

Computerized Trans-Diagnostic Dialectical Behavior Therapy Skills Training for Emotion
Dysregulation

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Abstract

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Doctor Marsha M. Linehan
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Over the last several decades, research in clinical psychology has generated many different treatments targeting many different mental disorders. Yet many individuals with mental health problems do not receive evidence based treatments (EBTs) fitting their clinical profile (Kessler, Merikangas, & Wang, 2007; Shafran et al., 2009; Stobie, Taylor, Quigley, Ewing, & Salkovskis, 2007). Two important obstacles to this goal are: (1) the current symptom-based classification system for mental health disorders, and (2) the dearth of cost-effective treatment dissemination mechanisms.

Following an increase in understanding psychopathology driven by behavioral studies and cognitive neuroscience, the field has witnessed the emergence of trans-diagnostic treatments targeting general dysfunctional processes and mechanisms of change common across disorders.

Large-scale treatment dissemination remains a grand challenge for the field (Biederman, Newcorn, & Sprich, 1991; Regier, Narrow, Kuhl, & Kupfer, 2009). Common barriers include the

high cost of face-to-face treatment, mental health stigma, and inaccessibility due to geographical locations (Biederman et al., 1991; Conway, Compton, Stinson, & Grant, 2006). Computerized psychotherapy treatments can enable large-scale dissemination of EBTs and several have been found efficacious in depression and anxiety disorders (Cartreine, Ahren, & Locke, 2010; Marks, Cavanagh, & Gega, 2007; Marks, Kenwright, McDonough, Whittaker, & Mataix-Cols, 2004; Proudfoot et al., 2003; D. Richards & Richardson, 2012).

This project builds on both a theoretical model proposing emotion dysregulation as a trans-diagnostic mechanism of disorder and on supporting evidence that DBT skills training can be an effective treatment for decreasing emotion dysregulation trans-diagnostically (Neacsiu, 2012; Neacsiu, Eberle, Kramer, Weismann, & Linehan, 2014). This project unfolded in two phases. In Phase 1 of this project we developed and tested feasibility and in Phase 2 we evaluated a computerized trans-diagnostic DBT skills training intervention targeting individuals with difficulties regulating their emotion who met diagnostic criteria for mood and anxiety disorders.

Seven men and women who met criteria for at least one mood or anxiety disorder and who reported high emotion dysregulation were included in Phase 1 of the study. They went through the computerized intervention by coming to our research laboratory and then they provided qualitative and quantitative feedback on different components of the intervention and their experience during a post-session interview with a research assistant. Phase 1 participants were assessed before treatment started at the middle of treatment and at the end of treatment. Participants reported reductions in emotion dysregulation, anxiety, depression as well as increases in mindfulness and use of skillful behavior. Phase 1 participants found the intervention acceptable and usable. Qualitative feedback from Phase 1 participants was utilized to modify the intervention by improving its usability and acceptability resulting in the intervention evaluated in

Phase 2.

Twenty five men and women participated in Phase 2 of the intervention meeting similar inclusion criteria to Phase 1 (reported high emotion dysregulation and met criteria for at least one mood or anxiety disorder). Participants went through the intervention online in their own environment. Participants were assessed before treatment started, at the middle of treatment, at the end of treatment and at two months follow-up. Participants reported reductions in emotion dysregulation, anxiety, depression, general distress as well as increases in mindfulness and use of skillful behavior. Results were compared to findings from a historical control study that recruited a similar clinical population (high in emotion dysregulation and meeting diagnostic criteria for a mood and/or anxiety disorder) and taught DBT skills in a face-to-face format.

Findings and future directions are discussed in the context of the current treatment literature. Comparison to historical control study revealed post-treatment effect sizes comparable at a descriptive level with the effect sizes of face-to-face therapy. Future work includes using the iDBT intervention as an add on to individual therapy, expanding the intervention to different clinical groups, expanding the intervention to include all DBT skills, as well as using the intervention within a stepped care model.

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Introduction

The Dissemination Problem in Mental Health Psychological Treatments

Over the last decades significant progress has been made in creating and evaluating efficacious psychological treatments, for a wide range of mental disorders. A review of meta-analyses for Cognitive Behavior Therapy (CBT), one of the most researched Evidence-Based Treatments (EBT)s, found large effect sizes for unipolar depression, generalized anxiety disorder, panic disorder with or without agoraphobia, social phobia, posttraumatic stress disorder, and childhood depressive, and anxiety disorders (Butler, Chapman, Forman, & Beck, 2006). CBT effect sizes for bulimia nervosa and schizophrenia were in the large range. Moderate effect sizes were found for marital distress, anger, childhood somatic disorder, and chronic pain. CBT was even found effective, with small to medium effect sizes for reducing psychotic symptoms and distress (Wykes, Steel, Everitt, & Tarrier, 2008). Taking a step back and considering face-to-face psychotherapy, in general as it addresses clinical problems, treatment effect sizes are generally in the medium range (Lambert & Ogles, 2004; Luborsky et al., 1999; Smith & Glass, 1977). Indeed Wampold concludes regarding the effectiveness of traditional, face-to-face evidence based psychotherapy “Simply stated, *psychotherapy is remarkably efficacious*”(Wampold, 2001) (p. 71).

The enthusiasm for the proven efficacy of psychotherapy, as we know it, is tempered though by the fact that many individuals in need do not get to benefit of this efficacious tool (Andrews, Henderson, & Hall, 2001; Lepine, 2002). Indeed, making EBTs widely available remains a great challenge in the field (Addis, 2002; Barlow, Levitt, & Bufka, 1999). Barriers to wide-scale dissemination of treatment include: a) low availability due to dearth of practitioners

trained in EBTs; b) the resource intensive process of performing effectiveness studies when transitioning an EBT from the research lab to clinical practice; c) the high cost of face-to-face therapy; d) the logistics involved in getting people in regular face to face appointments with professionals; and e) mental health stigma that keeps people away from professional help (Lyons, Hopley, & Horrocks, 2009; S. M. Turner, Beidel, Spaulding, & Brown, 1995; Wright et al., 2009).

Using Computerized Treatments to Address the Dissemination Problem

In response to these difficulties to disseminate EBTs on a large scale, computer-aided psychotherapy (CP) have emerged and gained momentum over the last few decades. Specialized journals dedicate most of their space to research on such CP systems¹ and other high-impact journals with a more general target include CP articles in their scope². CP holds great promise to address at least some of the barriers to disseminating efficacious EBTs on a large scale.

Treatment delivered entirely through software does not require training, does not tire, remains at fidelity, can be easily replicated, and can be easily updated. Computerized treatments can also be made available to individuals in need regardless of geographic location, provided computers and potentially an internet connection are available. Cost savings compared to face-to-face psychotherapy can be significant. In the case of anxiety disorders, for example, studies have estimated savings in the range of \$540-\$630 per client when traditional face-to-face therapy is replaced by computerized interventions (Newman, Consoli, & Taylor, 1997). When comparing the cost of computerized therapy for depression with the cost of antidepressant medication,

¹ For example, *Computers in Human Behavior*, *Computers in Human Service*, *Cyberpsychology and Behavior*, *Journal of Telemedicine and Telehealth*, *Journal of Medical Internet Research*, as cited in (Marks, Cavanagh, & Gega, 2007) p.1.

² For example, *American Journal of Psychiatry*, *Archives of General Psychiatry*, *Behavior Research & Therapy*, *Behavioural & Cognitive Psychotherapy*, *Behavior Therapy*, *British Journal of Clinical Psychology*, *Journal of Clinical Psychology*, *Clinical Psychology*, *Journal of Consulting & Clinical Psychology*, as cited in (Marks et al., 2007) p.1.

National Institute for Health and Clinical Excellence (NICE, UK) estimates a savings of \$2,000 to \$16,000 per client in costs due to sickness, disability and lost income (National Institute for Health and Care Excellence, 2002; Stuhlmiller & Tolchard, 2009). There is also less stigma associated with performing an activity on a computer compared to receiving therapy in a practitioner's office. People also found it easier to tell a computer sensitive information such as suicide risk, an attempted suicide or a past criminal record, than to a human (Classen & Larkin, 2005; Greist et al., 1973). Changes in treatments propagate more quickly to consumers when the need for additional training is replaced by a software update. Similarly, the effort for adapting the treatment to a different target population might be contained only to generating new examples. Advances in the research areas of multimedia eLearning and persuasive technology have interesting potential clinical applications.

Review of Computerized Psychotherapy's Efficacy

Though the field of computerized psychotherapies has exploded in the last decade, the main goal has been to figure out if therapy delivered through technology is efficacious compared to no or inert interventions or to find if there are any differences between computerized psychotherapies and face-to-face therapy; a very worthwhile endeavor considering the skepticism with which computerized therapies have been initially received. In what follows, we summarize efficacy findings from systematic meta-analyses investigating computerized interventions published between January 2006 and March 2015.

We performed a search on Cochrane Library, Medline and PsychInfo publications databases for RCTs, systematic reviews and meta-analyses published between 2007 and March 2015. We identified eight meta-analyses, two of those addressed anxiety disorders, one depression, one anxiety and depression, one anxiety or depression, one depression or GAD, or

panic disorder, or social phobia, one insomnia, and one all problems treatable by psychotherapy. We will summarize their main findings from these meta-analyses guided by several questions of interest. One of the limitations of this approach is that the comments and conclusions we draw are necessarily limited to the scope and information contained within these eight meta-analyses.

Are computerized psychotherapies efficacious?

This has been the question most pursued so far in studies on computerized psychotherapy. Table 1 summarizes the effect sizes identified for the eight meta-analyses considered. A meta-analysis focused on *anxiety, phobic disorders, panic disorders and PTSD* that included 19 RCTs yielded the following mean effects sizes: CP versus waitlist 0.76 (95% CI 0.60, 0.92), CP versus placebo 0.86 (95% CI 0.61, 1.11) and CP vs. TAU 0.03 (95% CI -0.35, 0.41) (Reger & Gahm, 2009). Among the 10 waitlist controlled studies, no significant difference in effect size was found between studies who included participants meeting full diagnostic criteria (4 studies) and studies who included participants meeting partial criteria or who were below diagnostic threshold (6 studies).

Another meta-analysis focusing on *anxiety disorders* (panic disorder, agoraphobia, social phobia, specific phobia, OCD, PTSD, and GAD) included 23 RCTs and identified a large average post-treatment effect size $d = 0.99$ (95% CI: 0.86 to 1.13) following a fixed-effects model (FEM), and a larger effect size of $d = 1.98$ (95% CI: 0.84 to 1.32) according to a random-effects model (REM), (Cuijpers et al., 2009). A subset of the studies included conducted follow-up assessments (1, 3, 6 or 12 months post-treatment). Effect sizes computed for the follow-up assessments compared to post-treatment were non-significant indicating that treatment gains remain stable.

A meta-analysis of CPs for *anxiety* (7 RCTs) and *depression* (5 RCTs) that included both treatment (11 RCTs) and prevention studies (2 RCTs) found a mean FEM effect size of 0.24 (95% CI: 0.16 to 0.33) and a REM effect size of 0.51 (95% CI: 0.28 to 0.74). 0.40 (95% CI: 0.29 to 0.51) for a FEM and a mean effect size of 0.60 (95% CI: 0.35 to 0.86) for a REM (Spek et al., 2007). Due to high heterogeneity the authors conducted post-hoc subgroup analyses dividing the studies based on target (treatment versus prevention), condition treated (depression versus anxiety) and presence of therapist support. Treatment studies had a FEA effect size of 0.40 (95% CI: 0.29 to 0.51), mixed effect analysis (MEA) effect size of 0.60 (95% CI: 0.35 to 0.86). Prevention studies had a FEA effect size of 0.03 (95% CI: -0.11 to 0.71), MEA effect size of 0.06 (95% CI: -0.17 to 0.30). The studies on depression had a FEA effect size of 0.27 (95% CI: 0.15 to 0.40) and a MEA effect size of 0.32 (95% CI: 0.08 to 0.57). The studies on anxiety had a FEA and MEA effect size of 0.96 (95% CI: 0.69 to 1.22). Studies offering therapist support (5 RCTs) had a FEA and MEA of 1.00 (95% CI: 0.75 to 1.24). Studies not offering therapist support (6 RCTs) had a FEA of 0.24 (95% CI: 0.11 to 0.37) and a MEA of 0.26 (95% CI: 0.08 to 0.44).

Andrews et al. 2010 focused on CP for *depression*, *GAD*, *panic disorder* and *social phobia* analyzing 22 studies (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010). The overall effect size superiority of CP over control groups across all disorders was $g = 0.88$ (95% CI: 0.76 to 0.99). Similar results were obtained for depression $g = 0.78$ (95% CI: 0.59 to 0.96), social phobia $g = 0.92$ (95% CI: 0.74 to 1.09), panic disorder $g = 0.83$ (95% CI: 0.45 to 1.21) and GAD $g = 1.12$ (95% CI: 0.76 to 1.47). No significant difference in effect size was found for studies using a waitlist control group versus studies using TAU or other control groups. Fourteen of the

22 studies reported follow-up data from 4 to 52 weeks (median 26 weeks) and none gave evidence of relapse.

Andersson et al. 2009 examine CPs for *depression* (13 RCTs), including also 2 studies on depression or anxiety (Andersson & Cuijpers, 2009). A mean effect size of $d = 0.41$ (95% CI: 0.29 to 0.54) was found.

Richards et al. 2012 conducted a review and meta-analysis on CPs for *depression* disorders including 19 RCTs (D. Richards & Richardson, 2012). The meta-analysis revealed a mean post-treatment effect size of $d = 0.56$ (95% CI: -0.71 to -0.41). The effect for studies with less than eight sessions was significantly greater $d = 0.75$ (95% CI: 0.41 to 0.71) than the effect for studies with eight or more sessions $d = 0.39$ (95% CI: 0.22 to -0.56). Studies performed in community settings and primary or secondary care settings had similar effect sizes ($d = 0.52$ vs. $d = 0.46$). Studies using waitlist controls had greater effects than studies using TAU controls ($d = 0.58$ vs. $d = 0.39$). A statistically significant effect size of $d = 0.20$ was found in favor of CP compared to controls. Greater follow-up results were also found for supported versus non-supported therapies.

Barak et al. 2008 performed a meta-analysis on 92 studies focusing on CP with a broad scope: problems treatable through psychological interventions (Barak, Hen, & Boniel-Nissim, 2008). The average effect size found across the 92 studies over all dependent measures was 0.53, (range 0.10 to 1.68). The range of effect sizes across all dependent variables was also very high from a low 2.90 (self-report of pain severity in treating chronic back pain) to 5.10 (self-report of “total phobia” follow-up compared to pre-treatment in treating phobic and panic disorders). Out of the 746 effects calculated 75 (10%) were zero or less; out of the 92 mean effect sizes calculated per study 40 (5.4%) were negative. Effects were moderated by type of measure used

to assess outcome, with effects varying from 0.93 for evaluations by experts and raters to 0.19 for physical measures (e.g. blood pressure, brain waves). Another moderator of effect size was the type of problem addressed. Effect sizes in increasing order were: weight loss (0.17), physiological problems (0.27), depression (0.32), body image (0.45), drinking (0.48), smoking cessation (0.62), panic and anxiety (0.80), and PTSD (0.88). No significant difference was found between studies who measured effectiveness post-treatment versus at follow-up (follow-up interval ranging from 4 weeks to a year).

A meta-analysis evaluating CPs for insomnia included 6 RCTs and found an effect size of $d = 0.22$ (95% CI: -0.03 to 0.46) for total sleep time, a decrease in number of awakenings corresponding to an effect size of $d = .045$ (95% CI: 0.20 to 0.70) and a decrease in sleep onset latency effect size of $d = 0.55$ (95% CI: -0.30 to -0.80).

What are the theoretical orientations of CPs?

Of the eight meta-analyses summarized, seven described theoretical orientation for all studies included. Reger et al. (2009), Spek et al. (2007), Andrews et al. (2010) included solely CBT based CPs. Richards et al. (2012) included 17 studies using CBT CPs, two Problem Solving Therapy CPs and one Structured Writing Intervention CP. Andersson et al. (2009) included 11 CBT based CPs, two Problem Solving Therapy CPs and one psychoeducation CP. Of the 92 studies analyzed by Barak et al. (2008), 51 use CBT CPs, 25 psychoeducation CPs, 14 behavioral CPs and 2 other type CPs. Only studies implementing computerized behavior therapy for insomnia (CCBT-I) were selected for inclusion in the meta-analysis for insomnia.

Does contact with a therapist matter?

Roger et al. (2009) divides studies into two groups based on whether they had face-to-face clinical contact or no clinician contact except via email in some cases. No significant

difference was found between the two groups, regardless of the control condition (waitlist, placebo, or TAU). Spek et al. (2007) conducted *post-hoc* subgroup analyses based on presence or absence of therapist support and found that interventions without support ($n = 6$) had a mean effect size of 0.24 (95% CI: 0.11 to 0.37) and interventions with support ($n = 5$) had a mean effect size of 1.00 (95% CI: 0.75 to 1.24). The authors concluded that effect sizes for anxiety had larger effect sizes but these differences could be explained by amount of therapist support. Andersson et al. (2009) found the presence versus absence of support to moderate overall treatment effect, with supported treatments having an effect size of $d = 0.61$ (95% CI: 0.45 to 0.77) and unsupported therapies having an effect size of $d = 0.25$ (95% CI: 0.14 to 0.35). Richards et al. (2012) performed subgroup analyses based on presence and type of support. Studies that used therapist support and administrative support had a similar pooled effect size ($d = 0.78$ and $d = 0.58$) and a lower effect size was found for studies without support ($d = 0.36$). No significant differences in effect size were found between administrative and therapist support or between no support versus admin support, the difference between no support and therapist support though was significant.

How does CP compare to face-to-face psychotherapy?

Cuijpers (2009) examined CP and face-to-face care in 13 comparisons finding an effect size of -0.06 (95% CI: -0.22 to 0.10) indicating a small, non significant difference in favor of face-to-face care. This conclusion held across type of disorder (panic/agoraphobia, other phobias, other) and system used (stand-alone PC, palmtop computer). Three studies conducted 1 or 3 months follow-ups and no differences were found between CP and face-to-face therapy. Andersson et al. (2009) also found no difference comparing CP and face-to-face therapy. The authors highlight that not finding differences between CP and face-to-face therapy does not

warrant a conclusion that the two forms of therapy are equivalent and emphasize the importance of designing studies to test for equivalence. Barak et al. (2008) identified 14 studies comparing CP with face-to-face therapy and find an effect size for CP of 0.39 and an effect size for face-to-face therapy of 0.34; the difference between the two was non-significant.

Which psychological problems have computerized therapies targeted and which ones have been left out?

Table 2 summarizes the number of studies involving computerized psychotherapies for a variety of psychological problems. In reaching these numbers we have put together all studies targeted by the meta-analyses and eliminated the ones included more than once, resulting in a collection of 130 unique studies.

Most computerized psychotherapies analyzed focused on depression and anxiety disorders and in general on single disorder conditions. No computerized psychotherapy has targeted individuals meeting criteria for multiple disorders (the exception being one study on depression and anxiety) or Axis II disorders. Also, more severe disorders like bipolar disorder or schizophrenia, psychotic disorders in general have not been targeted yet.

What drop-out rates do computerized therapies have?

Cuijpers et al. report drop-out rates between 2 to 29%. No difference was found in drop-out rates in CP versus face-to-face care based on eight studies reporting such data (odds ratio OR = 1.28; 95% CI: 0.81 to 2.03). Richards et al. (2012) found a high drop-out rate (74%) for unsupported treatments. Drop-out was similar for therapist supported (28%) and administrative supported treatments (38%), rates comparable to dropout in face-to-face treatments ranging from approximately 30% to 60% (Piper et al., 1999; Ries & Brown, 1999) as cited in (Richards &

Richardson, 2012). An average of 78% (range between 67% to 100% across studies included) of participants completed the computerized CBT intervention for insomnia (Cheng & Dizon, 2012).

Are computerized therapies acceptable?

Andrews et al. (2010) proposed adherence to treatment and satisfaction as indicators of acceptability of CP to patients. Across their 22 studies they found good adherence, with a median of 80% of people beginning these programs completing all lessons (range 48% to 100%). Ten of the studies provided data on patient satisfaction and a median of 86% (range of 70% to 100%) of patients reported that they were satisfied or very satisfied. Richards et al. (2012) commented individually on the acceptability of CP in the studies analyzed. One study reported that 80% of users were generally satisfied with CP (called Deprexis), 82% reported the program benefitted them and 78% that it met or exceeded their expectations, 74% felt the program equaled or was better than a 'real' therapist and 95% would recommend the program to others. No adverse effects from using the CP were reported (Meyer et al., 2009). Participants using another program for depression and anxiety (called Beating the Blues) found it useful, relevant and easy to use (Learmonth & Rai, 2008). Another study reported 93% of users were satisfied with program received (Cavanagh, Seccombe, & Lidbetter, 2011). Another program on depression received acceptable levels of satisfaction from users and was considered helpful (Perini, Titov, & Andrews, 2009). The Overcoming Depression program received high overall satisfaction ratings from users with the majority finding it easy to use, preferred it over a workbook and reported that it improved their moods (Whitfield, Hinshelwood, Pashely, Campsie, & Williams, 2006). Some users found MoodGym demanding and geared towards a younger age group (Topolovec-Vranic et al., 2010). A study evaluating the computerized CBT intervention for insomnia reported an

average satisfaction of 6.2 (\pm 3.0) on a scale of 1-(extremely dissatisfied) to 10-point (extremely satisfied) scale (Ritterband et al., 2012).

Summary of findings

Based on the eight meta-analyses summarized above, computerized psychological interventions can be efficacious in treating clinical problems, even to an extent comparable to the efficacy of face-to-face therapies. The fact that no significant differences were found when comparing CP to face-to-face therapies should not be interpreted as the two therapies being equally efficacious. Future work should include studies designed to test for equivalence for such conclusions to be warranted. The largest effect sizes have been obtained when treating anxiety disorders. Effects for treating depression seem to be lower than effects for treating anxiety. However, overall the efficacy of CP approaches that of face-to-face therapies with a medium effect overall. The vast majority of interventions have been designed based on CBT and are targeting anxiety disorders and depression although other psychological problems have been addressed. Concerns over drop-out rates, lack on engagement and satisfaction have not materialized. Meta-analyses have found significant differences between CP offering support and not offering support both in terms of effect sizes and drop-out rates pointing to the importance of identifying and testing strategies to keep clients engaged and motivated to continue CP. CP can be efficacious, with even large effects. However, the clinical problems approached so far by CP are mostly single Axis I disorders with a heavy emphasis on depression and anxiety. More complex clinical presentations such as individuals meeting criteria for Axis II disorders, substance use disorders, bipolar disorder, schizophrenia, and psychotic disorders are yet to be targeted successfully by CP. The field of CP research needs to continue to identify new techniques to be able to engage in treatment more challenging clinical populations.

Current Challenges in CP Research

As reviewed above there are promising results in terms of efficacy of CP interventions across a relatively wide array of mental health problems. At the same time future work is needed to address specific challenges faced by CP research.

Need for clarity and consistent terminology

First, the field has lacked consistency of terminology in defining CP interventions. Many terms have been used to describe CP such as web-based therapy, e-therapy, eHealth, computer-mediated interventions, etc. The diversity of technologies and features that can be part of CPs increases their potential efficacy but also the need for clarity and precision in describing them. Barak et al. highlights the need for the field to develop and adhere to consistent terminology and professional standards and he proposed a set of terminology and definitions (Barak, Klein, & Proudfoot, 2009).

Need for replication and independent evaluation

Due to the CP research field being still in its infancy most of the time the developers and evaluators of particular interventions are the same entity increasing the likelihood that the evaluation results are unintentionally biased. Cartreine et al. urges the field to move towards independent validation and comparisons of programs (Cartreine et al., 2010).

Recruitment and characteristics of research sample

Andersson and Titov discuss the advantages and disadvantages of CPs in regards to recruitment of participants, the possibility of undetected negative outcomes, internet-based assessment and diagnosis, the management of co-morbidity, as well as dissemination into clinical settings (Andersson & Titov, 2014).

The majority of participants in CP research are self-referred responding to direct research advertisement, as opposed to being referred by clinicians. From one perspective that is encouraging as it addresses the treatment gap in mental health. With the advent of CPs individuals who were never engaged in care and even assessments have an opportunity to be part of treatment. At the same time difference in characteristics of research subjects compared to individuals seen in clinics raises concerns in terms of generalization of the findings to a clinic population.

Assessment and diagnostic

Assessment and diagnostic represent a crucial part of the research process. Self-report questionnaires are relatively easy to administer via the Internet to screen potential participants for studies. Security of information collected is an important aspect to be addressed. However for more severe clinical populations self-report questionnaires are often not sufficient and more in depth assessment is needed in order to determine the diagnostic picture. Some studies have used the Mini-International Neuropsychiatric Interview via phone to select and describe a clinical sample (Sheehan, Lecrubier, & K.H., 1998). Other studies require patients to first receive a diagnosis in person at a clinic (Hedman, Ljotsson, & Ruck, 2013). However that approach can negatively impact the dissemination potential of CPs.

Tracking and reporting negative outcomes

Reporting of negative outcomes is a neglected aspect of psychotherapy trials in general (Barlow, 2010) but the risk of such problems going undetected is higher for CPs. Potential negative outcomes can occur both during assessment and diagnostic as well as during CP treatment. Without having the client in the room it is more difficult for clinicians to evaluate and respond to distress.

Co-occurring conditions

While most individuals presenting for face-to-face treatments meet criteria for multiple diagnoses most EBTs focus on a single disorder. The problem of co-occurring diagnoses is no different in CP compared to face-to-face therapy.

Following an increase in understanding psychopathology and common underlying mechanisms that create and maintain disorder (Goschke, 2014; Hiatt Racer & Dishion, 2012), the field has witnessed the emergence of trans-diagnostic face-to-face treatments for anxiety (Norton, Hayes, & Hope, 2004), depression (Barlow, Allen, & Choate, 2004), and eating disorders (Fairburn, Cooper, & Shafran, 2003). These treatments target general dysfunctional processes and mechanisms of change common across disorders. Trans-diagnostic treatments are also thought to be easier to disseminate as they have a lower learning curve compared to the plethora of single-disorder treatments they seek to replace. The results from evaluating these treatments are encouraging with large effect sizes being observed (Farchione et al., 2012).

While the vast majority of CPs target individual disorders, two approaches in particular were developed to address co-occurrence of disorders: trans-diagnostic (Titov, Andrews, Johnston, Robinson, & Spence, 2010) and tailored CPs (Johansson, Sjoberg, & Sjogren, 2012).

The trans-diagnostic CP treatments are in line with their face-to-face counterparts and have similar benefits and drawbacks. They address common mechanisms of disorder that cut across individual diagnoses and have the potential to be relevant to a broader group. They also run the risk of missing opportunities to help participants with issues specific to a particular disorder. Adding optional additional material represents a way to address this challenge in CPs. Providing optional material places the selection responsibility on the participant and has the risk of overwhelming participants.

Tailored treatments rely on a selection of content from a set of modules according to participant's specific co-occurring problems (Carlbring, Maurin, Tornngren, Linna, & Eriksson, 2011; Silfvernagel, Carlbring, Kabo, Edstrom, & Eriksson, 2012). Some evidence has emerged to support the superiority of tailored treatments compared to standard approaches particularly for increased severity and co-occurring problems (Johansson et al., 2012). Similarly to having optional material, in CP the responsibility is placed on the participant to decide which components of the treatment apply to them.

The role of the therapist in CP

One of CP's most frequent critiques is an assumed decrease in strength of the therapeutic alliance due to loss of face-to-face visibility, and the resulting inability to perceive and respond to client's non-verbal cues (Wells, Mitchell, Finkelhor, & Becker-Blease, 2007). A decrease in or even loss of the therapeutic alliance, long believed to significantly mediate treatment outcomes, was feared to lead to low credibility and satisfaction, low treatment compliance, high drop-outs and overall decreased efficacy of the interventions.

One way in which computerized therapies have addressed the loss of alliance concern, in a natural progression from face-to-face therapy, has been to use the computer for delivering the largest part of the therapy content but to still involve therapist support, sometimes to a significant degree, for a client going through the program. Such therapist support has been delivered in many ways: though predetermined or on demand phone calls or emails, through therapist's participation in online message boards or chats to answer questions or comments, replying via email to verify homework completion and provide feedback on progress, text messages with reminders or encouragement (Marks et al., 2007). The amount of time therapists spend assisting

each client in CP varies from a few minutes to in excess of five hours for the duration of the intervention (Kiropoulos et al., 2008; Van Voorhees et al., 2009).

When therapist support was provided in these different forms, research has found that the therapy processes as they emerged online were similar to the ones in face-to-face therapy, with some particularities. For example, for clients having contact with therapists via email or chat the therapeutic alliance was rated similarly and sometimes even superior to that of face-to-face therapy (Cook & Doyle, 2002; Reynolds, Stiles, & Grohol, 2006; Schmidt, 2003). Men with high emotionality were found to prefer online therapy more than men with low or restricted emotionality (Rochlen, Land, & Wong, 2004). When computerized therapy was compared to face-to-face therapy in several studies, similar rates of drop-out, credibility and satisfaction were found (Carlbring, Ekselius, & Andersson, 2003; Carlbring, Westling, Ljungstrand, Ekselius, & Andersson, 2001; Dolezal-Wood, Belar, & Snibbe, 1998; Przeworski & Newman, 2006; J. C. Richards & Alvarenga, 2002). One review found the presence of human support to moderate the extent of treatment effects with studies not offering human support having a small effect size while those involving human support having a large effect size (Spek et al., 2007). Thus, it seems that computerized therapies have found ways to maintain the therapeutic alliance through this new communication medium.

Maintaining therapists in CP to provide support can be argued for, considering that the therapeutic alliance can be maintained online and considering that therapist contact improves outcomes. At the same time keeping therapists in the loop is costly and can negatively impact the dissemination of CPs. While therapists can spend significantly less time in CP compared to the time spent in individual, one-on-one therapy, time spent by a qualified professional per client still becomes a bottleneck when considering dissemination on a really large scale. Indeed,

careful analysis needs to be performed to make sure that group therapy is not the more effective option, if we only consider therapist time involved. For example, a therapist conducting weekly two-hour group therapy with 10 clients would have to spend less than 12 minutes per CP client individually assisting the same 10 clients for CP to bring any time savings.

Avenues for decreasing the significant human effort in CP

Involving highly skilled professionals to offer support in CP remains a bottleneck to disseminating computerized therapies on a large scale. One potential solution is to decrease the level of expertise required to deliver the human support. Indeed, several studies investigated this possibility with promising results. A non-inferiority Randomized Controlled Trials (RCTs) found no difference in efficacy of treatment when support is delivered by a technician as opposed to a clinician with more advanced training (Robinson et al., 2010; Titov et al., 2009). Decreasing level of training required to offer CP support in computerized psychotherapies mitigates the problem but does not eliminate it as it still maintains humans in the loop.

