MONASH University

Advancing the empirical evidence for, and theoretical understanding of, Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) as a transdiagnostic intervention for mental health conditions

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ABSTRACT

Transdiagnostic therapies that focus on processes that are shared across a range of mental health conditions rather than on a specific diagnosis can provide cost-efficient interventions since multiple conditions both within and across individuals can be treated simultaneously. Mindfulness-integrated cognitive behaviour therapy (MiCBT) is a mindfulness-based intervention (MBI) designed for transdiagnostic mental health conditions.

The rationale of MiCBT is based on the co-emergence model of reinforcement which conceptualises interoceptive conditioning co-emerging with thoughts as the basis of emotional reactivity. Consequently, MiCBT focuses on developing metacognitive and interoceptive awareness together with equanimity. The aim of this research is to progress the empirical evidence for, and theoretical understanding of MiCBT, as an intervention for transdiagnostic mental health conditions.

The first paper is a theoretical analysis comparing MiCBT with the more widely-researched mindfulness-based cognitive therapy (MBCT), designed originally for relapse prevention in depression. MBCT is based on the cognitive model of depressive relapse while MiCBT includes a more explicit integration of Buddhist psychology with cognitive behaviour therapy (CBT) to address acute conditions. The two programs are compared from the perspectives of their purpose, origins and Buddhist influences, integration of CBT principles, specific mindfulness methods, and the role of ethics.

The second and third papers describe the design and results respectively of a randomised controlled trial evaluating the effectiveness of a group-based eight-week MiCBT program delivered in primary mental healthcare to decrease depression and anxiety symptoms in a transdiagnostic population. The role of putative mechanisms including interoceptive and

metacognitive awareness, equanimity and social functioning were also examined. Eligible patients were randomised to either MiCBT or a treatment-as-usual wait-list control. The hypotheses were that, compared to the control group, the MiCBT group would show decreased depression, anxiety and stress and increased life satisfaction and flourishing with improvements maintained over six-months.

The primary outcome was severity of depression, anxiety and stress as measured by the Depression, Anxiety and Stress Scale (DASS-21). Secondary outcome measures were the Kessler Psychological Distress Scale (K10), the Satisfaction with Life Scale (SWLS), and the Flourishing Scale (FS). Process measures were included to explore putative mediators. Measures were administered at program start, mid-program, program completion and at 6-month follow-up. The results showed significant improvements in the MiCBT group compared to the controls in all measures, except for the SWLS, with small-medium effect sizes. Equanimity emerged as most influential mediator, consistent with the co-emergence model of reinforcement.

The theoretical analysis from this body of work suggests that MiCBT diverges from MBCT in useful ways. MiCBT potentially makes a unique and versatile contribution to the emerging suite of mindfulness-based interventions because of its transdiagnostic applicability, its conceptualization of emotional reactivity based on interoceptive conditioning, its focus on developing interoceptive awareness and equanimity, and the explicit inclusion of ethics as an expression of compassion. In addition, the empirical findings support the effectiveness of MiCBT in reducing symptoms of depression, anxiety and stress and improving wellbeing for groups with heterogeneous mental health conditions and highlights the potentially pivotal role of equanimity in bringing about such change.

DECLARATION

This thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Signature: …  ……

Print Name: Sarah Francis…….

Date: ……13/05/2021…….

PUBLICATIONS DURING ENROLMENT

Francis S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020) Study protocol for a randomised control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry 20:7.

Correction to: Study protocol for a randomised control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. Francis et al., BMC Psychiatry (2020) 20:136.

THESIS INCLUDING PUBLISHED WORKS DECLARATION

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes one original paper published in a peer reviewed journal and two submitted publications. The core theme of the thesis is an investigation of the effectiveness of Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) in a primary health care setting. A secondary theme of the thesis is an exploration of how MiCBT differs from other widely researched clinical mindfulness-based interventions. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within the Department of Psychiatry under the supervision of Dr. Frances Shawyer, Professor Graham Meadows and Dr. Bruno Cayoun.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of chapters 3, 3 & 4 my contribution to the work involved the following:

Thesis Chapter	**Publication Title**	**Status** (published, in press, accepted or returned for revision, submitted)	**Nature and % of student contribution**	**Co-author names and nature of co-author's contribution**	**Co-authors Monash student Y/N**
2	Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) and Mindfulness -based Cognitive Therapy (MBCT):	Submitted for publication	70% Conception and publication drafting	Frances Shawyer: 15% advice throughout and critical revisions Bruno Cayoun: 5% critical revisions	N

	differentiating mechanisms and clinical applications			Andrea Grabovac: 5% critical revisions Graham N. Meadows: 5% critical revisions	
3	Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behaviour therapy (MiCBT) transdiagnostic group intervention for primary care patients	Published	70% Conception, and publication drafting	Frances Shawyer: 15% advice throughout, assistance with statistical content and critical revisions Bruno Cayoun: 5% critical revisions Joanne Enticott: 5% statistical advice Graham N. Meadows: 5% critical revisions	N
4	Group mindfulness-integrated cognitive behaviour therapy reduces depression and anxiety and improves flourishing in a transdiagnostic primary health-care sample compared to a treatment-as-usual waitlist control	Submitted for publication	70% Conception, implementation, data collection, data analysis, and publication drafting	Frances Shawyer: 20% advice throughout, assistance with statistical analyses, and critical revisions Bruno Cayoun: 2% critical revisions Joanne Enticott: 6% statistical analyses Graham N. Meadows: 2% critical revisions	N
Sarah Francis: First Author and Principal Researcher Frances Shawyer: Primary Supervisor Bruno Cayoun: Secondary Supervisor Joanne Enticott: Statistics Consultant Graham N. Meadows: Secondary Supervisor Andrea Grabovac: Mindfulness-based interventions expert advisor					

The sections of submitted or published papers have been renumbered in order to generate a consistent presentation within the thesis.

Candidate name: Sarah Francis

Student signature:  **Date:** 13 May 2021

I hereby certify that the above declaration correctly reflects the nature and extent of the student and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

Main Supervisor signature:  **Date:** 13 May 2021

ACKNOWLEDGEMENTS

This research would not have been realised without the support of my supervisors, Dr Frances Shawyer, Professor Graham Meadows and Dr Bruno Cayoun whose guidance, expert input and patience directly contributed to the project's success. I would also like to acknowledge the assistance of Dr Joanne Enticott and Shrinkhala Dawadi for assistance with statistical advice and the data analyses. In addition, I thank Dr. Sabura Allen who supported the approval and early stages of the project before she relocated to the U.S.A. I would like to thank my children, Dean and Kim, my extended family and my colleagues and friends for their ongoing support and encouragement to complete the work.

I thank Debbie Lang who assisted with preparation of materials and administering gift vouchers to participants. Finally, I offer my sincere gratitude to the participants and to their referring medical practitioners without whom this work would not have been possible.

TABLE OF CONTENTS

ABREVIATIONS USED IN THIS THESIS

MiCBT	Mindfulness-integrated Cognitive Behaviour Therapy
DASS-21	Depression, Anxiety and Stress Scale
K10	Kessler Psychological Distress Scale
SWLS	Satisfaction with Life Scale
FS	Flourishing Scale
MAIA	Multi-dimensional Assessment of Interoceptive Awareness
NAS	Non-Attachment Scale
MSES-R	Mindfulness-based Self-efficacy Scale
MSES-R-I	Mindfulness-based Self-efficacy Scale (Interpersonal Skills)
MSES-R-E	Mindfulness-based Self-efficacy Scale (Equanimity)
EQ	Experiences Questionnaire
MBCT	Mindfulness-based Cognitive Therapy
MBI	Mindfulness-based Intervention
CBT	Cognitive Behaviour Therapy
MBP	Mindfulness-based Program
TAU	Treatment as usual
MMRM	Mixed methods repeated measures
ITT	Intention to treat
MCAR	Missing completely at random
CONSORT	Consolidated Standards of Reporting Trials
IV	Independent variable
DV	Dependent variable
CI	Confidence intervals
SPSS	Statistical Package for the Social Sciences
SBS	Special Broadcasting Service
ABS	Australian Bureau of Statistics

1 CHAPTER ONE: Introduction

1.1 MiCBT: A transdiagnostic mindfulness-based intervention

This research was conducted to investigate from a theoretical and empirical perspective the utility and effectiveness of a group-based implementation of Mindfulness-integrated Cognitive behaviour therapy (MiCBT;Cayoun, 2011, 2015; Cayoun, et al., 2019). Specifically, the research was designed to demonstrate the transdiagnostic capability of MiCBT as a group-based intervention to reduce symptoms in patients with mild to severe psychiatric conditions in a primary health care setting. This is important because the mindfulness-based therapies, that include formal meditations to facilitate the change processes, require to be adapted for specific diagnoses to incorporate a rationale that accommodates the particular symptoms for each diagnosis. MiCBT on the other hand has a rationale grounded in Buddhist psychology that accommodates a broad range of psychological conditions. Futhermore, MiCBT incorporates specific well researched cognitive and behavior change strategies that are enhanced by the development of equanimity towards interoceptive signals during distressing experiences.

1.2 Current trends in mindfulness-based therapies

Mindfulness-based interventions (MBIs) have become increasingly popular over the last twenty-five years since the early work of Jon Kabat-Zinn in developing mindfulness-based stress reduction (Kabat-Zinn, 1982, 1990, 1994). MBIs have been shown to provide benefits to mental health and wellbeing (Creswell, 2017) and the credibility of mindfulness meditation for mental wellbeing has been enhanced by recent neuroscientific interest in positive neural changes that occur in meditators. There now exist a variety of mindfulness-based programs and therapeutic approaches and a significant differentiating factor is the inclusion or not of formal meditation as a key aspect of the program. As many of the meditation methods used in MBIs have been adapted from Buddhist meditations, a recent debate in the scientific literature concerns the extent of influence and acknowledgement of Buddhism in the array of mindfulness-based interventions

and this is discussed in detail in Paper one. To provide some context for the current research, the paper includes a description of the historical background and Buddhist origins of MBSR as the prototype for the most well-known of the mindfulness-based programs involving formal meditation practices.

The availability and popularity of mindfulness meditation has been further enhanced by popular texts and the development of a range of meditation apps (Flett et al., 2019) generating an industry devoted to the creation and promotion of meditation-related products. Different categories of mindfulness programs have evolved; one category comprising wellbeing or stress management "products" for the general population and another comprising "clinical" mindfulness-based programs or interventions that are designed to address significant mental health conditions. MiCBT was designed as a clinical intervention for heterogeneous populations with moderate to severe mental health conditions although it is more recently being applied to general well-being (Cayoun 2015). Paper three adds support to the existing body of evidence regarding the effectiveness of MiCBT with mild - severe mental health conditions.

The program of work described in this thesis is concerned with MiCBT, an intervention that has meditation practices in line with the Burmese Vipassana tradition as a key element. In a theoretical analysis, MiCBT is compared and contrasted with other apparently similar interventions to consider whether it might have a unique contribution to offer among the current abundance of MBIs. The empirical work investigates the effectiveness of MiCBT via a randomised controlled trial implemented in a primary healthcare setting. Henceforth the term mindfulness-based intervention (MBI) is applied only to those programs that require formal meditation practices.

1.3 Rationale for the current research

An important motivator for this research was the observation in the candidate's clinical practice of the apparent capacity of MiCBT to facilitate significant and enduring mental health improvements in patients with a range of clinical presentations including comorbid conditions. It was of particular interest to the candidate to explore MiCBT because of the universality and utility of its underlying model and its capacity to be offered as a group intervention (although it is frequently used in individual therapy) with heterogeneous populations who may also have comorbid conditions. This is consistent with recent trends towards unified protocols that address the underlying processes that are shared across conditions instead of attempting to have treatment programs that are specific to particular diagnoses (Farchione et al., 2012). In terms of cost efficiency in treatments, a more unified approach would appear to be appropriate given the cost burden to communities of complex medical and comorbid mental health conditions. Group interventions are both cost effective and particularly amenable to research. In 2012, when the current work commenced, there was limited research evidence regarding the effectiveness of MiCBT. This situation has changed in the last 8 years and paper one includes a description of the current body of published MiCBT research.

A pilot non-controlled study in a primary healthcare setting investigating the effectiveness of MiCBT as a group intervention was previously conducted by the candidate that indicated significant improvement in clinical measures of depression, anxiety and stress as well as mindfulness-based self-efficacy and life satisfaction (Francis 2013). The current research sought to build on this pilot study to further investigate the capacity of MiCBT to impact changes in clinical measures by increasing the scope of outcome measures, and by including a mediation analysis to examine putative mechanisms and including a control group.

1.4 Aim of research study

This research program aimed to profile MiCBT in relation to MBCT and to investigate the potential contribution of MiCBT to the MBI field and the effectiveness of MiCBT delivered as a group-based intervention delivered in the naturalistic primary health care setting of a private psychology practice.

1.5 Study design

The empirical arm of this program of work is a randomised controlled study that aimed to recruit 120 participants in order to be powered to detect medium effect size (*d*=.5) in the clinical outcome and allow for attrition. Intention to treat analysis was used so that all available data could be utilised. The full details of the study design are described in the protocol paper, Paper two. The trial received ethical approval from the Monash University Human Research Ethics Committee and was registered with the Australian New Zealand Clinical Trials Registry.

In order to explore the mechanisms of clinical change in MiCBT, the selection of measures was important. The study utilized two clinical measures to detect changes in anxiety, depression and stress (Depression, Anxiety and Stress Scale; DASS-21, and Kessler Psychological Distress Scale; K10) and two well-being measures (Satisfaction with Life Scale; SWLS and Flourishing Scale; FS).

As well as clinical measures, instruments were required to assess the theoretical model of MiCBT, namely that both awareness and equanimity are key agents of clinical change. The theoretical framework of MiCBT is the co-emergence model of reinforcement which is described in detail in the first paper. According to the model, interoceptive cues co-arise with thoughts and it is proposed that reactivity is a response to the co-emerging body sensations. Therefore, awareness of the arising of thoughts and co-emergent body sensations are necessary preconditions for managing reactivity. Awareness measures therefore needed to include

metacognitive and interoceptive awareness. However, the MiCBT co-emergence model posits that awareness is necessary but not sufficient for psychological well-being; equanimity is also required. We therefore sought measures of metacognitive awareness, interoceptive awareness as well as equanimity.

Metacognitive awareness is conceptualized as awareness of one's thinking as it takes place and this detached attitude towards thoughts and has been termed decentering: "The capacity to shift experiential perspective—from within one's subjective experience onto that experience" (Bernstein et al., 2015). The Experiences Questionnaire (EQ; Fresco et al., 2007) which was designed to measure the ability to take a detached approach to ones thoughts and emotions was selected as a measure of decentering and is described in Paper two.

Interoceptive awareness, is described as "the conscious perception of sensations from inside the body that create the sense of the physiological condition of the body, such as heart beat, respiration, satiety, and the autonomic nervous system sensations related to emotions" (Mehling et al., 2012). The Multi-dimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2012), was developed to measure body awareness, recognizing the potential benefits of body awareness in affect regulation, providing bidirectional feedback that included evaluative processes. The MAIA therefore seemed to be an appropriate measure of interoception for the current study.

Equanimity has only relatively recently attracted research attention in the psychological literature. At the commencement of this program of study, the measurement of equanimity was in its infancy although recently two equanimity dedicated measures have been developed (Juneau et al., 2019; Rogers et al., 2020). Considered to be a non-reactive stance towards arising phenomena, equanimity is proposed to be a key mechanism in MiCBT. Equanimity has been defined as "an even-minded mental state or dispositional tendency toward all experiences or

objects, regardless of their origin or their affective valence (pleasant, unpleasant, or neutral)" (Desbordes et al., 2015). The most suitable available measure at the time of the study appeared to be the Nonattachment Scale (NAS; Sahdra et al., 2016). Nonattachment as defined in terms of a non-clinging and non-suppressing manner of relating to experience and thus appears to be a closely related construct to equanimity. The Mindfulness-based Self Efficacy Scale (MSES-R; Cayoun 2011) is a measure with six subscales three of which appear to tap the equanimity construct and three tap into an interpersonal skills construct. We chose to include the MSES-R to measure a) equanimity and b) changes in interpersonal skills. All measures had satisfactory psychometric properties (see Paper 2).

1.6 Presentation of thesis content

The program of work is largely described in three papers. An introduction is provided for each of the papers and the work is summarised in a final chapter which summarises the findings with concluding comments and suggestions for future research.

Paper one (Chapter 2)
Francis, S.E.B., Shawyer, F., Cayoun, B., Grabovac, A., & Meadows, G.N. (2020)

Mindfulness-based Cognitive Therapy (MBCT): differentiating mechanisms and clinical applications. Submitted to Mindfulness for review in October 2020.

