OUTCOME EVALUATION OF AN IN-PATIENT PSYCHOTHERAPY PROGRAM: MINDFULNESS, DIFFICULTY WITH EMOTION REGULATION, AND MOOD AND ANXIETY SYMPTOMS

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List of Abbreviations

AA	Anxious Arousal
BPD	Borderline Personality Disorder
DBT	Dialectical Behaviour Therapy
DERS	Difficulty with Emotion Regulation
DERS-SF	Difficulty with Emotion Regulation – Short Form
DSM5	Diagnostic and Statistical Manual, 5th Edition
ER	Emotion Regulation
FFMQ	Five Facets of Mindfulness Questionnaire
GD	General Distress
GD-A	General Distress-Arousal
GD-D	General Distress-Depression
GPD	General Personality Disorder
ICD10	International Classification of Diseases – 10
MASQ	Mood And Anxiety Symptoms Questionnaire
MASQ-D30	Mood And Anxiety Symptoms Questionnaire – D30
MBIs	Mindfulness-Based Interventions
MDT	Multidisciplinary Team
NA	Negative Affect
PA	Positive Affect
SA	Somatic Arousal
USA	United States of America

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Introduction, Background, and Significance

There is emerging consensus linking emotion dysregulation with depression and anxiety disorders (Freundenthaler, Turba, & Tran, 2017). The important role of emotion regulation is increasingly acknowledged in psychiatric research (Gross & Munoz, 1995). Evidence of associations of trait mindfulness with strategies of emotion regulation among clinical samples (Desrosiers, Vine, Klemanski, & Nolen-Hoeksema, 2013) and meditators (Tran et al., 2014) suggest that emotion regulation could be one of the important aspects of how mindfulness results in improved psychological well-being. Even though research evidence confirms the effectiveness of mindfulness in clinical and nonclinical settings, the fundamental mechanisms of effect of mindfulness-based interventions are not yet known (Desrosiers et al., 2013).

Mindfulness is commonly defined as "paying attention in a particular way; on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994). It involves being attentive and accepting of internal and external moment-to-moment experience and paying attention to thoughts and emotions in a decentered manner as "mental events," rather than accurate reflections of the self and reality.

South Africa faces a significant burden of mental illness. Herman et al. (2009) found that the lifetime prevalence of common mental disorders in South Africa is 30.3%, and the most prevalent 12-month and lifetime disorders are the anxiety disorders. The Western Cape has the highest 12-month and lifetime prevalence rates of common mental disorders in South Africa. The National Mental Health Policy Framework and Strategic Plan 2013-2020 (National Department of Health, 2013) calls for the periodic evaluation of mental health services to assist in planning and improving service delivery.

Psychotherapeutic interventions are often delivered as part of a program that delivers mental health services to a defined clinical population. A rigorous evaluation of existing mental health programs that deliver mindfulness-based interventions, such as Dialectical Behaviour Therapy (Linehan, 1993), provide the opportunity to study the mechanism through which mindfulness effects change. The purpose of program evaluation research is to generate knowledge about the effectiveness of a program and represents the blending of research and program evaluation (Frankfort-Nachmias & Nachmias, 2008). As a type of program evaluation, an outcome assessment evaluation aims to answer the question: "To what extent is any noticeable change or difference in participants related to having received the program interventions" (Issel, 2009)?

In order to determine whether an intervention is beneficial to recipients, it is necessary to measure

changes occurring in the symptoms targeted by the intervention. Evaluation of such interventions are needed to ensure effectiveness, that the intervention is not harmful, and in order to understand the underlying causal mechanisms that lead to improvement. By identifying the specific components of the intervention that result in therapeutic change, it is possible to improve the intervention, as well as minimize the components that does not contribute to improvement. In order to understand how therapeutic interventions work, the hypothesized mechanisms of effect need to be measured (Baer, 2011). Further elucidating mechanisms of change would inform the use of mindfulness-based interventions by allowing for more focused and refined applications of mindfulness-based interventions and enhancing mindfulness psycho-education.

Research Aim

The current study aims to explore the possible effect of mindfulness skills training and the psychosocial skills training component of Dialectical Behaviour Therapy (DBT) included in an in-patient psychotherapy program on difficulty with emotion regulation, dispositional mindfulness, and features of anxiety and depression in a clinical population with diverse psychiatric morbidity.

Research Objectives

Objective 1: To describe the demographics, and principle psychiatric diagnoses of program participants at the start of the program, and to describe program implementation factors, such as number of DBT psychosocial skills training and mindfulness practice sessions attended, by the end of the 4-week program, and whether medication with proven mood and anxiety effect were prescribed upon discharge from the program.

Objective 2: To assess the outcome of the program on participants in terms of pre-and post-intervention changes on Mood and Anxiety Symptoms Questionnaire (MASQ-D30), the Difficulties in Emotion Regulation Scales – Short Form (DERS-SF), and the Five Facets of Mindfulness Questionnaire (FFMQ).

Objective 3: To characterize if changes in mindfulness (FFMQ), sub-scales of emotion regulation difficulty (DERS-SF), and prescription of medication with proven mood and anxiety effect are associated with improved mental health, as measured by the Mood and Anxiety Symptoms Questionnaire (MASQ-D30), across clinical populations.

Research Hypothesis

We hypothesize that at post-intervention follow-up, program participants will report improved emotion regulation, improved dispositional mindfulness, and improvement in mood and anxiety features, compared to pre-intervention.

It is further hypothesized that mindfulness and emotion regulation will correlate with mood and anxiety features, with improved dispositional mindfulness and improved emotion regulation predicting improved mood and anxiety features, post-intervention.

Literature Review

A non-systematic search of the literature was carried out to determine what previous studies have been undertaken to evaluate the role of mindfulness skills in emotion regulation, and its impact on mental health. Three databases (Academic Search Premier, Pubmed, and Psychinfo) were searched, using various combinations of the key terms "Dialectical Behavior Therapy," "mindfulness," "emotion regulation," "depressive symptoms," "anxiety," "in-patient psychotherapy," and "program outcome evaluation." Additional references were obtained from the bibliographies of the articles found.

Mindfulness

Many psychological disorders are increasingly treated by mindfulness-based therapies (Allen et al., 2006; Baer, 2003). There is empirical evidence that mindfulness-based interventions are effective in the treatment of a range of psychiatric disorders such as anxiety disorder (Evans et al., 2008), substance use disorder (Hayes, Strosahl, & Wilson, 1999), the prevention of relapse of major depressive disorder (Ma & Teasdale, 2004; Teasdale et al., 2000), and post-traumatic stress and related disorders (Follette, Palm, & Pearson, 2006).

There is considerable variation in psychologic literature in the description of mindfulness at a theoretical and operational level (Dimidjian & Linehan, 2003; Hayes &Wilson, 2003). Mindfulness has been defined as a self-regulatory capacity (Brown & Ryan, 2003), embodied emotion regulation (Guendelman, Medeiros, & Rampes, 2017), an acceptance skill (Linehan, 1994), and a meta-cognitive skill (Bishop et al., 2004).

Brown and Ryan (2003) define mindfulness as "a receptive attention to and awareness of present events and experience." They elaborate on this definition by describing mindfulness as concerning "a clear awareness of one's inner and outer worlds, including thoughts, emotions, sensations, actions, or surroundings as they exist at any given moment." Mindfulness involves observing stimuli entering one's awareness with non-interference with

this process of observation. It requires intentionally paying sustained attention to ongoing sensory, cognitive, and emotional experience, without elaborating upon or judging any part of that experience.

It is not entirely clear what the causal mechanisms are that produce the positive outcomes of mindfulness-based treatments. Research into the mechanisms of effect of mindfulness have focused on psychological and neurocognitive processes, as well as neurostructural and functional processes. Chambers, Gullone, and Allen (2009) summarize that mindfulness-based interventions are associated with lower intensity and frequency of negative affect, reduced anxiety, more adaptive responding to stress, decreased negative self-focused attention, improved attentional and working memory functioning, and decreased ego-defensive responsivity under threat. Neuroscientific studies of mindfulness have concluded that mindfulness promotes long-term structural and functional neurologic changes in the frontopolar cortex, sensory cortices, the insula, the hippocampus, the anterior and mid-cingulate cortex, the orbitofrontal cortex, the superior longitudinal fasciculus, and the corpus callosum (Wheeler, Arnkoff, & Glass, 2017). The same authors note in their review of literature the following:

> "Taken as a whole, the literature reviewed here suggests that both dispositional and intentional mindfulness activates areas of the brain typically known to be involved in the normal processes of emotion regulation. In addition, there is emerging evidence that engagement in intentional mindfulness deactivates the "default mode" network of the brain, which has been found to correlate with increased self-referential processing and to be overactive during the experience of rumination and worry. Instead, it appears that engagement in intentional mindfulness activates areas of the brain that are associated with focused attention on present moment sensory experiences. We propose that the means by which intentional mindfulness meditation may facilitate psychological well-being is by encouraging a detachment of narrative-focused thought from interoceptive experience."

Even if mindfulness-based interventions result in measurable changes on neuroscientific and psychological measures, they are of minimal value unless they are associated with behavioral changes (Fox, Dixon, Nijeboer, Girn, Floman, & Lifshitz, et al., 2016). In order to measure behavioral changes associated with mindfulness-based interventions, a number of mindfulness questionnaires have been developed and validated for research use, e.g. Freiburg Mindfulness Inventory (Buchheld, Grossman, & Walach, 2001), Mindful Attention Awareness Scale (Brown & Ryan, 2003), Kentucky Inventory of Mindfulness Skills (Baer, Smith, & Allen, 2004), Cognitive and Affective Mindfulness Scale – Revised (Feldman, Hayes, Kumar, Greeson, & Laurencau, 2007), Southampton Mindfulness Questionnaire (Chadwick et al., 2008), and the Five Facet Mindfulness Questionnaire

(Baer, 2006). There is encouraging evidence in published literature that the mindfulness questionnaires are robust, as suggested by the significant correlation of scores among them (Baer, 2011).

The current debate in mindfulness research calls for further research to better understand the potential reach and confines of application of mindfulness-based interventions, including limiting conditions. For example, can mindfulness and the means used to foster it, be harmful as well as helpful (Brown & Ryan, 2003)? Other questions include whether mindfulness-based interventions result in increases in the general tendency to respond mindfully to the experiences of daily life, and if so, whether these changes are causing the improvements in mental health (Baer 2011).

Research is needed on the mechanisms of change associated with improvement in dispositional mindfulness following participation in mindfulness-based interventions (Brown, Ryan, & Creswell, 2007). Currently there is insufficient evidence to allow prediction for whom and under what conditions mindfulness training is most effective, but there is some preliminary evidence to suggest individual differences cause variation in effectiveness (Keng, Smoski, & Robins, 2011). It is important to appropriately identify the type of populations and psychological conditions that are most likely to benefit from mindfulness-based interventions, in order to maximize the effectiveness and clinical utility of mindfulness interventions.

Mindfulness training has been increasingly integrated with various psychotherapeutic interventions and it is important to explore how mindfulness-based interventions work when integrated into these psychotherapeutic techniques (Keng, Smoski, & Robins, 2011). Replication of previous promising pilot studies of the therapeutic applications of mindfulness-based interventions is needed (Keng, Smoski, & Robins, 2011). Research needs to examine practical issues surrounding the implementation, delivery, and dissemination of the therapeutic applications of mindfulness interventions. Little is known about their cost effectiveness, nor about the amount and type(s) of training that is required for mindfulness practitioners (Keng, Smoski, & Robins, 2011).

Van Dam et al. (2017) summarize a critical evaluation of research on mindfulness and describe a research agenda. They review the alternative semantic interpretations of "mindfulness" and discuss the problematic ramifications of semantic ambiguity in the meaning of "mindfulness." They urge researchers to move away from a broad rubric of "mindfulness" toward a more explicit, differentiated denotation of exactly what mental states, processes, and functions are being taught, practiced, and investigated. They recommend a list of study design features for a mindfulness-based intervention, including teacher information, practice information, general information (e.g. instructor adherence, adverse events monitored), participant information, and conflicts of

interest.

Wheeler et al. (2017) address the importance of differentiating between concepts such as mindfulness, meditation, state mindfulness, and trait mindfulness. They propose that future researchers should differentiate between the degree of intentionality for engagement in mindfulness, and the extent of mindfulness training. They recommend the use of the term "dispositional mindfulness" to refer to the tendency (either intrinsic of resulting from both unlearned and learned factors) to pay attention mindfully to one's surroundings and experiences. They further differentiate between four degrees of intentionality of mindfulness: individuals untrained in formal mindfulness, novice mindfulness practitioners, experienced mindfulness practitioners, and expert mindfulness practitioners. A further distinction is made between dispositional mindfulness and the deliberate practice of mindfulness (either meditation or other deliberate mindfulness-related practices).

