An Initial Feasibility Study of Brief Cognitive Behavioral Therapy for Suicidal Inpatients

Rationale. Suicide is a major public health problem: suicidal ideation affects 14% of the adult U.S. population, and as many as 5% have a lifetime history of suicide attempts.[1] Among individuals with depressive disorders, there is an 11% mortality rate from suicide.[2]

Although inpatient treatment provides immediate stabilization and crisis management, the risk of suicide post-discharge is substantial. Approximately one third of all suicides by individuals with mental disorders occur in the 90 days following hospitalization.[3] 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).[4]

Cognitive behavioral therapy (CBT) has been shown to reduce both suicidal ideation and behavior.[5-8] Though specific protocols vary, typical interventions include problem-solving training,[9] cognitive restructuring,[10] and training in emotion regulation skills.[11] To date, most of the existing research on CBT has been in outpatient samples, and the efficacy of inpatient CBT for suicide prevention is not clear.

Project Aims. The aims of the proposed project are to:

1. develop and implement a brief CBT for suicide prevention on the adult inpatient units;
2. conduct a brief feasibility test and collect initial pilot data on efficacy; and
3. collect preliminary data on the effects of CBT on implicit cognitive suicide associations.

Method. We selected Rudd et al.'s[12] CBT protocol for the proposed project. This protocol was tested in a randomized controlled trial (RCT) of outpatients and 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 treatment as usual.[13] Of the 6 RCTs that measured suicidal behavior, this was the strongest behavioral effect documented.[7]

There will be two phases involved in this project, which are described below:

In Phase 1 of the project, we will work with Dr. Rudd to modify his treatment protocol for use in an inpatient setting, and attend a two-day training in the protocol from Dr. Rudd.

In Phase 2 of the project, we will conduct an initial feasibility trial with 5-10 inpatients.

Participants. We will recruit 5-10 consecutive adult inpatients (dependent on flow within the 6-month treatment window) from the Donnelly units. Inclusion criteria will be:

1. males and females
2. age 18-65 inclusive
3. fluent in English (speaking, reading, and writing)
4. having made a suicide attempt within one week preceding admission. Admission will be defined as admission to either Harford Hospital medical floor (in cases where medical stabilization is required prior to transfer to IOL) or to IOL (in cases where medical stabilization is not required). A suicide attempt will be defined as behavior that is self-directed and deliberately results in injury or the potential for injury to oneself for which there is evidence, whether explicit or implicit, of intent to die.

Exclusion criteria will be:

1. age <18 or ≥66 years old
2. history of schizophrenia spectrum disorder
3. history of mental retardation or organic brain illness
4. current substance use disorder

5. active mania or other psychiatric or medical condition that would preclude informed consent or participation in the trial, in the investigator's opinion
6. ECT included on patient's inpatient treatment plan. Patients who are referred for ECT after starting the study will be withdrawn from the study.

Measures. Participants will complete a brief self-report demographic form. Diagnostic status will be measured at pre-treatment using the Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Disorders (DIAMOND).[14] Suicidal ideation and behavior will be assessed using the Columbia-Suicide Severity Rating Scale (C-SSRS).[15] The C-SSRS can be scored to yield an ideation severity score (range 0-5) and a behavior severity score (0-5); suicidal behavior can also be scored dichotomously (present/absent). The C-SSRS will be administered with the timeframe for the "past week" at admission (i.e., pretreatment), and "since admission" at posttreatment, and "past week" at follow-up assessments. Depressive symptoms will be measured using the Structured Interview Guidelines for the Hamilton Rating Scale for Depression (SIGH-D),[16] a well-validated clinician-rated interview for depression. Treatment acceptability will be measured using the Client Satisfaction Questionnaire (CSQ),[17] an 8-item self-report measure.

At pre-treatment and post-treatment, we will also administer an *Implicit Association Test* (IAT).[18] The IAT is a brief computer-administered test that uses people's reaction times when classifying semantic stimuli to measure the automatic mental associations they hold about various topics, in this case, life and death/suicide. Participants 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.

