Study Title: A Feasibility Open Trial of App-Enhanced Brief CBT for Suicidal Inpatients

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Research Proposal

Literature and Background

The Importance of Improving Suicide Risk Management Following Discharge from Psychiatric Hospitalization. The risk of suicide for patients discharged from psychiatric hospitalization for suicidal thoughts and behaviors is 200 times the global rate (Chung et al., 2017). Although psychiatric hospitalization can provide a safe and supportive environment for acutely suicidal individuals, inpatient intervention methods often do not directly target risk factors for suicide (Ghahramanlou-Holloway et al., 2015). Although risk for suicide remains significantly elevated throughout the year following discharge from the hospital, the time period immediately following discharge is the most risky. Approximately one third of all suicides by individuals with mental disorders occur in the 90 days following hospitalization (Huisman et al., 2011). 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) (Olfson et al., 2016).

The Importance of Using Targeted Cognitive Behavioral Approaches. Currently, there is a lack of empirically supported interventions for suicidal behavior. In adults, it has been established that treatments specifically targeting suicidal thoughts and behaviors are more effective at reducing subsequent suicide risk than are broader treatments for depressive symptoms (Meerwijk et al., 2016). One good example of such a treatment is BCBT, a cognitive-behavioral intervention designed to target core skills deficits among suicidal individuals. In adult outpatient samples, BCBT reduced suicide attempt rates by 60% (Rudd et al., 2015). In addition, BCBT demonstrated the strongest effect on improving suicidal behavior in a meta-analysis of adult outpatient CBT interventions (Mewton & Andrews, 2016). Our research team adapted BCBT to be administered to an inpatient adult sample and found the intervention was feasible in an open trial (Diefenbach et al., 2021) and we are currently conducting a larger efficacy trial.

The Importance of Integrating Technology-Based Interventions into Young Adult Suicide Prevention. Suicidal individuals, particularly younger patients, can be quite challenging to engage and retain in interventions (Kurz & Moller, 1984). For example, rates of dropout and treatment refusal among suicidal adolescents are a substantial concern (Rotheram-Borus et al., 2000) including in studies of BCBT (Sinyor et al., in press). In order to adapt the protocol to enhance engagement of young adults, we propose to use a BCBT app in conjunction with one-on-one treatment sessions. Younger cohorts are highly familiar and comfortable with the use of internet and phone-based applications (Subrahmanyam & Lin, 2007) and use electronic devices for about 7.5 hours per day on average (Rideout et al., 2010). They further demonstrate a preference for technology-based over talk-based psychological interventions (King et al., 2006). One previous study included use of an app in a suicide prevention treatment for adolescent inpatients (Kennard et al., 2018). In that study, treatment was comprised of a 3-hour intervention delivered on the inpatient unit reviewing CBT skills including safety planning (an intervention specifically targeting reducing suicide behaviors) as well as emotion regulation skills designed to improve psychiatric symptoms more generally. Following discharge, participants continued using the app for 24 weeks, rating their mood daily and receiving suggestive feedback for skill use. Results demonstrated that adolescents utilized the app and reported high levels of treatment

satisfaction. In addition, retention through the 24-week follow-up was excellent (88%). However, there were no significant differences between CBT and supportive therapy in terms of satisfaction or clinical outcomes. This limited treatment effect found by Kennard and colleagues (2018) may have been due to the intervention focusing more heavily on regulation of emotional distress as opposed to suicide prevention skills specifically. The current proposal will target the core suicide prevention treatment components from BCBT, a treatment program with prior empirical validation.

The Importance of Assessing Suicide-Related Outcomes. Although the treatment target of BCBT is suicidal ideation and behavior, we will also assess psychiatric distress and suicide-related thoughts to characterize the sample and explore any ancillary treatment effect. It is important to assess concomitant treatments in any treatment outcome study to provide a context for interpretation of study results. In addition, assessment of service utilization will provide a confirmation of patient engagement with continuing care as well as indicate whether or not crisis services (ED, psychiatric readmission) were accessed.

Specific Aims/Hypotheses

As a pilot feasibility open trial, this study is not powered for statistical significance. However, we outline our predictions here in relation to descriptive statistics and/or effect sizes.