Van Dam et al. (2017) discuss concerns about scientific integrity and reproducibility of mindfulness research. The difficulties in operationalizing and measuring mindfulness are reviewed and they highlight the problematic aspects of self-report questionnaires. The authors recommend that future research on mindfulness should aim to produce a body of work for describing and explaining what biological, emotional, cognitive, behavioral, and social functions change with mindfulness training.

Van Dam et al. (2017) caution about the methodological challenges of research using mindfulness-based interventions (MBIs): They recommend that researchers provide explicit detail of mindfulness measures, primary outcome measures, mindfulness practices, and intervention protocol. They recommend that researchers must be explicit about the exact hypothesis they are testing and consider the various limitations that might accompany treatment designs. They also recommend measurement of adverse effects of meditation-based interventions.

Research findings suggest that mindfulness practice is associated with improved emotion regulation (Hölzel et al. 2011), and higher trait mindfulness has frequently been reported to be associated with better emotion regulation (Desrosiers et al. 2013; Hill and Updegraff 2012; Tran et al. 2014). Freudenthaler et al. (2017) summarize the proposed mechanisms through which trait mindfulness is associated with better emotion regulation. First, reappraisal entails the re-interpretation of the meaning of stimuli in order to modulate one's emotional response. Even though reappraisal may lead to experiential avoidance and may differ on a conceptual level from a mindful state where one does not need to act on each-and-every stimulus or emotion (Chambers et al. 2009), there is evidence of a reciprocal promotion occurring between trait mindfulness and reappraisal (Garland, Gaylord, & Fredrickson, 2011).

A second mechanism through which trait mindfulness is associated with improved emotion regulation is extinction (Hölzel et al. 2011). The concept of extinction involves the gradual fading away of intense emotional responses, such as fear or sadness, allowing for a sense of safety and well-being to emerge.

Finally, non-reactivity to inner experiences is considered a core component of mindfulness (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) that also has ramifications for emotion regulation. During mindfulness practice the attention is focused on the current moment (internal and external experiences) without reacting and without judging experiences as good or bad. This emphasis on non-reactivity to inner experiences links mindfulness to exposure therapy (Hölzel et al., 2011), which is effectively used in the treatment of anxiety disorders (Chambless & Ollendick, 2001).

Emotion regulation

Gross (1998) describes emotions as "biologically-based processes that facilitate rapid decision-making and adaptive behavior by influencing (among other things) cognitive processes and have clear adaptive benefits." Dysregulated emotions can lead to negative physiological and psychological consequences. The optimal functioning of emotions in mental processes requires various emotion regulation strategies (Chambers, Gullone, & Allen, 2009).

Emotion regulation is increasingly seen as being at the core of many psychological disorders (Gross & Munoz, 1995). Emotion regulation (ER) is a new field of psychological investigation and, consequently, there is still ongoing debate in academic discourse on how ER is operationalized. Emotion regulation refers to the process of fine-tuning one or more aspects of an emotional experience or response (Gross, 1998a, b). Emotion regulation is seen as central to adaptive behavior and mental health (Gross & Munoz, 1995). There are different components to ER, including the subjective experience and emotion-related behavioral responses (Gross, 1998a; Mauss, Evers, Wilhelm, & Gross, 2006), and concomitant changes in physiological, behavioral, and cognitive processes (Bridges, Denham, & Ganiban, 2004). Emotion regulation can also be linked to bottom-up (e.g. perceptual) processes such as appraisal, and top-down (e.g. cognitive) processes like working memory and volitional control of attention (Bell & Wolfe, 2004). Another dimension of ER may involve interpersonal processes such as social interaction, for instance interactions between a mother and child (Cole, Martin, & Dennis, 2004).

Emotion regulation deficits or problems have been identified in over half of the primary psychiatric disorders (American Psychological Association, 2013; Gross & Munoz, 1995). Emotion dysregulation and affective instability have been found to be part of multiple psychiatric disorders (Koenigsberg et al., 2002; Phillips,

Drevets, Rauch, & Lane, 2003; Rottenberg & Gross, 2007). Both depression (Ochsner & Gross, 2007; Silk, Steinberg, & Morris, 2003; Strauman, 2002) and anxiety disorders (Coan & Allen, 2004; Mennin, Heimberg, Turk, & Fresco, 2002) have been linked with emotion dysregulation.

Although the assessment of emotion dysregulation has been useful in clinical practice, there are few assessment measures of emotion dysregulation in adults. Most of the measures used to assess emotion regulation deficits are actually measures of closely-related constructs, such as coping, mood regulation, defenses, and affect regulation, leading some researchers to use multiple measures in an attempt to capture the construct of emotion regulation (Mennin, Heimberg, Turk, & Fresco, 2002).

A number of measures of emotion regulation have been developed and validated for use in research studies. Catanzaro & Mearns (1990) developed the Generalized Expectancy for Negative Mood Regulation Scale (NMR) that measures beliefs that some behavior or cognition will alleviate a negative state or induce a positive one, emphasizing the elimination and avoidance of negative emotions. Salovey, Mayer, Goldman, Turvey, & Palfai (1995) developed the Trait Meta-Mood Scale (TMMS) that measures individual differences in the ability to reflect upon and manage one's emotions. The NMR and TMMS measures only limited aspects of emotion regulation and subsequently Gratz & Roemer (2004) developed the Difficulties in Emotion Regulation Scale (DERS). The DERS items were chosen to reflect difficulties within the following dimensions of emotion regulation: (a) awareness and understanding of emotions; (b) acceptance of emotions; (c) the ability to engage in goal-directed behavior, and refrain from impulsive behavior, when experiencing negative emotions; and (d) access to emotion regulation strategies perceived as effective.

Gratz & Roemer (2004) developed the 36-item DERS based on a sample of North American undergraduate college students. The DERS demonstrated good internal consistency, test-retest reliability, and construct validity. Fowler et al. (2014) assessed the construct validity and latent factor structure of the DERS in a large sample of adult psychiatric inpatients with serious mental illness in the United States. They found that the DERS was a strong measure with excellent internal consistency and good construct validity.

There is a hypothesized link between emotion regulation and mindfulness whereby mindfulness meditation has been shown to facilitate attentional self-regulation and emotion regulation (Chambers et al., 2009). There is evidence of a significant relationship between self-reported levels of mindfulness and scores on the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004). A strong correlation was found between self-reported mindfulness and self-reported use of adaptive emotion regulation strategies (Feldman, Hayes,

Kumar, Greeson, & Laurenceau, 2007). Non-judgmental awareness may allow a person to remain aware of inner emotional states at an optimal level of engagement, allowing a changing relationship with one's inner experiences (Ivanovski & Malhi, 2007).

Despite its clinical significance, however, the effect of emotion dysregulation on the development and maintenance of psychiatric disorders is incompletely understood. There is the need for more research on a facet and subscale level of trait mindfulness and emotion regulation (Freudenthaler et al., 2017). It is important to identify the unique components of emotion regulation processes to more precisely understand the mechanisms by which mindfulness attenuates symptoms of anxiety and depression. Berking & Wupperman (2012) identify the need for further research to clarify the following: (a) which individuals have; (b) what kinds of emotion regulation difficulties with; (c) which types of emotions; and (d) what interventions are most effective in alleviating these difficulties.

Mood and anxiety symptoms

The concept of "mood" is differentiated from the concept of "emotion" based on the following distinctions as summarized by Gross (1998):

> "Mood is the pervasive and sustained 'emotional climate' and emotions are fluctuating changes in emotional 'weather'. A second distinguishing feature is that emotions typically have specific objects and give rise to behavioral response tendencies relevant to these objects. By contrast, moods are more diffuse, and although they may give rise to broad action tendencies such as approach or withdrawal, moods bias cognition more than they bias action."

Previous research among persons with mood and anxiety disorders seeking treatment suggested that rumination and reappraisal mediate the association between trait mindfulness and depression, whereas worry mediates the association between trait mindfulness and anxiety (Desrosiers et al. 2013). Rumination involves constant reflection on negative events in the past and present, and worry involves anticipating negative outcomes in the future. It appears as if experienced meditators have increased emotional clarity and are accepting towards emotions, with improved ability to control impulsive behavior, while using emotion regulation strategies (Tran et al. 2014).

There is substantial overlap in anxiety and depressive moods and the conceptual similarities between depression and anxiety have been acknowledged in literature (Mineka, Watson, & Clark, 1998). Measurement

instruments that use self-report of symptoms of anxiety and depression are often highly correlated. This suggests that there is only a modest discriminant validity between self-report measures of anxiety and depression (Clark & Watson, 1991).

Clark and Watson (1991) proposed a tripartite model of anxiety and depression to include both the shared and distinct symptoms of depression and anxiety and to circumvent the problem of co-morbidity. According to their model, mood can be dissected into three components: negative affect (NA), positive affect (PA), and somatic arousal (SA) (Clark & Watson, 1991; Tellegen, Watson, & Clark, 1999). Wardenaar et al. (2010) summarize the components of the model:

> "Whereas NA is characterised by aversive emotional states such as fear, anger and guilt that are associated with both anxiety and depression, PA represents positive emotional states such as feeling active, excited, delighted, enthusiastic and interested. A lack of PA is described as feeling 'tired and sluggish' and is associated with depressive moods. The SA dimension represents symptoms of physiological hyperarousal such as trembling, shaking, dizziness, sweating and heart racing."

These symptoms appeared to better differentiate anxiety (especially panic disorder) from depression than symptoms of subjective fear (Joiner et al., 1999). Since its development the tripartite model has been utilized widely in research on psychiatric disorders (Joiner, Catanzaro, & Laurent, 1996; Keogh and Reidy, 2000; Chorpita and Daleiden, 2002; Marshall, Sherbourne, Meredith, Camp, & Hayes, 2003; De Beurs, Hollander-Gijsman, Helmich, & Zitman, 2007).

To measure the dimensions of the tripartite model, Watson et al. (1995a, b) developed the Mood and Anxiety Symptoms Questionnaire (MASQ). The MASQ is a 90-item self-report questionnaire that consists of five symptom scales. The Anhedonic Depression (AD) scale measures a lack of PA and the Anxious Arousal (AA) scale measures symptoms of SA. The General Distress (GD) scale measures non-specific symptoms of general distress or NA. The General Distress-Depression (GD-D) scale measures NA symptoms that are traditionally considered depressive and the General Distress-Anxiety (GD-A) scale measures NA symptoms that are traditionally viewed as anxious.

Dialectical Behaviour Therapy

Dialectical Behaviour Therapy (DBT) was developed in the late 1980s by Linehan (1993), originally for patients with recurrent suicidal behaviour, and then extended to patients with borderline personality disorder

(BPD). Linehan (1993) proposed that emotion dysregulation is one of the central features of borderline personality disorder and underlies many of the associated behaviors of this disorder. Since its development DBT has been successfully modified and evaluated in the treatment of psychiatric disorders associated with emotion dysregulation, particularly in the treatment of BPD and substance use disorder (Linehan et al., 1999, 2002; Dimeff & Linehan, 2008), post-traumatic stress disorder (Bohus et al., 2013), and depression (Lynch et al., 2007).

A main focus of DBT is teaching emotion regulation skills (Fassbinder, Schweiger, Martius, Brand-de Wilde, & Arntz, 2016). Skill-training is embedded in four modules: mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance. Intensive psychoeducation is included in DBT skills training, focusing on the adaptive value of emotions. Emotions are considered as complex, brief, involuntary, patterned, full-system responses to internal and external stimuli (Ekman & Davidson, 1994). Fassbinder et al. (2016) summarize Linehan's model:

> "The DBT model of emotion and emotion regulation contains six interacting subsystems: (a) Emotional vulnerability factors; (b) Internal and external events that serve as emotional cues (e.g., prompting events); (c) Appraisal and interpretations of cues; (d) Emotional response tendencies (including physiological, cognitive, experiential responses and action urges); (e) Non-verbal and verbal expressive responses and actions; (f) After-effects of the initial emotion, including secondary emotions and after effects of problem behaviour like social isolation or problematic peer relationships."