Another option to solve the human support bottleneck is to analyze and understand the function of human support both for face-to-face and CP therapy and to propose ways to automate the same functions.

The therapist as an agent of persuasion for change

Assuming that the therapeutic alliance is an important mediator of treatment outcomes two important questions are: a) what do therapists do to promote clinical change and b) how is the strength of the therapeutic alliance impacting outcomes?

A starting point in answering these questions is to review the functions of psychotherapy treatment in general. Linehan describes five functions of treatment: a) motivating and engaging clients, b) enhancing clients' capabilities, c) skills generalization, d) structuring the environment,

and e) motivating and engaging treatment providers (Marsha M. Linehan, 1993). The therapist helps the client build and maintain motivation and engagement with treatment, teaches new skills or new approaches to problematic situations, and helps the client apply these new skills in relevant environments. For clients' lives to be different through therapy, therapy has to ultimately enact some level of change in a person's thoughts, beliefs, and/or actions. This is not to diminish the important role of validation and acceptance in therapy, which help clients tolerate the difficult process of change (M. M. Linehan, 1997; M. M. Linehan & Lungu, 2012).

From this perspective we view the therapist as functioning, at least to some extent, as an agent of persuasion for change. Indeed, persuasion has meant "human communication designed to influence the autonomous judgments and actions of others"(Simons & Jones, 2011). Other definitions of persuasion are "to move by argument, entreaty, or expostulation to a belief, position, or course of action", "to induce to believe by appealing to reason or understanding; to convince"(Merriam-Webster, 2006). These definitions are close to what a therapist attempts to do in many if not all therapy sessions. Our hypothesis is that one implication of a stronger therapeutic alliance is that it makes the therapist better able to persuade a client to become more motivated and engaged in treatment, learn new skills or be willing to risk new approaches and behaviors in different environments. If we see the therapist's function as at least partially an agent of persuasion for behavior change (where we understand behavior as including thoughts, actions, urges, attitudes) the next question is: can we fulfill the same function in a different way than through human contact?

The advent of relational agents

Changing therapy from a face-to-face context to a computer/technology context not only closes avenues for persuasion (such as not being able to see non-verbal communication) but also

opens new ones. Interestingly, some studies have found that bond and working alliance may be achieved even when working with an automated software agent.

Relational agents (RA)– computational artifacts designed to build and maintain long-term social emotional relationships with users - have emerged (Bickmore, 2003). Since a relationship develops in the context of multiple interactions RAs are designed to remember past history and incorporate that to manage future expectations and interactions. Furthermore, the social and emotional aspect are core to developing relationships so RAs are designed to incorporate detailed knowledge of human social psychology and human affect to build relationships as natural as possible (T. W. Bickmore, 2003) p.3.

Such a RA developed by Bickmore et al. at MIT has been used in a health behavior change intervention to increase physical activity. The agent have been constructed to incorporate “relational” skills like empathy, social dialogue, nonverbal immediacy behaviors to build and maintain good relationships over multiple interactions (Bickmore, Gruber, & Picard, 2005). Use of such relational skills significantly increases working alliance, measured through the Working Alliance Inventory (Hovath & Greenberg, 1989) comparing with relational agents that don’t use such relational skills. Such relational agents have also been proposed to foster relationships with older adults and support their exercising (Bickmore, Caruso, Clough-Gorr, & Heeren, 2005). The agent was significantly more efficacious at increasing physical activity versus the standard-of-care. Furthermore, the agent was accepted and liked and, with many participants, it reached the goal of establishing a relationship, sometimes being perceived as more of a person than a machine (“She was nice and friendly, and honest, with the stuff she say.”, “You’d be talking to her and sometimes you forget and think she’s a real person”, “Well, just turning on the computer every night, and realizing that this is not a human being, though I am carrying on an intelligent

conversation with this, with Laura. And, like I said after maybe the third or fourth night, that thought wasn't even in my mind anymore. I was not talking to a computer. I realized it was not a human being but it was not a computer.”) (Bickmore et al., 2005). Conversational agents have also been proposed to help in smoking cessation (Grolleman, van Dijk, Nijholt, & van Emst).

“The Media Equation” is a communication theory supporting the potential of technology to foster connection. The theory hypothesizes that people tend to treat computers and other media as if they were real people and places. The proponents of this theory, Nass and Reeves (Reeves & Nass, 2003) posit that people respond to media as if it were a person, by being polite, cooperative, attributing characteristics like aggressiveness, humor, expertise and even gender. Nass and Reeves demonstrated the following relational effects: a) computers that use flattery or praise rather than criticize their users are liked better; b) computers that praise other computers are better liked than computers that praise themselves; c) users prefer computers that match them in personality over those who don't; d) users prefer computers that become more like them over time than those who maintain a consistent level of similarity, even when the resultant similarity is the same; e) users who are “teamed” up with a computer will cooperate better with a computer (Reeves & Nass, 2003 as cited in Bickmore, 2003) p. 27.

In another example, students interacting with a computer in solving a task responded similarly to how they would to a human being, considering the computer a teammate, being motivated by praise from the computer, and even repaying computers for favors done (Fogg, 1997).

Relational agents have not yet been tailored for the purpose of delivering psychotherapy in the context of mental health disorders. We hypothesize that there is potential in utilizing such

technology in order to maintain some of the gains of a strong therapeutic alliance in therapy while decreasing the cost of maintaining humans in the loop.

The advent of persuasive technology

Persuasive technology has emerged as an area of research investigating the use of technology designed to change attitudes or behaviors of users through persuasion and social influence but not through deception or coercion (Fogg, 2003). Similarly, *persuasive systems* can be defined as “computerized software or information systems designed to reinforce, change or shape attitudes or behaviors or both without using coercion or deception” (Oinas-Kukkonen & Harjumaa).

B. J. Fogg is one of the most prominent proponents of a persuasive technology, if not its creator. His visionary book “Persuasive Technology Using Computers to Change What We Think and Do” (Fogg, 2003) helped conceptualize the field of persuasive technology by organizing the strategies and mechanisms through which computers can persuade. At a high level, he proposes three different functions that computers can fulfill as persuasive agents: *computers as tools*, *computers as media* and *computers as social actors*. The first corner of this functional triad, “computers as tools”, refers to persuading a user towards change by making tasks and activities easier through computers. “Computers as media” refers to the ability of persuading through sensory media to provide interactive experiences to motivate and engage (such as simulations or virtual reality environments). Computers as social actors refers to the property that when individuals use an interactive technology they often respond to it as if it were a living entity, becoming emotionally attached.

Detailing this taxonomy at a finer granularity level B. J. Fogg proposed specific techniques through which computers and technology can persuade.

Persuasive technology has also identified three different *types* of persuasion: *interpersonal persuasion*, *computer-mediated persuasion* and *human-computer persuasion* (Harjumaa & Oinas-Kukkonen; Oinas-Kukkonen & Harjumaa, 2008). Interpersonal persuasion occurs when two or more people interact with one another. Computer mediated persuasion refers to humans persuading other humans through the use of computers (using email, instant messaging, bulleting boards, social networking sites etc.). Finally human-computer persuasion refers to how people are persuaded through the use of computer technology alone.

Five years after Fogg published his book Oinas-Kukkonen and Marjumaa (Oinas-Kukkonen, 2010; Oinas-Kukkonen & Harjumaa, 2008a) reorganized his taxonomy within the Systematic Framework for Designing and Evaluating Persuasive Systems around four different *functions* a persuasive system could fulfill: *primary task support*, *dialogue support*, *system credibility support*, and *social support*. The specific persuasive strategies fitting each of the four categories in Oinas-Kukkonen's Systematic Framework for Designing and Evaluating Persuasive Systems are summarized in Table 3.

Although the field of behavioral health has incorporated findings from the area of persuasive technology, to the best of our knowledge the field of computerized psychotherapies has not followed suit. For example, a single research paper on mental health describing a CP for depression (Langrial, Oinas-Kukkonen, Lappalainen, & Lappalainen, 2014) has been published in the "Persuasive Technology Conference" in all its years of existence (2006-2014) though many papers were published on behavioral health. There seems to be a gap between the research areas of persuasive technology and computerized psychotherapies despite computerized psychotherapies being in effect persuasive systems, systems that fall within the domain of persuasive technology.

Although the CP research area is a story of success so far, with CP's efficacy being proven repeatedly, the field needs to improve *engagement and motivation strategies* in order to engage more challenging clinical groups. Also, we view *persuasion* as a critical component of classic face-to-face therapies that needs to be successfully embodied in CP to support clinical change. Finding new ways of keeping clients engaged in CP, ideally without requiring human contact is clearly a worthwhile goal for advancing CP research.

We consider traditional, face-to-face psychotherapy to fall under the *interpersonal persuasion* category. Components of current CPs that are fully automated (such as an Internet delivered self-help intervention guiding a user through treatment modules) are best categorized as *human-computer persuasion*; however, therapist support through the use of email for example (to provide homework review, feedback on progress) would fall under the category of *computer-mediated persuasion*; we believe CPs can be built that incorporate all functions defined in persuasive technology (*primary task support, dialogue support, system credibility support, and social support*).

The CP system developed in this work incorporates many of the persuasive technology strategies presented above as described in Table 4.

Emotion Dysregulation: Potential Common Maintenance Mechanism Across Disorders

Emotions can be defined as complex, involuntary, patterned, full-system responses to internal and external stimuli (M. M. Linehan, Bohus, & Lynch, 2007). Emotions play a key role in human behavior. They communicate to ourselves and others, organize knowledge and meaning of events, motivate us for action, and influence how well we function in different circumstance and our general level of satisfaction. Emotions significantly impact our perception and engagement with reality.

The vast majority (approximately 85%) of psychological disorders reference some disturbance in emotional processes (Kring & Sloan, 2009). Emotion regulation comprises the set of processes through which emotions are increased, maintained or decreased, experienced or expressed differentially at a conscious or subconscious level (Gross & Thompson, 2007). Emotion dysregulation refers to failure to change the emotional response in a desired way or to having detrimental long term costs when the change happens.

Difficulty in regulating emotions has been proposed as a common maintenance mechanism across a large number of mental disorders (Kring & Sloan, 2009). Borderline personality disorder has been conceptualized as largely a disorder of the emotion regulation system (Marsha M. Linehan, 1993) . For mood disorders, *major depressive disorder* (MDD) and *bipolar disorder* have been conceptualized as disorders of emotion regulation, the former being characterized by failure to up-regulate positive emotion and the latter by failure to down-regulate positive emotion. Level of depression is positively correlated to increased sadness, guilt, shame, irritability while level of mania is positively correlated to elevated pride and euphoria (Kring & Bachorowski, 1999). Depression symptoms have also been found to have a strong association with maladaptive emotion regulation strategies such as rumination, avoidance, problem solving, and suppression (Aldao, Nolen-Hoeksema, & Schweizer, 2010).

Difficulties regulating emotions are also increasingly recognized in the theoretical understanding and treatment development research for *eating disorders* (Brockmeyer et al., 2014). When problems stem from food restriction, eating can function as an emotion regulation strategy in response to stress (Koole, 2009).

The emotions that are difficult to regulate in *anxiety disorders* are fear and anxiety (Kring & Werner, 2004). Theorists have proposed a model for anxiety disorders where failure in

emotion regulation is at the core of symptom development through moderating the consequences of fear conditioning (Cisler, Olatunji, Feldner, & Forsyth, 2010). Failures to effectively regulate emotion have been identified in *generalized anxiety disorder* (heightened emotional intensity, rigid use of emotion regulation strategies), *post traumatic stress disorder* (Brett T. Litz, 1992; B. T. Litz, Orsillo, Kaloupek, & Weathers, 2000), *obsessive compulsive disorder* (overestimation of threat, intolerance of uncertainty, dysfunctional appraisal and control of thoughts and difficulty coping with anxiety as well as with other intense emotions (McKay et al., 2004)), *social phobia* (Goldin, Manber, Hakimi, Canli, & Gross, 2009), and *specific phobia* (Carlsson et al., 2004; Hermann et al., 2009).

Evidence also exists that emphasizes the role of emotion regulation in *substance use disorders* (SUD) (Kober, 2015). Disorders characterized by impulsivity such as *trichotillomania*, *pathological gambling* can also be linked to difficulties in emotion regulation as impulsive action often has the function to avoid an undesirable emotion through a change in mood (Shusterman, Feld, Baer, & Keuthen, 2009; Williams, Grisham, Erskine, & Cassedy, 2012). Evidence has also accumulated to view emotion dysregulation playing an important role in body dysmorphic disorder, where the problematic emotions are fear and disgust. Difficulties in regulating emotions may also underlie problems that don't match a specific diagnosis but can be quite impairing such as problems with anger, aggression (Cohn, Jakupcak, Seibert, Heidebrandt, & Zeichner, 2010), marital difficulties (Bloch & Levenson, 2014), complicated grief (Ogrodniczuk, Piper, & Joyce, 2005), difficulties in care giving (Coon, Thompson, Steffen, Sorocco, & Gallagher-Thompson, 2003), prolonged fatigue (Schutte, Malouff, & Brown, 2008). To conclude, creating a trans-diagnostic treatment targeting emotion dysregulation has potential to impact many disorders and psychological problems.

Dialectical Behavior Therapy (DBT) is an Effective Treatment for Emotion Dysregulation

Dialectical Behavior Therapy (DBT) is an internationally recognized evidence-based treatment (EBT) for clients who meet criteria for multiple diagnoses including Borderline Personality Disorder (BPD; Stoffers et al., 2012; SAMHSA, 2006; Kliem, Kröger & Kosfelder, 2010). Originally developed to address suicidal behavior (Linehan, 1991; Linehan, 1993a; Linehan, 1993b), DBT has been expanded and evaluated as a psychosocial treatment for a wide variety of dysfunctional behaviors (e.g., non-suicidal self-injury, drug use) across multiple disorders. Its success with different psychological problems and attractiveness to clinicians has led to an exponential increase in DBT research conducted. A PsycInfo search shows an average of 10 peer reviewed DBT publications per year from 1993 until 2000, 64 publications per year from 2001 to 2010, and 94 per year since 2011. To date, 28 distinct RCTs have been conducted on DBT and DBT skills only, with a total of approximately 35 publications culminating from these RCTs. The rapid proliferation of research mirrors the clinical enthusiasm about this treatment: over 180 sites nationwide have providers trained in DBT (SAMHSA, 2012).

In terms of DBT's fit for targeting emotion dysregulation specifically, DBT has the most research supporting its efficacy in treating BPD, a disorder of characterized by pervasive emotion dysregulation (Lynch, Trost, Salsman, & Linehan, 2007). For individuals with BPD, DBT has been found efficacious in reducing hospitalizations, suicidal, self-harm behaviors (Koons et al., 2006; M. M. Linehan, Heard, & Armstrong, 1993; McMain et al., 2009; R. M. Turner, 2000) and in improving indicators of emotion regulation such as measures of depression, hopelessness, anxiety, anger (Koons et al., 2006), impulsivity (Verheul et al., 2003) or a direct index of emotion dysregulation (Neacsiu, Rizvi, & Linehan, 2008). DBT has also been adapted to other populations and found effective with depression (Lynch, Cheavens, et al., 2007), eating

disorders (Safer, Telch, & Chen, 2009), trichotillomania (Keuthen et al., 2010), substance abuse (Dimeff, Rizvi, Brown, & Linehan, 2000; M. M. Linehan et al., 1999; van den Bosch, Verheul, Schippers, & Van den Brink, 2002), ADHD (Hirvikoski et al., 2011), incarcerated adults (Shelton, Sampl, Kesten, Zhang, & Trestman, 2009), and stalking offenders (Rosenfeld et al., 2007). Neacsiu and Linehan have proposed a model that highlights the potential for DBT to treat emotion dysregulation trans-diagnostically (Neacsiu, 2012).

Brief DBT Emotion Regulation Focused Skills Improve Emotion Dysregulation

The use of brief intervention and brief therapy techniques (Cummings & Sayama, 1995; Nieuwsma et al., 2012) has become an increasingly important treatment alternative when longer treatments are not feasible due to limited resources or low client interest (Monti, Rohsenow, Michaelc, Martin, & Abrams, 1997). Evidence suggests that DBT skills training briefer than one year is efficacious in improving indices of emotion regulation. A one time intervention teaching three DBT emotion regulation skills to young drinkers was efficacious in improving indices of emotion regulation, depression and anxiety (Whiteside, 2009). A four month DBT skills training targeting emotion regulation across mood and anxiety disorders was efficacious in improving skills use, emotion dysregulation, anxiety, depression and general distress compared to a supportive therapy group; most gains occurred in the first two months of therapy Neacsiu et. al (2012). A six weeks intervention investigated the specificity of the ER skills in improving indices of emotion dysregulation. Compared to the IE skills module and to an activity group teaching the ER skills was superior on laboratory measures of emotion regulation (Bedics, Dixon-Gordon, & Fruzzetti, 2012). These results suggest high potential for brief DBT skills interventions to impact emotion regulation and other general distress.

DBT's Modularity: a Characteristic in Line with Computerization³

Because DBT was built for high risk, multi-diagnostic, complex clients, the clinical problems which were addressed in therapy were complicated. Well-known strategies for approaching and resolving complex problems are modularity and hierarchy. Modularity can be used to separate the functions of a treatment/intervention into independent modules such that each module contains everything necessary to carry out one specific aspect of the desired treatment. At a conceptual level modularity infers separation of concerns by emphasizing logical boundaries between components. For modularity to work in solving a complex problem each module needs to have clearly defined its goals, how to reach them, and throughout this process, how to communicate outcomes or difficulties and problems to be solved with the other modules. When decision making is also involved, modularity needs to be augmented with hierarchy to specify where the responsibility lies in making a decision.

DBT is conceptually modular at several levels. First DBT clearly articulates, at a high level, the functions of treatment that it addresses, namely: 1) to enhance individual's capability by increasing skillful behavior, 2) to improve and maintain client's motivation to change and be engaged with treatment, 3) to ensure generalization of change occurring through treatment, 4) to enhance motivation of therapists to deliver effective treatment, and 5) to assist the individual in restructuring or changing his or her environment such that it supports and maintains progress and advancement towards goals (see Figure 1).

From the perspective of "computerizing" DBT, particularly the skills training component, this modularity is very important because it allows different technical features to be responsible for accomplishing the different functions of treatment. For example the function of enhancing the

³ Adapted with permission from (Lungu & Linehan, 2015)

individual's capabilities described above can be achieved through teaching a new skill through a video format. Improving client's motivation to change and engagement with the treatment can be done via interactive strategies that guide in applying the skills in client's own life. Similarly, ensuring generalization of change occurring through treatment can be done via mobile applications that can prompt the client to practice new skills in their environment away from the therapist's office and away from a desktop computer. Technological features in the environment such as calendars, to-do applications, alerts can organize and prompt behavioral steps needed to generalize change.

Second, to effectively provide DBT's functions, treatment is delivered in a variety of modes (individual therapy or case management, group and individual skills training, between session coaching, and regular team consultation for therapists), each having different targets and also different strategies available for reaching those targets (see Figure 2). There is also clarity in how the different modes of treatment communicate and collaborate. From the perspective of computerizing DBT, this modularity is important because it allows for the modes to be delivered using different technologies and features. Between sessions coaching can be delivered for example via phone (as in standard DBT) but also via an online forum where questions can be asked and the answers reviewed by an individual or the entire group. Coaching can also be done automatically using predetermined decision trees (Rizvi, Dimeff, Skutch, Carroll, & Linehan, 2011).

Third, the skills training itself is modular, in that the content is divided in separate skills that can be taught separately (see Figure 3). Skills are further modular by the topics they address (mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance) such that

clients can work on a single set of skills at a time that limits being overwhelmed by all the things they need to learn and change (see Figure 3).

At the same time, once clients have mastered or made progress in a set of skills they can easily incorporate those skills while working on a new module. Some of the more complex skills, such as the interpersonal assertiveness skills are also modular in that they are comprised of smaller parts, taught separately to increase comprehension and accessibility (see Figure 3). The “DEAR MAN” skill for example is an interpersonal assertiveness skill that targets how to effectively ask for things and say no to demands keeping in mind priorities for the interaction (achieving the objective, maintaining or improving relationships with others, as well as self-respect). The skill is comprised of several steps (Describe, Express, Assert, Reinforce, Mindful, Appear confident, Negotiate, see the original DBT manual (Linehan, 1993) for more details). The skills training is modular also in following the same well defined structure in how the skills training sessions unfold as a succession of steps. This level of modularity in terms of content and structure is also a good fit in terms of computerizing the treatment because it allows for skills to be taught across multiple sessions at the pace that best fits a particular client. The subset of skills taught can also be customized for each client based on the presenting problems. If each skills training follows a similar structure that can be taken advantage of in the development of the computerized modules. Once a skill is developed it can be used as a template for the remaining skills likely bringing down the cost of the entire development.

Conclusion

In this introduction, I highlighted the potential for a brief computerized DBT skills training intervention to decrease emotion dysregulation, a trans-diagnostic mechanism of disorder across mood and anxiety disorders. The support for such an approach comes from

several bodies of research. First, emotion dysregulation has been identified as a trans-diagnostic mechanism of disorder. Second, there is strong evidence to support the effectiveness of standard DBT as well as the skills only component of DBT in decreasing emotion dysregulation across disorders. Furthermore, DBT has a modular structure that favors computerization. Third, there is strong evidence to support the effectiveness of computerized interventions for mood and anxiety disorders. Forth, developments in persuasive technology can address some of the challenges faced by computerized psychotherapies providing strategies to increase potential for such interventions as persuasive agents for change. Figure 5 depicts the influence of these diverse research areas in the development of iDBT-ER.

Current Study

The current study was designed to develop and evaluate the effectiveness of a pilot computerized, trans-diagnostic Dialectical Behavior Therapy (DBT) skills training (Linehan, 1993b) in reducing emotion dysregulation in individuals with significant mental health disorders. The study was designed to be comprised of 2 phases. Phase 1 focused on iterative intervention development through a combination of qualitative interviews and quantitative feedback while Phase 2 focused on evaluating the intervention resulted from incorporating feedback from Phase 1 through an open trial design. The intervention was named iDBT for Emotion Regulation (iDBT-ER) given the emphasis on self-help and on emotion regulation.

DBT Skills Training

As discussed DBT skills training, being a structured, short-term, present-focused, psycho-educational treatment is especially suited for computerization. DBT skills were preferred to other treatments as foundation because they include skills for changing all different components

present in theoretical models of emotion regulation (Gross, 1999) (situation, attention, feedback loops, thoughts, physiological changes and behavioral urges).

Given the study's focus on emotion regulation, and feasibility, iDBT-ER includes the DBT emotion regulation skills as well as two distress tolerance crisis survival skills (selected to cover the area of regulation of intense emotions and based on their high popularity with clients (Lindenboim, Comtois, & Linehan, 2007)). The mindfulness skills were also largely included (the wise mind skill was excluded for feasibility) considering that mindfulness represents a foundation for DBT and awareness of emotion is critical for emotion regulation. Table 6 describes the iDBT-ER skills training curriculum.

In addition to the computerized aspect of iDBT-ER changes were made to the timeline of the treatment. The duration of the treatment protocol was shortened from 24 weeks in standard DBT to 8 weeks. This change was based on the length of other effective interventions as well as for feasibility given the pilot nature of the study. Furthermore, in a 16 week study focusing on teaching DBT skills trans-diagnostically across mood and anxiety disorders in a face-to-face format, the largest clinical change was identified in the first 2 months of treatment (Neacsiu, Eberle, Kramer, et al., 2014; Neacsiu, Eberle, & Linehan, 2014).

Development of iDBT for Emotion Regulation

The iDBT-ER was developed keeping in mind multiple goals in order to respond to established challenges in CPs. Table 5 summarizes the goals we pursued and the resulting intervention features.

iDBT-ER treatment structure

The structure of the iDBT-ER intervention was created keeping in mind the general structure of standard DBT skills training as well as general CBT principles. The treatment structure is illustrated in Figure 5 and Table 6.

The intervention starts with a welcome video from the DBT creator orienting the participant to the goal of skills training particularly skills training for emotion regulation. Key concepts are introduced such as: what emotion regulation is, the focus on participant's goals in regulating emotions, the importance of homework and practicing the skills outside of the program, the strong research support for DBT skills training for emotion regulation (Neacsiu et al., 2008; Neacsiu, Rizvi, & Linehan, 2010).

A more detailed orientation to treatment logistics follows that incorporates information such as topics to be covered (mindfulness and emotion regulation skills) number of sessions and frequency, duration of session, homework assignment and expectation of practice, and use of handouts and worksheets throughout the intervention.

A brief psychoeducational video segment from the DBT creator orients the participants to the connection between mindfulness practice and emotion regulation. That segment was introduced to provide the rationale for starting the treatment with mindfulness and prevent participant's believing that mindfulness is not relevant to them and hence they should not continue with the intervention.

The first session is the only one of the eight that progresses to teaching the first set of mindfulness skills without an initial mindfulness practice. Each session ends with a different brief encouraging video message from the treatment developer that congratulates the participant for completing the session, encourages him/her to practice the skills learned thus far, to return to the program the following week and to fight urges to quit. The last session is followed by a

message again congratulating the participant for completing the intervention, expressing hope that the skills will be useful and saying good bye.

iDBT-ER treatment session structure and components

Figure 6 describes the session structure. Each iDBT session beyond the first starts with an overview of the material to be covered, followed by a 5-7 minute mindfulness practice, a review of the homework from the last session with feedback, troubleshooting barriers to practice if homework was not completed, teaching of new skills, in session practice of the new skills to the extent possible, assignment of the new homework, and finally, troubleshooting what could get in the way to get the assignment completed for the following week.

Mindfulness practice

We included two different types of mindfulness practices throughout the program. Each session starts with a longer mindfulness practice with similar roles to the practice in standard DBT groups: build the skill of mindfulness through practice and increasing awareness of the present moment right before session. The specific mindfulness practices were selected from mindfulness of sounds, breath, sensation on skin, and thoughts. We also included several brief mindfulness practices of less than 1 minute to illustrate that mindfulness can be practiced in everyday life for brief periods of time.

Homework review and feedback

Homework assignment and review are important and efficacious parts of cognitive behavioral interventions in general (Addis & Jacobson, 2000; Burns & Spangler, 2000; Kazantzis, Deane, & Ronan, 2006; Kazantzis & L'Abate, 2010).

The homework review follows the mindfulness practice. We check completion of the following elements of the assignment: a) the skills practice itself (asking participants if they tried

the skill assigned at least once since the last session); b) writing down at least one practice; and c) completing the daily diary card at least 3-4 times during the week.

A negative response to checking the writing of the practice and to diary card completion is followed by encouragement to engage in the behavior for the following week and revisiting of rationale for doing these tasks. A positive response is followed by verbal praise and encouragement to continue performing the behavior.

Not only does DBT assign and check on homework, it also focuses on assessing the barriers getting in the way of homework completion and suggesting strategies for overcoming such barriers (Linehan, 1993). Specifically DBT comprises a technique called “missing links analysis” that entails performing an assessment to identify the factors that contributed to a desired behavior not being completed. Once such factors are identified a DBT therapist works collaboratively with a patient to identify changes that will result in the desired behavior being completed in the future. We incorporated the “missing links analysis” approach to troubleshooting situations in which the patient reports not completing the homework. Figures 7 and 8 present the algorithm for reviewing the homework using the missing links analysis technique under the guidance of the DBT treatment developer.

Another homework review approach common in CBT and DBT is to actually go through the homework completion and check correct performance from the participant. For some of the skills that were comprised of several steps, we added a supplementary homework review component that is asking them if they went through specific components of the skill practice. Figure 9 describes going through the algorithm of asking the participants if they completed different steps of the check the facts skill and providing feedback. Basically the algorithm guides the participant through the steps of the skills and for the steps missed it suggests the participant

engages in that step right then. This is similar to the homework review process in a standard DBT group.

Oftentimes participants encounter challenges in their skills practice, especially in the beginning. After going through the process of reviewing homework completion and troubleshooting what may have gotten in the way to practice skills that week we also assess if the participant had encountered barriers specific to that skill that interfered with the practice. We present common challenges for that skill and ask the participants to indicate which of those they find relevant. For the challenges selected as relevant, we offer suggestions that might help overcoming them. Figure 10 describes the common challenges highlighted and associated suggestions for practicing applying the model of emotion.

Teaching new skills

After the weekly mindfulness practice and the homework review, a session progressed to the teaching of new DBT skills. The presentation of new skills didactic content is primarily done via video instruction segments. The teaching segments have between 5-10 minutes of video material and are interspersed with other activities meant to engage the participants in learning and practicing the new skill such that it is more likely to generalize outside of the skills training session.

The different activities to be performed by participants in between video teaching segments were grounded in DBT theory and approaches, theory for multimedia learning, and theory of information processing.

iDBT-ER Self-Referencing prompts examples

The concept of “self” has been proposed and explored throughout the history of psychology. Allport suggested that there must exist some aspect of personality that allows an

individual when awakening in the morning to be sure he or she is the same person that went to bed the night before (Allport, 1937). Hallowell proposed that people are likely to develop an understanding that they are physically distinct and separable from others (Hallowell, 1955). More recently researchers have studied the relationship between memory and self-related processes arguing that information about the self has superior elaborative and organizational properties in memory and is more frequently accessed (Kihlstrom et al., 1988; Klein & Loftus, 1988; Maki & Carlson, 1993; Markus, 1977). Indeed, information related to the self is better remembered than more general information, a pattern referred to as the Self-Referencing Effect (SRE) (Rogers, Kuiper, & Kirker, 1977). A meta-analysis has found that information encoded in relation to the self is better remembered than information encoded in terms of semantics or in reference to others (Symons & Johnson, 1997).

DBT skills training already incorporates self-referencing by consistently asking participants to consider how the information presented is relevant to them. Such approaches are encouraged throughout the standard DBT skills training teaching notes. Self-referencing prompts were frequent in the video iDBT-ER skills training materials. We incorporated a similar approach in the activities conducted by participants in between these video segments. Participants are prompted to consider their goals and areas in their lives in which they would be interested of applying specific skills.

Table 8 presents iDBT-ER Self-Referencing activities examples. From the first video welcoming participants to the iDBT-ER, the goal of the program is revealed to be that of helping participants regulate emotions they personally want to change (as opposed to emotions that others want them to change). Building on this orientation participants are instructed to consider and select areas in their lives where they would like to be more mindful (be present more,

become a better observer, become better at describing non-judgmentally, participating more). Figures 11 and 12 present example activity asking participant about areas in their lives where they would like to be more mindful in general and better observers in particular. Other self-referencing prompts target to change participant's thinking patterns about their emotions in order to decrease judgment and dysregulation. Figures 13 and 14 present an example asking participants to consider if there are any biological or environmental factors that make it harder for them to regulate emotions compared to other people. If participants endorse those factors the narrator prompts the participant to consider being less judgmental of their particular emotional experiences.