Aim 1: To describe the feasibility, acceptability, and tolerability of app-enhanced BCBT. Feasibility will be assessed using enrollment rates as well as a qualitative assessment of treatment implementation barriers and patient and clinician feedback. Acceptability will be assessed using the Client Satisfaction Questionnaire and app-user feedback. We expect that participants will continue to engage with the treatment after discharge via the SmartPhone App, as assessed using the Utility of Techniques Questionnaire and utilization data (e.g., number of times accessed) collected by the app. Tolerability will be assessed using rates of discontinuation and adverse events. We predict that descriptive data will demonstrate good feasibility, acceptability, and tolerability.

Aim 2: To collect initial descriptive pilot data and BCBT effect size estimates from pretreatment through follow-up for reducing suicidality and improving other suicide-related-outcomes. We predict that participants will demonstrate a large reduction in suicidal ideation from pretreatment to each follow-up assessment as evidenced by a Hedges' *g* of 0.8 (large effect) or greater. Effect sizes for changes in suicide-related outcome measures (psychiatric distress, suicide-related cognitions, service utilization) will also be explored. We predict that descriptive data will show low levels of suicidal behavior and psychiatric readmission over follow-up. For exploratory purposes, we will also assess other types of service utilization over follow-up (e.g., outpatient, ED visits).

Research Design

Sampling. We will enroll 4 young adults (ages 18-24) admitted for inpatient treatment with a history of suicide attempt (lifetime) and active ideation (with or without plan or intent) on admission who own and have access to their phone (iPhone or Android with capability to

download apps) during their inpatient stay. Admission will be defined as admission to either the medical floor (in cases where medical stabilization was required following a suicide attempt) or to the psychiatric inpatient unit (in cases where medical stabilization was not required). Suicide attempt will be defined as self-directed behavior that results in injury or the potential for injury, and in which there was evidence, whether implicit or explicit, of intent to die. Inclusion criteria will also include ability to understand the nature of the study and provide written informed consent, willing and able to provide at least two verifiable contacts for emergency or tracking purposes, and expected length of stay long enough to complete the entire treatment protocol. Participants will be excluded if they are not fluent in English, are experiencing current mania or psychosis, have lifetime history of schizophrenia spectrum disorder, intellectual disability, or organic brain illness, if the inpatient treatment plan includes detox protocol or electroconvulsive therapy, or any other psychiatric or medical condition that in the investigator's opinion would preclude informed consent or participation in the trial. Participants who are not fluent in English will be excluded given that at least some assessments are available in English only, the research is utilizing an app only available in English and treatment is not validated using a translator. We expect that all enrolled participants will complete at least one treatment session; however, if there is attrition prior to completing at least one treatment session we will continue to enroll additional participants until we meet this target sample.

Measures. The Measurement Schedule is outlined in Table 1 and measures are detailed below.

Diagnoses. Diagnostic status will be assessed at pre-treatment using the Diagnostic Interview for Anxiety, Mood, and Obsessive-Compulsive and Related Disorders (DIAMOND, Tolin et al., 2018) 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, symptoms of borderline personality disorder will be assessed using the McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD, Zanarini et al., 2003). The MSI-BPD is a 10-item self-report measure that has demonstrated good sensitivity and specificity in detecting symptoms of borderline personality disorder. Diagnoses will also be extracted from the medical record.

Demographic and Health Status. Demographic information will be obtained from the medical record and through self-report. Participants will also complete a self-report measure indicating the presence of chronic medical conditions.

Suicidal Behavior. Suicidal behavior will be assessed using the Columbia Suicide Severity Rating Scale (C-SSRS), a widely used suicide assessment measure (Posner et al., 2011). 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 during "the past month." At subsequent assessments the "since last visit" version will be administered. The behavior scales of the C-SSRS have demonstrated sensitivity to change across treatment, sensitivity and specificity in identifying lifetime actual and interrupted attempts (Posner et al., 2011), and predictive validity for identifying future suicidal behaviors and rehospitalization (Greist et al., 2014; Horwitz et al., 2015). Documented incidences of suicide attempt will also be extracted from the medical record.

Suicidal Ideation/Intent. Suicidal ideation and intent will be assessed using the severity and intensity subscales of the same C-SSRS versions and timeframes as described above (Posner et

Table 1. Measurement Schedule.