It appears as if targeting behavioral skills can be a potent mechanism of change for emotion dysregulation across disorders. The exact mechanisms of effect are still unknown, and evidence is preliminary. Within DBT there are more than 60 DBT-skills described and it is not known which skills are more critical for improved emotion regulation, and how the skills should be applied in different situations, populations, and settings. Despite a growing evidence base confirming efficacy and effectiveness, there is limited research on specific mechanisms of change in DBT (Kliem et al, 2010; Neacsiu et al, 2010; Neacsiu & Tkachuck, 2016). A clear understanding of the mechanisms of change involved in DBT psychosocial skills training could lead to a more focused and effective treatment and improvement of emotion dysregulation (Fassbinder et al, 2016).

Program Outcome Assessment Evaluation

The purpose of program evaluation is to assess and improve the quality of a program, and to assess the effectiveness of the program. Process evaluation collects data and informs stakeholders of important findings that could improve a program or its delivery, and allows for appropriate changes before the program is fully

implemented (Mackenzie, Neiger, & Thackeray, 2009). Important elements that are measured in a process evaluation include the following: multiplicity (degree to which multiple components are built into the program); evidence (degree to which the program is evidence-based); capacity (extent to which professionals have adequate knowledge and skills to implement a program); fidelity (extent to which the program was delivered as planned); and dose (number of program units delivered).

A summative or outcome evaluation uses any combinations of measurements that permit conclusions to be drawn about the impact, outcome, or benefits of the program. Different types of program evaluation designs exist, i.e. experimental, quasi-experimental, or nonexperimental design. An evaluation design is deemed nonexperimental when there is no use of a comparison or control group. A nonexperimental program outcome assessment consists of an observational design that uses one-group, pre-test/post-test, and discrete outcomes. This type of evaluation design has limited ability to prove causality and limit bias. Specifically, nonexperimental designs are vulnerable to threats to internal and external validity. This type of design can answer the evaluation question of whether any noticeable change or difference occurred, but it cannot confirm that the intervention was the source of the change (Issel, 2009).

The advantages of a one-group, pre-test/post-test design are that data can be analysed for indications of the amount of change in program participants, and often the data are collected in a manner that allows for connecting the pre-test/post-test data from a single individual (Issel, 2009). For this reason, Issel (2009) suggests that the design is used mostly with individual-level programs. The difference between pre-test and post-test scores for the outcome variables are usually easy to calculate and understand. Because there is no expense involved in finding and gathering data from non-participants, this design has a relatively low cost. The disadvantage of this design is that both history and maturation can affect the data. A testing effect may occur when the process of being involved in providing the pre-test data in some way affects the post-test data.

A program theory explains how a program intervention is understood to contribute to a change of results that produce the intended or actual impacts (Issel, 2009). It shows the overall logic of how the intervention is understood to work. Program evaluation research objectives are guided by the program effect theory (see Figure 1, adapted from Issel, 2009):

The program effect theory is composed of three theories:

a) The causal theory explains the relationships among the existing factors, the main causal factors of the mental health problem, the moderating and mediating factors, and the mental health outcome.

b) The intervention theory specifies how the programmatic interventions change the main causal factors of the mental health problem, as well as the moderating and mediating factors.

c) The impact theory explains how the immediate mental health outcomes become the longer-term mental health impacts.

The effect evaluation uses these theories as the basis for deciding what to measure, specifically with regard to the main causal factors of the mental health problem and the mental health outcomes. For programs with multiple intervention components and multiple mental health outcomes, at least one mental health outcome per program component needs to be measured. The intervention theory related to that component will help identify those variables that are central to achieving program success. Those dependent outcome or impact variables need to be measured.

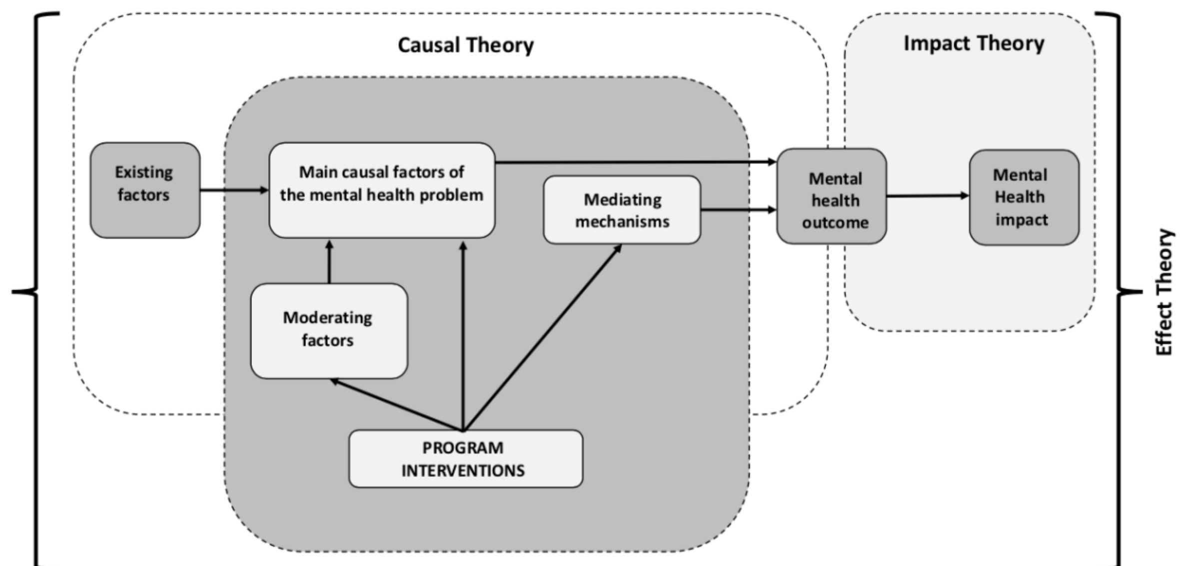

Figure 1. The effect theory guiding program evaluation (Adapted from Issel, 2009)

Program outcome evaluation measures program effects in the target population by assessing the outcome objectives that the program is to achieve. By synthesizing the interactions between mindfulness, emotion regulation, mental health, and DBT programmes, a program effect theory can be articulated for the existing in-patient psychotherapy program evaluated in this study:

a) The causal theory: Poorly regulated emotions and low levels of dispositional mindfulness can engender a number of adverse physiological and psychological consequences such as worry and rumination.

b) The intervention theory: Participation in an in-patient psychotherapy program that delivers mindfulness training based on a DBT model, will improve dispositional mindfulness as well as improve emotion regulation.

c) The impact theory: Participation in the intervention will result in lower levels of depression and anxiety symptoms.

The review of the literature on mood and anxiety symptoms, mindfulness skills training, emotion regulation, and in-patient psychotherapy program evaluation indicate the need for additional research in clinical settings. An exploration of how these interventions are applied in a clinical intervention such as an in-patient psychotherapy program, a description of program participants, and measurement of program outcomes allows for identification of variables that are central to achieving program success, guiding further program development and evaluation.

CHAPTER 2: PUBLICATION-READY MANUSCRIPT

OUTCOME EVALUATION OF AN IN-PATIENT PSYCHOTHERAPY PROGRAM: MINDFULNESS, DIFFICULTY WITH EMOTION REGULATION, AND MOOD AND ANXIETY SYMPTOMS

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ABSTRACT

This exploratory enquiry into the effectiveness of an in-patient psychotherapy program measured the changes in mood and anxiety symptoms, difficulty with emotion regulation, and dispositional mindfulness in a clinical population with diverse psychiatric morbidity. Participants were 53 adults (74.5% female, mean age = 35 years) who participated in a 4-week in-patient psychotherapy program offering a variety of interventions, including mindfulness skills training, and Dialectical Behaviour Therapy-psychosocial skills training. Program input data, demographic variables, psychiatric morbidity, and medication on discharge were tracked. There was an average improvement of 29.86 ± 20.56 on the Mood and Anxiety Symptoms Questionnaire-D30 and 12.43 ± 17.75 on the Difficulty with Emotion Regulation Scale-Short Form, indicating an improvement in mood and anxiety symptoms and emotion regulation post-intervention. There was an average improvement of 17.6 ± 23.66 on the Five Facets of Mindfulness Questionnaire, indicating an increase in dispositional mindfulness post-intervention.

Key words: Mindfulness; Emotion regulation; Depressive symptoms; Anxiety; Program evaluation; In-patient psychotherapy program

Introduction, Background, and Significance

There is emerging consensus linking emotion dysregulation with depression and anxiety disorders (Freundenthaler, Turba, & Tran, 2017). The important role of emotion regulation is increasingly acknowledged in psychiatric research (Gross & Munoz, 1995). Evidence of associations of trait mindfulness with strategies of emotion regulation among clinical samples (Desrosiers, Vine, Klemanski, & Nolen-Hoeksema, 2013) and meditators (Tran et al., 2014) suggest that emotion regulation could be one of the important aspects of how participation in mindfulness-based interventions result in improved psychological well-being. Even though research evidence confirms the effectiveness of mindfulness-based interventions in clinical and nonclinical settings, the fundamental mechanisms of mindfulness are not yet known (Desrosiers et al., 2013).

Mindfulness is commonly defined as "paying attention in a particular way; on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994, p.4). During mindfulness practice the attention is focused on the current moment (internal and external experiences) without reacting and without judging experiences as good or bad. Internal and external experiences are seen as "mental events" in a non-judgmental and decentred manner, while acknowledging that these "mental events" are not an accurate reflection of the self and reality.

South Africa faces a significant burden of mental illness. Herman et al. (2009) found that the lifetime prevalence of common mental disorders in South Africa is 30.3%, and the most prevalent 12-month and lifetime disorders are the anxiety disorders. The Western Cape has the highest 12-month and lifetime prevalence rates of common mental disorders in South Africa. The National Mental Health Policy Framework and Strategic Plan 2013-2020 (National Department of Health, 2013) calls for the periodic evaluation of mental health services to assist in planning and improving service delivery.

Psychotherapeutic interventions are often delivered as part of a program that delivers mental health services to a defined clinical population. A rigorous evaluation of existing mental health programs that deliver mindfulness-based interventions, such as Dialectical Behaviour Therapy (DBT) (Linehan, 2015), provide the opportunity to study the mechanism through which mindfulness effects change. The purpose of program evaluation research is to determine the effectiveness of a program, to explore the mechanisms underlying the changes occurring due to the program interventions, and to identify the unique components of the program that are essential for its effectiveness (Issel, 2009). As a type of program evaluation, an outcome assessment evaluation aims to answer the question: "To what extent is any noticeable change or difference in participants related to having received the program interventions?"

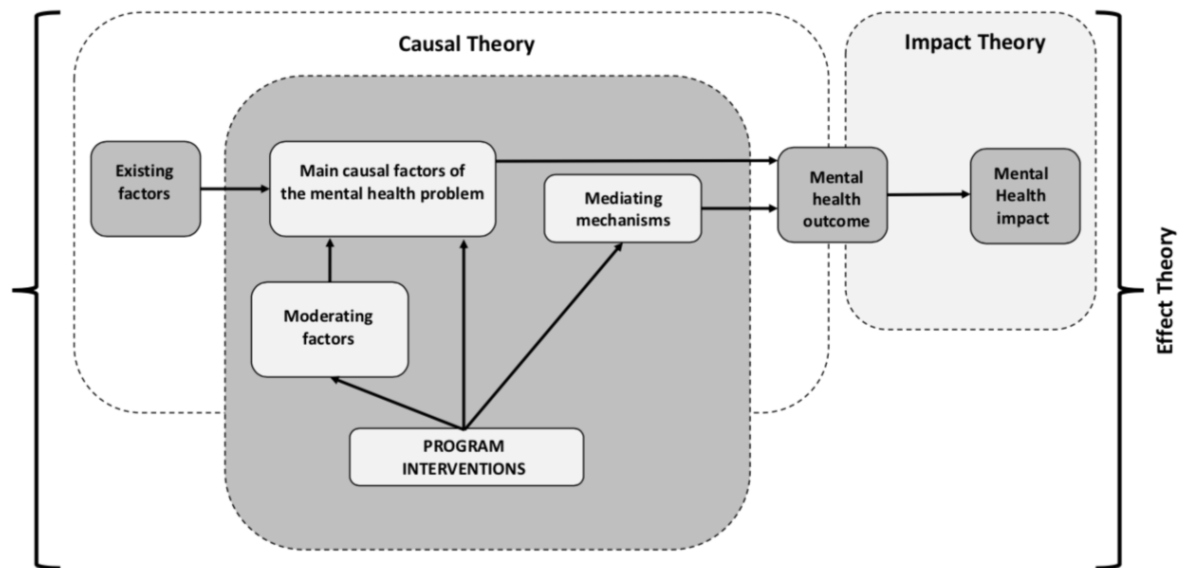

Figure 1. The effect theory guiding program evaluation (Adapted from Issel, 2009)

Program outcome evaluation measures effects in the target population by assessing the outcome objectives that the program is to achieve (see figure 1). By synthesizing the interactions between dispositional mindfulness, emotion regulation, mental health, and DBT interventions, a program effect theory (Issel, 2009) can be articulated for the existing in-patient psychotherapy program evaluated in this study:

a) The causal theory: Poorly regulated emotions and low levels of dispositional mindfulness can engender a number of adverse physiological and psychological consequences such as worry and rumination.

b) The intervention theory: Participation in an in-patient psychotherapy program, that deliver mindfulness training based on a DBT model, will improve dispositional mindfulness as well as improve emotion regulation.

c) The impact theory: Participation in the intervention will result in lower levels of depression and anxiety symptoms.

