Brief Interventions for Suicidal Individuals Not Engaged in Treatment

Erin Faye Ward-Ciesielski

A dissertation

submitted in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

University of Washington

2015

Reading Committee:

Marsha M. Linehan, Chair

Lori Zoellner

James Mazza

Program Authorized to Offer Degree:

Psychology

University of Washington

Abstract

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Erin Faye Ward-Ciesielski

Chair of the Supervisory Committee
Professor Marsha M. Linehan
Psychology

Non-treatment engaged individuals experiencing suicidal thoughts have been largely overlooked in the intervention literature, despite reviews suggesting that the majority of individuals who die by suicide were not in treatment immediately prior to their death. These individuals clearly represent a group in need of additional empirical attention. An intervention has been developed with these individuals in mind and involves a brief, one-time intervention wherein participants are presented with a selection of emotion regulation and distress tolerance skills from the dialectical behavior therapy (DBT) skills training curriculum (Ward-Ciesielski, 2013). This DBT brief suicide intervention (DBT-BSI) has been shown to have promise as an intervention to reduce suicidal ideation, but has yet to be rigorously tested with a control condition. The aims of the present study were 1) to compare evaluate the safety of the DBT-BSI relative to a relaxation training (RT) control condition for adults not engaged in mental health treatment with respect to potential adverse events on participants, 2) to assess the feasibility of the research methodology, and 3) to preliminarily estimate the immediate and long-term degree of change and variability of response to DBT-BSI relative to RT on the primary outcomes of suicidal ideation, emotion

dysregulation, and skills use as well as a number of secondary outcomes (e.g., depression, anxiety). The study was a randomized controlled trial of two one-session interventions and three follow-up interviews over three months conducted from 2012-2013. Participants were randomly assigned to one of the two conditions and outcome assessors were blind to study condition assignment. Suicidal ideation, depression severity, and anxiety severity all significantly improved during the follow-up period; however, there were no significant differences between conditions and skills use and emotion dysregulation did not significantly change over time for either condition. The implications of these findings are discussed.

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ACKNOWLEDGEMENTS

I would first like to express my appreciation to the Psychology Department of the University of Washington. The support, encouragement, and resources they have provided have made this entire process possible. Specifically, I would like to thank my advisor and mentor, Dr. Marsha Linehan, for her knowledge and guidance throughout the course of this research process, without which such an endeavor would never have happened.

My dissertation committee – Drs. Lori Zoellner, Kevin King, Rick Ries, and Jim Mazza – have also played an invaluable role in the design and development of this project, as well as seeing it through to its completion. I would also like to thank my Data and Safety Monitoring Board (Drs. Dave Jobes, Tom Ellis, and Bob Gallop). I am so grateful to all of them for the time and energy they have invested in my professional growth and development. I would also like to thank the National Institute of Mental Health, the American Psychological Foundation/Council of Graduate Departments of Psychology/Friedman-Klarreich Family Foundation, the American Psychological Association, and the Society for a Science of Clinical Psychology for their financial investment in this research.

I would also like to shout from the rooftops how much I am indebted to my friends and family for their support and cheerleading over these last several years. Of special note are my husband (Jeff Ciesielski) – the keeper of my sanity and the always-available barrel of relaxation and rejuvenation ideas – my brothers (Michael Ward and Connor Braniff), my parents (Ron and Donna Ward, Deb and Gary Braniff), my aunt and uncle (Bob and Becky Hornyak), and my friends (Stephanie Thompson, Andrada Neacsiu, and Magda Rodriguez Gonzalez) who have all helped me maintain perspective, determination, and motivation when I didn't always make it easy to do so.

It takes a small army to conduct studies like this and I am honored that so many individuals have volunteered their time and energy. To the assessor-therapists who spent countless hours learning the interventions, practicing the interventions, and meeting with me to get feedback on their delivery of the interventions (Sarah Shreeve and Amanda Gilmore), thank you for sticking with it and for supporting my efforts to give our participants a positive mental health experience! And to the research assistants who have poured their sweat and tears into making this study possible and keeping my eye on the prize, thank you from the very bottom of my heart. That includes Julia Tidik, Mandy Edwards, Hyejin Jin, Connor Jones, Christine Le, Madeline Wielgus, Geneva Pritchett, Edward Ko, Betsy Devich, Kat Eun, Grant Gustafson, Melissa Hernandez, Avinash Papatla, MacKenzie Stapleton, Jeremy Ayres, Brian Bauer, Sarah Han, Jeff Ho, Jiaqi Li, and Stephanie Violante. To my DBT consultation team (Anita Lungu, Janie Jun, Adrianne Stevens, Helen Valenstein, Sam Yard, Ashley Maliken, Lyndsey Moran, Andrew Fleming, Hollie Granato, Dorian Hunter, Erin Miga, and Hong Nguyen), I am especially thankful for your support and assistance in helping me maintain a balance between my professional and personal life. To my colleagues at the Behavioral Research and Therapy Clinics (Melanie Harned, Katie Korslund, Chelsey Wilks, Susan Bland, Elaine Franks, and Thao Truong), thank you all for providing me a home base and willingness to help, even when called in at the eleventh hour and for all of your contributions – large and small, direct and indirect – that made this a success.

Finally, I would like to thank the participants who had the courage to call us and the willingness to share their experiences despite their anxieties and who let us poke and prod some of their most difficult memories and their most guilt- and shame-ridden experiences. Their

openness and honesty are truly amazing and I feel so fortunate to have gotten to know them and to have had a hand in helping them during a difficult time

Introduction

Suicide and suicidal behavior are major public health problems. Suicide alone results in an estimated $34.6 billion in annual medical- and work-loss costs in the United States [Centers for Disease Control and Prevention (CDC), 2014]. In 2010, suicide was the 10th leading cause of death in the United States (CDC, 2014) collapsed across all age groups. For individuals aged 10 to 54, suicide was among the top four causes of death (CDC, 2014). Suicide claimed 38,364 lives in the United States in 2010 and an estimated 800,000 individuals die by suicide in the world each year (World Health Organization, 2014). Further, in the United States an estimated one million people report making a suicide attempt and more than two million report thinking about suicide each year (CDC, 2013). Given the stigma associated with acts of suicidal behavior and self-injury (e.g., Czyz, Horwitz, Eisenberg, Kramer, & King, 2013; Downs, 2012), it is likely that these figures are an underestimation of the scope of suicidal behavior.

The pervasiveness and longevity of the problem of suicide led to the development of a field of study devoted to understanding and reducing suicide events: Suicidology. One of the most widely studied, yet poorly understood subfields within Suicidology seeks to determine a way to predict who will die by suicide. A search through any reference database yields a list of the thousands of articles published in the last decade on this topic (e.g., PubMed, PsycINFO). Associations with suicide have been found with a variety of factors ranging from the brain-derived neurotrophic factor gene (e.g., Zai et al., 2012) to cigarette smoking (e.g., Li et al., 2012) to parental suicidal behavior (e.g., Geulayov, Gunnel, Holmen, & Metcalfe, 2012) to sleep disturbance (e.g., Pigeon, Pinquart, & Conner, 2012). The literature is expansive; however, we remain unable to reliably predict who will die by suicide (e.g., Fawcett, 2006; Large & Nielssen, 2012; Maris, 2002; Pridmore & Walter, 2013). Determining risk and protective factors for

subsequent suicide is, without a doubt, an important aspiration and a worthy target of research attention and effort. Unfortunately, the current trend remains such that this topic is studied to the neglect of attempting to find ways to intervene and prevent suicide.

Theories of Suicidal Behavior

In order to develop interventions for suicidal populations, it is necessary and important to have guiding theories. The theory then dictates the philosophy, rationale, and techniques utilized in the intervention. There are several proposed theories for explaining suicidal behavior beginning in the 1800s when philosophers attempted to explain how suicide, a behavior that spans recorded human history, could be understood. While Socrates is widely considered the first to debate the morality of suicide, the first published theory of suicide came from sociologist Emile Durkheim's now infamous book, *Le Suicide* (1897). Taking a sociological perspective, Durkheim utilized available data related to suicide deaths to create his theory. He viewed suicide as the result of the extent to which a society has control over its individuals and their social and moral behaviors.

Despite the longevity of Durkheim's writings on suicide and the resultant theoretical discussions (e.g., Leenaars, 2004; Robertson, 2006; Stack, 2004), little empirical research has attempted to further support his work. In fact, the most common discourse involving Durkheim's theory of suicide relates to the operational definitions of each of his four proposed subtypes and whether various populations fit rightly in one category over another (Lester, 1999). Without an empirical base, the theory—which is widely considered to be written in such a way so as to make scientific inquiry difficult to conceptualize—has remained a staple in the history of the field without having much, if any, impact on research or clinical practice.

Sigmund Freud provided what is commonly believed to be the first psychological explanation for suicide. Specifically, he posited that humans possess a life force (Eros) and a death force (Thanatos), which are in opposition and struggle within the individual (Freud, 1917, 1920). While the life force works to survive and procreate, the death force seeks to return the individual to an inanimate state. Depression, he argued, was the result of anger toward a loved object that had been turned back toward the self, creating self-hatred. For individuals in whom this self-hatred became extreme, "self-murder" became the solution. Thus, Freud conceptualized suicide as inverted murder; a state in which the individual sees themselves as an object upon whom they can enact their hostility (Campbell, 2010). As with many of Freud's theoretical writings, his thoughts on suicide have not received empirical investigation. Instead, like Durkheim, the few authors who have addressed Freud's theory in more contemporary times have focused on further expanding the theory and clarifying Freud's original arguments (e.g., Briggs, 2006) rather than using them to prompt research inquiry.

Much more recently, after founding the field of Suicidology (i.e., giving it a name and a structure), Edwin Schneidman took note of the high rates of depression and other psychological disorders in those who engaged in suicidal behaviors and coined the term "psychache" to explain the intense and unbearable emotional suffering experienced by these individuals (Schneidman, 1993). Reflecting on his career, Schneidman asserted, "I think I can now say what has been on my mind in as few as five words: *Suicide is caused by psychache"* (1993; p. 51). In essence, he theorized that suicidal behavior was the result of an attempt by an individual to put an end to the psychological pain, anguish, and misery that had reached a threshold that was unbearable and unendurable. Once this threshold had been crossed, suicide was seen as the only alternative. This theory represented a shift in the type of theories proposed. From this point, more recent

theories have commonly incorporated an attempt to understand the suicidal individual, rather than the suicide phenomenon, per se.

Extending this theory of suicide resulting from unbearable psychological pain, Marsha Linehan (1987) theorized that suicidal behavior is a maladaptive attempt to regulate that pain. In one of the clearest explanations of this hypothesis provided in her treatment manual for borderline personality disorder (1993a), Linehan theorizes that negative and painful emotions become so overwhelming that people will engage in a wide range of maladaptive behaviors to alleviate them. This can include behaviors such as using drugs, risky sexual behaviors, and even self-injurious and suicidal behaviors. Regardless of their form, the function of these behaviors is to regulate (i.e., reduce or distract from) emotional misery. Thus, these behaviors become quickly reinforced when an individual feels relief after engaging in self-injurious behavior or receives warmth, love, and support after making a suicide attempt. More than preceding theories of suicidal behavior, Linehan's theory provides an explanation for the way in which repeated and chronic suicidal behaviors come to exist and why they are so difficult to treat. It also provides a testable theory that has been investigated over the past two decades.

The most expansive literature outlining the role of emotion dysregulation or regulating emotions in maladaptive ways comes from the field of non-suicidal self-injury (NSSI). NSSI researchers generally accept that self-injurious behavior most commonly occurs as an attempt to regulate painful, negative emotions (e.g., Dixon-Gordon, Harrison, & Roesch, 2012; Yu, Jiang, & Wu, 2011). Furthermore, whether investigating self-injury in adolescent samples (In-Albon, Bürli, Ruf, & Schmid, 2013), clinical samples (e.g., Slee, Spinhoven, Garnefski, & Arensman, 2008), or in individuals meeting criteria for borderline personality disorder (Gratz, Dixon-Gordon, & Tull, 2014; Welch, Linehan, Sylvers, Chittams, & Rizvi, 2008), self-injury is

consistently found to be a reaction to a strong emotion that the individual cannot otherwise control or regulate.

More recently, problematic attempts to regulate emotions have also been demonstrated in the emergence of suicidal ideation and suicide attempts (e.g., Jiao, Lu, Yang, Chen, & Liu, 2010; Miranda, Tsypes, Gallagher, & Rajappa, 2013; Neece, Berk, & Combs-Ronto, 2013; Rajappa, Gallagher, & Miranda, 2012). For instance, Miranda and colleagues (2013) assessed 143 emerging adults (aged 18-25) and found that those who attempted suicide multiple times prior to the baseline assessment had significantly elevated emotion dysregulation – including an inability to access effective emotion regulation strategies. This research team (Rajappa, Gallagher, & Miranda, 2012) also conducted a survey study in which they found that in a sample of adults, those with a history of multiple suicide attempts had a significantly reduced perception of their ability to access emotion regulation strategies as compared to those without suicidal ideation and those with no prior suicide attempts. These studies, and the numerous others investigating the relationship between emotion regulation and suicidal and self-injurious behaviors, point to the important role of Linehan's theory. Namely, there is strong evidence supporting the role of suicidal and self-injurious behaviors as an attempt to regulate painful emotional experiences.

In another contemporary development, Thomas Joiner (2005) added a theory which has received considerable attention and empirical investigation. Joiner's interpersonal psychological theory of suicide (Joiner, 2005; Van Orden, Witte, Cukrowicz, Braithwaite, Selby, & Joiner, 2010) posits that the desire for suicide is characterized by the presence of thwarted belongingness and perceived burdensomeness. Thwarted belongingness results when the psychological need to belong is unmet. Perceived burdensomeness, on the other hand, results when an individual feels as though they are a liability and a burden to others. Furthermore,

Joiner theorizes that the desire to die by suicide is not sufficient to prompt engaging in suicidal behavior. Instead, individuals must also possess the acquired capability to harm themselves. Operationally, he defines this acquired capability as a loss of the sense of fear associated with self-injurious behaviors and an increased tolerance of physical pain. When all three of these factors are present (i.e., the desire for suicide concurrent with the capability for suicide), lethal or near lethal suicide attempts occur.

Each of the three components that comprise this theory explaining elevated risk for suicidal behavior has received research attention. For example, Van Orden and colleagues (2008) found that the co-occurrence of thwarted belongingness and perceived burdensomeness predicted suicidal desire in a sample of undergraduate students, that acquired capability predicted the number of suicide attempts newly enrolled outpatients reported, and that all three variables occurring simultaneously predicted occurrence of suicidal behavior. Other research teams have also found the interaction between thwarted belongingness and perceived burdensomeness to predict suicidal desire (e.g., Hill & Pettit, 2014; Monteith, Menefee, Pettit, Leopoulos, & Vincent, 2013); however, some research teams have failed to support other predictions proposed by the theory (e.g., Monteith et al, 2013; Christensen, Batterham, Soubelet, & Mackinnon, 2013).

The common thread among these contemporary theories is an emphasis on psychological pain and distress. Notably, only Linehan's theory (1987) has resulted in the development of a treatment for suicidal individuals. Alternatively, Schneidman and Joiner's theories have had the most sizeable impact on the field of suicide risk assessment (e.g., Ribeiro, Witte, Van Orden, Selby, Gordon, Bender, & Joiner, 2014; Van Orden, Witte, Gordon, Bender, & Joiner, 2008).

Interventions for Suicidal Populations

While theories explaining the occurrence of suicidal behavior and the prediction of such behaviors are an important endeavor prior to developing an intervention framework, only a limited number of investigations have attempted to take available theories and move them into an applied setting (e.g., Linehan, 1993a).

To date, there have been only approximately 50 published randomized, controlled trials of interventions specifically targeting suicidal behaviors (Ward-Ciesielski & Linehan, 2014). The number of trials ranges from 40-60, as the multiple reviews of the literature have used various criteria to define the trials they include in their analyses (e.g., Ward-Ciesielski & Linehan, in press; Winter, Bradshaw, Bunn, & Wellsted, 2013). This number is surprisingly small considering the 1,306 trials targeting depression, the 81 targeting bipolar disorder, the 208 targeting substance use disorder, and the 112 targeting alcohol use disorder found by searching the Cochrane Register of Controlled Trials (2014; 60 results are obtained when searching for randomized trials targeting suicide). Of these approximately 50 trials, only a small subset have been shown to have a significant impact on suicidal behaviors compared to the control condition. In fact, only 18 trials (36%) have found that the experimental intervention significantly outperformed relative to the control condition on suicidal outcomes (Ward-Ciesielski & Linehan, 2014).

The length and intensity of the experimental interventions has varied considerably. Brief interventions requiring 4-10 sessions have had varying levels of success (e.g., Brown, Ten Have, Henriques, Xie, Hollander, & Beck, 2005; McLeavey, Daly, Ludgage, & Murray, 1994; Salkovskis, Atha, & Storer, 1990; Tyrer et al., 2003; Weinberg, Gunderson, Hennen, & Cutter, 2006), and long-term or intensive interventions (e.g., Guthrie et al., 2001; Harrington et al., 1998; Termansen & Bywater, 1975; Van Heeringen, Jannes, Buylaert, Henderick, de Backquer,

& van Remoortel, 1995; Welu, 1977) have rarely been effective. Of those 12 unique interventions that have demonstrated improvement of suicidal outcomes, only two interventions have been replicated (Ward-Ciesielski & Linehan, 2014). The first is sending caring letters at predetermined intervals to individuals who did not follow-up with treatment referrals (Carter, Clover, Whyte, Dawson & D'Este, 2005; Hassanian-Moghaddam, Sarjami, Kolahi, & Carter, 2011; Motto, 1976; Motto & Bostrom, 2001). In each trial, the individuals who received the letters had a lower rates of suicidal behavior (suicide attempts or suicide deaths) than those who did not receive the letters. In fact, in Motto's (1976; Motto & Bostrom, 2001) study – the first caring letters trial – the rates of death by suicide in the group who received the letters was half the rate of those who did not receive them. Unfortunately, the rates became equivalent once the letters ceased. While encouraging in its minimal resource expenditure, this suggests that such an effort would need to continue indefinitely in order to maintain its effectiveness which has significant disadvantages (e.g., availability of continuous funding, maintaining contact information).

The second intervention with replicated support is Dialectical Behavior Therapy (DBT) and there have been six RCTs demonstrating its efficacy over various control conditions at reducing suicidal behaviors (Koons et al., 2001; Linehan, Armstrong, Suarez, Allmon, & Heard, 1991; Linehan et al., 2006; McMain, Links, Gnam, Guimond, Cardish, Korman, & Streiner, 2009; Pistorello, Fruzzetti, MacLane, Gallop, & Iverson, 2012; Verheul, van den Bosch, Koeter, de Ridder, Stijnen, & van den Brink, 2003). Across these multiple trials, DBT has been shown to reduce episodes of self-injury (including suicide attempts) throughout the treatment and during follow-up phases, typically lasting at least one year each. These differences have resulted in up to a 50% decrease in suicidal behavior in the DBT condition (e.g., Linehan et al., 1991). The

concordance of findings by different research teams further underscores how uniquely DBT stands apart from other interventions for suicidal populations.

Mental Health Contact and Suicidal Populations

While research consistently supports the effectiveness of DBT as a treatment for suicidal individuals, in general, there is a subpopulation that has been traditionally overlooked in this field: individuals who do not seek treatment in times of suicidal crisis. With only very minor exceptions (i.e., Litman & Wold, 1976; Oquendo et al., 2011; Weinberg et al., 2006), intervention studies targeting suicidal samples have required that potential participants receive referrals into the research trial from their current mental health providers. This recruitment strategy presumes that suicidal individuals who are already receiving mental health treatment comprise a sample that is representative of suicidal individuals as a whole. The limited research that has been conducted to address this issue suggests that this assumption requires investigation.

In one of the first comprehensive investigations, Luoma, Martin, and Pearson (2002) reviewed 40 studies that reported rates of contact with mental health services prior to suicide. This review found that in the year prior to death by suicide, an average of only one-third (32%) of individuals had made contact with mental health services, while approximately 77% of these individuals had been in contact with primary care providers. Even more strikingly, in the month prior to suicide, rates of contact were approximately 19% for mental health services and approximately 45% for primary care. These results call the assumptions implicit in current recruitment strategies into question.

Luoma and colleagues (2002) also estimated average proportions of contact between genders and across the lifespan. While rates of mental health contact were relatively low across all demographic groups, in general, individuals aged 55 or older and males had the lowest rates

of contact (estimated rates of 11% and 18%, in the previous year, respectively). Individuals aged 35 and younger and women consistently had higher rates of contact with mental health services (15% and 36%, respectively).

Age differences in rates of mental health contact are commonly observed. For instance, Beautrais and colleagues (1998) found that among 13-24 year olds who made medically serious suicide attempts (defined as "those for which hospital admission for more than 24 hours was required and which, during admission, met one of the following treatment criteria: (1) treatment in specialized units; (2) surgery under general anesthesia; or (3) medical treatment beyond gastric lavage, activated charcoal, or routine neurological observations," p. 505), 78.3% had a lifetime history of contact with psychiatric services, but only 58.9% of youth had been in contact with services in the month before their attempt. Renaud and colleagues (2009), by contrast, found that 63.6% of suicides between the ages of 11 and 18 years had been in contact with mental health services in their lifetime, while only 20% of them had been in contact in the month prior to their death. A potential explanation for the discrepancy in these findings is that Beautrais and colleagues (1998) studied serious suicide attempts, while Renaud and colleagues (2009) were interested in suicide deaths. There is still little understanding of the extent to which even very medically serious suicide attempts are a useful and valid proxy for understanding suicide deaths (e.g., Beautrais, 2003; DeJong, Overholser, & Stockmeier, 2010; Gilbert, Garno, Braga, Shaya, Goldberg, Malhotra, & Burdick, 2011).

These findings are not unique to the United States. Lee, Lin, Liu, and Lin (2008) examined mental health service utilization among suicides in Taiwan. Similar to the rates seen by Luoma and colleagues (2002), Lee and colleagues found that 83.1% of suicides had utilized non-mental health services in the year prior to their death, while only 22.2% had used mental

health services. Additionally, they found that men and individuals aged 55 and older were significantly less likely to have mental health contact prior to their deaths than women and other age groups, respectively. Similarly, in Eastern Europe, Rodi, Roškar and Marušič (2010) found that 39% of suicides in Slovenia were in contact with their primary care physician in the month prior to their death and that in just 30% of those visits, the reason reported for the appointment was related to mental health problems.

Clements and colleagues (2013), using a national database related to suicide and homicide, studied suicide cases in which the deceased had been diagnosed with bipolar disorder in an English sample. In contrast to the proportions reported in other diagnoses and in other samples, Clements and colleagues found that suicides in individuals with bipolar disorder were significantly more likely to have been in contact with mental health services. In fact, more than 60% of their sample had been in contact with services in the week prior to suicide; however, in the majority of cases, these individuals were assessed to be at low or no risk for imminent suicide.

In summarizing the results of these studies, two important points emerge. First, assuming that studies that recruit treatment-engaged samples are generalizable to the wider suicidal population is fallacious. In fact, the majority of individuals who die by suicide do not make contact with mental health services leading up to their death. This suggests that this group needs further targeted research attention. Second, the proportion of individuals who are in contact with their primary care physician is much higher than contact with a mental health provider, which suggests that primary care settings play a critical role in suicide intervention efforts.

In a study by Rhodes, Bethell, and Bondy (2006), one possible explanation for the low rates of contact with mental health services surfaces. In their examination of data collected as

part of a national Canadian health survey, they found that among subjects who reported suicidal ideation in the previous 12 months, only 37.2% also reported depression. Further, among those who reported having made a suicide attempt in the last year, only about half (56.1%) reported also experiencing depression. Rhodes and colleagues found relatively higher rates of mental health contact for individuals experiencing depression and suicidal ideation (61.6%) and depression alone (50.8%) than for those experiencing suicidal ideation alone (26.8%).

Perhaps, then, the large percentage of individuals who die by suicide, but do not seek mental health services are those who are not also experiencing depression. Despite the methodological flaws inherent in psychological autopsy studies (e.g., Hawton, Appleby, Platt, Foster, Cooper, Malmberg, & Simkin, 1998), meta-analyses of these studies have reported rates of diagnosable mental disorders in up to 90-95% of cases of death by suicide (e.g., Cavanagh, Carson, Sharpe, & Lawrie, 2003; Isometsä, 2001; Sher, Oquendo, & Mann, 2001). As a result, the field of Suicidology has largely taken this figure as a truism and built its science around mental disorders. Furthermore, the broader field of clinical psychology has taken the approach of treating disorders to reduce suicidality. Given Rhodes and colleagues' findings (2006), it may be the case that those individuals reporting suicidal ideation but not depression are instead faced with anxiety, personality, or substance use disorders – or no diagnosable disorders at all (as they are currently classified in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, American Psychological Association, 2013). Clearly, more research into the relationship between suicidality and mental disorders is needed.