Paper two (Chapter 3)
Francis Frances, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G.N. (2020). Study protocol for a randomised control trial to investigate the effectiveness of an 8-week Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry, 20 (1), 1-13.

Due to a typographical error in the spelling of the first authors name a correction was immediately published.

Francis, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G.N. (2020). Correction to: Study protocol for a randomised control trial to investigate the effectiveness of an 8-week Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) transdiagnostic group intervention for primary care patients. *BMC Psychiatry, 20* (1), 131

Paper three (Chapter 4)
Francis, S.E.B., Shawyer, F., Cayoun, B., Enticott, J., Meadows, G.N. (2020) Group mindfulness-integrated cognitive behavior therapy (MiCBT) reduces depression and anxiety and improves flourishing in a transdiagnostic primary care sample compared to a treatment-as-usual waitlist control. Submitted to Mindfulness for review in November 2020.

Chapter 5
Findings, Concluding remarks and Future Research

1.7 Relevance of current research

The availability of transdiagnostic interventions is important because of the high level of comorbidity in mental health conditions. Symptoms of anxiety and depression are frequently present in a range of conditions, including physical illness. Mindfulness-based approaches, such as MBCT, have captured the public interest but have had to be adapted for use with conditions other than recurrent depression for which it was designed with modifications to the program content. Therefore, a program that needs no modification for specific conditions provides a transdiagnostic applicability for a heterogenous population of patients.

Despite the increasing interest in MiCBT, and its routine transdiagnostic using clinical practice, to this candidate's knowledge, no randomised controlled studies have so far investigated the effectiveness of this intervention in a transdiagnostic population, despite the fact that MiCBT was developed with this population in mind. Furthermore, MiCBT has not been widely implemented compared to MBCT and so the differences between MiCBT and MBCT are not broadly understood. It is hoped that this body of work will assist clinicians understanding and application

of mindfulness-based therapies, further develop the evidence base for MiCBT, and inspire other researchers to further investigate this promising mindfulness-based intervention.

2 CHAPTER TWO: Comparing MiCBT with MBCT

2.1 Rationale of the theoretical paper

MiCBT was first piloted over eighteen years ago but despite the publication of comprehensive training manuals, its existence has been overshadowed by other MBSR- and MCBT-based therapies. Because it is not as widely practiced or well researched as other such MBIs, it is likely to be less understood. This was reinforced by feedback from the expert reviewers of the protocol paper, (Paper two) who suggested that the differences between MiCBT and MBCT were not clear. In an increasingly crowded space of MBIs, it was therefore considered important to consider and communicate what MiCBT had to offer that distinguished it from its better known cousin MBCT and related interventions. To this end, the theoretical differences between MiCBT and MBCT are discussed in Paper one of this thesis. Superficially both programs appear to be quite similar in that both can be delivered as an eight-week intervention, both require formal meditation methods derived from Buddhist practices and the name of both contains cognitive therapy. On close examination, the interventions differ in their respective rationales, the populations for whom they are developed, and in the type of meditation and cognitive and behavioural strategies deployed. Paper one explores in some detail the nature of differences and the clinical implications which may facilitate appropriate treatment choices. In summary, despite some similarities between the interventions, the structure and rationale of MiCBT enable transdiagnostic application without any modification of content for differing diagnoses. In the context of a demonstrated need for transdiagnostic MBIs by mental health services, this potentially represents an important distinguishing feature of MiCBT and one which is consistent with the current trend towards process-based therapies rather than diagnosis-specific treatments. Paper one has been submitted for publication to the journal *Mindfulness* which has an impact factor of 3.581.

2.2 Manuscript submitted for review

Francis, S.E.B., Shawyer, F., Cayoun, B.A., Grabovac, A., Meadows, G. Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) and Mindfulness-based Cognitive Therapy (MBCT): differentiating mechanisms and clinical applications. Submitted to *Mindfulness*.

Mindfulness-integrated Cognitive Therapy (MiCBT) and Mindfulness -based Cognitive Therapy (MBCT): differentiating mechanisms and clinical applications

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This project was undertaken through Monash University.

Abstract

Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) is a mindfulness-based program (MBP) which addresses a broad range of psychological conditions in either individual or group formats. Although the MiCBT group program may appear similar to the better-known Mindfulness-based Cognitive Therapy (MBCT) group program, there are a number of important differences between the two. While MBCT was developed for relapse prevention with recurrent depression, MiCBT is a comprehensive therapy designed for heterogeneous psychiatric populations. MBCT is based on the cognitive model of depressive relapse and incorporates the mindfulness elements from Kabat-Zinn's Mindfulness-based Stress Reduction (MBSR) program which in turn is informed by a number of Buddhist traditions. MiCBT has a stronger focus on behavior change aspects of CBT and is informed by the Burmese Buddhist vipassana tradition. In contrast to MBCT, in which compassion and ethics are embedded implicitly into the program, MiCBT explicitly teaches compassion methods, including the role of ethical living in psychological well-being. This article compares MiCBT and MBCT from a number of perspectives, including: 1) origins, context, theoretical rationale and the manner in which CBT principles are incorporated, 2) specific mindfulness and meditation practices and techniques, and 3) overall similarities and differences with associated clinical implications. It is concluded that MiCBT makes a unique contribution to the emerging suite of MBPs and the family of CBT therapies because of its transdiagnostic applicability, its conceptualization of emotional reactivity based on interoceptive conditioning, its focus on developing interoceptive awareness and equanimity, and the explicit inclusion of ethics as an expression of compassion.

Mindfulness has become a ubiquitous phenomenon, used across health, educational and organizational contexts, and has been the subject of a vast amount of research (Goleman and Davidson 2017). This variety and diversity in intellectual analysis has produced an abundance of theoretical perspectives and mindfulness-based programs (MBPs). Possibly the most widely cited operational definition of mindfulness is that of the developer of Mindfulness-based Stress

Reduction (MBSR; Kabat-Zinn 1990), Jon Kabat-Zinn: “paying attention in a particular way; on purpose, in the present moment, and non-judgmentally” (Kabat-Zinn 1994, p. 4). This innovative program, created initially to address chronic pain, taught about the mind and body connection, utilized mindfulness exercises, meditation and yoga and had a focus on regulating attention (Kabat-Zinn 1982). Mindfulness-based Cognitive Therapy for Depression (MBCT; Segal et al. 2002) adapted key elements of MBSR and incorporated them into a clinical intervention to promote relapse prevention in recurrent depression. As the focus of MBCT was specifically on mental health based on a cognitive model of depressive relapse, it utilized the meditations and mindfulness exercises without emphasizing the underlying Buddhist and yogic traditions that had influenced Kabat-Zinn in the development of MBSR.

Mindfulness-integrated Cognitive Behavior Therapy (MiCBT; Cayoun 2011) is a clinical mindfulness-based approach designed as a comprehensive therapy for heterogeneous psychiatric populations. MiCBT is applicable with both individual clients and groups and is delivered as an eight to ten-week program, although it can be flexibly extended as needed. MiCBT addresses the need for transdiagnostic methods applicable across psychiatric conditions, such as the need for cognitive reappraisal, addressing emotional avoidance and using exposure techniques, which have long been proposed to be effective strategies in treating emotional disorders (Barlow et al. 2004).

The initial naming of approaches provides an interesting insight into the respective developers' initial conceptualizations. For example, MBSR started out as "Stress Reduction and Relaxation Program" (Kabat-Zinn 1982) as the word "stress" was deemed acceptable in the medical community. MBCT's initial name was Attention Control Training (Dimidjian et al. 2010) as attentional control was seen as central to the prevention of depressive relapse. In contrast, the initial naming of MiCBT as "Equanimity Training" suggests that the quality of bringing an equal

interest to body sensations regardless of their affective valence, and the consequent non-reactivity, was a key focus for this approach (Cayoun et al. 2019).

In this paper, MiCBT is compared and contrasted with MBCT in terms of its origins, rationale, techniques and practices, including the role of ethics and compassion. Similarities and differences are then summarized with consideration given to the implications for clinicians in the selection of MBP's for particular client issues and circumstances.

Origins, theory and evidence base for MiCBT and MBCT

MiCBT origins

MiCBT developed from Cayoun's interest in bringing Vipassana meditation into a scientific and clinical context to assist with the personal growth required to outgrow the sources of unnecessary suffering (Cayoun et al 2019). MiCBT was developed as a manualized psychological treatment based on an integration of mindfulness meditations (in the Burmese vipassana tradition of Ledi Sayadaw and U Ba Khin, as taught by Satya Narayan Goenka), with cognitive and behavioral therapy principles. It was developed as a transdiagnostic therapy to address a wide range of moderate to severe psychiatric conditions and piloted in both individual and group contexts (initially with in-patient psychiatric populations) and later extended to community settings (Cayoun 2004). MiCBT was developed between 2001 and 2003, and subsequently piloted until 2010 (Cayoun et al. 2019).

MiCBT draws on a Buddhist view of human suffering. Psychological difficulties conceptualized as automatic or subconscious reactivity manifesting as craving for pleasant experiences and avoidance of unpleasant experience.

The "root" of these difficulties is considered to be 'ignorance': the unawareness that this reactive process is taking place and the unawareness that all experiences are impermanent. This was expressed in Goenka's words as follows: when a problem occurs "the tension originates at a level

of bodily sensations therefore this is the level at which one must work to solve the problem to change the habit pattern of mind. One must learn to be aware of all the different sensations without reacting to them accepting their changing impersonal nature." (Hart 1987, p. 18). From the perspective of MiCBT “tension” is interpreted as a phenomenon arising in the body, i.e. a body sensation. Accordingly, MiCBT develops interoceptive awareness using body scanning techniques taught for the purpose of directly experiencing the arising body sensations and the reality of impermanence of the physical world in one's own body *with equanimity.* Equanimity has been defined as "an even-minded mental state or dispositional tendency toward all experiences or objects, regardless of their affective valence (pleasant, unpleasant or neutral) or source" (Desbordes et al. 2015 p. 4).

MiCBT is composed of four stages, Stage 1 (personal stage) focuses on self-regulation through meditation; Stage 2 (exposure stage) is a behavior-regulation stage that integrates meditation with exposure methods: Stage 3 (interpersonal stage) is an interpersonal regulation stage focusing on developing mindfulness-based interpersonal skills; Stage 4 (empathic stage) is a transpersonal regulation stage that develops a sense of interconnectedness through integrating mindfulness, compassion and ethics for the clinical purpose of maintaining well-being and preventing relapse.

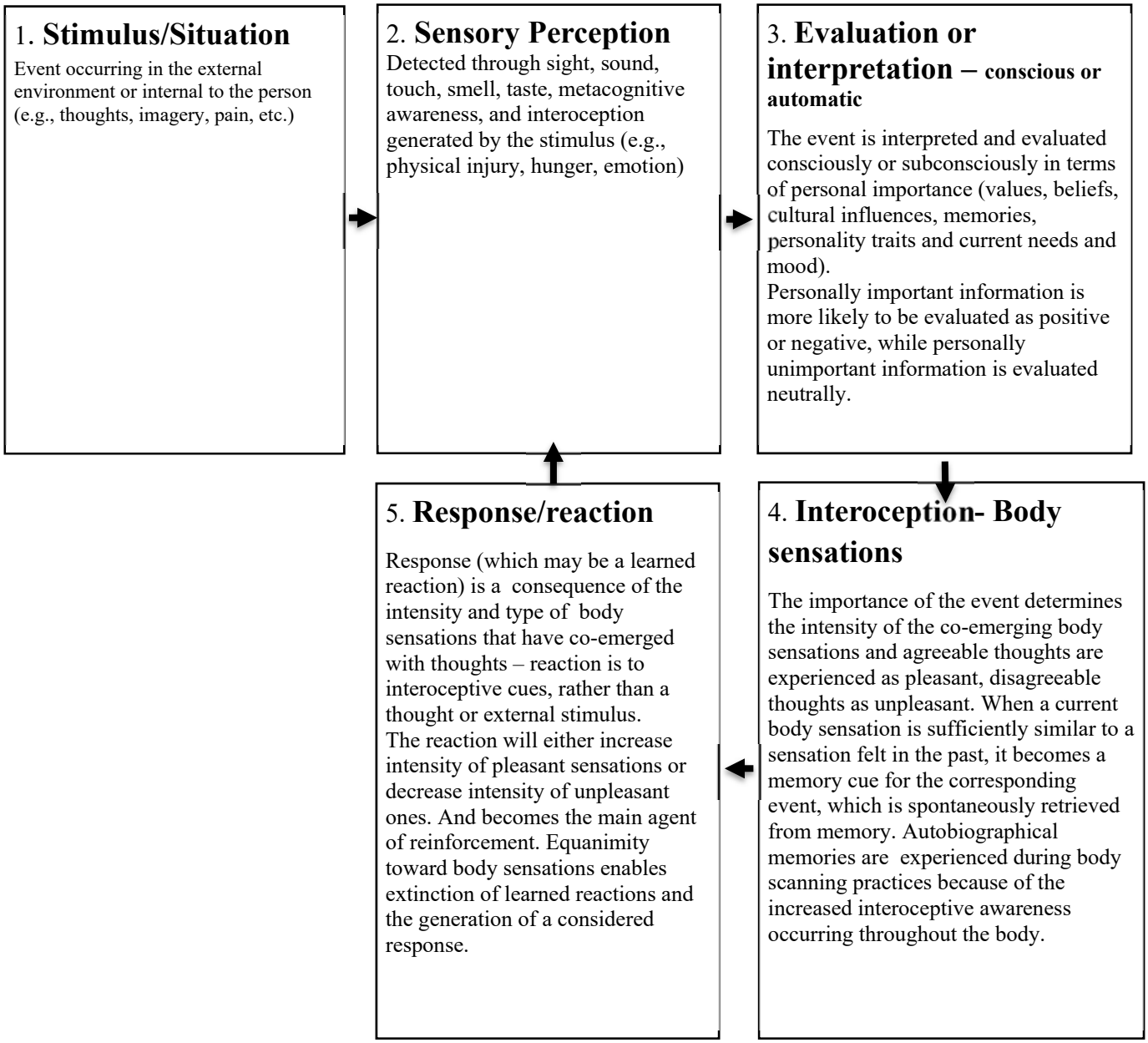
Training manuals were developed and made available to MiCBT clinical (mental health) trainees from 2004, until the publication of the first MiCBT clinical text (Cayoun 2011). The MiCBT program, while retaining its basic structure, has been revised from 8-week to 10-weeks duration (Cayoun 2011; Cayoun et al. 2019). Since MiCBT is not a diagnostic-specific program, it is also increasingly used to promote well-being and personal growth in the general community (Cayoun 2015).

MiCBT theory

In MiCBT, behavior change strategies incorporate operant learning principles and are guided by the co-emergence model of reinforcement (Figure 1), which underpins the program's rationale. This model is consistent with Theravada Buddhist teachings and is used during MiCBT for clients' psychoeducation and experiential exploration of schematic and reactive mechanisms.

Figure 1

Co-emergence model of reinforcement (Adapted from Cayoun, 2011)



The co-emergence model of reinforcement (Figure 1) is described in detail elsewhere (Cayoun 2011; Cayoun et al. 2019). Briefly, the model can be understood as follows: the *Stimulus* is perceived *(Sensory perception)* through what is traditionally regarded as the senses (sight, touch, smell, taste, sound) as well as through metacognitive awareness and interoceptive awareness, and is immediately categorized and consciously or subconsciously evaluated *(Evaluation)* neutrally or through self-oriented perspectives, including personal values, beliefs, autobiographical memories, personality traits, current mood, perceived needs, and cultural predispositions. On a continuum of self-relevance, the stimulus is evaluated as personally unimportant (neutral), or personally important either in an agreeable ('positive') or disagreeable ('negative') way. Consistent with learning theory (Mowrer 2001), reinforcement is posited to occur once the *Reaction* (the fifth component of the model) successfully leads to a decrease in unpleasant body sensations or increase in pleasant ones. Hence, the model proposes that the reinforcement of a learned response depends on the response to *Co-emergent Interoception* or body sensations (the fourth component) rather than the response to the *Stimulus*, thus differentiating it from Skinner's standard operant conditioning model, which assumes that "the behavior *operates* upon the environment to generate consequences" (Skinner 1953, p.65). According to the co-emergence model, the likelihood of a response manifesting as reactive behavior (sometimes 'automatic' or habitual) increases with interoceptive intensity. From this perspective, the focus on cognitive distortions that tends to be at the forefront of cognitive therapy distracts from attending to the unpleasant body sensations that co-emerge with a negative cognition. It also distracts from realizing that reactivity is a consequence of interoception rather than cognition (Cayoun, 2004).

