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Study Title Dialectical Behavior Therapy Skills Group Pilot Evaluation

NCT Number NCT02499406

Document date: last reviewed and approved: June 4 2019 by Human Studies Subcommittee at VA Connecticut Health Care System

i. **Principal Investigator:** Suzanne Decker, Ph.D.

Project title: Dialectical Behavior Therapy Skills Group Pilot Evaluation

ii. **Purpose:**

The proposed investigation is designed to evaluate the feasibility and acceptability of a group skills training intervention, Dialectical Behavior Therapy Skills Groups (DBT-SG). This intervention has been clinically piloted at VACHS as a group skills training intended to help Veterans learn new ways of coping and reduce emotion dysregulation. Part I of this project will establish a cohort of Veterans from administrative VACHS data who have been referred to DBT-SG to assess acceptability and feasibility and to provide descriptive data on Veterans who have been screened for and participated in this group to date. Part II will include prospective data collection from Veterans with recent suicidal ideation and emotion dysregulation who are referred to DBT-SG to examine feasibility, acceptability, and preliminary data on change in emotion dysregulation, suicidal ideation, coping skills, and mental health symptoms.

Specific Aim 1: Examine feasibility and acceptability of Dialectical Behavior Therapy Skills Groups (DBT-SG).
Hypothesis 1a: DBT-SG will be feasible as indicated by skills group leader fidelity to the manualized skills group protocol at or above cutoff level for acceptable (Part II).
Hypothesis 1b: DBT-SG will be acceptable to Veterans as indicated by attendance at 50% or more of scheduled sessions (Part I, Part II).
Hypothesis 1c: DBT-SG will be acceptable to Veterans who participate as indicated by positive feedback on written satisfaction evaluations (Part II).
Hypothesis 1d: DBT-SG will be acceptable to Veterans' primary mental health providers as indicated by positive feedback on written satisfaction evaluations (Part II).

Specific Aim 2: Examine preliminary efficacy of DBT-SG to reduce emotion dysregulation and suicidal ideation, and to increase skillful coping (Part II)
Hypothesis 2a: DBT-SG will be associated with reduction in emotion dysregulation from pre-treatment levels (Difficulties in Emotion Regulation Scale)
Hypothesis 2b: DBT-SG will be associated with reduction in suicidal ideation from pre-treatment levels (Beck Scale for Suicidal Ideation; Suicidal Behaviors Questionnaire)
Hypothesis 2c: DBT-SG will be associated with increased skillful coping from pre-treatment levels (DBT Ways of Coping Checklist)

Exploratory Aim 1: Examine preliminary efficacy of DBT-SG on symptoms of PTSD (PCL-5), depression (BDI-II), borderline personality disorder (BSL-23), self-efficacy (GSES), pain (PEG), and suicidal behavior (BSBI).
Exploratory Aim 2: Examine preliminary efficacy of DBT-SG on impulsive behavior (Impulsive behaviors checklist, DSHI, BAM-C, OAS-M, and urine toxicology screens for individuals with substance use disorder).

iii. Background:

Suicide risk among Veterans is 66-87% greater than for the general population (McCarthy et al 2009). Several different mental health diagnoses and risk factors are associated with Veteran suicidality, suggesting that a cross-diagnostic or theory-driven approach to identifying and treating Veterans at risk for suicide is indicated. Emotion dysregulation is characterized by unawareness of emotions, lack of strategies to modulate strong emotions, inability to control impulsive behavior when feeling negative emotions, and inability to pursue goals when feeling strong emotions (Gratz & Roemer, 2004). **Among Veterans, emotion dysregulation is associated with suicidality** (Guerra et al., 2011; Mrnak-Meyer et al., 2011; Pietrzak et al., 2011) and increased severity of depression and posttraumatic stress disorder (PTSD; Klemanski et al., 2011). Emotion dysregulation is also associated with impulsive behaviors including substance abuse (Fox, Axelrod, Paliawal, Sleeper, & Sinha, 2007; Fox, Hong, & Sinha, 2008), suicide attempts (Miranda et al., 2013), and deliberate self-harm behavior (Gratz & Tull, 2010). Individuals with emotion dysregulation are less likely to benefit from evidence-based treatment for substance use (Berking et al., 2011). However, when individuals with emotion dysregulation are provided with skills-based treatment to manage emotions, reductions in emotion dysregulation appear to moderate their ability to reduce substance abuse (Axelrod, Perepletchikova, Holtzman, & Sinha, 2011). Similarly, the addition of emotion regulation skills training to CBT for depression has been associated with greater remission from depressive symptoms (Berking et al., 2013). While VA now offers evidence-based treatments for many specific mental health diagnoses, **treatments to help Veterans reduce emotion dysregulation have not been systematically studied at VA**. The proposed study will establish an administrative dataset to examine existing VACHS data on a group skills training treatment targeting emotion dysregulation (Part I) and conduct prospective data collection among Veterans participating in a group skills training treatment targeting emotion dysregulation (Part II) to evaluate the feasibility, acceptability, and preliminary efficacy of a group skills training treatment to reduce emotion dysregulation and suicidal ideation and improve coping among Veterans.