Hamdi, Price, Qassem, Amin, and Jones (2008) provide some further support for the theory that individuals who are not in contact with mental health services are those who have not been diagnosed with a mental disorder. In their retrospective study of all suicides in a catchment

area in the United Kingdom, they found that those who were not in contact with mental health services in the year prior to their suicide death were more likely to be male, employed, living with others, not diagnosed with a mental disorder, and had lower history of previous self-harm. Not only does this suggest that relying on a recorded diagnosis to prompt intervention attempts is misguided, it also presents a picture of no-contact suicides that would likely result in a lower estimation of imminent risk for suicide than might be expected. Thus, it is important for subsequent efforts to reach those who have not been in contact with services to gather more data on these issues to further address any relevant differences between groups.

While the estimates of contact with mental and medical health services vary across studies, what remains stable is the significant disparity in the rates of contact between the two. Reliably, individuals who die by suicide more commonly interact with medical or primary care providers in the time leading up to their death (e.g., Andersen, Andersen, Rosholm, & Gram, 2000; Denneson, Basham, Dickinson, Crutchfield, Millet, Shen, Dobscha, 2010). Deisenhammer and colleagues (2007) even found that rates of contact with physicians in the year prior to suicide were significantly increased from rates of contact at other points in the earlier life of the deceased. Specifically, the highest rates of contact were seen in the quarter of the year prior to the quarter in which the suicide occurred (i.e., 3-6 months before the suicide). The consistent findings of proportionally higher levels of contact with medical than mental health services, underscore to the critical role that primary care can play in suicide intervention and prevention efforts. This point will again become relevant in the later discussion of the need for development of briefer interventions for suicidal populations.

Treatment-seeking and Treatment Engagement

Treatment seeking and treatment engagement represent two overlapping, yet distinct topics in the mental health field. Treatment seeking is most commonly characterized by an individual's acknowledgement or awareness of a problem that would benefit from intervention, interest in receiving mental health treatment, and action toward facilitating the start of that treatment. On the other hand, definitions of treatment engagement – which are commonly addressed in the context of substance use treatments – typically center on regular attendance, compliance with treatment procedures, and completion of the course of intervention (e.g., Donaldson, Spirito, & Boergers, 2010; Korchmaros & Stevens, 2013; Shim, Compton, Rust, Druss, & Kaslow, 2009). Given the previously discussed low rates of mental health contact in those who die by suicide, the clear implication is that it is necessary to more fully understand both treatment seeking and engagement in this population.

While the field appears to be moving toward acknowledging that intervention trials usually rely on enrollment of treatment-seeking volunteers via clearer article naming conventions, it is far less common for the authors to address the implications of extracting data from a treatment-seeking sample on the generalizability of study findings. Even when researchers do attempt to examine the potential differences between their clinical research samples and the population as a whole, they regularly overlook the opportunity to address a question of particular importance: are those who seek treatment qualitatively or quantitatively different from those who do not? For example, Stiles-Shields and colleagues (2013) sought to understand whether treatment studies of adolescents with eating disorders were enrolling clinically relevant samples to the population. They ultimately compared those enrolled in research trials to those presenting to an outpatient clinic for treatment (i.e., comparing treatment-

seekers to treatment-seekers) – a comparison not equipped to provide information on differences between those who do and do not seek services.

A limited number of researchers have attempted to address this issue of treatment-seeking more directly. For instance, using an epidemiological dataset, Johnson and Coles (2013) examined the rates of treatment seeking and the reasons given for delayed treatment seeking in a sample of individuals with anxiety disorders. Beyond highlighting that individuals were less likely to seek treatment for an anxiety disorder than for other disorders, they found that a lack of knowledge and negative beliefs about mental illness were among the most common reasons for delayed treatment. Zinzow and colleague (2013) conducted focus groups with active-duty army personnel to understand the barriers to seeking mental health treatment. While their participants reported concerns about the impact of treatment on their military career and stigma about receiving treatment, it is important to note that Zinzow and colleagues may also have missed an important perspective in these focus groups. These focus groups were comprised of army personnel who eventually sought treatment. Therefore, the unaddressed question in both of these studies is whether individuals who never sought treatment would have a different perspective on the relevant barriers.

In a rare comparison of treatment-seekers to non-treatment-seekers, Milner and De Leo (2010) used data collected as part of the World Health Organization's efforts to better understand suicide prevention to examine the factors related to service utilization in an Australian sample following a suicide attempt. They found that individuals who utilized services following an attempt were more likely to have attempted suicide via overdose, communicated suicidal thoughts, and to have had a history of psychological problems, previous attempts, and help-seeking behavior. Conversely, those who did not seek help in the prior 12 months were more

likely to be male and reported no history of having previously sought help or communicated suicide intent. This literature suggests that the similarities and differences between treatment seeking and non-treatment seeking populations are still poorly understood and additional, direct investigations of these two groups are still needed. Furthermore, studies which attempt to generalize results obtaining from treatment-seeking samples should acknowledge the limitations of such an interpretation.

Treatment engagement boasts a larger empirical literature than that of treatment seeking; however, there remains a paucity of investigations attempting to extract knowledge from the substance use field into a suicidal population (Lizardi & Stanley, 2010). To begin, several recent efforts have been published in which researchers attempt to come to a consensus as to the most appropriate definition for treatment engagement. Staudt (2007) reviewed the extant literature attempting to define treatment engagement and isolated two primary components: behaviors and attitudes. She argues that both components are critical and that engagement in one domain does not necessarily result in overall engagement. Thus, engagement appears to be a dual-process construct in which an individual's behavior (e.g., performing tasks that are necessary to achieve goals) and his or her attitudes (e.g., "buy-in" or expectancies that treatment will help with a set of problems) interact to result in engagement with treatment and desired clinical outcomes.

Attempts to define engagement have also frequently involved interviews with providers to ascertain how they define treatment engagement, what important barriers they believe impact engagement in specific target populations, and what strategies they have found to be effective to improve engagement. In one such publication, Staudt, Lodato, and Hickman (2012) summarized the results of focus groups with mental health providers. The essence of treatment engagement, from the perspective of their participants, was the therapeutic relationship. This included the

strength of the relationship as well as the ease of building therapeutic rapport. Unfortunately, this definition provides reference to the subjective, affective experience of a provider working with a client, rather than a concrete definition from which engagement can be measured or tracked over time.

Pullman and colleagues (2013), also utilizing focus groups comprised of mental health providers, attempted to operationalize treatment engagement related to adolescent substance use treatment. They identified five necessary components comprising a definition for treatment engagement. These elements are conduct (observable behaviors related to change and moving toward recovery), attitudes (commitment to treatment and belief in its usefulness), relationships (therapeutic relationship, including collaboration), empowerment (the adolescent's power in the treatment process), and social context (social support and community willingness to facilitate recovery). Their focus groups also yielded examples of behaviors that would indicate engagement under each component, suggesting that these dimensions could be measured and changes in engagement could be evaluated over time. This provides a more readily useful foundation from which to build an understanding of treatment engagement, including behaviors to target should engagement be lacking.

Once engagement is defined (e.g., Pullman, Ague, Johnson, Lane, Beaver, Jetton, & Rund, 2013; Staudt, 2007) it becomes possible to utilize the literature identifying barriers to mental health treatment in an attempt to improve engagement. These efforts have ranged in focus across veteran samples faced with homelessness (Smelson et al., 2013), PTSD (Murphy, Thompson, Murray, Rainey, & Uddo, 2009), suicidal ideation (Britton, Patrick, Wenzel, & Williams, 2011), alcohol and substance use disorders (Smelson et al., 2012; Stecker, McGovern, & Herr, 2012), and primary care medical appointments (Zanjani, Miller, Turiano, Ross, & Oslin,

2008) to civilian tobacco users (McClure et al., 2013; Zanis, Derr, Hollm, & Coviello, 2010), prescription drug users (Zahradnik, Otto, Crackau, Löhrmann, Bischof, John, & Rumphf, 2009), pregnant drug users (Jones, Svikis, Rosado, Tuten, & Kulstad, 2004), and those with chronic back pain (Kerns et al., 2013). While many of these efforts have met with success (e.g., Seal, Abadjian, McCamish, Shi, Tarasovsky, & Wiengardt, 2012; Smelson et al., 2013; Stecker, McGovern, & Herr, 2012), others have failed to impact engagement outcomes (e.g., Kerns et al., 2013). Of those interventions that have impacted engagement, the most common strategies incorporated into these interventions are personalized, tailored referral and discussion of the barriers to seeking treatment (e.g., Seal et al., 2012; Stecker, Fortney, & Sherbourne, 2011), motivational enhancement strategies via telephone (e.g., Seal et al., 2012; Stecker, Fortney, & Sherbourne, 2011; Zanjani et al., 2008), and/or pre-treatment group or individual sessions to address possible engagement issues (e.g., Smelson et al., 2012; Murphy et al., 2009; Britton et al., 2011; Zahradnik et al., 2009).

Considering Treatment-seeking and Engagement when Designing an Intervention

While many attempts to increase utilization of and engagement with mental health resources have not been met with objective success, in addition to those commonalities across intervention efforts (i.e., pre-treatment, personalized discussion of engagement issues utilizing motivational enhancement strategies either in person or by phone) the existing literature also suggests some common explanations for low rates of contact with mental health services that should be considered when designing and implementing interventions aimed at a population less likely to seek treatment. Of those who have investigated the factors impacting the low rates of contact, researchers have found that explanations commonly cluster into two categories: practical barriers and emotional barriers (e.g., Donaldson, Spirito, & Boergers, 2010; Kjølseth, Ekeberg,

& Steihaug, 2010; Zinzow et al., 2013). Practical barriers include those factors that impede an individual who would otherwise be interested in treatment from obtaining it. This includes a lack of mental health insurance, the unavailability of mental health providers (including providers with experience treating specific behaviors or disorders), and an insufficient number of crisis or short-term options for intervention. Emotional barriers include factors such as the fear of disclosing suicidality and the consequences that may result, stigma surrounding mental health treatment, and distrust of mental health professionals.

These various factors point to a need for new and innovative solutions to attempt to engage and help this sizeable population. Specifically, a few recommendations can be distilled from the review above: 1) brief interventions may be beneficial; 2) recruitment may benefit by expanded advertising and strategic messaging; 3) a positive mental health service experience may mitigate future unwillingness or reticence to seek services. First, briefer interventions would not only allow for more individuals to be seen by each provider, but they may also be more desirable to individuals who have had previous mental health service experience in which their treatment lasted longer than they found useful or those for whom insurance or financial barriers are involved. Furthermore, brief interventions are possible to provide in a range of settings (e.g., primary care) and when resources (e.g., provider time and availability) are scarce. Second, although the majority of research trials targeting suicidal individuals have relied on referrals from other mental health providers in the community, this clearly neglects those who have not already been in contact with services. Thus, advertising services in a wider variety of settings throughout the community may yield a greater response from the non-treatment-engaged population. Further, emphasizing the time-limited or immediate benefit of services may also attract individuals who have been reticent to seek services. Third, providing a positive mental

health experience is a common goal of treatment providers. However, attending to the experience of patients being seen in mental health settings, assessing areas of satisfaction and dissatisfaction, and being responsive to patient input may also work to impact the negative opinions of providers reported as a barrier to service utilization.

Selecting an Appropriate Intervention

Taken in concert, the literature suggests that DBT is the most effective intervention for suicidal behaviors (i.e., DBT is effective as a treatment targeting individuals who have problems coping with negative emotions), treatment engagement requires an added consideration in the design of relevant procedures, and brief interventions may be an important first step toward engaging these individuals in treatment (especially in settings where these individuals do present for services, such as medical or primary care offices). Brief versions of DBT have been evaluated in several studies (e.g., Iverson, Shenk, & Fruzzetti, 2009; Meaney-Tavares & Hasking, 2013; Soler et al., 2009; Stanley, Brodsky, Nelson, & Dulit, 2007; Van Dijk, Jeffrey, & Katz, 2013). Most commonly, these "brief" versions are reported in pilot trials and consist of between eight and 24 weeks of group skills training. Unfortunately, only one of these pilot studies reported outcomes related to suicidal behaviors (i.e., Stanley et al., 2007). In Stanley and colleagues' (2007) non-randomized trial, they enrolled twenty individuals meeting criteria for borderline personality disorder in a six-month DBT treatment program (including individual and group therapy, phone coaching, and therapist consultation team). They found significant decreases in urges for and instances of non-suicidal self-injury, suicidal ideation, subjectively-rated distress, depression, and hopelessness at the end of the treatment phase. However, even a "shortened" six-month treatment may be too long to appeal to individuals who are not interested in mental health treatment.

Given the absence of an exact model of very brief DBT or of a successful brief intervention for a suicidal population, it was necessary to look outside the suicide literature and find a plausible model that could be easily adapted. A randomized trial by Whiteside (2011) provides just such a model for a very brief intervention for individuals who are not necessarily interested in treatment. She randomly assigned college students who were mandated to an alcohol intervention after being identified as engaging in problematic drinking behaviors (e.g., drinking alcohol in university dorms) to one of three conditions: 1) the Brief Alcohol Screening and Intervention for College Students (BASICS, Dimeff, Baer, Kivlahan, & Marlatt, 1999), 2) BASICS with the addition of a selection of DBT skills (DBT-BASICS), or 3) a relaxation control. Despite the fact that these participants did not self-refer to treatment and, presumably, were not particularly interested in receiving treatment for their alcohol use, Whiteside found significant improvements in depression, anxiety, drinking to cope with negative emotions, and emotion regulation over three months of follow-up interviews in the DBT-BASICS condition relative to the relaxation condition.

Three important points about this trial are worth underscoring. First, these were participants who did not seek out treatment for the problem targeted by the intervention, yet they benefited from the DBT skills they were provided in important outcome domains (i.e., problematic coping behaviors). Second, they were also selected as a group who was drinking to cope with negative emotions, a coping style Linehan's (1987; 1993a) theory would predict to map on to suicidal and self-injurious behaviors. And third, the intervention lasted only one hour and the improvements were still observable three months later. This provides a solid starting point for further research investigation to determine the scope of very brief interventions and their impact over the span of several months.

Summary

Linehan's theory (1987; 1993a) posits that the ubiquity of suicidal behavior is the result of problematic attempts to regulate painful emotions. Individuals who do not seek treatment in times of suicidal crises represent a population in special need of research attention. The literature suggests that addressing practical and emotional barriers will be an important design characteristic in attempts to engage this group. Additionally, incorporating personalized discussion of issues related to engagement, using motivational enhancement techniques, and considering the intervention to be a pre-treatment addition to improve the likelihood of following through with referrals appear as common elements of efforts to improve engagement. DBT-BASICS (Whiteside, 2011) offers an intervention that is very brief (i.e., one session), targets emotion regulation and has demonstrated a positive impact three months later, and is feasible to implement with a group who is not necessarily interested in mental health treatment.

Preliminary Study

In preparation for the present study, an intervention development pilot trial was conducted (Ward-Ciesielski, 2013). It was necessary to develop and test the appropriateness of the proposed intervention prior to conducting a randomized, controlled trial in order to evaluate the feasibility and acceptability of the intervention and the preliminary effectiveness over a follow-up period. Given the exploratory nature of the open pilot trial, both individuals who had and had not received previous mental health treatment were recruited and included. Treatment-seeking individuals were defined as those currently receiving mental health treatment (psychotherapy or medications), while non-treatment-seeking individuals were those who were not currently in treatment and were not interested in participating in mental health treatment at the time of the phone screening.

Recruitment efforts were designed to reach individuals who may or may not have access to a provider who could refer them into the study. Instead, advertisements were posted around the community in grocery stores, on community bulletin boards, and online (i.e., craigslist.org). Recruitment materials also highlighted the brief, one-time nature of the study and stated that there was no commitment to treatment required. Inclusion criteria required participants to be 18 years or older, currently experiencing suicidal ideation, living in King County, Washington, and willing to consent to recording and assessment. Individuals were excluded if they were younger than 18 years old and/or were non-English-speaking.

Participants in the pilot trial completed assessments at three time points: phone screening, in-person, and one-month after the intervention. Assessments covered demographic information, treatment history, suicidal ideation, and the use of coping skills. Participants completed the assessment and intervention procedures in a one time, one-on-one, in-person appointment. Following the assessment portion of the appointment, participants were provided individualized feedback about the coping skills they were already using and then offered the opportunity to learn some additional coping strategies. Motivational interviewing strategies (Miller & Rollnick, 2002) were used to elicit participants' willingness to learn alternative ways of coping. All participants accepted the offer and participated in learning the selected coping skills.

The intervention portion of the appointment involved the presentation of five pre-selected DBT skills (Linehan, 1993b; in press): mindfulness, two emotion regulation skills, and two distress tolerance skills. The mindfulness and emotion regulation skills were selected based on the DBT-BASICS curriculum (Whiteside, 2011) and were identical to those used in the DBT-BASICS intervention (i.e., mindfulness, mindfulness of current emotions and opposite-to-emotion action). The two distress tolerance skills (i.e., improving the moment and distraction)

were added in anticipation of the deficits of the target sample in tolerating and managing extreme emotions. The skills are described in detail in the "Intervention" section of the present study. Following the presentation of the coping skills, each participant completed a feedback interview with another member of the research team in which they answered questions about their overall experience, suggestions for improvement, and their expectancies. This feedback interview was the primary vehicle to assess the acceptability of the intervention procedures to participants.

Eighteen participants were enrolled in the study and 14 participants also completed the one-month follow-up assessment (i.e., there was a 22.22% drop out rate). This rate is comparable to other intervention studies requiring follow-up assessment and suggests that it is feasible to recruit, enroll, and retain this sample in a brief trial and follow-up period. Fourteen participants provided feedback on their experiences after completing the intervention. There were no significant differences in the feedback provided by treatment-seekers compared to non-treatment-seekers and the majority of participants (78.5%) reported feeling better at the end of the intervention, despite only two participants reporting that they expected to feel better. Further, 85.7% of participants reported that the skills training was helpful and the remaining two participants reported that it was somewhat helpful. These results suggest that participants, treatment-seeking or not, found the brief intervention helpful and acceptable.

Pre-and post-intervention scores on suicidal ideation (Beck Scale for Suicidal Ideation; Beck, Kovacs, & Weissman, 1979) and skills use (DBT Ways of Coping Checklist; Neacsiu, Rizvi, Vitaliano, Lynch, & Linehan, 2010) were compared. There was a significant reduction in suicidal ideation and a significant increase in the use of skills taught in the intervention at the one-month follow-up compared to before the intervention. There were no significant differences in the overall reductions in suicidal ideation or increases in skills use between treatment-seekers

and non-treatment-seekers. However, comparing those who were in treatment at the time of the phone screening to those who were not, those who were not showed greater reductions in suicidal ideation at the follow-up.

This pilot trial utilized a very small sample size, which may have impacted the power to detect differences between the treatment-seeking and non-treatment seeking groups. However, the significant decreases in suicidal ideation and increases in skills use suggest the promise of this intervention. Further, the varied types of psychological and pharmacological treatments reported by the treatment-seeking participants likely confounded the analytical picture. These limitations make it critical that the RCT include an adequately powered sample size and that issues of other treatments be explicitly addressed. The open trial also lacked a control condition, so it was impossible to tell whether the intervention was effective because of the coping skills provided or because of some other uncontrolled variable (e.g., regression to the mean, subject expectancies, time spent with and attention from a caring assessor). Additionally, the reductions in suicidal ideation may be better accounted for by the state-dependent nature of suicidal ideation, a topic which has unfortunately received minimal empirical attention (e.g., Russ, Kashdan, Pollack, & Bajmakovic-Kacila, 1999; Witte, Fitzpatrick, Joiner, & Bradley Schmidt, 2005). Thus, in order to further develop this intervention, it must be compared to a rigorous control condition that controls for any factors that are not specific to the intervention itself.

Summary

Despite the limitations, the open pilot intervention development trial provided valuable information regarding the feasibility of enrolling suicidal individuals who are not interested in treatment and the acceptability of a brief, one-time in-person intervention. Furthermore, the significant impact on suicidal ideation and skills use one month after the intervention

appointment suggests that more rigorous evaluation of the intervention is warranted. The results of this pilot trial have significantly informed the design and implementation of the present study and the results of the present study are meant to continue this line of research toward developing and evaluating a brief intervention for non-treatment-engaged suicidal populations.

Current Study

The current study was designed to evaluate the effectiveness of the brief, one-time, Dialectical Behavior Therapy (DBT) skills-based intervention for currently suicidal individuals who are not already engaged in mental health treatment. A randomized, controlled trial was conducted comparing this brief DBT skills-based intervention to a relaxation intervention designed to control for non-specific factors.

Target Sample

The focus of this study was on suicidal individuals who had not received recent mental health treatment. To increase the generalizability of the findings to other suicidal samples, inclusion and exclusion criteria were kept to a minimum. Individuals who had recently received mental health treatment via a face-to-face appointment with a mental health provider (e.g., psychologist, counselor, psychiatrist) were excluded. However, participants were asked whether they were interested in receiving mental health treatment at the time of their in-person appointment and this was used as a matching criterion to ensure that equal numbers of participants (i.e., those who were interested and those who were not) were randomized to each of the intervention conditions.

Based on impressions from the pilot trial, individuals with significant cognitive impairment were excluded as the speed at which material was presented in the DBT-BSI condition prohibited engagement in those with intellectual difficulties. Cognitive impairment was assessed during the phone screening using the 6-Item Cognitive Impairment Test (6CIT; Katzman, Brown, Fuld, Peck, Schechter, & Schimmel, 1983), a very brief assessment commonly used in medical screening settings.

Specific Aims

Aim 1. Aim 1 was to evaluate the safety of the treatment with respect to potential adverse events on participants.

Aim 2. Aim 2 was to assess the feasibility of the research methodology (e.g., reliability of the measures used; feasibility of random assignment to treatment; appropriateness of the control condition; adequacy of follow-up assessments).

Aim 3. Aim 3 was to preliminarily estimate the immediate (one week) and long-term (one- and three-month) degree of change and variability of response to DBT-BSI relative to RT on the primary outcomes of suicidal ideation, emotion dysregulation, and skills use as well as a number of secondary outcomes.

Hypothesis 1. DBT-BSI would result in lower levels of suicidal ideation and emotion dysregulation, relative to the RT control condition.

Hypothesis 2. DBT-BSI would result in higher levels of skills use, in general, and in greater use of the specific skills taught in the DBT-BSI, relative to the RT control condition.

Hypothesis 3. DBT-BSI would result in lower levels of depression and anxiety, relative to the RT control condition.

Hypothesis 4. DBT-BSI would result in greater utilization of mental health resources during the follow-up period, relative to the RT control condition.

Exploratory Aim. Given the insufficient power to detect significant differences in suicidal and self-injurious behavior between conditions, these outcomes will be examined in exploratory analyses.

Method

Participants

Participants were 93 adults from the community who volunteered to participate in a research study and were currently experiencing suicidal ideation, but had not received mental health treatment in the previous month[1]. Individuals were considered eligible if they were 18 years or older, reported experiencing suicidal ideation in the last week (i.e., scoring 10 or higher on the Scale for Suicidal Ideation; Beck, Kovacs, & Weissman, 1979), had not received mental health treatment in the month prior to screening, lived within commuting distance to the University of Washington, and were willing to consent to assessment. Individuals were excluded from participation if they were non-English speaking or had significant cognitive impairment (i.e., scoring 8 or higher on the 6CIT; Katzman et al., 1983). Inclusion and exclusion criteria are defined in Table 1.

Recruitment

Potential participants were recruited from the community using a variety of strategies meant to be visible to a wide population beyond those individuals who were already receiving mental health services in some capacity. These recruitment strategies were largely a replication and expansion of strategies used in the pilot trial (Ward-Ciesielski, 2013). Study advertisement flyers were posted around King County, Washington on community bulletin boards. These bulletin boards were located in grocery stores, churches, Alcoholics Anonymous and Narcotics Anonymous meeting halls, and around local college campuses. Additional advertisements were

[1] For the first seven months of active enrollment, eligibility requirements were such that participants were only eligible if they had not received mental health treatment during the previous year. When recruitment was progressing much more slowly than projected, inclusion criteria were revised to exclude only those individuals who had received treatment in the last month. This is noted again and its impact on the study's analytic strategy is discussed in the "Data Management and Analysis" section.

posted on websites, circulated in local newspapers, and announced on the radio. These recruitment methods each contained a variant of the statement, "Are you feeling suicidal but resisting harming yourself? We want to hear from you." This statement was selected owing to its success in recruiting participants in the open pilot trial (Ward-Ciesielski, 2013) and in previous studies (e.g., Welch et al., 2008).

