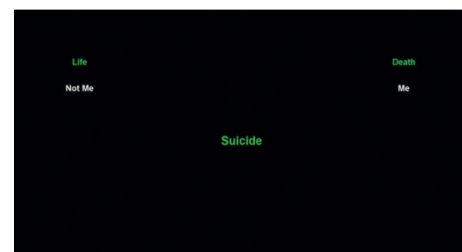
Fig. 3. Current patient flow (4 months) applying proposed RCT criteria.



F.2.5. Suicidal Ideation/Intent. Suicidal ideation and intent will also be assessed using the same C-SSRS versions and timeframes as described above (Section F.2.2).⁷³ Two subscales as described by Posner and colleagues⁷³ will be extracted: severity and intensity. The severity subscale is a single item describing the nature of suicidal thoughts: 1 = “wish to be dead,” 2 = “nonspecific active suicidal thoughts,” 3 = “suicidal thoughts with methods,” 4 = “suicidal intent,” and 5 = “suicidal intent with plan.” The C-SSRS severity subscale does not include a category for patients endorsing suicidal thoughts, with a specific plan, but without intent. For the purposes of this study participants meeting those criteria will be scored a “5”, as this is the only item that includes a specific plan (i.e., a plan with details fully or partially worked out) in the description. The intensity subscale is comprised of five items assessing the characteristics of suicidal ideation (frequency, duration, controllability, deterrents to intent and/or attempt, and reason for the ideation). The C-SSRS severity and intensity scales show moderate agreement with other measures of suicidal ideation.⁷³ The C-SSRS intensity scale has demonstrated adequate internal consistency ($\alpha = .73$)⁷³ and both suicidal ideation scales have shown moderate agreement with other measures of suicidal ideation.^{73,79,80} Further, the suicidal ideation scales have demonstrated predictive validity to detect future suicidal behaviors and rehospitalization.^{77-79,83} The C-SSRS shows good inter-rater reliability and multi-method agreement.^{80,81,84} Suicidal ideation will also be assessed using the Adult Suicidal Ideation Questionnaire (ASIQ)⁸⁵, a 25-item self-report scale designed to assess the frequency and severity of suicidal ideation. The ASIQ has demonstrated moderate positive correlations with depression, hopelessness, and past suicide attempts, good internal reliability, and good test-retest reliability.⁸⁵ Suicidal ideation/intent will also be assessed through self-reported intensity of Wish to Live and Wish to Die (0 = “Not at all” to 8 = “Very Much”) and listing and rank ordering by importance up to five reasons for living and reasons for dying.⁸⁶ To reduce participant burden the reasons for living/dying listing task will be completed only at the posttreatment assessment.

F.2.6. Implicit Association Test. As described in section A.5, the IAT⁷¹ is a brief computer-administered test that uses patient’s reaction times when classifying semantic stimuli to measure the automatic mental associations they hold about life and death. The IAT (see Fig. 4) is a computerized test that requires participants to classify stimuli representing the constructs of “death” (i.e., die, dead, deceased, lifeless, and suicide) and “life” (i.e., alive, survive, live, thrive, and breathing) and the attributes of “me” (i.e., I, myself, my, mine, and self) and “not me” (i.e., they, them, their, theirs, and other). Response latencies for all trials are recorded. The relative strength of each participant’s association between “death” and “me” is indexed by calculating a *D* score for each participant; positive *D* scores represent a stronger association between death and self (i.e., faster responding on the “death”/“me” blocks relative to the “life”/“me” blocks), and negative scores represent a stronger association between life and self. Participants will complete a web-based version of the IAT, which will allow for assessment both during treatment and during follow-up. The web-based version of the IAT is hosted by Millisecond using HIPAA-compliant software. IAT reaction time data are stored on a Millisecond server for download by ADC study staff. No PHI will be stored on the server. However, data on the server are labeled with a code provided by ADC study staff for future linking with other participant data by ADC study staff. Only ADC study staff will have access to the list linking the IAT codes with other participant identifiers. Storage of coded IAT reaction time data on the Millisecond server is described in the study consent form.

Fig. 4. Screen shot from the suicide Implicit Association Test (IAT).