Further elucidating mechanisms of change in mental processes would inform the use of mindfulness-based interventions by allowing for more targeted and refined applications of mindfulness and enhancing mindfulness psycho-education. In addition to exploring the mechanisms of change that result in treatment outcomes, it is important to determine whether any pre-treatment patient characteristics are associated with treatment outcomes, as such information can guide expectations for treatment.

Research Aim

The study aims to explore the possible effect of mindfulness skills training and the psychosocial skills training component of Dialectical Behaviour Therapy (DBT) included in an in-patient psychotherapy program on difficulty with emotion regulation, dispositional mindfulness, and features of anxiety and depression in a clinical population with diverse psychiatric morbidity.

Research Objectives

Objective 1: To describe the demographics and principle psychiatric diagnoses of program participants at the start of the program, and to describe program implementation factors, such as number of DBT skills and mindfulness practice sessions attended, by the end of the 4-week program, and whether medication with proven mood and anxiety effect was prescribed on discharge from the program.

Objective 2: To assess the outcome of the program on participants in terms of pre-and post-intervention changes on Mood and Anxiety Symptoms Questionnaire (MASQ-D30), the Difficulties in Emotion Regulation Scales – Short Form (DERS-SF), and the Five Facets of Mindfulness Questionnaire (FFMQ).

Objective 3: To characterize if changes in mindfulness facets (FFMQ), sub-scales of emotion regulation difficulty (DERS-SF), and prescription of medication with proven mood and anxiety effect are individually or cumulatively associated with improved mental health, as measured by the Mood and Anxiety Symptoms Questionnaire (MASQ-D30), across the participants in the program.

Research Hypothesis

We hypothesized that at post-intervention follow-up, program participants will report improvement in emotion regulation, dispositional mindfulness, and mood and anxiety features, compared to pre-intervention.

It is further hypothesized that dispositional mindfulness and emotion regulation will correlate with mood and anxiety features, with improved dispositional mindfulness and lower emotion dysregulation predicting improved mood and anxiety features, post-intervention.

Methods

Study type

A prospective cohort descriptive study, using an observational design with one-group, pre-test/post-test, and discrete outcomes, was conducted. This was an outcome assessment evaluation of an existing in-patient

psychotherapy program delivered at a South African public sector tertiary-level psychiatric hospital.

Participants

The in-patient psychotherapy program admitted patients between the ages of 18 and 60. It catered for individuals with mood disorders particularly major depressive disorder, bipolar mood disorder, as well as anxiety disorders including post-traumatic stress disorder, generalized anxiety disorder, adjustment disorder, personality disorders and trauma related difficulties. Program interventions were delivered primarily in English and the anticipated level of education and language ability of participants in the program would require them to have the ability to converse in English.

All patients were referred from the hospital catchment areas, including urban and rural areas. Referrals to the program were managed by a consultant psychiatrist and psychiatric registrar. Following review of referrals, prospective program participants were contacted to confirm their interest in the program, and to ensure suitability for the psychotherapeutic milieu. In some cases, out-patient assessment was indicated before determining final suitability for admission. Patients were admitted on a voluntary basis and program participants received interventions over a period of four weeks during their admission. On average 2-4 additional patients per week were admitted to the program on Mondays, while an average of 2-4 patients were discharged on Fridays. Patients had home leave every weekend unless they lived far away and were accommodated in the pre-discharge wards at the psychiatric hospital.

Sampling and Procedures for Sampling

Through convenience sampling, all patients admitted to the in-patient psychotherapy program during a 10-month period in 2018 were eligible for inclusion in the study. The program followed an existing protocol to manage referrals and decisions regarding suitability for program participation, independent of the proposed research study.

Program-specific exclusion criteria included the following: (a) younger than age 18, and older than age 60 years; (b) active substance use disorder; (c) high risk for suicide and homicide; (d) involuntary in-patient treatment under the South African Mental Health Care Act; (e) patients who cannot provide informed consent and tolerate group work due to, for example, active psychosis, hypomania, mania, or moderate to severe intellectual disability; (f) severe physical or sensory disabilities that require intensive support (e.g. blindness, deafness, and limited mobility); (g) primary substance abuse, eating disorders, and dementia. In addition to the program's eligibility

criteria, patients were eligible to participate in the study if they provided informed consent, and they were excluded from the study if they were unable or unwilling to provide informed consent, and if they were unable to understand spoken English.

On the day of admission to the program, following initial assessment by the psychiatric registrar, individual program participants were shown to a separate office on the premises where a research assistant verbally delivered a brief invitation to them, inviting him/her to receive additional information regarding the study, with the option to participate. When the program participant indicated their interest to receive additional information, the research assistant conducted screening for eligibility. If inclusion criteria were met, and no exclusion criteria were present, program participants were offered the option to receive additional information regarding the study with the option to participate. When program participants agreed to this step, the trained research assistant, not affiliated with the program, conducted the informed consent and data collection processes.

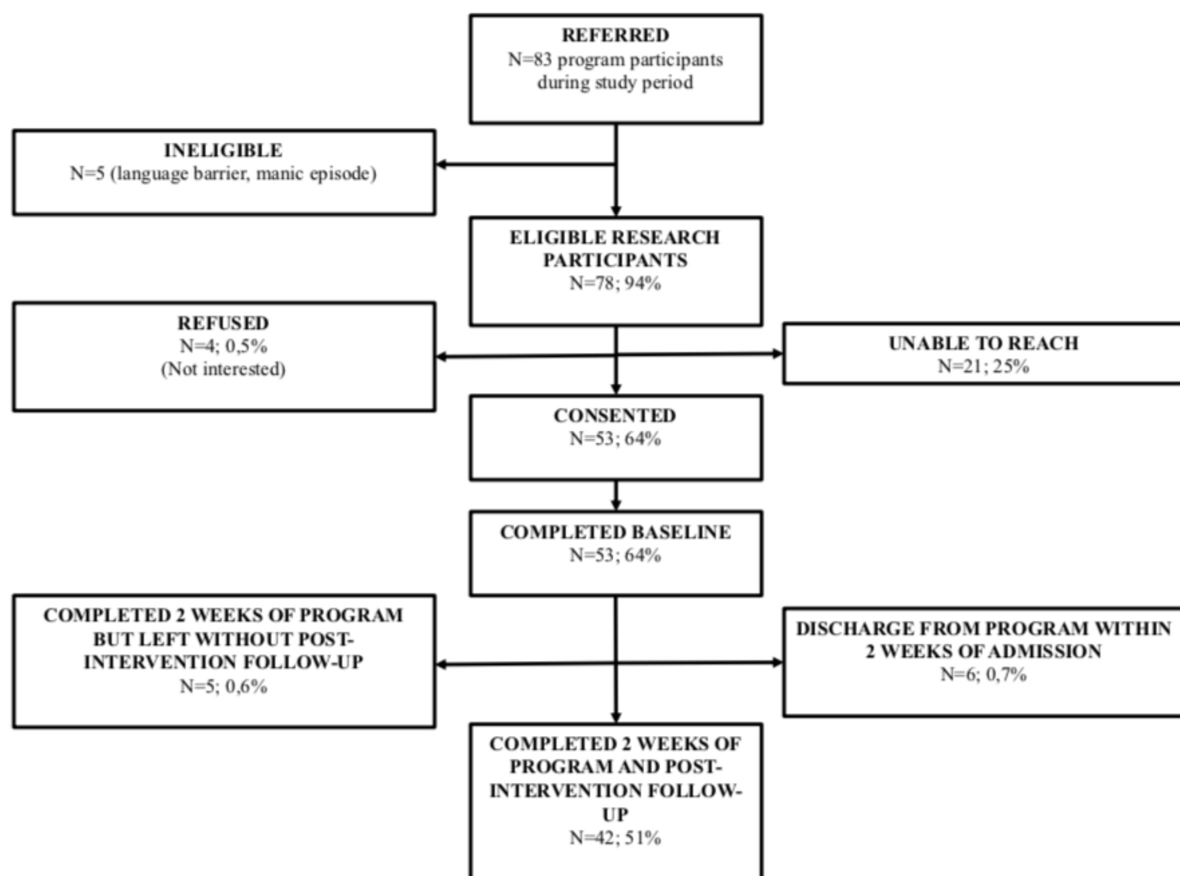

Figure 2. Study recruitment and participants

Intervention Description

The psychotherapeutic in-patient program offered specialized in-patient crisis management, diagnostic assessment, psychological therapy, and aftercare for people with non-psychotic mental disorders. The program consisted of a 4-week voluntary in-patient intervention. The program provided individual and group psychotherapy sessions, problem-solving training, psychosocial skills component of DBT psychosocial skills group therapy, and 20 facilitated mindfulness practice sessions over the 4-week period.

During the first week program participants were assessed in term of their presenting problems, mental state, risks, diagnosis and suitability for specialized group psychotherapy. This was followed by a 3-week period of continuing assessment and group therapy. Patients were admitted to the program on Monday mornings, and joined the program on the day of admission. All program participants participated in all aspects of the program. During the first week of the program, in addition to standard program activities, newly admitted participants underwent individual assessment by case managers.

Table 1. Summary of program interventions during 4-week admission

Intervention	Description	Duration and frequency
DBT psychosocial skills training	See table 2 for features of the DBT psychosocial skills training included in the program	
Mindfulness skills training	See table 3 for features of mindfulness skills training in the program	
Psychoeducation group meetings	Trauma	1 x 1-hour session in group setting facilitated by clinical psychologist
	Self-awareness	4 x 1-hour sessions in group setting facilitated by mental health nurse
	Boundary setting	4 x 1-hour sessions in group setting facilitated by mental health nurse
	Problem solving	4 x 1-hour sessions in group setting facilitated by mental health nurse
	Sexual health	1 x 1-hour session in group setting facilitated by medical doctor
	Sleep hygiene	1 x 1-hour session in group setting facilitated by mental health nurse
Occupational therapy group activities	Beading	4 x 1-hour sessions in group setting with facilitator

	Mosaic	4 x 1-hour sessions in group setting with facilitator
	Exercise	4 x 1-hour sessions in group setting with facilitator
	Yoga	4 x 1-hour sessions in group setting with facilitator
	Guided relaxation	4 x 1-hour sessions in group setting with facilitator
	Journaling	4 x 1 hour periods assigned for individual journaling
	Employment education	1 x 1-hour education in group setting by occupational therapist
Life skills group meetings	Understanding emotions	2 x 1-hour sessions in group setting facilitated by occupational therapist and social worker. 2 x 1-hour individual homework exercises.
	Communication	2 x 1-hour sessions in group setting facilitated by occupational therapist and social worker. 2 x 1-hour individual homework exercises.
	Managing stress	2 x 1-hour sessions in group setting facilitated by occupational therapist and social worker. 2 x 1-hour individual homework exercises.
	Thinking patterns	2 x 1-hour sessions in group setting facilitated by occupational therapist and social worker. 2 x 1-hour individual homework exercises.
Case management	Admission and pre-discharge assessment.	Psychiatric interview and assessment on admission and at discharge.
	Case manager oversees and co-ordinate mental healthcare while admitted to program.	Weekly 1-hour case management sessions. Additional individual psychotherapy input if indicated.
	Program orientation and climate meeting	4 x 1-hour sessions in group setting facilitated by mental health nurse
	Weekend planning	3 x 1-hour sessions in group setting facilitated by mental health nurse
	Weekend feedback	3 x 1-hour sessions in group setting facilitated by mental health nurse

The program was staffed by a multidisciplinary team which consisted of the psychiatrist, nurses, clinical psychologist, occupational therapist, psychiatric registrar, and social worker. The team assessed the participant's

difficulties, formulated an understanding of these difficulties in terms of their life context, and developed a treatment and management plan. Participants attended daily group therapy and were allocated to a specific case manager, who coordinated their care and had weekly individual sessions with them.