Assessment

The assessment domains were selected based on the aims of the study. Therefore, assessment domains included demographic information, cognitive impairment, suicidal ideation and suicidal behaviors, emotion regulation, depression, anxiety, skills use, treatment-utilization, and self-efficacy (see Table 2). Additionally, measures to prompt assessment and documentation of suicide risk were included.

Demographic information. Demographic information was collected using the Demographic Data Schedule – Short Version (DDS; Linehan, 1982) which obtains a selection of demographic data including age, sex, ethnicity, marital status, income, educational level, and occupation. High concurrent validity was established comparing DDS responses to hospital chart data for a sample of psychiatric inpatients (Linehan, 1982).

Cognitive impairment. Cognitive impairment was assessed using the 6-Item Cognitive Impairment Test (6CIT; Katzman et al.,1983). The 6CIT assesses for present orientation, memory, and reasoning and was developed as a brief screening tool for cognitive impairment. It has been shown to strongly correlate with the Mini-Mental State Exam (r^2 = -.91) and to outperform the MMSE in milder forms of impairment (Brooke & Bullock, 1999).

Suicidal ideation & suicidal behaviors. During the phone screening and follow-up interviews, suicidal ideation was assessed using the Scale for Suicidal Ideation (SSI; Beck,

Kovacs, & Weissman, 1979). The SSI is a 19-item self-report assessment that addresses domains related to suicidal ideation including the intensity and frequency of suicidal thoughts, attitudes toward suicidal thoughts, planning and preparation for a suicide attempt, and discussing thoughts of suicide with others. The SSI has demonstrated moderate internal consistency (α = .84-.89) and high interrater reliability (r = .83-.98) (Beck, Brown, & Steer, 1997; Beck, Kovacs, & Weissman, 1979).

During the in-person appointment and follow-up interviews, suicidal ideation and behaviors were also assessed using both the Suicidal Behaviors Questionnaire (SBQ; Linehan, 1996) and the Lifetime Parasuicide Count (LPC; Comtois & Linehan, 1999). The SBQ is a 34-item self-report measure of suicide ideation, suicide expectancies, and suicide threats and communications. The SBQ has demonstrated strong psychometric properties with adult samples (Addis & Linehan, 1989). The LPC assesses the frequency of intentional self-injury and suicide attempts during the lifetime. Additionally, a count is obtained for a wide range of self-injurious behaviors (e.g., cutting, burning, overdosing, banging or hitting oneself, strangling or hanging, etc.), the number of times the behaviors have occurred with true or ambivalent intent to die, and the times that medical treatment was obtained. Further, detailed information is obtained regarding the most recent suicide attempt, the most severe episode of self-injury, and the first lifetime episode of self-injury.

Emotion dysregulation. Emotion dysregulation was assessed using the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004), a 39-item self-report measure that assesses individuals' typical levels of emotion dysregulation across six domains: non-acceptance of negative emotions, inability to engage in goal-directed behaviors when experiencing negative emotions, difficulties controlling impulsive behaviors when experiencing negative emotions,

lack of emotional awareness, and lack of emotional clarity. The DERS has been found to have high internal consistency (α = .93), good test-retest reliability (*r* = .88), and adequate construct and predictive validity. The DERS total score and the subscale reflecting the use of emotion regulation strategies were evaluated as outcome variables in the longitudinal analyses.

Depression. Depression severity was assessed using the Patient Health Questionnaire (PHQ; Spitzer, Kroenke, & Williams, 1999), a 9-item self-report inventory that assesses the degree to which participants have experienced various symptoms of depression during the past two weeks. Importantly, for the present study, the time frame assessed by the questionnaire was the last week to prevent overlap in reporting periods across assessment time points. The PHQ is widely used, has high internal consistency (α = .92), and is sensitive to symptom change (Spitzer, Kroenke, & Williams, 1999).

Anxiety. Anxiety severity was assessed using the Beck Anxiety Inventory (BAI; Beck & Steer, 1990), a 21-item self-report inventory that lists various symptoms related to anxiety and asks participants to rate each symptom on a 0-3 scale based on its relevance during the last week. The BAI has high internal consistency (α = 0.92) and high test-retest reliability (*r* = 0.75) (Beck, Epstein, Brown, & Steer, 1988).

Skills use. Skills use was assessed in three ways: 1) the DBT Ways of Coping Checklist (DBT-WCCL; Neacsiu et al., 2010), a 59-item self-report measure that assesses different methods of coping with stress, 2) a subset of the DBT-WCCL items directly related to the skills taught as part of the DBT-BSI, and 3) a study-generated questionnaire which asked questions related to the skills taught in each of the intervention conditions. The DBT-WCCL has strong psychometric properties and does not include the names of the specific skills within the items. Therefore, it is a general measure of coping strategies used by participants. Participants rate the

extent to which they have used the skill to cope with stressful events on a scale from 0 (never used) to 3 (regularly used). The measure produces two subscale mean scores: functional coping (i.e., using DBT skills) and dysfunctional coping. The first outcome measure of skills use utilized the functional coping subscale which is comprised of 38 items. Second, given the length of the DBT-WCCL and the pilot trial results indicating significant changes on only those items related to the skills that were actually taught as part of the DBT-BSI, a mean was obtained using the items from the DBT-WCCL that were directly related to the skills taught in the DBT-BSI (12 items).

Third, specific questions related to the skills that were taught as part of the intervention were asked. These questions were related to the participant's behavior since the last assessment and included: 1) a yes or no question in which participants indicated whether they had used any of the strategies they discussed during their intervention appointment; 2) an open-ended description of which strategies, if any, they used and under what circumstances they were attempted; 3) an open-ended description of which strategies, if any, were helpful; and 4) an open-ended description of which strategies, if any, were unhelpful and what happened when they tried them. These questions were identical for both conditions; however, a reminder of which strategies were discussed was provided at the start of the questions that was specific to each condition. The outcome measure was whether participants reporting using any of the strategies they were taught since the last assessment.

Treatment utilization. During the phone screening, brief questions were asked to determine whether participants had received any mental health treatment in the previous year. Then, during the in-person assessment, recent mental health treatment history (i.e., treatment received in the previous year as well as information about when treatment was most recently

received, if more than a year ago) was assessed using a shortened version of the Treatment History Interview (THI; Linehan & Heard, 1987). The THI uses a timeline follow-back method of assessment to describe the participant's involvement with various psychological and pharmacological treatments (i.e., individual and/or group psychotherapy, counseling, crisis management, case management, drug and alcohol rehabilitation, pharmacotherapy). Reliabilities for the THI are high; for example, for clients who reported hospitalization in the past year, analyses have revealed 90% agreement between client report and hospital records for number of admissions per client (r = .99; Linehan & Heard, 1987). Information obtained from the THI (e.g., time since most recent treatment, type of provider seen, duration of most recent treatment, reason for ending treatment) was used descriptively and to compare baseline history to treatment obtained during the follow-up period.

During the follow-up interviews, a referral follow-up questionnaire was used to determine whether participants had contacted any of the personalized referral resources they were given during the in-person appointment, whether they had scheduled and/or attended any mental health treatment appointments, and whether there were any other types of mental health services they had been in contact with since their previous assessment (e.g., crisis line, emergency room). Yes or no questions related to their contact with services as well as a count of the number of contacts and appointments participants had made and attended were included in the questionnaire.

Self-efficacy. Self-efficacy, or one's belief and confidence in their ability to manage problems, deal with difficult situations, and general confidence in oneself were assessed using the General Self Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995). The GSES is a 10-item self-report questionnaire that asks participants to indicate the extent to which various presented

statements are true about themselves on a rating scale from 0-3. Used in more than 30 languages around the world, the GSES has high reliability, ranging from $\alpha = .76$ to $\alpha = .90$ (Schwarzer, 2014).

Participant feedback. Feedback was obtained at the end of the final follow-up interview using a modified version of the Subject Feedback Questionnaire (SFQ) that was used in the pilot study. The SFQ assessed participants' experiences among three domains: 1) their overall experience throughout participation in the study (including phone assessments, the in-person appointment, interactions with their in-person therapist), 2) their expectations about how they would feel about their participation (e.g., how they thought they would feel after the in-person appointment compared to how they actually felt), and 3) their suggestions for improvement (e.g., procedures, advertising). Questions were presented with multiple response options (e.g., better/worse/the same, completely positive/mostly positive/neutral/mostly negative/completely negative) and were followed by an opportunity to provide open-ended descriptions or explanations of ratings that were given.

Suicide risk assessment. The University of Washington Risk Assessment Protocol (UWRAP; Linehan, Comtois, & Ward-Ciesielski, 2012) is an assessment protocol which includes 1) assessment of suicide and self-injury risk pre- and post-assessment, 2) strategies to decrease distress and related suicidal and self-injurious urges, 3) strategies to improve mood, and 4) procedures for when to increase the level of response (e.g., escorting the participant to the hospital). The UWRAP was completed each time a subject completed an assessment over the phone or in-person. Assessors and therapists were extensively trained in how to use this protocol prior to conducting phone interviews.

Additionally, the University of Washington Risk Assessment and Management Protocol (UWRAMP; Linehan, Comtois, & Ward-Ciesielski, 2012) was completed following each interview with the exception of phone screenings in which the potential participant was excluded prior to answering any questions related to their suicidal ideation. The UWRAMP prompts for documentation of current imminent risk and protective factors for suicidal behavior and recording of the determined level of risk for imminent suicide. The assessor or therapist conducting each interview completed the risk assessment note and, in the case of the research assistant assessors, the note was reviewed by the supervisor to corroborate the assigned level of imminent risk.

Intervention

Common intervention procedures. Regardless of condition, the intervention was conducted in a one-on-one basis. The intervention was completed in the same appointment and by the same therapist as the in-person assessment. After all assessment was completed, participants were randomized into their treatment condition and the therapist used the appropriate intervention manual and materials related to the selected condition. At the start of each intervention session, participants were asked to briefly describe the factors they believed to be associated with their suicidal ideation and any patterns they had noticed in the occurrence of the ideation. At the end of each session, participants were provided an individualized list of mental health resources. These resources were primarily compiled based on financial and geographic considerations.

DBT Brief Suicide Intervention (DBT-BSI). The DBT Brief Suicide Intervention (DBT-BSI) procedures were designed to last 45-60 minutes. As in the open pilot trial, the DBT-BSI involved presenting participants with five pre-selected DBT skills (Linehan, 1993b; in

press). Four of the five skills (i.e., mindfulness, mindfulness of current emotions, opposite-to-emotion action, and distraction) were retained from the open pilot trial (Ward-Ciesielski, 2013). Mindfulness skills are meant to provide concrete descriptions of how to be present to and participate in the present moment. In DBT, these skills are divided into two components: 1) what to do with one's attention or mind during a practice (i.e., observing, describing, and participating) and 2) how to engage in mindfulness practice (i.e., one-mindfully, non-judgmentally, and effectively).

After teaching about mindfulness, the therapist presented two emotion regulation skills: mindfulness of current emotion and opposite-to-emotion action. Mindfulness of current emotion is a specific type of mindfulness skill that involves observing and describing specific sensations (i.e., physical sensations) associated with emotions. This skill is important to individuals with emotion regulation difficulties as it provides a mechanism to experience emotions without attempting to suppress them, block them, or necessarily act on them (Linehan, in press). Instead, mindfulness of current emotions involves curiously watching physical sensations over time. As emotions rise and fall in intensity, so do physical sensations. Finally, opposite-to-emotion action in DBT involves: 1) exposure to the stimuli or cues that are evoking a particular emotion, 2) blocking the behavior prompted by the emotion's action urge, and 3) acting in a way that is opposite or inconsistent with the emotional response. Especially for participants for whom depression and anxiety are significant correlates to suicidal behavior, opposite-to-emotion action briefly presents a skill that summarizes principles that underlie other evidence-based treatments for depression and anxiety (e.g., Foa, Hembree, & Rothbaum, 2007; Martell, Dimidjian, & Herman-Dunn, 2013).

Owing to the high-risk nature of an intervention for suicidal individuals, it was determined that emotion regulation skills would likely be insufficient to handle acute suicidal crises and a "skills breakdown point" (Linehan, in press) may interfere with practicing emotion regulation skills. Thus, two skills for tolerating distress without acting on distressing thoughts or urges were presented after the emotion regulation skills and were meant to address moments of crisis during which the abovementioned skills may potentially be unfeasible. The two skills taught within the pilot study were 1) distraction of attention and 2) improving the moment. Distraction is a common strategy for coping with negative emotions; however, anecdotally many individuals do not seem to use it effectively or they overuse it to the point where it serves as avoidance of experiencing negative emotions altogether. Thus, it was included in the curriculum in order to teach participants when and how to effectively use distraction for acute crises. Improving the moment, in DBT, includes skills such as imagining doing relaxing or pleasant things, searching for meaning in painful situations, prayer, relaxation, and self-encouragement.

The fifth skill in the pilot trial, improving the moment, was replaced in the current study. This was done for two reasons. First, in conducting the intervention sessions with participants in the pilot trial, it was clear that in a very brief skills training session, the more nuanced differences between distraction and improving the moment were not salient. That is, while distraction was explained as a strategy to deal with short-term or acute crises and improving the moment was explained as a strategy for dealing with chronic stressors or a life that is not the life that you wanted (Linehan, in press), this distinction was not clear to participants and they conceptualized the two skills as the same. As a result, it was necessary to either remove the second distress tolerance skill or to replace it with another. We decided to replace the skill with a set of strategies called "Changing your body chemistry" in order to provide another way to deal

with highly intense emotional arousal, which was commonly reported by participants in the pilot trial as contributing to their suicidal thoughts and behaviors. "Changing your body chemistry" is a set of skills that are meant to rapidly reduce physiological arousal (Linehan, in press). This includes dunking your face in ice water, intensely exercising, pacing your breathing, and progressively relaxing muscles. Each of these strategies was explained to the participant and, when appropriate and when the participant was willing, they were practiced during the appointment.

The DBT-BSI was provided utilizing DBT strategies (Linehan, 1993a). The central dialectic in DBT is balancing acceptance and change. This requires the therapist to move between validation and problem-solving, depending on what is needed in the situation. The intervention was provided using both the core and stylistic DBT strategies. The core strategies of validation and problem-solving were implemented to balance acceptance of where the participant is in the moment and their current capabilities while simultaneously trying to help them change and learn the selected skills. The stylistic strategies include reciprocal communication and irreverent communication. Reciprocal communication refers to the therapist's genuineness, responsiveness to the participant, and their warmth and engagement with the participant in the session. Irreverent communication strategies are used to balance reciprocal communication in order to keep the participant off balance or to "unstick" them from rigid or unhelpful cognitive or behavioral patterns. The DBT-BSI condition was didactically focused, emphasized modeling and metaphors, incorporated instructions, and encouraged practice of the new skills.

Relaxation training (RT). The relaxation training (RT) procedures were designed to last 45-60 minutes and to control for non-specific factors that were left uncontrolled in the pilot trial. Namely, the factors targeted for experimental control were the amount of time spent with a

caring assessor, providing a rationale for usefulness of the information presented, and expectancies of a positive experience. The intervention was also based on principles of supportive therapy in which the assessor functions as a supportive, validating, and caring individual (e.g., Pinsker, 1997). This was operationalized as ensuring that the therapist attended to the participant by actively listening, conveying a sense of unconditional positive regard, communicating understanding and validation, asking clarifying questions in order to identify stressors in a concrete way, and clarifying understanding by summarizing, paraphrasing, and organizing the participant's thoughts and emotions.

The intervention began with an open-ended discussion of the participant's current life stressors and the ways that they attempt to manage stress. This discussion lasted for approximately 20-25 minutes, or until the participant had described all aspects of their stressors. After this discussion, a rationale for relaxation was provided. The rationale provided emphasized the importance of building up resources to be able to deal with stressors and difficult events more easily. Importantly, relaxation was not introduced as a skill. Instead, the therapist moved into encouraging the participant to try a relaxation practice and then walked the participant through a sensory awareness relaxation activity. The sensory awareness activity was based on a similar practice first developed by Goldfried and Davison (1976) and involves the therapist reading a series of questions designed to prompt the participant to notice or pay attention to different sensations. Examples of the types of questions included in the practice are: "Can you feel your hair touching your head?" "Can you imagine something far away?" "Can you notice how one arm is warmer than the other?" The relaxation practice lasted approximately 10-15 minutes and was followed by a discussion of the impact of the practice on current stress and distress levels.

This type of activity provided some confidence in the safety and potential effectiveness of the control condition; namely, there is reason to believe that relaxation techniques may partially serve a distress tolerance function. Additionally, relaxation training was likely to provide immediate reduction in distress levels (Briggs, Webb, Buhagiar, & Braun, 2007; Rausch, Gramling, & Auberbach, 2006), making it acceptable to participants. However, if deficits in emotion regulation and distress tolerance skills are responsible for increased suicidal ideation, one would expect a greater reduction in suicidal ideation in the DBT-BSI condition over the RT control condition. This control condition was also selected because Whiteside (2011) successfully implemented a relaxation control in the study of DBT-BASICS and it was unlikely to duplicate content covered in the DBT-BSI. Talking about skills, presenting relaxation practice as a skill, and problem-solving were all prohibited in the RT control.

Study Procedures

Assessors. The principal investigator and research assistants, trained extensively in the assessment and management of suicide risk, conducted phone assessments. Assessors were bachelors'-level or undergraduate research assistants. Phone screening interviews were conducted by all assessors; however, all follow-up interviews were conducted by the trained research assistants who were kept blind to participants' intervention condition assignment to maintain the integrity of the research data collected. The one exception to the blind assessment was during the follow-up phone interviews when a non-blind assessor (typically the principal investigator) interviewed the participant regarding their use of specific strategies taught in their assigned intervention condition. During this part of the interview, the blind assessor was absent from the room. All undergraduate and post-baccalaureate research assistant assessors were supervised live during phone interviews with participants.

Therapists. Therapists were three masters'-level doctoral graduate students. The principal investigator conducted 77.4% of the in-person appointments and supervised the training and subsequent intervention appointments conducted by the other two therapists.

Phone screening. Figure 1 shows the timeline of study procedures. Interested individuals contacted the research office via telephone or email. They were provided with information about the study and what participation would entail. Individuals still interested underwent a phone screening to determine their eligibility according the aforementioned criteria. They completed a cognitive impairment screening (i.e., 6CIT) and then responded to questions about their demographic characteristics, current suicidal ideation, and mental health treatment history during the previous year. The schedule of assessments and domains assessed at each time point are included in Table 2.

In-person appointment. Individuals who were determined to meet all study eligibility requirements were then scheduled for a one-time in-person appointment with a therapist. Every attempt was made to schedule this appointment within the next 72 hours; however, this was not always possible. The average time between the phone screening and the in-person appointment was 6-7 days (median = 5 days). This appointment was composed of two parts: assessment and intervention. The assessment included interviews to assess the participant's history of mental health treatment and any history of suicide attempts or intentionally self-injurious behavior. Additionally, participants completed self-report questionnaires related to emotion dysregulation; suicidal thoughts, feelings, and behaviors; depression; anxiety; self-efficacy; and ways of coping with stressful situations. The intervention consisted of either the DBT-BSI or the RT procedures.

Follow-up interviews. Participants completed three follow-up assessment interviews over the phone. These interviews occurred one-week, four-weeks, and twelve-weeks following

the in-person appointment. During the one-week follow-up assessment, participants answered questions about their suicidal ideation, depression, anxiety, and use of the skills they learned as part of the intervention condition to which they were assigned. During the four- and twelve-week assessments, participants answered the same questions as those presented in the one-week follow-up as well as questions about emotion dysregulation, suicidal thoughts and behaviors, self-efficacy, and coping strategies. Also, at the end of the twelve-week follow-up interview, participants were asked about and provided feedback on their experiences throughout their participation in all aspects of the study.

Payment. As compensation for their participation and as an incentive to complete all follow-up interviews, participants received minimal payments following each assessment. At the conclusion of the in-person appointment, participants received $5, for the one- and four-week follow-up phone interviews, participants received $10 each, and for the twelve-week follow-up phone interview, participants received $20. Thus, participants could receive up to $45 by completing all assessment interviews.

Protocols

Risk assessment and management. Several steps were taken to protect participants against risks associated with their participation in the study. First, participants were fully informed of the range of items and the most sensitive and personal items in the consent form and were informed that they were free not to answer any questions they did not wish to answer and could refuse to participate or withdraw from the study at any time. They were encouraged to talk with the investigator in the event that they experienced distress or discomfort as a result of their participation.

To address participant suicide risk, an assessment for monitoring the current suicide risk of participants (i.e., the University of Washington Risk Assessment Protocol described above) involved ratings of stress and suicidality both before and after participation in each assessment session of the study. The UWRAP asks participants to rate the a) current level of stress, 2) urge to harm themselves, 3) intent to kill themselves, and 4) desire to use drugs or alcohol. These ratings are made on a scale of one to seven and an increase of more than two points or any value over a four is considered sufficient for further assessment. In the rare events when further assessment was warranted, the principal investigator took over the phone call to further assess imminent risk and a licensed, doctoral-level psychologist (usually Dr. Linehan) was contacted for consultation and follow-up. The follow-up interview, among other things, assesses the presence of a plan, access to means, and the likelihood of being interrupted by others. While this was not necessary during the trial, in the event that a participant was determined to be at high risk based on this interview and the clinical judgment of Dr. Linehan, a safety plan would have been developed with the cooperation of the participant and the principal investigator.

Even for those participants who did not report an increase in their levels of stress or suicidality, the procedures were expected to potentially cause stress or contribute to a negative mood. Thus, all participants were offered mood-improvement activities at the end of their participation. These activities were determined collaboratively with the participant at the start of the interview and reviewed again at the end. The most common mood-improvement activities were taking a walk, watching a movie, calling a friend or family member, or eating a meal after the interview ended. The University of Washington Risk Assessment and Management Protocol (UWRAMP) was also completed at the conclusion of all phone and in-person appointments. Further, a trained clinician with expertise in suicidal behavior, ordinarily Dr. Linehan, was

always on call should any emergency arise that research staff and the principal investigator were not equipped to handle.

Drop-out. Following the in-person appointment, participants were considered to have dropped out if they expressly indicated to study staff that they did not wish to complete further assessment interviews. Participants were also considered to have dropped out once they stopped completing subsequent follow-up phone interviews (e.g., missed 4-week and 12-week follow-up interviews). Participants who missed assessment time points, but who completed subsequent assessments (e.g., missed 1-week follow-up, but completed 4-week follow-up) completed the same battery of interviews as all other participants at that time point, with the addition of further inquiry into their suicidal and self-injurious behavior and any new mental health treatment, when applicable.

Medications. Current psychiatric medication was not an exclusionary criterion. That is, participants were accepted into the study regardless of whether they were taking psychiatric medications. However, individuals for whom medications were prescribed by a mental health provider (e.g., psychiatrist) and those who had met with the prescribing provider within the previous month were excluded. The rationale for the inclusion of individuals who were taking medications but who had not met with a provider in the past month was two-fold. First, it is not uncommon for individuals to be prescribed psychiatric medications by primary care physicians who conduct neither psychotherapy nor thorough assessments of psychological functioning. Additionally, emerging research suggests that individuals who are not engaged in regular mental health treatment may also have poorer medication adherence (e.g., Jaeger et al., 2013; Jones, Corrigan, James, Parker, & Larson, 2013), suggesting that the addition of the study interventions would still be of value. Second, given the prevalence of psychiatric prescriptions in the suicidal

population, inclusion of these individuals expands the generalizability of the results. As a secondary intervention outcome was related to engagement with mental health treatment (including psychiatric treatment), it was important not to prohibit participants from seeking out this treatment during their participation in the study. Psychiatric medications reported at baseline were evaluated as a confounding variable in all analyses.

Unanticipated problems and adverse events. The Office for Human Research Protections (OHRP) of the United States Department of Health and Human Services (2007) has published guidelines for defining and reporting unanticipated problems and adverse events when conducting research trials. While their definitions are broadly defined and require interpretation for specific cases, they provide guidelines for what should be considered an unanticipated problem and/or an adverse event in research with human subjects. Per their guidelines, unanticipated problems include events that meet each of the following criteria: 1) they are unexpected given the research procedures and the subject sample being studied, 2) they are related or possibly related to participation the research procedures, and 3) they suggest that the research places subjects at a greater risk of harm than was previously known. Adverse events, on the other hand, are unwanted or unfavorable medical occurrences that are temporally associated with the subject's participation in the research procedures, whether or not it is related to their participation. OHRP highlights an event can be an unanticipated problem, an adverse event, or both, depending on the details of the event.

Potential unanticipated problems and adverse events were documented and reported to the University of Washington Human Subjects Division (HSD) and the Data and Safety Monitoring Board (DSMB, described below), per reporting procedures outlined in the data and safety monitoring plan and the HSD documentation procedures and timeline. While there were

no events that required modification of study procedures, such events would have been managed in consultation with the HSD and the DSMB.