Throughout the sessions participants are also encouraged to select, from a wide range of skills practice options, ways in which they are interested to apply the skills they learn. For example, lists spanning multiple pages present ideas for how to practice the mindfulness skills (observe, describe, participate, one-mindfully, non-judgmentally, effectively), as well as for how to add daily pleasant events to one's life.

iDBT-ER activities: modeling and behavioral rehearsal examples.

Modeling and behavioral rehearsal are core established learning strategies for fostering behavioral change (Naugle & Maher, 2003). Modeling and behavioral rehearsal are especially salient within the context of skills learning and their efficacy has been shown in the context of assertiveness training (Kazdin, 1982; Kazdin & Mascitelli, 1982). In session rehearsal of new behaviors is pervasive throughout standard DBT skills training. We incorporated many activities to promote modeling and behavioral rehearsal in the iDBT-ER program as described in Table 8. Modeling is accomplished through both short videos presenting a character applying the skills taught in different circumstances as well as in brief text and narration based vignettes. A

character named Trevor is introduced in Session 1 of iDBT. He is described to apply the DBT skills in the intervention to better cope with symptoms of anxiety and depression. Throughout the intervention Trevor serves as a model of skills application and generalization in the context of a coherent story.

All the skills taught have activities supporting behavioral rehearsal. Figures 15 and 16 show modeling and behavioral rehearsal of the mindfulness describe skill where participants are instructed to describe an image of a tree and of a couple that appears to be arguing. An example is available for participants to compare their describe content with one provided. The narration prompts noticing of interpretations added on top of what is observed in the pictures as well as of any differences in experience depending on the level of emotional content (describing a couple that appears to be arguing versus a tree).

iDBT-ER activities: planning and scheduling skills practice examples

Additionally participants are prompted throughout the intervention to consider changes they can make to their routines to increase generalization of specific skills. For example, participants are prompted to consider what they would need to be able to practice the ICE water DBT skill (a skill that needs some materials such as ice-packs or ice cubes in the freezer). Similarly, the program asks the participant how their routine could change to incorporate practice of adding pleasant events in their lives.

iDBT-ER activities: repeating information in a different format

It is a general principle in psychology that individuals remember information better when it is repeated. Elaborative rehearsal in which an individual actively thinks about the new content in a meaningful way (for example by relating it to prior relevant information) increases learning more than maintenance rehearsal in which information is purely repeated (Goldstein, 2014).

Furthermore multisensory instructional methods for learning (using multiple senses such as seeing and hearing) can enhance learning of new information (Shams & Seitz, 2008).

Interaction is a common feature of multimedia learning systems and supports a deeper level of content processing. The concept of situated cognition or situated learning proposed by Brown, Collins and Duguid in 1989 posits that contrary to many existing teaching practices that abstract knowledge from context meaningful learning will only take place if it is embedded in the social and physical context in which it will be used (Brown, Collins, & Duguid, 1989). Multiple activities in iDBT-ER conform to principles like elaborative rehearsal, interactivity, situated learning. Figures 19 and 20 for example depict activities in which the users click to reveal how different prompting events and different interpretations can lead to different emotions. The examples use situations that could occur in daily life. The activities are aimed at solidifying understanding of the theoretical model of emotion.

A similar application of the multimedia learning principles described above is on motivating participants to decrease their level of being judgmental by exploring the disadvantages of being judgmental (such as the negative impact on relationships, increasing emotions like anger and frustration, and rendering individuals less effective in changing a problematic situation). Figure 21 presents this activity.

Homework assignment

Planning homework activities and concrete ways in which new skills can be integrated in a participant's life are common strategies in cognitive behavioral therapies. Consistent to standard DBT skills training principles homework is assigned at the end of each session. The homework assignment reiterates several important aspects: a) the rationale behind the in between session practice of generalizing skillful behavior to situations that will make a difference in

participants' lives; b) the specific homework assignment for that week; c) the emphasis on not being perfectionistic about the homework and having realistic expectations about the pace of learning new skills; d) anticipating potential urges to quit and practicing not giving in to such urges; and e) suggestion to track skills practice using the daily diary card.

iDBT-ER homework assignment includes identifying barriers to homework completion as well as troubleshooting solutions. We incorporated these principles in iDBT-ER as described in Table 9. Specifically at the end of each session we assign homework practice and prompt the participant to consider potential barriers that might interfere with plans to practice. Suggested solutions are presented based on the specific barriers participants select as being salient for them for the following week. The participant selects solutions they are willing to try for the following week based on the barriers they anticipate (See Figures 17 and 18).

In between session skills practice prompts

Generalization of new behavior learned in particular of new skills is a critical aspect of CBT in general and DBT in particular. At a high level new behavior needs to happen in relevant contexts for one's life to change for the better.

Homework assignment discussed above is one way of supporting generalization of skills practice. However if homework is only assigned at the end of a session and the participant is not reminded of it until the next session the opportunity for generalization of skills practice is not fully maximized. Behavioral prompts are known to increase the frequency of engaging in a specific behavior. Text messaging deliver behavioral prompts in a participant's environment. Text messaging interventions have been found to be efficacious in the field of behavioral health (Cole-Lewis & Kershaw, 2010; Fogg & Adler, 2009). We considered the fact that some participants might not have text messaging options on their cell phone but might have access to

email. iDBT-ER also included daily messages delivered via text or email message encouraging participants to practice the skills assigned for homework and offering specific suggestions for practice. We opted to also prompt participants to practice mindfulness since mindfulness is such a core component of DBT and emotion regulation. The prompting messages were delivered once a day in the morning.

Daily diary card

Participants in standard DBT are asked to complete a diary card daily to mark their skills practice. We implemented the same concept in iDBT-ER. At the end of the day, participants are sent an email or text message (based on their preference) that incorporates a link to a daily diary card that contains all the skills iDBT-ER covered until that point.

Technical set-up for iDBT-ER

Figure 22 describes the technical set-up enabling the iDBT-ER intervention. Several information components are incorporated into each session. The videos teaching the DBT skills with the DBT treatment developer were professionally recorded and edited with the Final Cut Pro software. The editing process included selecting the most effective teaching material from among multiple takes, segmenting the teaching materials into 5-7 minutes chunks as well as incorporating graphics to support learning and retention (diagrams, animations, images). The final edited videos were uploaded on the video streaming server vimeo.com (www.vimeo.com). The iDBT-ER lessons were assembled into the e-Learning course development software Articulate Storyline (www.articulate.com). Once a session was developed in Articulate Storyline it was ‘published’ according to specific standards (see description below) to be hosted in the Articulate Online Learning Management System (LMS). Users would login to access the iDBT-

ER content through the Articulate Online LMS that would in turn build the content of the lesson by accessing Vimeo on demand to play the teaching videos.

The learning modules (the iDBT-ER lessons) were ‘published’ in Articulate Storyline according to the Shareable Content Object Reference Model (SCORM; www.scorm.com) standard. SCORM defines a specific way of constructing Learning Management Systems and training content so that they work well with other SCORM conformant systems. The SCORM standard governs how the content is packaged (what documents are presented, what is the name of particular content) and how data is exchanged at run-time (what requests are placed to outside providers such as the vimeo.com streaming server to get access to desired content).

In selecting the Articulate Storyline content development software, several options were evaluated including Lectora (www.Lectora.com) and Captterra (www.capterra.com) to identify the package that enabled the type of functionality desired. Demonstration lessons were developed using these software packages that led to identification of their limitations. The software Articulate Storyline (www.articulate.com) was selected because it incorporated the features that allowed for the development of desired functionality in iDBT-ER. Specifically Articulate Storyline includes a scripting language that allows the developer to build an e-learning module (a DBT-ER session) with a flow of information that can branch depending on user preferences. The availability of variables to code for user choices and branch the information flow accordingly allow increased interaction and customization of the content. Variables also allowed for content fields that requested information from a user (e.g. asking users to type in a brief description of a prompting event for an emotion) and that information was later on used in the teaching activities (e.g. by building a model of emotion specific to that participant using the information he or she typed in earlier). Figure 23 shows the Articulate Storyline development

environment including the lesson information flow (on the left) a session slide (in the center), a component editor (on the bottom) and variable management and programming (on the right). Figure 24 details the navigation through a lesson depending on user selection. Specifically the figure captures a point in the lesson navigation where users are asked for their preference of emotion to work on and the lesson continues by presenting examples depending on that user choice.

The Articulate Online Learning Management System was also selected after evaluation of several options including WestNet Learning (www.westnetmlp.com). Articulate Online was preferred for ease of functioning as well as multitude of features that enables user access management and tracking of content access and lesson completion. Figure 25 presents the main activity tracking panel that helps evaluate user activity for all content items. Figure 26 describes the user management panel in Articulate Online presenting options for adding new users to the system, changing their permission access and their membership in user groups. Figure 27 shows the content management panel that allows an overview over activity for each content item and further investigation of completions and progress.

Targeted population

The study focuses on individuals with significant difficulties regulating their emotions. To perform a feasible trans-diagnostic evaluation of the intervention we included individuals diagnosed with a mood or anxiety disorder. To maximize generalizability of the findings and taking into account that emotion dysregulation is a core characteristic in BPD we limited the percentage of participants who met BPD criteria to 30% of the sample. To preserve consistency with prior studies assessing the effectiveness of DBT, similar inclusion/exclusion criteria as described in the DBT literature were used.

We used a predetermined cutoff on the Difficulties in Emotion Regulation Scale (Chapman, Gratz, & Brown, 2004), a measure with strong psychometric properties and widely used in the field, to operationalize emotion dysregulation (e.g. Gratz & Gunderson, 2006).

Specific Aims

Aim 1. The first aim, pursued in Phase 1 of the study, was to develop the computerized iDBT-ER skills training intervention for emotion regulation (cDBT-ER) and evaluate initial feasibility and acceptability to inform revisions. Our goal was to gain insight into the experience of our participants going through the intervention and to learn how to improve the intervention to minimize drop-outs, and maximize acceptability and efficacy. We wanted to incorporate such feedback from Phase 1 of the study into an updated version of the intervention to be evaluated for efficacy in Phase 2. At the same time we wanted the findings from Phase 1 to be generalizable to the clinical population the intervention was aimed at. Thus our goal was to select for Phase 1 a clinical sample from the clinical population that the intervention was designed for.

The primary target of the intervention was to decrease emotion dysregulation in individuals high in emotion dysregulation who met diagnostic criteria for a mood or anxiety disorder.

Phase 1 of the study was not powered for statistically significant results on any of the measured constructs. However we hypothesized that iDBT-ER will lead to an average increase in skillful behavior and mindfulness and a decrease of anxiety and depression.

Aim2. The second aim of the study was to evaluate the efficacy of the iDBT-ER by conducting an open trial with individuals high in emotion dysregulation who also met criteria for at least one mood or anxiety disorder (except bipolar I disorder or depression with psychotic features). We hypothesized the iDBT-ER will lead to statistically significant increased in skillful behavior and

mindfulness as well as statistically significant decreases in emotion dysregulation, anxiety, depression, and general distress.

It is important to note that Aim 2 of this research was not to demonstrate that iDBT-ER works better than other face-to-face psychosocial treatments for reducing mental illness, but rather to demonstrate that iDBT-ER in its computerized, highly disseminable form is itself efficacious at producing change in emotion regulation independent of diagnosis.

The research literature at the time when this study was conducted suggested that DBT skills as a face-to-face group skills training intervention was a promising intervention for emotion dysregulation as well as depression. However, no research was identified at the time the study was conducted to evaluate a computerized treatment model.

We were interested in evaluating the impact of the intervention for the duration of the study and at a 2 months follow-up.

Aim 3. The third aim was to compare the outcomes of the current study with a historical control study that taught DBT skills in a face-to-face format to a similar clinical sample (Neacsiu, 2012; Neacsiu, Eberle, & Linehan, 2014). More specifically the historical control implemented a 16-week DBT skills training intervention for individuals high in emotion dysregulation meeting similar inclusion/exclusion criteria. Our goal was to compare the effect sizes obtained at the end of the current study to the effect sizes obtained at the 2-month assessment point in the historical control study. The two studies used the same measures on the primary and secondary outcomes of interest (emotion dysregulation, skills use, anxiety, depression, mindfulness, general distress).

Method

Participants

Phase 1. Participants were 7 men and women with high emotion dysregulation as defined by a score on the DERS higher than 97 who met criteria for at least one mood or anxiety disorder (except for bipolar I disorder and major depressive disorder with psychotic features). To establish this sample, 28 participants were initially screened for the study by phone. All participants provided informed consent using protocols approved by the University of Washington Human Subjects Division. (See Figure 28 for participant flow and Table 12 for Exclusion Criteria.) Participants were first screened for high emotion dysregulation and for a willingness to participate in computerized therapy without also having an individual therapist. The latter criterion required that some participants terminate pre-existing psychotherapy; thus, to meet phone screen criteria, the participant had to agree to terminate any current psychosocial treatment for the duration of the study.

To maximize the generalizability of our findings we utilized largely the same inclusion/exclusion criteria for selecting participants for Phase 1 of the study as the criteria for the evaluation phase of the study, Phase 2.

We utilized the Difficulties in Emotion Regulation Scale (DERS) and a threshold of 97 at screening to identify individuals high in emotion dysregulation and also as the instrument to measure impact of treatment over time (Gratz & Roemer, 2003).

Participants were excluded if they were at high risk for suicide defined as having had (a) a suicide attempt that occurred more than 1 year prior and current suicidal ideation of any severity, (b) a suicide attempt that occurred within the past year, or (c) current suicidal ideation that included a preferred method and a specific plan. This exclusion criterion was included

because of lack of 24-h access to a therapist and the computerized nature of the study. We considered that given the limitations of the study we could not provide a sufficient level of care for highly suicidal individuals. Such participants were given referrals to other treatment options, including the number for the King County crisis line.

In addition, participants were excluded at the phone screening if they (a) were mandated to mental health treatment, (b) had a chronic and current absence of shelter or an impending jail/prison sentence of more than 3 weeks, (c) lived outside of commuting distance, (d) had received more than five sessions of outpatient DBT (individual or group), or (e) did not have access to email or a phone that they were willing to use for the purpose of the study. They were also excluded if they (e) could not communicate or understand English at sufficient levels to benefit from treatment or (f) were younger than 18.

Given the treatment development and feasibility evaluation for Phase 1 of the study, we utilized a patient-centered iterative treatment development approach. Participants were invited to complete the intervention at our research lab and were interviewed by research staff for approximately 30 minutes following each session. We conducted a quantitative and qualitative analysis to generate feedback from participants with regards to their experience going through the intervention. The feedback from Phase 1 was then incorporated in an updated version of the intervention that was evaluated in Phase 2.

Participants who passed the phone screen were invited to an in-person screening in which they participated in a structured diagnostic interview with study assessors. At this phase, participants were excluded from the study if they (a) met diagnostic criteria for bipolar disorder or a psychotic disorder, (b) met criteria for current chemical dependence or life-threatening anorexia that required immediate treatment, or (c) did not meet criteria for a mood or anxiety

disorder. Also, considering that our goal was to develop a trans-diagnostic treatment across mood and anxiety disorders, we decided to include up to three participants presenting with exactly the same diagnostic pattern. For example, if three participants were to present with solely a diagnostic of depression and social phobia the fourth with the same clinical diagnoses would be excluded. However if a fourth participant presented with diagnoses of depression, social phobia, and generalized anxiety disorder, he or she would be included in the study.

Seven men and women met all inclusion criteria and were invited to participate in the study. Each of these participants met criteria for at least one of the following diagnoses: major depressive disorder (MDD), dysthymic disorder, generalized anxiety disorder, post-traumatic stress disorder, social phobia, specific phobia, panic disorder with or without agoraphobia, obsessive-compulsive disorder, and anxiety disorder NOS. To join the study, participants had to verbally agree to discuss with their medication prescriber to stay on the same dosage of psychotropic medication (if any) throughout the study's duration if that was appropriate for them. Seven participants signed consent for the study and were invited to participate which constituted the intent-to-treat (ITT) group.

Demographic characteristics were analyzed to check for statistically significant differences between individuals who were rejected and those who were accepted for the study. Independent samples t-tests were used to assess differences between groups for continuous variables (age). Mann-Whitney U tests were used to assess differences between groups for ranked variables (highest level of education and level of income). Chi-Squares tests were used to assess differences between groups for nominal variables (gender and ethnicity).

Phase 2. Inclusion and exclusion criteria were very similar for Phase 1 and Phase 2 of the study. Table 12 details the exclusion criteria for Phase 2 of the study. The differences between phases

were the following: a) in Phase 2 participants needed to reside in Washington state for the duration of the study as opposed to within commuting distance in Phase 1; b) in Phase 2 we no longer excluded individuals if three participants were accepted before them with the same diagnoses; c) in Phase 2 participants were required to have access to the internet through a computer.

Twenty five men and women met all inclusion criteria and were invited to participate in Phase 2 of the study and are considered the intent-to-treat sample (ITT).

Similarly to Phase 1, independent samples t-tests, Mann-Whitney tests and Chi-Squares tests were used to assess potential differences in demographic characteristics between the ITT group and the group not accepted into the study.

Procedure

Recruitment

Recruitment was similar for Phase 1 and Phase 2 and included several strategies. We contacted local mental health treatment communities, private practitioners, and counseling centers to provide information about the study and facilitate referrals. Providers who agreed to facilitate recruitment were mailed informational materials and inclusion/exclusion criteria. We distributed flyers, brochures, cards, and posters in libraries, supermarkets, coffee shops, community centers, and universities to publicly advertise the study. Information about the study and referral options was placed in several local newspapers as well as on a website, blogs, and advertising websites (e.g., Craigslist and Backpage).

Initial Telephone Screening

Recruitment materials instructed interested individuals to call the study number to

evaluate eligibility. The Phase 1 and Phase 2 phone screens were similar in questions asked to determine if preliminary exclusion criteria were met. The phone screen for Phase 2 asked participants if they had internet access and if they lived in Washington State.

Participants were given general information about the study, including its computerized delivery as well as a general overview of the phone screening process including the type of questions that will be asked and the option to skip questions or end their participation at any time. The average amount of time required to complete the telephone screening was 20-30 min. Individuals were also told that at the conclusion of the phone screening they may be asked to come to our research facility for an in-person assessment prior to determining if they are an appropriate fit for the study. Any caller not eligible for continued screening (either due to failed inclusion criteria or self-discontinuation from screening) was provided with a treatment referral list.

The initial phone screen questioned gathered the information necessary to evaluate the inclusion/exclusion criteria described in Table 12 and Table 13. We used the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004), as measure of emotion dysregulation to select individuals with high dysregulation for the present study. The DERS is a popular measure of emotion dysregulation and has strong psychometric properties. The same cutoff of one standard deviation above the mean of non-clinical populations was used as in another study evaluating DBT skills training for individuals with mood and anxiety disorders (Neacsiu, 2012; Neacsiu, Eberle, & Linehan, 2014). Participants who scored 97 or lower on the DERS at phone screen were excluded from the study as not meeting criteria for high emotion dysregulation.

Second Screening

A second screening process was used for Phase 1 and Phase 2 to determine complete eligibility for the study. In Phase 1 this secondary screening was done in person and in Phase 2 it was done over the phone. This secondary screening was scheduled when the caller met phone screen eligibility criteria. The second screening started with the informed consent process.

In Phase 1 participants were presented with the informed consent documents, they were allowed time to read them and then a research assistant guided them through the documents highlighting the critical points and answering questions the participants may have had.

For Phase 2 participants were emailed the informed consent documents prior to the second screening and were asked to read them prior to the assessment time. Research assistants again guided them through the informed consent documents highlighting critical pieces of information and answering questions. In Phase 1 participants physically signed the informed consent documents in ink while in Phase 2 they typed their name for the signature and emailed the documents back to the study email address. The additional screening started once the informed consent process ended.

Treatment

Phase 1: the iDBT-ER intervention was provided for both Phase 1 and Phase 2 of the study to be completed without therapist support. Since Phase 1 focused on intervention development feedback from early sessions of the intervention were incorporated into the later sessions of the intervention. Also the 7 participants were divided into two groups. Feedback from the first 4 participants was incorporated into an updated version of iDBT-ER that was presented to the remaining 3 participants. Feedback from the entire Phase 1 was incorporated into the

intervention evaluated in Phase 2. Figure 29 describes the feedback information flow in the development and evaluation of iDBT-ER.

Protocols

Starting Treatment (Phase 1). Two cohorts one of 4 and the other one of 3 participants were iteratively engaged in treatment and provided feedback. The intervention was administered individually through a computer in our research lab and not in a group format. Feedback was solicited individually in a one-on-one interview at the end of each session. Participants were able to start the skills training treatment as soon as they successfully completed the in-person screening and pre-treatment assessments.

Treatment Orientation (Phase 1). Before accessing the skills training intervention, participants went through a brief in person orientation (that lasted approximately 5 minutes) where intervention format, goals, and confidentiality were reiterated. Participants were oriented again to some of the information present in the informed consent form. Namely they were reminded that:

1. The study consists of 8 weekly computerized skills training sessions, with additional reminder/prompt messages provided through their preferred method(s) of contact (via email, SMS, or Twitter);
2. No therapy support was to be provided by the study besides the computerized skills training and reminder/prompt messages;
3. Answers to the reminder/prompt messages would not be monitored by the research staff through any of the communication avenues used (email, SMS) thus participants were told to not use these avenues to communicate any time sensitive information to the research staff;

4. Even though they would be provided with a phone number to contact the study PI (or another research assistant) with questions about the study, that will not be an avenue for engaging in psychotherapy;
5. Crisis help contact information was also made available and given to participants in a printed form and participants were encouraged to call the crisis line in between sessions in the event of experiencing increased distress or an emotional crises not directly related to engaging in study related activities;
6. Were they to experience distress as a direct result of engaging in study related activities they were welcome to contact the study staff by phone at the number provided and someone would respond to their message within 24-48h
7. Participants were given a phone number to call to clarify any potential misunderstanding or ask additional questions of the study at a later time.

Treatment Orientation (Phase 2). The brief orientation that was provided in person to Phase 1 participants was provided via phone for Phase 2 participants or via email if participants granted permission for that communication to be done via email.

Medication management (Phase 1 and Phase 2). Participants on psychotropic medication were allowed to continue their medication treatment under the management of their outside prescriber while participating in the study. To reduce confounding effects, one requirement for study inclusion was for participants to verbally agree to discuss with their provider not changing their medication for the duration of the study if that was appropriate for them.

Treatment and Assessment Termination Policy (Phase 1). Given the treatment development focus in Phase 1 the study assessment and treatment were considered a shared aspect of a subject's study participation. Subjects were told that if they dropped out of the treatment they

also dropped out of the assessment component of the study. Similarly subjects could not drop out of assessments and stay in the treatment component of the study. This point was explained as part of the informed consent process and clarified if a subject expressed a desire to terminate participation in any component of the study.

The intervention lasted for 8 weekly sessions. Participants could not continue accessing the intervention beyond the 8 sessions. Participants who did not show up for 3 scheduled sessions in a row were considered to have dropped out of the study. Participants were contacted by phone after each missed session and reminded of the intervention and their next scheduled session. Participants were also given the chance to reschedule a missed session. A session rescheduled and taking place within the same week of the initial appointment was not considered missed. A subject's participation ended if they expressed a desire to withdraw from the study or request that all contact be ceased. The assessments were completed in the same visit to the research lab. Specifically the baseline assessment was completed before starting Session 1; the mid-treatment assessment was completed after completion of Session 4 and the end of treatment assessment was completed after Session 8.

All participants who wished to receive psychotherapy at the conclusion of their treatment (regardless of whether they dropped from treatment or completed treatment) were given treatment referrals. If participants believed at any point during the intervention that the intervention did not provide them with sufficient therapeutic support were given referral information for other forms of therapy available in the community.

Treatment and Assessment Termination Policy (Phase 2). Given the focus on evaluation of the intervention in Phase 2 of the study participation in the treatment and assessment components of the study was handled differently compared to Phase 1. Participants could stay in the assessment

component of the study after dropping out of treatment. Participants however could not continue in the treatment component of the study without being in the assessment component. In particular participants could not start Session 1 of the intervention without completing the baseline assessment. Similarly participants could not progress to Session 6 of the program without completing the mid-point assessment component (assigned after completion of Session 4).

If a participant did not complete a session within 4 days after it was made available an attempt was made to contact them by phone (if they preferred phone reminders) or by email to remind them of the session. A subsequent attempt was made after 3 additional days if participants did not complete the session. Participants who did not access a session made available to them in two weeks received a phone or email notification that if they did not complete the session in one additional week their access to the intervention would be disabled. Participants who did not complete an intervention in three weeks were considered to have dropped out of the study and their access to the intervention was disabled.

Crisis Response Policy (Phase 1). All participants were asked about suicidal behavior or suicidal ideation as part of the screening assessment. Individuals at high risk for suicide, defined as: a) having had a suicide attempt in last year, or b) having had a suicide attempt more than 1 year ago and experiencing current suicide ideation, or c) experiencing current ideation including having a preferred method and plan, were not included in the study.

Risk for suicide and distress were assessed in relation to the assessment and treatment components of the study. All study assessors and research personnel were trained in the distress/risk assessment and protocols prior to conducting assessments and conducting other study procedures.

Participants were assessed at the beginning of each assessment in terms of current level of stress as well as current urges to engage in self-harm behaviors, to attempt suicide, to binge, to purge, or to use alcohol or drugs. Also at the beginning of each assessment the assessor and participant discussed specific strategies that were likely to be helpful to the participant during the assessment and at the end of the assessment to manage distress. Information obtained at the beginning of assessments was used by assessors to structure and pace the assessment. Breaks were proposed by assessors as needed. The same questions for assessing level of distress and urges to engage in dysfunctional behaviors were asked at the end of the assessment. The assessor then compared the levels of stress and urges before and after the assessment. If there was any elevation in stress or urges at the end of the assessment compared to at the beginning the assessor and participant actively attempted to engage in the activities identified at the beginning of the assessment to reduce distress and made a crisis plan for the participant to follow after leaving the research lab.

All participants were given a printed sheet of crisis numbers to have available if they needed support during a crisis around issues not resulting directly from engaging in study procedures.

Suicide ideation and urges were assessed at the beginning of each computerized treatment session. Those ratings were checked by research assistants while the participant completed the session on the computer. The research assistant alerted the supervisor on call if the participant reported urges higher than a 3 on a 0 to 5 scale (0 = *no urge*; 5 = *extremely high urge*) or if a participant reported having thoughts that they were better off dead more than half the days during the previous week.

A therapist was available to come to the research facility while the participants conducted the online intervention if needed to address any distress occurring from engaging in study procedures. If high levels of distress or suicide ideation were communicated during the computerized skills training the therapist was able to consult with Dr. Linehan or another licensed clinician in person or by phone with regards to the level of risk. Based on the level of risk, the therapist could recommend commitment to a crisis plan, reach out to crisis services, or call 911 if needed. Therapists performing risk assessments were guided by the LRAMP suicide risk assessment and management protocol (Linehan, Comtois, & Ward-Ciesielski, 2012). The LRAMP is comprised of a checklist form that documents the clinician's risk assessment and interventions provided as well as the clinical decision making process.

Crisis Response Policy (Phase 2). Similarly to Phase 1, participants considered at high risk for suicide were not included in the study. Crisis line information was posted on the webpage for easy review at the beginning of each session. At the beginning of each session participants were asked about their suicide ideation. If participants reported experiencing any level of suicide ideation subsequent questions asked them about their intent to carry out a plan to commit suicide, the highest urge they experienced the previous week and their current level of urges to commit suicide. Answers to these questions were monitored twice per day by the research staff.

Participants were considered to be at elevated suicide risk if they reported: a) having thoughts they would be better off dead more than half the days for the past week , or b) intent to carry out a plan to commit suicide higher or equal to a 7 on a scale of 0-10 (0 = *no intent at all*; 10 = *highest intent*), or c) highest urge to commit suicide current or during the past week higher or equal to 3 on a scale of 0-5 (0 = *no urge at all*; 5 = *highest urge*). Participants who were

considered at elevated risk were called by a therapist who followed the LRAMP risk assessment and management protocol by the end of the business day.

Based on the level of risk, the therapist could recommend commitment to a crisis plan, reach out to crisis services, or call 911 if needed.

Assessments

Assessment schedule and protocol (Phase 1). All interviews were conducted by assessors trained to reliability on all assessment instruments. Participants invited to take part in the study were asked to complete a baseline assessment before starting Session 1, then a mid-treatment assessment after completing Session 4 (at 4 weeks after treatment started) and after completing Session 8 (approximately at 8 weeks after treatment started). Each assessment consisted of a 30-40 minutes set of computerized self-report measures. Participants were also asked to complete a brief assessment before each session asking them to rate their level of joy, level of distress, and skills practiced for the previous week as well as their suicide ideation and urges. A brief post-session questionnaire asked participants how useful they found the session and what they would change about the session if they could.

Each assessment covered the following areas of interest: emotion dysregulation, skills use, general distress, and Axis I psychopathology (anxiety and depression).

Given that the primary outcome of the study was emotion dysregulation the DERS was administered both at phone screen and at baseline before starting Session 1.

Participants were interviewed for an average of 30 minutes after completing each session using an interview guide (see Appendix 1). Not all questions on the interview guide were asked for each interview. As the interview progressed, the interviewer had the flexibility to select which topics were more relevant for a participant's experience.

Participants were offered an Amazon.com gift card of \$25 value as incentive to complete each post-session interviews (for a total of up to \$200 in gift cards for each participant). No compensation was offered for completing the screening and treatment assessments.

Assessment schedule and protocol (Phase 2). Similarly to Phase 1 all interviews were conducted by assessors trained to reliability on all assessment instruments. The second screening was performed over the phone as opposed to in person in Phase 1. Participants were asked to complete baseline, mid-treatment, and end of treatment assessments; each assessment consisted of a 45-60 minute set of computerized self-report measures. Assessments covered the same 4 areas of interest evaluated for Phase 1 (emotion dysregulation, skills use, general distress, and Axis I psychopathology (anxiety and depression)) however some additional instruments were added.

Self-report measures were also included to assess feasibility (client satisfaction) as well as potential confounds such as expectancies for treatment efficacy and psychotropic medication usage.

Participants were offered an Amazon.com gift card of \$25 value as incentive to complete each of the assessment interviews (baseline, mid-treatment, end of treatment) for a total of up to \$75 in gift cards for each participant. No compensation was offered for completing the screening assessments.

Assessment measures of emotion regulation.