Dialectical Behavior Therapy (DBT) is an evidence-based and theory-driven treatment for chronic suicidality in adults with chronic emotion dysregulation who are diagnosed with Borderline Personality Disorder (Clarkin et al., 2007; Kliem et al., 2010; Koons et al., 2001; Linehan et al., 1991; Linehan et al., 2006; McMain et al., 2009). DBT includes a strong focus on reducing emotion dyregulation by teaching individuals to understand and cope with strong emotions. However, comprehensive DBT is not widely available in many VA settings, including VACHS. DBT includes multiple components: weekly individual DBT therapy, DBT Skills Group, between-session access to therapist by telephone, and therapist team consultation. A central component of DBT is the DBT Skills Group, a manualized group skills training intervention that actively teaches participants new skills. The DBT Skills Group manual includes skills on managing strong emotions (emotion regulation), assertive communication and problem solving (interpersonal effectiveness), use of healthy coping methods to replace impulsive behaviors (distress tolerance), and mindfulness skills (Linehan, 1993; Linehan et al., 2006). In three large randomized clinical trials, skills learned during DBT Skills Groups fully mediated decreases in

suicidality and anger (Neasciu, Rizvi, & Linehan, 2010), suggesting that **DBT Skills Groups may be the most beneficial component of comprehensive DBT**. Moreover, DBT Skills Groups as a stand-alone intervention (DBT-SG) are associated with reduced suicidality (Harley et al., 2007; Soler et al., 2009) and improved ability to regulate strong emotions like anger (Koons et al., 2006; Soler et al., 2009). **To date, no studies have investigated the feasibility, acceptability, and initial efficacy of DBT-SG to reduce emotion dysregulation and suicidal ideation among Veterans.**

The proposed study seeks to use existing VACHS data to systematically examine the feasibility and acceptability of a group skills training intervention to help Veterans with emotion dysregulation (Part I). Additional prospective data collection (Part II) will examine acceptability of this intervention to Veterans who participate in it (attendance, satisfaction), feasibility of delivering this skills training as designed (fidelity to protocol), and whether Veterans participating in DBT-SG experience changes in emotion dysregulation, suicidal ideation, coping skills, and mental health symptoms. Data from this study will provide important initial information about the feasibility and acceptability of this skills training intervention in a VA setting and provide preliminary evidence about the potential utility of skills training approaches to assist Veterans in reducing emotion dysregulation and suicidal ideation and to potentially impact mental health outcomes.

iv. Significance:

This pilot study will provide important preliminary data about (a) the feasibility and acceptability of a group skills training treatment to reduce emotion dysregulation and suicidal ideation among Veterans, and (b) preliminary data about potential changes in emotion dysregulation, suicidal ideation, coping, and mental health symptoms that may be associated with participation in DBT-SG. Although recent evidence suggests that emotion regulation skills training may be associated with improvements in multiple symptom domains, this has not yet been investigated in Veterans. Information gathered during this pilot investigation will be used to generate hypotheses for further research studies. If information from this pilot investigation is promising, further studies will be proposed to examine the efficacy of DBT-SG for Veterans with emotion dysregulation and suicidal ideation. Should DBT-SG for Veterans with emotion dysregulation prove efficacious in larger studies, the intervention can be disseminated so that Veterans with emotion dysregulation will have access to services targeted to their specific treatment needs. Findings from this study will be disseminated through presentations and publications, and used to support future funding applications.

v. Research Plan:

To achieve study objectives, an administrative cohort will be established (Part I) and recruitment for data collection will be conducted (Part II); see Table 1 for description.

Part I: Administrative Cohort: DBT-SG is an existing clinical intervention that is part of routine clinical care for some Veterans. We will seek a waiver of informed consent to examine existing data from the medical record for all Veterans who have been referred by a VACHS clinician for DBT-SG between 7/1/2011 and 6/30/2015. Using a data collection sheet, research personnel will review the chart to extract demographic information (e.g., age, race, gender,

marital status, education), mental health diagnoses, MST, suicide high risk flag status, problems reported during the DBT-SG screening visit, information about participation in DBT-SG and other treatments (e.g., number of DBT-SG group sessions attended, number of other mental health treatment sessions attended), and information about symptoms from CPRS. This information will be used to generate descriptive data on individuals referred to and participating in DBT-SG, and rates of participation in DBT-SG to investigate feasibility and acceptability. A waiver of informed consent and waiver of HIPAA authorization are sought for collection of these data.