The co-emergence model has been described above in an equilibrium state. However, when well-being is disturbed, the processing of the Evaluation and Reaction components of the model is over-emphasized while there is an under-emphasis on the Sensory Perception and Body Sensations/Interoception components (Cayoun 2011). Persistence of the resulting state of disequilibrium produces neurobiological adaptation over time, producing over-judgmental

attitudes and overreactive behavior. By training clients to increase processing in Sensory Perception and decrease processing in Evaluation and Reaction (by remaining equanimous toward Co-emergent Interoception) they are assisted in reversing pathological brain reorganization responsible for the maintenance of mental illness. As equanimity develops, the intensity and duration of reactivity decreases and the system can return to its state of equilibrium. The key role of co-emergent interoception in the reinforcement system is consistent with the view that body sensations are the building blocks of emotions and the observation that interoceptive impairment is an important characteristic of mental health disorders (Khalsa et al. 2018; Kleckner et al. 2017; Garfinkel and Critchley 2013; Damasio and Carvalho, 2013).

According to the co-emergence model, the intensity of interoception that precedes a reaction is a function of the personal importance attributed to the stimulus. Moreover, the more agreeable the evaluation, the more pleasant the body sensation, and the more disagreeable the evaluation the more unpleasant the body sensation. Self-referential evaluations are encoded in memory with co-emerging body sensations, and then stored and later retrieved in a co-emergent way (Cayoun et al. 2019). Awareness of body sensations associated with the memory while remaining equanimous enables the emotional content (and associated reactivity) to be neutralized. This is consistent with evidence that each time a memory is recalled, it is destabilized and subject to alterations, requiring a reconsolidation process to be maintained in its original state (Bohanek et al. 2005; Duvarci and Nader 2004). Interfering with reconsolidation can alter the memory indefinitely (Nader and Einarsson 2010). In MiCBT, equanimity is proposed to inhibit reconsolidation, and extinction of the reaction becomes possible. This principle is applied across the four stages of MiCBT, where interoceptive desensitization remains central to behavior change. Treatment goals in MiCBT are accomplished by integrating psychoeducation on co-emergence principles with mindfulness meditation techniques and with behavior modification using equanimity-based exposure techniques. These techniques are applied in the later phases of therapy to assist in developing interpersonal insights and compassion for oneself and others to

help prevent relapse. MiCBT is designed to be a transdiagnostic intervention because it addresses common processes that are present across a range of diagnoses. MiCBT has the co-emergence model of reinforcement as its underpinning rationale.

The case for common processes that underpin a range of disorders has been made in a comprehensive review by Barlow (Barlow 2004). High rates of comorbidities have been widely reported, the most prevalent being between anxiety and mood disorders (Brown et al., 2001; Kessler et al, 1996, 1998). Based on this evidence, Barlow proposes common underlying processes and coined the term "negative affect syndrome" to include anxiety and depressive disorders based on the evidence that the similarities between these mood disorders outweigh the differences (Norton & Paulus, 2016). Additionally, interventions designed for an anxiety disorder have been shown to produce significant improvement in comorbid mood disorders (Borkovec et al 1995., Brown et al, 1995). Furthermore, a range of different emotional disorders treated with antidepressant medications respond in an equivalent manner suggesting that symptoms have psychophysiological mechanisms in common (e.g., Hudson & Pope, 1990). Consequently, Barlow proposes a unified treatment protocol to address the underlying processes associated with a range of emotional disorders.

Three components of such a unified treatment are described; appropriate cognitive appraisal of events; allowing emotional experience (preventing avoidance) and facilitating behaviours that are not reactive to dysregulated emotions (Barlow 2004). Furthermore, the context of the treatment is described as "provoking emotional expression, emotional exposure through situational internal and somatic (interoceptive cues) as well as through mood induction exercises" (Barlow, 2004 p.205).

Similar to Barlow's conceptualisation of shared underlying processes and unified treatments, MiCBT, designed for transdiagnostic psychiatric populations, has both a rationale for common

processes and elements in common with the type of unified protocol described by Barlow. According to MiCBT the processes common to affective disorders include the process of evaluating events in terms of personal impact and the avoidance of the co-emerging body sensations.

It has been shown that emotional valence, the extent to which an emotion is positive or negative, is an important component of emotional experience (Feldman 2005). Additionally, emotions are linked to individual preferences (De Houwer, 2001) and therefore how we interpret and experience an event depends on our evaluation. The evaluative element means that individuals classify an experience in terms of its emotional valence (as pleasant/positive or unpleasant/negative) and use emotional terms to describe the experience (such as happy, sad, angry) which are felt as body sensations. Emotional valence may be determined as a result of pairing a recalled event with the current circumstances and in this sense likes and dislikes are learned. Thus, emotional valence is determined by the characteristics of the physiological impact of the evaluative process. This phenomenon is known as evaluative conditioning and has been empirically established (De Houwer, Baeyer & Field, 2005).

In circumstances where the evaluative process repeatedly produces an emotional reaction or elevated arousal level (interoceptive disturbance), disturbances may result in psychopathology as for example in the case of anxiety disorders (when arousal is elevated in the absence of real threats), eating disorders, depression and substance use disorder (Khalsa 2017). Interoception is widely recognised as a key mechanism underpinning emotion (Garfinkel & Crithchley, 2013; Damasio and Carvalho (2013 and Seth and Critchley, 2013; Levenson 20; Cayoun & Shires, 2020) and in mental health conditions interoception is frequently impaired (Khalsa 2018). This is consistent with interoceptive awareness being shown to be associated with inhibitory control

(Rae et al., 2019). Therefore, the ability to deactivate the reactivity to interoceptive cues is important for homeostatic and thus emotion regulation.

Emotion regulation is addressed in the MiCBT protocol by teaching trainees to notice and modify evaluative thinking and have an equanimous attitude towards all co-arising sensations; pleasant, unpleasant or neutral i.e., independent of emotional valence. This is achieved by a) developing metacognitive awareness of evaluative thinking and b) interoceptive awareness through systematic body scanning exercises described in the section below.

The MiCBT protocol, based on the co-emergence model as described has much in common with Barlow's conceptualisation of a unified protocol which includes as noted above appropriate cognitive appraisal of events; allowing emotional experience, and facilitating behaviours that are not reactive to dysregulated emotions (Barlow, 2004). By comparison, the MiCBT protocol develops 1) metacognitive awareness (enabling cognitive reappraisal) using mindfulness of the breath 2) acceptance of and non-reactivity towards interoceptive disturbances (rather than avoidance) developed through body scanning and 3) applying interoceptive insight in order to prevent emotional reactivity and thus developing equanimity.

MiCBT facilitates metacognitive awareness and cognitive reappraisal through the evaluation component of the co-emergence model (see Figure 1). The model facilitates understanding of the connection between the interpretation of an event and the co-emergent body sensations through the Body Sensations component of the model and the use of exposure strategies. The development of equanimity towards body sensations facilitates the capacity for appropriate response as opposed to a habitual reaction.

The MiCBT protocol can be considered from the perspective of both behavioral and Buddhist psychology. From the perspective of behavioral psychology, MiCBT posits that the *precipitating factor* for psychological difficulties is the inability to accept an unwanted change. From a Buddhist psychological perspective this 'suffering' is caused by an inability to accept the impermanence of all phenomena. The behavioural *reinforcing factor* of suffering is the short-term positive reinforcement associated with obtaining what is desired or attached to, or the short-term negative reinforcement of avoiding what is disliked (manifesting in terms of increasing pleasant or decreasing unpleasant body sensations, respectively). The Buddhist psychological perspective describes this as craving for what is pleasant or aversion to what is unpleasant. The behavioural *maintaining factors* of suffering are the lack of awareness that these precipitating and reinforcing factors are transitoryand the consequent tendency to identify with the experience (Cayoun 2015). From a Buddhist perspective this is ignorance.

From the perspective of Buddhist psychology, the co-emergence model adapts the *Mahasatipatthana Sutta*'s description of the aggregates of the mind as expressed by Goenka (Hart 1987), using more psychologically relatable terminology. Specifically, *vinnana* equates to "sensory perception" in the model, *sanna* equates to the "evaluation" component, *vedana* equates to the body sensations component and *sankhara* to the reaction component. It is to be expected that meditators will have a range of experiences as they continue with meditation practice (Grabovac 2015) and realize the transience of experience. Accordingly, the development of wise, compassionate equanimity to all arising phenomena is seen as the most skillful way to navigate suffering (Batchelor 2018; Hart 1987). The emphasis on body-scanning techniques to develop interoceptive awareness *with equanimity*, is consistent with the proposition that an emotional experience is interoceptive in essence (Barrett 2006; Pollatos and Schandry 2008; Seth and Critchley 2013).

MiCBT evidence base

Randomised controlled trials (RCTs) demonstrate that MiCBT is efficacious in treating anxiety and depression in pregnant women (Yazdanimehr, Omidi, Sadat, & Akbari, 2016), in women with multiple sclerosis (Bahrani et al. 2017), and in men and women with type 2 diabetes (Sohrabi et al. 2020). Other RCTs report MiCBT to be efficacious in reducing perceived pain and increasing pain self-efficacy in patients with breast cancer (Mozafari-Motlagh et al. 2019), reducing anxiety, depression and fatigue while improving sleep quality and hope in patients with multiple sclerosis (Pouyanfard et al. 2020), reducing substance addiction compared to established treatment (Wickham 2013), and reducing sports-anxiety and pessimism and increasing flow and adherence in competitive athletes (Scott-Hamilton et al. 2016). MiCBT was piloted in a heterogenous sample in a psychology clinic context and seems to be equally effective when delivered in groups and individual therapy sessions (Roubos 2011). A recent randomised controlled trial (manuscript in preparation) demonstrated that MiCBT was effective in decreasing clinical symptoms of anxiety, depression and stress and improving flourishing in a transdiagnostic group (Francis et al., 2020).

MBCT origins

MBCT is focused specifically on mental health (depression in the first iterations) and as such, targets particular conditions, departing from the transdiagnostic approach of MBSR in which the term ‘stress’ subsumes a multitude of conditions including stress, pain and medical illness (Kabat-Zinn 2011). MBCT was designed as a manualized group training program for prevention of depressive relapse and includes mindfulness exercises and aspects of CBT for depression (Segal et al. 2002; 2013). As the mindfulness elements of MBCT are adapted from MBSR, it is helpful to briefly explore MBCT's lineage. MBSR was born out of Kabat-Zinn's interest in meditation and its general application in medicine rather to psychological sciences and was specifically designed to be congruent with Buddhist philosophy on human suffering: “… from the very beginning there was for me one primary and compelling reason for attempting to bring

mindfulness into the mainstream of society. That was to relieve suffering and catalyze greater compassion and wisdom in our lives and culture." (Kabat-Zinn 2011, p. 285). Kabat-Zinn describes the roots of MBSR as being in a number of eastern spiritual traditions, including Zen Buddhism and Vipassana, and teachers such as Krishnamurti and Nisargadatta Maharaj (Husgafvel 2018; Kabat-Zinn 1982, 2011).

MBSR began as an outpatient program for chronic pain patients at the University of Massachusetts Medical Center in 1979 (Kabat-Zinn 1982). The MBSR program introduced mindfulness meditation to foster the ability to "facilitate an attentional stance towards proprioception known as detached observation. This was described as "causing an "uncoupling" of the sensory dimension of the pain experience from the affective/evaluative alarm reaction and reducing the experience of suffering via cognitive reappraisal" (Kabat-Zinn 1982, p. 33). Cognitive reappraisal and self-regulation skills are developed through several meditation and mindfulness methods, including gentle Hatha Yoga techniques.

MBCT developed out of a quest to develop a maintenance version of Cognitive Therapy (CT) for patients in recovery, building on acute-phase CT which had been shown to reduce rates of depressive relapse (Segal et al. 2002). The developers were attracted to the affective and cognitive strategies in MBSR (Dimidjian et al. 2010), in particular, the ability of the program to focus on "learning to deploy one's attention in specific and intentional ways, a skill that seemed highly relevant to helping patients notice early warning signs of depression" (Dimidjian et al. 2010, p.309). Furthermore, they were impressed by the metacognitive awareness aspect of the program, decentering from thoughts in order to facilitate "clear-sightedness" (Dimidjian et al. 2010, p 310). After unsuccessfully trialing Attentional Control Training (Teasdale et al. 1995), the developers observed that MBSR included asking participants to have a welcoming attitude towards all experience, thus extending their earlier conceptualization of decentering to encompass "even the most intense negative experiences utilizing decentering more widely and deeply than we did"

(Segal et al. 2013 p. 59). This represented a significant shift from the CT method of working to modify thoughts and solve problems as means to reduce difficult emotions, such that it was the attitude to thoughts that was to be changed. Accordingly, this was the context for incorporating mindfulness training from MBSR into the MBCT program. The psychoeducational elements in MBCT about depression use similar techniques to those used in Beck's cognitive therapy (Beck 1979), including thought monitoring, challenging cognitive rehearsal, dealing with dysfunctional attitudes and noticing indications of relapse (Segal et al. 2002). MBCT is typically delivered as an eight-week group program.

MBCT theory

MBCT is primarily described in terms of a cognitive theoretical perspective rather than the Buddhist-based approach of MBSR and is fully described elsewhere (Segal et al. 2013). The cognitive model of depression posits that symptoms of depression result from the development of irrational assumptions or beliefs (and resulting automatic negative thoughts) that are associated with unpleasant emotions (Hawton et al. 1989). Incidents can trigger a dysfunctional belief that sets in motion a vicious cycle in which the more one becomes depressed, the more one engages with and believes the depressive thoughts, and subsequently the more the depressed one becomes, establishing schematic thought patterns. Accordingly, relapse prevention was proposed to be accomplished by modifying the dysfunctional schema (Hawton, et al. 1989). However, even among populations receiving cognitive therapy for depression, rates of depressive relapse continued to be high, between 30% and 40% (Lin 1998; van Weel-Baumgarten et al. 1998) and new strategies to decrease this were sought.

To this end, the MBCT program was developed based on an enhancement of cognitive theory using the information-processing theory of depressive relapse (Teasdale et al. 1995) and integrating mindfulness. The Interactive Cognitive Subsystems model suggested by Barnard and Teasdale (1991) proposes a ‘central engine’ in which sensory information is either coded in a

propositional (factual) way or in an implicational way, in terms of its personal importance. With implicational coding, experiences are processed in terms of recurring relationships, creating schema whose focus is elaborative self-oriented ruminative thinking, which then prolongs depressive symptoms (Nolen-Hoeksema and Morrow 1991; Teasdale, et al. 1995).

The core skills in MBCT are viewed as awareness of thoughts and feelings, control of attention towards thinking patterns, decentering from thoughts to prevent being caught up in them, and the ability to experience present reality as it is (Teasdale et al. 2002). This more accepting and acknowledging stance towards thoughts and the maintenance of attention (e.g., on breath) provides alternatives to elaborative, ruminating thinking. Research demonstrates the capacity of MBCT to improve attentional capacity (Semple 2010; Grossman 2011; Jha et al. 2007). The incorporation of cognitive therapy principles with mindfulness practice in MBCT represents an important shift from the focus on thought content in traditional cognitive therapy to a focus on the relationship to thinking and the awareness of thinking processes. The pedagogical framework for the MBCT program uses what is termed "inquiry", a specific process of dialogue between participants and instructors in which instructors adopt an open and curious stance while assisting participants to "bring mindful awareness to their experience" (Segal et al. 2013, p 252). The inquiry process embodied by instructors enables a non-judgmental exploration of participants' actual present-moment experience, the personal context of the experience and how this links to the aims of MBCT (Segal et al. 2013). The group format facilitates reframing of common challenges such as providing support for regular meditation practice and normalizing depressive symptoms.

MBCT evidence base

MBCT is arguably the most widely known mindfulness-based program for mental health, depression in particular. Although there is developing evidence for its application with other conditions including acute depression (Eisendrath et al., 2016; Hofmann and Gomez 2017), it has

been shown to be most effective in patients who have had three or more episodes of depression and is at least as effective as maintenance medication for relapse prevention (Kuyken et al. 2016; Hoffman et al. 2010). Research evidence for the efficacy of MBCT in preventing depressive relapse is strong (Churchill et al. 2010; Kuyken et al. 2015; Kuyken et al. 2016; Dunning et al. 2019; Hofmann et al. 2010; Galante et al. 2013). MBCT has had a major impact on the uptake of mindfulness-based therapies and the dissemination of MBCT has been significantly facilitated by funding and research in the UK, and its inclusion in the National Institute for Health and Clinical Excellence guidelines for treatment of depressive relapse (Rycroft-Malone et al. 2014). Research continues to demonstrate the efficacy of MBCT and cost-efficient implementation models are being explored (Meadows et al. 2019).