Data Management and Analysis

Randomization and matching. In order to account for potential covariates that may spuriously impact analytic results, participants were matched on three variables to control for any differences resulting from disproportional randomization into the intervention conditions. These three variables were identified gender (male, female), history of suicide attempts (yes, no), and whether they were interested in mental health treatment (yes, no). Following completion of the in-person assessment battery, matching data for all participants was entered into a computerized system that utilized the minimization randomization algorithm to ensure equal numbers of participants at each level of the matching variable. This strategy for randomization to condition was developed specifically for studies in which the number of matching criteria is large in relation to the number of participants being randomized. The randomization algorithm was implemented by entering matching criteria information into a computerized program designed by and for use at the Behavioral Research and Therapy Clinics. Following entry of the matching criteria values, the program randomly assigned each participant into one of the intervention conditions. Participants were randomized using a 1:1 ratio, such that equal numbers of participants were assigned to the experimental condition (DBT-BSI; $n = 46$) as to the control condition (RT; $n = 47$).

Power analyses. For the present study, the sample size was determined using G-Power (Faul, Erdfelder, Lang, & Buchner, 2007). Based on Cohen's (1988) discussion of effect sizes, the effect size from the pilot study was consulted (Ward-Ciesielski, 2013). The effect size for the decrease in suicidal ideation observed during the pilot study was 0.56, which is considered a

medium effect. Considering this effect size, 53 participants completing all follow-up assessments were needed to test the hypothesis that suicidal ideation would decrease differentially over time as a result of the intervention condition to which individuals were assigned. During the pilot study, 20.8% of participants who met inclusion criteria and scheduled an in-person appointment did not show up or cancelled prior to their scheduled appointment (5 out of 24 participants). Additionally, four participants (22.2%) who completed the in-person procedures dropped out of the study before the one-month follow-up assessment (i.e., they were unreachable to complete the interview). Given this information and the history of retaining participants in treatment studies at the Behavioral Research and Therapy Clinics, a drop-out rate of approximately 30% between the intervention appointment and the three-month follow-up assessment point was expected.

Assuming 30% attrition, the final sample size was determined to be 138 participants (69 per condition) completing the intervention. However, owing to slower-than-anticipated recruitment and enrollment for the first several months of the trial, the target sample size was reduced. The reduced sample size was 92 participants (46 per condition) completing the intervention. Based on power calculations for the full sample and the maximum expected decline and attrition rates, this reduced sample provided the study with 80% power to detect differences between the two groups in the medium range (Cohen's *d* between 0.5 and 0.6; Cohen, 1988) and less than adequate power to detect small differences. This sample size is a balance between adequately being able to detect differences between conditions and the pilot design of the trial.

Data management. Data was collected using 1) computerized interviews and surveys and 2) paper surveys that were subsequently double-entered into SPSS by two independent

research assistants. All computerized survey information was stored in a de-identified state and identifiable information was housed in a separate area of the server. Audio recordings of phone interview (i.e., phone screening, follow-up interviews) and video recordings of the in-person appointment were made using a web camera and were stored on a secure server at the Behavioral Research and Therapy Clinics where they were only accessible by the server administrator and relevant study staff.

Confidentiality was carefully protected. Data were only identified with a code number, generated for study purposes only. This code number was linked to identifiers for the length of time necessary to complete the study. Only the principal investigator and necessary research assistants had access to the linking information that was stored on a secure server that is password protected and requires special authorization to access. Furthermore, because of the sensitive nature of the information collected from participants, a Certificate of Confidentiality was obtained from the National Institute of Mental Health as an extra measure of protection.

Additionally, a Data and Safety Monitoring Board (DSMB) was convened and a data and safety monitoring plan was developed to be sure that the current study was conducted with the utmost conscientiousness. Consistent with NIMH guidelines, the DSMB consisted of three people and oversaw and monitored the safety of study participants and the validity and integrity of the research data. No DSMB members were directly involved in other aspects of the project or had a stake in its outcome. Upon establishing the DSMB, the University of Washington Institution Review Board was notified of the operating protocol with regard to the aforementioned data and safety monitoring plan. An initial meeting of the DSMB, the primary investigator, and Dr. Linehan occurred prior to the start of the study. Thereafter, members of the DSMB and the principal investigator met biannually and reports of study progress were

circulated quarterly throughout the active recruitment, enrollment, and follow-up of study participants. Reports included information related to recruitment progress, participant retention, progress of data management and analysis, and any new information that might alter the risk/benefit ratio for participating in the study.

Missing data. Data were assumed to be missing at random (MAR; Rubin, 1976) based on the theoretical construction of the data. MAR assumes that the probability of missing data depends on observed data, but not on missing data (Schafer & Graham, 2002). Missing completely at random (MCAR), a special case of MAR, assumes that the probability of missing data depends on neither missing data nor observed data. Given that clinical trials commonly experience attrition when participants improve as well as when their symptoms deteriorate (i.e., missing data may be related to observed data), it is unreasonable to assume MCAR. Missing not at random (MNAR), on the other hand, results when the distribution of missing data does depend on missing values (e.g., a participant feels depressed, so does not complete an assessment). When the data are MAR and the parameters that account for the mechanism of the missing data are distinct from parameters measured and included in the model, the missing data is said to be "ignorable" (Laird, 1988; Rubin, 1976; Schafer & Graham, 2002).

Confounding variables. Potential confounding variables were both theoretically- and empirically-derived. Three *a priori* confounding variables were identified: psychiatric medications at baseline, the therapist who conducted in in-person procedures, and date of phone screening. As noted above, participants were not excluded if they were being prescribed psychiatric medications by a provider they had not seen in the past month. Thus, psychiatric medication at the time of the phone screening interview was evaluated as a potential confounding variable to ensure that individuals currently taking medications were not driving any results

obtained. Furthermore, therapists other than the principal investigator conducted in-person appointments in order to evaluate any therapist-specific effects. This variable was also evaluated as a potential confounding variable. Finally, to account for the change in inclusion criteria after enrollment began (i.e., requiring participants to be without mental health treatment for one month instead of one year prior to their enrollment), participants accepted prior to this change were compared to participants accepted after.

Additional potentially confounding variables were identified via chi-square and *t*-test comparisons of each demographic and baseline clinical characteristic. These analyses were conducted to identify any significant differences between the two conditions. Any significant comparison was treated as another potential confounding variable. These potential confounding variables were included in the longitudinal analyses as covariates to determine whether they were a significant predictor of the outcome variable. If a main effect of a confounding variable was significant, this confounding factor was added as a covariate in the analyses. If there was no significant main effect for the confounding variable, it was left out of the final model. For all outcome measures (i.e., SSI, DERS, DBT-WCCL, PHQ, BAI, and GSES), the critical significance value was set to 0.05, two-tailed. Therefore, the confounding factor was considered to have a significant main effect if its corresponding *p*-value was 0.05 or less.

Normality assumption. In addition to assessing the difference between groups on demographic and clinical characteristics to determine confounding variables, exploratory analyses were conducted on each outcome of interest to assess whether the data satisfied the assumptions required for subsequent analyses. These exploratory analyses varied depending on the format (e.g., continuous, binary) of the outcome variable. A key assumption of longitudinal

modeling with continuous outcomes is the normality of the outcome variable. To account for any non-normality, various transformations are often applied (e.g., log, natural log, squared).

Shapiro and Wilk (1965) provide one test statistic for normality. The Shapiro-Wilk *W* test statistic ranges from 0 to 1, where larger values indicate greater resemblance to the normal distribution. This *W* statistic is used to test whether the normality assumption has been rejected for a variable. The significance level of the Shapiro-Wilk statistic is sensitive to sample size and statisticians have suggested that it may not be a reliable indicator of normality for smaller sample sizes (Royston, 1991). As a result, a *W* statistic of greater than 0.90 was used to indicate normality regardless of its corresponding significance value. It was assumed that if an outcome variable was normally distributed at each time point, the variable could be considered normally distributed for the longitudinal analysis. None of the continuous outcome variables required transformation to address normality.

Continuous longitudinal outcomes. Intervention effects were evaluated by examining changes in the primary (suicide ideation, emotion dysregulation, skills use) and secondary (depression, anxiety, self-efficacy) outcomes as a function of treatment condition using multilevel modeling (i.e., Hierarchical Linear Modeling). Level-1, the within-subjects model, included the estimates of the individual changes in repeated measures of suicide ideation, emotion dysregulation, skills use, depression, anxiety, and self-efficacy assessed over time (e.g., baseline, one-week, one-month, three-months post-intervention). Level-2, the between-subjects model, incorporated condition assignment as a predictor of the Level-1 growth parameters. This model accounted for the variance attributable to individual difference in outcomes (the slope of the outcome over time) as well as variance owing to the intervention assignment.

Hierarchical linear modeling (HLM; Bryk & Raudenbush, 1992; Raudenbush & Byrk, 2002) was selected as the best analysis for testing the proposed hypotheses because it allowed for variation at multiple levels. First, individual variability among participants over time was expected. Additionally, variability was also expected between conditions. Using HLM, a regression line is computed for each participant, allowing both types of variability (i.e., over time and between conditions) and their interaction to be tested.

Another benefit of using HLM is its approach to handling missing data. In addition to allowing multiple sources of variability, HLM operates in such a way that if a data point is missing for a participant, the regression line can still be constructed under the assumption that if the data point had not been missing, it would have followed the trajectory of the participant's data from other assessments that were completed.

Appropriate covariance structures were analytically determined based on a comparison of model fit criteria (Verbeke, 1997). Three models were compared: random intercept, random intercept and random slope, and unstructured. The random intercept model assumes that all participants have the same change trajectory over time, without individual variability. The random intercept and random slope model allows participants' change trajectories to vary throughout the follow-up period. Finally, the unstructured model allows the random intercept and random slope to be correlated. The random intercept and random slope model was determined to be the best fit for all analyses. This model does not assume a relationship between participants' baseline scores and their progression over time. Instead, participants may vary in their trajectories throughout the follow-up period. That is, the model assumes participant variability in slope, but sets the covariance between the random slope and the random intercept to zero. To improve the likelihood that the model would converge, SPSS-19 was set to perform

the maximum number of iterations it allows. The covariance structure was also analytically derived by comparing goodness-of-fit statistics. The scaled identity covariance structure was determined to be the best fit. This covariance structure assumes that the variance at each time point remains constant and that the outcome at each time point is independent.

As outline above, missing data imputations were not specified. Instead, a restricted estimated maximum likelihood (REML) model was used to account for missing data in HLM analyses. In this approach, time is treated as a continuous variable and a regression line is modeled for each participant based on the number of available time points. The model does not assume that each outcome contains data from the same number of time points; therefore, the regression line is created with any available time points. In this way, participants with missing data are still modeled using any data points they did provide (Schafer & Graham, 2002).

Multilevel modeling output from SPSS provides an estimated coefficient and an *F*-test assessing the significance for each fixed effect and interaction effect. In these analyses, the fixed effects are assessment time point and condition and the interaction effect is time-by-condition. A significant effect of time suggests that participants significantly changed over time, regardless of condition. A significant effect of condition suggests that participants in one condition significantly differed from participants in the other condition, regardless of time. A significant interaction between time and condition suggests that participants in one condition changed differently over time (i.e., faster or more slowly) the participants in the other condition.

The *F*-test of significance does not explain the source of any differences. Therefore, an *a priori* set of contrasts were created for each analysis to better understand the main effects and interactions. Two tests assessing whether the slope for each condition is significantly different from zero were included in the HLM model. These tests provided a slope estimate for each

condition and a t-test assessing the significance of the slope. For cases in which one condition's slope was significantly different from zero, but the other was not, the outcome for the condition with the significant slope was considered superior even if a significant time-by-condition interaction was not obtained owing to the *a priori* hypotheses that the rate and degree of change would be different between conditions.

Binary longitudinal outcomes. Intervention effects for binary outcomes (i.e., use of the skills taught during the intervention, beginning mental health treatment, and suicidal behaviors) were evaluated in much the same way as continuous outcomes. Specifically, an extension of the generalized linear model, the generalized estimating equation approach (Liang & Zeger, 1986; Zeger & Liang, 1986) was used. GEE is an increasingly popular approach to longitudinal and repeated measures designs, especially in the case of binary and categorical outcomes (Ballinger, 2004) owing to its simplicity relative to mixed models for fitting binary data. By contrast to mixed models (e.g., HLM), which 1) treat correlation between the elements of the outcome variable as random effects, 2) assume that all outcomes are independent, and 3) rely on a likelihood analysis which requires specification of the form of the outcome distribution, GEE 1) treats the correlation as a nuisance variable (i.e., as a covariate), 2) does not assume independence of outcomes, and 3) uses a quasi-likelihood analysis in which only the relationship between the mean and variance must be specified in the form of a variance function (Zeger & Liang, 1986). Additionally, an advantage of GEE is its robust estimation of regression coefficients and standard errors, even when the working correlation structure is misspecified (Norton, Bieler, Ennett, & Zarkin, 1996).

Another benefit of GEE for binary outcomes is the way that the model handles missing data. Similar to HLM, GEE allows for randomly missing observations. That is, only missing

observations are treated as missing, rather than implementing a listwise deletion that ignores all data for any participant with a missing data point. Thus, analyses are conducting using all available data for a given time point.

Owing to the fact that the data are clustered, an autoregressive covariance structure was specified. This structure assumes that measurements taken closer together in time are more correlated than measurements taken farther apart in time. Effectively, the GEE procedure within SPSS 19 initially performs a repeated measures logistic regression assuming that the observations within subjects are independent. The probability distribution is set to binomial and the link function to logit. Residuals (i.e., error terms) are calculated from this model and a working correlation matrix is estimated from the residuals. Then regression coefficients are refit using this working correlation matrix, correcting for the correlation. Ultimately, the within-subject correlation structure is treated as a nuisance variable (i.e., as a covariate). This is important with binary outcomes because ignoring within-group correlation commonly leads to underestimated standard errors which can lead to increased Type I error (i.e., false-positives).

The model fit is not tested in GEE because it is an estimating procedure; therefore, there is no likelihood function to test. Goodness-of-fit statistics (e.g., chi-square) and the estimates of the regression coefficients and standard errors resulting from the working correlation matrix are reported.

Effect size. Feingold (2009) reviewed the literature related to effect sizes in treatment studies. He concluded that treatment effect sizes for longitudinal analyses are best obtained by using pretreatment raw scores, rather than change scores. This approach minimizes bias in estimating the treatment effect from longitudinal results. The resulting equation from which effect sizes were determined is,

$$Effect\ size = \frac{\beta * time}{SD_{raw}}$$

where β is the estimated coefficient of the difference in slope for each condition (i.e., DBT-BSI slope, RT slope), SD_{raw} is the pooled standard deviation between conditions at pretreatment, and time is the number of time points included in the analysis (in the present study, time equals two or three, depending on the outcome variable). The resulting effect size is interpreted using Cohen's specifications (1988).

For outcomes in which there was no significant interaction between time and condition, effect sizes were calculated using the means and standard deviation of each group. That is, for significant main effects of time, the effect size was calculate using the equation,

$$d = \left|\frac{M_1 - M_2}{SD_{pooled}}\right|$$

where M_1 is the baseline mean score, M_2 is the follow-up mean score (using data from all available participants who completed that follow-up assessment point), and SD_{pooled} is the pooled standard deviation between conditions. For outcomes in which there was a significant main effect of condition, the same formula was used, with M_1 as the DBT-BSI mean score and M_2 as the RT mean score.

Cohen's *d* is best suited to continuous outcomes in longitudinal analyses. For binary outcomes, relative risk ratios were calculated (McGough & Faraone, 2009). Relative risk (RR) ratios are an indicator of the proportion of participants in one condition who improve or engage in a behavior relative to the proportion of participants in the other condition who do so as well. Thus, the equation from which RRs are computed is,

$$RR = \frac{Probability\ of\ improvement\ in\ condition\ 1}{Probability\ of\ improvement\ in\ condition\ 2}$$

RR ratios range from 0 to infinity. Using all available data, a RR of 1 would indicate that the outcome does not differ between the two groups. An increasingly larger RR, on the other hand, indicates that the experimental condition (i.e., DBT-BSI) has a greater probability than the control condition (i.e., RT) of improvement or engagement in the outcome behavior while an RR below 1 indicates that the controol condition (i.e., RT) has a greater probability than the experimental (i.e., DBT-BSI) of engagement or improvement.

Clinically significant change. In order to translate statistical significance into a meaningful form for application in clinical settings, clinically significant change as described by Jacobson and Truax (1991) was also examined. Clinically significant change refers to functional changes that are meaningful to participants engaged in psychosocial interventions. A comparison of multiple methods for assessing reliable change concluded that the initial method developed by Jacobson and Truax (1991) is the simplest and yields results similar to those obtained via more complicated, yet more accurate, means (Bauer, Lambert, & Nielsen, 2004).

Jacobson and Truax (1991) propose a two-step model for determining whether reliable change has taken place. The first step establishes a cut-off score to differentiate between clinical and non-clinical samples for the outcome of interest. Three types of cutoffs can be computed: 1) based on the clinical sample included in the study (cutoff *a*), 2) based on known functional norms (cutoff *b*), or 3) based on a weighted midpoint between the means of functional and dysfunctional samples (cutoff *c*).

The second step involves determining whether participant change from intervention to follow-up is an artifact of measurement error or indicative of actual change. For this determination, a reliable change index (RCI) is computed based on the test-retest reliability of the measure and its standard deviation at baseline. If the post-test score exceeds the chosen

cutoff and the RCI is greater than 1.96, the participant is classified as "recovered." If the RCI is greater than 1.96, but the post-test score falls below the cutoff, the participant is classified as "improved." If neither criterion is met, the participant is classified as "unchanged/deteriorated."

Clinical significance analyses were performed on primary and secondary outcome variables that could offer a better understanding of the treatment effects, including the SSI, DERS, DBT-WCCL, PHQ-9, and BAI. Cutoffs and RCIs for each measure were determined *a priori*. Because the three groups into which participants can fall are ranked, Mann-Whitney *U* analyses were performed between conditions at each time point to assess for differences in the proportion of participants who remained unchanged, who improved, and who recovered between conditions.

Results

Participants

Two hundred and ninety-eight individuals were screened over the phone for study eligibility (see Figure 2). One hundred and thirty-two participants were invited to participate in the study procedures. Of these individuals, 96 attended an in-person appointment (72.7%). Three participants (3.1%) were determined to be protocol deviations after revealing during their in-person appointments that they had previously denied ongoing mental health treatment and are not included in subsequent analyses. This resulted in an intent-to-treat sample of 93 participants. Those participants who were invited but did not come in for their in-person appointment (n = 36) were more likely to be Asian than those participants who did become part of the intent-to-treat sample (Table 3).

Participants were 59.1% male (35.9% female, 4.3% transgender), with a mean age of 40.22 (SD = 15.15). The sample was primarily White/Caucasian (84.1%). Demographic and clinical information is presented in Tables 4 and 5. Eighty-three (89.2%) participants reported receiving mental health treatment during their lifetime. For 29 (31.2%), this treatment occurred during the last year. For participants who had not received treatment in the last year, the average time since most recent mental health treatment was 3.71 years (SD = 5.71).

Additionally, 56 (60.2%) participants reported making a suicide attempt in their lifetime, while 19 (20.4%) participants reported a suicide attempt in the last year and five (5.4%) participants reported a suicide attempt in the last month. Fifty (53.8%) participants reported engaging in non-suicidal self-injury (NSSI) in their lifetime. Forty-five participants (48.4%) reported both suicidal and non-suicidal forms of self-injurious behavior, 11 (11.8%) reported

suicidal behavior alone, and five (5.4%) reported NSSI alone. In total, 61 (65.6%) participants reported engaging in some form of self-injurious behavior in their lifetime.

Of note, a comparison of the proportion of participants in each condition reporting a lifetime history of NSSI highlighted that significantly more participants in the DBT-BSI condition reported this history than participants in the RT condition (χ^2 (1, N = 61), 9.35, p = .01). As a result, this variable was evaluated as a potential confounding factor in the longitudinal outcome analyses described below.

The 23 participants who were lost to attrition during the three-months of follow-up assessments, compared to the remaining 70 participants, reported significantly higher levels of depression (t(88) = 2.72, p = .01) and anxiety (t(90) = 2.49, p = .02) at baseline than participants who completed the follow-up (Table 7). There were no other differences in the demographic or clinical characteristics of those who dropped out during follow-up and those who did not (Tables 6 and 7).

Matching Results

Participants were randomized to one of the two intervention conditions using the matching procedure described above. This procedure led to equal distribution of important characteristics between the two groups (see Table 8). Of the 93 intent-to-treat participants, twenty-seven (58.7%) participants who received DBT-BSI and 30 (63.8%) who received RT were male. Twenty-eight (60.9%) DBT-BSI participants and 28 (59.6%) RT participants reported a lifetime suicide attempt. Thirty-six (78.3%) DBT-BSI participants and 39 (83.0%) RT participants reported being interested in receiving mental health treatment at the time of the in-person appointment.

Study Implementation

Recruitment effectiveness. In order to determine what recruitment methods resulted in potential participants contacting the research office, during the phone screening interview callers were asked how they heard about the study. Table 9 summarizes the recruitment methods that were reported. A sizeable majority of screened individuals reported learning about the study via advertisements in local newspapers (70.1-76.4% of participants). Additionally, participants reported learning about the study via community bulletin board flyers (5.1-18.1%), online advertisements (1.7-5.8%), radio advertisements (1.7-3.6%), and other mediums (2.4-3.4%).

Assessment interviews. Phone interviews were conducted by the principal investigator and undergraduate- and bachelors'-level research assistants. All follow-up interviews were conducted by research assistants who were blind to the condition to which the participant had been randomized. The mean duration of the phone screening assessment was 22 minutes (range = 1.5 – 66.5 min). The briefest follow-up interview occurred one-week after the in-person appointment and averaged 26 minutes (range = 15.5-60.5 min). The four-week follow-up interview averaged 52 minutes (range = 24-80.5 min) and the twelve-week interview averaged 57 minutes (range = 23-110 min).

The in-person appointments were conducted by three masters' level therapists. The principal investigator conducted 72 (i.e., 77.4%) of the appointments, while the other two therapists conducted the remaining 22.6%. The mean duration of the assessment portion of the in-person appointment was 27.5 minutes (range = 7-90 min). There were no significant differences in the duration of the assessment portion of the in-person appointment between the three therapists.

Intervention fidelity and feasibility. Two masters'-level therapists were trained in the assessment and intervention procedures by the principal investigator. This training consisted of

reviewing the intervention manual written for each condition, watching videos of appointments for each condition conducted by the principal investigator, recording role-plays of each intervention condition with a research assistant to be reviewed by the principal investigator until sufficient competence was achieved, and attending a weekly supervision/consultation meeting with all study therapists. Additionally, each intervention session conducted by the study therapists was reviewed by the principal investigator and supervision and feedback were provided.

There were no significant differences in the duration of the intervention procedures between the three therapists (M = 47 min, range = 19-98 min). Additionally, there were no significant differences in the outcome measures as a result of the therapist who conducted the in-person appointment.

Sixty-seven participants provided complete feedback during their final follow-up phone interview. Participants in the DBT-BSI condition were significantly more likely to provide feedback (i.e., to complete the final follow-up interview in its entirety) than RT participants (χ^2 (1, N = 93) = 5.05, p = .03). Similar to the open pilot trial, participants reported finding their participation in the study to be helpful and valuable (see Table 10). Specifically, more than 70% of participants reported that they felt better at the end of the in-person appointment than when they came in, while only 4 participants (6%) reported feeling worse. Additionally, most participants (75.8%) rated their experience with their therapist as completely positive and an additional 18.2% rated their experience as mostly positive. More than 90% of participants reported that the in-person appointment was helpful. Interestingly, the only feedback provided that differed between conditions was the extent to which participants found the phone interviews helpful. Participants in the DBT-BSI condition found the phone interviews significantly more

helpful than RT participants (χ^2 (3, N = 65) = 9.46, p = .02), with 75.0% of DBT-BSI participants rating the phone interviews as helpful or somewhat helpful and only 62.1% of RT participants rating the same. This may explain why significantly greater numbers of DBT-BSI participants completed all follow-up interviews.

Feedback from participants whose intervention appointments were conducted by each of the three therapists was also compared to determine whether participants' experiences differed depending on who conducted their appointment (Table 11). There were no significant differences in the feedback provided by participants depending on which therapist conducted their in-person appointment.