Table 1: Study Components

Part	Design	Eligibility	Variables of Interest
Part I	Administrative data	INCLUSION: (1) Veterans at VACHS who were referred by a VACHS clinician for DBT Skills Group between 7//12011 and 6/30/2015 (2) Ages 18-65	Demographic (e.g., age, race, gender, marital status, education), mental health diagnoses, MST, suicide high risk flag status, referral outcome, problems reported during the DBT-SG screening visit, information about participation in DBT-SG and other treatments (e.g., number of DBT-SG group sessions attended, number of other mental health treatment sessions attended); symptom reports including urine toxicology screen results during period of time participating in DBT-SG
Part II	Questionnaire, interview, administrative data	INCLUSION: (1) Veterans at VACHS who are referred or self-referred to DBT Skills Group (2) Ages 18-65 (3) Able to understand written and spoken English (4) DERS score 105 or greater (5) Suicidal ideation within past 3 months (answer of “often, or very often” to item assessing past 3 months’ suicidal ideation, or, “sometimes” to item assessing past 3 months suicidal ideation on SBQ and “often or very often” to item assessing past 4 weeks suicidal ideation on SBQ) (6) Seeing an individual mental health provider at VACHS at least monthly (7) Willing to create or review a Mental Health Safety Plan, and stated willingness to use this plan to maintain safety (8) Consent to participate in study assessments (9) Consent to recording of group sessions EXCLUSION: (1) Inability to understand written or spoken English	Emotion dysregulation, impulsive behavior, suicidal ideation, suicidal behavior, PTSD symptoms, depression symptoms, use of coping skills, substance use

		(2) Diagnosis of schizophrenia, schizoaffective disorder, bipolar I, antisocial personality disorder, or thought disorder in CPRS problem list and confirmed by current mental health provider	

Part II: Additional Data Collection:

Procedures

Recruitment: DBT-SG is a clinical intervention that is part of routine clinical care for some Veterans. Referrals to this clinical intervention are made by a Veteran's primary mental health treatment provider from the VACHS Mental Health Service Line. The PI or study staff will introduce this study to mental health treatment providers at VACHS psychiatric inpatient unit, Psychiatric Emergency Room, psychology service committee meeting, psychiatry resident or fellow seminars, PTSD clinic, NPSY clinic, Women's Clinic, Substance Abuse Day Program, Methadone Maintenance Program, Outpatient Substance Abuse Clinic, and mental health clinics at Newington Campus through attendance at clinical or administrative rounds or email, and will provide information about this study to VACHS Suicide Prevention Coordinators via in-person attendance at meetings and via email. Approved recruitment materials will be distributed to mental health treatment providers and Suicide Prevention Coordinators for use in discussing the study with Veterans. Approved flyers to identify the study to potential participants will be posted in clinical areas at VA Connnecticut Health Care System. When potential participants are self-referred, the research staff will conduct phone screening which includes a discussion of how often the potential participant is seeing a mental health treatment provider; if the potential participant is seeing a mental health treatment provider at least monthly, the research staff will continue phone screening and notify the mental health care provider of record of the potential participant's interest in the study. If the potential participant is not currently in mental health treatment or not seen at least monthly, research staff will refer the Veteran to the appropriate screening clinic or refer the potential participant to discuss with his or her mental health care provider. The PI will conduct a brief chart review for referred or self-referred Veterans (see attached requests for WIC and WOA), and call referred Veterans to conduct a brief telephone screening to determine whether the Veteran meets screening eligibility criteria (interested in learning about a skills group; seeing a mental health provider monthly or more often; reporting suicidal ideation often or very often in past 3 months; interested in hearing more about a research study; see attached telephone screening protocols; see attached WWIC for telephone screening).

Eligibility determination: Veterans who meet screening criteria above and are interested in learning more about the study will be invited to attend an initial study session to review and complete informed consent forms. Informed consent will be obtained from participants prior to assessment. After the informed consent process, questionnaires will be used to confirm study eligibility (DERS; SBQ). Veterans who do not meet study criteria will be given feedback on evaluation results and offered a referral to alternate treatment (e.g., participation in screening for an alternate DBT-SG group that is not included in Part II of this study; referral to other symptom-

specific groups at VACHS Mental Health Service Line). Veterans who meet study eligibility criteria will be asked to fill out further measures (see measures section) and to participate in a clinical interview to set goals for DBT-SG.

Risk assessment and management during initial assessment session: As participants will be asked to complete questionnaires about suicidality, participants will be monitored for subjective distress and suicidal ideation during the screening session using the University of Washington Risk Assessment Protocol (UWRAP; attached). The UWRAP is an assessment protocol that includes pre-assessment discussion, planning for coping strategies to use in the event of distress experienced during the assessment session, and monitoring of distress during and after the assessment session. The UWRAP was developed to assess and monitor risk during assessment sessions with individuals with emotion dysregulation. In addition, all Veterans who are screened for DBT-SG who are on the facility High Risk for Suicide list have an individualized safety plan in their VA medical chart. A copy of this written individualized safety plan is available to DBT-SG research staff. DBT-SG research staff will review the individualized safety plan and work with the Veteran to improve the safety plan if desired. If an individualized safety plan is not already in place, DBT-SG research staff will assist the Veteran in creating one, following VA clinical guidelines. DBT-SG research staff will invite the participant to take steps to reduce access to lethal means (e.g., planning to get rid of razors) if appropriate. Should a participant indicate unwillingness to use safety planning or require additional evaluation, the participant will be escorted to the Psychiatric Emergency Department at VACHS for further evaluation, assessment, and emergency treatment.