The relative strength of each participant’s association between “death” and “me” is indexed by calculating a *D* score for each participant; positive *D* scores represent a stronger association between death and self (i.e., faster responding on the “death”/“me” blocks relative to the “life”/“me” blocks), and negative scores represent a stronger association between life and self. Participants will complete a web-based version of the IAT, which will allow for assessment both during treatment and during follow-up. The web-based version of the IAT is hosted by Millisecond using HIPAA-compliant software. IAT reaction time data are stored on a Millisecond server for download by ADC study staff. No PHI will be stored on the server. However, data on the server are labeled with a code provided by ADC study staff for future linking with other participant data by ADC study staff. Only ADC study staff will have access to the list linking the IAT codes with other participant identifiers. Storage of coded IAT reaction time data on the Millisecond server is described in the study consent form.

F.2.7. Service Utilization. Prescribed medication will be determined at intake and discharge through the electronic medical record. Interviews with the participant at each follow-up assessment will track changes in medication. Service utilization will also be assessed at each follow-up assessment through interview with the participant using a modified version of the Cornell Service Index Short Form and using a query of the HHC electronic medical record to determine changes in prescribed medications, as well as the number of encounters recorded for ER visits, outpatient behavioral health, and inpatient behavioral health (including length of stay).

F.2.8. Implementation Metrics. Implementation data will be collected from patients and the system. **Patients.** Acceptability will be assessed in part through refusal and discontinuation rates. To obtain additional information about potential barriers and facilitators to implementation, patients who refuse study participation

and/or discontinue study participation will be asked 1) the reason for refusal/discontinuation and 2) if there are any changes that could be made that would make BCBT a more acceptable treatment option. Patients in the experimental condition will also complete the Client Satisfaction Questionnaire CSQ,⁷⁵ at discharge assessment. The CSQ is an 8-item self-report assessing perceived quality and effectiveness of services, satisfaction with services, whether participants would return for similar treatment, and whether they would recommend this treatment to others. There is also a space for “comments” where the participant can write additional qualitative feedback. Each quantitative item is rated from 1 to 4 with higher numbers indicating higher satisfaction. The CSQ demonstrates good internal consistency and correlates with alternative satisfaction measures⁸⁷. Patients will also complete the Utility of Techniques questionnaire at each monthly follow-up assessment. The Utility of Techniques questionnaire asks whether or not the patient learned the skill during inpatient stay, and for those skills endorsed “yes”, participants rate the frequency of use and helpfulness (if skill was used) of the five strategies taught during BCBT: Crisis Response Plan, Survival Kit, Reasons for Living List, Coping Cards, and Means Restriction. The questionnaire contains 5 to 10 items, as the helpfulness item for each skill is only prompted if some use is indicated. All patients will complete a modified version of the Views on Inpatient Care (VOICE) questionnaire at baseline and posttreatment assessments. The original VOICE questionnaire has 7 sections, and it has been modified by only utilizing 2 sections. The modified version is a 7-item self-report assessing perceived quality of care on the inpatient unit, with an emphasis on adequacy of staff, therapy, and activities. Each quantitative item is rated from 1 to 6, with higher numbers indicating higher satisfaction and there are two spaces for comments for qualitative feedback. The VOICE measure has good validity and internal and test-retest reliability. **System.** All study staff will track barriers encountered during study implementation via the Implementation Barriers Log. In addition, qualitative feedback regarding staff’s views on barriers and facilitators to BCBT implementation will be collected via an anonymous survey at the end of study enrollment. Costs will be estimated via tracking of time for implementation of treatment and related documentation procedures.

F.2.9. Adverse Event Assessment. Adverse events will be assessed at every study visit using the questions “Have there been any changes to your physical health since the last time we met?” and “Have there been any changes to your mental health since the last time we met?” worded for the appropriate timeframe of each assessment timepoint. Adverse events will be tracked and reported according to policy 910.