The program included a variety of psychotherapeutic interventions, with emphasis on mindfulness training and Dialectical Behaviour Therapy (DBT) psychosocial skills training modules. The following DBT modules were introduced to program participants in a group setting: mindfulness, distress tolerance, interpersonal effectiveness, and emotion regulation. DBT group-work followed a DBT manual adapted to the program's needs and included only the psychosocial skills training component of the formal DBT program. See table 2 for a description of the adapted DBT psychosocial skills training used in the program.

Table 2. Features of the program's DBT psychosocial skills training sessions

Domain	Facilitator 1	Facilitator 2	Facilitator 3
Formal training received in DBT-skills training	Clinical Psychologist; On-line training via BehavioralTech/ Linehan Institute	Clinical Psychology Intern; Received didactic teaching at masters' level.	Psychiatry Registrar: Received didactic teaching on DBT during registrar training
Clinical qualifications of facilitator	Masters level	Masters level	MB ChB
Number of months or years with experience in DBT-skills training	7 years	4-week observation and consultation feedback of skills groups before participating	4-week observation and consultation feedback of skills groups before participating
Physical setting	320x450cm brick and mortar room located within the program building		
Social setting	Up to 10 group members with 2 facilitators		
DBT psychosocial skills included	1. Interpersonal effectiveness 2. Emotion regulation 3. Distress tolerance 4. Mindfulness		
Duration of meetings	1 hour for each session		
Frequency of meetings	2 x 1-hour sessions per week		
Types of instructional material	Facilitated group discussion; Use of whiteboard; Exercise sheets; Small group training; Role-play		

Participants may also have received additional exposure to individual facilitated mindfulness practice sessions, when offered in individual psychotherapy. Psychotherapy was offered by the senior clinical

psychologist, intern clinical psychologist, and psychiatry registrar. Psychotherapy approaches varied and included supportive psychotherapy and psychodynamic-informed psychotherapy.

In addition to the DBT psychosocial skills training and group therapy and mindfulness practice groups, program participants received input from nursing staff, occupational therapists, social workers, and clinical psychologists during the 4-weeks on the following topics: sleep hygiene, problem solving, boundary setting, self-awareness, life skills (thinking patterns, stress management, communication, understanding emotions), yoga and exercise, trauma psycho-education, sexual health education, and employment education. Although these interventions may be important mediating factors, assessment of the outcome of these aspects of the program fell outside the scope of this study, due to time and resource limitations.

Table 3. Features of the mindfulness skills training in the program

Domain	Facilitator 1	Facilitator 2	Facilitator 3
Formal training received in mindfulness-skills training	Clinical Psychologist: On-line training via BehavioralTech/ Linehan Institute. Group therapy participant in Mindfulness based Cognitive therapy	Clinical Psychology Intern: Possibly received didactic teaching at masters' level, depending on university	Psychiatry Registrar: Possibly received didactic teaching on mindfulness during registrar training
Clinical qualifications of facilitator	Masters level clinical psychologist	Masters level clinical psychology intern	MB ChB
Number of months or years with experience in contemplative instruction	7 years	None	None
Physical setting: room type, set-up	320x450cm brick and mortar room located within the program building.		
Social setting: average group size	Up to 10 group members + 2 facilitators		
Duration of average meeting session	20-40 minutes		
Duration of contemplative exercises in a session	5-10 minutes		

Content of contemplative practice sessions	Guided mindfulness meditation followed by feedback from participants on their experience during the guided mindfulness meditation. Facilitators reflect on participants' experiences and the application of mindfulness skills in practice: Learning to observe, to describe and to participate without self-consciousness, taking a non-judgmental stance, focusing on one thing in the moment, and being effective.
Frequency of contemplative practice	5 x weekly contemplative practice sessions: • 2 x 5 minutes • 2 x 20 minutes • 1 x 40-minute session Additionally, every fourth week: • 2 x 1-hour sessions covering Mindfulness theory and practice, which includes practice of: o 2 x 5 minutes o 2 x 20 minutes
Types of instructional materials used	Verbally guided by facilitator Audio recorded material: guided meditation
Other comments	Facilitators were not blinded to experimental hypotheses. Instructor adherence was not assessed as part of study. Adverse events were not routinely monitored as part of study. Participants were not routinely required to keep log of meditation sessions. Prior meditation experience was not considered as an eligibility criterion for participation.

Intervention Fidelity

Rigorous evaluation of the program requires intervention fidelity, to ensure that the study is evaluating an intervention that was delivered as it was intended. The following steps were taken to assess and monitor the reliability and validity of the program as described above: (a) the use of a weekly schedule of program activities with standardized interventions; (b) the use of an adapted DBT manual that standardized skills training sessions and mindfulness training sessions; (c) and supervision, teaching, and debriefing of program staff by a senior clinical psychologist skilled in DBT psychosocial skills training and mindfulness skills training.

Measures

Demographics

The following demographic measures were collected from participants on admission to the program: age,

gender, highest level of education, ethnicity, and employment status.

Psychiatric morbidity

Measures of psychiatric morbidity of program participants were collected by recording the DSM5 principle diagnosis and DSM5 comorbid diagnosis following admission and assessment by the psychiatric registrar and multidisciplinary team.

Mood and Anxiety Symptoms Questionnaire (MASQ-D30)

The Mood and Anxiety Symptoms Questionnaire (MASQ-D30) is based on the tripartite model of anxiety and depression (Wardenaar, Van Veen, Giltay, De Beurs, Penninx, et al., 2010). It is a brief, reliable, valid, and widely used, self-administered questionnaire that addresses comorbidity by making a distinction between overlapping and non-overlapping symptoms of anxiety and depression. The MASQ-D30 was adapted from the 90-item Mood and Anxiety Symptom Questionnaire (MASQ) developed by Clark and Watson (1991).

The MASQ-D30 includes three subscales: General Distress (GD), Anhedonic Depression (AD), and Anxious Arousal (AA). The questionnaire takes less than 15 minutes to complete, and in this study the questions were verbally administered by the research assistant. For each item, the respondent rated how much they have experienced the designated feeling, sensation, or problem during the previous 2 weeks on a 5-point Likert scale that runs from 1 ("not at all") to 5 ("extremely"). A score for each dimension of the tripartite model is obtained by summing the responses for the respective subscale, and the variable was used as a scale in the analysis.

The MASQ-D30 was developed by Waardenaar et al. (2010) based on a sample of psychiatric out-patients. Validation was done in two large clinical and non-clinical samples of Dutch-speaking subjects. Previous research on the MASQ by Talkovsky and Norton (2015) in the United State of America support the use of the MASQ across the four most common racial groups (Hispanic, African American, European American, and Asian American).

Difficulty with Emotion Regulation Scale – Short Form (DER-SF)

The Difficulty in Emotion Regulation Scales – Short Form (DERS-SF) is an abridged version of the Difficulties in Emotion Regulation Scale (DERS). The DERS is a well validated and widely used self-report measure for assessing emotion regulation problems among adolescents and adults (Gratz & Roemer, 2004). Kaufman et al. (2016) developed a validated short-form version (DERS-SF) of the DERS. Emotion dysregulation is operationalized and defined by six dimensions or facets of emotion dysregulation in the DERS: (a) lack of

emotional clarity; (b) lack of emotional awareness; (c) non-acceptance of emotional responses; (d) impulse control difficulties; (e) difficulties engaging in goal-directed behaviour; and (f) limited access to emotion regulation strategies (Gratz & Roemer, 2004).

The DERS-SF is a self-administered questionnaire that consists of 18 questions about emotion regulation behavior, with responses captured on a Likert scale (1-Almost Never; 5-Almost Always). In this study the questionnaire was verbally administered in English by a research assistant. There are 6 sub-scales, i.e. Strategies, Non-acceptance, Impulse, Goals, Awareness, and Clarity. Scales were scored using sums or average of items. All subscales were scored so that higher values reflect greater difficulty with emotion regulation. A score for each dimension of difficulty with emotion regulation was obtained by summing the responses for the respective subscale, and the variable was used as a scale in the analysis.

Both the DERS-SF and the DERS were developed in English-speaking non-clinical populations in the USA (Gratz and Roemer, 2004; Kaufman et al., 20016). The DERS has been validated with international samples and translated into multiple languages (e.g., Côté et al. 2013; Fossati et al. 2014; Sarıtaş-Atalar et al. 2014). The DERS-SF was developed and validated in relatively large pooled sample sizes, with the inclusion of participants from diverse settings (i.e., community, clinical, inpatient, outpatient, and two different regions of the United States), and the wide range of ages represented across the sample (Kaufman, et al., 2016).

Five Facets of Mindfulness Questionnaire

The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al. 2006) is a 39-item self-administered questionnaire. It consists of consists of 39 questions about facets of mindfulness with responses captured on a Likert scale (1-Almost Never; 5-Almost Always). The FFMQ measures five elements of mindfulness: (a) observing; (b) describing; (c) acting with awareness; (d) non-judging of inner experience; and (e) non-reactivity to inner experience.

In this study the questionnaire was verbally administered in English by a research assistant. The total FFMQ score was used as a scale in analysis. Facet scores were computed by summing the scores on the individual items. Facet scores range from 8 to 40 (except for the non-reactivity facet, which ranges from 7 to 35), with higher scores indicating higher levels of dispositional mindfulness.

The FFMQ was developed in an English-speaking non-clinical sample in the USA. The validity of the FFMQ has been confirmed in a number of studies (Baer et al., 2006; Carmody and Baer 2008; Kuyken et al. 2010;

Baer, Walsh, & Lykins, 2009). Curtiss and Klemanski (2014) validated the FFMQ in an out-patient clinical population with mood and anxiety disorders. Baer et al (2011) found that the FFMQ is suitable for pre–post intervention measurement in the assessment of mindfulness-based treatments.

Use on discharge of medication with proven mood and anxiety effect

As part of routine psychiatric care and treatment of program participants, psychiatrists assessed participants for the need of treatment with medication with proven mood and anxiety effects, such as antidepressants, antipsychotics, mood stabilizers, and benzodiazepines. This was an important variable that required monitoring to account for the potential effect of medication on program outcomes.

Program participants' medication upon discharge were routinely recorded by program staff on the electronic discharge summary. The electronic discharge summary contained a summary of the participant's diagnosis, treatment, response to program input, prescription of medication, and plans for further care. The variable 'discharge on medication with proven mood and anxiety effect' were coded based on information captured in the electronic discharge summary. It was not feasible to capture information about any changes made to medication or whether new medication was initiated during admission to the program. Only the type of medication that was prescribed on discharge were reliably captured, and therefore used in the analysis.

Data collection

Program input data were collected by the investigator from program management staff and program documents, at the beginning of the study period. This included data on program interventions (type, dosage, and frequency) and program staff capacity (formal qualifications, training, and professional experience). Data from program participants were collected by a trained research assistant within 72 hours of admission and at pre-discharge from the program. The co-investigator trained all research assistants and supervised data collection to ensure data quality and compliance with the research study protocol.

The duration of research assessments was approximately 30 minutes per participant, on admission, and 30 minutes per participant pre-discharge from the program. The questionnaires were administered in a private office on the ward premises. Participants were offered a rest period between questionnaires. Questionnaires were administered in the same order for all participants, at pre-intervention and post-intervention. The rationale for verbally administering questionnaires was that differences in participants' reading and language comprehension ability may have negatively impacted data collection accuracy and completeness if using a self-administered

mode. Using verbally administered questionnaires by the same research assistant also improved standardization. If a participant refused to answer an item on the questionnaire, the research assistant left the answer blank, and proceeded to the next question. No personal identification data was recorded. Participants were assigned unique identifiers for data capturing and data analysis.

As per standard program routine, throughout the 4-week program, each program participant received input by an assigned case-manager, with weekly feedback to the program's multidisciplinary team. This approach allowed for rigorous diagnostic assessment during admission to the program. Following discharge from the program, the treating psychiatrist completed an electronic discharge summary, noting the DSM5 primary diagnosis, comorbid diagnosis, and medication prescribed on discharge.