Unanticipated problems and adverse events. As previously described, unanticipated problems and adverse events were documented and reported as they occurred. During the course of the study, there were no events that were classified as unanticipated problems. That is, there were no unexpected events that were determined to be related or possibly related to research procedures and that suggested that the procedures were placing participants at greater risk of harm than was previously anticipated. There were 18 adverse events during the study period. That is, there were 18 instances when unfavorable occurrences that were temporally associated with study participation were reported by participants. Six participants attempted suicide and nine participants engaged in NSSI during the three-month follow-up period. This resulted in a total of 18 events by 14 individuals during the follow-up phase. Given the population sampled – namely, suicidal individuals – it is not unexpected that self-injurious behaviors occurred during the study period. Each of these events was documented in quarterly reports to the DSMB and discussed in the bi-annual meetings. When necessary, consultation with the University of Washington HSD was sought to determine whether an adverse event should also be considered

an unanticipated problem. In all cases, the event was determined to not meet the criteria for an unanticipated problem. Additionally, when events occurred, risk assessment and management procedures as outline above were followed.

Longitudinal Outcome Analyses

Confounding factors analyses. Before conducting any longitudinal analyses, confounding factors were explored. Confounding factors, as described above, were determined theoretically (i.e., psychiatric medication, in-person therapist, accepted before or after inclusion criteria change) and based on chi-square analyses of baseline demographic and clinical characteristics. Fifteen participants (8 in the DBT-BSI condition and 7 in the RT condition) reported being prescribed psychiatric medications during the phone screening assessment (Table 12). Chi-square analyses of baseline demographic and clinical characteristics yielded one additional confounding factor: lifetime history of non-suicidal self-injury (Table 5). Thus, confounding factors were explored by including each variable into the outcome model to determine whether it explained a significant portion of the variance.

Psychiatric medication at baseline, in-person therapist, and time of acceptance did not explain significant variance for any outcome measure and, as a result, none of these variables was added into any outcome analyses presented below. There was a trend for psychiatric medication to be a significant predictor for skills taught in the DBT-BSI condition ($p = .07$).

Lifetime history of non-suicidal self-injury (as reported during the in-person assessment) was a significant predictor for suicidal ideation, emotion dysregulation, DBT skills use, use of the skills taught in the intervention, and self-efficacy. It was included in the final model for each of these outcomes.

Suicidal ideation (Tables 13 and 14; Figure 3). HLM analyses revealed a significant main effect of time ($F(1,126.20) = 15.48$, $p < .001$), but neither a significant main effect of condition ($p = .75$) nor an interaction between time and condition ($p = .56$) in predicting suicidal ideation. Both the DBT-BSI and RT slopes were significant (Table 14), suggesting that participants in both conditions experienced a significant reduction in suicidal ideation over the course of the follow-up period; however, there were no differential effects of the condition assignment on this outcome suggesting that the rate of change was not different between conditions. The effect size for the difference between baseline and 12-week follow-up scores of suicidal ideation was large ($d = 1.12$).

Skills use (Tables 13-16; Figures 4 and 5). HLM analyses revealed no significant main effect of time ($p = .31$), yet a significant main effect of condition ($F(1,200.45) = 10.79$, $p = .001$) in predicting use of DBT skills via the DBT skills use subscale of the DBT-WCCL. There was no significant interaction between condition and time ($p = .79$). The slopes for both conditions were non-significant (Table 14). This suggests that participants in each condition had significantly different levels of skills use across all assessment points; however, there were no significant changes in skills use over time. Specifically, participants in the DBT-BSI condition reported higher levels of skills use than RT participants at the in-person and 4-week follow-up assessments, but DBT-BSI participants' skills use was not significantly different than RT participants at the 12-week follow-up. The effect size for this difference between conditions, when pooled across all three assessment points, was small ($d = 0.21$).

Similarly, HLM analyses revealed no significant main effect of time ($p = .71$), yet a significant main effect of condition ($F(1,163.53) = 7.21$, $p = .01$) in predicting use of DBT skills via the subset of 12 items related to skills taught as part of the DBT-BSI. Similar to the previous

analysis, there was no significant interaction between time and condition (p = .76). The slopes for both conditions were also non-significant (Table 14), suggesting that participants in each condition had significantly different levels of use of the skills taught as part of the DBT-BSI. Again, participants in the DBT-BSI condition reported higher levels of skills use than RT participants at the in-person and 4-week follow-up assessments while skills use reported at the 12-week follow-up was not different between conditions. The effect size for this overall difference between conditions, when pooled across all three assessment points was also small at (d = 0.19).

Finally, GEE analyses revealed no significant main effect of time (p = .35), but a significant main effect of condition (Wald χ^2 = 7.59, p = .01) in predicting use of any strategies taught (DBT-BSI or RT) as part of the intervention appointment (Table 15). As with the other analyses of skills use, there was also no significant interaction between time and condition (p = .31). This suggests that participants in each condition had significantly different levels of utilization of the strategies they were taught as part of their intervention appointment, but this difference did not change over time, nor did the rate of strategy use change. Participants in the DBT-BSI condition reported significantly greater use of the strategies they were taught than participants in the RT condition. Participants in the DBT-BSI condition had a 1.5 times greater probability of using skills than RT participants at the one-week follow-up, a 1.2 greater probability at the 4-week follow-up, and a 1.5 times greater probability at the 12-week follow-up (Table 16).

Emotion dysregulation (Tables 13 and 14; Figures 6 and 7). HLM analyses revealed a significant main effect of condition (F(1,191.38) = 5.85, p = .02); however, there was no significant main effect of time (p = .17) and no significant interaction between time and

intervention condition (p = .17) in predicting total emotion regulation difficulties. The RT slope was significant (Table 14), highlighting that once the variability attributable to the lifetime history of NSSI covariate was controlled, the overall change over time in emotion regulation difficulties was no longer significant. That is, the inclusion of the significant covariate in the model eliminated the statistical impact of time in predicting changes in emotion dysregulation for RT participants. In general, participants in the RT condition reported higher total levels of emotion dysregulation than participants in the DBT-BSI. The effect size for this difference between conditions, when pooled across all three assessment points, was small (d = 0.24).

HLM analyses revealed no significant main effect for time (p = .32), condition (p = .11), nor the interaction between the two (p = .57) in predicting use of emotion regulation strategies. Both the DBT-BSI and RT slopes were significant (Table 14), suggesting that participants in both conditions experienced a significant improvement in the use of emotion regulation strategies during the follow-up period; however, the covariate (i.e., lifetime history of NSSI) was included in the model, resulting in the non-significant model fit test statistics. This suggests that baseline differences in the lifetime history of NSSI better explained changes in the outcome than time.

Depression (Tables 14 and 17; Figure 8). HLM analyses revealed a significant main effect of time (F(1,120.92) = 7.68, p = .01) in predicting depression. There was no significant main effect for condition (p = .31), nor was there a significant interaction between time and condition (p = .69). The slopes for both conditions were significant (Table 14), suggesting that regardless of condition assignment, participants showed significant reduction in depression during the follow-up period. The effect size for the difference between the baseline and 12-week follow-up depression scores was medium (d = 0.61).

Anxiety (Tables 14 and 17; Figure 9). HLM analyses revealed a significant main effect of time ($F(1,116.94) = 10.41$, $p < .02$) in predicting anxiety. There was no significant main effect for condition ($p = .31$), nor was there a significant interaction between time and condition ($p = .56$). Not surprisingly, the slopes for both conditions were significant (Table 14), suggesting that all participants experienced a significant reduction in anxiety; however, there were no differential rates of improvement between conditions. The effect size for the difference between the baseline and 12-week follow-up anxiety scores was also medium ($d = 0.59$).

Self-efficacy (Tables 14 and 17; Figure 10). HLM analyses revealed a significant main effect of condition ($F(1,181.26) = 5.52$, $p = .02$) in predicting self-efficacy. There was no significant main effect for time ($p = .38$), nor was there a significant interaction between time and condition ($p = .57$). The slopes for both conditions were not significant (Table 14), suggesting that participants did not experience a change in self-efficacy over time, despite differing levels of self-efficacy between the groups. Participants in the DBT-BSI condition reported higher levels of self-efficacy than participants in the RT condition. The effect size for this difference between conditions, when pooled across all three assessment points, was small ($d = 0.27$).

Treatment utilization (Tables 18 and 19). GEE analyses revealed a significant main effect of time (Wald $\chi^2 = 10.49$, $p = .01$) in predicting participants' contact (either by phone or in-person) with mental health resources during the follow-up period. There was no significant main effect for condition ($p = .25$), nor was there a significant interaction between time and condition ($p = .93$). This suggests that over time, participants were more likely to contact mental health services; however, there were no differences in the rates of contact across conditions. Although the difference was non-significant, participants in the RT condition had a 1.3 times

greater probability of making contact with mental health resources than participants in the DBT-BSI condition during the one-week follow-up period, a 1.2 greater probability during the 4-week follow-up, and a 1.1 greater probability during the 12-week follow-up.

GEE analyses also revealed a significant main effect of time (Wald $\chi^2 = 8.36$, $p = .02$) in predicting participants' appointments with mental health services during the follow-up period. Again, there was neither a significant main effect of condition ($p = .37$) nor a significant interaction between time and condition ($p = .32$). This further suggests that participants increased in their actual appointments with mental health services during the follow-up period, but there were no differences in the rates of contact across conditions. While rates were not significantly different between conditions, participants in the RT condition had a 2.2 times greater probability of attending an appointment with a mental health provider than participants in the DBT-BSI condition during the one-week follow-up period, a 2.9 greater probability during the 4-week follow-up, and a 1.6 greater probability during the 12-week follow-up (Table 18). Specifically, although not significant, overall participants in the RT condition were 1.3 times more likely to begin psychotherapy, while DBT-BSI participants were 1.3 times more likely to begin taking psychiatric medications (Table 19).

Suicidal behavior and non-suicidal self-injury (Table 20). Descriptively, three participants in each condition made suicide attempts, with one participant in the RT condition reporting attempts at both the 4- and 12-week follow-up assessments. Nine participants (9.7% of the total sample intent-to-treat) engaged in NSSI during the follow-up period, including five participants in the DBT-BSI condition and four participants in the RT condition. A total of 14 (15.1% of the total intent-to-treat sample) participants engaged in suicidal and/or non-suicidal self-injurious behavior during the three months of follow-up (7 DBT-BSI participants, 7 RT

participants). There was no difference between conditions in the number of participants who engaged in suicidal and/or non-suicidal self-injury (χ^2 (1, N = 142) = 0.99, p = .42). Although the difference was not significant, RT participants had a 2.4 times greater probability of engaging in self-injurious behavior between the four- and twelve-week follow-up interviews relative to DBT-BSI participants.

GEE analyses revealed no significant main effect for time (p = .13) or for condition (p = .43) in predicting self-injurious behavior. There was also no significant interaction between time and condition (p = .18). This suggests that there was neither a difference between conditions nor across time in the occurrence of suicidal or non-suicidal self-injurious behaviors. This is not surprising given the less than adequate power to detect differences in suicidal behavior.

Gender and older age as predictors of outcome. Owing to the commonly low rates of treatment-seeking and engagement in mental health treatment in male and older adult samples (i.e., adults 55 years and older; Lee, Lin, Liu, & Lin, 2008; Luoma, Martin, & Peterson, 2002) yet the relatively high proportion of these groups within the study sample, these two variables were evaluated as predictors of the longitudinal outcome variables to determine whether there were differential effects based on gender or age. Neither of these variables was a significant predictor when included in the model in place of condition assignment. That is, there were no differential changes in any of the longitudinal outcome analyses between genders (male, female, transgender), nor were there differential changes between age groups (younger than 55 years old, 55 years and older).

Summary of longitudinal outcomes. Suicidal ideation, depression, and anxiety all improved significantly over the course of the three-month follow-up period. While each condition exhibited significantly different levels of skills use, emotion dysregulation, and self-

efficacy, these domains did not change over time. Across conditions, participants' contact with mental health services over the follow-up period significantly increased. Finally, the frequency of suicidal and non-suicidal self-injurious behavior was not different across conditions.

Clinical Significant Analyses

Clinical significance analyses were conducted on outcomes where moving from a "clinical" to a "non-clinical" distribution was meaningful. Thus, analyses were conducted for the SSI, DERS, DBT-WCCL, PHQ-9, and BAI. For each of these outcomes, reliable changes were assessed at each follow-up time point when the measure was administered (i.e., one-, four-, and twelve-weeks for SSI, PHQ, and BASI; four- and twelve-weeks for DERS and DBT-WCCL). Analyses were conducted using all available data from participants (i.e., those who completed each assessment at each assessment time point) and a Mann-Whitney *U* nonparametric test was used to assess significant differences in classification between conditions at each time point. Table 21 shows the classification results for each outcome by condition at each assessment period.

In order to classify individuals as deteriorated or unchanged, improved, or recovered, a cutoff and an RCI computation procedure were established before analyses were conducted. When established cutoffs and reliable change indices were not found for an outcome measure, the indices were manually computed as described below.

Reliable change in suicidal ideation. The SSI is a well-used measure of suicidal ideation; however, no norms currently exist for this measure. Owing to the fact that clinical and non-clinical samples have been evaluated with the SSI, the third method for determining a cutoff was used (Jacobson & Truax, 1991). For a cutoff *c*, three published studies which present both clinical and non-clinical sample mean and standard deviation scores were consulted (Beck,

Brown, & Steer, 1997; Chioqueta & Stiles, 2006; Zhang & Brown, 2007). The non-clinical mean in these three samples ranged from 0.16 to 4.84 (SD range 0.78-5.02) resulting in a true non-clinical mean of 0.62 (*SD* = 2.06). The clinical sample means in these three studies ranged from 9.96 to 11.46 (SD range = 5.18-9.5), yielding a true clinical mean of 10.84 (*SD* = 7.83). The resulting weighted mean which was used as the cutoff for clinically significant change was 2.76.

To compute the reliable change index (RCI), test-retest reliability from the original psychometric publication (Beck, Brown, & Steer, 1997) was used. The published test-retest reliability for the SSI was $r = 0.74$, $p < .05$. This reliability index, as well as the standard deviation on the SSI at baseline (*SD* = 5.31), were used to compute an RCI for each individual. If the person scored below 2.76 and had an RCI greater than 1.96, they were classified as recovered. If the RCI was above 1.96, but the person scored above 2.76, the subject was classified as improved. If neither criterion was met, the subject was classified as unchanged or deteriorated.

At the one-week follow-up, 17.6% of participants in the DBT-BSI condition and 21.6% of RT participants were classified as recovered. These rates increased for both conditions (35.9% vs. 40.0%) by the twelve-week follow-up interview. At this final follow-up interview, approximately 50% of participants in each condition had either improved or recovered. Nonparametric tests indicated no significant difference in classification between conditions at any of the follow-up time points, $U_{1\text{-}week} = 622.50$ ($p = .93$), $U_{4\text{-}week} = 544.50$ ($p = .36$), $U_{12\text{-}week} = 550.50$ ($p = .64$).

Reliable change in emotion dysregulation. The DERS is a well-established measure of emotion dysregulation; however, no norms currently exist for this measure. Because the normal

and clinical distributions for this measure are likely to overlap and because data for computing a non-clinical norm can be found, the third method to establish a cutoff was employed (Jacobson & Truax, 1991). As in the case of the SSI, the mean and standard deviation for a non-clinical and clinical sample were needed. Five studies used the DERS with non-clinical participants (Fox, Axelrod, Paliwal, Sleeper, & Sinha, 2007; Gratz & Roemer, 2004; Harrison, Sullivan, Tchanturia, & Treasure, 2009; Salters-Pedneault, Roemer, Tull, Rucker, & Mennin, 2006; Whiteside, Chen, Neighbors, Hunter, Lo, & Larimer, 2007). Means ranged from 60.90 to 78.88 (*SD* range = 14.46-22.00), resulting in a true non-clinical mean of 77.82 (*SD* = 19.75). To calculate a true clinical mean, five studies were combined (Cohn, Jakupcak, Seibert, Hildebrandt, & Zeichner, 2010, Fox et al., 2007; Harrison, Sullivan, Tchanturia, & Treasure, 2009; Salters-Pedneault et al., 2006; Whiteside et al., 2007), resulting in a mean of 81.83 (*SD* = 29.86). Thus, cutoff *c* for the DERS was established to be 79.42.

The RCI was computed using the published test-retest reliability ($r = 0.88$, $p < .05$; Gratz & Roemer, 2004) and the present study's baseline standard deviation (*SD* = 22.69). If the subject scored below 79.42 and had an RCI greater than 1.96, they were classified as recovered. If the RCI was above 1.96, but the subject scored above 79.42, they were classified as improved. If neither criterion was met, the subject was classified as unchanged or deteriorated.

Table 21 shows that 13.9% of participants in the DBT-BSI condition and 10.3% of participants in the RT condition were classified recovered at the four-week follow-up interview. By contrast, 10.3% of DBT-BSI participants and 12.5% of RT participants were classified as such at the twelve-week follow-up interview. At the twelve-week follow-up interview, approximately 80% of participants across both conditions remained unchanged or deteriorated. Nonparametric tests indicated no significant difference in classification between conditions at

either the four- or twelve-week follow-up interviews, $U = 655.00$ ($p = .46$) and $U = 585.50$ ($p = .51$), respectively.

Reliable change in skills use. In the case of the DBT-WCCL skills sub-scale, no cutoff or RCI norms exist. In addition, there is not enough data published on the measure to empirically determine means and standard deviations for clinical and non-clinical samples. Therefore, cutoff *a*, as described by Jacobson and Truax (1991) was computed. The baseline mean for the study sample ($M = 1.85$, $SD = 0.48$) was chosen to be the mean representing a clinical distribution. The cutoff was established to be two standard deviations above the mean, assuming that clinical samples use fewer skills than non-clinical samples. Thus, cutoff *a* for the DBT-WCCL was computed to be 2.81. For RCI computations, the test-retest reliability coefficient presented in the original validation study ($r = 0.71$, $p < .05$; Neacsiu et al., 2010) and the baseline standard deviation ($SD = 0.48$) were used. As the subset of items included in the analyses for skills taught as part of the intervention were aggregated for this study, this study-specific subscale was not evaluated for reliable change.

As reported in Table 15, rates of improvement and recovery on skills use were very small. At the four-week follow-up, 4.3% of DBT-BSI participants and 5.6% of RT participants were classified as recovered (i.e., improved by two standard deviations from baseline). These rates were slightly improved at the twelve-week follow-up with 7.9% of DBT-BSI participants and 10.0% of RT participants recovered. However, nonparametric tests indicated no significant difference in classification between participants at either the four- or twelve-week assessments, $U = 629.00$ ($p = .98$) and $U = 558.00$ ($p = .76$), respectively.

Reliable change in depression. For the PHQ-9, the test-retest reliability indicated in the original validation study ($\rho = 0.84$, $p < .05$; Kroenke, Spitzer, & Williams, 2001) and the baseline

standard deviation from this sample (*SD* = 5.91) were used for the RCI index. Based on the literature, a cutoff score *c* between a non-clinical sample (*M* = 3.3; *SD* = 3.8; Kroenke, Spitzer, & Williams, 2001) and a depressed sample (*M* = 17.3, *SD* = 5.0; McMillan, Gilbody, & Richards, 2010) was computed to be 9.34.

At the one-week follow-up, 17.1% of DBT-BSI participants and 12.8% of RT participants were classified as recovered with an additional 4.9% and 15.4% in each condition classified as improved. As reported in Table 21, by the twelve-week follow-up, 15.4% of DBT-BSI participants remained recovered while 22.6% of RT participants were classified as such. Nonparametric tests indicated a trend for significance or a significant difference in classification between conditions at the four-week follow-up ($U = 555.00$, $p = .07$), but no significant difference for the one- or twelve-week follow-up interviews ($U = 765.50$, $p = .67$ and $U = 547.50$, $p = .39$, respectively).

Reliable change in anxiety. The original psychometric analysis of the BAI presents a cutoff score of 9 for non-clinical samples (Beck & Steer, 1990). For the RCI index, the one-week test-retest reliability coefficient presented in the original analyses ($r = 0.75$, $p < .05$) and the baseline standard deviation of the study sample (SD = 9.81) were used.

Similar to other outcomes, small rates of recovery were small for each condition at each assessment point (Table 21). Only 9.8% of DBT-BSI participants and 15.4% of RT participants were classified as recovered at the one-week follow-up and at the twelve-week follow-up, 7.7% of DBT-BSI participants and 16.1% of RT participants were classified as such. Nonparametric tests revealed no significant differences in classification between conditions at the one-week, four-week, or twelve-week follow-up interviews ($U = 767.00$, $p = .65$; $U = 666.00$, $p = .73$; and $U = 561.50$, $p = .42$, respectively).

Discussion

The present study examined two brief, one-time interventions for suicidal individuals not already engaged in mental health treatment. This randomized controlled trial comparing five DBT skills to a supportive, relaxation training control condition sought to examine the safety of the intervention with respect to potential adverse events, to assess the feasibility of the methodology, and to estimate the degree of change and variability of response to the DBT-BSI relative to the RT condition. The hypotheses predicted that participants who received the DBT-BSI would show more improvement than participants who received the RT. However, there was no evidence of differential rates of change across conditions over the follow-up period. Several other important findings emerged.

Main Findings

Suicidal ideation, depression severity, and anxiety severity all significantly improved during the three month period following the one-time intervention appointment. Specifically, suicidal ideation decreased more than nine points from the time of the phone screening (M = 19.21, SD = 5.34) to the twelve-week follow-up interview (M = 9.69, SD = 8.92), resulting in a final mean that is below the inclusion criterion cutoff score of 10. Although there were no significant differences in the rate of change between conditions, this sizeable mean decrease in suicidal ideation over time is noteworthy. The stability of suicidal ideation over time has been implicitly assumed, yet rarely studied (e.g., Russ et al., 1999; Witte et al., 2006). However, the large effect size for the change in suicidal ideation over time, the proportion of participants who fell into the recovered or improved range during follow-up, and the simultaneous decreases in depression and anxiety suggest that these findings should not be dismissed, but instead warrant further investigation of the impact of brief interventions on these domains.

Unlike the results of the open pilot trial (Ward-Ciesielski, 2013), skills use did not appreciably change over time. While DBT-BSI participants were significantly more likely to report using the skills that they were taught during the intervention, this did not translate into an overall effect of skills use over time. Furthermore, emotion dysregulation did not change over time, contrary to what DBT's underlying theory that emotion dysregulation results in maladaptive coping would predict. This suggests two hypotheses: 1) the intervention conditions were too similar and 2) using DBT skills is not the mechanism of action through which suicidal ideation, depression, and anxiety decreased in this study.

The first hypothesis is that the two intervention conditions were similar enough that the study was underpowered to detect differences between them. Although DBT-BSI participants were significantly more likely to use the skills they were taught, nearly two-thirds of RT participants also continued to use the relaxation activity they practiced. Instead of observing differential effects for participants in each condition based on different content covered in each intervention, perhaps teaching at least one strategy during a one-time contact is an active ingredient in both interventions and the specific strategies are less critical in such a brief format. While the RT intervention was meant to control for non-specific factors such as time engaged in research activities and attention from a therapist, it was instead an active comparison condition. This would mean that a much larger sample size would be necessary to detect differences between the two active interventions and that the present study may have been vulnerable to a type II error in which it was falsely concluded that there were no differences across interventions (Freedland, Mohr, Davidson, & Schwartz, 2011; Mohr et al., 2009).

Alternatively, while the interventions provided in the present study were sufficient to produce short-term change on a limited number of domains, long-term change may require more

(i.e., longer) intervention. It is also possible that the mechanisms through which the observed changes were enacted were not directly measured via the outcome domains described.

Potential mechanisms of change. There are many factors or mechanisms of action that may account for the pattern of results observed in this study. Four important potential mechanisms that should be investigated further in subsequent research projects are: 1) a validating, supportive, and nonjudgmental environment, 2) practicing new behavioral skills, 3) improved problem-solving ability, and 4) improved cognitive flexibility.

Validation and a non-judgmental stance. The first of the potential mechanisms relates to participants' experience of being heard, understood, supported, and not judged. Participants disclosed suicidal thoughts by simply calling to learn more information about the study. By interacting with a research staff that was compassionate, non-judgmental, and patient, it is possible that these individuals became more comfortable acknowledging their ideation, disclosing the areas in which they are struggling, and asking for help to deal with difficulties as they are encountered.

The importance of a nonjudgmental stance and the impact of a matter-of-fact style of discussing suicidal behaviors is not a new idea. In fact, reviews of common practices for crisis intervention providers (e.g., Leenaars, 1994; Thomas & Leitner, 2005) and guidelines published by the American Association of Suicidology (2014) explicitly highlight the importance of not judging an individual who discloses suicidality, but instead engaging in an up-front conversation. Furthermore, in his review of common factors involved in treatments for suicidal individuals, Weinberg and colleagues (2010) identified supportive interventions as one commonality involved in several effective interventions. A positive experience with the mental health field – characterized by validation, education, and support (Weinberg, Ronningstam, Goldblatt,

Schechter, Wheelis, & Maltsberger, 2010) – could explain why the patterns of change are not different between conditions. These elements of their experience were commonly reported by many participants, regardless of their condition. It may be valuable to experimentally manipulate this positive experience such that participants receive the DBT-BSI (for example) with the exclusion of validation to assess whether this component is critical for changes. Additionally, it may be possible to determine whether the face-to-face support is most important by incorporating an assessment-only control condition. This design would also permit evaluating whether repeated assessment with the same instruments accounts for any sizeable proportion of the changes in outcome over time.