F.2.10. Moderators. Substance Use. Substance use disorder diagnoses will be obtained using the DIAMOND as described in section F.2.1. Severity of alcohol use will be assessed using the Alcohol Use Disorders Identification Test (AUDIT),⁸⁸ a 10-item self-report measure of problematic alcohol use. The AUDIT has demonstrated strong internal consistency, test-retest reliability, and sensitivity and specificity compared to other measures of alcohol use.⁸⁹ Severity of drug use over the past year will be assessed using the Drug Abuse Screening Test (DAST),⁹⁰ a 20-item self-report measure. The DAST has demonstrated excellent internal consistency, and adequate convergent and divergent validity.⁹⁰⁻⁹² **Depression.** Depression symptoms will be assessed using the depression subscale of the 21-item Depression Anxiety Stress Scales-21 (DASS-21).⁹³ The DASS-21 has demonstrated good internal consistency across scales, and good convergent validity with other measures.⁹³ **Impulsivity.** Impulsivity will be measured using the impulsivity scale of the Difficulties in Emotion Regulation Scale (DERS).⁹⁴ The DERS has demonstrated high internal consistency, good test-retest reliability, and adequate construct and predictive validity.⁹⁴ **Hopelessness.** Hopelessness will be assessed using the State-Trait Hopelessness Scale (STHS).⁹⁵ The STHS is a 23-item self-report scale that consists of the 10-item State Hopelessness Subscale (SHS) and the 13-item Trait Hopelessness Subscale (THS), both of which assess negative attitudes about the future. Both subscales have demonstrated internal reliability and moderate correlations with the Beck Hopelessness Scale and Patient Health Questionnaire.⁹⁵ Trait hopelessness will also be assessed using a brief version of the Suicide Cognitions Scale (SCS).⁹⁶ The SCS includes 18-items assessing beliefs about burdensomeness, unlovability, and intolerance of distress, which confer vulnerability to suicidal thoughts and behaviors independent of the individual’s current state. The SCS has demonstrated good predictive validity for suicidal ideation and future suicide, and adequately discriminates between those with and without a history of suicide attempts.⁹⁶ The Brief SCS is a 9-item self-report including the same three subscales as the original scale.⁹⁷ **Borderline Personality Disorder.** Symptoms of borderline personality disorder will be assessed using the McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD).⁹⁸ The MSI-BPD is a 10-item self-report measure that has demonstrated good sensitivity and specificity in detecting symptoms of borderline personality disorder compared to the Diagnostic Interview for DSM-IV Personality Disorders (DIPD-IV),⁹⁹ good test-retest reliability, and acceptable internal

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consistency.⁹⁸ **History of Suicidal Behavior.** As noted above (See Section F.2.2), history of suicidal behavior (number of prior suicide attempts) will be assessed using the lifetime version of the C-SSRS. **Distress Tolerance.** Distress Tolerance will be assessed using the Distress Tolerance Scale (DTS).¹⁰⁰ The DTS is a 15-item self-report measure assessing the degree to which individuals experience negative emotions as intolerable (e.g., “When I feel distressed or upset, all I can think about is how bad I feel”). The DTS has evidenced good reliability and internal consistency in clinical samples.¹⁰¹ **Insomnia.** The Insomnia Severity Index (ISI) is a 7-item self-report of sleep problems (onset, maintenance), dissatisfaction, interference, and distress with good psychometric properties.¹⁰² **Schizophrenia Spectrum Disorder.** If $n = 1$ participant is enrolled with this diagnosis we will analyze the data with and without including this participant. If 5 or more participants with schizophrenia spectrum disorder are enrolled we will explore this diagnosis as a moderator.

F.3. Brief CBT. As described in section E.3, we had previously adapted Bryan and Rudd’s⁶ treatment manual for an inpatient setting. This protocol included up to 10 sessions (depending on length of stay). However, our pilot data suggested that this protocol was too lengthy, as no patients received the full protocol. As noted above the average number of sessions attended was 4. In addition, feedback from the study clinician and supervising psychologists (including one psychologist who listened to audiotapes of all pilot treatment sessions) suggested that introducing a variety of CBT skills in rapid succession (i.e., with one new skill introduced each day) as was done in Phase II of the pilot treatment manual may not have provided adequate time for practice and consolidation of the “core” crisis management skills introduced in Phase I. Thus, in the RCT we will only include the Phase 1 Crisis Management sessions (sessions 1-3) delivered daily (excluding weekends and legal holidays), plus a relapse prevention session (session 4) delivered as close to discharge as possible. In cases where the patient is discharged earlier than the expected four business days from attending consult, two sessions may be completed in the same day and/or the all skills review may be incorporated into whatever session is final in order to cover as much treatment material as possible prior to discharge. Delivering a 4-session, behavioral skill-based protocol in the RCT is consistent with the typical experience of patients in our pilot study (M sessions = 4) and is supported by meta-analytic research indicating that the most efficacious CBT suicide prevention protocols are those that focus on treating suicidal behaviors directly (rather than targeting comorbid psychiatric distress).⁴ This protocol will also be a more feasible, focused, and standardized product for the next step of dissemination. Details of the 4-session protocol are outlined below. In cases where the session material is not completed in one meeting, additional meetings will be scheduled in order to cover all session material.