Table 4. Data collection procedures

<table>
<tr><th>Study phase</th><th>Data collection instrument</th><th>Data source</th><th>Procedure</th></tr>
<tr><td>Pre-intervention</td><td>Program input data</td><td>Program staff</td><td>Routine program input data extracted from program documentation and program staff interviews</td></tr>
<tr><td>Pre-intervention</td><td>Demographics form</td><td>Participant interview</td><td>Research assistant verbally collected demographic information from study participant following informed consent within 72 hours of admission to program</td></tr>
<tr><td>Pre-intervention</td><td>MASQ-D30</td><td>Participant self-report questionnaire</td><td rowspan="7">Research assistant verbally asked the questions from the questionnaires and recorded participants' responses on paper-based answer sheets within 72 hours of admission to program and on day of discharge from program.</td></tr>
<tr><td>Pre-intervention</td><td>DERS-SF</td><td>Participant self-report questionnaire</td></tr>
<tr><td>Pre-intervention</td><td>FFMQ</td><td>Participant self-report questionnaire</td></tr>
<tr><td>Post-intervention</td><td>MASQ-D30</td><td>Participant self-report questionnaire</td></tr>
<tr><td>Post-intervention</td><td>DERS-SF</td><td>Participant self-report questionnaire</td></tr>
<tr><td>Post-</td><td>FFMQ</td><td>Participant self-</td></tr>
</table>

intervention		report questionnaire	
Post-intervention	DSM5 primary diagnosis, comorbid diagnosis	Electronic discharge summary	Investigator retrospectively reviewed content of participant electronic discharge summary
Post-intervention	Discharge on medication with proven mood and anxiety effect	Electronic discharge summary	

Ethical Considerations

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Approval for this research study was received from the University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee (HREC reference number: 839/2017). The study received approval from the Research Committee of the Provincial Government of the Western Cape and hospital management. Informed consent was obtained from all individual participants included in the study. The program staff and hospital management participated in the design of the research protocol. Program staff met regularly throughout the study period with the investigator and research assistant to coordinate data collection activities.

There are no known conflicts of interests. The principle investigator, co-investigators, and research assistant were not involved in screening or selecting patients who were admitted to the program and were not involved in delivering program interventions. The principle investigator, co-investigators, and research assistant were not involved in the delivery of mental healthcare to study participants, during the duration of the study. Program staff did not have access to research data collected during the study period.

Data analysis

Initially, data cleaning involved (a) checking the data for obvious data entry errors, (b) reviewing the data for skip patterns, i.e. systematic non-responses to items on a questionnaire, and (c) checking the data for outliers. The decision to include or exclude outliers was made on a case-by-case basis.

Data were analyzed using parametric tests where possible. If violations of statistical assumptions occurred, the appropriate non-parametric tests were used. Data were only analyzed for participants who

successfully completed the intervention (participants were considered to have received a "dose" of the intervention if they completed at least 50% of the program activities). For missing data, the participant was excluded from that specific analysis but not the whole dataset. The DERS-SF, FFMQ, and MASQ-D30 scores was calculated according to standard scoring procedures and used as continuous variables in the analyses described below.

In the linear regression model, improvement in mood and anxiety was chosen as the direct variable (i.e., change in MASQ scores), and all the other variables were chosen as independent variables. In all other analyses the changes in MASQ-D30, DERS-SF and FFMQ were the direct variables and the other variables the indirect variables (pre-intervention scores, demographics, psychiatric morbidity, and discharge on medication with proven mood and anxiety effect). All categorical variables with either a yes/no answer option were categorized as dichotomous and all other categorical variables were categorized as nominal**.** Data analyses were done using SPSS Version 25.

Results

Demographic and clinical characteristic of the sample are presented in Table 5. During the study period 83 program participants were referred for assessment, and 53 program participants were included in the final analysis. The average age of participants was 35 ± 12 years. The sample's ethnic characteristics reflected those of the local population in the Western Cape province. The majority of the participants were female (74.5%), had at least secondary (60.4%) or post-secondary (37.7%) education, and were unemployed (58.5%). The most prevalent principle diagnoses were Depressive Disorder (39.6%) and Bipolar Disorder (22.6%). Upon discharge, 84.6% of participants were on anti-depressants, 44.2% on anti-psychotics, 30.8% on mood stabilisers, and 26.9% on benzodiazepines.

Table 5. Demographics and clinical characteristics of participants

	n = 53	%
Gender		
Female	38	74.5
Male	13	25.5
Highest Level of Education		
Primary	1	1.9
Secondary	32	60.4
Post-secondary	20	37.7

Employment		
Student	9	17
Full-time	11	20.8
Part-time	2	3.8
Unemployed	31	58.5
Principle Diagnosis		
General Personality Disorder	4	7.5
Cluster B Personality Disorder	5	9.4
Cluster C Personality Disorder	1	1.9
Bipolar Disorder	12	22.6
Depressive Disorder	21	39.6
Anxiety Disorder	4	7.5
Trauma and Stress Related	5	9.4
Psychotic	1	1.9
Comorbid Diagnosis		
General Personality Disorder	5	10.6
Cluster B Personality Disorder	4	8.5
Depressive Disorder	2	4.3
Anxiety Disorder	8	17.0
Trauma and Stress Related	1	2.1
Substance Use and Addiction	16	34.0
Eating Disorder	2	4.3
Impulse Control Disorder	1	2.1
Neurocognitive	1	2.1
Neuropsychiatric	5	10.6
Neurodevelopmental	1	2.1
Obsessive Comp Disorder	1	2.1

Table 6 shows the change in scores on the MASQ-D30, FFMQ and DERS-SF from pre- to post-intervention. There was an average improvement of 29.86 ± 20.56 on the MASQ-D30 and 12.43 ± 17.75 on the DERS-SF, indicating a reduction in mood and anxiety symptoms and emotion regulation difficulties post-intervention. There was an average improvement of 17.6 ± 23.66 on the FFMQ, indicating an increase in dispositional mindfulness post-intervention. All the above results were statistically significant (all *p's* < .001). Across all three scales, the largest percentage change was on the MASQ-D30. All MASQ-D30 subscales showed significant improvement post-intervention, and most sub-scales on the DERS-SF showed reduced emotion dysregulation, except on the Non-Acceptance and Awareness sub-scales. Results showed a significant improvement on all FFMQ subscales except the Observe and Non-reactivity sub-scales.

Table 6. Changes in measures from pre-intervention to post-intervention

	Pre-score $n = 42$	Post-score $n = 42$	Change-score $n = 42$	% change	t	p	d
MASQ-D30 Total	107.24 (16.90)	77.38 (19.96)	-29.86 (20.56)	-27.8	9.41	< .001*	1.45
MASQ-D30 GD	37.64 (7.31)	24.98 (9.03)	-12.67 (9.70)	-33.7	8.47	< .001*	1.31
MASQ-D30 AD	42.62 (6.83)	29.60 (8.94)	-13.02 (9.59)	-30.5	8.81	< .001*	1.36
MASQ-D30 AA	26.98 (9.63)	23.07 (8.04)	-3.90 (7.67)	-14.5	3.30	.002*	0.51
FFMQ Total	100.83 (18.61)	118.43 (26.93)	17.60 (23.66)	17.5	-4.82	< .001*	0.74
FFMQ Observe	24.57 (6.70)	26.12 (7.28)	1.55 (6.74)	6.3	-1.49	.145	0.23
FFMQ Describe	19.42 (7.99)	24.02 (8.37)	4.60 (7.24)	23.7	-4.11	< .001*	0.64
FFMQ Aware	20.71 (5.55)	25.38 (7.97)	4.67 (7.45)	22.5	-4.06	< .001*	0.63
FFMQ Non-judge	17.00 (5.63)	20.95 (6.60)	3.95 (7.79)	23.2	-3.29	.002*	0.51
FFMQ Non-react	19.00 (6.17)	21.38 (5.64)	2.38 (7.39)	12.5	-2.09	.043	0.32
DERS-SF Total	63.31 (13.74)	50.88 (15.53)	-12.43 (17.75)	-19.6	4.54	< .001*	0.70
DERS-SF Strategies	11.62 (3.24)	9.00 (3.55)	-2.62 (4.01)	-22.5	4.24	< .001*	0.65
DERS-SF Non-accept	10.17 (3.48)	8.36 (3.35)	-1.81 (4.35)	-17.8	2.70	.010	0.42
DERS-SF Impulse	9.98 (3.20)	7.74 (3.40)	-2.24 (3.57)	-22.4	4.06	< .001*	0.63
DERS-SF Goals	12.62 (2.84)	10.10 (3.57)	-2.52 (4.33)	-19.9	3.78	.001*	0.58
DERS-SF Awareness	8.79 (3.63)	7.81 (3.05)	-0.98 (3.57)	-11.1	1.77	.084	0.28
DERS-SF Clarity	10.19 (3.82)	7.88 (3.46)	-2.31 (4.09)		3.66	.001*	0.56

Note. Means are presented with standard deviations in parentheses.
*Statistically significant at the Bonferroni corrected p-value of .003.

Neither age, gender nor ethnicity were associated with changes in difficulty with emotion regulation, dispositional mindfulness, or mood and anxiety symptoms. Higher level of education had no significant impact on change scores, except for FFMQ-Non-Reactivity ($t(40) = -2.67$, $p = .011$, $d = 0.85$). Participants with a post-secondary level of education showed a significantly larger increase in FFMQ-Non-Reactivity scores compared to those with a secondary school education level ($M = 6.0 \pm 7.51$ vs 0.15 ± 6.49).

A series of one-way ANOVA's revealed that no primary diagnosis was associated with changes in difficulty with emotion regulation, dispositional mindfulness, or mood and anxiety symptoms. There was however, a trend towards significance for FFMQ-Non-Reactivity ($F(5,39) = -2.06$, $p = .095$). Post hoc analyses showed that participants with a General Personality Disorder (GPD) experienced a worsening in FFMQ-Non-Reactivity scores, whereas all other primary diagnosis groups showed an increase. This difference was significant between GPD and Bipolar Disorder ($p = .030$), and between GPD and Trauma and Stress Related Disorders ($p = .004$).

Patients discharged on anti-psychotic medication had a significantly larger improvement in FFMQ-Non-Reactivity scores compared to patients not discharged on anti-psychotic medication ($M = 5.17\pm$ vs 0.46 ± 7.28, $t(39) = -2.07$, $p = .045$, $d = 0.66$). Patients not discharged on benzodiazepines had a significantly larger improvement in DERS-SF-Total scores compared to patients discharged on benzodiazepines ($M = -16.13\pm16.74$ vs -1.18 ± 16.83, $t(39) = -2.53$, $p = .016$, $d = 0.89$), a significantly larger improvement in DERS-SF-Clarity sub-scale scores ($M = 3.07\pm3.66$ vs 0.36 ± 3.98, $t(39) = -2.60$, $p = .013$, $d = 0.92$), and a significantly larger improvement in DERS-SF-Impulse sub-scale scores ($M = -3.10\pm4.10$ vs -0.91 ± 4.91, $t(39) = -2.78$, $p = .008$, $d = 0.98$).

Higher MASQ-D30-Total scores pre-intervention were negatively correlated with change in MASQ-D30-General Distress ($r = -.388$, $p = .011$), MASQ-D30-Anxious Arousal ($r = -.436$, $p = .004$), and DERS-SF-Clarity ($r = -.430$, $p = .005$) subscale scores. This indicates that those participants who had greater mood and anxiety symptoms at the start of the program showed greater improvement at post-intervention in their general mood and anxiety symptoms, anxious arousal, and lack of emotional clarity.

Higher DERS-SF-Total scores pre-intervention were negatively correlated with change in DERS-SF-Strategies ($r = -.357$, $p = .020$), DERS-SF-Non-Acceptance ($r = -.347$, $p = .024$), DERS-SF-Impulse ($r = -.543$, $p < .001$), and DERS-SF-Clarity ($r = -.512$, $p = .001$) subscale scores. This indicates that those participants who had greater difficulty with emotion regulation at the start of the program showed greater improvement in emotion regulation post-intervention.

A backwards linear regression was conducted to determine whether pre-intervention scores and changes in emotion dysregulation and dispositional mindfulness predicted improvement in mood and anxiety features post-intervention. None of the data violated assumptions of normality or independence. Some of the independent variables in the regression analyses were highly correlated (see Table 7), but this is expected since changes in scores are related to pre-intervention variables. Variation inflation factor (VIF) figures were close to 1.5,

providing evidence to suggest some problems with multicollinearity. Again, this is expected since changes in scores are related to pre-intervention variables.