Practicing behavioral skills. Given that participants in the DBT-BSI condition were significantly more likely to use the strategies they were taught, this may be an important element explaining the potential effect on suicidal behaviors. The role of practicing new skills has been incorporated into treatment development efforts in suicidology previously. For example, Brown and colleagues (2005) provided a ten-session cognitive therapy intervention wherein they used cognitive and behavioral strategies (e.g., identifying and challenging thoughts and beliefs) to reduce suicidal behaviors. At the end of treatment, participants underwent "suicidality priming" in which the specific thoughts and feelings they experienced prior to their most recent suicide attempt were primed and they were then instructed to respond to a problem in a skillful way. Success at this task was a criterion for treatment termination. This rests on the theory that being able to practice new behaviors in situations in which suicidal behaviors may occur is a critical component toward changing the course of these behaviors. In the present study, participants in the DBT-BSI condition were encouraged to practice the strategies and specific applications of each strategy were discussed. This may have facilitated increased practice after the appointment.

Additionally, the majority of participants in the RT condition practiced the relaxation exercise during the follow-up period. The practice of a new effective strategy, regardless of the specific type of strategy, may be most important for change in suicidal ideation, depression, and anxiety.

Improved problem-solving. While problem-solving skills, per se, were not taught in the intervention, presenting multiple strategies and including points related to the most appropriate time to use each one may have provided participants with a strategy for solving emotional problems in which they could determine which strategy was best suited for their particular situation. Problem-solving deficits are well-documented in suicidal populations (e.g., Pollock & Williams, 1998; Sadowski & Kelley, 1993; Schotte & Clum, 1987; Schotte, Cools, & Payvar, 1990) and attempts have been made to address these deficits via targeted intervention with minimal success (e.g., Fitzpatrick, 2005; Lerner & Clum, 1990). While these interventions targeting problem-solving take a very pragmatic approach by teaching individuals the steps in effective problem-solving, the results of the present study suggest that more indirect targeting may be effective. In fact, teaching multiple strategies from which an individual can select for their given circumstances may result in improved problem-solving capability which may then positively impact levels of suicidal ideation and depression. This association and the temporal sequence of changes on each domain warrants further investigation.

Cognitive flexibility. Cognitive constriction or inflexibility has commonly been cited as a characteristic cognitive style in suicidal individuals (e.g., Patsiokas, Clum, & Luscomb, 1979; Miranda, Gallagher, Bauchner, Vaysman, & Marroquín, 2012). This population has replicated difficulty thinking outside of the immediate "tunnel vision" which leads them to suicide because it appears to be the only option (e.g., Schotte & Clum, 1987; Sheehy & O'Connor, 2002). As DBT-BSI participants were given multiple strategies resulting in more than one way of dealing

with an emotional experience or problem, perhaps the intervention addresses this constriction and begins to facilitate cognitive flexibility and expansion. Furthermore, RT participants were engaged in a conversation about the ways they cope with stressors, which may have similarly primed them to think about a list of coping strategies that could be used instead of engaging in suicidal or self-injurious behaviors.

Summary. These potential mechanisms represent important areas for further study. While it is unlikely that one study would be able to address them all, subsequent endeavors can follow up on these hypotheses in the service of further expanding our understanding of the reasons for the documented effectiveness of DBT in other trials, the results of the present trial, and the similarities and differences across applications. Furthermore, these mechanisms should be investigated across multiple populations to continue to elucidate the qualitative and quantitative differences between those who seek treatment and those who do not as it is not yet known whether this characteristic moderates intervention effects.

Secondary Findings

Encouragingly, more than one-third of all participants began psychotherapy or received prescription medications during the three-month follow-up period. In fact, nearly 10% of participants began psychotherapy by the one-week assessment. This suggests an additional benefit of the interventions with a non-treatment engaged population. Although there were no differences in the outcomes of individuals who began treatment during the follow-up period at the final assessment, the impact of the structure or format of the intervention appointments may have been important. As previously discussed, the matter-of-fact and non-judgmental discussion of past and current suicidal ideation and behaviors, and providing an experience that participants find positive and valuable may be as important, if not more important than, the remaining

content of the session. Further evidence for this hypothesis can be found in the consistently higher rates of contact with mental health services in the RT participants who engaged in more of an open-ended discussion of their stressors. Perhaps the mechanism for facilitating mental health contact is different than the one driving changes in other outcome domains.

Additionally, all participants were provided with an individualized list of mental health referrals prior to leaving their in-person appointment. Another important element of the intervention (and a similarity across both conditions) may be this tailored referral list, which is similar to a common component in several effective interventions to increase treatment engagement (e.g., Seal et al., 2012; Stecker, Fortney, & Sherbourne, 2011).

In addition to increases in treatment-seeking behavior during the follow-up, the occurrence of self-injurious behaviors was not altogether unexpected owing to the fact that nearly 40% of participants had attempted suicide in the year prior to their in-person appointment, and more than half of participants reported a lifetime history of NSSI. Although significant differences were not expected owing to the low base rate of suicidal behavior relative to the sample size obtained, the occurrence of these behaviors during a briefer follow-up period suggest the generalizability of this sample to other published RCTs. Furthermore, RT participants were more than two times more likely to engage in self-injurious behavior than DBT-BSI participants between the four-and twelve-week follow-up interviews. Even though this difference was not statistically significant, the relative risk of self-injurious behavior within a relatively small sample size suggests that with a larger sample, such a difference may have favored the DBT-BSI.

Such a difference in a larger sample would lend new and unique support to DBT's empirical base. Previously, relatively lengthy DBT applications (i.e., six months to one year)

have consistently shown reductions in self-injurious behavior (e.g., Koons et al., 2001; Linehan et al., 2006; Stanley, Brodsky, Nelson, & Dulit, 2007). However, no DBT application to date has utilized such a brief format. This would suggest that the mechanism by which DBT is so effective at reducing suicidal behaviors is active in a one-session format. The most prominent mechanisms proposed to drive DBT's effectiveness are emotion regulation and behavioral skills. While the lack of significant changes in either of these domains over the follow-up period suggests that they were not impacted by the DBT skills-based intervention, the aforementioned mechanisms could explain the consistent pattern of results related to suicidal behaviors despite the failure to produce changes in emotion regulation or skills.

Safety, Feasibility, & Acceptability

At the start of the present study, recruitment efforts were not yielding consistent new, interested potential participants and those interested individuals were commonly ineligible for the study. Two strategies were employed to address this issue. First, the inclusion criteria were modified so that rather than needing to be without any mental health treatment for one year prior to acceptance, participants instead only needed to be without treatment for one month prior to acceptance. Second, additional funding was sought and recruitment efforts were expanded to cover a wider range of mediums which may be encountered by the target population. Ultimately, the enrollment period was extended beyond what was initially projected and fewer participants were enrolled than originally proposed. This reduced sample resulted in several important findings related to the successful recruitment and enrollment of a non-treatment engaged suicidal sample. Namely, posting flyers in Alcoholics Anonymous and Narcotics Anonymous meeting halls and other churches as well as posting newspaper advertisements in "paid research" sections were much more effective at reaching the target sample. Additionally, alternating newspapers in

which advertisements were posted on a weekly or monthly basis and ordering ads for several weeks at a time allowed for infrequent readers or individuals who do not read the classified ads on a regular basis an opportunity to encounter the listing.

Overall, despite the difficulties outlined above, it was possible to recruit, enroll, and retain suicidal participants who were not already engaged in mental health treatment. Newspaper advertisements were the most effective advertising method and yielded a sizeable influx of new interested callers. These interested callers were also well-suited to the aims of the study and the target population we were trying to reach. For example, approximately 10% of participants had never received any mental health treatment in their lifetime, yet they were willing to participate in a research study where they would have an in-person meeting with a therapist. The payment amount was relatively insubstantial, especially for the in-person appointment (i.e., $5), suggesting that compensation was unlikely to be the primary driving force behind participation. Additionally, among the nearly 60% of participants who had received mental health treatment at some point in their lives, but not in the year prior to their enrollment, the average time since their most recent treatment was 3.71 years. Thus, even when individuals have not been in contact with services in years, they are accessible when options for self-referral are made available. This further underscores the importance of moving away from exclusively requiring individuals to enroll in research trials or in clinical services via clinical referrals from their current providers. Furthermore, the study sample consisted of 55 (59.1%) men and 20 (21.5%) individuals aged 55 or older. In total, 14 (15.1% of the total sample) of the male participants were 55 years or older. The reduced rates of mental health contact in these demographic areas (e.g., Peterson, Luoma, & Pearson, 2002) suggest that the recruitment methods employed are useful to engage previously unreached individuals.

Additionally, it was possible to develop intervention manuals and train two masters'-level therapists in the intervention procedures for each condition. While developing a training protocol and training the first therapist took longer than anticipated, resulting in a lower proportion of sessions being conducted by someone other than the principal investigator, the fact that neither the outcomes nor the feedback obtained from participants were different between therapists suggests that these interventions are transportable.

Further of note is the fact that no study-related unanticipated problems occurred during the course of the trial. Although suicidal and self-injurious behavior occurred during the follow-up period, these events were determined not to be the result of study procedures. Additionally, such behaviors were not unexpected given the target population of suicidal individuals. Thus, it was possible to safely implement the research methods without harming participants.

Study Limitations and Strengths

Limitations. There are several limitations that warrant discussion. As has been noted previously, one explanation for the lack of differences in outcomes between conditions may be the similarity of the two conditions. While efforts were made in the study design to differentiate the conditions so that significant overlap would not confound the results, presenting at least one strategy in each condition may have undermined this intention. In the RT condition, the relaxation practice was designed to be a quick demonstration of the effect of stress on suicidal ideation. However, in such a brief format, it is likely that this practice and rationale were conceptualized by participants as a strategy to practice. This comparison condition may have been more powerfully evaluated via a study with a much larger sample size. Additionally, asking participants during follow-up interviews if they had used the relaxation strategy may have given the suggestion that they were expected to practice it after the intervention appointment.

Relatedly, all three therapists conducted both types of intervention appointments. While this was intended to consolidate resources and more accurately model non-research environments where the interventions may be implemented (e.g., primary care, emergency department, outpatient practice), there may have been a stylistic overlap between the conditions. Research is as yet lacking on the effect of stylistic strategies in DBT on patient outcomes; however, the rationale provided in the treatment manual (Linehan, 1993a) suggests that irreverent and reciprocal communication are critical elements of the treatment and are meant to facilitate movement as well as communicate acceptance. It is reasonable to hypothesize that having prior experience providing DBT (which was the case for all three therapists) may have resulted in an overlap in the therapists' communication style (i.e., in a more irreverent and reciprocal communication style in the RT condition than would have occurred if the therapists were not trained in DBT). Given that fidelity to the intervention procedures was not evaluated in either condition owing to the stage of treatment development, this possibility cannot be ruled out. The extent to which stylistic strategies impact outcome warrants further investigation and future evaluations of these type of brief interventions should include fidelity assessment.

Another limitation is the repeated assessment using identical assessment instruments over time. It is possible that participants' responded to questions differently because 1) they were familiar with the questions in later time points or 2) the repeated inquiry led to an increased awareness of problem areas and personal strengths. Becoming familiar with the assessment, or practice effects, is important to consider across all research fields in which repeated measures designs are employed. Researchers have found that participants perform better after repetition (e.g., Donovan & Radosevich, 1999) and, in the case of the present study participants may have ascertained what the researchers were looking for as they completed the assessments multiple

times. If not practice effects, than it is possible that the assessments themselves had a therapeutic benefit. Perhaps the process of answering the assessment questions increased participants' awareness of issues they were avoiding or, conversely, reminded them of problems they were working on improving. Either way, the effects of the assessments themselves and the extent to which they may explain the results obtained is unknown.

Another limitation is the loss of participants to attrition during follow-up. While 18 participants did not complete the follow-up interviews because they refused to schedule or scheduling could not be arranged, six participants were entirely unreachable. Every effort was made to establish contact; however, it is possible that these participants were incarcerated, died by suicide, or were lost for reasons relevant to the aforementioned outcomes of interest. This is an important factor in interpreting the results of the current study.

Finally, the final sample size was smaller than expected. To reliably detect medium differences between conditions, an additional 36 participants were required to complete the final follow-up interview. In an attempt to correct slower-than-anticipated enrollment, inclusion criteria were changed and recruitment efforts were expanded. These efforts did yield improved enrollment; however, the most robust sample size was not achieved. Thus, while no differential rates of change between conditions were observed, this may be the result of an inadequate sample size to detect medium and smaller differences.

Strengths. Despite these weaknesses, the present study also boasts many important strengths. First, individuals who are not engaged with mental health treatment yet are struggling with suicidal thoughts and urges represent a vastly underserved and understudied population (e.g., Lizardi & Stanley, 2010). This study is one of a very few to specifically target those who are not engaged in treatment, and it is the only study to date geared toward those who are also

suicidal. The decreases in suicidal ideation, depression, and anxiety following the one-session intervention appointments present an important step toward reaching out to this population, understanding the factors preventing engagement with available services, and learning what interventions are helpful and valuable for them. Furthermore, the success in recruiting and enrolling a sizeable number of males and individuals 55 and older suggest that the recruitment strategies employed (most notably, not requiring a clinical referral) have begun to create a path toward these high-risk, underserved individuals.

Utilizing the extant literature on improving treatment seeking and engagement reviewed previously, the present study shares a number of commonalities with effective interventions targeting these issues. Specifically, a tailored referral list (e.g., Seal et al., 2012), telephone contact to increase motivation (e.g., Stecker, Fortney, & Sherbourne, 2011), and a very limited number of sessions to address engagement difficulties (e.g., Smelson et al., 2012) were all included to some extent in the present study; however none was experimentally manipulated. Controlling each of these factors in future studies would help to elucidate the role that they play in both symptom improvement and treatment engagement in this non-treatment engaged suicidal population.

Additionally, the retention rate between enrollment and the twelve-week follow-up assessment was 75%. The sample recruited and enrolled in the present study was willing to follow up on relatively low-cost advertisements (e.g., flyers posted around the community, inexpensive newspaper advertising) and continue completing follow-up interviews via phone three months after the one-time in-person contact. Furthermore, the majority of participants rated the intervention appointment favorably and more than half of participants reported that they found the phone interviews to be helpful. Thus, a significant strength of the present study and its

methodology is the acceptability to a historically difficult to reach and retain population and the value that participants experienced by participating.

The RCT methodology is a further strength of the study. Utilizing multiple repeated measures (thereby expanding upon the pre-post assessment of the open pilot trial) allowed the analysis of change over time, as well as investigation into whether gains were maintained beyond any immediate reductions that might be more temporary. Additionally, two additional therapists were trained and delivered the intervention procedures to enhance the generalizability of the findings.

Future Directions

The most important extension of this work is a continued focus on underserved subsets of suicidal individuals. This study is only the beginning of a line of research aimed at a more complete understanding of the factors that contribute to low rates of treatment engagement and the ways in which intervention can overcome these barriers. Future studies would benefit by having additional assessments to determine the factors that impact suicidal individuals' decisions to seek mental health treatment or avoid it. This would allow investigation into the extent to which those who seek treatment are the same or different than those who volunteer for research studies and those who neither seek treatment nor volunteer for research. It would also allow for an assessment of the way that a brief intervention, like the DBT-BSI or the RT, impacts these factors and the ways that such interventions can be modified or enhanced to more adequately address important barriers. For instance, if an individual identifies financial barriers to seeking and engaging in treatment, additional emphasis while creating a list of relevant referrals may be placed on identifying options for low- or no-fee services or organizations designed to assist with treatment costs. Ideally, such an emphasis would also involve encouragement to learn about

available options and support to find the best treatment option as well as information about how to choose a therapist or a treatment. It may also involve developing a working relationship between research teams and local mental health resources to facilitate the process of connecting individuals with services.

Future research should also incorporate larger sample sizes and a more evenly distributed proportion of cases seen by each therapist. While efforts were made to increase the number of participants each additional therapist saw, logistic constraints related to relying on volunteer availability made this difficult to put into practice. Having multiple offices where appointments could be held simultaneously and having wide availability – including evenings and weekends – may also extend the capability to manage a larger sample size.

Additional design considerations may be valuable to investigate empirically. For instance, future research may evaluate these interventions in real-world settings in which providers have relatively brief contact with patients (e.g., primary care, emergency department). Additionally, perhaps participants would have benefited more from a second intervention session where they could either review the skills they were taught and ask questions (in the DBT-BSI) or further discuss difficulties and receive support (in the RT). This may have resulted in more robust changes in the DBT-BSI condition, although we would not expect there to be much added benefit on outcomes related to skills use or emotion regulation in the RT condition. Another change might be the length of the intervention session. In the present study, every attempt was made to ensure that the appointment was kept brief and focused. However, it is possible that adding more time to the appointment would be beneficial and result in more robust gains that could be maintained over a longer period of time.

There are also design modifications that could address some potential explanations of the results obtained in the present study that have been mentioned above. First, the potential overlap in the two intervention conditions could be minimized in future studies in multiple ways. For instance, the relaxation practice could be removed from the control condition and instead focus exclusively on supportive therapy techniques of validation, reflective listening, and encouragement and support. This would remove the potentially confounding effect of discussing a strategy and would maintain the uniqueness of skills training within the DBT-BSI. Another possible method to address the similarity of the interventions is to include multiple control conditions to pinpoint the mechanism of action behind reductions in suicidal ideation, depression, and anxiety. For example, if teaching *any* strategy, regardless of its theoretical relation to suicidality, is the mechanism through which change occurs, a condition which focuses exclusively on a skill that is likely to be unrelated (or only minimally related) to suicidality could be included. Such a condition might involve time management strategies or social rhythm psychoeducation.

A second way to evaluate the results obtained from the present study would be to address whether the significant reductions in suicidal ideation, depression, and anxiety—despite the absence of change in skills use and emotion regulation—would be to evaluate whether this pattern can be better understood as regression to the mean. This may involve incorporating a waitlist control condition wherein participants are randomly assigned to receive the DBT-BSI or to be entered on a waitlist. As an example, participants randomized to the waitlist condition might then receive the experimental condition after a period of three months to determine whether changes in the outcomes of interest would have been likely to naturally occur, even without intervention.

Summary and Conclusions

The present study continues a line of research aimed at developing and evaluating interventions for suicidal individuals who are not engaged with mental health services. The success in recruiting and retaining these individuals via relatively inexpensive and easily implemented means provide evidence for the potential to access and understand this underserved population. The findings of significant reductions in suicidal ideation, depression, and anxiety resulting from a one-time intervention appointment underscore the promise awaiting continued treatment development in this area. This study has, in many ways, laid the groundwork upon which future researchers can continue to expand our ability to engage and help these previously ignored individuals.

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Table 1

Study Eligibility Criteria

Inclusion Criteria:
1. 18 years or older
2. Current suicidal ideation (i.e., scoring 10 or higher on Scale for Suicidal Ideation; Beck et al., 1979)
3. Not currently receiving mental health treatment
4. No mental health treatment in the previous month
5. Consents to recording and assessment
Exclusion Criteria:
1. Cognitive impairment (i.e., scoring 8 or higher on 6-Item Cognitive Impairment Test; Katzman et al., 1983)
2. Living outside commuting distance to the University of Washington
3. Non-English-speaking

Table 2

Assessments and Assessment Schedule

	Assessment Instrument	Phone Screening	In-Person Assessment	1-Week Follow-Up	4-Week Follow-Up	12-Week Follow-Up
1.	6-Item Cognitive Impairment Test (6CIT)	X				
2.	Demographic Data Schedule (DDS)	X				
3.	Scale for Suicidal Ideation (SSI)	X		X	X	X
4.	Treatment History Interview (THI)	X	X	X	X	X
5.	Patient Health Questionnaire (PHQ)		X	X	X	X
6.	Beck Anxiety Inventory (BAI)		X	X	X	X
7.	Difficulties in Emotion Regulation Scale (DERS)		X		X	X
8.	Suicidal Behaviors Questionnaire (SBQ)		X		X	X
9.	Lifetime Parasuicide Count (LPC)		X		X	X
10.	General Self-Efficacy Scale (GSES)		X		X	X
11.	DBT Ways of Coping Checklist (DBT-WCCL)		X		X	X
12.	Referral Follow-Up Questionnaire (RFQ)			X	X	X
13.	Skills Used Since Intervention (SUSI)			X	X	X
14.	Subject Feedback Questionnaire (SFQ)					X
15.	University of Washington Risk Assessment Protocol (UWRAP)	X	X	X	X	X
16.	University of Washington Risk Assessment and Management Protocol (UWRAMP)	X	X	X	X	X

Table 3

Participant Demographics at Baseline of All Invited Participants (n=129)

	Intent-to-Treat (*n*=93)			No Show/Drop Out (*n*=36)				
	%	M	SD	%	M	SD	χ^2	*p*
Age		40.2	15.2		43.9	16.5	1.16[a]	0.25
Gender[1]							3.75	0.11
Male	59.1			41.7				
Female	36.6			55.6				
Transgender	4.3			2.8				
Ethnicity[1]							9.69	0.05*
Caucasian	84.1			72.7				
American Indian	2.3			3.0				
African American	9.1			9.1				
Asian	1.1			15.1				
Other	3.4			0				
Highest education[1]							7.12	0.63
Less than high school	5.6			9.1				
High school or equivalent	14.5			27.3				
Some college	41.1			39.4				
Bachelors' degree	20.0			15.2				
Beyond bachelors' degree	12.2			3.0				
Annual income[1]							6.58	0.46
< $10,000	42.1			59.4				
$10,000-24,999	38.6			28.2				
$25,000-50,000	15.9			9.4				
> $50,000	3.4			3.1				
Homeless (% lifetime)	53.8			66.7			1.63	0.20
Before age 11	2.0			4.5				
Age 11-17	30.6			31.8				
Age 18 or older	87.8			100.0				
Marital status[1]							5.53	0.20
Married	9.8			3.0				
Separated	4.3			3.0				
Divorced, single	19.6			39.4				
Widowed	2.2			0.0				
Single, never married	64.1			54.5				
Children (% yes)	33.3			34.4			0.01	0.92
Number of children		2.3	1.39		1.9	0.94	0.86[a]	0.40
Nearby family (within 50 miles) (% yes)	56.2			54.5			0.03	0.87

Note. The total accepted sample in this table (*n* = 129) excludes the three accepted participants who were protocol violations. [1]For chi-square comparisons in which there are fewer than five

cases in a cell, the Fisher's exact test is reported. [a] A t-test is reported to compare the mean number of children between groups.

Table 4

Participant Demographics at Baseline by Condition (n=93)

	DBT-BSI			RT			Total				
	%	M	SD	%	M	SD	%	M	SD	χ^2	*p*
Age		38.6	15.0		41.8	15.3		40.2	15.2	1.00[a]	0.32
≥ 55 years	19.6			23.4			21.5			0.16	0.69
Gender[1]											
Male	56.5			61.7			59.1			0.41	0.87
Female	39.1			34.0			36.6				
Transgender	4.3			4.3			4.3				
Ethnicity[1]										3.86	0.41
Caucasian	88.4			80.0			84.1				
American Indian	2.3			2.2			2.3				
African American	9.3			8.9			9.1				
Asian	0.0			2.2			1.1				
Other	0.0			6.7			3.4				
Highest education[1]										9.54	0.28
Less than high school	2.3			8.7			5.6				
High school or equivalent	15.9			13.0			14.5				
Some college	45.5			37.0			41.1				
Bachelors' degree	27.3			13.0			20.0				
Beyond bachelors' degree	4.6			19.5			12.2				
Annual income[1]										4.31	0.79
< $10,000	44.2			40.0			42.1				
$10,000-24,999	44.2			33.3			38.6				
$25,000-50,000	9.3			22.2			15.9				
> $50,000	2.3			4.4			3.4				
Homeless (% lifetime)	52.2			55.6			53.8			0.11	0.75
Before age 11	0.0			4.0			2.0				
Age 11-17	20.8			40.0			30.6				
Age 18 or older	95.8			80.0			87.8				
Marital status[1]										4.69	0.30
Married	6.5			13.0			9.8				
Separated	4.3			4.3			4.3				
Divorced, single	26.1			13.0			19.6				
Widowed	0.0			4.3			2.2				
Single, never married	63.0			65.2			64.1				
Children (% yes)	30.4			36.4			33.3			4.54	0.61
Number of children		2.2	1.19		2.4	1.59	2.3			0.31[a]	0.76
Nearby family (within 50 miles) (% yes)	61.4			51.1			56.2			11.65	0.39

Note. [1]For chi-square comparisons in which there are fewer than five cases in a cell, the Fisher's exact test is reported. [a] A t-test is reported to compare the mean number of children between groups.