The Difficulties in Emotion Regulation Survey (DERS; (Gratz & Roemer, 2004)) is a 39 item self-report measure of difficulties in emotion regulation on six domains: a) non-acceptance of negative emotions, b) difficulties engaging in goal-directed behaviors, c) difficulties controlling impulsive behaviors, d) limited emotion regulation strategies, e) lack of emotional

awareness, and f) lack of emotional clarity. Responses are given on a 5-point Likert-type scale ranging from 1 (*almost never*) to 5 (*almost always*). It has high internal consistency ($\alpha = .93$), good test-retest reliability ($\rho I = .88, p < .01$) and adequate validity.

Acceptance and Action Questionnaire (AAQ; (Hayes et al., 2004)) is a 16-item self-report measure of experiential avoidance with excellent construct validity, good test-retest reliability, and adequate internal consistency.

Assessment Measures of General Psychopathology and Distress.

The Overall Anxiety Severity and Impairment Scale (OASIS; (Norman, Cissell, Means-Christensen, & Stein, 2006)) is a 5-item self-report measure that assesses general anxiety experienced in the previous week with strong test-retest reliability ($\rho I = .82, p < .05$), and good internal consistency ($\alpha = .80$). Each item is rated on a 5-point scale ranging from 0 (*little or none*) to 4 (*extreme*) endorsement. The scale has been shown to have good discriminability in identifying individuals who meet criteria for an anxiety disorder. A cutoff of 8 or more on the scale accurately classified 87% of a sample of 925 patients in terms of meeting criteria for an anxiety disorder (Campbell-Sills et al., 2009).

The Patient Health Questionnaire-9 (PHQ-9; (Kroenke & Spitzer, 2002)) is a 9-item self-report measure of depression with high internal consistency ($\alpha = .89$) good test-retest reliability ($\rho I = .84$) over a 2-day interval.

The Outcome Questionnaire (OQ-45; (Lambert et al., 1996)) is a 45-item self-report measure of general psychopathology. It measures functioning along three domains: subjective discomfort, interpersonal relationships, and social role performance. Items are rated on a 5-point Likert-type scale ranging from 0 (*never*) to 4 (*almost always*). The OQ-45 has been reported to have adequate reliability and validity specifically adequate test-retest reliability over a 3-week

interval ($\rho I = .84$), as well as excellent internal consistency (Cronbach's $\alpha = .93$), and validity (Lambert et al., 1996).

Diagnostic assessment measures

Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; (First, Spitzer, Gibbon, & Williams, 1995)). The SCID-I is a semi-structured clinical interview used to assess DSM-IV Axis I disorders. The interview is comprised of six modules for the assessment of: mood episodes; psychotic symptoms; psychotic disorders; mood disorders; substance use disorders; and anxiety, adjustment, and other disorders. We administered all six modules of the SCID-I in the suggested sequence. Assessors rate each item as 1 (*absent*), 2 (*subthreshold*), or 3 (*threshold*). The interview is navigated based on predetermined logic patterns. The SCID-I was administered as part of the secondary screening, which was done in person for Phase 1 and over the phone for Phase 2.

Structured Clinical Interview for DSM-IV Axis II Personality Disorders-BPD Module (SCID-II-BPD; First, Spitzer, Gibbon, & Williams, 1997). The SCID-II-BPD is part of the broader SCID-II for assessment of personality disorders. We used solely the SCID-II BPD as we were interested in identifying individuals meeting criteria for Borderline Personality Disorder (BPD) to avoid over-representation of such patients in the study sample. Similarly to the SCID-I the language of SCID-II criterion items closely resembled the diagnostic criteria in the DSM-IV. Assessors rate each item as 1 (*absent*), 2 (*subthreshold*), or 3 (*threshold*).

Additional measures

The Brief Demographic Data Survey (B-DDS) is a face-valid questionnaire that was administered as part of the phone screening to collect information about gender, sexual orientation, racial and ethnic background, marital status, and income.

Brief Treatment History Interview (B-THI). The B-THI is an adaptation of the Treatment History Interview (THI; (Linehan & Heard, 1987) that assesses for ongoing mental health treatment including face-to-face therapy, hospitalizations, and psychotropic medication (including type prescribed and reason for prescription).

Client Satisfaction Questionnaire (CSQ; Attkisson & Zwick, 1982) is an 8-item face-valid self-report measure of individuals' satisfaction with specific aspects of the treatment. The CSQ has excellent internal consistency (Cronbach's $\alpha = .93$) and significantly correlates with clients' self-ratings of global improvement ($r = .53, p < .001$) and with therapists' estimates of client satisfaction ($r = .56, p < .01$). The CSQ was administered at the end of treatment.

Data Management and Analysis

Power analyses

The sample size for the current study was determined considering a prior study that evaluated a face-to-face intervention delivered to a similar clinical sample (Neacsiu, 2012; Neacsiu, Eberle, Kramer, et al., 2014). Neacsiu and others found a large effect-size $d = 0.89$ for the emotion regulation using the DERS scale at a 2 months assessment. Considering the same effect size a sample of 12 individuals was needed to detect such a large effect for $\alpha = .05$ and a power of .80. Twenty-five participants were included in Phase 2 to allow for a detection of effect size in the presence of a high drop-out rate and a potentially attenuated effect due to the computerized nature of the intervention.

Data management

Assessors and participants entered all data directly through an online interface into a catalyst survey. All data were cleaned for logical inconsistencies and other types of errors using

SPSS version 19. In addition, frequency counts and cross-tabulations were generated to check for outliers and consistent relationships among the variables.

Outcome domains

We considered two primary outcome domains to be of main theoretical interest in this study: emotion dysregulation and skills use. We also included three exploratory outcomes of interest: general distress, emotional distress, mindfulness, and reduction in psychopathology.

A Bonferroni correction was employed to control for multiple comparisons in emotion dysregulation. The main outcome measure for skills use was the DBT Skills Subscale score from the DBT-WCCL.

On each of these outcome variables, we hypothesized significant changes as treatment progressed over time. Primary analyses were conducted on intent-to-treat participants (i.e., those who completed the pretreatment assessment and the first session), and treatment completers; results from each sample are reported. Analysis of potential confounds are also examined.

Treatment attendance and satisfaction

Treatment satisfaction data was analyzed for the Client Satisfaction Questionnaire (CSQ). Participants were also asked about their urges to quit treatment at the beginning of each session in both Phase 1 and Phase 2. We also discuss the rates of drop-out.

Statistical analysis strategy

Normality assumption. Data were analyzed to determine whether they satisfy the normality assumption required for later analyses. Particular forms of the General Linear Model (GLM) such as Analysis of Variance, Analysis of Covariance, Linear Regression, Longitudinal and Mixed Effect Model can be used for analyses when the normality assumption is satisfied.

When data is not normally distributed transformations can be applied to change the form of the distribution towards a normal one.

The Shapiro and Wilk (1965) statistic can be used to evaluate whether a distribution is normally distributed. The Shapiro-Wilk W test statistic ranges from 0 to 1. The closer a value is to 1 the more normal the distribution for the data. The Shapiro-Wilk statistic is applied at a univariate level. Data was tested for normality at each assessment point. We made the assumption that if data is normally distributed at each assessment point the entire set is fitted for longitudinal analysis under the GLM.

Longitudinal outcome analyses (Phase 1). Given the pilot nature of the study and the small sample size (5 complete sets) of the Phase 1 of the study, we analyzed the outcome data using paired sample t-tests. A paired sample t-test was run between the pre-treatment and the mid-treatment and another one between the pre-treatment and the end of treatment values. This approach allowed use of all data gathered for the mid-treatment assessment.

Pearson's correlation is widely used as an effect size for paired quantitative data. Pearson's r can vary in magnitude from -1 to 1 . Effect sizes lower than $.01$ are considered small, between $.01$ and $.30$ are considered medium and above $.50$ are considered large.

Longitudinal outcome analyses (Phase 2). The primary data analytic tool for Phase 2 of the study was hierarchical linear modeling (HLM; (Bryk & Raudenbush, 1992)) also known as mixed effects or multilevel modeling (Pinheiro & Bates, 2000). Compared to other methods, including the repeated measures ANOVA method used for Phase 1 of the study, HLM is more flexible as it treats time as a continuous factor. HLM models allow for variability in rate of change over time and in starting point (intercept) for each participant. Another advantage of HLM is that it can handle missing data points in the sample without needing to delete incomplete

data sets. For data to be fit to be modeled with HLM it needs to meet assumptions for homoscedasticity, normality, and independence of the error terms. Tests were conducted to evaluate each of these assumptions and the assumptions were met unless otherwise noted.

Our primary hypothesis for Phase 2 of the study was that participants will improve with time across all outcomes of interest. In order to test this hypothesis, growth curve analysis was used to estimate baseline and change in observed outcomes for each participant during the intervention. We tested separate growth curve models for all variables of interest (emotion dysregulation, skills use, mindfulness, general distress, anxiety and depression) to test for mean change and variability in change. The use of growth curve models allowed us to estimate individual slopes and intercepts for all participants in the sample, as well as sample-average slopes and intercepts.

A series of nested models with increasing levels of complexity (fixed intercept, fixed time; random intercept, fixed time; fixed intercept, random time; and random intercept, random time) were tested to determine the best model fit among the ones considered. The unstructured and autoregressive heterogeneous covariance structures were also tested to determine the best model fit. The final considered model and covariance structure were analytically determined based on a mixture of chi-squares in comparing nested models and model fit criteria (Verbeke, 1997). All analyses were conducted using SPSS 19.0 (Corp., 2010).

Confound analyses (Phase 2).

An iterative process was used to assess whether confounding factors explained significant variance within each outcome model. The potential confounds were initially added to the outcome model as a main effect. If the main effect corresponding to a potential confound was significant, the confound was added to the final model as a covariate. For the DBT-WCCL, OQ,

PHQ-9 and OASIS, significance was set to a p value lower than .05. For DERS, and AAQ, significance was considered to be a p value lower than .025 (using a Bonferroni correction for two multiple comparisons). The following potential confound were evaluated: age, expectancies for improvement evaluated at pre-treatment, whether a participant reported receiving therapy or being prescribed psychotropic medication in the prior year, whether they reported receiving therapy from outside the study for the duration of the study, whether they reported being prescribed new medication during the study.

Completer analyses (Phase 2).

Separate analyses were completed for the group of participants who did not drop out of the study.

Qualitative Analysis and Iterative Intervention Design and Implementation

Data Collection.

Semi-structured feedback interviews lasting approximately 30 minutes were conducted with all Phase 1 participants immediately after completing the iDBT-ER sessions. Interviews were conducted by research assistants who received focused training for this task. No interviews were conducted by the principal investigator to minimize the deference effect (people telling what they think investigators want to know in order to not offend) (Bernard & Ryan, 2010) p33. This set-up was selected such that it would maximize participant's recall of their experience going through each session. All interviews were video recorded. Interviewers asked questions from the interview guide (see Appendix 1) and took detailed notes during the feedback sessions. Immediately following the interview interviewers revised the notes and added content and clarification if needed. Notes and video recordings were watched by the study PI and the notes were updated to reflect this additional review.

The interview guide was intended to cover a wide range of questions about the different components of the intervention and allow the interviewer to be flexible about which questions to select. It was expected that interviewers would not be able to ask all the questions in the interview guide in each encounter due to limited time. Probing questions were provided to help elicit further information in cases where responders did not elaborate specific points. Several kinds of probes were utilized. The “Tell-Me-More” probe was utilized by asking participants to elaborate on the reasons why they gave particularly high or low ratings on specific elements of the intervention. The “Echo” probe and “Uh-huh” probes were also used to encourage participants to reveal their feedback (p. 31-32, Bernard & Ryan, 2010) where participants are encouraged to expand on points they already made. Interviewers were prepared to jog people’s memories by providing specific descriptive details about a particular session such that a participant could better remember their in session experience (p. 38, Bernard & Ryan, 2010).

The interview guide contained an initial set of quantitative questions asking for ratings on usefulness of several components of the intervention (mindfulness practice, written teaching content, video teaching content, video vignettes illustrating skills application, in session practice of skills, quizzes, written case examples, homework review and homework assignment). These initial questions were used to allow the interviewer to identify particular areas of high satisfaction or high dissatisfaction with intervention components and then to probe more around those areas. To maximize efficient use of time interviewers asked more questions about the components participants particularly liked or disliked as opposed to components they reported feeling more neutral about.

At different points in the intervention development process the emphasis changed in the questions asked of participants. For example, in the beginning of the iterative development

process we addressed dissatisfaction with the homework review process. Since homework review is such a critical component for CBT and DBT interventions and presents significant challenges from a computerization perspective we initially allocated significant time to get feedback around that component. Once we addressed the homework review component to the point that participants no longer expressed particular dissatisfaction with it we switched the focus of the interviews to other areas.

Data analysis and interpretation.

An a-priory codebook was created for the intervention that identified themes to look for in the feedback interview content. Table 32 describes the codebook and the type of information sought.

We were interested in feedback on both content and functionality of the iDBT-ER intervention. Specifically we were interested in direct feedback from participants on specific content elements. We wanted to see if particular content items were unclear, were liked or disliked to adjust them accordingly. As participant made comments that could be categorized according to the codebook that information was extracted into a separate spreadsheet.

We were also interested in feedback on specific functions of the intervention. For example we wanted to know if participants find the homework assignment or homework review process acceptable and useful. Similarly we were interested in whether the in between session messages were considered useful overall and also if there were particular units of content within the messages that were perceived as useful or not-useful. Since feedback data was available from multiple participants, we looked for themes in responses, or for participants providing concordant feedback both at the level of feedback and functionality. Both notes and video recording of interviews were reviewed for analysis.

Results Phase 1

Participant Demographics

The seven participants accepted into the study were primarily single, White women who had either completed some college or were college graduates and were employed outside the home. Most participants earned less than \$10,000 per year. The most common current axis I disorders were generalized anxiety disorder (GAD; 57.14% of participants), posttraumatic stress disorder (PTSD; 57.14%), major depressive disorder (MDD; 28.57%), substance abuse or dependence (28.57%) and specific phobia (28.57%). A minority of the sample met criteria for BPD (28.57%). All participants who did not meet criteria for MDD at screening met criteria for MDD in the past.

Missing Data

For Phase 1 of the study participants could not drop out of the treatment and still continue the assessments. Data was missing from one participant at both the 4 week and 8 week assessment points and from one participant at the 8 week assessment point. Table 7 contains a break down as well as the reasons for the missing data.

Longitudinal Outcome Analyses

Table 22 presents the results comparing participants at the beginning and end of treatment. On average participants experienced significantly lower emotion dysregulation at the end of the study ($M = 87.6$, $SE = 7.0$) than at the beginning of the study ($M = 125.0$, $SE = 9.17$), $t(4) = 4.35$, $p < .05$, $r = .9$. Participants used significantly more skills at the end of treatment ($M = 2.05$, $SE = 0.10$) than at the beginning ($M = 1.47$, $SE = 0.09$), $t(4) = -4.37$, $p < .05$, $r = -.9$. Participants also experienced significantly less anxiety at the end of treatment ($M = 5.4$, $SE =$

1.28) compared to the beginning ($M = 10.2$, $SE = 1.62$), $t(4)=8.23$, $r=.97$. Similarly participants reported being more mindful at the end of treatment ($M = 3.27$, $SE = 0.21$) than at the beginning ($M = 2.60$, $SE = 0.24$), $t(4) = -3.24$, $p<.05$, $r=.85$. There was a trend for participants experiencing less depression at the end of treatment ($M = 7$, $SE = 2.28$) than at the beginning ($M=12$, $SE = 2.58$), $t(4) = 2.75$, $p = .051$, $r = .80$.

Table 23 presents the results comparing participants at the beginning and mid treatment. In terms of the mid-treatment assessment point participants reported significantly less anxiety at mid-treatment ($M = 7$, $SE = 0.85$) compared to the beginning of treatment ($M = 10.83$, $SE = 1.47$), $t(5)= 4.05$, $p<.05$, $r = 0.87$. There was a trend for participants experiencing less emotion dysregulation at mid-treatment ($M=111.33$, $SE = 8.14$) than at the beginning of treatment ($M = 128$, $SE = 8.07$), $t(5) = 2.19$, $r = 0.69$. Similarly there was a trend for participants to report using more skills at mid-treatment ($M = 1.66$, $SE = 0.08$) than at the beginning of treatment ($M=1.47$, $SE = 0.07$), $t(5) = -2.4$, $p=.055$, $r = .74$. Results for mindfulness and depression were not significant and did not reveal a trend.

Qualitative analysis

Qualitative analysis

A dialectical tension was identified in transforming the feedback from participants into changes to the intervention. On the one hand, the goal in the iterative design process was to respond to as many points of dissatisfaction from users as possible. On the other hand, we wanted to preserve therapeutic elements that had a strong research base for effectiveness. Some decisions on how to change the intervention needed a resolution to this dialectical tension.

For example some participants resented the concept of homework altogether and had a negative response to being asked to do homework. At the same time homework is a critical part

of CBT/DBT interventions. We decided to resolve this tension by keeping the homework assignment component and adding elements linking the homework to participant's goals, encouraging letting go of perfectionism while doing homework, giving suggestions for addressing willfulness in doing the homework, etc. Relatedly some participants reported feeling ashamed when asked by the program about the homework due to not completing the homework. We added a narrative component to be traversed on the first homework review if a participant has not done the homework. The narrative component introduces in detail the missing link analysis approach and addresses potential shame. The participant is guided through an analysis that identifies whether homework was completed, whether shame was experienced, etc.

Some examples are provided in Table 33 on the type of changes implemented in the iDBT-ER intervention as a result of Phase 1 feedback. Changes were made to how the homework was assigned and reviewed, to the amount of narration, to the video vignettes included, to the content of text and email messages sent as reminders.

Satisfaction with treatment

Several indicators of participant satisfaction were measured on a weekly basis while others were retrieved at the end of treatment. Treatment drop-out, urges to quit, and perceived usefulness of sessions were indicators available on a weekly basis. The client satisfaction survey was given at the end of treatment. Figure 31 presents the data for weekly urges to quit treatment (scale of 0 to 5; 0 = *no urge*, 5 = *highest urge*). Of the two participants who dropped treatment, Participant 2 reported being ambivalent to start treatment as she was working with a therapist she was reluctant to terminate therapy with. Participant 5 dropped treatment at session 6 after mentioning the week before (session 5) that she had urges to quit the treatment because she was feeling much better. The ratings of satisfaction (CSQ; $M=23.60$, $SD = 2.88$) were similar to

ratings obtained for treatment as usual in community mental health settings ($M=23.75$, $SD=6.84$) as reported by Lunnen et al. (Lunnen, Ogles, & Pappas, 2008).

Adverse events

One adverse event took place during Phase 1 of the study. One of the video teaching materials contained an image of a house on fire to illustrate a story about fear and when fear fits the facts. One of the participants had PTSD around a traumatic event involving a fire and had a strong reaction to the image. The situation was identified during the feedback interview and addressed by assisting the participant to handle the distress. The study materials were reviewed and images that could potentially be triggering for individuals with a traumatic history were removed (the house on fire, the image of a robbery, and the image of a soldier).

Results Phase 2

Participant Demographics

Twenty-five participants entered into the study were primarily single, White women who had either completed some college or were college graduates and were employed outside the home. Most participants earned more than \$10,000 per year. Four participants reported a past suicide attempt and 8 had suicidal ideation at the time of the study.

The most common current axis I disorders were generalized anxiety disorder (GAD; 52% of participants), posttraumatic stress disorder (PTSD; 40%), major depressive disorder (MDD; 64%), and social anxiety disorder (28%). A minority of the sample met criteria for BPD (16%).

Missing Data

For Phase 2 of the study participants could drop out the treatment and still continue in the assessment part of the study. Data was missing from three participants at the 4 week assessment

point and from 6 participants at the 8 week assessment point.

Longitudinal Outcome Analyses

Outcome analyses were conducted to assess each of the four domains of interest: emotion dysregulation, skills use, general distress, and psychopathology. Table 21 includes means and standard deviations for each outcome broken by assessment time point.

Confounding Factors Analyses

The only confounding factor that explained significant variance of any of the outcomes was expectancies for improvement evaluated at pre-treatment. Expectancies was added as a covariate for the model evaluating changes in emotion dysregulation (DERS), skills use (DBT-WCCL), and depression. None of the potential confounding factors explained significant variance for any outcome measure and therefore no covariate was added to outcome analyses. There was a trend for use of medication to be a significant predictor for skills use ($p=.06$), affect control and alexithymia ($p=.02$, $p=.08$ respectively), general distress ($p=.06$), shame and anger suppression ($p=.02$). There was a trend for expectancies to be a significant covariate for general distress ($p=.07$) and for anger expression ($p = .04$). Expectancies for improvement was thus added as a covariate to the models for skills use (DBT-WCCL), depression (PHQ9), general distress (OQ45), and emotion dysregulation (DERS).

Compliance with Study Protocols

Compliance with study protocols was evaluated at the end of the study. Specifically we were interested if participants received psychotherapy from other sources outside of the study. Only one participant reported receiving additional therapy for the duration of the study (for 5 sessions). Another potential confound we investigated at the end of the study was if participants

were prescribed new psychotropic medication during the study. One participant reported being prescribed new psychotropic medication during the study.

Tables 27 and 28 present the slope estimates for all outcomes for the ITT and completer sample respectively. Overall significant results were obtained in the predicted direction signifying improvement across all outcomes measured.

Emotion Dysregulation as an Outcome of Treatment

Two measures for emotion dysregulation were employed: the DERS, and the AAQ. Bonferroni adjustments were made for multiple comparisons and significant values were set at $.05/2=.025$.

All participants in the ITT sample received the DERS both at phone screen and at pre-treatment. The scores at pre-treatment were used for all analyses as baseline. The random intercept, fixed slope represented the best model for the data. There was a significant effect for intercept, $F(1, 37.35) = 786.91, p < .01$ and a significant effect for time, $F(1, 42.73) = 30.53, p < .01$, suggesting that participants started treatment at different levels of emotion dysregulation but followed a similar slope in improvement in emotion dysregulation during treatment (Figure 31). In completer analyses, the same random intercept, fixed slope model represented the best fit for the data.

For the second measure of emotion dysregulation, the AAQ a random intercept, random slope with unstructured covariance represented the best model for the data. There was a significant effect for intercept, $F(1, 25.02) = 2184.92, p < .01$ and a significant effect for time $F(1, 23.64) = 21.98, p < .01$ suggesting that participants started treatment at different levels of emotion dysregulation as measured through the AAQ and followed different slopes in improvement in

emotion dysregulation during treatment (Figure 32). In complete analyses the same random intercept, random slope model represented the best fit for the data.

Skills Practice as Outcome of Treatment.

For the model analyzing skills practice the expectancies for success at pre-treatment represented a significant effect and were included as a covariate in the model. The random intercept, fixed slope represented the best model for the data. There was a significant effect for intercept $F(1, 27.86) = 25.07, p < .01$ and a significant effect for time $F(1, 45.32) = 28.67, p < .01$ suggesting that participants started treatment at different levels of skills practice but followed a similar slope in improvement during treatment. The effect of expectancies for success at pre-treatment was also significant $F(1, 26.10) = 10.97, p < .05$ suggesting that individuals with higher expectations for success had better results in treatment (Figure 33). In complete analyses the same random intercept, fixed slope model with expectancies for success as covariate represented the best fit for the data.

Mindfulness as Outcome of Treatment.

For mindfulness the random intercept, random slope model with unstructured covariance represented the best model for the data. There was a significant effect for intercept $F(1, 24.92) = 885.58, p < .01$ and a significant effect for time $F(1, 22.49) = 18.38, p < .01$ suggesting that participants started treatment at different levels of mindfulness as measured through the KIMS and followed different slopes in improvement in mindfulness during treatment (Figure 34). In complete analyses the same random intercept, random slope model represented the best fit for the data.

Psychopathology as Outcome of Treatment.

Measures of anxiety (OASIS) and depression (PHQ9) were used as main indicators of

psychopathology. For our analysis of anxiety the random intercept, fixed slope represented the best model for the data. There was a significant effect for intercept $F(1, 39.02) = 172.13, p < .01$ and a significant effect for time $F(1, 44.30) = 9.05, p < .01$ suggesting that participants started treatment at different levels of anxiety but followed a similar slope in improvement in anxiety during treatment (Figure 35). In complete analyses the same random intercept, fixed slope model represented the best fit for the data.

Expectancies for success of treatment accounted for significant variance in the model for depression and were included as a covariate. The random intercept, random slope model with unstructured covariance and expectancies for success as a covariate represented the best model for the data. There was a significant effect for intercept $F(1, 32.21) = 81.22, p < .01$ and a significant effect for time $F(1, 24.35) = 22.20, p < .01$ suggesting that participants started treatment at different levels of depression as measured through the PHQ9 and followed different slopes in improvement in depression during treatment (Figure 36). In complete analyses the same random intercept, random slope model, with expectancies for success as a covariate represented the best fit for the data.

General Distress as Outcome of Treatment

Expectancies for success of treatment accounted for significant variance in the model for general distress and were included as a covariate. The random intercept, random slope model with unstructured covariance and expectancies for success as a covariate represented the best model for the data. There was a significant effect for intercept $F(1, 29.41) = 109.16, p < .01$ and a significant effect for time $F(1, 24.05) = 22.55, p < .01$ suggesting that participants started treatment at different levels of general distress and followed different slopes in improvement in general distress during treatment. In complete analyses the same random intercept, random slope model,

with expectancies for success as a covariate represented the best fit for the data.

Satisfaction with treatment

Similarly with tracking participant satisfaction in Phase 1 several indicators of participant satisfaction were measured on a weekly basis while others were retrieved at the end of treatment. The client satisfaction survey was given at the end of treatment. Figure 31 presents the data for weekly urges to quit treatment (scale of 0 to 5; 0 = *no urge*, 5 = *highest urge*).

The treatment retention rate in iDBT-ER was 80%, which is slightly higher than 65% the retention rate reported for Beating the Blues, another 8 week computerized intervention for anxiety and depression (Proudfoot et al., 2004) as reported in (Kaltenthaler, Parry, Beverly, & Ferriter, 2008). The 80% retention rate is lower than the 90.9% retention reported at 2 months for the historical control study. However, in the historical control participants committed in the beginning to a 16 week intervention, which might impact retention at the 2 month time.

The ratings of satisfaction (CSQ; $M=24.94$, $SD = 4.82$) were slightly higher than the ratings for Phase 1 and slightly higher than ratings obtained for treatment as usual in community mental health settings ($M=23.75$, $SD=6.84$) as reported by Lunnen et al. (Lunnen et al., 2008).

Adverse events

One participant with a long history of dissociative episodes reported experiencing dissociation after viewing a session. She could not identify specific aspects of the intervention that she could attribute the dissociation to. One participant dropped out of treatment after the first two mindfulness sessions reporting that she is experiencing too much emotion in an interpersonal environment that was not supportive or encouraging of that. The participant reconnected with her prior therapist for handling the distress.

Comparison to Historical Control

One of the aims of the study was to permit a tentative comparison of treatment impact of DBT skills training targeting emotion dysregulation trans-diagnostically across mood and anxiety disorders in a computerized versus face-to-face delivery (Neacsiu, 2012; Neacsiu, Eberle, Kramer, et al., 2014). Given the pilot nature of the current study and the small sample size, our goal was not to evaluate equivalence between the two treatments but rather to enable a very preliminary comparison.

The historical control study and the current study targeted a similar clinical sample: individuals with high emotion dysregulation who met diagnostic criteria for mood and anxiety disorders. Furthermore, both studies used very similar inclusion and exclusion criteria and the same threshold on emotion dysregulation to define the ITT sample. The historical control study delivered DBT skills training over a 4 month treatment. The group DBT skills training sessions in the historical control study were led by two therapists and took an average of two hours. Over the 8 weeks considered for comparison iDBT-ER made available up to approximately 8 hours of skills training while DBT-ST up to 16 hours. The iDBT-ER had no therapist support and sessions were designed to be completed within one hour each week. The specific DBT skills taught in both treatments overlapped to a significant degree but were not the same. Results of the comparison need to be interpreted with caution. We compare the end of treatment outcomes for iDBT-ER with the results obtained on DBT-ST at the 2 month assessment point. Table 29 summarizes descriptives for both studies as well as Cohen's d effect sizes across the measures that were common between the two studies.

In terms of the main outcomes of the current study iDBT-ER had a pre-post effect size $d = 1.14$ and DBT-ST a larger effect size of $d = 1.29$. Both studies had the same effect size of $d =$

1.11 for skills practice. Descriptively DBT-ST had a higher effect size for anxiety (OASIS; $d_{DBT-ST}=2.0$ compared to $d_{iDBT-ER} = 0.98$), depression (PHQ9; $d_{DBT-ST}=1.56$ compared to $d_{iDBT-ER} = 0.69$), and general distress (OQ45; $d_{DBT-ST}=1.24$ compared to $d_{iDBT-ER} = 1.00$). iDBT-ER had a large effect size for mindfulness compared to DBT-ST ($d_{DBT-ST}=-1.07$ compared to $d_{iDBT-ER} = -0.02$).

Discussion

Main Findings

First and foremost the current study is grounded in prior research on DBT that has produced and evaluated a highly efficacious treatment for decreasing emotion dysregulation in severe clinical populations. The current study also builds on previous theoretical and empirical work that proposed to use DBT skills training to decrease emotion dysregulation trans-diagnostically across mood and anxiety disorders (Neacsiu, 2012; Neacsiu, Eberle, Kramer, et al., 2014). This prior study was used as historical control to anchor the current results to the results for a related face-to-face intervention. A large part of the methodology of selecting participants as well as evaluating results was selected to match to the extent possible the historical control study.

This work also builds on prior findings in computerized interventions that showed promise for addressing mood and anxiety problems through such a delivery mechanism. Prior work on multimedia learning was integrated to contribute findings on effective teaching methodology regardless of teaching subject/content. Findings from Persuasive Technology were also incorporated to increase engagement and help persuade individuals to try new skillful behaviors.

The current study thus developed and evaluated a computerized DBT skills training intervention with high potential for dissemination. We developed the intervention in an iterative fashion incorporating participant feedback to improve the final intervention.

Overall participants improved over the course of iDBT-ER treatment on indices across all dimensions of interest: emotion dysregulation, skills use, mindfulness, emotional distress and psychopathology. These results were not dependent on completing treatment. Participants mostly complied with the study requirement of not engaging in additional psychotherapy with one exception. Such departures did not explain significant variance in outcome analyses.

iDBT-ER as a DBT skills training intervention delivered in a computerized format to a group of individuals meeting criteria for different DSM disorders was feasible. Overall satisfaction with iDBT-ER was comparable to treatment-as-usual satisfaction in community mental health settings (Lunnen et al., 2008). iDBT-ER had an 80% retention rate for Phase 2 which is higher than 65% reported for a CBT intervention for depression and anxiety delivered over a similar period of time (Proudfoot et al., 2004). This also compares well against other brief DBT treatments for depression 76-77% (Harley, Sprich, Safren, Jacobo, & Fava, 2008) (Harley et al., 2008; Kwan, Dimidjian & Rizvi, 2010). Participants who dropped the iDBT-ER treatment did so primarily because they wanted individual face-to-face therapy or because they did not find the intervention overall to be a good fit. It is possible that giving individuals the option to add iDBT-ER to individual therapy might increase appeal and decrease drop-out rates.