Relevant clinical information (e.g., suicidal ideation; any updates to individualized safety plan) will be communicated by the assessor to the Veteran's primary mental health treatment provider.

Data collection: Those who meet study eligibility criteria will be invited to participate in a DBT-SG research group for approximately 26 group sessions (further details below) and to attend three further data collection sessions to complete surveys. These assessment sessions will occur at treatment midpoint (3 months), at post-treatment, and at a 3-month follow-up visit; see Table 2. At each assessment session, participants will be invited to complete written surveys to assess emotion dysregulation, suicidal ideation and behavior, coping skills use, and mental health symptoms (see measures section for a complete list). An interview will be used to assess participation in other forms of mental health treatment. Participants' individual mental health providers will be invited to complete a questionnaire about their impressions of the participant's progress at treatment midpoint, post-treatment, and follow-up points. Participants who are not able to attend in-person data collection sessions (i.e. have moved away from area or are homebound) at midpoint, post-treatment, or follow-up will be offered the option of receiving and sending back completed surveys by mail (using a stamped self-addressed return envelope) or completing surveys and interviews by telephone. Written assessments will not include the participant's name or other identifiers.

All assessments involving assessment of suicidal ideation or behavior (SBQ, BSSI, BDI-II, Brief Suicide Behavior Interview) will be conducted by telephone so that appropriate risk assessment and management can be conducted. As in in-person assessments, participants will be invited to review their safety plan during telephone assessment. Prior to telephone assessment, participants will be asked to confirm their mailing address for mailing purposes, and so that they can be given telephone contact information for their local VA suicide prevention coordinator and nearest emergency room.

Risk assessment and management during ongoing assessment sessions: Completed questionnaires about suicidal ideation or risk behavior (SBQ; BSSI; Brief Suicide Behavior Interview; DSHI; BDI-II item 9) will be reviewed. Participants who communicate recent suicidal ideation or risk behavior will be interviewed individually to assess current suicidal ideation and intent and to assess safety. Participants will be invited to review their safety plan prior to leaving the assessment session. Participants who require additional evaluation will be escorted to the Psychiatric Emergency Department at VACHS for further evaluation, assessment, and emergency treatment. In a telephone assessment, the PI will assess suicidal ideation, intent, plan, and preparation, and determine whether the participant requires immediate evaluation (e.g., in the case of suicide ideation with imminent intent, making plans to help the participant get to the nearest emergency room, or, calling 911 to notify emergency personnel if participant is unwilling to contract for safety). The local VA suicide prevention coordinator will be notified in the event of suicide ideation with intent for participant safety reasons.

Description of intervention: DBT-SG is an existing clinical intervention at VACHS that follows a well-established skills training manual (Linehan, 1993; Linehan, 2014a, 2014b). The DBT-SG research group will follow similar procedures. During the initial assessment session, the assessor will assess emotion dysregulation, provide feedback, provide information about DBT-SG structure and guidelines, and elicit goals for DBT-SG participation from the Veteran (see clinical interview). The participant will be invited to complete a worksheet to detail his or her goals for participation and to identify areas where DBT-SG skills could potentially be useful. During the informed consent process, group guidelines and procedures are reviewed. A review of group guidelines and procedures will also occur during the first group session (see attached DBT Skills Group Guidelines for review during first group session, adapted from Linehan, 1993). DBT-SG group sessions include review of skills practiced in the past week, a brief mindfulness practice, review of previous week's practice exercises ("homework"), instruction in new skills, and assignment of new practice exercises ("homework") for the following session.

Retention in this intervention is enhanced through telephone calls to Veterans who do not attend a scheduled group session and a clearly described group attendance policy that is reviewed during the informed consent process and during the first DBT-SG session. If a participant develops a pattern of missing several group sessions in a row, DBT-SG group leaders will contact the participant to encourage problem-solving to attend group more regularly. If a participant misses 3 group sessions in a row, he or she will be discharged from the group. The participant may continue participating in assessment if desired.

DBT-SG group leader will communicate any relevant clinical information (e.g., suicidal ideation) to the Veteran's primary mental health treatment provider through documentation in CPRS and through direct contact (i.e., a telephone call to the provider).

Supervision of intervention: DBT-SG is adapted from Dialectical Behavior Therapy, which includes weekly peer supervision using a consultation team format. DBT-SG group leaders will participate in weekly consultation team meetings to enhance fidelity to DBT-SG protocol and to provide support to providers working with suicidal Veterans with chronic emotion dysregulation. Group leaders will work to problem-solve issues that occur in DBT-SG group sessions. This is consistent with how DBT-SG has been conducted as a clinical intervention at VACHS and will be clearly specified in the informed consent process.