Specific mindfulness and meditation practices and techniques

MiCBT practices

MiCBT places practices in a specific sequence throughout the program because of its hierarchical stages in teaching mindfulness and behavioral skills, in accordance with the co-emergence model. Reflection on the practices of both meditation and behavioral tasks is facilitated using Socratic questioning as used in CT (e.g., Padesky 1993). In the first session the exercises are not formal meditation practices, but are intended to develop attentiveness to body posture, movements and tensions, while preventing personal judgements regarding the body (e.g., its shape, weight or appeal). This is developed in two ways: a) with progressive muscle relaxation to develop a sense of agency over muscle tension that may be stress related, and b) by paying attention to posture and movement in the body during daily activities. Thus, commitment to self-care practices is established in the first session. In the second session, mindfulness of breath meditation is taught. The method consists of sustaining attention on the sensations associated with the breath at the entrance of the nostrils, without controlling the breath or affecting it in any way, while deliberately inhibiting one's reaction to intrusive thinking and calmly shifting attention back to the breath when the focus of attention digresses (Cayoun 2011). From session three onwards, a

series of body-scanning techniques is taught, each being practiced for a week. The purpose of these body-scanning methods is to progressively increase interoceptive awareness and accuracy in an impersonal and non-reactive (i.e., equanimous) manner. This is done initially by systematically surveying the body vertically and then transversally (from surface to internal scanning) over subsequent weeks. Body-scanning instructions are to sit upright and remain alert while experiencing sensations as they are in the present without imagining, visualizing, seeking relaxation or otherwise affecting the experience encountered in each body part, while remaining equanimous. Apart from the first week, relaxation in MiCBT is achieved as a by-product of equanimity.

The co-emergence model of reinforcement is introduced to patients in the form of a 'Diary of Reactive Habits', which is used as a worksheet to demonstrate how distressing situations are processed and reacted to because of co-emerging sensations. The model is applied to the patient's real-life experience, and schematic beliefs that arise are explored using Socratic dialogue and the guided discovery ('downward arrow') technique. This facilitates exploration of the relationship between underlying cognitive schemas, associated co-emerging body sensations, and the resulting reactivity to strong body sensations. The experience of observing the transient and impersonal nature of body sensations equanimously through daily body-scanning practice is applied to real life scenarios to minimize emotional reactivity. This is done using progressive iterations of an applied mindfulness practice called the Mindfulness Interoceptive Exposure Task (MIET). The deeper and more subtle aspects of body sensations and their interactions are carefully investigated and experienced as four 'objective' (impersonal) characteristics: *mass*, *temperature*, *motion* and *fluidity*, manifesting in varying patterns (see Cayoun et al. 2020, for application in chronic pain). This interoceptive insight enables the understanding that different emotions have their own profile of characteristics or 'interoceptive signature'. Thus, MiCBT teaches experientially that emotional reactivity can be reduced by being equanimous while feeling transient sensations (for example, of heaviness when being sad, heat and agitation when

angry, or constriction when anxious). Through this practice, patients realize that experiences of depressed mood or anxiety are not permanent and thus there is no need to identify with them. The sense of a permanent self (a 'self' that identifies with 'my' depression) can be progressively modified. Using the co-emergence model in this psychoeducational and experiential manner helps patients to understand that awareness (both metacognitive and interoceptive) alone is insufficient to address reactivity and must be accompanied by equanimity. The emotional disturbance that creates suffering is recognized as being unnecessary when experience is understood as being transient and impersonal. MiCBT introduces loving kindness meditation as the final practice to develop self-compassion and compassion for others. Compassion has been defined as "the will to extend oneself for the purpose of minimizing one's own or another's suffering." (Cayoun 2017 p. 177). The practice requires pairing the pleasant sensations produced by the subtle body-scanning techniques with positive thoughts towards self and others. These include positive affirmations such as "may I be peaceful", "may I be kind to myself" and "may I share my compassion with all beings". The generation of such positive affirmations acts as counterconditioning by pairing pleasant co-emerging body sensations with previously aversive stimuli producing a sense of well-being and reinforcing the continuity to practice outside the context of meditation. Furthermore, it is in contrast with the sense of hopelessness associated with negative affirmations such as "I am useless" and "I am unlovable" that co-emerge with unpleasant sensations which can become automatic and maintain depression.

Compassion training provides the context for the ethics component of MiCBT. It explicitly teaches harm minimization within the framework of compassion training on the basis that it is not possible to be compassionate while causing harm (Cayoun 2017). This is consistent with the traditional Theravada view of ethics and compassion in which "the inclination toward kindness and compassion for others also contributes to increasingly wholesome ethical standards since if compassion is a primary emotion in the relationship, lying, stealing, harming, or taking sexual advantage of another would be anathema"(Amaro, 2015 p. 72).

In stage four of the MiCBT program, patients are invited to adopt five basic ethical challenges for a week as a behavioral experiment and notice the consequential impact on well-being. In particular, they are asked to observe how it feels at an interoceptive level if they behave unethically, causing harm to oneself or others, and compare this to how it feels when deliberately preventing harm. In line with Kabat-Zinn's approach, ethics are understood as necessary for the development of accurate and useful mindfulness practice (Kabat-Zinn 2011). From the MiCBT perspective, unethical behavior contributes to either craving or aversive experiences (wanting more pleasant sensations or less unpleasant sensations despite causing harm) thus maintaining reactivity to unpleasant and pleasant sensations. and being detrimental . Using mindfulness skills and equanimity to increase self-awareness and prevent harmful, often habitual, actions is proposed to improve therapy outcomes through the reduction in mental disturbance and contribute to relapse prevention (Cayoun 2017).

MBCT practices

With the exception of the three-minute breathing space, the mindfulness practices used in MBCT are derived from MBSR and the rationale in MBCT links to the cognitive model as described. The first half of the MBCT program has its focus on mindfulness practices contextualized in terms of working "skillfully with the thoughts, emotions, and bodily sensations and emotions that create vulnerability to depressive relapse" (Dimidjian et al. 2010, p. 319). The second half of the program focuses on preventing depressive relapse through acceptance and skillful action. Each class is thematically organized and taught through the practices and subsequent group inquiry processes. Learnings at each session are reflected upon and consolidated through reflective inquiry.

MBCT starts by introducing mindfulness with a mindful eating exercise. Participants are asked to eat a raisin while paying attention to the entire experience, including noticing the tendency for impulsive eating and the challenge to resist it (Segal et al. 2013). A body scan is then introduced.

Participants are asked to lie down (if able, sit if not) and attend to the body. Attention is first directed to the abdomen, then to toes and moved up through the whole body while directing breath in to and out from the different body parts. Breathing is an important part of the body scan method, such that "When you are ready, on an inbreath, feel or imagine the breath entering the lungs, and then passing down into the abdomen, into the left leg, the left foot, and out to the toes of the left foot. Then on the outbreath, feel or imagine the breath coming all the way back up, out of the foot, into the leg, up through the abdomen, chest, and out through the nose." (Segal et al. 2013, p.122-123) Instructions include becoming aware of tension or intense sensations and breathing into them, and "having a sense of letting go, or releasing, on the outbreath" (Segal et al. 2013, p.123). Hence, imagination and visualization are included in addition to the observation process. The rationale for the body scan in MBCT is based on attention: "to help them develop concentration, calmness, flexibility of attention and mindfulness" (Segal et al. 2013 p.120). A number of other mindfulness exercises are taught in subsequent weeks, including sitting meditation, mindfulness of sounds and thoughts, inviting difficulty in and working with it through the body, mindful movement, mindful seeing, hearing and walking. Psychoeducational components that particularly relate to managing depression are included. MBCT invites a choice of mindfulness practices after all have been learned. MBCT and MBSR each purport to include ethics implicitly (Crane et al. 2017; Kabat-Zinn 2011) through teachers embodying and role-modelling an ethical stance as part of the program (Crane et al. 2017).

Summary of similarities and differences between MiCBT and MBCT and their clinical implications

It has been suggested that examining the similarities and differences between MBPs, including the rationale, techniques, aims and outcomes will assist in refining understanding of the clinical applications of MBPs (Chiesa and Malinowski 2011). Accordingly, what follows is a summary of the overall similarities and differences between MiCBT and MBCT. Supplementary Table 1 provides a summary of program practices used in MBCT and MiCBT and Supplementary Table

2 tentatively suggests a possible differentiation of applications of MBSR, MBCT and MiCBT, highlighting the important treatment gaps that might be potentially filled by MiCBT. MBSR is explored in this chapter on pp 24-25 (because the mindfulness elements of MBCT are taken from MBSR) and so MBSR is included in Supplementary Table 2 in order to provide a comprehensive overview of concerns and conditions that might be addressed by each of these programs.

Purpose, methods and applications

MiCBT is a comprehensive standalone therapy, specifically designed for transdiagnostic applications, including for people with acute psychiatric conditions. The methods and underpinning rationale (co-emergent reinforcement) are used to identify and address unhelpful schemas and make the link between unhelpful thinking, felt experience and reactivity. In MiCBT, equanimity-based interoceptive exposure is a core desensitization process that underlies all exposure techniques used to address complex co-morbidities accompanying conditions such as mood and anxiety disorders, substance abuse, relationship dysfunction, self-harm and suicidality, post-traumatic stress and pain. Moreover, equanimity-based exposure techniques are applied to situational avoidance, such as phobias and trauma-related avoidance. They are also applied to interpersonal situations such as fear of social rejection, assertive communication or interpersonal conflict, thereby improving interpersonal effectiveness and reducing social anxiety. The inclusion of ethics enables investigation into the impact of behaviors that cause harm, such as intoxication, verbal or physical abuse, etc. Accordingly, MiCBT as either individual or group therapy is an appropriate program for patients experiencing acute psychological crisis and for those with long term chronic conditions.

MBCT was designed for patients in remission from depression as a relapse prevention program using mindfulness meditation practices together with cognitive-behavioral strategies and

psychoeducation about depression and depressive relapse. Mindfulness meditation contributes to cognitive theory to facilitate decentering from ruminative depressive cognitions. Mindfulness exercises are introduced in a gentle and inviting manner, always deferring to a patient's perceived capacity to do each exercise. The variety of ways that mindfulness is introduced allows for some choice of exercises. This invitational stance may make it more acceptable to those who initially struggle to engage in treatments that involve exposure to avoided situations. MBCT is designed as a group program and the class is conducted in a way that models acceptance of experience with an attitude of kindness which fosters self-compassion (Segal et al. 2013).

Although the majority of the evidence base for MBCT is for its original application with depressive relapse prevention, modifications to the program have been made for other conditions, such as anxiety (Kim et al. 2009; Evans et al. 2008), bipolar disorder in remission (Williams 2008; Ives-Deliperi 2013); vascular disease (Abbott et al. 2014) and chronic health conditions in older adults (Hazlett-Stevens et al. 2019). A study by Crane and Kuyken 2013 on the implementation of MBCT in the U.K. health system showed that MBCT is being offered to patients with a variety of conditions including anxiety and chronic pain/fatigue (Crane and Kuyken 2013). These continual modifications demonstrate the need for a flexible, transdiagnostic MBP, as MBCT was not designed with this purpose in mind.

Pedagogical approaches and professional training

The pedagogical and psychotherapeutic approaches utilized in MiCBT and MBCT are consistent with adult and group learning principles such as reflection and questioning, experimenting, seeking feedback and discussing outcomes (Edmondson 1999). MiCBT and MBCT also share the requirement for a significant amount of meditation practice as homework (45–60 minutes practice daily), which may be a barrier for some patients.

MiCBT uses Socratic dialogue techniques to explore experiences or thought patterns, their implications, and the impact of changing dysfunctional behavior (for an example see Cayoun et al. 2019, p. 101) and reflection and dialogue on the previous week's home practices. Reflective approaches are particularly useful when working with patients who resist engaging with highly focused body-scanning methods due to their aversion to interoceptive cues associated with suppressed emotions. MBCT uses inquiry to enable new means of understanding experiences including those encountered through meditation practice and those which create suffering (Segal et al. 2013). A key difference in these two approaches is that in MiCBT, the clinician takes an active stance in directly guiding the patient to tolerate all emerging interoceptive experiences, which enables MiCBT to work with a range of conditions, including those related to trauma.

It is a requirement that professionals undertaking MiCBT training have a prior mental health qualification and active professional registration. It is also recommended that they complete certification as MiCBT therapists and participate in ongoing professional development activities, including retreats. Teachers of MBCT are recommended to have clinical practice qualification and mental health training as well as MBCT teacher training and ongoing development including of their own meditation practice.

Buddhist lineage, ethics and compassion

Although there is no doubt that MBCT and MiCBT both have lineage in the Buddhist contemplative traditions on the one hand and are clinically grounded in cognitive and behavioral theories on the other, there is ongoing discussion in the literature about whether or not mindfulness, when applied in healthcare settings, should be de-contextualized from its Buddhist roots (Grossman and Van Dam 2011; Husgafvel 2016). The inclusion or omission of compassion and ethics in MBPs is one aspect of this discussion about the relationship between Buddhism and therapeutic mindfulness programs (Amaro 2015; Cayoun 2017; Monteiro et al. 2015). Although ‘mindfulness’ in psychology and medicine is often described as a non-judgmental present-

centered awareness (Kabat-Zinn 1994), mindfulness as understood in Buddhism is a more nuanced construct (Amaro 2015). MiCBT is aligned with the latter, and fully integrates Buddhist teachings on sati-sampajañña, which involves the clear comprehension of impermanence (Amaro 2015) and discernment of wholesome from unwholesome behavior (which necessarily involves some ethical judgement) as a fundamental skill for the alleviation of suffering (Feng et al. 2018). From a Buddhist perspective, "right" or informed mindfulness (samma-sati) fosters behavior that brings an individual and others the least distress (Amaro 2015). While MBCT, MBSR and MiCBT all integrate aspects of ethics, they do so in different ways; MiCBT both implicitly and explicitly, and MBCT and MBSR more implicitly (Kabat-Zinn 2011). For these principal reasons, MiCBT has been categorized as one of the 'second-generation MBPs', and MBSR, MBCT and approaches derived from them understood as "first-generation MBPs" (Crane et al. 2017; Van Gordon and Shonin 2020).

Conclusion

The evidence for the efficacy of MBPs is growing as the number of research studies continues to expand almost exponentially (Van Dam et al. 2017). Much of the attention of clinical research has been directed to MBSR- and MBCT-derived programs. The evidence supporting the clinical application of MBCT is strongest in relation to its core purpose, namely, depressive relapse, but applications to other diagnostic categories requires content modifications. The implementation of a transdiagnostic MBP has the potential to increase the accessibility of mindfulness-integrated techniques, which are often only available to patients with specific diagnoses. MiCBT, with its unique integration of Buddhist psychology and CBT techniques, packaged into a coherent and standardized treatment program for a broad range of psychiatric presentations, extends the range of treatment possibilities. Its unique focus on the development of deep levels of interoceptive awareness and equanimity, taught in the context of the co-emergence model of reinforcement, enables underlying psychopathology common to most psychological disorders to be addressed. Furthermore, a key advantage of this program is that it does not need to be modified to fit

particular diagnoses. MiCBT thus accommodates the demonstrated need for transdiagnostic treatment methods (Crane & Kuyken 2013) that address comorbidities by synthesizing psychological techniques and procedures into programs that are applicable to a range of patients whose life situations may differ but whose psychological processes are similar. Variables such as selection between MBCT and MiCBT may be influenced by the severity of psychological symptoms and the capacity of patients to engage with exposure methods. Future studies are needed to investigate possible differences in therapy outcomes between MBCT and MiCBT, including investigating the role of equanimity as taught in MiCBT.

Conflict of interest Statement

SF, BC and AG have been paid for developing and delivering educational presentations, workshops and professional training programs for the MiCBT Institute in Australia and North America. AG has been paid for delivering MBCT educational presentations, workshops and professional training programs internationally, and provides MBCT mentorship through the UCSD Mindfulness-based Professional Training Institute and the Center for Mindfulness Studies.

Contributions

SF led the writing of this paper as part of a PhD thesis and was responsible for the development of the ideas expressed. FS was the primary supervisor and BC, and GM were co-supervisors. FS, BC, GM and AG all contributed to the writing, editing and critical revision of the intellectual content of the manuscript. All authors approved the final version of this manuscript.

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References

Abbott, R. A., Whear, R., Rodgers, L. R., Bethel, A., Coon, J. T., Kuyken, W., ... & Dickens, C. (2014). Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *Journal of psychosomatic research*, *76*(5), 341-351. doi: 10.1016/j.jpsychores.2014.02.012.