Procedures. It is anticipated that the treatment component of the study will take place over a period of six months.

Participants will be recruited by a member of the research staff on the day following their inpatient admission or later (for example in the case of a Saturday admission). Patients who meet all of the inclusion criteria and none of the exclusion criteria and agree to participate will provide written informed consent prior to any study procedures. Informed consent will be documented using the Documentation of Informed Consent Form. For patients who are admitted to the hospital involuntarily documentation of competency to provide consent will be completed as well. Only those involuntarily committed patients who have been found competent to provide informed consent for research will be consented. Patients who decline participation will not be approached again. Patients who agree to participation will undergo the informed consent process. This process will involve providing the patient with the informed consent and HIPAA authorization forms to read. The study staff member obtaining consent will highlight the voluntary nature of the research and emphasize that the patient's decision whether or not to participate will not impact his "usual care" treatment plan; however, patients will also be informed that the information discussed with the study clinician is shared with the inpatient treatment team, and thus may be used by them when making decisions about discharge planning. Patients will be informed that they may keep the forms to review with others if they wish to do so before signing. In addition, all questions the patient has about study participation will be answered prior to obtaining written consent.

Enrolled participants will undergo a clinical assessment by an independent evaluator (IE), who will administer the DIAMOND, C-SSRS, SIGH-D, and IAT.

Participants will receive up to 10 daily 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 developed in Phase 1. The CBT protocol is designed to be delivered in two phases. In phase I, the therapist conducts a detailed assessment of the

patient's most recent suicidal episode or suicide attempt, identifies patient-specific factors that contribute to and maintain suicidal behaviors, provides a cognitive behavioral conceptualization, collaboratively develops a crisis response plan. The crisis response plan is reviewed and updated in each session by adding new skills and/or removing skills determined to be ineffective, impractical, or too challenging. In phase II, the therapist teaches the patient new coping skills inclusion emotion regulation strategies (e.g., relaxation, mindfulness) and cognitive strategies to reduce beliefs and assumptions that serve as vulnerabilities to suicidal behavior (*e.g.*, hopelessness, perceived burdensomeness, guilt and shame). During the first session of CBT, participants are provided with a small pocket-sized notebook (called a "smart book") in which they are directed to record a "lesson learned" at the conclusion of each session. Lessons learned include new skills learned or knowledge gained by participants during each session. Participants are encouraged to use the smart book in the future as a memory aid for managing emotional distress and solving problems.

Data Storage and Security. Audiotapes will be made of each session. All CBT sessions will be audiotaped using digital recorders. Audio files will be stored electronically with password-access login maintained on the HHC server. Access to the audiofiles will be limited to IRB-approved study staff. Files will be maintained for 6 years following studying closure at which time they will be permanently deleted. A psychologist trained in the CBT protocol will review audiotapes of all sessions and will rate treatment fidelity according to a checklist developed in collaboration with Dr. Rudd. Deidentified excerpts from audiorecordings may be transcribed for inclusion in research publications.

Participants will then meet with the IE again for the C-SSRS, SIGH-D, IAT, and CSQ after the 10th session or within 24 hrs. prior to discharge, whichever comes first. After discharge, participants will have a telephone interview at 1 month, 2 month, and 3 month follow-up. The IE will administer the C-SSRS during these calls. Chart review (via Epic) will also be completed on study eligible participants (whether or not recruited). Data retrieved at 1, 2, and 3-month post-discharge will include readmission rates to the IOL or ED. Whether suicide attempt preceded admission will also be recorded. Demographic and clinical information will also be collected from the medical record (age when < or = 89, sex, race/ethnicity, diagnoses, medication, length of stay, suicide method) to compare study eligible participants who were versus were not recruited to determine if the groups were matched on these variables. At least three telephone calls will be made to try to reach a participant to complete the follow-up assessments. If a participant is unable to be reached by phone for the follow-up assessment after three tries then a letter will be sent to the participant asking them to contact the IE to inform her whether or not they wish to continue in the study. If a participant fails to contact the IE within 1 week of the study team sending the letter then a second letter will be sent again requesting that the participant contact the IE to let her know whether or not they wish to continue in the study along with a date by which the participant should contact the IE. If the participant does not contact the IE by the date stated in the letter they will be withdrawn from the study.