Documentation of intervention: Information about participants' attendance at and participation in DBT-SG (completion of homework, skills practiced, and notes about any unusual clinical presentation such as suicidal ideation) and any telephone calls made to the participant will be documented in the participant's medical record via a CPRS progress note. The participant's primary mental health treatment provider will be added as an additional signer to the note. This is consistent with how DBT-SG has been conducted as a clinical intervention at VACHS and allows the participant's primary mental health treatment provider to remain informed about the participant's participation in DBT-SG. This will be clearly specified in the informed consent process.

Risk assessment and management during treatment sessions: Participants will have an established Mental Health Safety Plan prior to entering DBT-SG group. In each weekly group session, participants will be asked to fill out a Skills Group Check-In Sheet to assess current symptoms and willingness to use safety plans. Participants who indicate high suicidal ideation or indicate unwillingness to use their suicide safety plan will be briefly assessed and reminded to use their Mental Health Safety Plan; if needed, participants will be escorted to the Psychiatric Emergency Department at VACHS for further evaluation, assessment, and emergency treatment. DBT-SG group leader will communicate any relevant clinical information (e.g., suicidal ideation) to the Veteran's primary mental health treatment provider.

Session recording and fidelity: Feasibility of DBT-SG will be determined in part by monitoring group leader fidelity to DBT-SG protocol. During DBT-SG sessions, a group leader will complete a checklist of items to encourage fidelity to protocol. Audio or videotaping of DBT-SG sessions is necessary to ensure fidelity of these sessions. Recordings will be conducted on a VA-approved device. Participants who decline to participate in session recording will be referred for alternate treatment. DBT-SG leader will conduct the session recording and will upload recording files after each session to the secure VA server behind the VA firewall (\\vhaconfpc2\research\investigators\vhacondeckes). Recording files will be deleted from the recording device after uploading to the secure VA server behind the VA firewall. Recordings will be stored as secure electronic files behind the VA firewall. The device used for session recording will be locked in Bldg 35 Room 42 when not in use. Only approved research personnel will have access to the recordings. Recordings will be used for on-site supervision by

DBT-SG leader and fidelity ratings conducted using the established DBT Adherence Rating Scale. A portion of session recordings will be rated by the co-developer of the DBT Adherence Rating Scale, Kathryn Korslund, PhD, ABPP, at the University of Washington, the site of DBT treatment development. Dr. Korslund will rate sessions using the DBT Adherence Rating Scale. Session recordings will be sent to University of Washington on encrypted CDs via UPS, or personal transport in a locked briefcase by the PI. Encrypted CDs with session recordings will be returned to VACHS after rating is completed, using UPS, or personal transport in a locked briefcase by the PI. Once returned, encrypted CDs will be stored in a locked filing cabinet in locked research office (Building 35 office 42).

Table 2: Part II: Assessment visit schedule for additional data collection

Procedures	**Approximate number of months after beginning DBT-SG**	**Procedures and Assessments**
Informed consent process for study; Screening assessment	0: Prior to participation in DBT-SG	Consent process. UWRAP; review MH Safety Plan; DERS; SBQ. Provide feedback on eligibility. If eligible, CI, DBT-WCCL; BSSI; Brief Suicide Behavior Interview – Initial; DSHI; PCL-5, BDI-II; BSL-23; BAM; TSR-A' PEG, OASM; GSES
Mid treatment assessment	3	DERS; BSSI; SBQ; Brief Suicide Behavior Interview – Follow-Up; DBT-WCCL; DSHI; PCL-5, BDI-II; BSL-23; BAM; CSS; Tx Provider SS; TSR-A; PEG, OASM; GSES; SSA
Post- treatment assessment	6	DERS; BSSI; SBQ; Brief Suicide Behavior Interview – Follow-Up; DBT-WCCL; DSHI; PCL-5, BDI-II; BSL-23; BAM; CSS; Tx Provider SS; TSR-A; PEG, OASM; GSES; SSA
Follow up assessment	9	DERS; BSSI; SBQ; Brief Suicide Behavior Interview – Follow-Up; DBT-WCCL; DSHI; PCL-5, BDI-II; BSL-23; BAM; Tx Provider SS; TSR-A; PEG, OASM; GSES; SSA

Risk Management Protocol for Screening (see attached measures, Table 3):
University of Washington Risk Assessment Protocol (UWRAP): The risk assessment protocol is a structured method for assessing and managing suicide risk in research trials or clinical screening interviews (Reynolds et al., 2006). This protocol starts before other assessment measures are administered by assessing stress, self-harm ideation, suicidal intent, and urges for drug/alcohol use. Specific coping plans for any increase in these outcomes are agreed upon between the participant and assessor before any further assessment is conducted, and if, risk is particularly high, assessment stops. This allows the assessor and client to have a series of pre-planned coping activities in the event that the participant becomes more distressed or experiences an increase in risk. The risk assessment protocol concludes at the end of the assessment interview with a re-assessment of stress, urges to self-harm, intent for suicide, and urges for drug/alcohol use. The assessor compares post-interview ratings to pre-interview ratings to determine whether significant changes have occurred and whether further suicide risk assessment is warranted. Interventions are selected based on level of suicide risk and may range from use of a mood induction activity and reassessment to escorting the client to the Emergency Room.