Session 1. Session 1 begins with an introduction to the structure and content of CBT and specification of preventing suicide attempts as the treatment goal. Informed consent is confirmed following reminders about the voluntary nature of the treatment and limitations of confidentiality. Next, the therapist completes psychoeducation about the “suicide mode,”⁶ the CBT case conceptualization model for suicidal behavior. The suicide mode includes baseline risk factors (i.e., factors which predispose or make one vulnerable to suicide) interacting with triggering events leading to acute risk factors (i.e., temporary exacerbations in emotions, thoughts, physiology, and behaviors associated with suicide). The therapist further describes how CBT targets modifiable aspects of the suicide mode in order to enhance safety. Next, the therapist conducts a narrative assessment asking patients to tell their “story” of the index suicide attempt (i.e., the attempt which preceded current admission) and constructs an individualized suicide mode case conceptualization. At the end of the session, a crisis response plan is developed, which involves identifying warning signs, self-management strategies, supportive friends or family members, and professional resources which could be accessed if needed in a crisis. Session 1 lasts for 90 minutes and patients are provided with pocket-sized composition notebooks in which they record key concepts from the session such as the suicide mode, crisis response plan, and main takeaways or “lessons learned.” The treatment log is used to promote between-session practice as well as improve accessibility of the session content in the future. Following CBT the treatment log serves as a written relapse prevention tool.

Session 2. The primary goal of Session 2 is to increase cognitive flexibility and ambivalence toward suicide by focusing attention on positive aspects of living. Two interventions are introduced. First, the therapist introduces reasons for living by asking patients to describe reasons why they do not want to die and what prevents them from making another suicide attempt. For example, responsibility to children or pets, to enjoy pleasures such as certain foods or experiences, or to be alive during important future events are common reasons for living. The reason for living is reinforced through a visualization exercise focusing on vivid and specific details to increase emotional salience and improve access from memory. The second intervention is

creating a survival kit (sometimes also called a hope box). The therapist provides the patient with a white cardboard container and asks the patient to identify items that could be placed in the box that would serve as concrete visual reminders of positive experiences. Common items included in the survival kit include pictures of loved ones, inspirational quotes, or mementos from positive life events. The rationale for choosing each item is reviewed by the therapist in order to discourage inclusion of any potentially iatrogenic items.

Session 3. In Session 3 the therapist completes counseling on reducing access to lethal means. This is an essential component to preventing death by suicide. Because activations of the suicide mode are temporary, creating barriers to lethal means can create a window of opportunity for suicide distress to subside and/or for the patient to enact a crisis response plan. Even if the patient makes a suicide attempt, doing so with a less lethal form of means still reduces the likelihood of injury and improves the patient's chances of surviving. During session 3 the therapist assesses for access to means, including access to firearms, and then collaboratively develops a plan to restrict means. Common examples of means restriction are to remove firearms from the home or to have a family member lock up and dispense medications. The means restriction plan is shared with the unit clinician to review during family meetings. In session 3 the therapist also introduces coping cards to modify cognitive factors of the suicide mode. The suicide mode thoughts are written on one side of the card and alternative responses are written on the other side of the card. The coping cards provided a concrete memory aid for alternative thoughts when the patient's negative thoughts are activated in the suicide mode.

Session 4. In the final session, the therapist reviews all previous CBT skills and reinforces the treatment log as a reference to use after discharge. Two relapse prevention tasks are completed as well. The participant is directed to imagine the index suicide episode as well as a hypothetical future suicide episode. For each, the therapist assists guides the participant to imagine him- or herself utilizing one or more skills learned in BCBT to effectively manage the situation. In addition, anticipated high risk situations are identified and any necessary changes to the crisis response plan are made. This plan is also shared with the patient's unit clinician. The therapist discusses the upcoming discharge and reviews specific ways that CBT skills can be integrated into daily life.