Table 7. Correlations between outcome and predictor variables

	Change MASQ	Change DERS	Change FFMQ	Pre-MASQ	Pre-DERS	Pre-FFMQ
Change MASQ	1.00	.597**	-0.693**	-.446*	-.157	.093
Change DERS		1.00	-.628**	-.219	-.539**	.171
Change FFMQ			1.00	.219	-.028	-.205
Pre-MASQ				1.00	.533**	-.623**
Pre-DERS					1.00	-.534**
Pre-FFMQ						1.00

Note. Pearson's *r* correlation coefficients are presented. *$p < .05$. **$p < .001$.

All variables were coded as continuous. From the descriptive statistics, predictor variables had a weak to strong relationship with changes in mood and anxiety features post-intervention (*rs* ranged from .093 to .693). The weakest relationship was between changes in mood and anxiety features post-intervention and pre-intervention dispositional mindfulness, and the strongest relationship was between changes in mood and anxiety features post-intervention and changes in dispositional mindfulness post-intervention.

Table 8. Coefficients for predictors in model 2 of regression model

Variables	*b*	Std. Error	Beta	*t*	*P*
Constant	90.10	25.76	-	3.50	.001
Change DERS	0.26	0.14	0.22	1.89	.067
Change FFMQ	-0.45	0.10	-0.52	-4.32	<.001
Pre-MASQ	-0.63	0.15	-0.52	-4.34	<.001
Pre-FFMQ	-0.41	0.13	-0.37	-3.15	<.001

All variables were entered into one block in the regression analysis. This was exploratory to see which significantly correlated predictor variables would end up being significant predictors of mood and anxiety improvement. Results of the regression indicated that pre-intervention mood and anxiety features, pre-intervention dispositional mindfulness, and change in dispositional mindfulness post-intervention significantly predicted mood and anxiety improvement (see Table 8). Changes in emotion dysregulation were not a significant predictor of mood and anxiety improvement. The regression coefficients suggest that improved dispositional mindfulness predicted improved mood and anxiety features post-intervention. It also suggests that better dispositional mindfulness pre-intervention and more severe mood and anxiety symptoms pre-intervention predicted improved mood and anxiety features post-intervention.

Table 9. Regression model summary table

Model	R	R Square	Adjusted R Square	Std. Error of Estimate	R Square Change	F Change	Sig. of F change
1	.831	.690	.647	12.21	.690	16.03	< .001
2	.829	.687	.653	12.12	-.004	0.41	.524

1. Predictors: Pre-intervention MASQ, DERS and FFMQ, change in FFMQ, change in DERS
2. Predictors: Pre-intervention MASQ and FFMQ, change in FFMQ, change in DERS

Table 10. ANOVA summary table

Model	Sum of squares	Df	Mean Square	F	Sig.
1 Regression	11955.96	5	2391.19	16.03	< .001
Total	5369.18	36	149.14		
2 Regression	11894.15	4	2973.54	20.26	< .001
Total	5430.99	37	146.78		

These results suggest that those participants with higher levels of mood and anxiety symptoms and with some level of dispositional mindfulness at pre-intervention, are more likely to benefit from the program interventions. Overall, the model explains 65% of the variance in participants' mood and anxiety improvement (R = .829, R^2 = .653, F [4,37] = 20.26, $p < .001$; see Tables 9 and 10).

Discussion

The results of this study show that participation in the short-term in-patient psychotherapy program resulted in significant improvement in mood and anxiety symptoms, dispositional mindfulness, and with emotion regulation at the completion of the 4-week program. Results obtained show statistically significant improvement in the total scores of the MASQ-D30, DERS-SF, and FFMQ. The MASQ-D30 showed the largest improvement of all scales, with improvement noted in all three sub-scales of the MASQ-D30: General Distress, Anhedonic Depression, and Anxious Arousal. Linear regression modelling indicated that pre-intervention mood and anxiety symptoms, pre-intervention dispositional mindfulness, and change in dispositional mindfulness post-intervention significantly predicted mood and anxiety improvement (see Table 6).

Before considering inferences from these results, we would like to outline a number of limitations present in this study that should inform the interpretation of these results. Firstly, this outcome assessment evaluation addresses the existence of a relationship between those persons who received the program and the presence of a change, but does not attempt to determine whether the change was caused by the program. The study can support program effect theory by proving that program participants who received the program interventions demonstrated the desired outcomes. But the study cannot verify the program effect theory, as the study design cannot prove causality. Secondly, our study is vulnerable to a testing effect which may occur when the process of being involved in providing the pre-test data in some way affects the post-test data (Issel, 2009). There is the possibility that study participants were influenced by the pre-intervention questionnaires, and thereby adjusted their responses following exposure to the mindfulness and emotion regulation components of the program. Thirdly, our study included participants with diverse ethnicities and cultural backgrounds and although the study instruments were translated and validated for use in other geographic and cultural areas, there is the risk that the South African context may have an unknown impact on the validity of these instruments.

Fourthly, practical limitations precluded an assessment of specific program intervention, such that change cannot directly be tied to specific program interventions, and should be seen as the result of the combination of diverse program interventions. The study's evaluation design did not include process evaluation of the implementation and effects of sub-components of the program. The pre-test/post-test design evaluated the program as a whole, including multiple program components delivered during a 4-week period.

Fifthly, study resources precluded our ability to extend follow-up beyond discharge from the program, and consequently we were not able to assess the durability of treatment gains. We were also not able to include

measurement of adverse events of specific program interventions. Finally, by using self-report questionnaire data we have to consider the possibility of response bias, and that reliance on self-report measures may result in over-reporting of symptoms and inflation of observed relationships between study variables.

Bearing in mind these limitations, our findings suggest that improvement in emotion regulation and dispositional mindfulness are important components that contribute to the success of the program as measured by decrease in mood and anxiety symptoms. By synthesizing the interactions between dispositional mindfulness, difficulty with emotion regulation, mood and anxiety symptoms, psychiatric morbidity, medication prescribed on discharge, and program interventions, our findings support the proposed program effect theory: (a) Poorly regulated emotions and low levels of dispositional mindfulness can engender a number of adverse psychological consequences such as worry and rumination; (b) participation in an in-patient psychotherapy program, that delivers a combination of interventions such as mindfulness skills training and DBT psychosocial skills training, improve dispositional mindfulness, as well as improve emotion regulation; and (c) participation in the program result in lower levels of depression and anxiety symptoms.

The results of this study add to emerging evidence that link emotion dysregulation with depression and anxiety disorders (Freudenthaler et al., 2017). Our findings contribute to the evidence that emotion regulation could be one path through which mindfulness unfolds its positive effect on psychological wellbeing (Desrosiers et al., 2013; Tran et al., 2014). Surprisingly, our findings suggest that changes in emotion regulation difficulties were not a significant predictor of improved mood and anxiety symptoms following program participation. This is in contrast to changes in mindfulness skills post-intervention that significantly predicted mood and anxiety improvement. Possible explanations for this finding are that (a) in our study population mindfulness skills training did not significantly affect difficulty with emotion regulation, (b) the heterogeneity of our study sample diluted the effect that mindfulness skills training may have had on difficulty with emotion regulation, and (c) our sample size and instruments were insufficient to record an association that really existed.

Our findings contribute to efforts to parcel out the unique components of emotion regulation processes to more precisely understand the mechanisms through which interventions effect change (Freudenthaler et al., 2017). While the total score on the DERS-SF improved following program participation, the following DERS-SF sub-scales did not show improvement: DERS-SF-Non-Acceptance and DERS-SF-Awareness. The lack of emotional awareness and non-acceptance of emotional responses are two of the six dimensions of emotion dysregulation measured by the DERS-SF. These dimensions of emotion dysregulation are closely related to the

mindfulness concepts of ‘observing’ and ‘non-reactivity to inner experience.’ Both the sub-scales of FFMQ-Observe and FFMQ-Non-Reactivity did not show significant improvement following program attendance.

Although our findings indicate general improvement in emotion dysregulation and dispositional mindfulness, there appears to be a particular pattern that suggest that components of emotion dysregulation (emotional awareness and non-acceptance of emotional responses) and mindfulness (observing and non-reactivity to inner experience) did not improve following program attendance. These results suggest that the majority of participants may have deployed other mechanisms for emotion regulation, such as reappraisal and extinction (Garland et al., 2011; Hölzel et al. 2011). Participants may have also deployed emotion regulation skills taught in DBT psychosocial skills modules, and, as there are more than 60 DBT-skills, we were not able to demonstrate whether some skills were more important and useful than others.

Our results show that those participants with higher levels of mood and anxiety symptoms together with some level of dispositional mindfulness at pre-intervention, are more likely to benefit from the program interventions. A possible explanation for this association between baseline levels of dispositional mindfulness at pre-intervention and program outcomes, is that dispositional mindfulness may contribute to improved psychological health by encouraging a mindful attitude toward internal experiences (Bowlin & Baer, 2012). This characteristic at pre-intervention would theoretically enable a program participant to be in a better position to benefit from mindfulness skills training and other program interventions, thereby increasing their odds of improvement at post-intervention.

Non-reactivity to inner stimuli is considered a core component of mindfulness (Baer et al., 2006). Among demographic variables, post-secondary education showed a significant association with improvement on the FFMQ-Non-Reactivity sub-scale. This association raises questions about whether mindfulness interventions in the program were more accessible to participants with higher levels of education, and whether other characteristics that are associated with attainment of education may also have an effect on the ability to improve this facet of mindfulness.

The evidence provided by our study should inform service delivery and development, in keeping with calls to periodically evaluate mental health services to assist in planning and improving service delivery (National Department of Health, 2013). Our findings suggest that the current in-patient psychotherapy program is effective in alleviating mood and anxiety symptoms for a broad range of eligible participants. The program’s effectiveness

may be increased by refining the components that are responsible for therapeutic changes, and de-emphasizing components that do not contribute to improvement.

We emphasize that in this exploratory evaluation our results are preliminary and that further controlled studies comparing in-patient with out-patient programs, and control-groups are necessary to clarify the extent to which different types of program interventions affect mood symptoms, mindfulness skills, and emotion dysregulation.

Conclusion

In conclusion, the overall results of this study show evidence of the effectiveness of the in-patient psychotherapy program. Attendance of the program resulted in improvements in mood and anxiety symptoms, emotion regulation, and dispositional mindfulness. Differences in program outcomes and associations with demographic variables, psychiatric morbidity, and medication at discharge indicate that a nuanced approach to parcelling out the effects of program interventions is needed when considering a program effect theory.

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APPENDICES

A. Mood and Anxiety Symptoms Questionnaire

Instructions: Please rate how much you were experiencing each of the following in the last 2 weeks. Circle the number next to each statement that best describe your own opinion of what is generally true for you.

Statement	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
1. Felt confused	1	2	3	4	5
2. Startled easily	1	2	3	4	5
3. Felt successful	1	2	3	4	5
4. Felt worthless	1	2	3	4	5
5. Felt nauseous	1	2	3	4	5
6. Felt really happy	1	2	3	4	5
8. Felt dizzy or light-headed	1	2	3	4	5
9. Felt optimistic	1	2	3	4	5
10. Felt hopeless	1	2	3	4	5
11. Felt like I was having a lot of fun	1	2	3	4	5
12. Blamed myself for a lot of things	1	2	3	4	5
13. Felt dissatisfied with everything	1	2	3	4	5
14. Felt like I accomplished a lot	1	2	3	4	5
15. Was trembling or shaking	1	2	3	4	5
16. Felt like I had a lot to look forward to	1	2	3	4	5
17. Felt pessimistic about the future	1	2	3	4	5
18. Had pain in my chest	1	2	3	4	5
19. Felt really talkative	1	2	3	4	5
20. Had hot or cold spells	1	2	3	4	5
21. Was short of breath	1	2	3	4	5
22. Felt really ‘up’ or lively	1	2	3	4	5

23. Felt inferior to others	1	2	3	4	5
24. Muscles were tense or sore	1	2	3	4	5
25. Had trouble making decisions	1	2	3	4	5
26. Felt like I had a lot of energy	1	2	3	4	5
27. Heart was racing or pounding	1	2	3	4	5
28. Worried a lot about things	1	2	3	4	5
29. Felt really good about myself	1	2	3	4	5
30. Had trouble swallowing	1	2	3	4	5