Amaro, A. (2015). A Holistic Mindfulness.(Editorial). *Mindfulness 6*(1), 63-73 https://doi.org/10.1007/s12671-014-0382-3.

Bahrani, S., Zargar, F., Yousefipour, G., & Akbari, H. (2017). The Effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy on Depression, Anxiety, and Stress in Females with Multiple Sclerosis: A Single Blind Randomized Controlled Trial. *Iranian Red Crescent Medical Journal, 19*(4). doi: 10.5812/ircmj.44566.

Barnard, P. J., & Teasdale, J. D. (1991). Interacting cognitive subsystems: A systemic approach to cognitive-affective interaction and change. *Cognition &Emotion*, *5*(1),39. https://doi.org/10.1080/02699939108411021

Barlow, D. H., Allen, L. B., & Choate, M. L. (2004). Toward a unified treatment for emotional disorders. *Behavior therapy*, *35*(2), 205-230. https://doi.org/10.1016/S0005-7894(04)80036-4

Barrett, L. F. (2006). Valence is a basic building block of emotional life. *Journal of Research in Personality*, *40*(1), 35-55.

Beck, A. T., Rush, A.J., Shaw, B.F., Emery, G (1979). *Cognitive Therapy of Depression*. New York: Guilford Press.

Borkovec, T. D., Abel, J. L., & Newman, H. (1995). Effects of psychotherapy on comorbid conditions in generalized anxiety disorder. *Journal of Consulting and Clinical Psychology*, *63*(3), 479. https://doi.org/10.1037/0022-006X.63.3.479

Brown, T., Antony, M., & Barlow, D. (1995). Diagnostic comorbidity in panic disorder: effect on treatment outcome and course of comorbid diagnoses following treatment. *Journal of consulting and clinical psychology, 63 3*, 408-18 . DOI: 10.1037/0022-006x63.3.408

Brown, T. A., Campbell, L. A., Lehman, C. L., Grisham, J. R., & Mancill, R. B. (2001). Current and lifetime comorbidity of the DSM-IV anxiety and mood disorders in a large clinical sample. *Journal of Abnormal Psychology, 110*(4), 585–599. https://doi.org/10.1037/0021-843X.110.4.585

Cayoun, B. A. (2004). *Advances in mindfulness training integration: towards a non-dualistic cognitive-behaviour therapy.* Paper presented at the biennial conference of the Australian Psychological Society's Buddhism and Psychology Group, Deakin University, Melbourne, Australia.

Cayoun, B.A. (2011). *Mindfulness-integrated CBT: Principles and practice*. New York, United States: John Wiley & Sons.

Cayoun, B.A. (2015). Mindfulness-integrated CBT for well-being and personal growth : four steps to enhance inner calm, self-confidence and relationships. Chichester, West Sussex: Wiley/Blackwell.

Cayoun, B.A. (2017). The purpose, mechanisms and benefits of cultivating ethics in Mindfulness-integrated Cognitive Behavior Therapy. In C. M. Monteiro (Ed.), Practitioner's Guide to Ethics and Mindfulness-Based Interventions (pp. 163-192): Springer.

Cayoun, B. A., Francis, S. E., & Shires, A. G. (2019). The Clinical Handbook of Mindfulness-integrated Cognitive Behavior Therapy: A Step-by-step Guide for Therapists: John Wiley & Sons.

Cayoun, B. A., Simmons, A., & Shires, A. (2017). Immediate and lasting chronic pain reduction following a brief self-implemented mindfulness-based interoceptive exposure task: A pilot study. Mindfulness. 1-13. https://doi.org/10.1007/s12671-017-0823-x

Chiesa, A., & Malinowski, P. (2011). Mindfulness-based approaches: are they all the same? Journal of clinical psychology, 67(4), 404-424. Doi: 10.1007/s12671-012-0123-4

Churchill, R., Moore, T. H., Davies, P., Caldwell, D., Jones, H., Lewis, G., & Hunot, V. (2010). Mindfulness-based 'third wave' cognitive and behavioural therapies versus treatment as usual for depression. The Cochrane database of systematic reviews, (9). doi: 10.1002/14651858.CD008705

Crane, R.S., & Kuyken, W. (2013) The implementation of mindfulness-based cognitive therapy: learning from the UK health service experience. Mindfulness, 4 (3), 246-254. DOI 10.1007/s12671-012-0121-6

Crane, R., Brewer, J., Feldman, C., Kabat-Zinn, J., Santorelli, S., Williams, J., & Kuyken, W. (2017). What defines mindfulness-based programs? The warp and the weft. Psychological medicine, 47(6), 990-999.

Damasio, A. R., & Carvalho, G. B. (2013). The nature of feelings: Evolutionary and neurobiological origins. Nature Reviews Neuroscience, 14, 143-52. doi: 10.1038/nrn3403

De Houwer, J., Thomas, S., & Baeyens, F. (2001). Associative learning of likes and dislikes: A review of 25 years of research on human evaluative conditioning. Psychological Bulletin, 127, 853-869. DOI: 10.1037//033-2909.127.6.853

Baeyens, F., Field, A. P., & Houwer, J. D. (2005). Associative learning of likes and dislikes: Some current controversies and possible ways forward. *Cognition & Emotion*, *19*(2), 161-174. https://doi.org/10.1080/02699930441000265

De Houwer, J. (2007). A conceptual and theoretical analysis of evaluative conditioning. *The Spanish journal of psychology*, *10*(2), 230. DOI: 10.1017/s1138741600006491

Desbordes, G., Gard, T., Hoge, E. A., Hölzel, B. K., Kerr, C., Lazar, S. W., . . . Vago, D. R. (2015). Moving beyond mindfulness: defining equanimity as an outcome measure in meditation and contemplative research. Mindfulness, 6(2), 356-372. doi:10.1007/s12671-013-0269-8.

Dimidjian, S., Kleiber, B. V., & Segal, Z. V. (2010). Mindfulness-based cognitive therapy. Cognitive and behavioral theories in clinical practice, 307-331.

Duvarci, S., & Nader, K. (2004). Characterization of fear memory reconsolidation. Journal of Neuroscience, 24(42), 9269-9275.

Dunning, D. L., Griffiths, K., Kuyken, W., Crane, C., Foulkes, L., Parker, J., & Dalgleish, T. (2019). Research Review: The effects of mindfulness-based interventions on cognition and mental health in children and adolescents—a meta-analysis of randomized controlled trials. Journal of Child Psychology and Psychiatry, 60(3), 244-258. doi: 10.1111/jcpp.12980.

Edmondson, A., & Moingeon, B. (1999). Learning, trust and organizational change. Organizational learning and the learning organization, 157-175.

Eisendrath, S. J., Gillung, E. P., Delucchi, K. L., Chartier, M., Mathalon, D. H., Sullivan, J. C., ... & Feldman, M. D. (2014). Mindfulness-based cognitive therapy (MBCT) versus the health-enhancement program (HEP) for adults with treatment-resistant depression: a randomized control trial study protocol. BMC complementary and alternative medicine, 14(1), 95. 10.1186/1472-6882-14-95

Evans, S., Ferrando, S., Findler, M., Stowell, C., Smart, C., & Haglin, D. (2008). Mindfulness-based cognitive therapy for generalized anxiety disorder. Journal of anxiety disorders, 22(4), 716-721. doi:10.1001/archpsyc.1992.01820100046009

Feng, X. J., Krägeloh, C. U., Billington, D. R., & Siegert, R. J. (2018). To What Extent is Mindfulness as Presented in Commonly Used Mindfulness Questionnaires Different from How it is Conceptualized by Senior Ordained Buddhists? Mindfulness, 9(2), 441-460. doi:10.1007/s12671-017-0788-9. doi: 10.1007/s12671-017-0788-9.

Francis, S. E., Shawyer, F., Cayoun, B. A., Enticott, J., & Meadows, G. N. (2019). Study protocol for a randomized control trial to investigate the effectiveness of an 8-week Mindfulness-integrated Cognitive Behavior Therapy (MiCBT) transdiagnostic group

intervention for primary care patients. BMC Psychiatry. https://doi.org/10.1186/s12888-019-2411-1

Galante, J., Iribarren, S. J., & Pearce, P. F. (2013). Effects of mindfulness-based cognitive therapy on mental disorders: a systematic review and meta-analysis of randomized controlled trials. Journal of Research in Nursing, 18(2), 133-155. http://doi.org/10.1177/1744987112466087

Garfinkel, S. N., & Critchley, H. D. (2012). Interoception, emotion and brain: new insights link internal physiology to social behavior. Commentary on: "Anterior insular cortex mediates bodily sensibility and social anxiety" by Terasawa et al. (2012). Social Cognitive and Affective Neuroscience, 8, 231-234. doi:10.1093/scan/nss140

Goleman, D., & Davidson, R. J. (2017). Altered traits: Science reveals how meditation changes your mind, brain, and body: Penguin.

Grabovac, A. (2015). The Stages of Insight: Clinical Relevance for Mindfulness-Based Interventions. Mindfulness. doi:10.1007/s12671-014-0294-2

Grossman, P. (2011). Defining mindfulness by how poorly I think I pay attention during everyday awareness and other intractable problems for psychology's (Re)Invention of mindfulness: comment on Brown et al. Psychological assessment, 23, 1034–1040. doi: 10.1037/a0022713.

Hart, W., Goenka, S.N. (1987). The Art of Living. Onalaska,WA 98570: Pariyatti Publishing.

Hawton, K. E., Salkovskis, P. M., Kirk, J. E., & Clark, D. M. (1989). Cognitive behaviour therapy for psychiatric problems: A practical guide. Oxford University Press.

Hazlett-Stevens, H., Singer, J., & Chong, A. (2019). Mindfulness-based stress reduction and mindfulness-based cognitive therapy with older adults: a qualitative review of randomized controlled outcome research. Clinical Gerontologist, 42(4), 347-358. doi: 10.1080/07317115.2018.1518282.

Hofmann, S. G., Sawyer, A. T., Witt, A. A., & Oh, D. (2010). The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. Journal of consulting and clinical psychology, 78(2), 169. doi: 10.1037/a0018555.

Hofmann, S. G., & Gómez, A. F. (2017). Mindfulness-based interventions for anxiety and depression. Psychiatric clinics, 40(4), 739-749. doi:10.1016/j.psc.2017.08.008.

Hudson, J. I., & Pope, H. G. (1990). Affective spectrum disorder: does antidepressant response identify a family of disorders with a common pathophysiology?. *The American journal of psychiatry*. https://doi.org/10.1176/ajp.147.5.552

Husgafvel, V. (2016). On the Buddhist roots of contemporary non-religious mindfulness practice: Moving beyond sectarian and essentialist approaches. Temenos-Nordic Journal of Comparative Religion, 52(1), 87-126. doi:10.33356/temenos.55371

Husgafvel, V. (2018). The 'universal Dharma foundation'of mindfulness-based stress reduction: Non-duality and mahāyāna buddhist influences in the work of Jon kabat-ZINN. Contemporary Buddhism, 19(2), 275-326.

Ives-Deliperi, V. L., Howells, F., Stein, D. J., Meintjes, E. M., & Horn, N. (2013). The effects of mindfulness-based cognitive therapy in patients with bipolar disorder: a controlled functional MRI investigation. Journal of affective disorders, 150(3), 1152-1157. doi:10.1016/j.jad.2013.05.074.

Jha, A. P., Krompinger, J., & Baime, M. J. (2007). Mindfulness training modifies subsystems of attention. Cognitive, Affective, & Behavioral Neuroscience, 7(2), 109-119.

Khalsa, S. S., Adolphs, R., Cameron, O. G., Critchley, H. D., Davenport, P. W., Feinstein, J. S., ... Zucker, N. (2018). Interoception and mental health: A roadmap. Biological Psychiatry: Cognitive Neuroscience and Neuroimaging. doi:10.1016/j.bpsc.2017.12.004

Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. General hospital psychiatry, 4(1), 33-47

Kabat-Zinn, J. (1990). Full Catastrophe Living. New York: Delacorte.

Kabat-Zinn, J. (1994). Wherever you go there you are: Mindfulness meditation in everyday life. London: Piatkas.

Kabat-Zinn, J. (2011). Some reflections on the origins of MBSR, skillful means, and the trouble with maps. Contemporary Buddhism, 12(1), 281-306. doi:10.1080/14639947.2011.564844

Kim, Y. W., Lee, S. H., Choi, T. K., Suh, S. Y., Kim, B., Kim, C. M., ... & Song, S. K. (2009). Effectiveness of mindfulness-based cognitive therapy as an adjuvant to pharmacotherapy in patients with panic disorder or generalized anxiety disorder. Depression and Anxiety, 26(7), 601-606.

Kessler, R. C., Nelson, C. B., McGonagle, K. A., Liu, J., Swartz, M., & Blazer, D. G. (1996). Comorbidity of DSM–III–R major depressive disorder in the general population: results from the US National Comorbidity Survey. *The British journal of psychiatry*, *168*(S30), 17-30. DOI:10.1192/S0007125000298371

Kessler R.C., Stang P.E., Wittchen H., Ustun TB, Roy-Burne P.P., Walters EE. Lifetime Panic-Depression Comorbidity in the National Comorbidity Survey. *Arch Gen Psychiatry.* 1998;55(9):801–808. doi:10.1001/archpsyc.55.9.801

Kleckner, I. R., Zhang, J., Touroutoglou, A., Chanes, L., Xia, C., Simmons, W. K., . . . Feldman Barrett, L. (2017). Evidence for a large-scale brain system supporting allostasis and interoception in humans. Nature Human Behaviour, 1, 0069. doi:10.1038/s41562-017-0069 https://www.nature.com/articles/s41562-017-0069#supplementary-information

Kuyken, W., Warren, F. C., Taylor, R. S., Whalley, B., Crane, C., Bondolfi, G., . . . Dalgleish, T. (2016). Efficacy of Mindfulness-Based Cognitive Therapy in Prevention of Depressive Relapse: An Individual Patient Data Meta-analysis from Randomized Trials. JAMA Psychiatry, 73(6), 565-574. doi:10.1001/jamapsychiatry.2016.0076

Lin, E. H., Katon, W. J., VonKorff, M., Russo, J. E., Simon, G. E., Bush, T. M., ... & Ludman, E. (1998). Relapse of depression in primary care: rate and clinical predictors. Archives of Family Medicine, 7(5), 443.

Levenson, R.W., Blood, Sweat and Fears. (2003) Annals of New York Academy of Sciences 1000: 348–366 (2003). doi: 10.1196/annals.1280.016

Meadows, G. N., Ante Prodan, Patten, A.S.,Shawyer, F., Francis, S., Enticott, J.,Rosenberg, S., Atkinson, J., Fossey, E.,Kakuma, R. (2019). Resolving the Paradox of Increased Mental Health Expenditure and Stable Prevalence. (Manuscript No: ANP-2019-00087.R2).

Monteiro, L. M., Musten, R. F., & Compson, J. (2015). Traditional and Contemporary Mindfulness: Finding the Middle Path in the Tangle of Concerns. Mindfulness, 6(1), 1-13. doi:10.1007/s12671-014-0301-7

Moses, E. B., & Barlow, D. H. (2006). A new unified treatment approach for emotional disorders based on emotion science. *Current directions in psychological science*, *15*(3), 146-150. https://doi.org/10.1111/j.0963-7214.2006.00425.x

Mowrer, R. R., & Klein, S. B. (Eds.). (2000). Handbook of Contemporary Learning Theories. Psychology Press.

Mozafari-Motlagh, M.-R., Nejat, H., Tozandehjani, H., & Samari, A.-A. (2019). Effect of cognitive behavior therapy integrated with mindfulness on perceived pain and pain self-efficacy in patients with breast cancer. Journal of Nursing and Midwifery Sciences, 6(2), 51. doi: 10.4103/JNMS.JNMS_60_18

Nolen-Hoeksema, S., & Morrow, J. (1991). A prospective study of depression and posttraumatic stress symptoms after a natural disaster: The 1989 Loma Prieta earthquake. Journal of personality and social psychology, 61(1), 115-121. doi:10.1037/0022-3514.61.1.115

Padesky, C. A. (1993, September). Socratic questioning: Changing minds or guiding discovery. In A keynote address delivered at the European Congress of Behavioural and Cognitive Therapies, London (Vol. 24).

Pouyanfard, S., Mohammadpour, M., ParviziFard, A. A., & Sadeghi, K. (2020). Effectiveness of mindfulness-integrated cognitive behavior therapy on anxiety, depression and hope in multiple sclerosis patients: a randomized clinical trial. Trends in Psychiatry and Psychotherapy, 42(1), 55-63. doi: 10.1590/2237-6089-2018-0105.