Being in therapy the prior year or being prescribed psychotropic medication the prior year did not explain significant variance in the analysis. Expectancies of improvement was a significant covariate for some analyses. Because the current did not use an RCT design regression to the mean cannot be excluded as an explanation for the results.

We compared the results of the current study to a historical control teaching DBT skills in a face-to-face format to individuals high in emotion dysregulation and meeting criteria for mood and anxiety disorders. Results from the current study matched well against the comparison control on all dimensions evaluated. Pre-post effect sizes were similar for skills practice and emotion dysregulation and lower for iDBT-ER for anxiety, depression, and general distress. It is important to keep in mind when interpreting these results that the historical control provided 2 hours of therapy per week while iDBT-ER provided roughly 1 hour of treatment per week. The current study had a larger effect on mindfulness compared to the historical control. The current study also incorporated a treatment component not usually present in standard DBT that of daily reminder prompts sent to participants via text message and email. Participants were prompted daily to practice the skills assigned for that week and to practice mindfulness throughout the intervention. Standard DBT places a strong emphasis on mindfulness practice however specific mindfulness homework is only assigned when mindfulness is taught at a beginning of a module. It is possible that the addition of the daily reminder prompts for mindfulness practice are responsible for the increase in effect size for the current study compared to the historical control.

The study results support and extend the findings reported in the literature that DBT skills training by itself in the absence of DBT individual therapy can lead to a significant increase in skills use.

The results of the study also translate in implications for assessment. Our study replicated findings in the historical control study in that individuals screened for high emotion dysregulation met diagnostic criteria for mood and/or anxiety problems. All 31 individuals who passed the initial phone screen and scored above 97 on the DERS met inclusion criteria for at least one mood and/or anxiety disorder according to the DSM. The 4 participants who were

excluded at the second screen were excluded due to too high suicidality or to having psychotic symptoms but not due to not meeting criteria for a mood and/or anxiety disorder. The DERS took less than 10 minutes to administer and does not require reliability training.

Study limitations and strengths

A main limitation of the study is that it did not have a randomized control trial design. As such, the study did not control for common factors that could have been responsible for the treatment effects observed such as engagement in treatment or time spent watching the intervention.

A second limitation comes from the measures used to define the sample included in the study. Since the target group was selected as having high emotion dysregulation it is not clear how the results would generalize to a population not high in emotion dysregulation.

The study also has a number of limitations that are common to computerized interventions. For Phase 2 all study procedures were conducted without meeting the participants face-to-face. There was thus less control over knowing that the participants were indeed exposed to the intervention content. The fact that the learning management system (LMS) logged access and time spent in the intervention helps alleviate this concern to some degree.

Another limitation comes from the reliance on self-report measures to evaluate outcomes. Adding interview components to assessment could have alleviated this concern however it may have also increased perceived burden on participants.

Despite these limitations, this study has a number of strengths. First, it uses a fairly broad set of inclusion criteria that helps expand generalizability of the findings. Confound-analyses (in terms of medication regimen, prior therapy experience) provided further evidence for the theoretical explanation of the findings. The study used an intent-to-treat approach for

analyses incorporating all available data. We also performed separate analyses for intervention completers. Overall, we had a relatively low percentage of missing data, implying that the findings in this study are an accurate reflection of the changes that occurred with the sample included.

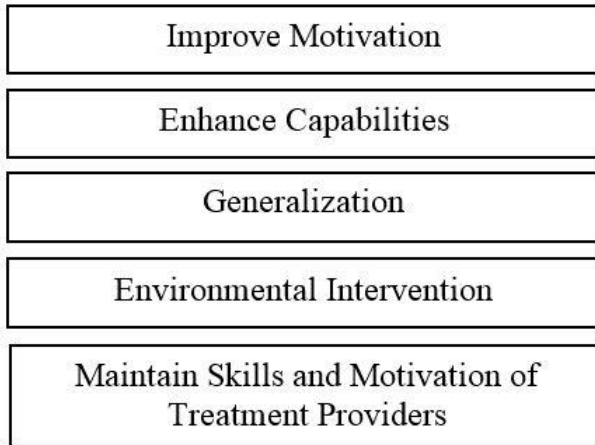
The study also generated a technical solution for developing and implementing the iDBT-ER intervention. It used an online course development platform and a series of subscription based services that made the development and hosting of such an intervention feasible on a small budget. Prior interventions used custom software platforms that needed extensive resources in terms of time and money to be realized. The entire iDBT-ER intervention was developed without any custom software on a relatively tight timeline.

Future Directions

The current study was designed to be a pilot in evaluating potential for a computerized delivery of DBT skills training. The results revealed such a potential. For feasibility reasons the current study was limited in terms of clinical population targeted, length of the intervention, features incorporated. iDBT-ER can be extended to address emotion dysregulation in other populations who might benefit from skills training to anger problems, parenting skills, conflictual relationships. Application of such an intervention can also expand to other settings. iDBT-ER can be potentially efficacious as an add on to individual therapy, or as an intervention provided in primary care. Further research can provide information on how to expand the intervention to add additional components such as an online discussion group, a peer support system (with or without therapist monitoring), integration of iDBT-ER with other technology such as online organizational tools.

Further research could try out other delivery schedules for the intervention. It is possible that a smaller/shorter intervention delivered more often than once per week would be more effective for some participants. There is also a lot of room to improve in terms of making the intervention custom to different participants. Allowing participants to decide on type, length, frequency of communication received (type of messages) to prompt practice could improve user satisfaction.

A natural next step for the study is to replicate the findings in an RCT design and control for common factors that could explain the results. Expanding the study with a larger sample size would allow more complex analyses to be performed to identify mechanisms of change through mediation and moderation analyses.

FIGURES**Figure 1.** Functions of comprehensive treatment**Figure 2:** Modularity of DBT treatment modes

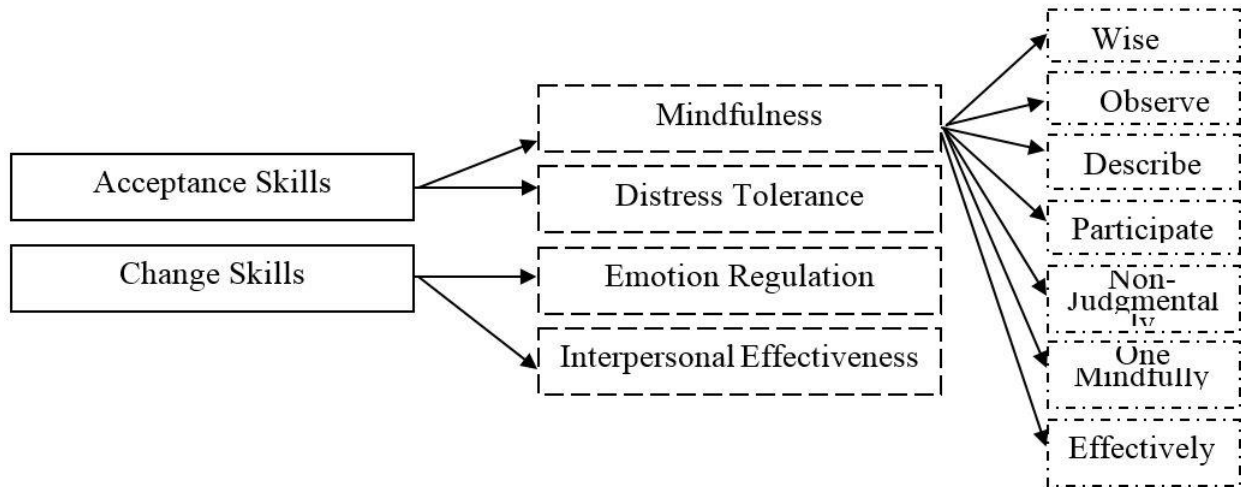


Figure 3: Modularity of DBT skills training

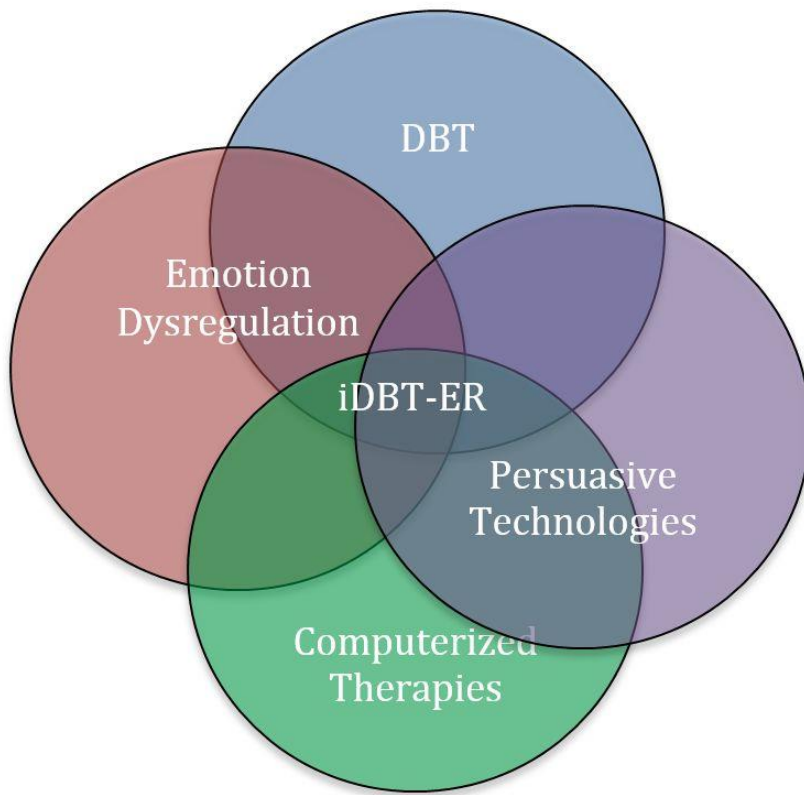


Figure 4: Relationship of research areas to current study.



Figure 5: Treatment structure

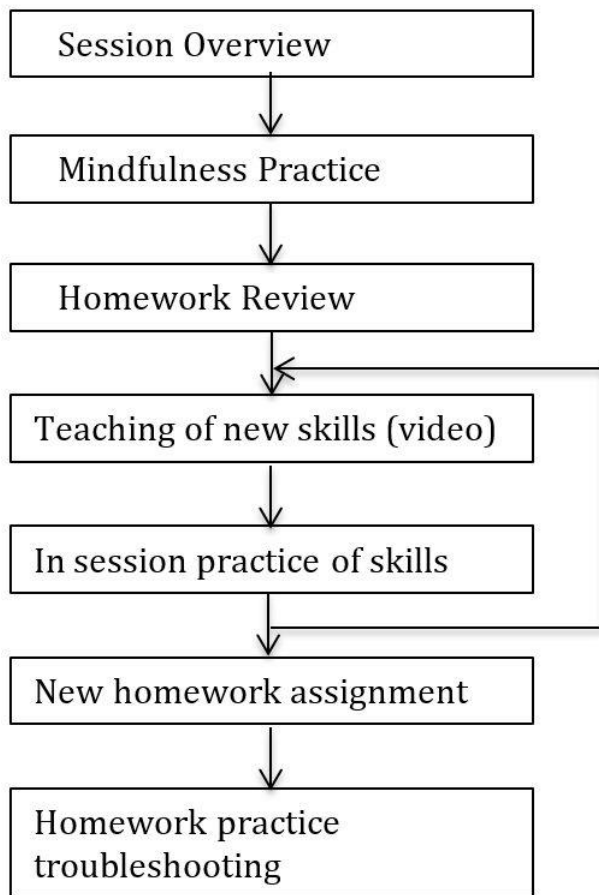


Figure 6: iDBT-ER session structure

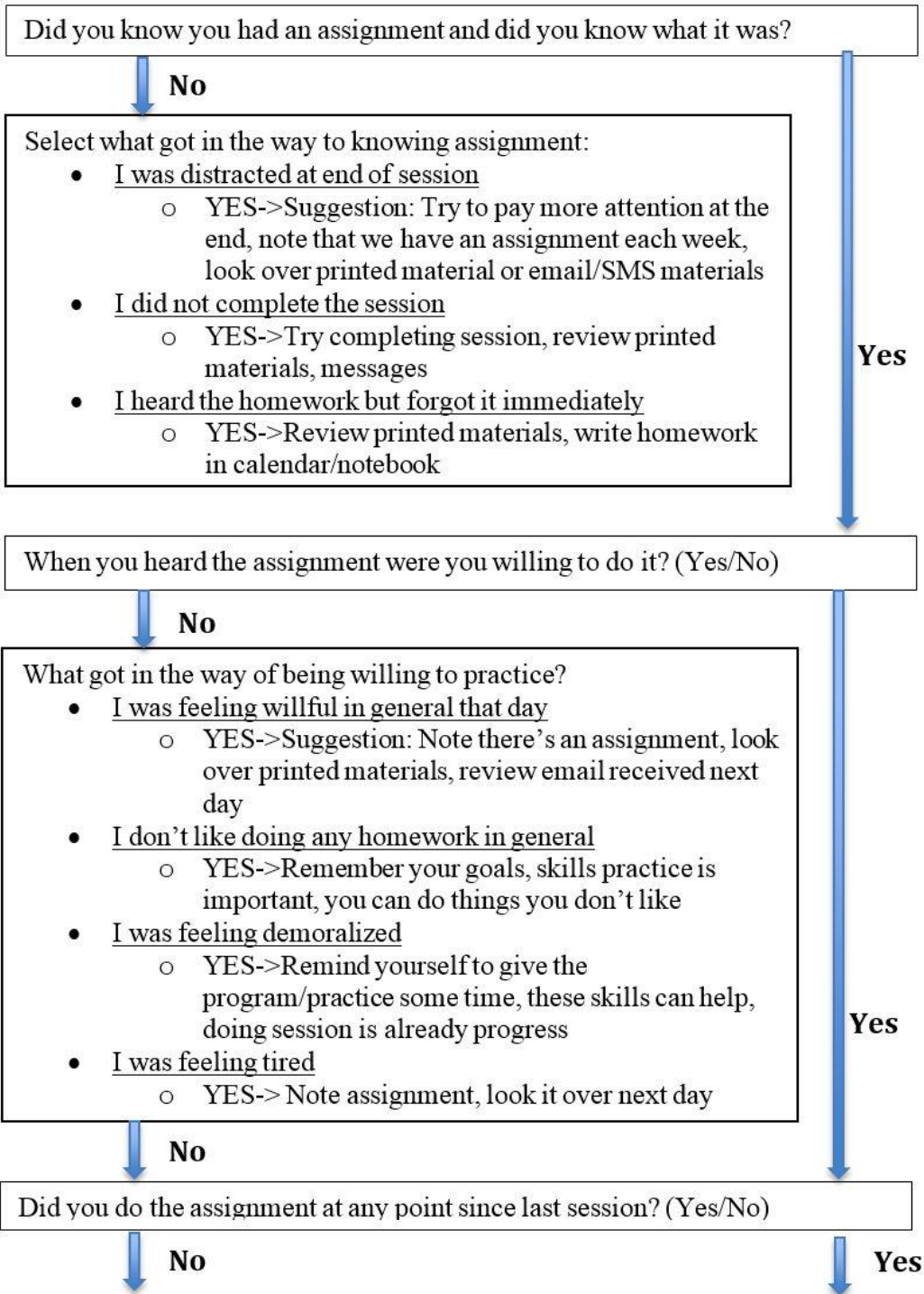


Figure 7. Homework review: Missing links analysis part 1⁴

⁴ Adapted with permission from Linehan, M.M (2014)

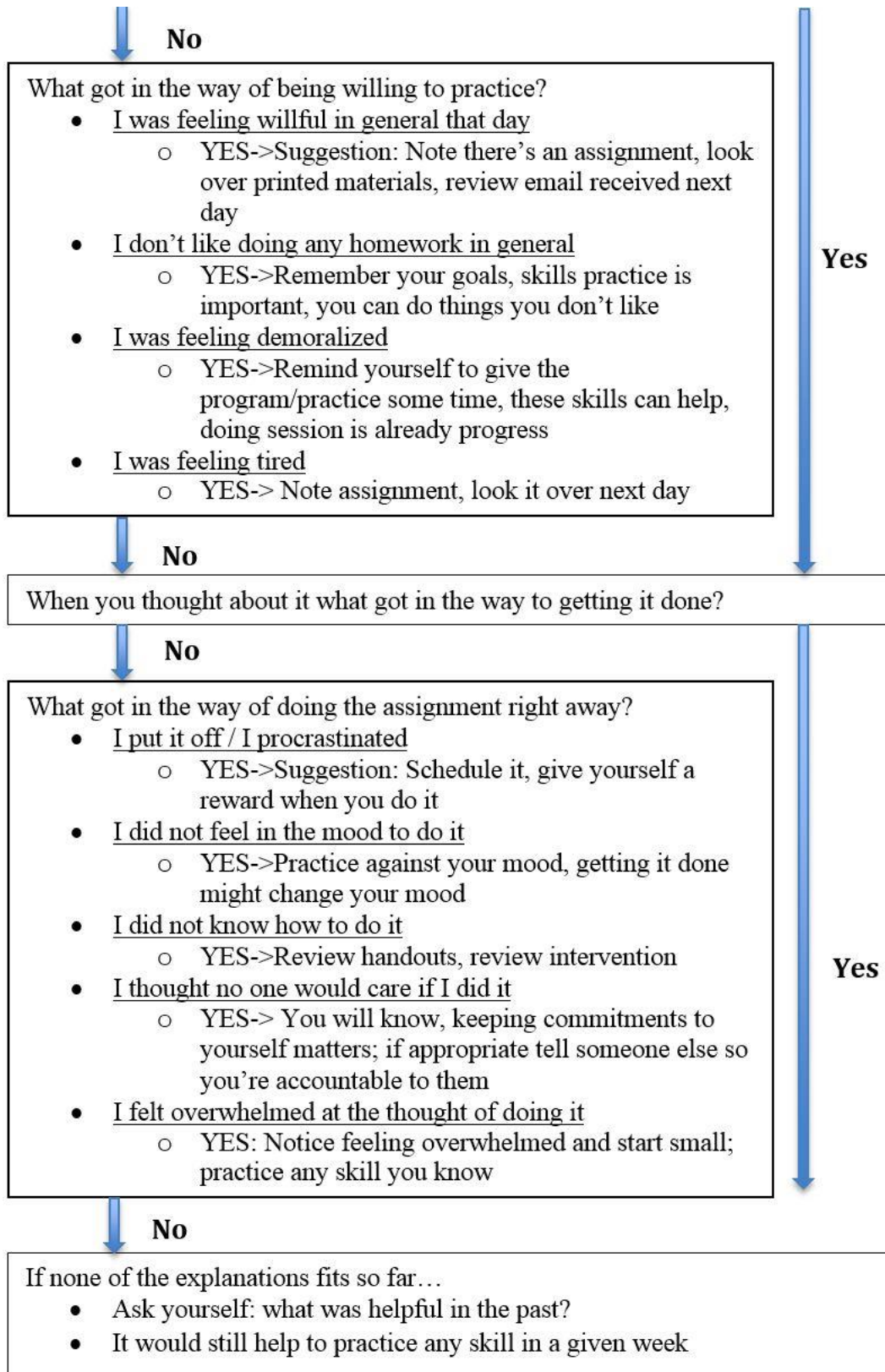


Figure 8. Homework review: Missing links analysis part 2

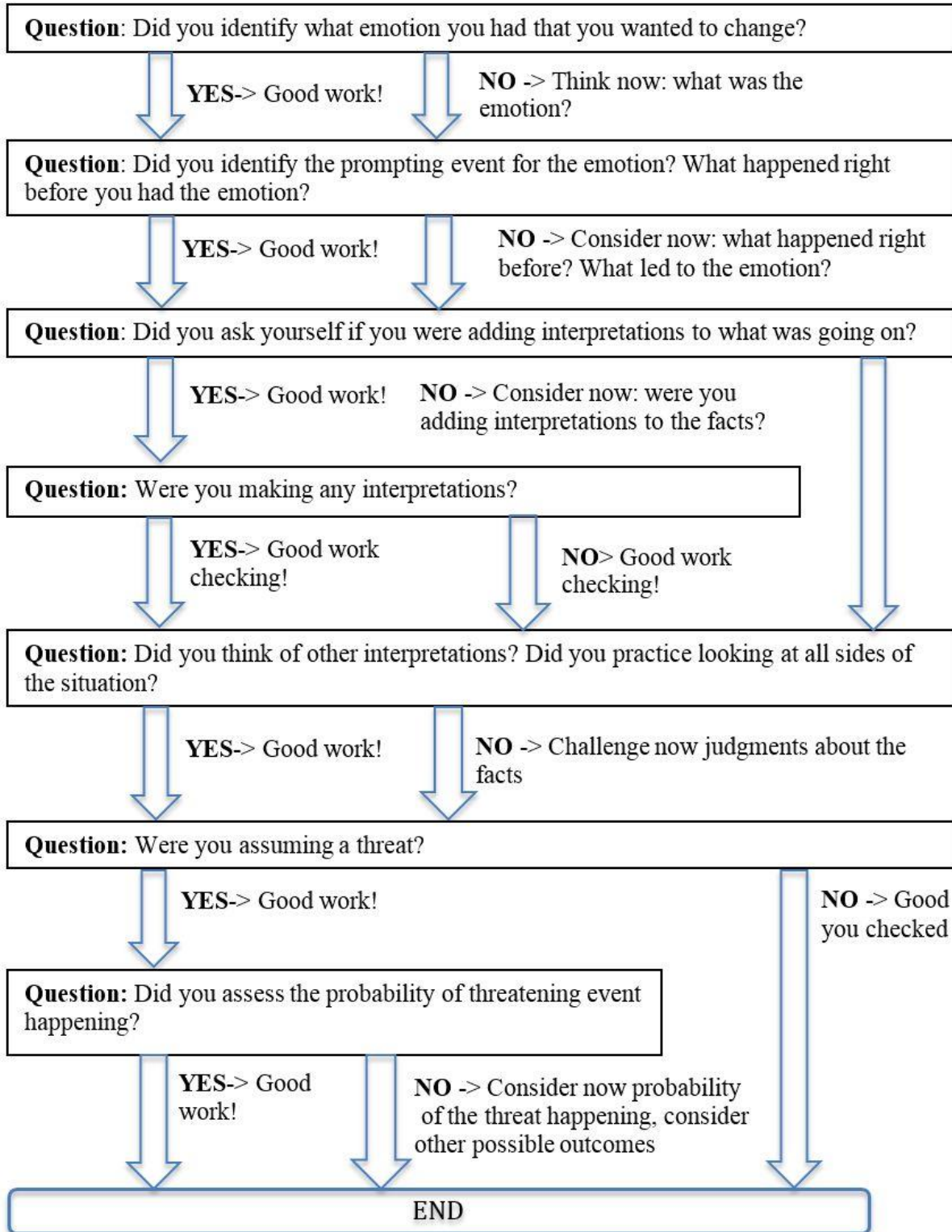


Figure 9. Homework review Check the Facts a step-by-step approach⁵

⁵ Adapted with permission from Linehan, M. M. (2014)


Model of Emotion: Common Challenges

- Feeling overwhelmed by the model of emotion
 - ➔ IF SELECTED: Suggestion: Remind yourself of bits of the model at a time
- Thinking “The model is just a theory, it cannot really impact my life”
 - ➔ IF SELECTED: Suggestion: Understanding emotions can help us be more in control of emotions
- Intense emotion gets in the way of applying the model
 - ➔ IF SELECTED: Suggestion: Start using the model/practicing at lower intensity of emotions
- Finding it hard to remember the information for each emotion
 - ➔ IF SELECTED: Suggestion: Break down the model into pieces, work first on the emotion most relevant to you

Figure 10. Challenges and associated suggestions for applying the Model of Emotion

Where would mindfulness have the biggest impact for you?

- At work
- In close relationships
- At home
- Other:
- No area comes to mind




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Figure 11. Self-referencing prompt: selecting relevant area to become more present/mindful

Is there an area where you'd like to become a better observer?

- In my hobbies/leisure time
- In my friendships
- At work
- At home
- Other:
- No area comes to mind



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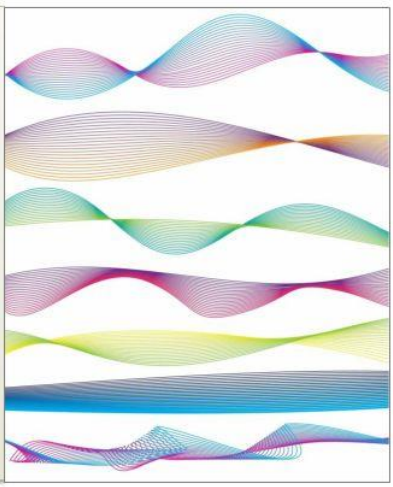
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Figure 12. Self-referencing prompt: selecting relevant area to become better observer

Figuring out your barriers to emotion regulation

- Is it more difficult for you to regulate/manage your emotions?

- Yes
- No



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Figure 13. Self-referencing prompt: evaluate your difficulty regulating emotion

Figuring out your barriers to emotion regulation

- Does your biology make it hard to regulate your emotions?
 Yes No
- Did you have too few opportunities to learn how to regulate/manage your emotions?
 Yes No

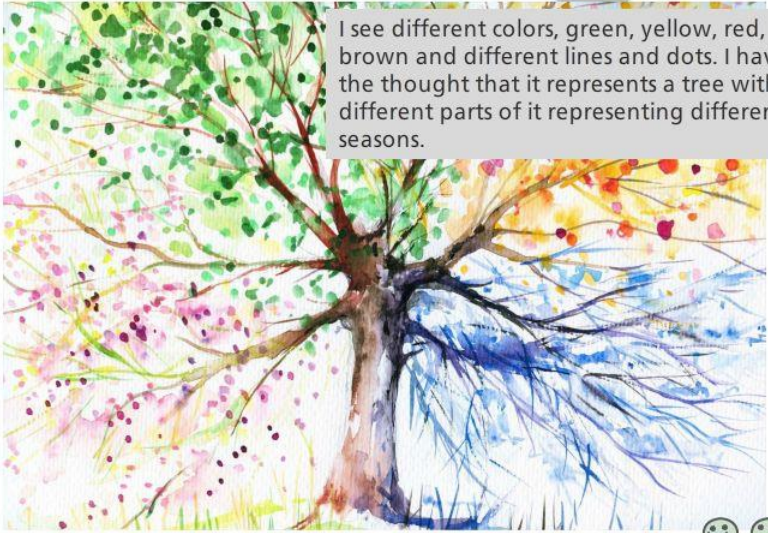


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Figure 14. Self-referencing prompt: figuring out your barriers to emotion dysregulation

Please describe the image in your own words. Click [here](#) for an example.



I see different colors, green, yellow, red, brown and different lines and dots. I have the thought that it represents a tree with different parts of it representing different seasons.

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Figure 15. Behavioral modeling and rehearsal example: practicing the mindfulness describe skill, low emotional salience.

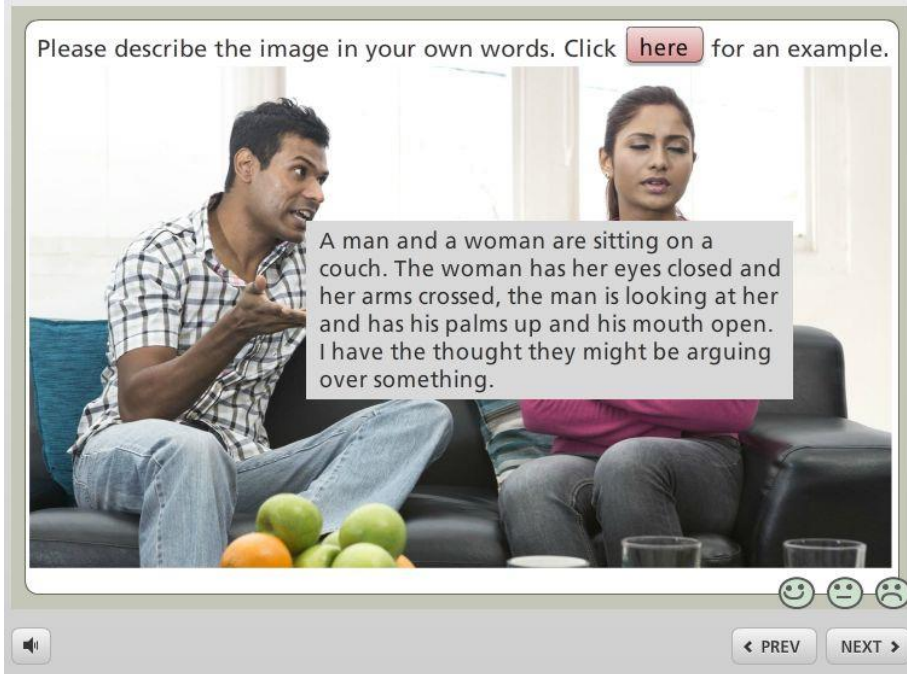


Figure 16. Behavioral modeling and rehearsal example: practicing the mindfulness describe skill, high emotional salience.