Table 5

Clinical Characteristics at Baseline by Condition (n=93)

	DBT-BSI			RT			Total				
	%	M	SD	%	M	SD	%	M	SD	χ^2	*p*
Suicide attempt (% yes)											
Lifetime	60.9			59.6			60.2			0.02	0.90
Past year	26.9			40.0			39.8			1.06	0.30
Past month	4.3			0.0			2.2			0.41	0.52
Non-suicidal self-injury (% yes)											
Lifetime	71.7			45.7			58.7			6.46	0.01[a]
Mental health treatment											
Past year	34.8			27.7			31.2			0.55	0.46
Never	10.9			10.6			10.8			0.00	0.97
Time since most recent (in years)[b]		3.30	4.52		4.12	6.70		3.71	5.71	0.65	0.52
Medications (at PS)	15.2			17.0			16.1			0.56	0.81

Note. [a]As a result of the significant difference in the proportions of participants in each condition who reported a lifetime history of engaging in non-suicidal self-injury, this variable was evaluated as a potential confounding factor in all analyses. [b]A t-test is reported to compare the mean time since most recent treatment across conditions.

Table 6

Baseline Demographics by Completion of 12-week Follow-up Interview

	Completed Follow-up (*n*=70)			Drop-out during Follow-up (*n*=23)				
	%	M	SD	%	M	SD	χ^2	*p*
Age								
≥ 55 years	23.5			18.2			0.28	0.60
Gender[1]							0.89	0.70
Male	58.6			60.9				
Female	35.7			39.1				
Transgender	5.7			0.0				
Ethnicity[1]							3.46	0.52
Caucasian	84.8			81.8				
American Indian	3.0			0.0				
African American	9.1			9.1				
Asian	1.5			0.0				
Other	1.5			9.1				
Highest education[1]							4.18	0.88
Less than high school	4.4			9.1				
High school or equivalent	13.3			18.2				
Some college	48.5			45.5				
Bachelors' degree	22.1			13.6				
Beyond bachelors' degree	11.8			13.6				
Annual income[1]							9.72	0.16
< $10,000	43.3			38.1				
$10,000-24,999	41.8			28.6				
$25,000-50,000	13.4			23.8				
> $50,000	1.5			9.5				
Homeless (% lifetime)	45.7			47.6			0.02	0.88
Before age 11	2.6			0.0				
Age 11-17	28.9			36.4				
Age 18 or older	94.7			63.6				
Marital status[1]							4.63	0.28
Married	7.1			18.2				
Separated	5.7			0.0				
Divorced, single	18.6			22.7				
Widowed	1.4			4.5				
Single, never married	67.1			54.5				
Children (% yes)	35.3			27.3			0.48	0.49
Number of children		2.3	1.4		2.2	1.6	0.26[a]	0.80
Nearby family (within 50 miles) (% yes)	56.7			54.7			0.03	0.86

Note. [1]For chi-square comparisons in which there are fewer than five cases in a cell, the Fisher's exact test is reported. [a] A t-test is reported to compare the mean number of children between groups.

Table 7

Baseline Clinical Characteristics by Completion of 12-week Follow-up Interview

	Completed Follow-up (*n*=70)			Drop-out During Follow-up (*n*=23)				
	%	M	SD	%	M	SD	χ^2	*p*
Depression (PHQ)		15.85	5.89		19.61	5.20	2.72[a]	0.01
Anxiety (BAI)		12.04	9.15		17.78	10.79	2.49[a]	0.02
Suicide attempt (% yes)								
Lifetime	61.4			72.7			0.93	.034
Past year	18.8			27.3			0.72	0.40
Past month	5.7			4.3			0.06	0.80
Non-suicidal self-injury (% yes)								
Lifetime	60.0			54.5			0.21	0.65
Mental health treatment								
Past year	28.6			43.5			1.76	0.19
Never	8.6			17.4			1.40	0.24
Time since most recent (in years)		3.92	6.03		3.02	4.53	-0.60[a]	0.55
Medications (at PS)	17.1			13.0			0.22	0.64

Note. PHQ = Patient Health Questionnaire – Depression Module. BAI = Beck Anxiety Inventory. [a]A t-test is reported to compare the means between groups.

Table 8

Randomization Algorithm Investigation

	DBT-BSI	RT	Total	χ^2	*p*
Lifetime suicide attempt (yes)	28 (60.9%)	28 (59.6%)	56 (60.2%)	0.02	0.90
Interested in treatment (yes)	36 (78.3%)	39 (83.0%)	75 (80.6%)	0.33	0.57
Identified gender (male)	27 (58.7%)	30 (63.8%)	57 (61.3%)	0.26	0.61

Note. Transgender participants were randomized based on their identified gender, rather than their biological sex.

Table 9

Recruitment Mediums and Effectiveness

	Screened		Invited		Enrolled		Retained	
	n	%	*n*	%	*n*	%	*n*	%
Newspaper	195	70.1	94	76.4	61	73.5	42	71.2
Flyers	50	18.0	21	17.0	15	18.1	13	5.1
Online	16	5.8	2	1.6	2	2.4	1	1.7
Radio	8	2.9	3	2.4	3	3.6	1	1.7
Other	9	3.2	3	2.4	2	2.4	2	3.4
Total	278		123		83		59	

Note. Based on information obtained during the phone screening interview.

Table 10

Participant Feedback from Subject Feedback Questionnaire at 12-week Follow-up Interview

	Condition							
	DBT-BSI		RT		Total			
Feedback Domain	*n*	%	*n*	%	*n*	%	χ^2	*p*
Provided feedback	38		29		67		5.05	0.03*
Feeling after in-person							1.36	0.91
Better	26	68.4	22	75.9	48	71.6		
Same	9	23.7	5	17.2	14	20.9		
Worse	2	5.3	2	6.9	4	6.0		
Don't know	1	2.6	0	0.0	1	1.5		
Total *n*	38		29		67			
Experience with in-person assessor							0.80	0.67
Completely positive	27	73.0	23	79.3	50	75.8		
Mostly positive	8	21.6	4	14.0	12	18.2		
Neutral	2	5.4	2	6.9	4	6.1		
Total *n*	37		29		66			
Understood by in-person assessor							4.24	0.33
Completely	20	54.1	18	64.3	38	58.4		
Mostly	14	37.8	6	21.4	20	30.7		
Somewhat	2	5.4	3	10.7	5	7.7		
Not really	1	2.7	0	0.0	1	1.5		
Not at all	0	0.0	1	3.6	1	1.5		
Total *n*	37		28		65			
In-person appointment helpful							0.49	1.00
Yes	34	91.9	26	89.7	60	90.9		
Somewhat	1	2.7	1	3.4	4	6.1		
No	2	5.4	2	6.9	2	3.0		
Total *n*	37		29		66			
Feeling after follow-ups							1.65	0.70
Better	12	34.3	13	44.8	25	39.1		
Same	19	54.3	13	44.8	32	50.0		
Worse	3	8.6	3	10.3	6	9.4		
Don't know	1	2.7	0	0.0	1	1.6		
Total *n*	35		29		64			
Phone interviews helpful							8.94	0.02*
Yes	19	52.8	16	55.2	35	53.8		
Somewhat	8	22.2	2	6.9	10	15.4		
No	5	13.9	11	37.9	16	24.6		
Don't know	4	11.1	0	0.0	4	6.2		
Total *n*	36		29		65			

Note. Based on the Subject Feedback Questionnaire which was completed at the end of the 12-week follow-up interview. For comparisons in which there are fewer than five cases in a cell, the Fisher's exact test is reported.

Table 11

Participant Feedback by Therapist

	Therapist					
Feedback Domain	1	2	3	Total	χ^2	*p*
Feeling after appointment					8.66	0.16
Better	38 (71.7)	6 (75.0)	4 (66.7)	48 (71.6)		
Same	12 (22.6)	2 (25.0)	0 (0.0)	14 (20.9)		
Worse	3 (5.7)	0 (0.0)	1 (16.7)	4 (6.0)		
Don't know	0 (0.0)	0 (0.0)	1 (16.7)	1 (1.5)		
Total *n*	52	8	6	67		
Experience with assessor					1.88	0.79
Completely positive	37 (71.2)	7 (87.5)	6 (100.0)	50 (75.8)		
Mostly positive	11 (21.2)	1 (12.5)	0 (0.0)	12 (18.2)		
Neutral	4 (7.7)	0 (0.0)	0 (0.0)	4 (6.1)		
Total *n*	51	8	6	66		
Understood by assessor					6.47	0.67
Completely	30 (58.8)	4 (50.0)	4 (66.7)	38 (57.8)		
Mostly	16 (31.4)	2 (25.0)	2 (33.3)	20 (30.3)		
Somewhat	3 (5.9)	2 (25.0)	0 (0.0)	5 (7.8)		
Not really	1 (1.9)	0 (0.0)	0 (0.0)	1 (1.5)		
Not at all	1 (1.9)	0 (0.0)	0 (0.0)	1 (1.5)		
Total *n*	51	8	6	66		
Appointment helpful					7.48	0.09
Yes	48 (92.3)	7 (87.5)	5 (83.3)	60 (89.6)		
Somewhat	0 (0.0)	1 (12.5)	1 (16.7)	2 (3.0)		
No	4 (7.7)	0 (0.0)	0 (0.0)	4 (6.0)		
Total *n*	52	8	6	67		

Note. Based on responses from the Subject Feedback Questionnaire completed at the end of the 12-week follow-up interview.

Table 12

Frequency of Medication Use Reported at Phone Screening Assessment

		Condition	
Generic name	Classification	DBT-BSI (n=8)	RT (n=7)
Lamotrigine	Anticonvulsant	2	1
Valproic acid	Anticonvulsant		1
Bupropion	Antidepressant	3	
Aripiprazole	Antipsychotic	1	
Buspirone	Azapirone		1
Clonazepam	Benzodiazepine	1	2
Gabapentin	GABA analog	1	1
Citalopram	SSRI		1
Escitalopram	SSRI	1	
Fluoxetine	SSRI		2
Sertraline	SSRI	2	2
Venlafaxine	SSRI		1

Note. Subjects may have reported more than one medication; therefore, totals do not equal the sample number.

Table 13

Means and Standard Deviations for Primary Outcomes

	Condition					
	DBT-BSI			RT		
Scale	n	M	SD	n	M	SD
SSI						
Screen	46	19.80	5.20	47	18.64	5.41
1-week	34	12.79	7.27	37	12.08	8.71
4-week	35	11.37	7.82	35	10.89	8.65
12-week	39	10.62	8.89	30	8.47	8.82
DBT-WCCL (total)[a]						
In-person	46	1.83	0.42	47	1.69	0.49
4-week	35	1.76	0.48	36	1.59	0.49
12-week	38	1.71	0.62	30	1.72	0.50
DBT-WCCL (skills taught)[b]						
In-person	38	1.91	0.40	40	1.79	0.55
4-week	35	1.90	0.46	35	1.68	0.57
12-week	37	1.84	0.56	29	1.90	0.47
DERS (total)						
In-person	46	102.74	21.91	47	108.76	23.29
4-week	36	95.00	24.17	39	100.54	25.60
12-week	39	91.21	18.84	32	96.13	27.67
DERS (ER strategies)						
In-person	46	23.78	6.33	47	24.55	7.18
4-week	36	20.97	6.04	39	22.90	8.10
12-week	39	20.59	4.77	32	21.19	7.67
SUSI						
1-week	41	0.98	0.16	38	0.63	0.49
4-week	35	0.91	0.28	36	0.78	0.42
12-week	38	0.92	0.27	30	0.60	0.50

Note. SSI = Scale for Suicidal Ideation; DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; SUSI = Skills Used Since Intervention; [a] Includes all skills. [b] Includes only items related to the skills taught as part of the DBT-BSI (12 items).

Table 14

Estimated Slopes for Each Condition during Follow-up for Intent-to-treat Participants (n = 93)

	Condition					
	DBT-BSI			RT		
Scale	Slope Estimate	S.E.	p[1]	Slope Estimate	S.E.	p[1]
SSI[2]	-2.08	0.38	<0.001*	-2.25	0.40	<0.001*
DBT-WCCL (total)[2]	-0.04	0.04	0.29	-0.00	0.04	0.95
DBT-WCCL (selected)[2]	-0.02	0.04	0.52	0.02	0.04	0.66
DERS (total)[2]	-1.11	2.45	0.65	-5.77	2.05	0.01*
DERS (ER strategies)[2]	-1.12	0.48	0.02*	-1.06	0.49	0.03*
PHQ	-1.17	0.45	0.01*	-1.43	0.48	0.003*
BAI	-1.66	0.63	0.01*	-1.89	0.66	0.004*
GSES[2]	0.67	0.45	0.13	0.77	0.46	0.10

Note. [1] p values for each slope were computed using a t-test that assessed whether the slope estimate was significantly different from 0. [2] The covariate of lifetime NSSI reported at the in-person assessment is included in the model.

Table 15

Estimated Slopes for Binary Outcomes for Intent-to-Treat Participants (n=93)

Scale	Estimate	S.E.	Wald χ^2	*p*
SUSI				
Condition	-2.38	0.71	11.41	0.001*
Time	0.02	0.04	0.40	0.53
Condition * Time	0.04	0.08	0.18	0.67
RFQ (any contact)				
Condition	-0.42	0.45	0.87	0.35
Time	-0.08	0.03	8.51	0.004*
Condition * Time	0.02	0.05	0.19	0.66
RFQ (attended appointment)				
Condition	-1.18	1.08	1.18	0.28
Time	-0.19	0.08	5.64	0.02*
Condition * Time	0.06	0.09	0.18	0.49
SASI				
Condition	-0.84	1.07	0.62	0.43
Time	0.10	0.06	0.03	0.87
Condition * Time	0.20	0.14	1.83	0.18

Note. SUSI = Skills Used Since Intervention; RFQ = Referral Follow-up Questionnaire; SASI = Suicide Attempt/Self-Injury Interview

Table 16

Proportion of Participants Using the Strategies Taught since the Last Assessment

	DBT-BSI				RT				
	Used		Not Used		Used		Not Used		RR[1]
	n	%	n	%	n	%	n	%	
1-week	41	97.6	1	2.3	23	62.1	14	37.8	1.54
4-week	33	91.7	3	8.3	28	77.8	8	22.2	1.18
12-week	35	92.1	3	7.9	18	60.0	12	40.0	1.54

Note. Based on information reported in the Skills Used Since Intervention questionnaire. [1]RR = Relative risk, or the ratio of participants in the DBT-BSI condition using the strategies they were taught compared to participants in the RT condition using the strategy they were taught. Values above 1 indicate that DBT-BSI participants were more likely to use skills than RT participants.

Table 17

Means and Standard Deviations for Secondary Outcomes

	Condition					
	DBT-BSI			RT		
Scale	n	M	SD	n	M	SD
PHQ						
In-person	37	18.32	4.91	41	18.44	4.84
1-week	33	15.09	6.84	34	15.03	6.61
4-week	27	14.26	6.58	32	13.94	7.09
12-week	30	14.03	6.54	26	13.65	7.26
BAI						
In-person	25	19.76	8.70	27	20.81	7.08
1-week	21	10.76	8.91	23	11.52	10.12
4-week	17	12.76	9.97	20	12.60	10.31
12-week	19	9.95	8.44	17	11.24	11.42
GSES						
In-person	46	27.17	6.52	47	25.51	6.13
4-week	35	29.37	5.77	36	27.25	6.66
12-week	38	28.95	5.98	30	27.73	6.55
RFQ (any contact)						
1-week	41	0.22	0.42	37	0.30	0.46
4-week	35	0.40	0.50	36	0.50	0.51
12-week	39	0.49	0.51	32	0.53	0.51
RFQ (attended appointment)						
1-week	41	0.02	0.16	38	0.03	0.16
4-week	35	0.06	0.24	36	0.17	0.38
12-week	39	0.18	0.39	32	0.28	0.46

Note. PHQ-9 = Patient Health Questionnaire; BAI = Beck Anxiety Inventory; GSES = General Self-Efficacy Scale; RFQ = Referral Follow-up Questionnaire.

Table 18

Proportion of Participants Contacting Mental Health Services since the Last Assessment

Any Contact with Mental Health Resources (by phone or in-person)									
	DBT-BSI				RT				
	Contact		No Contact		Contact		No Contact		
	n	%	n	%	n	%	n	%	RR[1]
1-week	9	22.0	32	78.0	11	28.2	26	59.1	0.78
4-week	14	40.0	21	60.0	11	37.9	18	62.1	0.82
12-week	19	48.7	20	51.3	17	53.1	15	16.9	0.94
In-person Contact with Mental Health Resources									
	DBT-BSI				RT				
	Contact		No Contact		Contact		No Contact		
	n	%	n	%	n	%	n	%	RR
1-week	1	2.4	40	97.6	2	5.4	35	94.6	0.48
4-week	2	5.7	33	94.3	6	16.7	30	83.3	0.35
12-week	7	17.9	32	82.1	9	28.1	23	71.9	0.65

Note. Based on information obtained from the Referral Follow-up Questionnaire. [1] RR = Relative risk, or the ratio of participants in the DBT-BSI condition in contact with mental health resources compared to participants in the RT condition in contact. Values above 1 indicate that DBT-BSI participants were more likely to contact resources than RT participants while values below 1 indicate that RT participants were more likely.

Table 19

Subjects Starting Treatment and/or Psychiatric Medications during Follow-up

Initiating Psychotherapy[1]							
	DBT-BSI		RT		Total		
Period	n	%	n	%	n	%	RR[3]
1-week	3	6.5	6	12.8	9	9.7	0.48
4-week	2	4.3	7	14.9	9	9.7	0.30
12-week	7	15.2	3	6.4	10	10.8	1.96
Total	12	26.1	16	34.0	28	30.1	0.77
Initiating Psychiatric Medications[2]							
	DBT-BSI		RT		Total		
Period	n	%	n	%	n	%	RR
1-week	2	4.3	3	6.4	5	5.4	0.63
4-week	1	2.2	0	0.0	1	1.1	-
12-week	2	4.3	1	2.1	3	3.2	1.68
Total	5	10.9	4	8.5	9	9.7	1.28
Initiating Therapy and/or Medications							
	DBT-BSI		RT		Total		
Period	n	%	n	%	n	%	RR
1-week	4	8.7	9	19.1	13	14.0	0.42
4-week	4	8.7	8	17.0	12	12.9	0.53
12-week	7	15.2	3	6.4	10	10.8	1.96
Total	15	32.6	20	42.6	35	37.6	0.77

Note. [1] Based on Referral Follow-up Questionnaire at each assessment for all intent-to-treat participants (N = 93). [2] Based on UW Risk Assessment Protocol assessment of medications at each assessment for all intent-to-treat participants (N = 93). [3] RR = Relative risk, or the ratio of participants in the DBT-BSI condition initiating services compared to participants in the RT condition. Values above 1 indicate that DBT-BSI participants were more likely to initiate treatment than RT participants while values below 1 indicate that RT participants were more likely.

Table 20

Subjects Engaging in Suicidal and Non-Suicidal Self-Injury at Baseline and during Follow-up

Lifetime History of Suicide Attempts and NSSI							
	DBT-BSI		RT		Total		
	n	%	n	%	n	%	
Suicide attempts only	1	2.2	12	25.5	13	14.0	
NSSI only	6	13.0	2	4.3	8	8.6	
Both	27	58.7	19	40.4	46	49.5	
Total	33	71.7	34	72.3	67	72.0	
Participants Attempting Suicide during Follow-up							
	DBT-BSI		RT		Total		RR[d]
Period	n	%	n	%	n	%	
4-week	2	4.3	2	4.3	4	4.3	1.06
12-week	1	2.2	2	4.3	3	3.2	0.42
Total	3	6.5	3[a]	6.4	6	6.5	1.02
Participants Engaging in NSSI during Follow-up							
	DBT-BSI		RT		Total		RR
Period	n	%	n	%	n	%	
4-week	4	8.7	4	8.5	8	8.6	1.08
12-week	1	2.2	2	4.3	3	3.2	0.39
Total	5	10.9	4[b]	8.5	9	9.7	1.28
Participants Engaging in NSSI and/or Suicide Attempts during Follow-up							
	DBT-BSI		RT		Total		RR
Period	n	%	n	%	n	%	
4-week	5[c]	14.3	6	15.8	11	11.8	0.90
12-week	2	5.3	4	12.5	6	6.5	0.42
Total	7	15.2	7	14.9	14	15.1	1.02

Note. Based on Lifetime Parasuicide Count at the baseline, four-week, and twelve-week follow-up interviews for all intent-to-treat participants (N = 93). [a] One participant reported a suicide attempt at both the four- and twelve-week follow-up assessment interviews. [b] Two participants reported NSSI at both the four- and twelve-week follow-up assessment interviews. [c] One participant reported both a suicide attempt and NSSI during the four-week follow-up interview. [d] RR = Relative risk, or the ratio of participants in the DBT-BSI condition in engaging in behavior compared to participants in the RT condition. Values above 1 indicate that DBT-BSI participants were more likely to engage in self-injurious behavior than RT participants while values below 1 indicate that RT participants were more likely.

Table 21

Clinically Significant Change Results at Each Time Point by Condition

		DBT-BSI				RT				
		Valid n	Unchanged/ Deteriorated	Improved	Recovered	Valid n	Unchanged/ Deteriorated	Improved	Recovered	p^1
SSI	1-week	34	20 (58.8%)	8 (23.5%)	6 (17.6%)	37	22 (59.5%)	7 (18.9%)	8 (21.6%)	0.93
	4-week	35	15 (42.9%)	15 (42.9%)	5 (14.3%)	35	21 (60.0%)	9 (25.7%)	5 (14.3%)	0.24
	12-week	39	20 (51.3%)	5 (12.8%)	14 (35.9%)	30	14 (46.7%)	4 (13.3%)	12 (40.0%)	0.70
DBT-WCCL	4-week	35	33 (94.3%)	0 (0.0%)	2 (4.3%)	36	34 (94.4%)	0 (0.0%)	2 (5.6%)	0.98
	12-week	38	35 (92.1%)	0 (0.0%)	3 (7.9%)	30	27 (90.0%)	0 (0.0%)	3 (10.0%)	0.76
DERS	4-week	36	28 (77.8%)	3 (8.3%)	5 (13.9%)	39	33 (84.6%)	2 (5.1%)	4 (10.3%)	0.46
	12-week	39	33 (84.6%)	2 (5.1%)	4 (10.3%)	32	25 (78.1%)	3 (9.4%)	4 (12.5%)	0.51
PHQ	1-week	41	32 (78.0%)	2 (4.9%)	7 (17.1%)	39	28 (71.8%)	6 (15.4%)	5 (12.8%)	0.67
	4-week	36	30 (83.3%)	3 (8.3%)	3 (8.3%)	38	24 (63.2%)	10 (26.3%)	4 (10.5%)	0.07
	12-week	39	30 (76.9%)	3 (7.7%)	6 (15.4%)	31	21 (67.7%)	3 (9.7%)	7 (22.6%)	0.39
BAI	1-week	41	34 (82.9%)	3 (7.3%)	4 (9.8%)	39	31 (79.5%)	2 (5.1%)	6 (15.4%)	0.65
	4-week	36	32 (88.9%)	4 (11.1%)	0 (0.0%)	38	33 (86.8%)	3 (7.9%)	2 (5.3%)	0.73
	12-week	39	34 (87.2%)	2 (5.1%)	3 (7.7%)	31	25 (80.6%)	1 (3.2%)	5 (16.1%)	0.42

Note. [1] Significant tests performed use the Mann Whitney *U* statistic. DBT-BSI = DBT Brief Suicide Intervention; RT = Relaxation Training; SSI = Scale for Suicidal Ideation; DBT-WCCL = DBT Ways of Coping Checklist (skills use subscale); DERS = Difficulties in Emotion Regulation Scale; PHQ = Patient Health Questionnaire – Depression; BAI = Beck Anxiety Inventory.