Roubos, L. (2011). A comparison of group-enhanced and individual implementations of Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT): An effectiveness study. Unpublished Master Dissertation.

Rycroft-Malone, J., Anderson, R., Crane, R. S., Gibson, A., Gradinger, F., Griffiths, H. O., ... & Kuyken, W. (2014). Accessibility and implementation in UK services of an effective depression relapse prevention programme–mindfulness-based cognitive therapy (MBCT): ASPIRE study protocol. Implementation Science, 9(1), 62. http://www.implementationscience.com/content/9/1/62.

Seth, A. K., & Critchley, H. D. (2013). Extending predictive processing to the body: emotion as interoceptive inference. Behavioral Brain Science, 36, 227-228. doi:10.1017/S0140525X12002270

Semple, R. J. (2010). Does mindfulness meditation enhance attention? A randomized controlled trial. Mindfulness, 1(2), 121-130. doi:10.1007/s12671-010-0017-2

Scott-Hamilton, J., Schutte, N. S., & Brown, R. F. (2016). Effects of a mindfulness intervention on sports-anxiety, pessimism, and flow in competitive cyclists. Applied Psychology: Health and Well-Being, 8(1), 85-103. http://dx.doi.org/10.1123/jcsp.2015-0020.

Segal, Z., Williams, M., & Teasdale, J. (2002). Mindfulness-based cognitive therapy for depression : a new approach to preventing relapse. New York: New York : Guilford Press.

Segal, Z., Williams, M., & Teasdale, J. (2013). Mindfulness-Based Cognitive Therapy for Depression (2nd revised ed. ed.). New York: Guilford Publications.

Seth, A. K., & Critchley, H. D. (2013). Extending predictive processing to the body: emotion as interoceptive inference. Behavioral Brain Science, 36, 227-228. doi:10.1017/S0140525X12002270

Sohrabi, F., Sohrabi, A., Shams-Alizadeh, N., & Cayoun, B. A. (2020). Effects of Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) on depression and type 2 diabetes management: A pilot randomised controlled trial. Manuscript submitted for publication.

Tang, Y. Y., Hölzel, B. K., & Posner, M. I. (2015). The neuroscience of mindfulness meditation. Nature Reviews Neuroscience, 16(4), 213-225. doi:10.1038/nrn3916

Teasdale, J., Moore, R., Hayhurst, H., Pope, M., Williams, S., & Segal, Z. (2002). Metacognitive awareness and prevention of relapse in depression: empirical evidence. Journal of Consulting and Clinical Psychology, 70(2), 275. doi: 10.1037//0022-006X.70.2.275

Teasdale, J., Segal, Z., & Williams, J. M. G. (1995). How does cognitive therapy prevent depressive relapse and why should attentional control (mindfulness) training help? Behaviour Research and Therapy, 33(1), 25-39.

Uddin, L. Q. (2014). Salience processing and insular cortical function and dysfunction. Nature Reviews Neuroscience doi:10.1038/nrn3857

Van Dam, N. T., van Vugt, M. K., Vago, D. R., Schmalzl, L., Saron, C. D., Olendzki, A., … Meyer, D. E. (2017). Mind the Hype: A Critical Evaluation and Prescriptive Agenda for Research on Mindfulness and Meditation. Perspectives on Psychological Science, doi:10.1177/1745691617709589.

van der Velden, A. M., Kuyken, W., Wattar, U., Crane, C., Pallesen, K. J., Dahlgaard, J., . . . Piet, J. (2015). A systematic review of mechanisms of change in mindfulness-based

cognitive therapy in the treatment of recurrent major depressive disorder. Clin Psychol Rev, 37, 26-39. doi:10.1016/j.cpr.2015.02.001.

Van Gordon, W., Shonin, E. (2020). Second-Generation Mindfulness-Based Interventions: Toward More Authentic Mindfulness Practice and Teaching. Mindfulness, 11, 1-4. https://doi.org/10.1007/s12671-019-01252-1

van Weel-Baumgarten, E. M., Schers, H. J., Van den Bosch, W. J., Van den Hoogen, H. J., & Zitman, F. G. (2000). Long-term follow-up of depression among patients in the community and in family practice settings: a systematic review. Journal of Family Practice, 49(12), 1113-1113.

Wickham, K. (2013). The effect of Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) on the experience of addiction. (Unpublished dissertation.), University of Tasmania, Hobart, Australia.

Williams, J. M. G., Alatiq, Y., Crane, C., Barnhofer, T., Fennell, M. J., Duggan, D. S., ... & Goodwin, G. M. (2008). Mindfulness-based cognitive therapy (MBCT) in bipolar disorder: Preliminary evaluation of immediate effects on between-episode functioning. Journal of affective disorders, 107(1-3), 275-279. https://doi.org/10.1016/j.jad.2007.08.022

Yazdanimehr, R., Omidi, A., Sadat, Z., & Akbari, H. (2016). The Effect of Mindfulness-integrated Cognitive Behavior Therapy on Depression and Anxiety among Pregnant Women: a Randomized Clinical Trial. Journal of Caring Sciences, 5(3), 195-204. http://doi.org/10.15171/jcs.2016.021

Supplementary Table 1
Summary of program practices for MBCT and MiCBT

Week	MBCT program Recommended practice time 45 mins once daily for six out of seven days each week. Information extracted and adapted from (Segal et al., 2013)	MiCBT program Recommended practice time 30 mins twice daily. Information extracted and adapted from (Cayoun et al., 2019)
1	**Theme:** Structure for each session - practice session, home practice review; group work and next learning topic; setting home practice Automatic pilot - understanding the difference between being on "automatic pilot" or a "doing mode" of ruminative thinking, which is a common feature of depression. Focus on intentionally paying attention, mindfully **Group Work:** Eating meditation - raisin exercise Body scan exercise Dyad discussion on dealing with obstacles to practice **Home practice:** Body scan Mindfulness of routine activity Mindful eating – at least one meal and throughout each day Complete practice record forms	**Theme:** Structure for each session - practice session, home practice review; group work and next learning topic; setting home practice Introduction to MiCBT - four stages; goal setting; gaining commitment to daily practice **Group Work:** Stage 1 - Progressive muscle relaxation Mindfulness of body **Home practice:** Progressive muscle relaxation twice daily with audio instructions Awareness of body movements and posture in day-to-day activities Complete practice record forms Baseline measurements for assessing outcome
2	**Theme:** Another way of knowing; living in our heads - knowing through thinking as opposed to knowing by experiencing; using mindfulness of the body to learn direct experience **Group Work:** Body scan meditation Thoughts and feelings exercise Set up pleasant experiences calendar Sitting practice - 10 min **Home Practice:** Body scan 6 out of 7 days Mindfulness of breath – 10 min - 6 out of 7 days Pleasant experiences calendar (one example daily) Mindfulness of a routine activity Complete practice record forms	**Theme:** Developing attention-regulation skills and metacognitive awareness **Group Work:** Mindfulness of breath Nature of thought intrusion as frequency, recency and co-emergence effects **Home Practice:** Mindfulness of breath - 30 mins twice daily with audio instructions Awareness of breath and types of thoughts during the day Attention regulation (practice of “Right Effort”) during the day Complete practice record forms

3	**Theme:** Gathering the scattered mind - understanding the distracted mind; using the breath and body to be present; moving from “doing” to “being” mode **Group Work:** Seeing or hearing exercise - 5-minute Sitting meditation (awareness of breath and body and how to respond to intense physical sensations) 3-minute breathing space Mindful stretching Set up unpleasant experiences calendar **Home Practice:** Stretch and breath - days 1,3,5 Mindful movement - days 2,4,6 Unpleasant experiences calendar (daily, using a variety of experiences) 3-minute breathing space – 3x daily Complete practice record forms	**Theme:** Mechanisms of emotional reactivity in terms of the co-emergence model; interoceptive awareness and equanimity **Group Work** Unilateral part-by-part body scanning (surveying the body part by part in areas of 8-10cms diameter) Explaining the co-emergence model using the Diary of Reactive Habits **Home practice:** Body scanning – unilateral part-by-part, 30 mins twice daily with audio instructions Fill out Diary of Reactive Habits Fill out Interoceptive Awareness Indicator Complete practice record forms
4	**Theme:** Recognizing aversion - observing the mind's tendency for rumination Worry and mind wandering as escape **Group Work:** Seeing or hearing exercise - 5-minute Sitting meditation Poem – Wild Geese The territory of depression - Automatic Thoughts Questionnaire 3-minute breathing space Mindful walking **Home Practice:** Sitting meditation (38 mins)- 6 out of 7 days 3-minute breathing space - regular (three times daily) 3-minute breathing space - responsive (whenever unpleasant feelings) Complete practice record forms	**Theme:** Applying practice and skill transfer - observing and accepting change **Group Work:** Unilateral part-by-part body scanning (no audio instructions and without moving) Observing the impermanence of thoughts and sensations and learning not to identify with experiences - letting go of attachment to "I" or "mine" **Home Practice:** Body scanning – unilateral part-by-part, 30 mins twice daily in silence (no audio instructions) while maintaining immobility and developing equanimity Applied mindfulness practice – awareness of body sensations with equanimity during the day and pre and post sleep Practicing applied equanimity using the Mindfulness-based Interoceptive Exposure Task (MIET) Complete practice record forms
5	**Theme:** Allowing/letting be - intentionally allowing all experience, including while turning towards the difficult **Group Work:** Sitting meditation – awareness of breath and body – noticing effects of difficulty on body and reactions to it	**Theme:** Integrating mindfulness to external situations and overcoming avoidance **Group Work:** Stage 2- Integration of mindfulness and behavior methods

	Breathing space Poem - The Guest House **Home Practice:** Working with difficulty meditation - days 1, 3, 5 Sitting with silence – day 2, 4, 6 3-minute breathing space - regular (three times daily) 3-minute breathing space - responsive (whenever unpleasant feelings) Complete practice record forms	Bilateral/symmetrical body scanning (surveying both sides of the body bilaterally while maintaining immobility) Immobility applies to all scanning tasks from here on Learning to notice very subtle sensations as indicators of distress arising Addressing avoidance by selecting items to work on using SUDS and bipolar exposure **Home exercises:** Body scanning – symmetrical scanning 30 mins twice daily with audio instructions Exposure tasks - using imaginal interoceptive and in-vivo exteroceptive exposure to address avoided situations Complete practice record forms
6	**Theme:** Thought are not facts - relating differently to thoughts Seeing the relationship between negative thoughts and moods **Group Work:** Siting meditation – focus on thoughts as mental events Moods, thoughts and alternative viewpoints exercise Use of breathing space as first step before taking wider view of thoughts Early warning signs of depression - relapse signature **Practice:** Choose from guided meditations – minimum 40 mins a day 3-minute breathing space - regular (three times daily) 3-minute breathing space - responsive (whenever unpleasant feelings) Working wisely with depression and unhappiness worksheet Complete practice record forms	**Theme:** Generalizing self-confidence and self-efficacy - advanced scanning and consolidating exposure skills **Group Work:** Partial sweeping body scanning (passing interoceptive attention in a continuous manner over large sections of the body) Understanding avoidance and its gradual assimilation into the self-concept Reviewing progress using distress relief on SUDS items Understanding how perceptions in the present are determined by past experiences (“causes and conditions”) **Home practice:** Body scanning – partial sweeping, 30 mins twice daily with audio instructions Continuing to use exposure tasks to address most pervasively avoided situations Complete practice record forms
	Day of mindfulness 6.5 hours - includes sitting meditation, mindful stretching, body scan, mindful eating, walking meditation, mountain meditation, review of experience and discussion	
7	**Theme:** How best can I take care of myself - skillful action for self-care	**Theme:** Developing interpersonal insight and addressing conflicts

	Group Work: Sitting meditation -awareness of breath and body Links between mood and activity exercise Activity scheduling for low mood 3-minute breathing space as first step before mindful action Identifying actions to deal with threat of relapse Generate list of pleasure and mastery activities 3-minute breathing space or mindful walking **Home Practice:** Sitting meditation – select practice of choice – daily Action plan for relapse prevention 3-minute breathing space - regular (three times daily) 3-minute breathing space - responsive plus action (whenever unpleasant thoughts or feelings) Complete practice record forms	Understanding "experiential ownership" **Group Work:** Stage 3 - Continued development of insight and equanimity while noticing subtle sensations as potential onset of emotion Sweeping *en masse* body scanning (passing interoceptive attention in a continuous manner over the entire body in a single pass; a single flow of attention) Exploring the possibility of blissful experience to be noticed with equanimity, without attachment or fear of the experience Learning to apply equanimity towards others' reactivity **Home practice:** Body scanning – sweeping "*en masse*" 30 mins twice daily with audio instructions Interoceptive and exteroceptive exposure to discomfort in interpersonal situations Experiential ownership exercise Complete practice record forms
8	**Theme:** Maintaining and extending new learning - planning for maintaining mindful way of being **Group Work:** Body scan Review whole course, including relapse prevention action plan Personal reflections Keeping up momentum Concluding meditation	**Theme:** Mindful communication skills – using exposure to address challenging interpersonal situations with equanimity and kind assertiveness **Group Work:** Transversal body scanning (passing attention part by part, transversally through the body interior, from front to back and back to front) Assertive communication - using interpersonal awareness and equanimity to gain clarity in conflicting situations while expressing one's needs or opinion through seven statements methodically arranged in a way that is congruent with the state of equilibrium in the co-emergence model of reinforcement **Home practice:** Body scanning – transversal scanning 30 mins twice daily with audio instructions Practice mindful assertiveness with experiential ownership Complete practice record forms
9		**Theme:** Stage 4 - Empathic stage – preventing relapse by cultivating compassion and connectedness with others through ethical living - five ethical challenges

		Group Work: Sweeping in depth body scanning (passing interoceptive attention in a continuous manner throughout the entire body, internally and externally, in a single vertical flow of attention) Feeling connected internally - realising that wholesome thoughts produce pleasant sensations and accepting self and others as they are Understanding the relationship between ethical behaviour and compassion - five ethical challenges set for the week (preventing harmful speech, taking what is not given, taking lives, inappropriate sexual actions, and intoxication) Loving kindness meditation - positive affirmation-based practice acting as counterconditioning by pairing pleasant free flow of pleasant body sensations with previously aversive stimuli **Home practice:** Body scanning – sweeping in depth 30 mins twice daily in silence, without audio instructions Loving kindness meditation with audio instructions following sweeping in depth Ethical challenges task as a 'behavioral experiment' for one week Complete practice record forms
10		**Theme:** Maintaining and cultivating well-being **Group Work:** Review of skills learned and review of goals Importance of maintaining daily practice Maintenance practice (45 min once daily in silence, comprising 10 min of mindfulness of breath, 25 min of sweeping in depth, and 10 min of loving-kindness meditation) **Program review:** review of the program and measure overall outcomes

Supplementary Table 2: Possible applications of selected mindfulness-based programs

Current health status – mental/physical	MBSR	MBCT	MiCBT
Well – seeking well-being/existential issues	✔		✔
Well – in remission looking to prevent depressive relapse		✔	✔
Stress related issues with physical illness	✔		✔
Stress related issues – life circumstances	✔	✔	✔
Mild to moderate depression – acute	✔	✔	✔
Mild to moderate depression – relapsed		✔	✔
Anxiety	✔	✔*	✔
Anxiety with other co-morbidities including depression		✔*	✔
Chronic pain	✔	✔*	✔
Bipolar depression – adjunctive		✔*	✔
Attention deficit hyperactivity disorder - MBCT adjunctive		✔*	✔
Post-Traumatic Stress Disorder		✔*	✔
Anger management		✔*	✔
Obsessive Compulsive Disorder		✔*	✔

Note: *with adaptations to the original MBCT program for depression that address the new target condition replacing depression

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3 CHAPTER THREE

3.1 Rationale of protocol paper

Study of protocol for a randomised controlled trial to investigate the effectiveness of an eight-week Mindfulness-integrated cognitive behaviour therapy (MiCBT) transdiagnostic group compared to a treatment-as-usual waitlist control for primary health care patients.

3.2 Reprint of Published Manuscript

Francis S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020) Study protocol for a randomised control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry 20:7. This first paper is the published protocol describing the background to the project, its aims and hypotheses and the project design in detail. BMC Psychiatry has an impact factor 2018-2019 of 2.86.

Note: Due to a mis-spelling of the first author name a correction was published on March 26, 2020:

Correction to: Study protocol for a randomised control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. Francis et al., BMC Psychiatry (2020) 20:136.