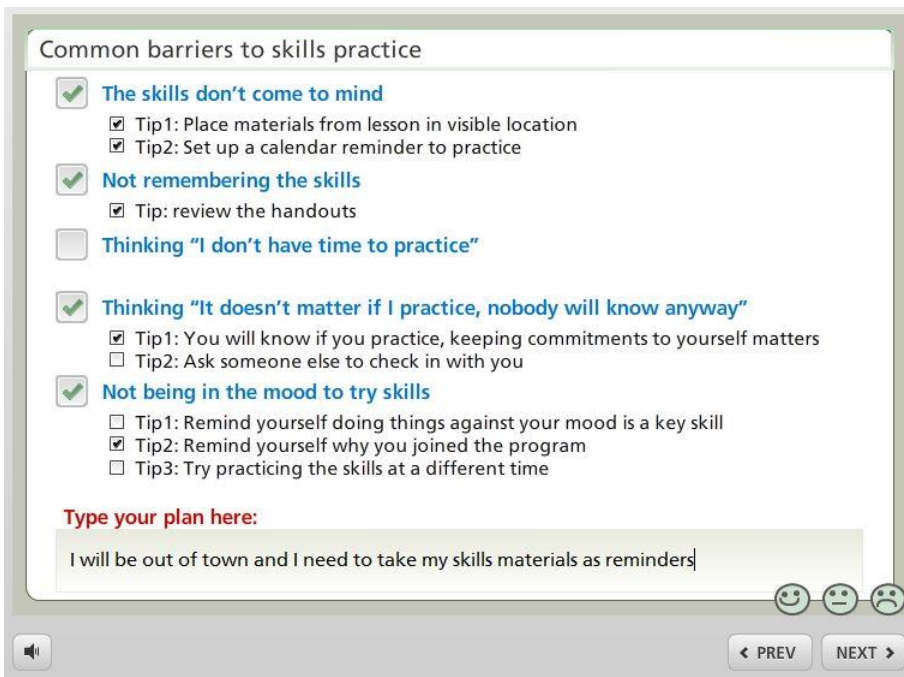


Figure 17. Identifying barriers to skills practice homework assignment

Anticipated barriers to skills practice & ideas to try

Anticipated **BARRIERS** to skills practice:

- * Skills don't come to mind
- * Not remembering the skills
- * Thinking "It doesn't matter if I practice, nobody will know anyway"
- * Not being in the mood for trying skills

TIPS to try :

- * Put lesson materials in visible place
- * Set calendar reminder to try skills
- * Review handouts
- * Ask someone else to check in
- * Remember why you joined program

I will be out of town and I need to take my skills materials as reminders

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Figure 18. Troubleshooting identified barriers to homework assignment completion



Figure 19. Solidifying learning of the relationship between prompting event and emotion through interactive real-life examples.

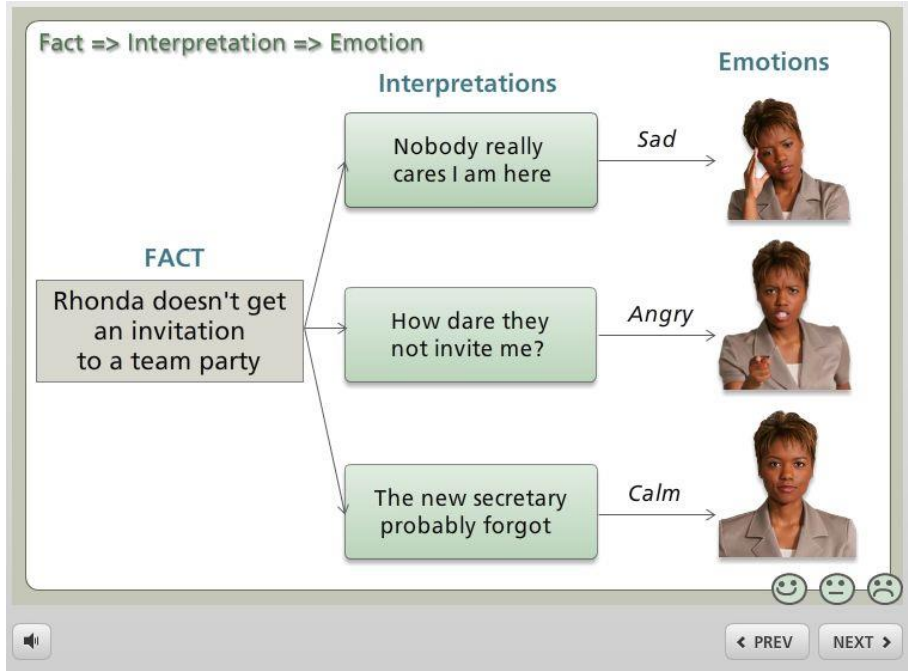



Figure 20. Solidifying learning of the relationship between facts, interpretation, and emotion through interactive real-life examples.

Why be non-judgmental? Please click the buttons to explore...

Being judgmental...

- ...can **destroy** relationships
- ...can have huge **impact on emotions**
- ...if often **less effective** at changing things than understanding causes



Adding judgments can have a huge impact on our emotions. When we add evaluations of good and bad to people or things around us, it can impact our emotional responses to the person or things we are judging.

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Figure 21. Solidifying understanding of impact of being judgmental

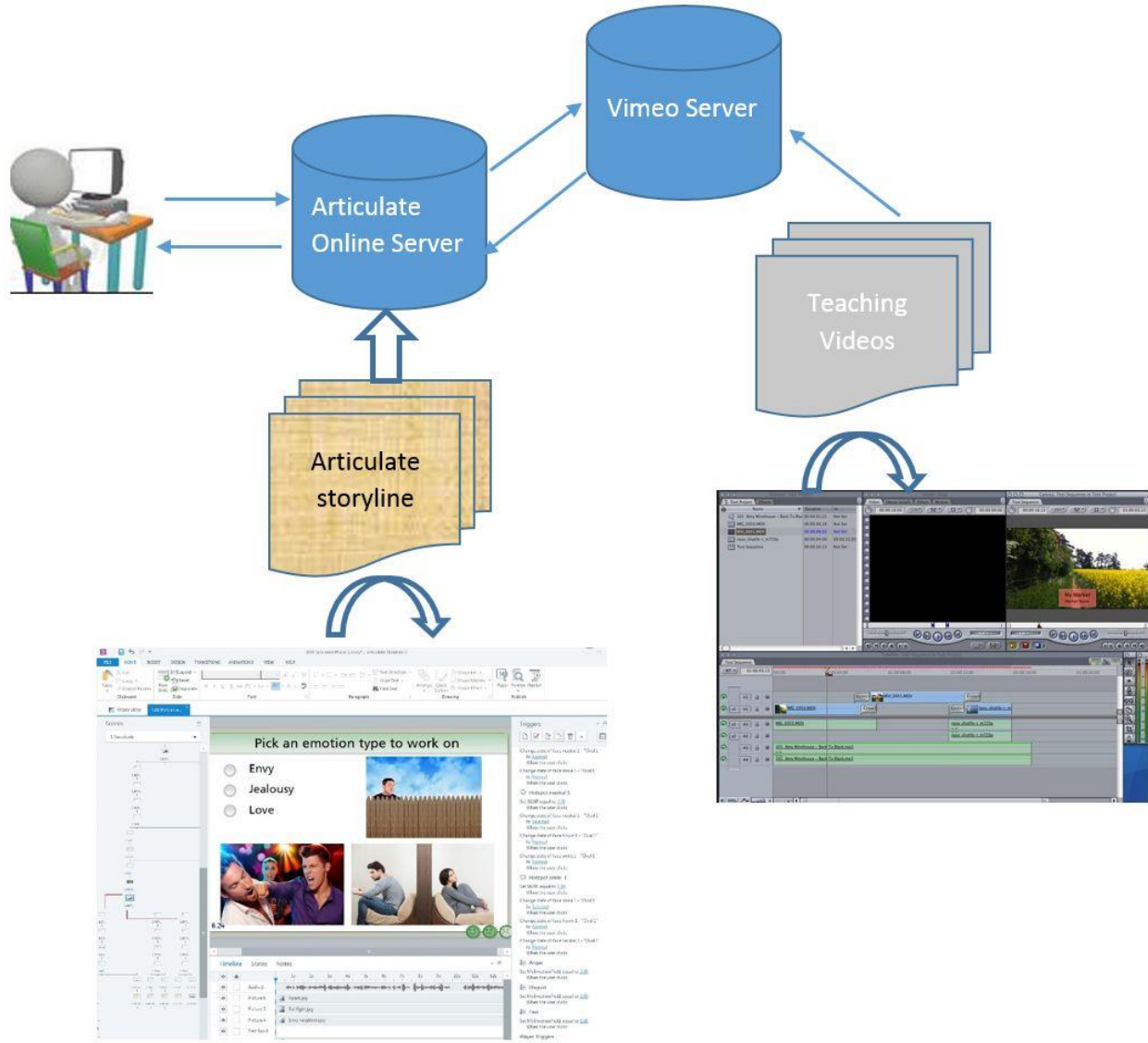


Figure 22. iDBT-ER Technical Set-up

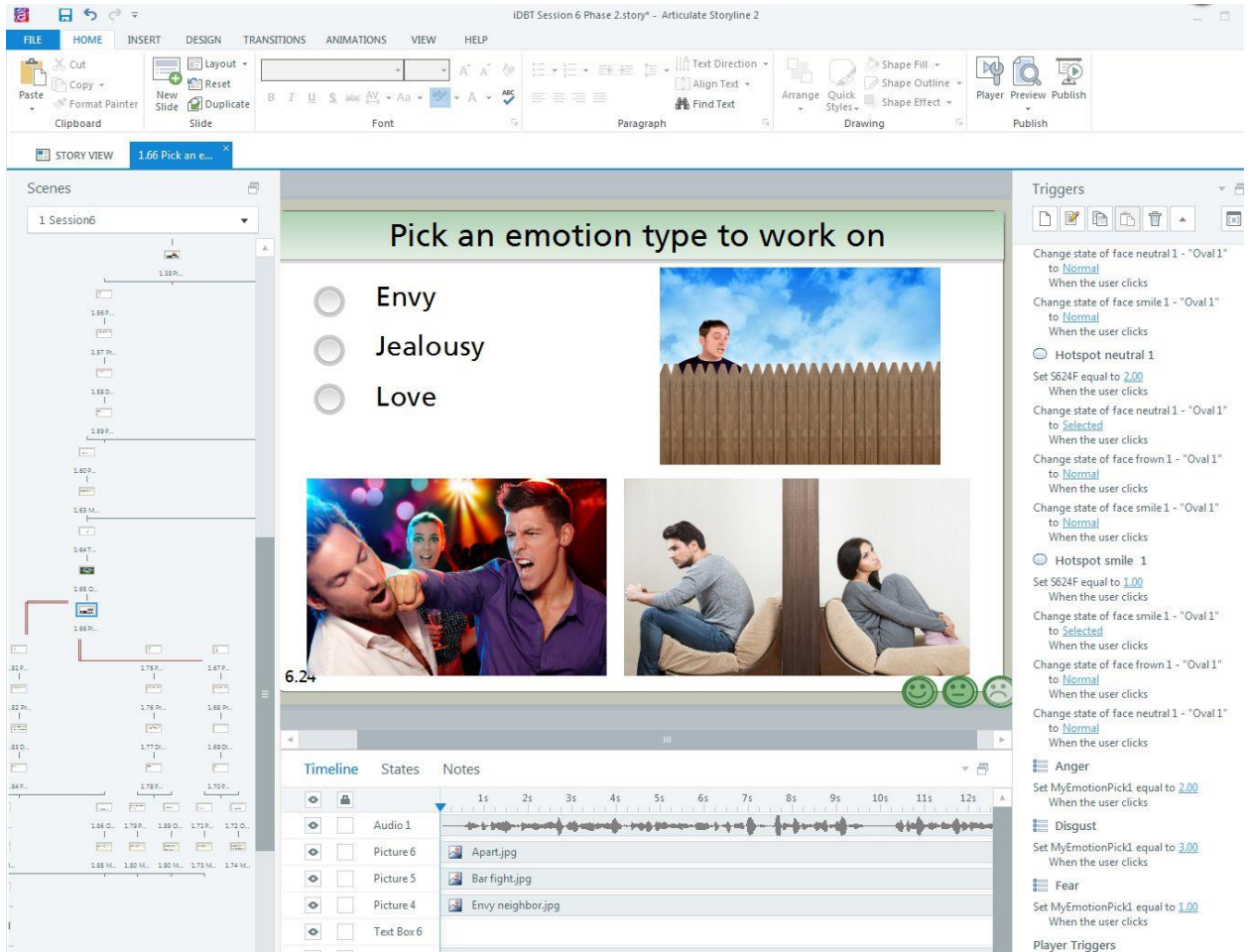


Figure 23. Articulate Online development environment

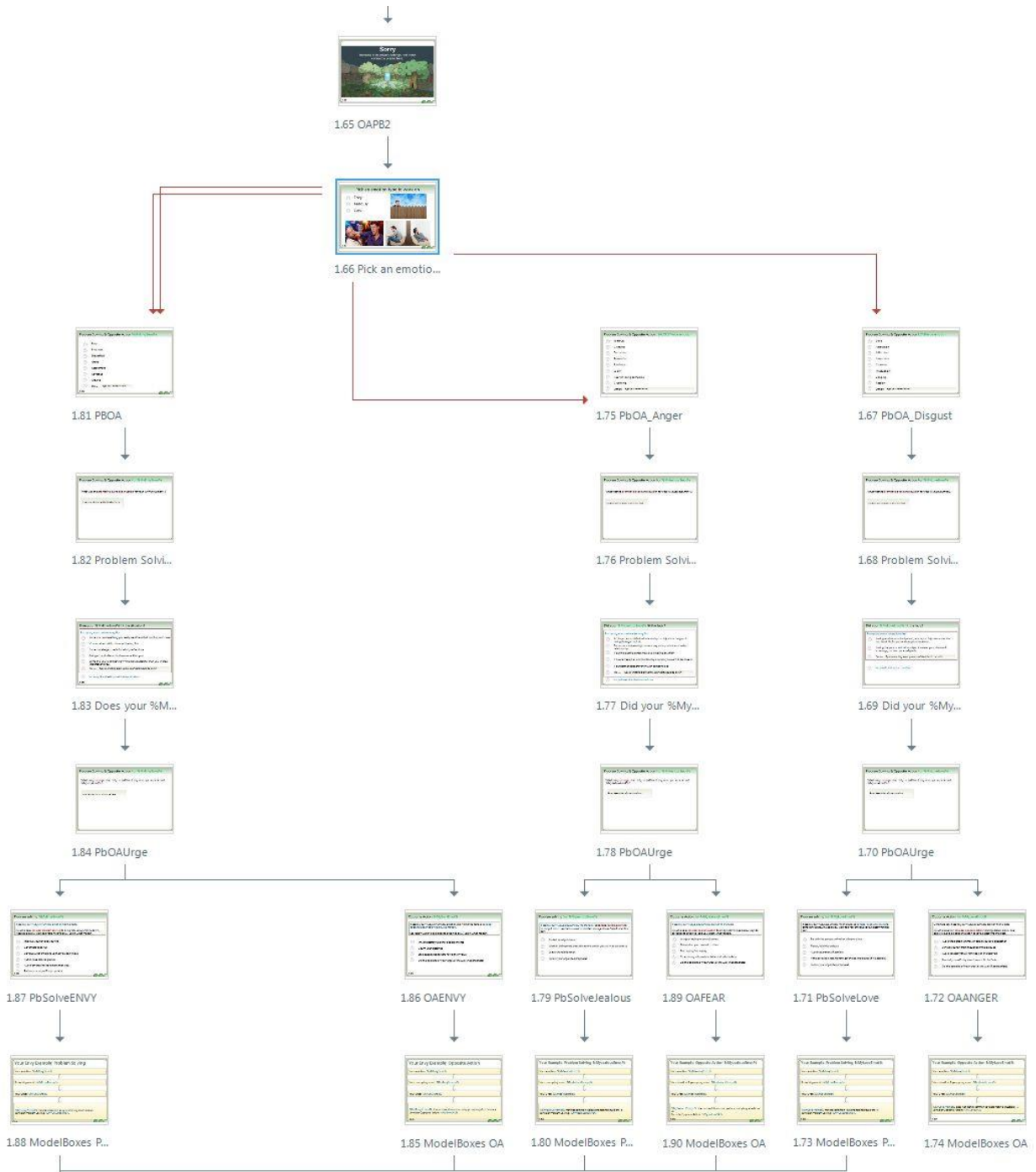
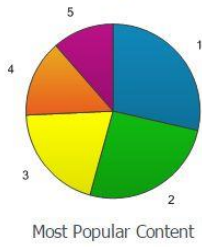


Figure 24. Example of session structure in Articulate Storyline

Welcome to Articulate Online

Your Content: Quick stats about your content



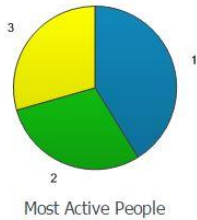
You have 10 content items.

MANAGE YOUR CONTENT

Your most popular content over the last 7 days:

- 1. Phase 2 iDBT Session 1 (10 views)
 - 2. Phase 2 iDBT Session 6 (9 views)
 - 3. Phase 2 iDBT Session 7 (7 views)
 - 4. Phase 2 iDBT Session 2 (5 views)
 - 5. Phase 2 iDBT Session 8 (4 views)
- [more...](#)

Your People: Summary of users



You have 45 users.

MANAGE YOUR PEOPLE

Your most active people over the last 7 days:

- 1. 8396@idbt.com (7 views)
 - 2. 9614@idbt.com (5 views)
 - 3. 4209@idbt.com (5 views)
- [more...](#)

Figure 25. Articulate Online tracking user activity

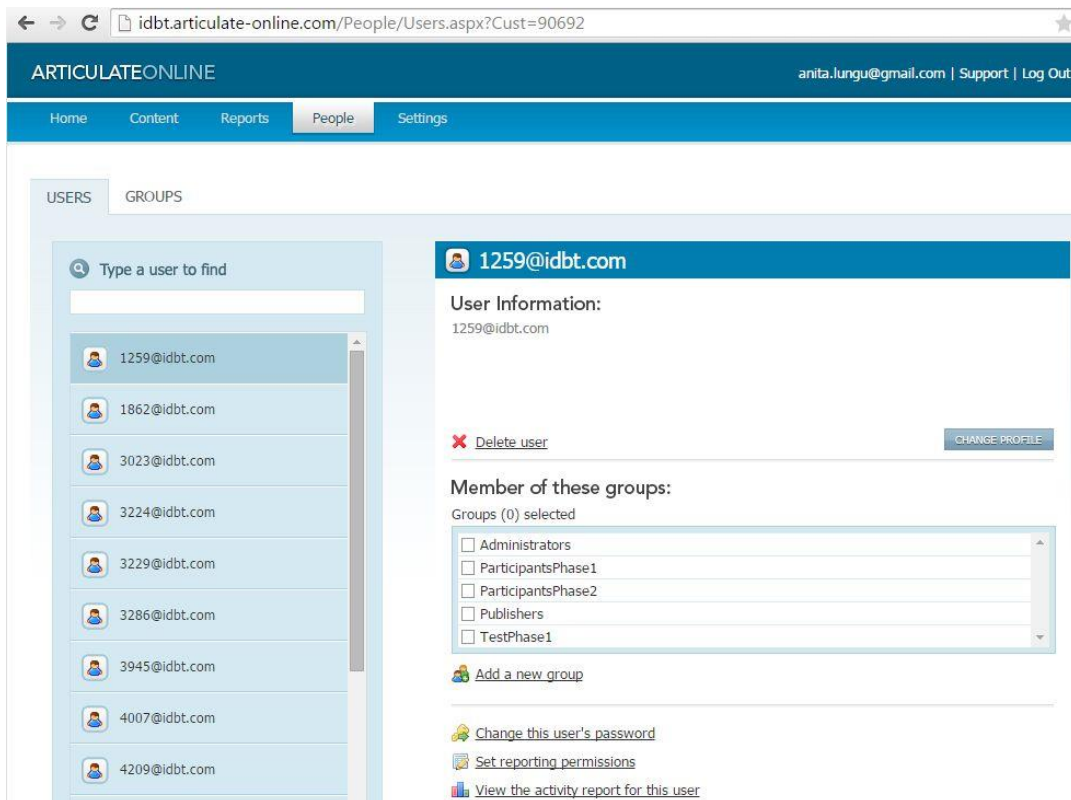


Figure 26. Articulate Online User Management































ARTICULATEONLINE		anita.lungu@gmail.com Support Log Out	
Home	Content	Reports	People Settings
CONTENT LIST		Showing all 10 content items	
		Sort by: Title ▲ Date ▼ Views ▼	
	iDBT Session 8 V1 March 13, 2015	 View  Manage	11 views
	iDBT Session 8 V2 March 19, 2015	 View  Manage	11 views
	Phase 2 iDBT Session 1 May 24, 2015	 View  Manage	177 views
	Phase 2 iDBT Session 2 May 24, 2015	 View  Manage	109 views
	Phase 2 iDBT Session 3 May 24, 2015	 View  Manage	69 views
	Phase 2 iDBT Session 4 May 24, 2015	 View  Manage	72 views
	Phase 2 iDBT Session 5 May 24, 2015	 View  Manage	46 views
	Phase 2 iDBT Session 6 May 24, 2015	 View  Manage	53 views
	Phase 2 iDBT Session 7 May 24, 2015	 View  Manage	38 views
	Phase 2 iDBT Session 8 May 24, 2015	 View  Manage	17 views

Figure 27. Articulate Online Content Management

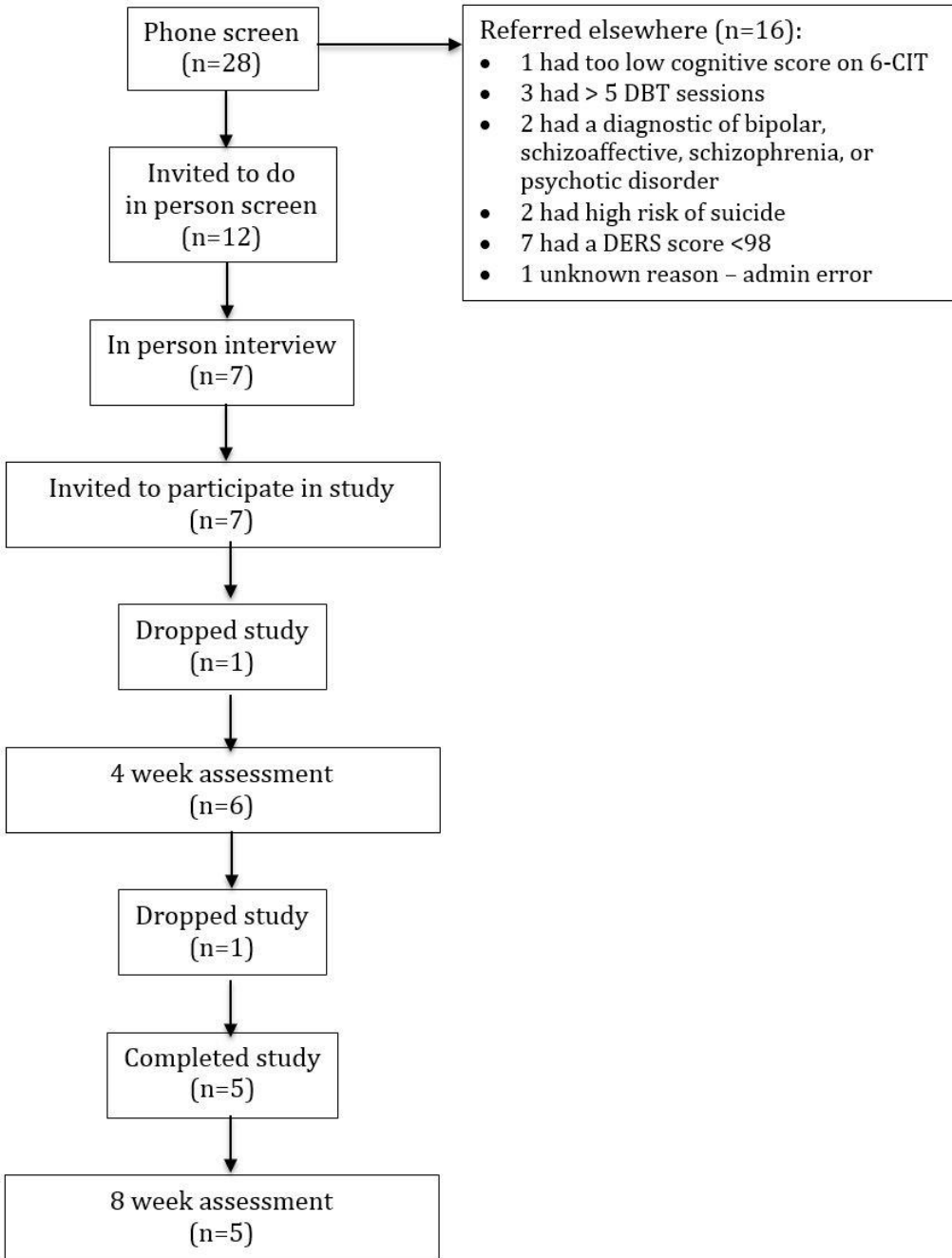


Figure 28. Phase 1 Participant Flow

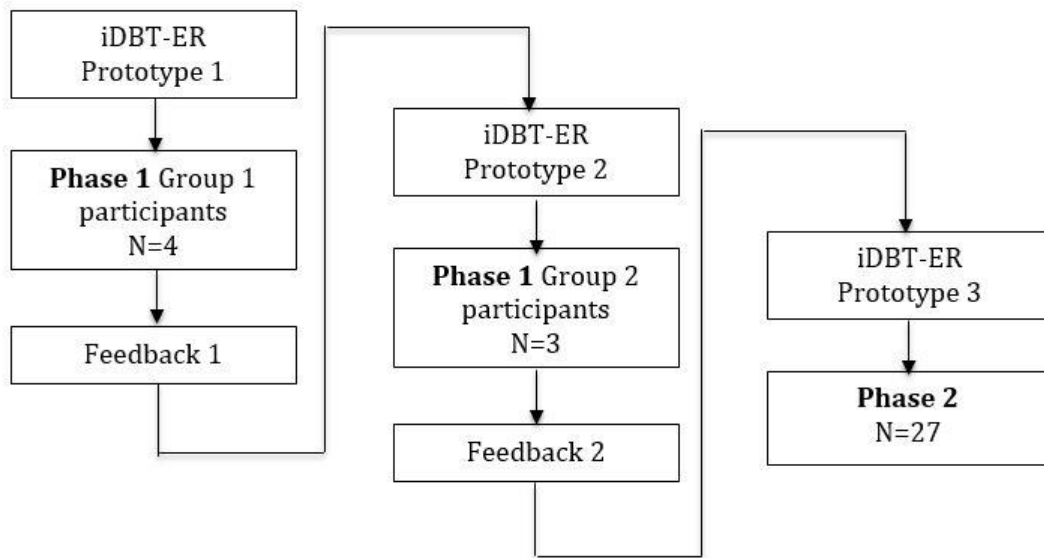


Figure 29. Information flow iDBT-ER treatment development (Phase 1) & evaluation (Phase 2)