B. Five Facets of Mindfulness Questionnaire

Instructions: Please rate the following statements based on how often they apply to you. Circle the number next to each statement that best describe your own opinion of what is generally true for you.					
Statement	**Almost never (0-10%)**	**Some-times (11-35%)**	**About Half of the Time (36-65%)**	**Most of the Time (66-90%)**	**Almost Always (91-100%)**
1. When I'm walking, I deliberately notice the sensations of my body moving.	1	2	3	4	5
2. I'm good at finding words to describe my feelings	1	2	3	4	5
3. I criticize myself for having irrational or inappropriate emotions	1	2	3	4	5
4. I perceive my feelings and emotions without having to react to them.	1	2	3	4	5
5. When I do things, my mind wanders off and I'm easily distracted.	1	2	3	4	5
6. When I take a shower or bath, I stay alert to the sensations of water on my body.	1	2	3	4	5
7. I can easily put my beliefs, opinions, and expectations into words.	1	2	3	4	5
8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	1	2	3	4	5
9. I watch my feelings without getting lost in them.	1	2	3	4	5
10. I tell myself I shouldn't be feeling the way I'm feeling.	1	2	3	4	5
11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	1	2	3	4	5

12. It’s hard for me to find the words to describe what I’m thinking.	1	2	3	4	5
13. I am easily distracted	1	2	3	4	5
14. I believe some of my thoughts are abnormal or bad and I shouldn’t think that way.	1	2	3	4	5
15. I pay attention to sensations, such as the wind in my hair or sun on my face.	1	2	3	4	5
16. I have trouble thinking of the right words to express how I feel about things	1	2	3	4	5
17. I make judgments about whether my thoughts are good or bad.	1	2	3	4	5
18. I find it difficult to stay focused on what’s happening in the present	1	2	3	4	5
19. When I have distressing thoughts or images, I “step back” and am aware of the thought or image without getting taken over by it.	1	2	3	4	5
20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing	1	2	3	4	5
21. In difficult situations, I can pause without immediately reacting.	1	2	3	4	5
22. When I have a sensation in my body, it’s difficult for me to describe it because I can’t find the right words	1	2	3	4	5
23. It seems I am “running on automatic” without much awareness of what I’m doing.	1	2	3	4	5
24. When I have distressing thoughts or images, I feel calm soon after.	1	2	3	4	5
25. I tell myself that I shouldn’t be thinking the way I’m thinking	1	2	3	4	5

26. I notice the smells and aromas of things.	1	2	3	4	5
27. Even when I’m feeling terribly upset, I can find a way to put it into words.	1	2	3	4	5
28. I rush through activities without being really attentive to them.	1	2	3	4	5
29. When I have distressing thoughts or images I am able just to notice them without reacting.	1	2	3	4	5
30. I think some of my emotions are bad or inappropriate and I shouldn’t feel them.	1	2	3	4	5
31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	1	2	3	4	5
32. My natural tendency is to put my experiences into words.	1	2	3	4	5
33. When I have distressing thoughts or images, I just notice them and let them go	1	2	3	4	5
34. I do jobs or tasks automatically without being aware of what I’m doing.	1	2	3	4	5
35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.	1	2	3	4	5
36. I pay attention to how my emotions affect my thoughts and behavior	1	2	3	4	5
37. I can usually describe how I feel at the moment in considerable detail.	1	2	3	4	5
38. I find myself doing things without paying attention.	1	2	3	4	5
39. I disapprove of myself when I have irrational ideas.	1	2	3	4	5

C. Difficulty with Emotion Regulation – Short Form

Instructions: Please rate the following statements based on how often they apply to you. Circle the number next to each statement that best describe your own opinion of what is generally true for you.					
Statement	**Almost never (0-10%)**	**Some-times (11-35%)**	**About Half of the Time (36-65%)**	**Most of the Time (66-90%)**	**Almost Always (91-100%)**
1. I pay attention to how I feel	1	2	3	4	5
2. I have no idea how I am feeling	1	2	3	4	5
3. I have difficulty making sense out of my feelings	1	2	3	4	5
4. I care about what I am feeling	1	2	3	4	5
5. I am confused about how I feel	1	2	3	4	5
6. When I'm upset, I acknowledge my emotions	1	2	3	4	5
7. When I'm upset, I become embarrassed for feeling that way	1	2	3	4	5
8. When I'm upset, I have difficulty getting work done	1	2	3	4	5
9. When I'm upset, I become out of control	1	2	3	4	5
10. When I'm upset, I believe that I will end up feeling very depressed	1	2	3	4	5
11. When I'm upset, I have difficulty focusing on other things	1	2	3	4	5
12. When I'm upset, I feel guilty for feeling that way	1	2	3	4	5
13. When I'm upset, I have difficulty concentrating	1	2	3	4	5
14. When I'm upset, I have difficulty controlling my behaviors	1	2	3	4	5

15. When I’m upset, I believe there is nothing I can do to make myself feel better	1	2	3	4	5
16. When I’m upset, I become irritated with myself for feeling that way	1	2	3	4	5
17. When I’m upset, I lose control over my behavior	1	2	3	4	5
18. When I’m upset, it takes me a long time to feel better	1	2	3	4	5

D. Participant information sheet and consent form

Researchers' names: Dr Marguerite Schneider and Dr Kobus van der Walt

Department of Psychiatry & Mental Health

University of Cape Town

Dear Participant,

Study title: OUTCOME EVALUATION OF AN IN-PATIENT PSYCHOTHERAPY PROGRAM: MINDFULNESS, DIFFICULTY WITH EMOTION REGULATION, AND MOOD AND ANXIETY SYMPTOMS

Who are the investigators?

This study will be carried out by investigators from the Department of Psychiatry and Mental Health, Faculty of Health Sciences, University of Cape Town. Dr Kobus van der Walt is a MMed student in the Department of Psychiatry & Mental Health, University of Cape Town. He is supervised by Dr Joe Starke and Dr Marguerite Schneider, both from the Department of Psychiatry & Mental Health, University of Cape Town.

What is the study about?

This consent form will tell you why we want to do this study.

Please ask us questions about anything you do not understand or if you would like more information. We are happy to explain this to you more than once.

You are invited to volunteer to participate in a research project on the effect of an in-patient psychotherapy program on mindfulness, difficulty with emotion regulation, and mood and anxiety symptoms.

This letter gives information to help you decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any questions, do not hesitate to contact me. You should not agree to take part unless you are completely happy about what I expect of you.

The purpose of this study is to see if the Ward 1 program improved your mood and anxiety levels, by helping you to deal with your emotions and being more mindful. By taking part in this study, you will allow us to see if the Ward 1 program works to improve the mood and anxiety of patients. This will help us to improve the

program, and you will help us to scientifically understand how the program works on different people.

What will happen to me in this study?

In order to do the research, we have discussed, we must collect your answers to 3 short questionnaires at the beginning of the program, and before leaving the program:

- The Mood and Anxiety Symptoms Questionnaire (MASQ-D30)
- The Difficulty in Emotion Regulation Scales – Short Form (DERS-SF)
- The Five Facet Mindfulness Questionnaire (FFMQ)

This may take about 30 minutes. You will be asked to answer a list of questions about your emotions and mood, and about the ways you respond when you are upset. A research assistant will also ask you questions about your personal background. The research assistant will ask you the questions from these questionnaires and will record your answers on an answer sheet. The research assistant will be available to answer any questions you have about the questionnaires.

The research assistant will also read the content of the Patient Care Plan that is in your medical folder. This will help us to record information about your mental health, such as psychiatric illnesses, and psychological problems.

When you are discharged from the Ward 1 program, doctors will write a summary of your illness, the treatment you received, changes made to your medication, and further follow-up treatment that you require. The researchers will also read the contents of the summary to see whether certain kinds of medication were added that may have an effect on your emotions and mood.

Why is the study being done?

The results of this study will tell us if the Ward 1 program is working to help patients to improve their skills in regulating their emotions and improving their mindfulness skills, and whether this causes patients having less depression and anxiety symptoms. By evaluating the effect of the Ward 1 program, Valkenberg Hospital can make changes and improve the program to provide a better service to patients. The results will also show us how different types of patients respond to the program in different ways, to help experts to design better programs for patients suffering from specific illnesses.

Where will the study take place?

The study will take place in Ward 1, Valkenberg Hospital. Participation in this study will not interfere in any of the Ward 1 activities.

Why have I been selected?

The aim of this study is to evaluate the effect of the Ward 1 program; therefore, all patients who are admitted to Ward 1 are eligible to participate in the study. Certain patients may not be eligible to participate for practical reasons, for example due to language differences and difficulty understanding questions.

When will the study begin and end?

The study aims to collect information from March-December 2018. We expect about 140 patients to take part in this study.

What will happen to the data?

To protect your privacy, we will replace your name with a code. We will only use this code on information about you. We will do our best to keep the code private. It is however always possible that someone could find out your name but this is very unlikely to happen.

What are the risks and discomforts of this study?

We want to tell you that there are some risks with this study. For example, there is a small chance that you may experience the questionnaires as stressful and that it may cause you to feel overwhelmed. If this occurs, the staff in the Ward 1 program will immediately be notified, and will offer you support. We anticipate that it will take about 30 minutes to complete the questionnaires. If you feel tired or exhausted, or need a break, please ask the research assistant for a rest period. One potential risk of participating in this study is that information about you may become known to people who should not have this information. There is a small risk that someone who should not have your information could learn something about you.

Are there any benefits to you for being in the study?

In general, individual results from this research project will not be given back to you or put into your medical records. You will not benefit immediately from the study, as the study is evaluating the Ward 1 program that you are currently attending.

What other choices do you have?

If you choose not to participate in the study, you will continue to participate in the Ward 1 program. Whether you decide to join or not to join the study, the way the Ward 1 program staff support you and provide treatment will be the same.

Will the results of the research be shared with you?

The results of the research will be shared with Ward 1 and the Valkenberg Hospital management. It will also be published in an academic journal. If you are interested in receiving a summary of the results, please contact the Principle Investigator.

Will you receive any reward (money or food vouchers) for taking part in this study?

You will not receive any rewards, such as money or food vouchers, for taking part in this study.

Who will see the information which is collected about you during the study?

The information collected about you during the study will not be linked to your personal identity. The information collected will be captured on questionnaire answer sheets and then transferred to a secured computer and only the research assistant, the researchers, and biostatistician will have access to this information.

Who do I speak to (or contact) if I have any questions about the study?

The Human Research Ethics Committee of the University of Cape Town, Faculty of Health Sciences granted written approval for this study. The study was also approved by the Department of Health, Provincial Government of the Western Cape, and the Valkenberg Hospital management.

Contact details for the Human Research Ethics Committee

The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant on this research study.

Contact details of the Principle Investigator:

The Principle Investigator is Dr Marguerite Schneider and co-investigator is Dr Kobus van der Walt. They can be contacted on 021 440 3185.

Voluntary nature of participation and right to withdrawal

It is a personal decision whether you take part in the study. In other words, it is up to you whether you want to participate in the study." You can say "yes" and join the study; or you can also say "No," you don't want to join. If you participate in the study, you can change your mind later and decide that you don't want to participate anymore. Whether you decide to join or not to join the study, the way the Ward 1 program staff support you will be the same. It is your decision whether to be in the study or not.

How participants' privacy will be protected

The questionnaires will be kept in a safe place. Please note that you will not be able to write your name on the questionnaire, this will ensure confidentiality. Your personal information will be stored for the duration of the study on a secure computer. You will also not be identified as a participant in any publication that comes from this study.

I sincerely appreciate your help.

Yours truly

Dr Kobus van der Walt

Consent form signature sheet

Study title: Outcome evaluation of an in-patient psychotherapy program: Mindfulness, difficulty with emotion regulation, and mood and anxiety symptoms

Principle investigator: Dr Marguerite Schneider

Co-investigator: Dr Kobus van der Walt

Before you complete and sign the form, please ask questions on any aspect of the study that is at all unclear to you. If you have any additional questions later, Dr Kobus van der Walt (Tel. 021 440 3185) will be happy to answer them. If at any time you have questions concerning your rights as a research subject, you may call the Human Research Ethics Committee of the University of Cape Town, Faculty of Health Sciences at tel. 021 406 6338.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

I acknowledge that I have received a personal copy of this consent form.

Copy received: _____ (initial)

______________ ______________________________ __________________

Date **Signature of study participant** **Time**

______________ ______________________________ __________________

Date **Signature of investigator/research assistant** **Time**

E. Ethics approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
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11 January 2018

HREC REF: 839/2017

A/Prof M Schneider
Department of Psychiatry & Mental Health
46 Sawkins Road
Rondebosch

Dear A/Prof Schneider

PROJECT TITLE: OUTCOME EVALUATION OF AN IN-PATIENT PSYCHOTHERAPY PROGRAM: MINDFULNESS, DIFFICULTY WITH EMOTION REGULATION, AND MOOD AND ANXIETY SYMPTOMS-(MMeD-candidate-Dr K van der Walt)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 January 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr K van der Walt will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RÉSEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 839/2017