Frances et al. BMC Psychiatry (2020) 20:7
https://doi.org/10.1186/s12888-019-2411-1

BMC Psychiatry

STUDY PROTOCOL Open Access

Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients

Sarah Frances[1,2*], Frances Shawyer[1], Bruno Cayoun[3], Joanne Enticott[1,4] and Graham Meadows[1,5,6]

Abstract

Background: Effective transdiagnostic treatments for patients presenting with principal or comorbid symptoms of anxiety and depression enable more efficient provision of mental health care and may be particularly suitable for the varied population seen in primary healthcare settings. Mindfulness-integrated cognitive behavior therapy (MiCBT) is a transdiagnostic intervention that integrates aspects of CBT, including exposure skills targeting avoidance, with training in mindfulness meditation skills adopted from the Vipassana or insight tradition taught by the Burmese teachers U Ba Khin and Goenka. MiCBT is distinguished from both cognitive therapy and mindfulness-based cognitive therapy by the use of a theoretical framework which proposes that the locus of reinforcement of behavior is the interoceptive experience (body sensations) that co-arises with self-referential thinking. Consequently, MiCBT has a strong focus on body scanning to develop interoceptive awareness and equanimity. Designed for clinical purposes, the four-stage systemic approach of MiCBT, comprising intra-personal (Stage 1) exposure (Stage 2), interpersonal (Stage 3), and empathic (Stage 4) skillsets, is a distinguishing feature among other mindfulness-based interventions (MBIs). The aim of this study is to investigate whether and how group MiCBT decreases depression and anxiety symptoms for patients with a range of common mental health conditions.

Methods: Participants ($n = 120$) recruited via medical practitioner referral will be randomized to MiCBT or a wait-list control. Inclusion criteria are age 18–75; fluent in English and having a Kessler Psychological Distress Scale (K10) score of 20 or more. The MiCBT treatment group receive an 8-week MiCBT intervention delivered in a private psychology practice. Participants complete a suite of online self-report measures and record the amount of meditation practice undertaken each week. The control group receive usual treatment and complete the measures at the same time points. Primary outcome measures are the Depression Anxiety Stress Scale-21 (DASS-21) and K10. Analysis will use mixed-model repeated measures.

(Continued on next page)

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(Continued from previous page)
Discussion: The potential ability of MiCBT to provide a comprehensive therapeutic system that is applicable across diagnostic groups would make it an attractive addition to the available MBIs.

Trial registration: This trial is registered with the Australia and New Zealand Clinical Trials Registry: ACTRN12617000061336; Date of registration: 11th January 2017.

Keywords: Mindfulness-integrated cognitive behavior therapy, MiCBT, Mindfulness-based intervention, Mindfulness, Transdiagnostic, Anxiety, Depression, Equanimity, Group therapy

Background

General symptoms of anxiety and depression are commonly present across a range of psychological, somatic and medical conditions and contribute to a poorer medical prognosis. Developing effective and enduring transdiagnostic treatments for patients presenting with general symptoms of anxiety and depression, with or without concomitant physical illness, means that therapy can be efficiently provided to a broad range of clients in a variety of therapeutic settings and may be particularly suitable for application in the varied population seen in primary care settings.

Cognitive behavior therapy

Since the 1970s, Cognitive Behavior Therapy (CBT) has enjoyed a dominant position in the plethora of available psychological therapies. It is one of the most widely used approaches and is regarded as treatment of choice for depression, either on its own or in conjunction with pharmacotherapy [1–3]. The efficacy of CBT has been shown across many diagnoses including depression, anxiety [4] and obsessive-compulsive disorder [5–7]. Data from meta-analyses also support the use of CBT for a range of disorders [8, 9]. The cognitive model used in CBT utilizes a structured experimental and collaborative approach to enable recognition and reappraisal of habitual dysfunctional and distorted thought patterns or behaviors [10].

Mindfulness-based programs and interventions

The past three decades has witnessed the emergence of a so-called "third wave" [11] of cognitive and behavioral therapies, often referred to as mindfulness-based interventions (MBIs). These interventions place less importance on the reframing of thought content and behavior modification, and more emphasis on changing the relationship with thoughts in order to prevent their proliferation [12]. A shift towards disengaging or decentering from thought content is proposed to reduce the tendency for recurrence of depressogenic thoughts contributing to depressive relapse. More generally, MBIs encourage mindful acceptance of difficult psychological experience [13], taking a more holistic approach to psychological health that includes developing metacognitive awareness together with an accepting and compassionate attitude [2, 14]. The MBIs that will be discussed here are those that emphasize formal meditation practices similar to MiCBT in that they require formal meditation practices, namely mindfulness-based stress reduction (MBSR – [15]), developed as a stress management program for medical patients, and programs developed from MBSR, including mindfulness-based cognitive therapy (MBCT - [12, 16]), developed as a relapse prevention program for depression. While acceptance and commitment therapy and dialectical behavior therapy are considered to belong to the body of third wave behavioral therapies, they do not include formal mediation practice as a key intervention.

There is increasing evidence to support the clinical use of MBIs for both physical and psychological conditions, including chronic pain and psoriasis [15, 17–19], cancer [20, 21], diabetes [22], depression [23] substance abuse [24, 25] and anxiety [26]. Programs such as the mindfulness-based eating program (MB-EAT- [27, 28]), mindfulness-based relationships enhancement (MBRE – [29]) have been developed for specific issues and are based on the MBSR or MBCT protocols. In the United Kingdom, MBCT is now listed in the National Institute for Health and Care Excellence (NICE) guidelines as an evidence-based treatment for relapse prevention in depression [30]. The Agency for Healthcare Research and Quality conducted a comprehensive review of meditation programs and found moderate strength of evidence for the benefit of mindfulness meditation programs for stress and for pain severity, moderate to low strength of evidence that mindfulness meditation, as taught in MBSR-based MBIs, decreases symptoms of anxiety, depression, and perceived stress/general distress, and reports low effects for stress and mental health-related quality of life, positive mood, attention and weight [31].

Mindfulness-integrated cognitive behavior therapy (MiCBT) - why another MBI?

MiCBT was developed over 15 years ago in Australia independently from MBSR and MBCT and has gained increasing recognition in recent years, especially following the publication of a protocol for an 8-week MiCBT program [32]. MiCBT was designed to be used as a

transdiagnostic intervention that is firmly grounded in a CBT approach, which includes a structured week by week protocol, use of Socratic questioning, exposure techniques and behavioral experiments as well as daily mindfulness meditation practices.

In MiCBT, it is proposed that thoughts and body sensations co-emerge and that the type and hedonic tone of body sensations have a key role in determining the type and intensity of behavioral reactivity.

The mindfulness meditation skills that are taught in MiCBT enable participants to understand and recognize co-emergence mechanisms experientially, as explained below. Following the introduction of attention training with mindfulness of breath, a series of body scanning practices are taught to develop interoceptive awareness together with equanimity (non-reactivity) so that interoceptive signals are experienced and understood to be transient events. The ability to remain equanimous towards sensations has a powerful impact on neutralizing reactivity.

The co-emergence model of reinforcement (see Fig. 1) proposes that a stimulus is perceived through the senses, (hearing, tasting, smelling, seeing, touching) and once perceived is then interpreted, evaluated and contextualized in terms of personal relevance. The model depicts that the stimulus may either be generated internally (as thoughts, memories or body sensations) or externally from the environment. The co-emergence model, in line with operant conditioning principles, proposes that when an experience is evaluated self-referentially (associated with "I", "me" or "mine"), evaluative thoughts co-emerge with body sensations (interoception). The more the stimulus is evaluated as being personally relevant, the more intense body sensations are perceived to be. These sensations are experienced as pleasant, unpleasant or neither pleasant nor unpleasant, and this determines the desire for more or less of the experience, which then prescribes a reaction; attachment or avoidant behavior. When the reaction successfully increases pleasant or decreases unpleasant hedonic tone, it is reinforced so that the locus of reinforcement is proposed to be the interoceptive experience. The co-emergence model (in Fig. 1) is depicted as a system in equilibrium, in which all components receive adequate attention. The model proposes that in this balanced state, emotional disorders are not likely to occur. In psychopathology, however, the system is seen in a maintained state of disequilibrium (Fig. 2), with depleted attention in the sensory perception and interoception components and increased attention and over-processing in the evaluation and reaction components. The goal of MiCBT is to restore the system's homeostatic balance by decreasing the amount of processing in over active components (evaluation and reaction) and reallocating attention to areas of depletion

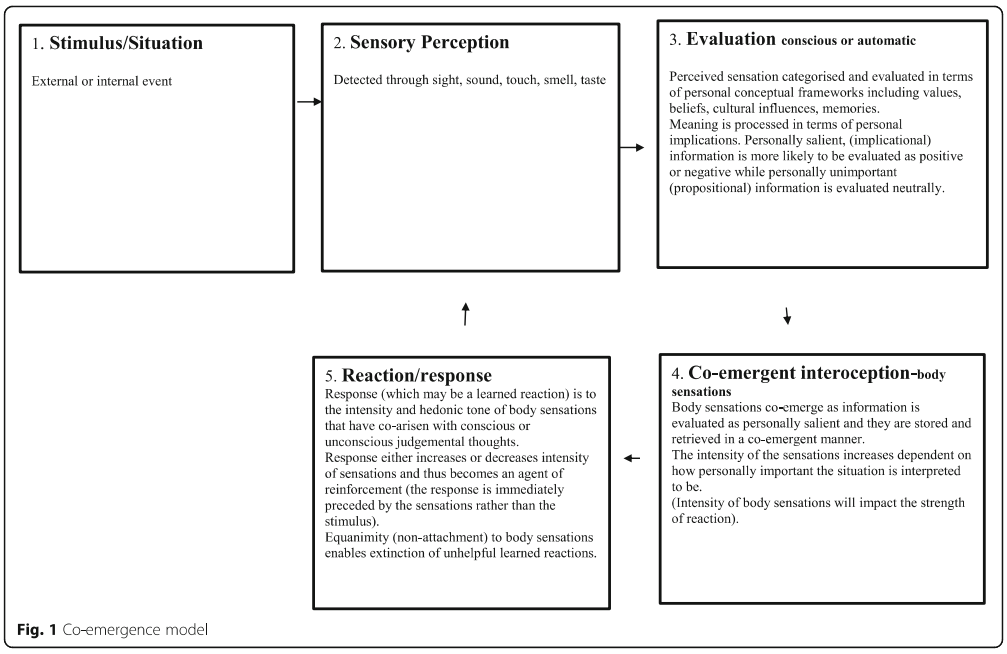

Fig. 1 Co-emergence model

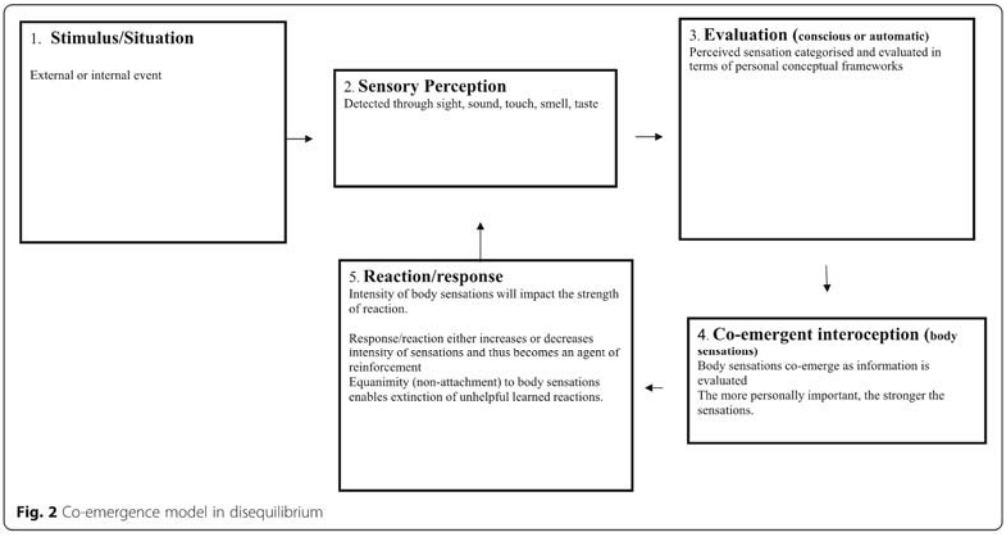

Fig. 2 Co-emergence model in disequilibrium

(sensory perception and co-emergent interoception), in situational, interpersonal and intra-personal contexts [32].

The MiCBT program structure (depicted in Fig. 3) is designed to systematically develop skills to achieve this rebalancing process. Stage 1 (weeks 1–3) teaches mindfulness meditations, both breath meditation and body scanning to develop attention regulation, metacognitive and interoceptive awareness together with response inhibition or non-reactivity/equanimity. Stage 2 (weeks 4–

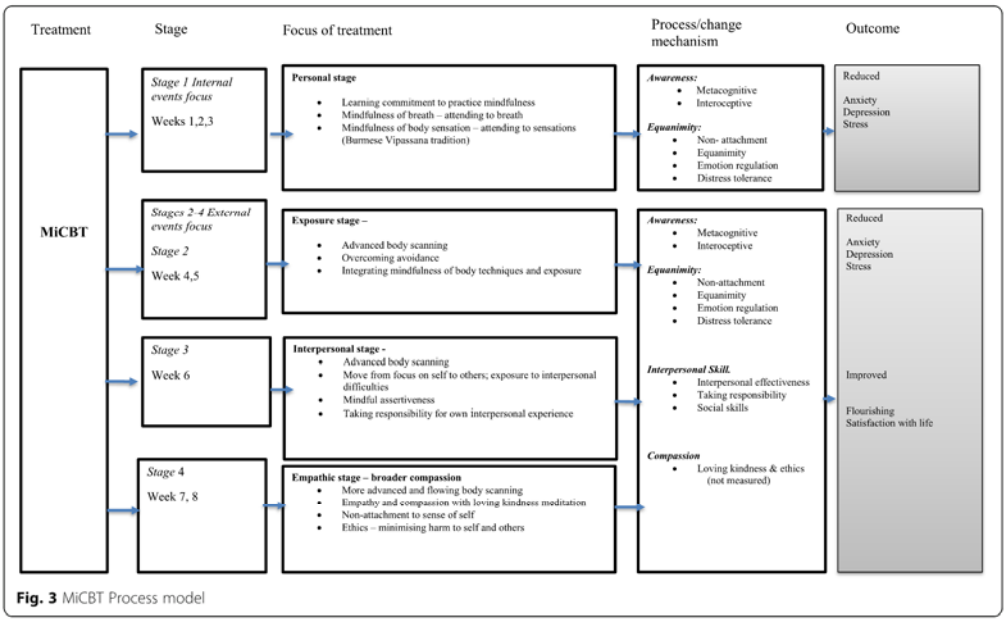

Fig. 3 MiCBT Process model

5) further develops interoceptive awareness, teaching the first body scan in a series of advanced and systematic scanning methods to enable sensitivity to even very subtle body sensations in all areas of the body, followed by imaginal and in vivo exposure techniques for managing avoidance. Stage 3 (week 6) uses faster body scanning techniques and uses exposure methods to address interpersonal issues and assertiveness. Stage 4 (weeks 7–8) teaches deeper levels of body scanning and introduces awareness of ethics and compassion for self and others. Increased awareness of, and equanimity towards, body sensations facilitates the introduction of behavior change strategies so that imaginal and in-vivo exposure to avoided situations (including interpersonal situations) becomes manageable. This practical technique positively impacts social functioning, enabling difficult avoided situations and conversations to be possible. The resultant improved social functioning and connectedness with others tends to enhance well-being and flourishing [33] and assist in preventing relapse [34]. The explicit practice of compassion and personal ethics as an aspect of psychological well-being, combined with the use of systematic exposure techniques, are features distinguishing MiCBT from other MBIs.

In terms of the mindfulness meditation components of MiCBT, the predominance of body scanning exercises is important because anxiety and mood disorders have been associated with inability to appropriately perceive and manage the interoceptive cues associated with disturbing phenomena [35, 36]. Given the increasing evidence of the depleted interoceptive processing in mental health disorders [36], psychological disorders may be considered to involve disturbances of homeostatic and allostatic mechanisms creating reduced ability to respond effectively to the present moment and maintaining learned reactivity, as opposed to responsiveness to current interoceptive signals [37]. From this perspective, anxiety and depression could be conceptualized as interoceptive disorders, in which homeostasis is habitually disrupted through self-referential interpretations of events, creating changes to interoceptive states. Thus, anxiety and depression manifest disturbed interoceptive awareness and compensatory top-down processing [38].