Table 1. Measurement Schedule.

	Intake	Discharge	Follow-Up					
			1-Mo	2-Mo	3-Mo	4-Mo	5-Mo	6-Mo
DIAMOND	X							
Demographic Form	X							
Health Form	X							
C-SSRS	X	X	X	X	X	X	X	X
IAT	X	X	X	X	X	X	X	X
ASIQ	X	X	X	X	X	X	X	X
DASS-21	X	X	X	X	X	X	X	X
STHS-State	X	X	X	X	X	X	X	X
STHS-Trait	X							
AUDIT	X							
DAST	X							
DERS-Impulsivity	X							
SCS	X	X	X	X	X	X	X	X
MSI-BPD	X							
VOICE modified	X	X						
Utility of Techniques			X	X	X	X	X	X
Client Satisfaction		X						
Service Utilization/CSI mod.			X	X	X	X	X	X
AE Assessment	X	X	X	X	X	X	X	X
Implementation Barriers Log	X	X	X	X	X	X	X	X
DTS	X	X	X	X	X	X	X	X
ISI	X							
Wish to Live\Wish to Die	X	X	X	X	X	X	X	X
Reasons for Living\Dying		X						

F.4. Treatment as Usual. TAU includes 24-hour care through a multidisciplinary team providing treatment on the basis of a short-term stabilization model. While each patient receives an individualized treatment plan, programming may include pharmacotherapy, group psychotherapy, case management/individual therapy, rehabilitation therapy, recreation therapy, vocational counseling, family therapy, and collaboration with outside

providers. As part of the Zero Suicide Initiative, telephone calls are made after discharge to all patients admitted following a suicide attempt to ensure that patients are following their discharge plans, including connecting with referrals to outpatient services. By the initiation of this study, all patients admitted following a suicide attempt will also be discharged with a personal safety plan.¹⁰³

F.5. Procedure. Eligible participants will be identified through the same multi-step screening process utilized in our pilot study, starting with a review of admission logs and followed by consultation with the participant's attending psychiatrist to confirm eligibility criteria. Participants passing both of these screens will be recruited either in person or by phone/videoconference by a member of the research staff. Interested participants will provide written informed consent prior to any study procedures. For patients who are admitted to the hospital involuntarily, documentation of competency to provide consent will be completed by the attending physician as well. The third step of the screening process will be a baseline clinical interview including the DIAMOND and C-SSRS. Given that randomization does not occur until after the baseline interview, this interview may be conducted by any Ph.D.-level clinical study personnel who has completed training certification in the administration of these measures. In situations where the intake is completed by a post-doctoral fellow, the fellow will be supervised by study personnel who is a licensed psychologist. The baseline assessment will also include the IAT and the following self-report measures: Demographic Form, ASIQ, AUDIT, DAST, DASS, STHS, DERS Impulsivity subscale, SCS, MSI-BPD, ISI, DTS, Wish to Live\Die, and VOICE modified (a full schedule of events is outlined in Table 1).