Surveys (see attached measures, Table 3):

i. Difficulties in Emotion Regulation Scale (DERS): This 36-item self-report measure assesses acceptance of emotional responses, ability to pursue goal-directed behavior when feeling negative emotions, impulse control when feeling negative emotions, access to strategies to manage emotions, emotional clarity, and emotional awareness (Gratz & Roemer, 2004). The six subscales demonstrate good internal consistency (Cronbach's α.80-.89) and the scale correlates significantly with other measures of emotion regulation.

ii. Beck Scale for Suicide Ideation (BSSI): Participants will be asked to rate past-week suicidal ideation (self-destructive thoughts or wishes) on this 21-item self-report measure (Beck, Steer, & Ranieri, 1988). This scale shows high internal consistency (Cronbach's α 0.93) and has a score range of 0-38.

iii. Suicide Behavior Questionnaire (revised; SBQ): This 30-item self-report measure assesses suicidal ideation, suicidal behavior, suicidal threats, and likelihood of future suicidal ideation and behavior (Addis & Linehan, 1989). Scores on this measure will be used to establish a baseline for suicidal ideation and behavior in the 90 days prior to DBT-SG and to assess suicidal ideation and behavior during and after participation in DBT-SG.

iv. Brief Suicide Behavior Interview (Initial and Follow-up versions). This interview adapted from a well-established suicide interview (Linehan Suicide Attempt Self-Injury Assessment Interview) assesses suicidal behavior, medical attention seeking, and attempt lethality in the lifetime, 9, 6, and 3 months before the intervention, and at 3 month intervals during and after the intervention. This will be used to generate descriptive data and to note any changes in the number of suicide attempts, ER presentations, or lethality of suicidal behavior.

v. DBT Ways of Coping Checklist (DBT-WCCL). This 59-item self-report measure assesses methods of coping with distress (Neasciu, Rizvi, Vitaliano, Lynch, & Linehan, 2010). Two subscales include effective methods of coping (i.e., DBT-SG skills), and ineffective methods of coping (e.g., avoiding problems, blaming others). The scale shows excellent internal

consistency (Cronbach's α 0.92-0.96) and acceptable test-rest reliability for individuals not exposed to DBT-SG (0.71).

vi. Deliberate Self-Harm Inventory (DSHI). This 17- item self-report measure assessing the presence or absence of deliberate self-harm behaviors over a predetermined period of time. This assessment has demonstrated good internal consistency (Cronbach's α .85, Gratz, 2001; .81, Fliege et al., 2006) and adequate test-retest reliability (phi .68, Gratz, 2001; r = .91, Fliege et al., 2006).

vii. PTSD Checklist (PCL-5). The PCL is a 20-item self-report measure of posttraumatic stress disorder (PTSD) symptomatology (Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013). This instrument is widely used in VA settings as a measure of PTSD symptom severity and change over time.

viii. Borderline Symptom List-23 (BSL-23) with Impulsive Behavior Checklist. This 23-item self-report measure assesses symptoms of Borderline Personality Disorder. It has excellent internal consistency (Cronbach's α 0.94-0.97), discriminates individuals with Borderline Personality Disorder from individuals with other psychiatric disorders, and shows sensitivity to change in individuals treated with DBT (Bohus et al., 2009).

ix. Beck Depression Inventory-II (BDI-II). This 21-item self-report measure of depression severity is routinely used in VA clinical care and shows good internal consistency (Cronbach's α .91; Beck, Steer, & Brown, 1996).

x. Brief Addiction Monitor (BAM). This 17-item self-report measure asks the respondent about substance use and other impulsive behavior, interpersonal conflict, in the last 30 days. Test-retest reliability for three factor-analytically derived factors (recovery protection, substance use and risk, physical and psychological problems) is excellent. The measure is sensitive to change over time in Veterans participating in substance use treatment (Cacciola et al., 2012).

xi. Skills Group Check-In Sheet (SGCS). A screening form administered during DBT-SG sessions to assess safety and willingness to use safety plans will be collected for ongoing monitoring.

xii. Client Satisfaction Survey (CSS). A survey measure created for this study will assess DBT-SG acceptability by assessing Veteran subjects' satisfaction with DBT-SG.

xiii. Treatment Provider Satisfaction Survey (TPSS). A survey measure adapted for this study from the Therapist Interview (Linehan & Heard, 1987) will assess DBT-SG acceptability by assessing the satisfaction of the Veteran's primary mental health treatment provider with DBT-SG.