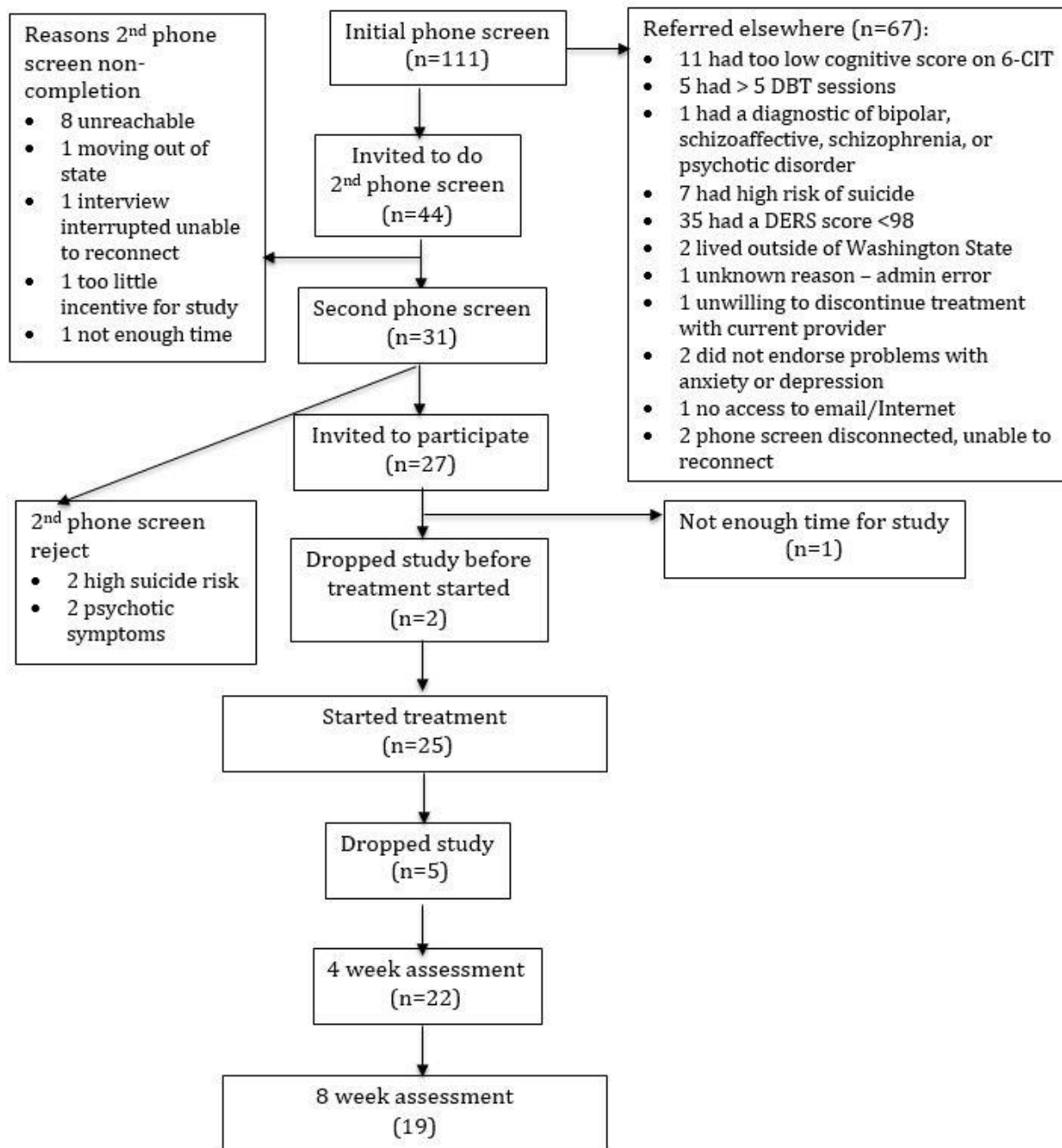


Figure 30. Phase 2 participant flow

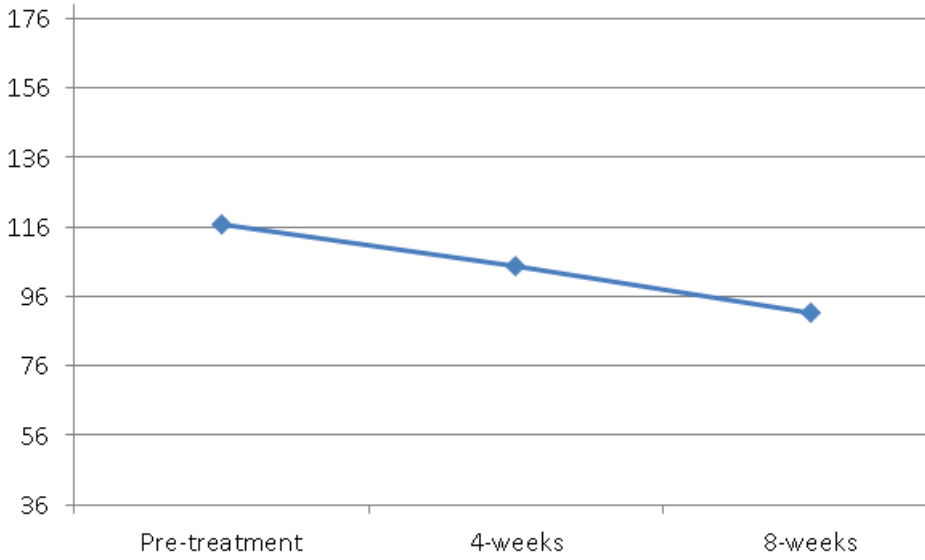


Figure 31. Phase 2 emotion dysregulation (DERS) as treatment outcome

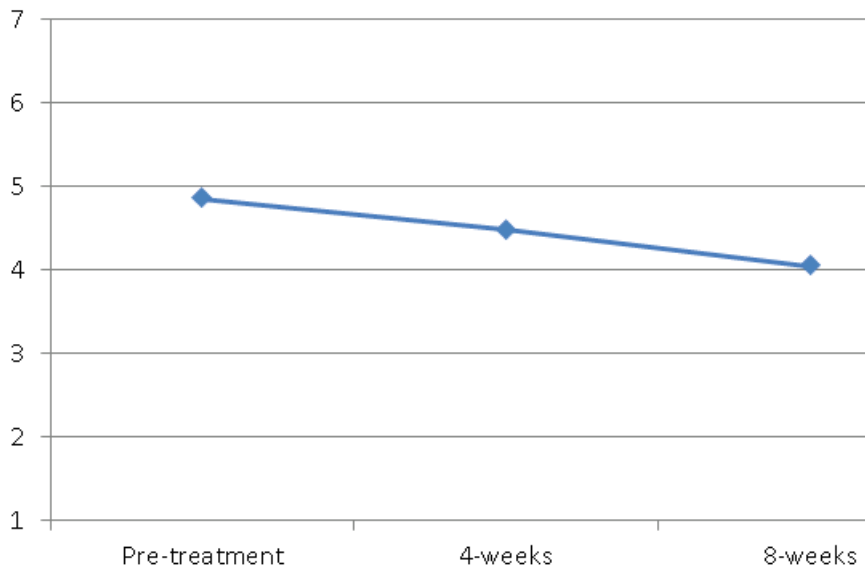


Figure 32. Phase 2 emotion dysregulation (AAQ) as treatment outcome

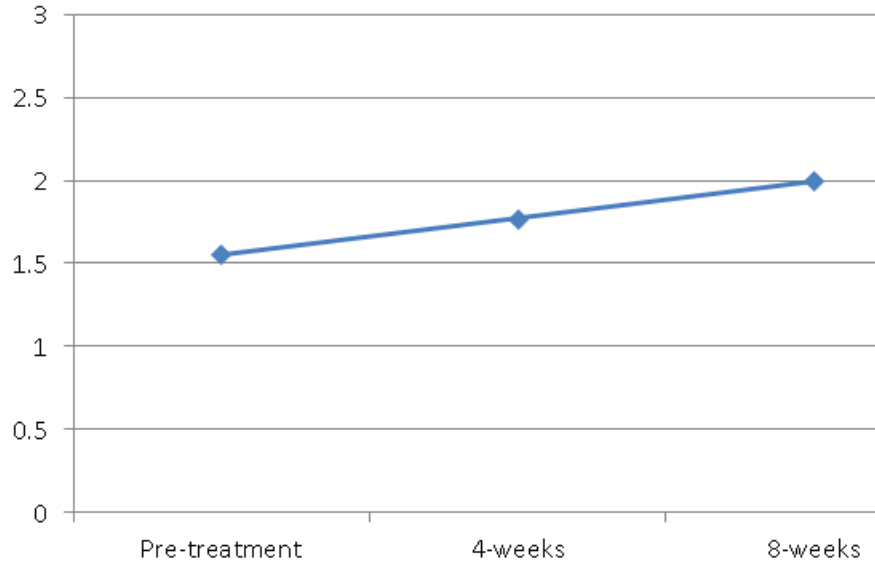


Figure 33. Phase 2 skillful behavior (DBT-WCCL) as treatment outcome

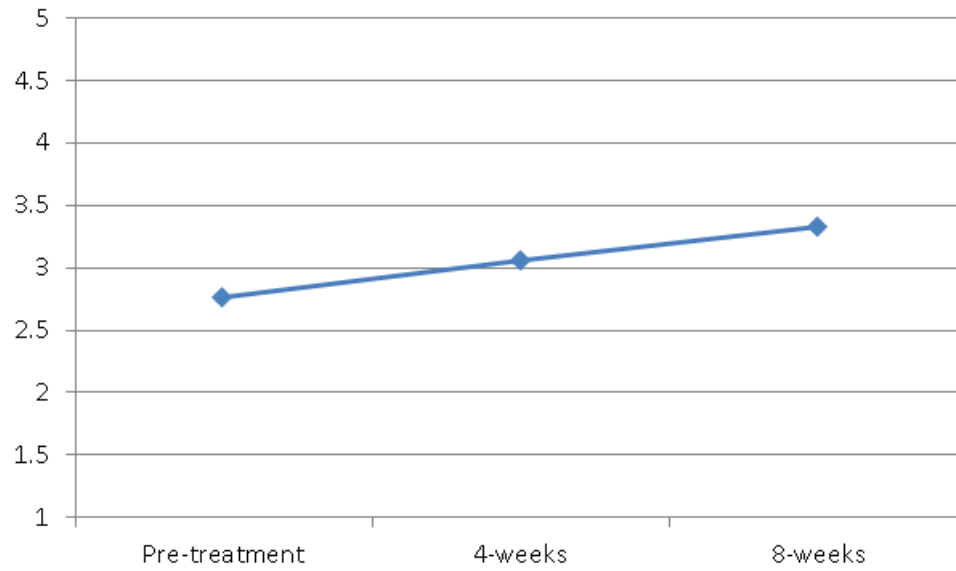


Figure 34. Phase 2 mindfulness (KIMS) as treatment outcome

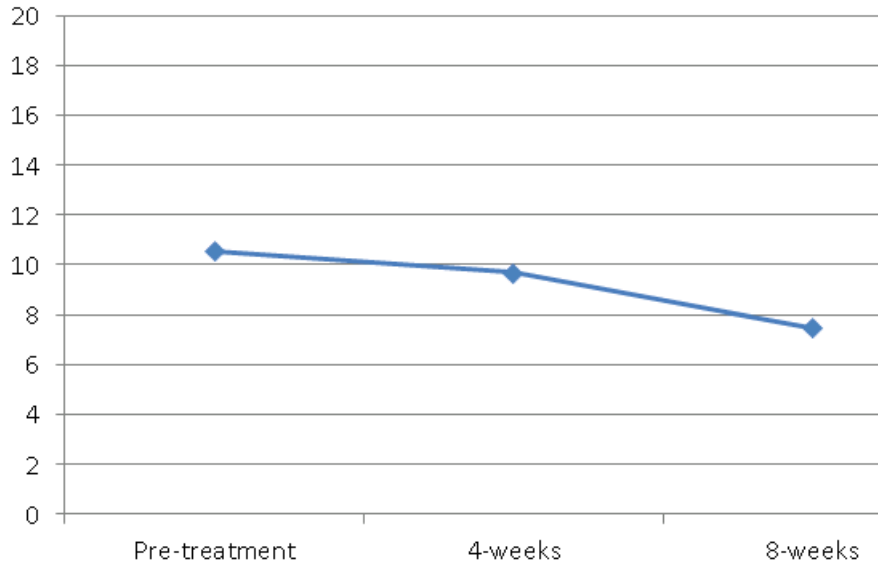


Figure 35. Phase 2 anxiety (OASIS) as treatment outcome

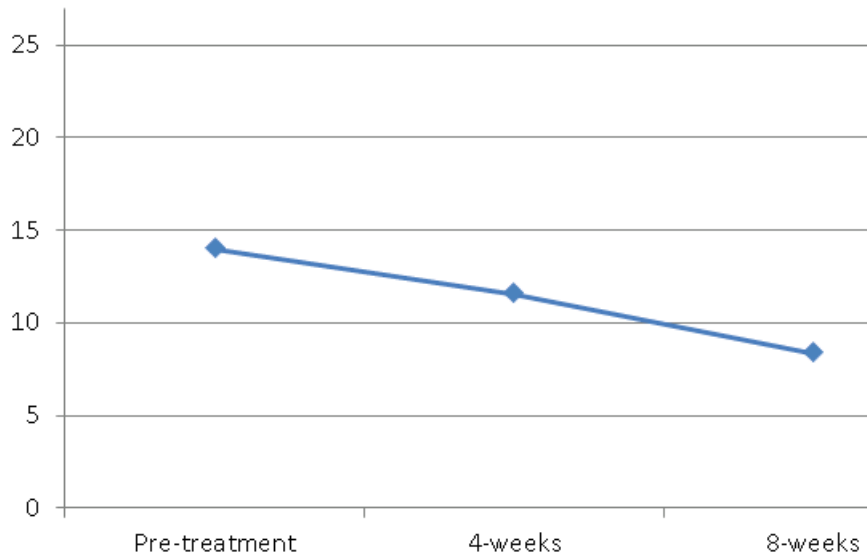


Figure 36. Phase 2 depression (PHQ9) as treatment outcome

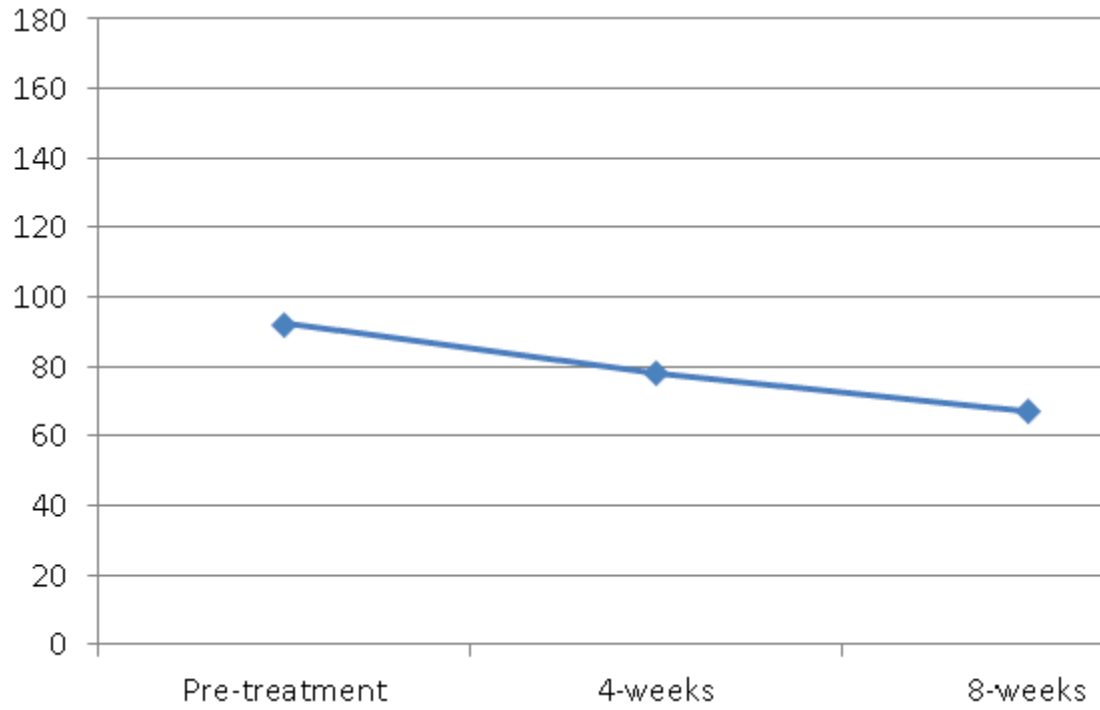


Figure 37. Phase 2 general distress (OQ-45) as treatment outcome

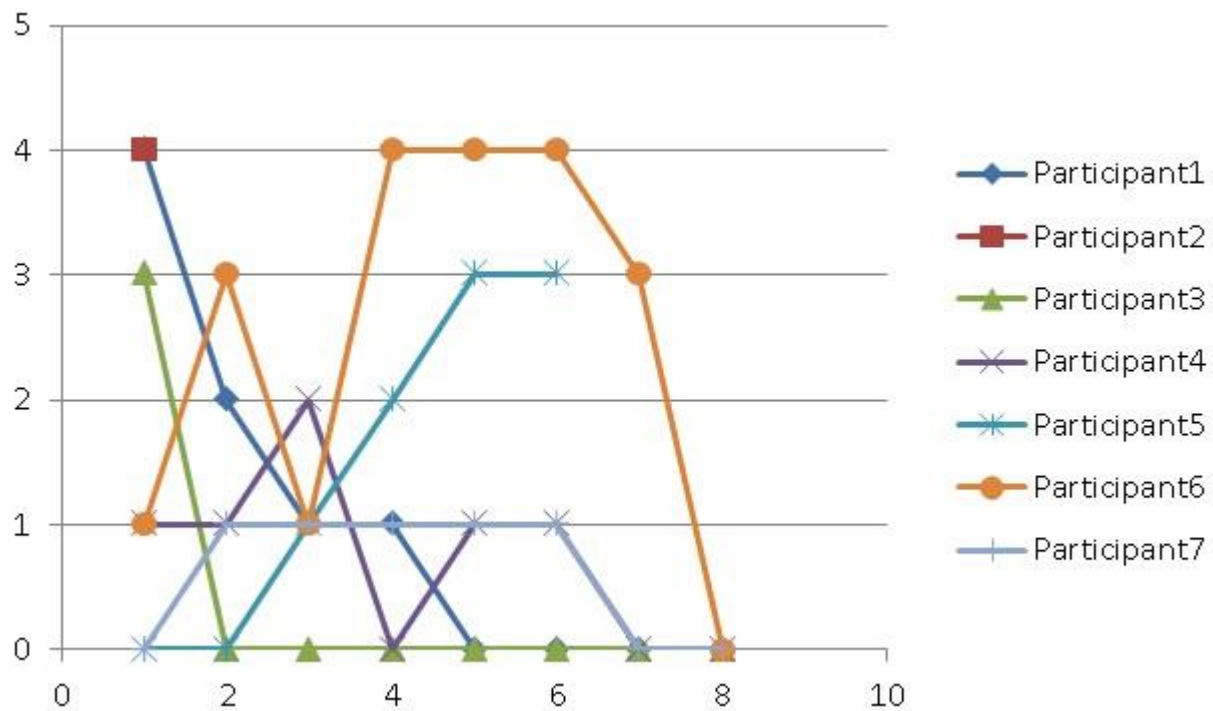


Figure 38. Phase 1 current urge to quit treatment (assessed before each session)

TABLES

Table 1. Summary of meta-analyses for computerized psychotherapies

Author, Year	# RCTs	Clinical Issue	Post-tx effect sizes
Reger et al., 2009	19	Anxiety	CP vs. WL 0.76 (95% CI: 0.6 to 0.92) CP vs. placebo 0.86 (95% CI: 0.61 to 1.11) CP vs. TAU 0.03 (95% CI: -0.35 to 0.41)
Cuijpers et al., 2009	23	Anxiety	0.99 (FEM; 95% CI: 0.86 to 1.13) 1.98 (REM; 95% CI: 0.84 to 1.32)
Spek et al., 2007	12	Anxiety, depression	Treatment 0.40 (FEA; 95% CI: 0.29 to 0.51) 0.60 (MEA; 95% CI: 0.35 to 0.86) Prevention 0.03 (FEA; 95% CI: -0.11 to 0.71) 0.06 (MEA; 95% CI: -0.17 to 0.30) Depression 0.27 (FEA; 95% CI: 0.15 to 0.40) 0.32 (MEA; 95% CI: 0.08 to 0.57) Anxiety 0.96 (FEA, MEA; 95% CI: 0.69 to 1.22) With therapist support 1.0 (FEA, MEA; 95% CI: 0.75 to 1.24) Without therapist support 0.24 (FEA; 95% CI: 0.11 to 0.37) 0.26 (MEA; 95% CI: 0.08 to 0.44)
Andrews et al., 2010	22	Anxiety, depression	Global 0.88 (95% CI: 0.76 to 0.99) Depression 0.78 (95% CI: 0.59 to 0.96) Social Phobia 0.92 (95% CI: 0.74 to 1.09) Panic 0.83 (95% CI: 0.45 to 1.21) GAD 1.12 (95% CI: 0.76 to 1.47)
Andersson et	15	Anxiety,	0.41 (95% CI: 0.29 to 0.54)

al., 2009		depression	
Richards et al., 2012	19	Depression	Global 0.56 (95% CI: 0.41 to 0.71) Interventions < 8 sessions 0.75 (95% CI: 0.49 to 1.02) Interventions >= 8 sessions 0.39 (95% CI: 0.22 to 0.56) Therapist support 0.78 (95% CI: 0.64 to 0.92) Administrative support 0.58 (95% CI: 0.28 to 0.88) No support 0.36 (95% CI: 0.10 to 0.61)
Barak et al., 2008	92	Psychological problems	Global 0.53 PTSD 0.88 Panic and anxiety 0.80 Smoking 0.62 Drinking 0.48 Body image 0.45 Depression 0.32 Physiological 0.27 Weight loss 0.17
Cheng and Dizon, 2012	6	Insomnia	Sleep onset latency -0.55 (95% CI: -0.80 to -0.30) Number of awakenings -0.45 (95% CI: -0.70 to -0.2) Total sleep time 0.22 (95% CI: -0.03 to 0.46)

Table 2. Psychological problems targeted by CP

<i>Problem targeted</i>	<i>Nr. studies</i>	<i>Problem targeted</i>	<i>Nr. studies</i>
Depression	43	Binge drinking	2
Depression and/or anxiety	2	Hazardous drinking	1
Depression in Parkinson's	1	Hazardous health behaviors	1
Panic disorder	10	Smoking cessation	5
Social phobia	10	Recurrent/chronic headache	3
Phobia and/or panic disorder	4	Chronic back pain	1
Panic disorder and agoraphobia	1	Traumatic event	1
Spider phobia	3	Traumatic brain injury	1
Flight phobia	2	Tinnitus	1
PTSD	4	Encopresis	1
OCD	1	Insomnia	1
Pre-counseling anxiety	1	Stress	1
Generalized anxiety disorder	2	Jet lag	1
Mixed anxiety	10	Loneliness in people with disability	1
Eating disorder/eating pathology	4	Heart transplant related psychological symptoms	1
Overweight, obese eating, weight loss/management	6	Various issues	1
Body image/body dissatisfaction	3	Insomnia	6

Table 3. Systematic Framework for Designing and Evaluating Persuasive Systems

<i>Persuasion category</i>	<i>Persuasion strategy</i>	<i>Definition</i>
1. Primary task support	1.1 Reduction	Reduction is persuading the user to perform a behavior by reducing complex tasks to easier or simpler steps.
	1.2 Tunneling	Tunneling refers to persuading a user by guiding him/her through a series of pre-determined steps, such that once the user has entered the “tunnel” he/she is likely to follow along.
	1.3 Tailoring	A message tailored to a user’s specific needs, interests, and goals is likely to be more persuasive if it decreases the effort involved when exposed to non-relevant information.
	1.4 Personalization	Personalization refers to offering the users capabilities to personalize the content and services offered to them to increase persuasion.
	1.5 Self-monitoring	A persuasive system with self-monitoring support helps the user keeping track of performance or status in achieving goals.
	1.6 Simulation	Simulation as a strategy persuades by allowing the user to immediately observe the cause-effect relationships.
	1.7 Rehearsal	Persuading through rehearsal refers to increasing the likelihood that a certain behavior will take place in the real world if it is rehearsed during an interaction with a system.
2. Supporting dialogue/relationship with users	2.1 Praise	Conveying praise to a client through a variety of tools (images, words, comments, or symbols) can reinforce the preceding behavior.
	2.2 Rewards	Rewards given for performing behaviors targeted to increase can lead to behavior change in the desired direction.
	2.3 Reminders	A persuasive system that reminds users to perform specific target behaviors is increasing the likelihood that those behaviors will happen.
	2.4 Suggestion	The principle of suggestion is that “A computing technology will have greater persuasive power if it offers suggestions at opportune moments”.

	2.5 Similarity	Similarity refers to the fact that people are persuaded more easily by systems that resemble themselves in some ways.
	2.6 Liking	A system that is designed to be likable and appealing to users can have increased power of persuasion.
	2.7 Social role	Social role refers to the system adopting a familiar, established social role to increase its persuasiveness.
3. System credibility support	3.1 Trustworthiness	A system viewed as trustworthy, unbiased, fair, without using coercion or manipulation will have a greater power of persuasion.
	3.2 Expertise	A system viewed as incorporating a high level of expertise (knowledge, experience and competence) will be more persuasive.
	3.3 Surface credibility	Surface credibility highlights that the first impression a system makes onto a user has a high impact on credibility of that system.
	3.4 Real-world feel	Real-world feel refers to having a system that underlines the people or organizations behind it to increase persuasion.
	3.5 Authority	Content viewed by users as being generated from a source of authority (person or organization) enhances persuasion.
	3.6 Third-party endorsement	Third-party endorsement, especially from well reputed systems increase credibility of a system.
	3.7 Verifiability	Verifiability refers to enhancing credibility of a system by making its information easily verifiable against external sources.
4. Social influence	4.1 Social learning	Social learning refers to persuading people to perform a specific behavior by enabling them to observe someone else performing that behavior.
	4.2 Social comparison	Social comparison increases persuasion by allowing users to compare their performance to that of other users.
	4.3 Normative influence	Normative influence refers to leveraging peer pressure to increase persuasion.
	4.4 Social facilitation	Social facilitation refers to increasing persuasion by allowing the user to discern that others are performing intended behaviors along with them.
	4.5 Cooperation	Cooperation offered through a system can increase

		user's motivation to perform target behaviors.
	4.6 Competition	Competition can increase motivation to engage in a particular behavior leveraging human's natural tendency to compete.
	4.7 Recognition	Recognition of performing a particular behavior can motivate users to continue to engage in the behavior.

Table 4. iDBT-ER application of Systematic Framework for Designing and Evaluating Persuasive Systems

<i>Persuasion category</i>	<i>Persuasion strategy</i>	<i>Definition</i>
1. Primary task support	1.1 Reduction	Reduction is persuading the user to perform a behavior by reducing complex tasks to easier or simpler steps. <i>iDBT-ER: Breaking complex skills like checking the facts, opposite action, problem solving into steps</i>
	1.2 Tunneling	Tunneling refers to persuading a user by guiding him/her through a series of pre-determined steps, such that once the user has entered the “tunnel” he/she is likely to follow along. <i>iDBT-ER: Guiding user through a step-by-step process of applying a skill or observing how a skill is explained in examples; guiding users through making a specific plan for implementing a skill</i>
	1.3 Tailoring	A message tailored to a user’s specific needs, interests, and goals is likely to be more persuasive if it decreases the effort involved when exposed to non-relevant information. <i>iDBT-ER: Users can make selections in terms of what emotions to work on, whether a teaching segment is relevant to them (nightmare protocol, sleep hygiene protocol); iDBT-ER targets individuals who have trouble regulating their emotions</i>
	1.4 Personalization	Personalization refers to offering the users capabilities to personalize the content and services offered to them to increase persuasion. <i>iDBT-ER: Users can select content most relevant to them, can select among suggestions for practice</i>
	1.5 Self-monitoring	A persuasive system with self-monitoring support helps the user keeping track of performance or status in achieving goals. <i>iDBT-ER: Daily diary card helps users self-monitor skills use</i>
	1.6 Simulation	Simulation as a strategy persuades by allowing the user to immediately observe the cause-effect relationships. <i>iDBT-ER: Users are prompted to enter details about their own situations into a model of emotion and to observe cause-effect relationships. Real life examples are presented</i>

		<i>in the context of the model for emotion to help integrate cause-effect relationships</i>
	1.7 Rehearsal	Persuading through rehearsal refers to increasing the likelihood that a certain behavior will take place in the real world if it is rehearsed during an interaction with a system. <i>iDBT-ER: Users can practice implementing complex skills in a step-by-step manner (problem solving); in session practice of mindfulness, cope-ahead, relaxation, paced breathing help rehearse skillful behavior</i>
2. Supporting dialogue/rel ationship with users	2.1 Praise	Conveying praise to a client through a variety of tools (images, words, comments, or symbols) can reinforce the preceding behavior. <i>iDBT-ER: Users receive praise via narration upon reporting homework completion and via video upon completing a session</i>
	2.2 Rewards	Rewards given for performing behaviors targeted to increase can lead to behavior change in the desired direction. <i>iDBT-ER: not supported</i>
	2.3 Reminders	A persuasive system that reminds users to perform specific target behaviors is increasing the likelihood that those behaviors will happen. <i>iDBT-ER: incorporates daily reminders for skills practice and self-monitoring (diary card prompts)</i>
	2.4 Suggestion	The principle of suggestion is that “A computing technology will have greater persuasive power if it offers suggestions at opportune moments”. <i>iDBT-ER: Homework assignments suggest what skills to be practiced the following week; daily prompts for skills practice prompt participants to rehearse skills</i>
	2.5 Similarity	Similarity refers to the fact that people are persuaded more easily by systems that resemble themselves in some ways. <i>iDBT-ER: Video modeling of individuals with emotion dysregulation problems are presented; models in examples solve problems relevant for emotion dysregulation</i>
	2.6 Liking	A system that is designed to be likable and appealing to users can have increased power of persuasion. <i>iDBT-ER: Designed to be user friendly</i>
	2.7 Social role	Social role refers to the system adopting a familiar, established social role to increase its persuasiveness.

		<i>iDBT-ER: Skills are taught by DBT skills trainer/therapist</i>
3. System credibility support	3.1 Trustworthiness	A system viewed as trustworthy, unbiased, fair, without using coercion or manipulation will have a greater power of persuasion. <i>iDBT-ER: System designed by reputed research lab</i>
	3.2 Expertise	A system viewed as incorporating a high level of expertise (knowledge, experience and competence) will be more persuasive. <i>iDBT-ER: System designed and implemented by reputed research lab and DBT creator</i>
	3.3 Surface credibility	Surface credibility highlights that the first impression a system makes onto a user has a high impact on credibility of that system. <i>iDBT-ER: Welcome video message designed to motivate users to engage with the program and demonstrate relevance of topics to come</i>
	3.4 Real-world feel	Real-world feel refers to having a system that underlines the people or organizations behind it to increase persuasion. <i>iDBT-ER: Developed by established research lab within a reputable university</i>
	3.5 Authority	Content viewed by users as being generated from a source of authority (person or organization) enhances persuasion. <i>iDBT-ER: Developed by established research lab within a reputable university</i>
	3.6 Third-party endorsement	Third-party endorsement, especially from well reputed systems increase credibility of a system. <i>iDBT-ER: Not implemented yet</i>
	3.7 Verifiability	Verifiability refers to enhancing credibility of a system by making its information easily verifiable against external sources. <i>iDBT-ER: References to research supporting the DBT skills (paced breathing skill, mindfulness skills, etc.)</i>
4. Social influence	4.1 Social learning	Social learning refers to persuading people to perform a specific behavior by enabling them to observe someone else performing that behavior. <i>iDBT-ER: Models of DBT skills application via video, narration or text</i>
	4.2 Social comparison	Social comparison increases persuasion by allowing users to compare their performance to that of other users.

		<i>iDBT-ER: Normalizing of difficulty with skills practice and common challenges encountered</i>
4.3	Normative influence	Normative influence refers to leveraging peer pressure to increase persuasion. <i>iDBT-ER: Not implemented yet.</i>
4.4	Social facilitation	Social facilitation refers to increasing persuasion by allowing the user to discern that others are performing intended behaviors along with them. <i>iDBT-ER: Not implemented yet.</i>
4.5	Cooperation	Cooperation offered through a system can increase user's motivation to perform target behaviors. <i>iDBT-ER: Not implemented yet.</i>
4.6	Competition	Competition can increase motivation to engage in a particular behavior leveraging human's natural tendency to compete. <i>iDBT-ER: Not implemented yet.</i>
4.7	Recognition	Recognition of performing a particular behavior can motivate users to continue to engage in the behavior. <i>iDBT-ER: Recognition of session completion, accessing the daily diary card, coming back to sessions</i>

Table 5. Goals pursued during iDBT-ER development process

iDBT-ER Treatment Development Goal	iDBT-ER implementation features
Maintaining fidelity to standard DBT skills training	<ul style="list-style-type: none"> • Teach material presented as video recordings of treatment developer Marsha Linehan • Maintain most of the DBT skills training session structure • Maintain written handouts and worksheets materials unchanged from standard DBT skills training • Adapt homework review to include “missing links analysis” and prompts to complete missed elements on the spot similar to standard DBT skills training • Resolve dialectical tension in intervention development between incorporating user preferences and following DBT and behavioral therapy principles • Link treatment goals to homework assignment • Troubleshoot potential barriers to homework completion • Provide reinforcement for homework, diary card, and session completion
Incorporating proven multimedia learning principles	<ul style="list-style-type: none"> • Utilize simple navigation through intervention • Allow user to progress through session self-paced • Allow user to progress through entire intervention self-paced while reserving time for practice • Divide materials into small segments to prevent dis-engagement • Supplement teaching with summarizing text, schematics, animations, images to illustrate content and promote learning • Supplement text with voice over material to guide participant through material and augment learning

	<ul style="list-style-type: none">• Learn through examples• Incorporate cognitive load theory of multimedia learning• Adopt a user centered design (incorporate feedback from targeted participants in development of intervention)
--	---

Table 6. Intervention structure and characteristics

iDBT-ER characteristics	
Number of sessions	8
Average length of session	50 minutes to 1 hour
Session frequency	1 session / week; no less than 5 days in between sessions
Homework assignment	1=Different skills practice assignments each week
Behavioral prompts	One skills practice prompt in the morning delivered via email, text message or both (based on preference)
Diary card	One prompt in the evening to complete online diary card tracking daily skills practice, delivered via email, text message, or both
Session reminders	Up to two phone/email reminders sent x days and x days for a session announced and not completed
Printable materials	Standard DBT skills handouts and worksheets for skills taught

Table 7. iDBT-ER curriculum

Week	Module ^a	Selected skills
1	Mindfulness	Observe
		Describe Participate
2	Mindfulness	Non-judgmentally
		One-mindfully
		Effectively
3	Emotion Regulation	Goals of Emotion Regulation
		Understanding and naming emotions
		Emotion myths
4	Emotion Regulation	Model of emotion
		Observing and describing emotions
5	Emotion Regulation	Check the Facts
		Opposite Action
6	Emotion Regulation	Problem Solving
		Putting Opposite Action and Problem Solving together
7	Emotion Regulation	Reducing Vulnerability (A B C) <ul style="list-style-type: none"> • Accumulating Positives Emotions Short-Term • Accumulating Positive Emotions Long-Term • Build Mastery • Cope Ahead

8	Emotion Regulation	Reducing Vulnerability (PLEASE)
		<ul style="list-style-type: none"> • Treat Physical Illness • Balance Eating • Avoid Mood Altering Drugs • Balance Sleep • Exercise
		TIP Skills
		<ul style="list-style-type: none"> • Alternate Temperature • Intense Exercise • Paced Breathing
		Mindfulness of Current Emotions
		Distracting

^aIndicates the DBT skills training module (Linehan, 1993a) from which each skill was derived

Table 8. iDBT-ER Self-Referencing activities examples. Participants are prompted to reflect on how a particular skill could be effective in their life

Session 1: Identify pros and cons of practicing mindfulness in an area of your life of interest to you
Session 1: In what area would you like to observe / describe / participate more?
Session 2: Where would you like to start being less judgmental: with yourself or with others?
Session 2: What was the impact on you when someone was judgmental of you? Did it make you feel closer to someone?
Session 3: Are there emotions you'd like to get rid of completely in your life? If yes, what negative consequences would that have for you?
Session 3: Is it more difficult for you to manage your emotions than for others? Do you have a biological vulnerability to being emotional? Did you have few opportunities to learn how to regulate your emotions? If so, does it make sense why it's harder for you to regulate emotions? This might help being less judgmental of your emotions.
Session 3: Pick the goals of emotion regulation that are meaningful to you
Session 6: Figure out whether to problem solve or do opposite action for changing an emotion you'd like to decrease
Session 7: Go through each of the ABC PLEASE skills, review what the skills are for and pick the ones relevant to you and an area to apply them
Session 8: Nightmare protocol: Is your sleep troubled by nightmares? Would you like to review strategy for handling nightmares?
Session 8: Sleep hygiene protocol: Do you have trouble sleeping? Would you like to review strategies to improve your sleep?
Session 8: Do you often worry about the future or ruminate about the past? Ice water skill can help with worry & rumination. Are you willing to work on a plan to apply the Ice water skill?