Participants meeting all inclusion and none of the exclusion criteria will be randomly assigned (using a computer-generated randomization schedule) to either CBT or TAU using stratified block randomization on SUD. We expect, based on pilot data analyses, that approximately two-thirds of patients in each group will be diagnosed with SUD. Patients assigned to CBT will participate in all aspects of their prescribed treatment plan (i.e., TAU) and in addition will receive up to 4 sessions of CBT (depending on length of stay), lasting 1.5 hours for the first session and 1 hour for the remaining sessions, following the manualized protocol described above. Treatment will be conducted by a doctoral-level clinician trained in the manualized procedures. Training will involve reading the manual, reviewing videos from the training conducted by Dr. Rudd's previously at the IOL, reviewing sessions of pilot study participant treatments, participating in mock treatment role-plays, and completing treatment of at least 2 participants under close supervision (i.e., with all sessions reviewed by the supervising psychologist). Audiotapes will be made of each session and transcriptions will be made from a subsample of participants who consented for transcription of their sessions. A psychologist trained in the CBT protocol will review audiotapes of 10% of sessions and will rate treatment fidelity according to a checklist developed in collaboration with Dr. Rudd and utilized in our pilot study ($\geq 90\%$ treatment fidelity was rated for all pilot participants). Transcriptions may also undergo qualitative coding for content analysis of case conceptualizations and treatment content (e.g., suicide mode features such as the role of substance use in suicide attempts). As preliminary analyses have found over 10% of the study sample identifies as transgender this study provides a unique opportunity to develop understanding of how minority stress relates to suicide risk for transgender patients as well as explore the experience of transgender patients engaged in suicide prevention therapy. We will code themes related to transgender minority stress in suicide attempt narratives and CBT treatment (e.g., environmental and external events such as discrimination or harassment; social connectedness; psychological vigilance; anticipation of negative events related to gender identity; internalized transphobia, resilience, gender-affirming care, and transitioning). We have obtained funding from the Hartford Hospital Medical Staff to support the additional time required to complete these transcriptions and content analyses ("Reducing Disparities in Suicide Prevention Treatment for Transgender People", Diefenbach, PI). Participants assigned to TAU will engage in usual care. For the post-treatment assessment, participants will meet with an independent evaluator (IE; a clinician who is not the patient's treatment provider and is blind to study group assignment) either in person or by phone/videoconference to complete the C-SSRS. The participant will also complete the IAT and self-report measures (ASIQ, DASS, STHS-State, SCS, DTS, Wish to Live\Die, Reasons for Living\Dying, Client Satisfaction) as close to discharge as possible. In the event that patients are discharged prior to completing this assessment, the assessment will be completed by phone and remote data collection as will typically be done for follow-up assessments. After discharge, participants will have a telephone interview each month for 6 months of follow-up. The IE will administer the C-SSRS, IE Medications Interview, and CSI modified interview. In addition, participants will complete the IAT remotely, and the ASIQ, DASS, STHS-State, SCS, DTS, Wish to Live\Die, and Utility of Techniques through REDCap,¹⁰⁴ a secure data management website. When patients are readmitted to one of the study units during the follow-up assessment time period, the follow-up assessment may be conducted on the unit with study staff providing

computer and phone access in order to complete data collection. Participants will be reimbursed \$50 for each post-treatment/follow-up assessment. IE meetings will also be audiotaped to facilitate monthly IE calibration meetings to prevent against rater drift. Transcriptions will be made from a subsample of participants who consented for transcription of their study meetings. After each interaction between IE and the participant, the IE will complete an IE Assessment of the Blind which tracks if and how IEs became unblinded to condition as well as requires IEs to guess the condition of the participant and rate their confidence.

We recognize that obtaining follow-up data is critical. Therefore, we will take several steps to optimize our ability to collect such data. During the informed consent process, participants will be asked to provide multiple forms of contact including a direct telephone contact and e-mail as well as the back-up numbers of at least two family members or friends in case study staff are unable to reach the participant at the direct number. If study staff is unable to reach the participant for follow-up at all contact numbers provided following no less than three call attempts, then a letter will be sent to the participant requesting that they contact the study staff. If no reply is received from 1 week of mailing the first letter, then a second letter will be sent requesting that the participant contact the study staff and also indicating a date by which study staff will no longer contact them to schedule follow-up calls. If no reply is received by the indicated date, then the participant will be considered lost to follow-up. In an effort to assess suicide attempts and other important outcome variables (e.g., readmission) over the follow-up period, medical records and publicly available death records will continue to be reviewed.

F.6. Data Analytic Plan

F.6.1. Power Analysis. We predict, based on remarkably consistent results from longitudinal studies of inpatients post-discharge,¹⁰⁵⁻¹⁰⁷ that the rate of suicidal behavior during the follow-up period for TAU patients will be approximately 37%. We further predict, based on Rudd et al.'s⁷ outpatient study that that CBT will reduce the incidence of suicidal behavior by approximately 73% over the 6-month follow-up period (i.e., the rate of suicidal behavior for CBT patients will be approximately 10%). To err on the conservative side, we will power for a 50% decrease in rate of suicidal behavior (i.e., 37% vs. 18.5%). To detect a difference of this magnitude with 80% power ($\alpha = 0.05$, two-tailed), we would need 90 individuals per group. To ensure robustness of results, we propose to recruit 100 patients per group. For the continuous outcome variables, assuming up to 20% dropout, this N will provide us with more than 80% power to detect a medium effect size ($d=0.50$, $f=0.25$ for the comparison of interest (i.e. between-group differences post-baseline) to address the primary aims at 0.025 significance level (adjusted for two outcome variables for aim 2).