xiv. General Self-Efficacy Scale (GSES). This ten-item scale assesses the respondent's general sense of self-efficacy and has norms available for comparison (Shwarzer & Jerusalem, 1995). Preliminary data on DBT interventions suggests that self-efficacy may increase during treatment and may mediate treatment outcome (Barnicot, personal communication, 2014).

xv. PEG. This four-item scale assesses the presence of chronic pain (item 1) and the level of pain severity, impact on life enjoyment, and interference of with life activities (Krebs et al., 2009). This scale is widely used in pain research including research with Veterans.

xvi. Overt Aggression Scale – Modified (self-report version; OAS-M). This self-report measure assesses aggression and irritability. The measure shows adequate test-retest reliability and

face validity (McCloskey & Coccaro, 2003). In prior studies on DBT, this measure has demonstrated reduction over time (Linehan et al., 2008).

xvii. Skills Satisfaction Assessment (SSA). A survey measure created for this study will assess the perceived utility of each skill. This survey measure will present the names and brief descriptions of each skill and ask the respondent to rate how useful the skill is for its intended purpose (e.g., how useful are each of these skills to help you manage strong emotions?).

Interviews (see attached measures, Table 3):

xviii. Treatment Services Review - Adapted (TSR-A). An interview measure assessing participation in treatment in the 3 months prior to each assessment will be adapted for this study from the Treatment Services Review (McLellan, 1992).

xix. Clinical interview (CI). An interview will be conducted during the initial assessment visit to review DBT-SG theory and review participants' goals for DBT-SG.

Session Rating Scales (see attached measures, Table 3):

i. Dialectical Behavior Therapy Skills Group Self-Rating Checklist (DBT-SG-SRC). A checklist of session items will be completed during DBT-SG sessions to encourage adherence to the protocol and used in clinical supervision. A percent of items completed correctly will be calculated for sessions overall.

ii. Dialectical Behavior Therapy Adherence Rating Scale (DBTARS). A rating scale will be used to rate taped sessions to determine whether DBT-SG is being delivered as designed, with fidelity to the model. The Dialectical Behavior Therapy Adherence Rating Scale (Linehan & Korslund, 2003) rates the adherence of skills group providers on DBT strategies. Inter-rater reliability for scale items ranges 0.78-0.83. Using the scale developer's cutoff score of 3.9 out of a total of 5 possible points, this scale will be used to determine whether DBT-SG sessions are being provided as designed.

iii. Weekly Participation Report Form (WPRF). This form will be filled out by study staff for each session to monitor attendance, homework completion, diary card completion, and notes about participation.

Table 3: Measures

Hypoth	Domain	Measure	Admin schedule
1	Feasibility: self-rating checklist	DBT-SG-SRC	Weekly during session by clinician
1	Feasibility: adherence rating scale	DBTARS	--
1	Acceptability (client)	WPRF	Weekly during session by clinician
1	Acceptability (client)	SSA	Mid-Tx; Post-Tx; Follow-Up
1	Acceptability (client)	CSS	Mid-Tx; Post-Tx; Follow-Up
1	Acceptability (provider)	TPSS	Mid-Tx; Post-Tx; Follow-Up
2a	Suicidal ideation – past 3 months	SBQ	Initial; Mid-Tx; Post-Tx; Follow-Up
2a	Suicidal ideation – past week	BSSI	Initial; Mid-Tx; Post-Tx; Follow-Up
2a	Suicidal ideation – current	CSI-w	Weekly during session
2b	Emotion dysregulation	DERS	Initial; Mid-Tx; Post-Tx; Follow-Up
2c	Coping	DBT-WCCL	Initial; Mid-Tx; Post-Tx; Follow-Up
Expl. 1	Depression	BDI-II	Initial; Mid-Tx; Post-Tx; Follow-Up
	PTSD	PCL-5	Initial; Mid-Tx; Post-Tx; Follow-Up
	Borderline PD symptoms	BSL-23	Initial; Mid-Tx; Post-Tx; Follow-Up
	Self-efficacy	GSES	Initial; Mid-Tx; Post-Tx; Follow-Up
	Chronic pain	PEG	Initial; Mid-Tx; Post-Tx; Follow-Up
	Suicidal behavior – lifetime and past 3 months	BSBI	Initial; Mid-Tx; Post-Tx; Follow-Up
Expl. 2	Non-suicidal self-injury	DSHI	Initial; Mid-Tx; Post-Tx; Follow-Up
	Substance use	BAM	Initial; Mid-Tx; Post-Tx; Follow-Up
	Aggressive behavior	OASM	Initial; Mid-Tx; Post-Tx; Follow-Up
--	Treatment participation	TSR-A	Initial; Mid-Tx; Post-Tx; Follow-Up
--	Clinical interview	CI	Initial

Analytic Plan

Part I: Descriptive analyses: Descriptive statistics (frequency, percent, mean, mode, standard deviation) will be used to describe the demographic and mental health status of individuals referred for DBT-SG. Numbers of participants starting, completing, and prematurely terminating DBT-SG will be generated. Acceptability of treatment will be examined by calculating the percent of DBT-SG sessions attended (number of sessions attended divided by number of sessions expected to attend) among those who participate in DBT-SG. Participation in other treatments will also be examined (e.g., mean and modal number of individual and group mental health sessions attended during participation in DBT-SG).