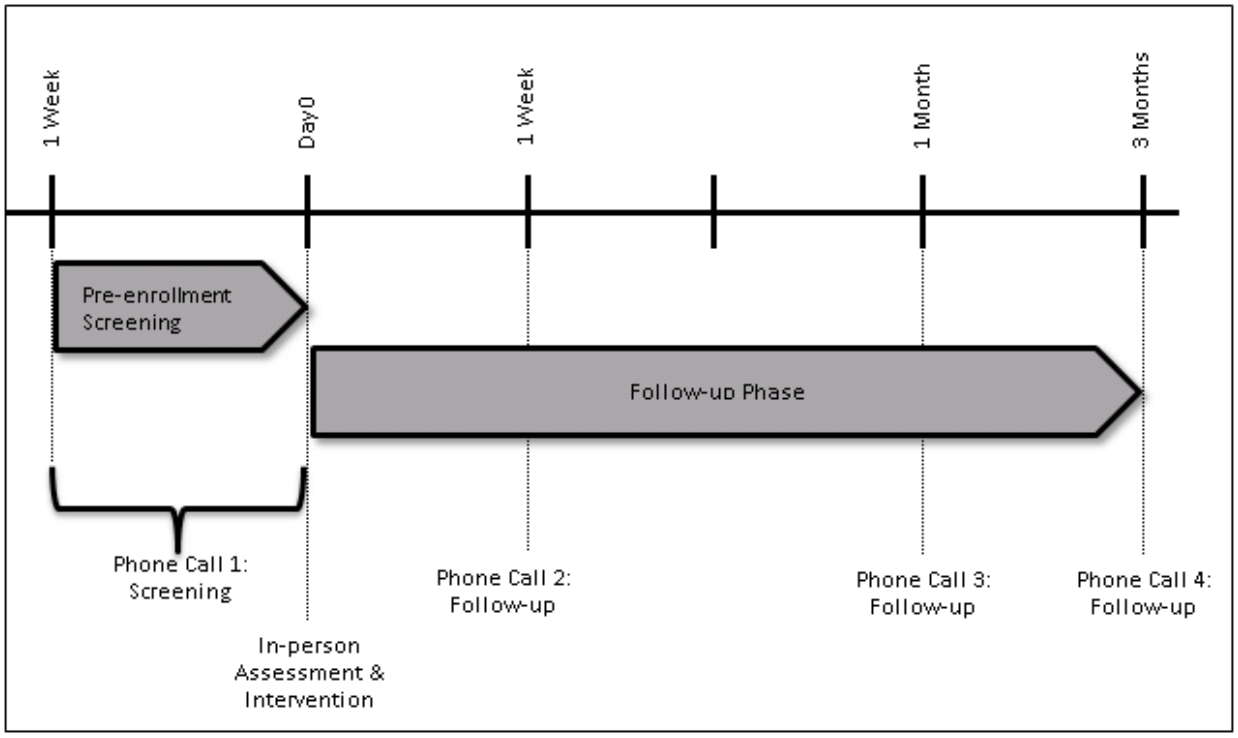

Figure 1. Study timeline

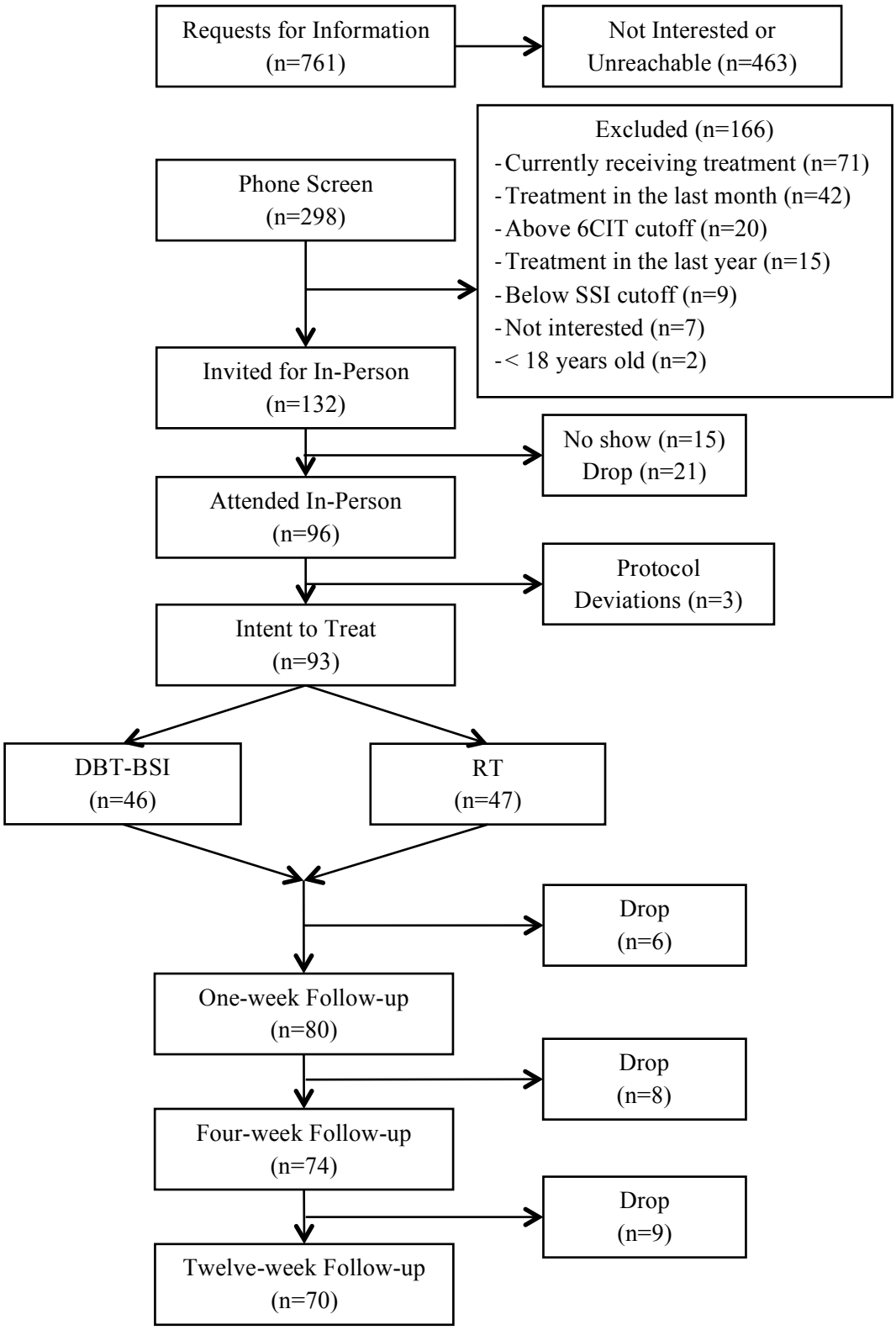

Figure 2. Study flow and enrollment

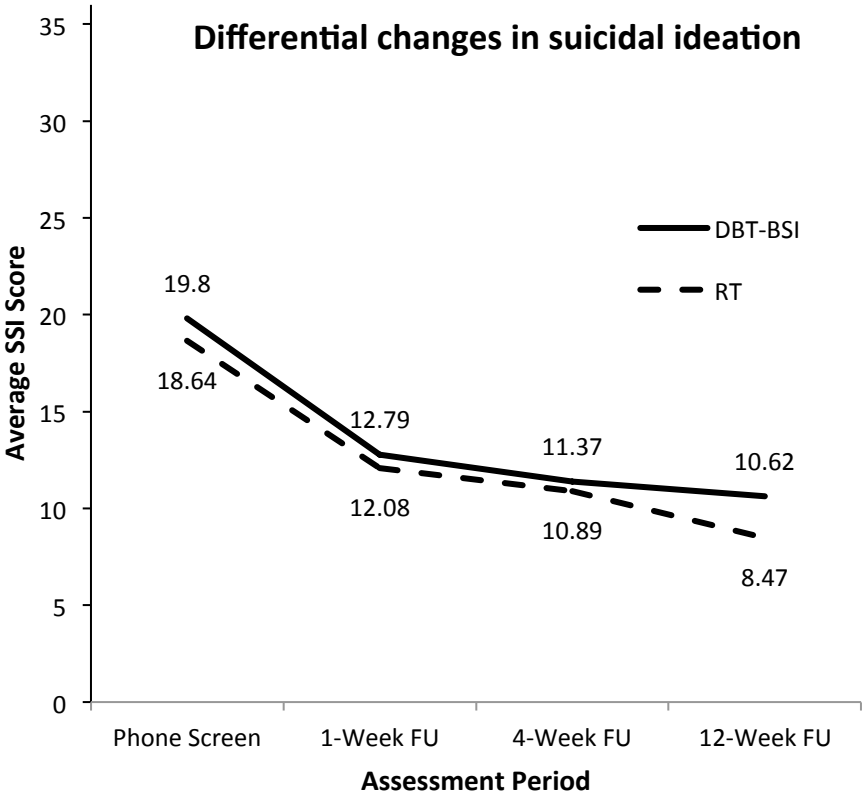

Figure 3. Scale for Suicidal Ideation graph using completed participant data

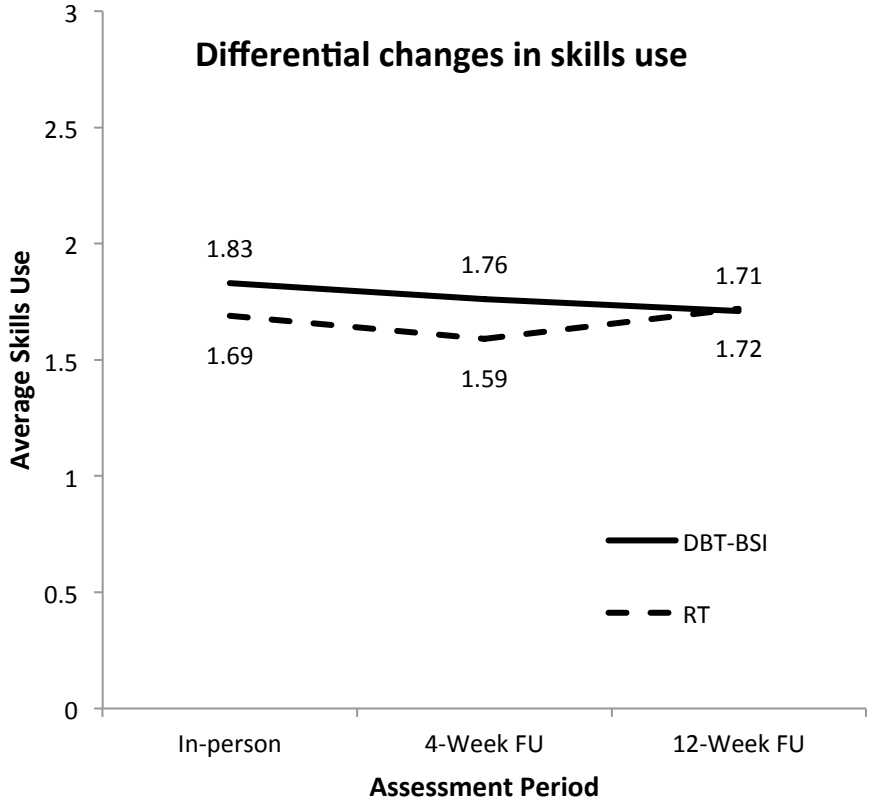

Figure 4. DBT Ways of Coping Checklist mean skills use graph using completed participant data

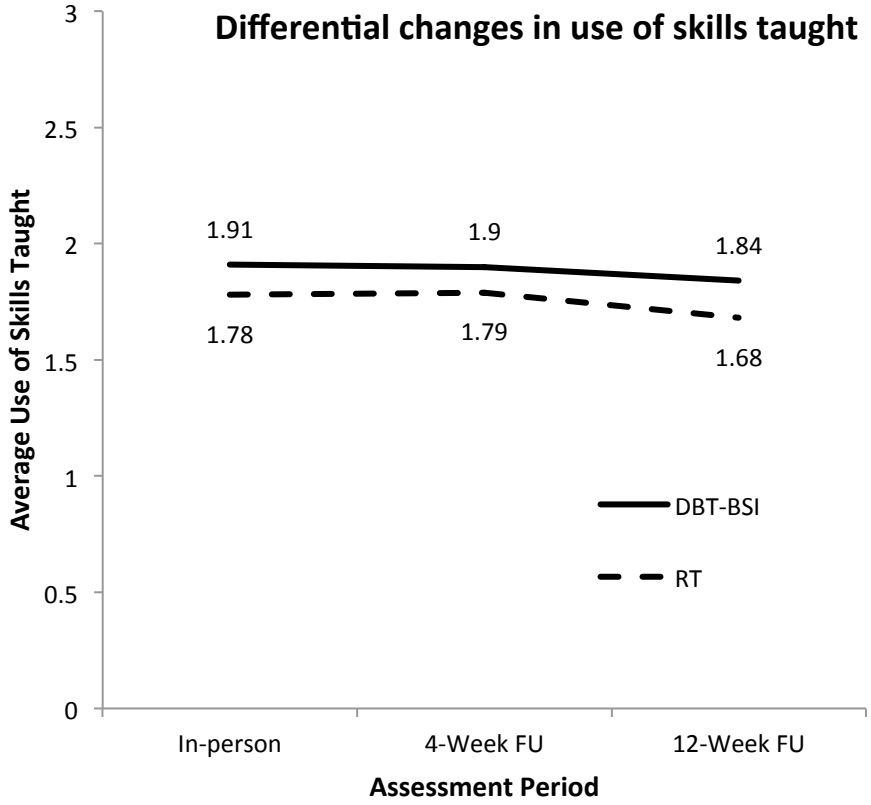

Figure 5. DBT Ways of Coping Checklist skills taught in intervention graph using completed participant data

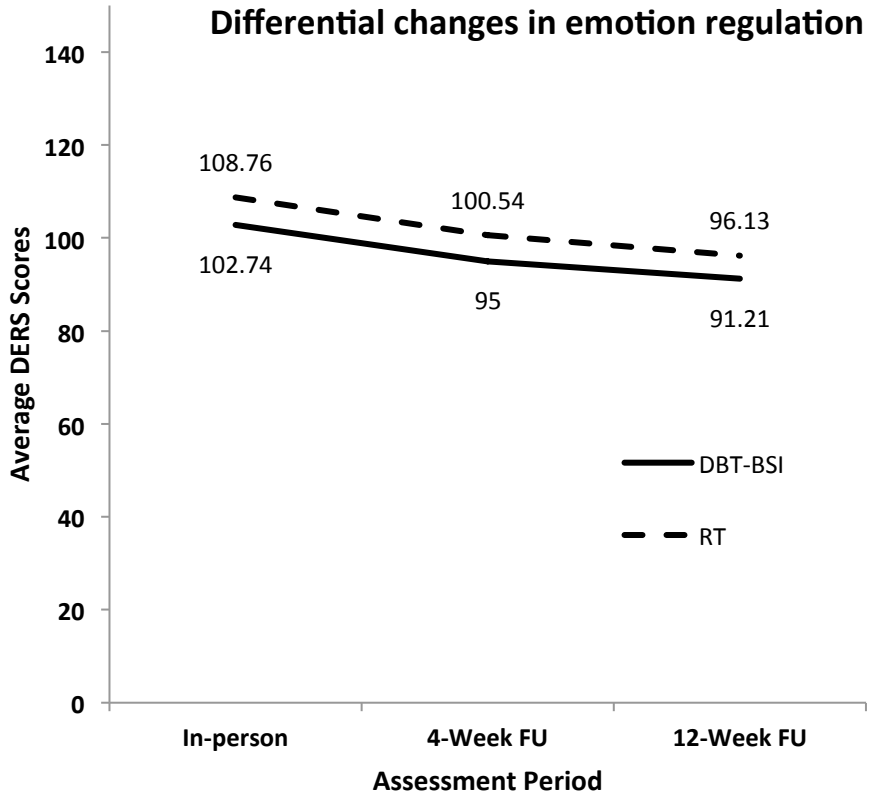

Figure 6. Difficulties in Emotion Regulation Scale total score graph using completed participant data

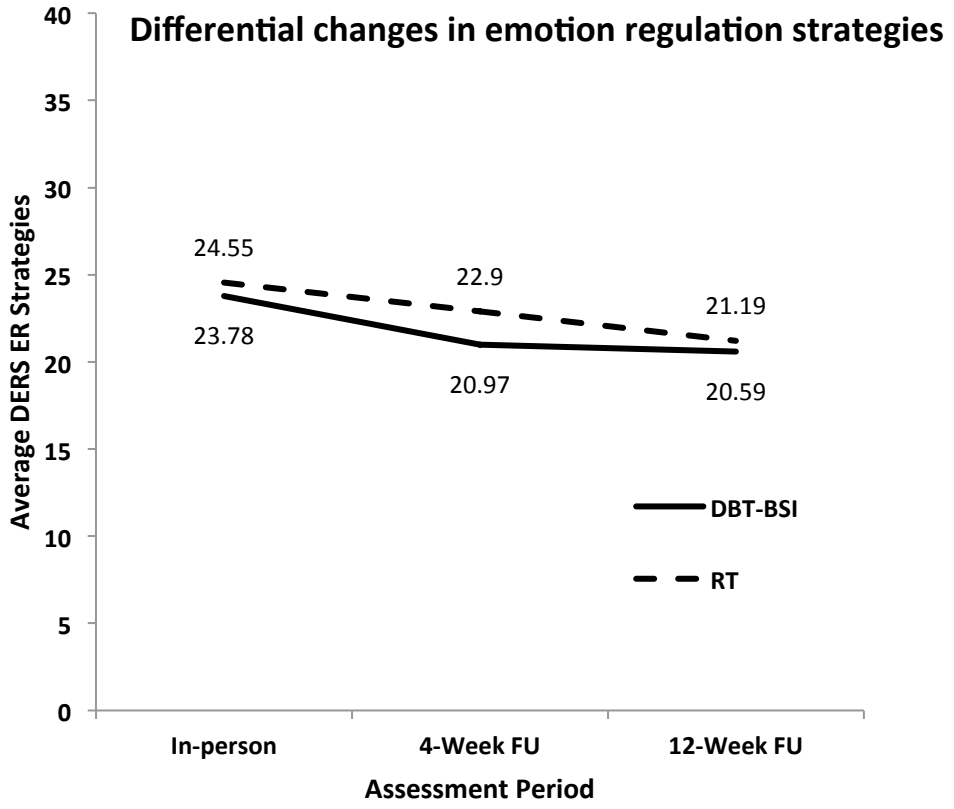

Figure 7. Difficulties in Emotion Regulation Scale emotion regulation strategies graph using completed participant data

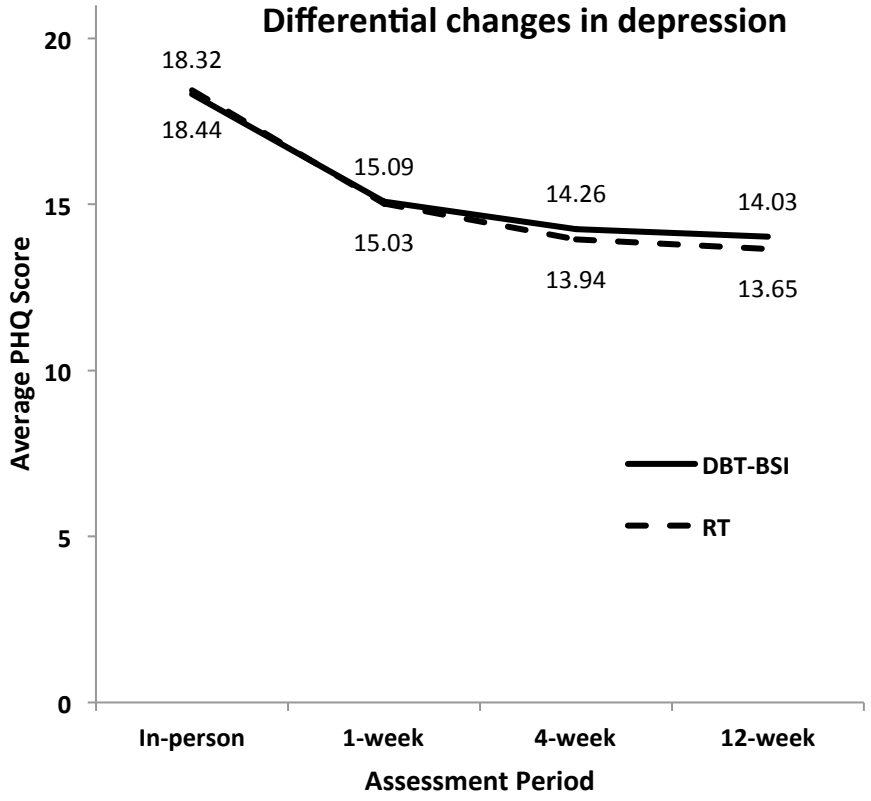

Figure 8. Patient Health Questionnaire Depression graph using completed participant data

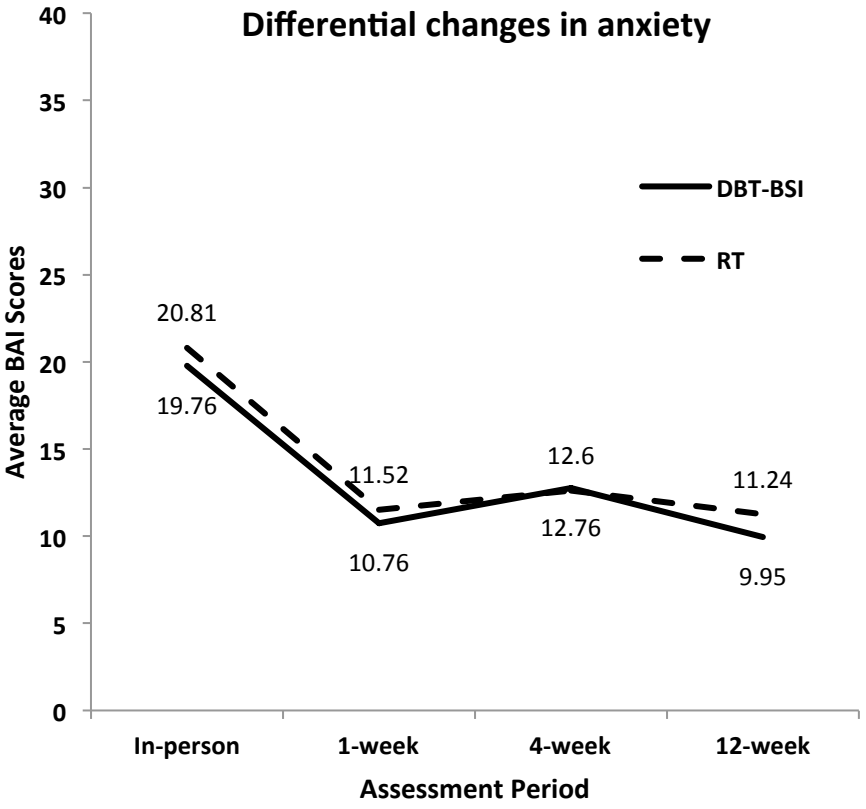

Figure 9. Beck Anxiety Inventory graph using completed participant data

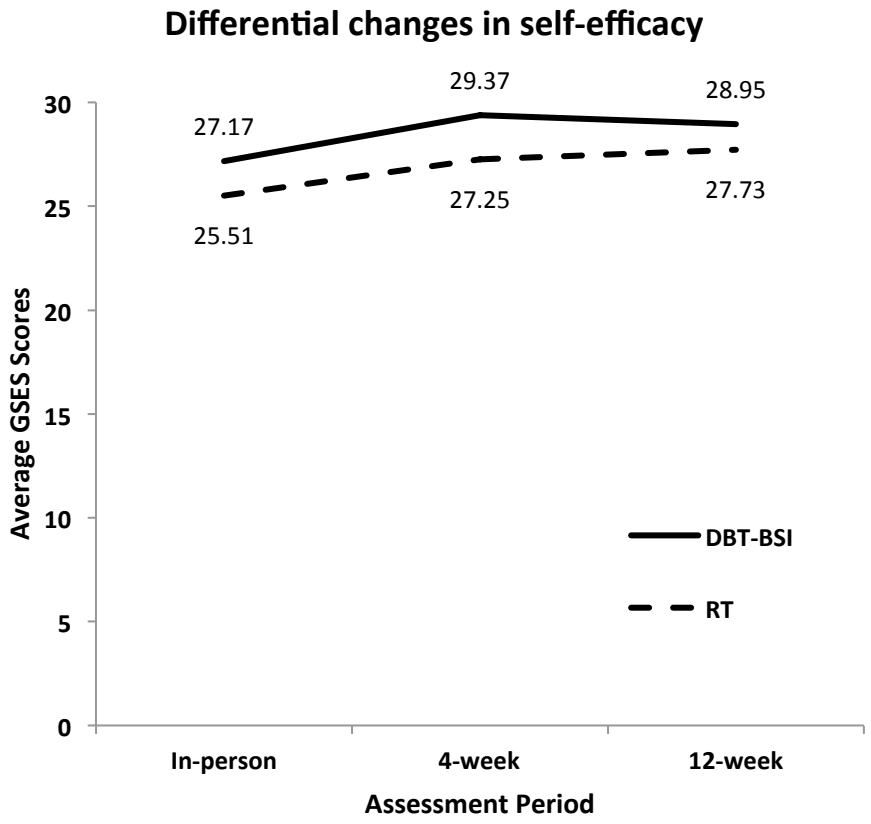

Figure 10. General Self-efficacy Scale graph using completed participant data