	Intake	Treatment	Discharge	1mo	2mo	3mo
DIAMOND	X					
Demographic Form	X					
Health Form	X					
MSI-BPD	X					
C-SSRS	X		X	X	X	X
ASIQ	X		X	X	X	X
DASS-21	X		X	X	X	X
SCS	X		X	X	X	X
DTS	X		X	X	X	X
DERS	X		X	X	X	X
Wish to Live\Wish to Die	X	X	X	X	X	X
Reasons for Living\Dying	X	X	X	X	X	X
AE Assessment	X	X	X	X	X	X
Implementation Barriers	X	X	X	X	X	X
Utility of Techniques		X	X	X	X	X
System Usability Scale		X	X	X	X	X
Qualitative Feedback		X	X	X	X	X
CBT Compliance Measure		X				
Client Satisfaction			X	X	X	X
Service Utilization/CSI				X	X	X

al., 2011). Suicidal ideation will also be assessed using the Adult Suicidal Ideation Questionnaire (ASIQ, Reynolds, 1991), a 25-item self-report scale. The ASIQ has demonstrated moderate positive correlations with depression, hopelessness, and past suicide attempts, good internal reliability, and good test-retest reliability (Reynolds, 1991). 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 (Jobes & Bonanno, 1995).

Psychiatric Symptoms. Psychiatric distress symptoms will be assessed using the 21-item Depression Anxiety Stress Scales-21 (DASS-21, Henry & Crawford, 2005). The DASS-21 has demonstrated good internal consistency across scales, and good convergent validity with other measures (Henry & Crawford, 2005). Psychiatric distress tolerance will be assessed using the Distress Tolerance Scale (DTS, Simons & Gaher, 2005). 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 (Hsu et al., 2013). The Difficulties in Emotion Regulation Scale (DERS, Gratz & Roemer, 2004) is a 36 item self-report measure of 6 facets of emotion regulation including awareness, clarity, impulsivity, goal-directed behavior, non-acceptance, and strategies for feeling better (e.g. "When I'm upset, I believe there is nothing I can do to feel better."). Items are rated on a scale from 1 to 5 (*almost never* to *almost always*) with higher scores indicated greater difficulty with emotion regulation. The DERS has demonstrated high internal consistency, good test-retest reliability, and adequate construct and predictive validity (Gratz & Roemer, 2004).

Suicide-Related Cognitions. Suicide-related cognitions will be assessed using the Suicide Cognitions Scale (SCS, Bryan et al., 2014) 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 (Bryan et al., 2014).

Treatment Acceptability and Implementation. **Implementation.** All study staff will track barriers encountered during study implementation via the Implementation Barriers Log. The log has been used in our previous suicide prevention studies and allows for tracking of logistical barriers to the study and treatment including room and participant availability. The Implementation Barriers Log has been adapted from our previous study to allow for descriptions of any technical difficulties or issues encountered with the SmartPhone app. Within session compliance will be tracked using the CBT Compliance Measure (CCM), a 9 item measure that assesses participant's adherence to the session protocol (Wootton et al., 2021). Sample items include "To what extent did the patient's words and actions in session adhere to the session agenda?" Responses are rated on a 4 point scale (*not at all* to *very* much) and are rated by the study therapist at the conclusion of each study treatment session. **App Use.** The System Usability Scale (SUS) is a valid and reliable 10-item measure that can be used to effectively differentiate between usable and unusable systems (Brooke, 1996; Dexheimer et al., 2017). Sample items are "I think that I would like to use this app frequently" and "I felt very confident using the system." Responses are rated using a 5-point (*strongly disagree* to *strongly agree*) Likert scale. Total scores range from 0 to 100. A score of 68 is the minimal indicator of usability. Participants will also provide qualitative feedback about app use (e.g., Did you think functions were missing in the app? Which ones? Is there anything else you think we should know to make this app better?) at each study visit occurring after downloading the app. Data on app utilization (e.g., number of times accessed) will also be collected via the app. **Treatment Satisfaction.** Overall treatment satisfaction will be assessed using the Client Satisfaction Questionnaire (CSQ), 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 (Nguyen et al., 1983). 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 measures (Attkisson & Greenfield, 1999). **Qualitative feedback.** Additional qualitative feedback from the participant will be obtained regarding app usability and suggestions for changes to the treatment program overall. The clinician will also provide feedback on the treatment sessions and make suggestions for how to

improve the treatment program overall. **Treatment Utility.** The Utility of Techniques (UT) questionnaire, which we developed and are using in our ongoing adult RCT, will assess frequency of use (rated "*not at all*" to "*more than 10 times per week*") and helpfulness (completed only if skill was used, rated "*not at all*" to "*extremely*") of each treatment component.

Adverse Events. As in our ongoing research, 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?" Adverse events will be tracked and reported according to IRB's policy 910.