Part II: Descriptive statistics (frequency, percent, mean, mode, standard deviation) will be used to describe the demographic and mental health status of individuals participating in screening for DBT-SG and participating in DBT-SG. Numbers of participants starting, completing, and prematurely terminating DBT-SG will be generated to examine feasibility. Acceptability of treatment will be examined by calculating the percent of DBT-SG sessions attended (number of sessions attended divided by number of sessions expected to attend) and completion of homework among those who participate in DBT-SG. Participation in other treatments will also be examined (e.g., mean and modal number of individual and other group mental health sessions attended during participation in DBT-SG). Descriptive statistics (mean, mode, standard deviation) will be used to describe participant and provider satisfaction with DBT-SG. Descriptive statistics (mean, standard deviation) will be calculated on adherence scores on the DBT-SG-SRC and DBT Adherence Rating Scale to determine whether the mean adherence rating is at or above the acceptable level.
Descriptive statistics will be used to describe emotion dysregulation, suicidal ideation, coping, satisfaction with the intervention, satisfaction with each skill, and mental health symptoms at each assessment time point. After data screening for linearity and normality, and transformation as needed, one-way repeated measures analyses of variance or general linear mixed model will be used to examine any changes over time in emotion dysregulation (DERS), depressive symptoms (BDI-II), coping (DBT-WCCL), suicidal ideation (BSSI, SBQ, CSI-w), self-efficacy (GSES), pain (PEG), suicidal behavior (BSBI), and impulsive behavior (BAM, DSHI, Impulsive Behavior Checklist, OAS-M). Comparison of suicidal ideation in the three months before treatment, at treatment mid-point, post-treatment, and follow-up point (SBQ) will occur using one-way repeated measures ANOVA or general linear mixed model. Paired sample t-tests examining pre- and post-treatment values for each variable will also be conducted. Corrections for multiple comparisons will be used as appropriate. The reliable change index, a measure of clinically significant change determined by the absolute magnitude of change divided by the standard error of the difference between two test scores (Jacobson & Truax, 1991), may also be used to compare pre- and post-DBT-SG scores to determine the number of participants improved on each variable.

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Summary of amendments reviewed and approved by VACHS IRB:

Staff additions approved 11/20/14: Lorig Kachadourian, Natalie Hung, Jennifer Presnall-Shvorin, Lauren Sippel, Christopher Cryan, Kathryn Hefner

Instrument changes approved 12/4/14: minor modifications to language SBQ, BSSI, DBT Skills Group Self-Rating Checklist, Treatment Provider Satisfaction Survey, Client Satisfaction Survey; Addition of General Self Efficacy Scale, OAS-M (aggression measure), PEG (chronic pain measure) to baseline, 3, 6, 9 month assessments; Addition of Skills Satisfaction Survey at 3, 6, and 9 month assessments; Deletion of weekly Client Satisfaction Survey measure that assessed satisfaction with skills immediately after they were taught and thus prior to participants having an opportunity to practice skills.

Recruitment changes approved 1/22/15: addition of advertisements to potential participants and clinicians; modified WIC and WOA to reflect that chart review will occur for self-referred potential participants; additional telephone screening script; modified inclusion criteria to report of "often or very often" to item assessing suicidal ideation in past 3 months, or, report of "sometimes" to item assessing suicidal ideation in past 3 months and report of "often or very often" to item assessing suicidal ideation in past 4 weeks.

Protocol changes approved 6/18/15: modifications to advertisements and telephone screening protocols; addition of Brief Suicide Behavior Interview (initial and follow-up); update of chart review data collection sheet to include military service data and to account for individuals who had multiple referrals; recruitment at additional staff and clinic meetings; addition of weekly participation report form.

Staff deletions approved 8/3/15: Lorig Kachadourian, Natalie Hung, Jennifer Presnall-Shvorin removed from protocol; Staff additions approved 8/3/15: Jennifer Doran, Candice Presseau, Laura Watkins added to protocol; expansion in duties for Kathryn Hefner

Protocol change approved 2/4/2016: Modification to allow data collection by mail or telephone for mid-treatment, end-treatment, and follow-up for individuals. Data about suicidal ideation is collected over the telephone by the PI. Prior to telephone assessment, information for nearest suicide prevention coordinator and emergency room is located and provided to the participant.

Staff change approved 10/5/2016: Addition of staff member Kathleen Taylor, PhD

Protocol change approved 10/26/2016: Moving PI's office and storage of study materials to building 35, room 42.

Staff change approved 7/18/17: Remove Kathleen Taylor, PhD; Laura Watkins, PhD; Jennifer Doran, PhD from protocol; add Steve Martino, PhD to protocol

Staff change approved 10/19/17: Add Mehmet Sofuoglu, MD, PhD to protocol