F.6.2. Assumptions. Data distributions of continuous variables will be checked for normality using normal probability plots prior to statistical analysis. Transformations will be applied if necessary. Descriptive statistics will be calculated using all available data at each time point. The analyses will be performed on the modified intent-to-treat sample (i.e., all randomized individuals that complete at least one CBT session).

F.6.3. Primary Hypotheses. We will test the primary aim hypotheses using mixed effects models (linear mixed effects models for continuous outcomes and generalized linear mixed models for categorical outcomes), a statistical approach that uses all available data on individuals and provides flexibility in modeling the correlational structure of the data, and results in unbiased and maximally efficient estimates under missing at random assumptions. Group, Time and the interaction of Group x Time will be fixed predictors. We will use all available data on individuals completing at least one CBT session and will include the stratification factor (SUD) as another factor in the models. The best-fitting variance-covariance structure (e.g., compound symmetry, autoregressive, etc.) for continuous outcomes will be selected using Schwartz's Bayesian Information Criterion (BIC). We expect a statistically significant interaction of Group (CBT versus TAU) x Time (pre-treatment, post-treatment, 1-month, 2-month, 3-month, 4-month, 5-month, 6-month follow-up) for the dependent variables of interest: suicidal behavior, suicidal ideation/intent, and rehospitalization with significant between-group differences at the post-baseline time points. Power is calculated based on the average of the post-baseline time-points but we will also have the ability to estimate effect sizes between groups by time point with associated confidence intervals. Analyses of suicide behavior will also be used to estimate absolute risk reduction between the treatment and control group and to derive estimates of numbers needed to treat to prevent one more suicide attempt.

F.6.4. Exploratory Moderator Analyses. We will explore the moderating effect of suicide risk variables (i.e., depression severity, impulsivity, hopelessness, BPD, DTS, ISI, number of previous attempts) on

CBT effects by repeating the analyses described above with moderator variables and its interactions with the other factors in the model (group, time) added as categorical predictors. Significant interactive effects of the moderator variable with treatment condition (TAU versus CBT) will be interpreted to meet this exploratory aim. For all potential moderators we will estimate treatment effect sizes with confidence intervals within level of the moderator (e.g. among individuals with SUD, among individuals without SUD) in order to inform future studies.

F.6.5. Exploratory Implementation Data Analyses. Exploratory implementation metrics will be summarized using descriptive statistics.

G. Strengths and Weaknesses

G.1. Strengths of the Proposed Study. The primary strength of this study is its high-impact focus, in which we aim to prevent suicide in the most highly vulnerable (yet understudied) population: inpatients admitted following a suicide attempt. Relatedly, a major strength is our use of an empirically-supported intervention for suicidal behavior that is ready for broad dissemination within this population following a successful RCT. The outpatient protocol has been tested in a RCT,⁷ and demonstrates the strongest effect of any cognitive-behavioral intervention on suicidal behavior.⁴ Our sample size ensures adequate power to test the study hypotheses. Our multimodal assessment, including implicit associations, will yield a rich database that allows us to test multiple hypotheses about treatment outcomes as well as moderating factors. Finally, the research environment is a significant strength. As part of a large, statewide healthcare system, we are poised, when the aims of the proposed study are met, to disseminate this treatment across hospitals.

G.2. Weaknesses of the Proposed Study. Because of the time-limited nature of inpatient hospitalization, it is noted that not all of the original outpatient treatment protocol⁶ will be used. Rather, this treatment is focused more on the acute issues of crisis stabilization and establishing reasons for living, with decreased (though not absent) emphasis on elements such as emotion regulation skill building. A similar truncated protocol has been found to be efficacious in controlled research in emergency departments¹⁸ and shows good feasibility and initial efficacy in our pilot work (see section E). We also note that because of varying lengths of stay, all patients may not receive the same “dose” of treatment. We considered standardizing length of stay, but opted against this for ethical reasons of providing least restrictive treatment. Our sample size and data analytic strategy will allow us to examine the relationship between number of sessions and treatment outcome.

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