Table 9. iDBT-ER Modeling and behavioral rehearsal examples. Participants are guided through in session practice of the skills taught

Sessions 1-8: Mindfulness practice at the beginning of session; brief mindfulness practices for observe your breath, observe your thoughts.
Session 1: Identify pros and cons for practicing mindfulness in area of interest to you
Session 1: Observe the video of a sunset at sea
Session 1: Describe non-judgmentally the image of a tree
Session 1: Describe non-judgmentally the image of a couple arguing
Session 1: Participate, throw yourself into a word game
Session 2: Trevor’s pros and cons example for being one-mindful
Session 2: Four scenarios for evaluating what’s more effective: a mother’s choice in reprimanding or validating and reinforcing good behavior when putting her daughter to bed; handling traffic situation when other driver does not give right of way; putting up with the paperwork in applying for food stamps; how to deal with being on hold for a long time when you need a medical prescription that day.
Session 4: Example of applying the model of emotion for a situation that elicits frustration
Session 5: Alicia’s example of checking the facts on believing she will be fired for making a mistake at work; Alicia’s model of emotion before and after Checking the Facts
Session 5: Your step-by-step example of Checking the Facts, before and after model of emotion
Session 5: Pick an emotion to work with, check the facts, plan for opposite action or problem solving
Session 6: Your step-by-step example for Problem Solving
Session 6: Hanna’s example for Problem solving keeping up with her school while handling other commitments
Session 7: Step-by-step guide to prioritizing your values and getting from values to action steps
Session 7: Cope ahead with a situation that elicits anxiety
Session 7: Relaxation practice after practicing coping ahead

Session 8: Step-by-step guide to prioritizing and selecting a PLEASE skill to work on
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Session 8: Guided practice of Paced Breathing skill with counter on screen

Table 10. iDBT-ER Planning and scheduling skills practice activities. Participants are guided through the steps needed to implement a particular skill in their lives.

Session 1: What can you do to observe / describe / participate more in an area of your life important to you?
Session 1: Pick from handouts mindfulness practices you'd be willing to do next week
Session 6: How would you do opposite action or problem solve for your particular situation and emotion you'd like to change?
Session 7: Identify two changes needed in your life to create a new routine for engaging in pleasant events
Session 7: Identify two changes needed to be more present to two pleasant events you already do routinely
Session 7: Make a step-by-step plan of accumulating positive emotions in your life on a long term
Session 8: Prioritize and select which PLEASE skills to work on now in your life, anticipate and troubleshoot potential barriers to implement selected skill
Session 8: Make a specific plan for how and when to practice the ICE water skill

Table 11. iDBT-ER Activities repeating information from a different perspective

Session 2: Explore different norms around public behavior in Eastern versus Western culture (non-judgmental skill)
Session 2: Explore different reasons to work on being non-judgmental (it can ruin relationships, it can impact emotions, it is often less effective at changing things than problem solving causes)
Session 3: Examples of how emotions communicate to others: social referencing in kids; communicating distress through emotion can make others more responsive
Session 4: Explore scenarios of prompting events and the emotions they elicit (frustration, shame, guilt, joy)
Session 4: Explore Rhonda's situation where her interpretation of not being invited to a team party leads to different emotions

Table 12. Components and roles in technical set-up of iDBT-ER

Component/actor	Role/functionality
iDBT-ER user	<ul style="list-style-type: none"> • Accesses iDBT-ER through a predetermined online link and logs in via a username and password • Navigates through iDBT-ER session content • As desired provides iDBT-ER with information when prompted that determines what content is shown
Vimeo video streaming server	Hosts the iDBT-ER teaching videos that were uploaded post editing
Final Cut Pro	Video editing software allows: <ul style="list-style-type: none"> • Cutting of videos into desired segments • Adding images, diagrams, animations to video
123rf.com stock photos	Allows downloading of images and videos
Articulate Storyline	Allows development of online course <ul style="list-style-type: none"> • Integrates external video streaming • Scripting that allows definition of branching in information flow based on user preferences (using variables) • Previews modules to enable debugging of functionality • Publishes the online content according to standards (SCORM)
Articulate Online	Learning Management System (LMS) that allows: <ul style="list-style-type: none"> • User management in terms of system and content access permissions • Tracking of user activity in terms of access, length of access, completion of assigned modules • Generation of activity reports for item completion, scores, etc.

Table 13. Phase 1 Participant exclusion criteria

Screening phase	Criteria
Phone	Is not willing to discontinue current psychosocial treatment
	Age < 18 years
	Is mandated to treatment by Court order Agency (e.g., CPS) Family
	DERS < 98
	Manifests cognitive impairment > =8 on 6-Item Cognitive Impairment Test
	Lives outside of commuting distance
	Has received > 5 sessions of outpatient DBT approach to therapy
	Is at high risk for suicide: Has attempted suicide within the last year Has attempted suicide > 1 year ago and reports current ideation Has never attempted suicide but reports current ideation, including a preferred method and plan
	Meets criteria for Borderline Personality Disorder if 3 patients with BPD have already been included in the study until this point
	Does not have access to email or phone that he is willing to use for the purpose of the study
	Meets criteria for a diagnostic pattern that has already been included in the study 3 times before
	Cannot communicate in or understand sufficient English language to benefit
In-person	Does not meet criteria for a current mood/anxiety disorder, including: Major Depressive Disorder Major Depressive Disorder NOS

	<p>Dysthymia</p> <p>Social Phobia</p> <p>Specific Phobia</p> <p>Post Traumatic Stress Disorder</p> <p>Obsessive Compulsive Disorder</p> <p>Panic Disorder (with or without agoraphobia)</p> <p>Agoraphobia without Panic Disorder</p> <p>Generalized Anxiety Disorder</p> <p>Anxiety Disorder NOS</p>
	<p>Meets diagnostic criteria for</p> <p>Bipolar Disorder</p> <p>Schizophrenia</p> <p>Schizophreniform Disorder</p> <p>Schizoaffective Disorders</p> <p>Psychosis NOS</p> <p>Substance Dependence (current, needing immediate intervention)</p> <p>Anorexia Nervosa (current, life-threatening, BMI<13)</p>
	<p>Is not willing to be video taped throughout study</p>
	<p>Is not willing to agree to discuss with prescribing physician staying on same dose of medication throughout study if appropriate for them</p>

Table 14. Phase 2 Participant exclusion criteria

Screening phase	Criteria
Initial Phone Screen	Is not willing to discontinue current psychosocial treatment
	Age < 18 years
	Is mandated to treatment by Court order Agency (e.g., CPS) Family
	DERS < 98
	Manifests cognitive impairment > =8 on 6-Item Cognitive Impairment Test
	Lives outside of Washington State
	Has received > 5 sessions of outpatient DBT approach to therapy
	Is at high risk for suicide: Has attempted suicide within the last year Has attempted suicide > 1 year ago and reports current ideation Has never attempted suicide but reports current ideation, including a preferred method and plan
	Meets criteria for Borderline Personality Disorder if 3 patients with BPD have already been included in the study until this point
	Meets criteria for a diagnostic pattern that has already been included in the study 3 times before
	Cannot communicate in or understand sufficient English language to benefit
2 nd Phone Screen	Does not meet criteria for a current mood/anxiety disorder, including: Major Depressive Disorder Major Depressive Disorder NOS Dysthymia Social Phobia

	<p>Specific Phobia</p> <p>Post Traumatic Stress Disorder</p> <p>Obsessive Compulsive Disorder</p> <p>Panic Disorder (with or without agoraphobia)</p> <p>Agoraphobia without Panic Disorder</p> <p>Generalized Anxiety Disorder</p> <p>Anxiety Disorder NOS</p>
	<p>Meets diagnostic criteria for</p> <p>Bipolar Disorder</p> <p>Schizophrenia</p> <p>Schizophreniform Disorder</p> <p>Schizoaffective Disorders</p> <p>Psychosis NOS</p> <p>Substance Dependence (current, needing immediate intervention)</p> <p>Anorexia Nervosa (current, life-threatening, BMI<13)</p>
	<p>Is not willing to be video taped throughout study</p>
	<p>Is not willing to agree to discuss with prescribing physician staying on same dose of medication throughout study if appropriate for them</p>

Table 15. Phase 1 Demographic characteristics

	All Screened <i>N</i> =28	Intent to Treat <i>N</i> =7
Gender:	N (%)	N (%)
Female	15 (60%)	4 (57.1%)
Male	10 (40%)	3 (42.9%)
# valid answers	25	7
Age in years: M (SD)	M (SD)	M (SD)
	37.2 (11.4)	32.1 (7.5)
# valid answers	25	7
Racial Background:	N (%)	N (%)
White	18 (85.7%)	6 (85.7%)
Black	2 (9.5%)	0 (0.0)
Korean	1 (4.8%)	0 (0.0)
Other	1 (4.8%)	1 (14.3%)
# valid answers	21	7
Marital Status:	N (%)	N (%)
Single, never married	16 (76.2%)	6 (85.7%)
Widowed/Separated/Divorced	5 (23.8%)	1 (14.3%)
Married	0 (0%)	0 (%)
# valid answers	21	7
Educational Background:		
< high school	0 (0%)	0 (0%)
High school graduate/GED	0 (0%)	0 (0%)
Some college	8 (38.1%)	3 (42.9%)
College graduate	8 (38.1%)	1 (14.3%)
Master's degree	4 (19.0%)	3 (42.9%)
Doctoral degree	1 (4.8%)	0 (0%)
# valid answers	21	7
Gross Annual Income: # (%)		
Less than \$10,000	10 (50%)	5 (83.3%)

\$10,000-\$30,000	2 (10%)	0 (0%)
Over \$30,000	8 (40%)	1 (16.7%)
# valid answers	20	6

Table 16. Phase 2 Demographic characteristics

	All Screened <i>N=111</i>	Intent to Treat <i>N=25</i>
Gender:	N (%)	N (%)
Female	77 (72%)	21 (84%)
Male	30 (28%)	4 (16%)
# valid answers	107	25
Age in years: M (SD)	M (SD)	M (SD)
	41.5 (14.7)	43.8 (14.5)
# valid answers	107	25
Racial Background:	N (%)	N (%)
White	67 (79.8%)	19 (82.6%)
Native American/American Indian	4 (4.8%)	1 (4.3%)
Black	7 (8.3%)	1 (4.3)
Chinese	2 (2.4%)	0 (0%)
Korean	1 (4.8%)	0 (0.0)
Mexican	1 (1.2%)	0 (0%)
East Indian	1 (1.2%)	1 (4.3%)
Other Latino	4 (4.8%)	1 (4.3%)
Other Asian	5 (6 %)	2 (8.7%)
Other	1 (1.2%)	0
# valid answers	84	23
Marital Status:	N (%)	N (%)
Single, never married	49 (57%)	9 (39.1%)
Widowed/Separated/Divorced	19 (22.1%)	8 (34.7%)
Married	18 (20.9%)	6 (26.1%)
# valid answers	86	23
Educational Background:		
< high school	7 (8.2%)	0 (0%)
High school graduate/GED	16 (18.6%)	1 (4.3%)
Some college	28 (32.6%)	14 (60.8%)

College graduate	20 (23.3%)	3 (13%)
Some graduate training	6 (7.0%)	1 (4.3%)
Master's degree	12 (14.0%)	6 (26.1%)
Doctoral degree	3 (3.5%)	1 (4.3%)
# valid answers	80	21
Gross Annual Income: # (%)		
Less than \$10,000	19 (23.8%)	6 (28.5%)
\$10,000-\$30,000	28 (35.1%)	6 (28.6%)
Over \$30,000	33 (41.3%)	9 (42.8%)
# valid answers	80	21

Table 17. Phase 1 Employment and diagnostic criteria met ITT sample

Current diagnoses	Number (%)
	ITT = 7
Major Depressive Disorder (MDD)	2 (28.5%)
Dysthymia	0 (0%)
Depression NOS	0 (0%)
Panic disorder	
Without agoraphobia	1 (14.2%)
With agoraphobia	0 (0%)
Agoraphobia without panic disorder	0 (0%)
Generalized Anxiety Disorder (GAD)	4 (57.14%)
Anxiety NOS	0 (0%)
Social Anxiety Disorder (SAD)	1 (14.2%)
Specific phobia	2 (28.5%)
Obsessive Compulsive Disorder (OCD)	0 (0%)
Posttraumatic Stress Disorder (PTSD)	4 (57.1%)
Somatoform disorder	0 (0%)
Eating disorder	1 (14.2%)
Substance abuse/dependence	2 (28.5%)
Borderline Personality Disorder (BPD)	2 (28.5%)
Primary presenting problem	
Depression	1 (14.2%)
Anxiety	6 (85.7%)
Lifetime diagnoses (not currently met)	
Anxiety disorder (any)	0 (0%)
Depressive disorder (any)	5 (71.43%)
Substance abuse/dependence (any)	2 (28.57)
Eating disorder (any)	1 (14.29%)
Employment	
Unemployed	1 (14.2%)

Employed outside the home	5 (71.43%)
Homemaker	0 (0%)
Student	1 (14.2%)
Retired	0 (0%)

Table 18. Phase 2 Employment and diagnostic criteria met ITT sample

Current diagnoses	Number (%)
Major Depressive Disorder (MDD)	16 (64%)
Dysthymia	2 (8%)
Depression NOS	1 (4%)
Panic disorder	
Without agoraphobia	1 (4%)
With agoraphobia	4 (16%)
Agoraphobia without panic disorder	3 (12%)
Generalized Anxiety Disorder (GAD)	13 (52%)
Anxiety NOS	5 (18.51%)
Social Anxiety Disorder (SAD)	7 (28%)
Specific phobia	1 (4%)
Obsessive Compulsive Disorder (OCD)	1 (4%)
Post-Traumatic Stress Disorder (PTSD)	10 (40%)
Somatoform disorder	2 (8%)
Substance abuse/dependence	1 (4%)
Borderline Personality Disorder (BPD)	4 (16%)
Primary presenting problem	
Depression	15 (60%)
Anxiety	10 (40%)
Lifetime diagnoses (not currently met)	
Anxiety disorder (any)	1 (4%)
Depressive disorder (any)	3 (12%)
Substance abuse/dependence (any)	9 (36%)
Eating disorder (any)	3 (12%)
Employment	
Unemployed	7 (28%)
Employed outside the home	13 (52%)
Homemaker	1 (4%)

Student	2 (8%)
Retired	2 (8%)
# valid answers 25	

Table 19. Phase 1 Number of missing data points and reasons at each assessment point

Assessment point	Number Missing /Total	Reasons for missing data
Pre-tx	0	
4-Weeks	1 (14.2%)	<i>Subject was a drop out (1)</i>
8-Weeks	2 (28.4%)	<i>Subject is a drop out (2)</i>

Table 20. Phase 2 reasons for missing data at each assessment point

Assessment point	Number Missing (%)	Reasons for missing data
Pre-tx	0 (0%)	
4-Weeks	3 (12%)	<i>Subject was a drop out (3)</i>
8-Weeks	6 (24%)	<i>Subject is a drop out (5)</i> <i>Subject was unreachable (1)</i>

Table 21. Phase 1 Number of sessions completed by participants

Total number of sessions completed	Number participants N (%)
1	1 (14.2%)
5	1 (14.2%)
8	5 (71.6%)

Table 22. Phase 1 Number of sessions completed by participants

Total number of sessions completed	Number participants N (%)
1	3 (12%)
2	2 (8%)
5	1 (4%)
6	4 (16%)
7	6 (24%)
8	13 (52%)

Table 23. Phase 1 Descriptive statistics for outcome measures per time point

Scale	<i>n</i>	<i>Mean</i>	<i>SD</i>
DERS			
Pre-tx	7	118.8	23.8
4-weeks	6	113.1	21.0
8-weeks	5	91.8	20.5
KIMS			
Pre-tx	7	2.77	0.53
4-weeks	6	2.66	0.32
8-weeks	5	3.16	0.61
DBT_WCCL			
Pre-tx	7	1.66	0.39
4-weeks	6	1.60	0.15
8-weeks	6	1.99	0.22
PHQ9			
Pre-tx	7	0.98	0.70
4-weeks	6	1.25	0.79
8-weeks	5	0.80	0.57
OASIS			
Pre-tx	7	1.88	0.84
4-weeks	6	1.61	0.59
8-weeks	5	1.12	0.57

Valid n list-wise = 5

Note: DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills; AAQ = Acceptance and Action Questionnaire

Table 24. Phase 2 Descriptive statistics for outcome measures per time point.

Scale	<i>n</i>	<i>Mean</i>	<i>SD</i>
DERS			
Pre-tx	25	116.64	21.34
4-weeks	22	104.90	21.28
8-weeks	19	91.31	23.25
KIMS			
Pre-tx	25	2.76	0.48
4-weeks	22	3.06	0.51
8-weeks	19	3.33	0.58
DBT_WCCL			
Pre-tx	25	1.55	0.41
4-weeks	22	1.77	0.36
8-weeks	19	2.00	0.40
PHQ9			
Pre-tx	25	13.97	6.30
4-weeks	22	11.55	6.17
8-weeks	19	8.36	5.04
OASIS			
Pre-tx	25	10.56	4.47
4-weeks	22	9.68	4.06
8-weeks	19	7.47	4.42
AAQ			
Pre-tx	25	4.86	0.51
4-weeks	22	4.48	0.58
8-weeks	19	4.05	0.82
OQ-45			
Pre-tx	25	92.24	24.14
4-weeks	22	78.13	28.23
8-weeks	19	67.10	25.87

Note: DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills; AAQ = Acceptance and Action Questionnaire

Table 25. Phase 1 Paired sample t-tests pre-tx to 8 weeks

Measure (Pre-tx – 8 weeks)	Mean	Std. Dev.	Std. Err. Mean	95% CI		t	df	Sig (2- tailed)	r
				Lower	Upper				
DERS	37.40	19.19	8.58	13.57	61.22	4.35	4	<.05	0.90
DBT-WCCL	-.58	.30	.13	-.95	-.21	-4.35	4	<.05	0.90
KIMS	-.67	.46	.20	-1.24	-.09	3.24	4	<.05	0.85
OASIS	4.80	1.30	.58	3.18	6.41	8.32	4	<.05	0.97
PHQ9	5	4.06	1.81	-.04	10.04	2.75	4	.051	0.80

Note: DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills;

Table 26. Phase 1 Paired sample t-tests pre-tx to 4 weeks

Measure (Pre-tx - 4 weeks)	Mean	Std. Dev.	Std. Err. Mean	95% CI		t	df	Sig (2- tailed)	r
				Lower	Upper				
DERS	16.6	18.64	7.60	-2.89	36.22	2.19	5	.80	
DBT-WCCL	-.19	.19	.07	-.39	-.01	-2.48	5	.055	0.74
KIMS	-.15	.34	.14	-.51	.21	-1.05	5	.34	
OASIS	3.83	2.31	.94	1.40	6.26	4.05	5	<.05	0.87
PHQ9	.83	3.12	1.27	-2.44	4.11	.65	5	.54	

Note: DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills

Table 27. Phase 2 HLM outcome analyses ITT sample (N=25)

Measure	Estimated slope	Std. Error	Significance
DERS	-12.2	2.57	<.05
DBT-WCCL			
Total score	0.22	0.04	<.025
Expectancy improvement	0.1	0.03	<.025
KIMS	0.28	0.07	<.05
OASIS	-1.3	0.43	<.05
PHQ9			
Total Score	-2.66	0.56	<.05
Expectancy improvement	-2.05	0.44	<.05
AAQ	-0.39	0.08	<.025
OQ			
Total Score	-12.2	2.57	<.05
Expectancy improvement	-9.29	2.24	<.05

Note: DBT-WCCL = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; OQ = Outcome Questionnaire; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills; AAQ = Acceptance and Action Questionnaire

Table 28. Phase 2 HLM outcome analyses completer sample (N=20)

Measure	Estimated slope	Std. Err	Significance
DERS			
Total score	-12.27	2.25	<.05
Expectancy improvement	-6.04	2.10	<.05
DBT-WCCL			
Total score	0.22	0.04	<.05
Expectancy improvement	0.1	0.03	<.05
KIMS	0.28	0.06	<.05
OASIS	-1.32	0.44	<.05
Total Score	-2.5	0.6	<.05
Expectancy improvement	-2.35	0.47	<.05
AAQ	-0.41	0.09	<.025
OQ			
Total Score	-12.15	2.76	<.05
Expectancy improvement	-11.78	2.41	<.05

Note: SKILLS = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; OQ = Outcome Questionnaire; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills; AAQ = Acceptance and Action Questionnaire

Table 29. Comparison descriptives and effect sized for historical control DBT-ST and iDBT-ER

	Time	N	Mean	SD	Cohen's	N	Mean	SD	Cohen
		DBT-	DBT-	DBT-	d	iDBT-	iDBT	iDBT-	's d
		ST	ST	ST		ER	-ER	ER	
DERS	Pre-tx	15	105.27	14.68		25	116.6	21.34	
							4		
	2 mo	15	82.73	19.67	1.29		91.31	23.25	1.14
OASIS	Pre-tx	22	11.04	3.45			10.56	4.47	
	2 mo	22	7.27	2.99	1.16		7.47	4.42	0.69
PHQ9	Pre-tx	22	13.04	4.29			13.97	6.30	
	2 mo	22	6.50	4.21	1.53		8.36	5.04	0.98
KIMS	Pre-tx	22	2.94	0.48			2.76	0.48	
	2 mo	22	2.95	0.41	-0.02		3.33	0.58	-1.07
SKILL	Pre-tx	22	1.76	0.40			1.55	0.41	
S									
	2 mo	22	2.18	0.35	-1.11		2.00	0.40	-1.11
OQ	Pre-tx	22	87.14	17.77			92.24	24.14	
	2 mo	22	62.55	21.46	1.24		67.10	25.87	1.00

Note: SKILLS = DBT Ways of Coping Checklist; DERS = Difficulties in Emotion Regulation Scale; OQ = Outcome Questionnaire; PHQ-9 = Patient Health Questionnaire-9; OASIS = Overall Anxiety Severity and Impairment Scale; KIMS = Kentucky Inventory of Mindfulness Skills

Table 30. Phase 1 Descriptives of perceived usefulness of iDBT-ER sessions (Scale 0-10; 0 = no usefulness; 10 = high usefulness)

Session number	N	Mean	Std. Deviation
S1	7	7.14	2.03
S2	6	8.00	.89
S3	6	7.00	1.41
S4	6	7.50	1.37
S5	6	7.67	1.21
S6	5	7.80	2.16
S7	5	8.20	1.48
S8	5	7.40	0.54

Table 31. Information coded for in reviewing feedback interview data

Level	Specific information sought
Content	<ul style="list-style-type: none"> • Specific type of content items participants like/dislike (quizzes, video vignettes, step-by-step examples, in session practices) • Specific content items participants like/dislike • Content items that are confusing
Functionality	<ul style="list-style-type: none"> • Specific functions of the intervention and their implementation participants like/dislike (homework assignment, homework review, in session practice, distribution of handouts, reminders) • Flow of information and tasks

Table 32. Changes to iDBT-ER as a result of feedback interviews

Type/level of change	Specific change
Content	<ul style="list-style-type: none"> • Removed one set of video vignettes • Removed quizzes • Added step-by-step guided practices for most skills • Removed specific disliked images • Changed specific practice examples • Changed content of reminder text messages to more varied practices • Changed content of reminder email messages to include content review items • Expanded session overview and added narration
Functionality	<ul style="list-style-type: none"> • Changed homework assignment to add narration, normalize challenges with practice, cheerleading statements • Changed homework review to use missing chain analysis • Change homework review to review skills practice in a step by step manner • Added narration to introduce the purpose of homework review and decrease shame associated with not doing the homework • Changed structure to allow more choices in content displayed • Decreased length of narration for practice exercises • Added reinforcing welcome message at the beginning of sessions

Table 33. Phase 1 Descriptives of perceived usefulness of iDBT-ER components (Scale 0-10; 0 = no usefulness; 10 = high usefulness)

iDBT-ER component	Number records	Mean	Std. Dev
Mindfulness practice	42	7.31	1.38
Video teaching	42	8.07	1.19
Written teaching	30	6.90	1.44
Video vignettes	42	6.07	2.04
Homework assignment	37	7.00	1.50
Homework review	34	6.26	1.88
In between sessions reminders	34	7.00	1.29

APPENDIX 1

UNIVERSITY OF WASHINGTON
BEHAVIORAL RESEARCH & THERAPY CLINICS

The Client Feedback Interview

[Interviewer] Hi, I would like to begin by thanking you for coming in today to work with our program. Now I would like to go with you through a series of questions about your experience overall. I'll start with asking you a series of questions about the different intervention components you engaged with that have a rating associated, they all use a scale of 1 to 10 where 1 means worst you can imagine and 10 means the best you can imagine).

[PART A QUANTITATIVE Questions]

1. On a scale of 1 to 10 (1= worst you can imagine; 10 = best you can imagine) where would you rate today's

Intervention component	Rating 1-10 (1 = worst you can imagine; 10=best you can imagine)
Mindfulness practice	
Written teaching content	
Video teaching content	
Video vignettes illustrating skills application	
[WHEN PRESENT] In session practice of the skills	
[WHEN PRESENT] Quizzes	
[WHEN PRESENT] Written case examples	
Homework assignment	
[WHEN PRESENT] Homework review	

[WHEN PRESENT] In between sessions reminder/prompt messages	
---	--

2. Thinking back over the last week, what would you say was your highest urge to quit the program (1=no urge at all; 10=highest urge I can imagine)?

[Interviewer] Now we'll go to more general or open ended questions.

[PART B Open ended questions - QUALITATIVE]

1. [WHEN MINDFULNESS PRACTICE PRESENT] What did you think about today's mindfulness practice?
 - a. Probing questions: Did it improve your knowledge of the skills? Did it improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?

2. What did you think about today's written teaching content?
 - a. Probing questions: Was it engaging? Did it improve your knowledge of the skills? Did it improve your willingness to try the skills outside of sessions? Did it make you think of areas and situations where you can apply the skills taught? How can we improve that part of the intervention?

3. What did you think about today's video teaching content?
 - a. Probing questions: Was it engaging? Did it improve your knowledge of the skills? Did it improve your willingness to try the skills outside of sessions? Did it make you think of areas and situations where you can apply the skills taught? How can we improve that part of the intervention? Was the technical quality appropriate?

4. What did you think about today's illustrative video vignettes?
 - a. Probing questions: Were they engaging? Did they improve your knowledge of the skills? Did they improve your willingness to try the skills outside of sessions? Did they make you think of areas and situations where you can apply the skills taught? How can we improve that part of the intervention?

5. [WHEN PRESENT] What did you think about the in session practice of the skills?
- a. Probing questions: Was it engaging? Did it improve your knowledge of the skills? Did it improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?
-
-
-
6. [WHEN PRESENT] What did you think about today's quizzes?
- a. Probing questions: Were they engaging/interesting? Did they improve your knowledge of the skills? Did they improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?
-
-
-
7. [WHEN PRESENT] What did you think about today's written case examples?
- a. Probing questions: Were they engaging? Did they improve your knowledge of the skills? Did they improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?
-
-
-
8. [WHEN PRESENT] What did you think about today's homework assignments?
- a. Probing questions: Did they seem useful? Did they improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?
-
-
-
9. [WHEN PRESENT] What did you think about today's homework review?
- a. Probing questions: Was it engaging? Did that improve your knowledge of the skills? Did that improve your willingness to try the skills outside of sessions? How can we improve that part of the intervention?
-
-
-
10. [WHEN PRESENT] Thinking back over the last week, what did you think about the in between sessions reminder/prompt messages?
- a. Probing questions: Did they seem useful? Did they remind you /prompt you to try the skills? Did they improve your willingness to try the skills outside of sessions? Can you give me an example of what happened after you received some of these

messages and the impact they had? How can we improve that part of the intervention?

11. Thinking back over the last week what was your experience overall with practicing the skills this past week? Probing questions:
- a. Did you identify any moments where regulating your emotions might have been useful?
 - b. Did the thought of practicing the skills enter your mind?
 - c. If you thought about the skills were you willing to give them a try?
 - i. If yes, what do you think contributed to you being willing to try them out?
 - ii. If no, what do you think contributed to you being unwilling to try them out?
 - d. What best describes your level of skills practice this last week? Did you practice the skills: never / a little / often / very often.
 - e. If/When you practiced the skills how successful were they in helping you regulate your emotion/experience less distress? Not successful / moderately successful / very successful.
 - f. Did the thought of quitting the program come to your mind? If yes what was the context (what were you doing at the time) what do you think contributed to that?
12. Do you have any other suggestions for how to improve today's skills training?
- a. What would make you more willing to try out the skills? What could increase your knowledge of the skills?
13. Anything else you'd like to tell us about?

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