Adverse Event reporting.

Any severe adverse events (SAEs) that occur will be reported to the HHC IRB in a timely fashion, according to policy 901. Unexpected Severe AE's – those rated 3-5 – will be reported within 7 calendar days of learning of the event.

Analytic Plan. It is noted that this is an initial test of feasibility and is therefore not powered for statistical significance. Though we will conduct significance tests, of greater importance are the following outcomes (all analyses will be intent-to-treat):

1. Mean CSQ scores at post-treatment, indicating acceptability of treatment.
2. Percent attrition rate, indicating acceptability of treatment.
3. Mean treatment fidelity rating, indicating our capacity to administer the treatment as described.
4. Effect size (Hedges's *g*) of IAT D scores from pre- to post-treatment

5. Effect size (Hedges's *g*) of C-SSRS ideation severity score from pre-treatment through follow-up
6. Effect size (Hedges's *g*) of C-SSRS behavior severity score from pre-treatment through follow-up
7. Effect size (Hedges's *g*) of SIGH-D score from pre-treatment through follow-up
8. Effect size (Hedge's *g*) comparing study enrolled versus study eligible (but not recruited) participants on readmission over the follow-up.

Future Plans. The proposed study will yield feasibility and initial efficacy data that will be used to inform a grant proposal to the American Foundation for Suicide Prevention. That proposal will fund a randomized controlled trial of CBT vs. treatment as usual. Concurrently, we will develop an in-house program to train other staff in the protocol, and will submit a second grant to investigate the efficacy of the training program as well as the efficacy of CBT by those clinicians (benchmarking analysis).

Budget and Budget Justification

David Tolin, Ph.D. (Principal Investigator, 5% time, no salary requested): Dr. Tolin will be responsible for overseeing all aspects of the proposed study. He will participate in weekly supervision with the therapist and with consultant Dr. Rudd. Dr. Tolin will conduct the outcome analyses and will bear responsibility for publishing the results of the study. Dr. Tolin will donate his time to the study.

David Rudd, Ph.D. (Consultant): Dr. Rudd is a leading expert in CBT for suicide prevention, the author of the treatment protocol used in the proposed study, and was principal investigator on an RCT of that protocol. His involvement is critical for ensuring adequate application of the treatment. Dr. Rudd will provide a 2-day training for the clinical staff ($11,000 for his fees plus travel expenses). Following that training, he will participate via videoconference in weekly group supervision meetings during the treatment phase of the study ($200 x 16 meetings = $3200).

Gretchen Diefenbach, Ph.D. (Project Manager, 10% time and salary): Dr. Diefenbach will supervise the research assistant and coordinate the day-to-day operations of the study. She will participate in the weekly supervision meetings. She will also listen to audio recordings of at least 10% of all sessions to rate treatment fidelity.

Carolyn Davies (Independent Evaluator, 10% time, no salary requested): Dr. Davies will serve as the IE. She will obtain informed consent and assess all participants in person at the admission and discharge points, and by telephone at each of the 3 follow-up points. Dr. Davies' time is currently paid by existing research and training funds, and no salary support is requested.

Psychology Intern (Therapist, 20% time, no salary requested): A predoctoral intern will serve as the CBT therapist, meeting with each of the 10 participants for up to 10 hours. The intern will attend weekly supervision with Drs. Tolin and Rudd.

Research Assistant (50% time and salary): The research assistant will be responsible for tracking inpatient admissions, data entry, and communication with the Hartford Hospital IRB. The research assistant will also communicate inpatient admissions with approved research personnel on study E-HHC-2017-0246 taking place on the Clinical Trials Unit in order to streamline participant recruitment.

Participant Remuneration: We will compensate participants $50 for each of the three follow-up interviews ($50 x 3 x 10 = $1500). This compensation is needed in order to insure adequacy of data collection.

Total Budget: $47,249

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