Service Utilization. Prescribed medication at intake and discharge will be determined through the electronic medical record. Assessments at each follow-up will also track changes in medication. Service utilization will also be assessed at each follow-up assessment using a modified version of the Cornell Service Index Short Form (CSI-SF; Sirey et al., 2005) 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).

Treatment. Four sessions of BCBT will be delivered by a study therapist using the same study protocol as in our ongoing RCT while also integrating use of a SmartPhone App. The app platform includes interactive features designed to support clinicians caring for patients with suicidality. It also contains patient-facing features (e.g., crisis response planning) used to teach patients suicide prevention skills. Specifically, the app is designed to help patients identify and change unhelpful ways of thinking and behaving while also teaching them effective problem-solving techniques. The app contains 12 sessions which are completed (after an initial introductory therapist-directed session) by the patient in a self-directed way. In the current study we will be using a 4-session version of the app (called OTX-209). App sessions will be completed in collaboration with the study therapist. During treatment sessions participants will use the app to supplement psychoeducation (e.g., watch educational videos) and create digital versions of individualized suicide prevention materials (e.g., crisis response plans). Between sessions and over the follow-up period the participant will interact with the app independently during which time they will be able to review psychoeducation and treatment materials, utilize functions on the app to facilitate skills practice (e.g., a deep breathing visualization exercise) and make edits (e.g., change contacts on the crisis response plan). The app is not monitored so no alert is created based on how the participant uses the app. The consent document informs participants that the app is not monitored and during the informed consent process participants will be verbally reminded that study personnel are not available for emergency needs. If all four sessions are not completed during the inpatient stay the patient will still have access to the remaining sessions on the app and may complete them independently if they choose to do so. The app is experimental and has not been used for this purpose with this content with this population. This is a new procedure/device treatment combination provided in addition to standard of care. Given that the app content is based on empirically-supported BCBT there is no reason to expect untoward outcomes, though this is part of the research question.

Session 1. In session 1, the patient completes psychoeducation about the "suicide mode," which is the BCBT 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 patient will also learn how BCBT 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.

Sessions 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, relationships with family, 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. For the second intervention, the patient creates a virtual "hope kit" by identifying items that could serve as concrete visual reminders of positive experiences. The rationale for choosing each item is reviewed by the therapist in order to discourage inclusion of any potentially iatrogenic items.

Session 3. Session 3 focuses on 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 method still improves the patient's chances of surviving. During session 3 access to means, including access to firearms, is assessed and a plan developed 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. In this session the therapist also introduces virtual coping cards to modify cognitive factors of the suicide mode. The coping cards provide a concrete memory aid."

Session 4. In the final session, the therapist reviews all previous skills and reinforces the app 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 suicidal episode. For each, the therapist 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. The therapist discusses the upcoming discharge and reviews specific ways that practicing skills can be integrated into daily life.

Procedure. Participants will be identified through electronic medical record review of daily admissions, and attending physicians will be consulted about each eligible participant to ensure study criteria are met and study participation is supported. Participants will provide written consent prior to initiation of study procedures. Assessments will be performed at intake, discharge, and 1-, 2-, and 3-months post-discharge. 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 be done for all follow-up assessments. Participants will complete up to 4 BCBT sessions (depending on length of stay). BCBT sessions will typically be administered once daily, but also with flexibility. In cases where the patient is discharged earlier than expected and prior to completing all treatment sessions, 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. In cases where the session material is not completed in one meeting, additional meetings will be scheduled in order to cover all session material. Assessments and treatment sessions will be audio-recorded. Self-reports will be collected through the HHC REDCap data system. Follow-ups will be completed using telephone interview and REDCap surveys. No study assessment measures are collected using the app.

Risk Management Procedures. Suicide risk will be assessed at every post-treatment study visit. A comprehensive risk management protocol is in place for managing suicidal symptoms based upon severity (low, medium, high-not imminent, high-imminent) in our current RCT and will also be used in this pilot study.

Statistical Analysis Plan

Analytic Plan. Descriptive statistics will be used to summarize quantitative (mean, standard deviation) and qualitative (frequencies) data for the following variables: recruitment and retention rates, implementation barriers, CSQ, treatment utilization (UTQ and app-derived utilization metrics), adverse events, service utilization (obtained from electronic medical record and CSI-SF), and suicidal behaviors. In addition to descriptive statistics, we will determine an effect size estimate Hedges's *g* for changes from intake to post-treatment and through follow-up for suicidal ideation, psychiatric distress, and suicide-related cognitions.

Power Analysis. This study is not powered for statistical significance. In the current study we propose the largest sample possible based upon feasibility considerations.

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