The rationale for learning to develop high levels of interoceptive awareness through body scanning is consistent with findings that interoceptive awareness (IA) is a pre-requisite for effective emotion regulation [39]. As described earlier, MiCBT rests on the proposition that the extent to which thoughts are interpreted as personally implicational reflects in the intensity of the physiological arousal (experienced as body sensations), which in turn determines the resultant behavior [40]. This resultant behavior may be a rationally thought out response or a learned and automatic reaction. Accordingly, the ability to be equanimous to arising body sensations downregulates emotional reactivity [41] and the consequent "dis-ease" that characterizes many psychological disorders.

Both MiCBT and MBCT clearly have shared origins in Buddhist psychology and teach focused attention, awareness and decentering. MBCT was founded on a cognitive model of depressive relapse and the skills taught, particularly awareness and decentering, aim to help patients recognize and step out of the automatic patterns of negative thinking that underlie depressive relapse [42]. The focus in MBCT is on depressive relapse prevention because the "risk of relapse and recurrence is brought about by increased cognitive reactivity to small changes in depressed mood" [43].

MiCBT is differentiated from MBCT rather in its operationalization of techniques than in its Buddhist philosophical underpinnings. A notable difference in MiCBT is its particular focus on the somatic, as well as the cognitive aspect of internal experience such that sensations co-arising with thoughts (at the conscious or sub-conscious level of awareness) are posited to be the locus of behavioral reinforcement. Thus, MiCBT has a cogent rationale for its applicability across clinical diagnoses because the underlying causes of mental disturbance are posited to be reactivity to interoceptive signals (co-arising with thoughts) that are deemed to be unacceptable. Therefore, MiCBT potentially offers a distinctive contribution amongst the suite of mindfulness interventions now available.

Interestingly, despite the inclusion of body-based activities to develop body awareness, including yoga exercises and mindful walking in programs like MBSR and MBCT, many mindfulness scales used in researching these programs make minimal reference to interoceptive awareness. The current research has attempted to address this issue by the inclusion of a measure of interoceptive awareness, the *Multidimensional Assessment of Interoceptive Awareness* (MAIA -[42, 44]).

MiCBT existing evidence

The publication of the book *Mindfulness Integrated CBT: Principles and Practice* [32] has enabled a manualised protocol for the delivery of MiCBT to be in the public domain. There is a growing number of clinicians trained in MiCBT and utilising this therapy with a range of clients, including children [32], but the increasing empirical evidence for the efficacy of MiCBT remains limited. Besides transdiagnostic group applications reported by non-controlled pilot trials [45],there are RCTs supporting the efficacy of MiCBT in a variety of contexts: drug and alcohol setting (Wickham K: The effect of Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) on the

experience of addiction, unpublished), depression with diabetes [46], procrastination and perfectionism in students [47], anxiety and depression in multiple sclerosis patients [48]; anxiety and depression in pregnant women [49], chronic pain [50], and sports anxiety and pessimism [51], suggesting that the delivery of the MiCBT treatment program in relatively homogenous group therapy settings shows good results across different patient populations. However, the claim that MiCBT is effective as a transdiagnostic group approach has not been demonstrated in heterogenous groups through a rigorous randomized controlled trial to date.

Aims and hypotheses

The primary aim of this study is to evaluate the effectiveness of a group delivery of MiCBT across a range of psychological disorders in a private practice setting. The secondary aim is to examine mechanisms of action underpinning MiCBT. It is hoped that the findings will also add to the body of knowledge on outcome measurement with mindfulness-based approaches, in particular the role of interoceptive, metacognitive awareness and equanimity as key mechanisms of change. Based on a preliminary pilot study [52] and experience of colleagues using MiCBT clinically, we hypothesize that the transdiagnostic application of MiCBT implemented in group format in a private psychology clinic will be more beneficial than the treatment-as-usual provided in the wait-list group. The hypotheses are that, compared to the wait-list control group, the MiCBT group will show greater decrease in clinical symptoms (self-reported levels of depression, anxiety and stress, life satisfaction and flourishing). It is further hypothesized that these improvements will be maintained over a six-month period post intervention. The study will also examine the key mechanisms of action. It is hypothesized that 1) improvements in depression, anxiety and stress scores as a function of MiCBT relative to the control group will be mediated by a) improvements in awareness (metacognitive and interoceptive awareness) and b) equanimity. Given the contribution of positive relationships with others to well-being and flourishing noted earlier, we were also interested in exploring the degree to which 2) changes in life satisfaction and flourishing scores are mediated by improvements in interpersonal skills compared to awareness and equanimity.

Methods/design

This study is a randomized controlled trial as it is an early stage trial. Participants will be recruited through medical practitioner referral from the metropolitan region of Melbourne randomized to one of two treatment conditions: MiCBT or a control condition. Both conditions will continue with usual treatment which may include medication and/or ongoing psychological therapy throughout the trial. It was not feasible due to lack of resources to conduct an active control for this study which will be conducted in a private practice setting in the context of a PhD project. However, a wait-list control condition control is appropriate for such an early phase RCT. In addition, the question as to whether any positive treatment outcomes reflect specific or general therapy effects is being addressed to some extent through the mediation analyses.

Eligibility criteria

Inclusion criteria are age 18–75; fluent in English and with a K10 score of 20 or more. Exclusion factors include: less than 18 years of age, non-English speakers, current psychotic symptoms, current diagnosis of borderline or antisocial personality disorder, and current drug or alcohol dependency, pervasive developmental delay, organic mental disorder, prescribed more than 20 mg diazepam equivalent per day. Informed consent is obtained by the researcher from all participants prior to commencement of the program.

Intervention

The MiCBT intervention is adapted from the published protocol [32] with the variation that individual sessions between each group session are not be routinely offered; such sessions are only offered to a participant if a crisis emerges that is deemed too complex to address in a group situation. The MiCBT group will receive the MiCBT treatment in a group format comprising weekly two-hour sessions to groups of 10–15 participants for 8 weeks. The program is delivered by one MiCBT-trained psychologist with 9 years of experience in delivering MiCBT, including twenty-five MiCBT groups. The intervention is administered in a psychology clinic. Participants will be asked to engage in specific mindfulness meditation for an hour each day; two half hour practice sessions and are asked to log their meditation practice hours. Audio instructions for the mindfulness exercises for each session are provided from Cayoun's (2015) text (used with permission). At the start of each session there is a facilitated group meditation for half an hour which introduces the meditation practice for the following week. There is a review and inquiry process about the experiences of the previous weeks practice and in the second hour of each session there is a psycho-educational component explaining the rationale for the following weeks practice or introducing specific homework designed to apply the skills acquired (e.g. an exposure task to avoided behaviors). Attendance at each session is recorded and non-attenders are followed up. Figure 3 maps the putative processes and outcomes in MiCBT.

Participant timeline

The baseline measure is the K10 administered by the General Medical Practitioner as part of the referral process. The remaining assessments will be administered 1 week prior to the commencement of the program post randomization (see Table 1) in order to fully standardize the assessment time frame across participants and address the considerable and varied delay between recruitment and commencing the program. Administering pre-treatment assessments as close as possible to the start of the intervention is expected to have the advantage of achieving maximum precision and sensitivity to change in the context of fluctuating mental health conditions with only low risk of systematic observer or participant bias which could nevertheless be readily gauged though pre- and post-randomization K10 analysis. Observer bias is unlikely because the assessments are conducted on-line. Participant bias, such as demoralization following allocation to control, is also considered unlikely as all participants will receive the program within a relatively short time frame and participants who express a strong desire to be allocated to MiCBT immediately will be recommended to seek alternative treatments and alternative treatments are recommended for participants who express a strong desire to be allocated to MiCBT immediately.

Measures

The intent of this study is to examine the effectiveness of MiCBT to create changes in clinical measures of depression, anxiety and stress. It is hypothesized that these changes will occur during the program in stages 1,2 and 3 and be enhanced in stage 4 because of the additional practice time. Compassion and ethics are taught in Stage 4 for relapse prevention which is not the focus of the current study.

Kessler Psychological Distress Scale (K10)

The K10 is a widely-used 10-question screening scale of psychological distress that focuses on anxiety and depressive symptoms experienced in the last 4 weeks. It has been shown to have good psychometric properties across major sociodemographic groups. The scales show excellent internal reliability and strongly discriminate between clinically significant disorders as defined in the DSM-IV and non-clinically significant disorders [53]. This measure was chosen because it is most commonly used by general practitioners in Victoria as a screening tool to identify those eligible for a Mental Health Care Plan and subsidized psychological treatment.

Depression, Anxiety, and Stress Scale (DASS-21)

The DASS-21 is a 21-item version of the DASS-42 and is a self-report questionnaire designed to measure three domains: depression, anxiety and stress [54] [55, 56]. Each subscale contains 7 items, and items are rated on a four-point likert scale. Higher scores indicate more severe symptoms. The DASS-21 is reported to have high internal consistency for each of the subscales (depression, r = .88; anxiety, r = .82; stress r = .90), and the total scale (r = .93) [55, 56].

Satisfaction with Life Scale (SWLS)

This is a widely used 5-item self-report measure of life satisfaction. The scale is conceptualized as having two components. a cognitive judgmental component and an

Table 1 Timeline for enrolment, allocation, intervention and assessment. -t1 time 1 - enrolment by GP referral; 0 - allocation to MiCBT or control group: t1- intervention week 1; t2 - mid intervention; t3 - post intervention (week 8); t4 - post 6 month follow up

	STUDY PERIOD					
	Enrolment	Allocation	Post Allocation			
TIMEPOINT	*-t1*	0	*t1*	*t2*	*t3*	*t4*
ENROLMENT						
Eligibility screening	X					
Informed consent	X					
Baseline measure	X					
Randomisation	X	X				
INTERVENTION						
MiCBT Group program			—	—	—	—
ASSESSMENTS						
Experimental group			—	—	—	—
Control group			—	—	—	—

-t1 time 1 - enrolment by GP referral; 0 - allocation to MiCBT or control group: t1- intervention week 1; t2 - mid intervention; t3 - post intervention (week 8); t4 - post 6 month follow up.

affective or emotional component [57]. The SWLS uses a 7-point Likert scale from 1 (*strongly disagree)* to 7 (*strongly agree*). The range of possible scores is from minimal satisfaction with life (5) to very high satisfaction with life (35). The SWLS has been shown to have convergent validity with other self-report measures of life satisfaction, including the Philadelphia Geriatric Center Morale Scale [58]. The SWLS appears to tap a single life satisfaction factor. Internal consistency is good with a Cronbach's alpha coefficient of .83.

The Flourishing Scale (FS)

The FS is an eight item self-report measure of psychological well-being [59]. The scale taps into aspects of human functioning such as feelings of competence, positive relationships, and purpose in life. It uses a 7-point Likert scale with responses from strong disagreement to strong agreement. Scores range from 8 to 56 and high scores indicate positive self-appraisal of psychological well-being. The scale developers report strong correlations with other psychological well-being scales and good internal consistency with Cronbach's alpha coefficient of 0.87.

Mindfulness-based Self-Efficacy Scale-Revised (MSES–R)

This 22-item self-report measure is designed to assess the changes in levels of perceived self-efficacy before, during and after mindfulness-based therapy [32]. There are six subscales, Emotion Regulation, Distress Tolerance, Equanimity (considered here as measuring aspects of equanimity), Taking Responsibility, Social Skills, and Interpersonal Effectiveness (considered here as measuring aspects of interpersonal skills). Items are rated on a 5-point Likert scale from 0 (*not at all*) to 4 (*completely*). Higher scores indicate higher mindfulness based self-efficacy. Subscales can be used separately to assist in identifying relative strengths and weaknesses or combined to provide a global score. The MSES-R total shows high internal consistency (Cronbach's alpha .86) [32]; has a good divergent validity, inverse relationships with the DASS-21 [60], and good concurrent validity with the Freiberg Mindfulness Inventory (FMI) [61], the Mindfulness Attention and Awareness Scale (MAAS), [62], the Kentucky Inventory of Mindfulness (KIMS), [63, 64] and the Five Factor Mindfulness Questionnaire (FFMQ), [65, 66].

The Experiences Questionnaire (EQ)

This is a 20-item self-report measure of decentring [67] and is conceptualized as a protective factor and capable of measuring resilience to depressive relapse. Decentring is a key element of metacognitive awareness [68, 69] as reflected here: "We refer to the process of experiencing negative thoughts and feelings within a decentred perspective as metacognitive awareness.." [70]. The EQ uses a 5-point Likert scale with responses from "never" to "all the time". This is a relatively new measure whose psychometric properties are still being investigated. A Spanish study [71] found (reliability: Cronbach's $\alpha = .89$; convergent validity: $r > .46$; and divergent validity: $r < -.35$).

Multi-dimensional Assessment of Interoceptive Awareness (MAIA)

This is a 32-item self-report measure of body awareness, both interoceptive and proprioceptive [44]. It uses a 6-point Likert scale with responses from 0 (never) to 5 (always). There are eight subscales; Noticing, Not-Distracting, Not-Worrying, Attention Regulation, Emotional Awareness, Self-Regulation, Body Awareness and Trusting [44]. The internal-consistency reliability of each of the 21 validity measures was reported by the scale developers as ranging from .70 to .93 (median .85) [44, 72].

The Nonattachment Scale (NAS)

This unidimensional measure is designed to tap the construct of being equanimous, flexible and receptive [73]. This appears to be congruent with cognitive flexibility, an attribute that is developed by mindfulness practice. The NAS is shown to correlate with a quality of consciousness related to constructs such as emotion regulation, interpersonal effectiveness, well-being and mental health [73]. It is a 30-item self-report scale and uses a 6-point Likert scale ranging from 1 (disagree strongly) to 6 (agree strongly). Internal consistency levels are >.80 (Cronbach's alpha).

Meditation practice

The amount of meditation practice completed by each participant is recorded daily by each participant and then collected each week on an individualized form. They are not disclosed to other participants.

Adverse effects

There is a weekly check in with participants about their practice and any issues raised are addressed. In the event of participants experiencing difficulties in relation to their meditation practice the following actions may be taken: a) modify the type of practice for the coming week or b) provide some individual counselling to the participant. The 6-month follow-up questionnaire includes a question about the occurrence of any adverse effects or other difficulties thought to be as a result of meditating. The questions were taken from a recent study about the broad ranges of experiences that occur in association with meditation practices [74]. The questions are:

1. "Did you have any unexpected, challenging, or difficult experiences that you associate with your practice of meditation?"
2. "How did these experiences impact your life"? [74].

All measures will be administered on line using Qualtrics survey software, with the exception of the amount of meditation practice which will be recorded by each participant and reported privately on a personalized form each week. There are inadequate resources available for this PhD study to administer the qualitative questions in person.

Participants are emailed a link to the measures utlizing their unique identification number. Reminder emails are sent to those who do not respond and if there is still no response the participant is telephoned.

Primary and secondary outcomes

The primary outcome measure is the DASS-21. The secondary outcome measures are the K10, SWLS and FS psychological well-being scales. Measurement will occur at baseline, mid-intervention, post intervention and at 6-month follow up.

Mediator hypotheses

It is hypothesized that the mediators of the clinical change will be reflected by changes in equanimity (NAS), decentering (EQ), interoceptive awareness (MAIA) and Mindfulness-based self-efficacy (MSES-R). The following mediation hypotheses will be tested: 1) improvements in the DASS-21 and K10 (clinical symptoms) at the end of MiCBT treatment will be mediated by improvements in the MSES-R (equanimity-related subscales), EQ and NAS mid-intervention; 2) improvements in clinical symptoms (DASS-21 and K10) at the six-month follow-up will be mediated by improvements in the MSES-R (equanimity-related subscales), EQ and NAS at the end of treatment. We will also explore the degree to which 3) improvements in the SWLS and FS at the six-month follow up is mediated by improvements in the MSES-R (interpersonal skills and social skills subscales) compared to MSES (equanimity subscales), EQ and MAIA measured at the end of treatment.

Measurements of ethical awareness and compassion as addressed in stage 4 of the program were not included as they would make the number of items unmanageable but could be considered in future studies and their target is relapse prevention which not the focus of this study.

Sample size

The trial is powered to detect significant differences relevant to the primary outcome. A power analysis (G-power 3.1) for medium effect (Cohen's $d = .5$) was conducted with power of .08, and using the conventional significance level (.05), resulting in a desired sample of 102 (51 participants in each group). Consistent with previous studies (e.g. [75]) allowing for a conservatively estimated attrition rate of 20% to follow up, a sample of 120 will be recruited. Based on the projected sample size of 102, power of 0.8, and zero, small, medium or large effect sizes conditions for the indirect effect, the mediation analyses are well-powered to detect a medium beta paths between the independent variable and the mediator and between the mediator and the dependent variable ($\beta = .0.39$) using bootstrapping and the Sobel test [76]. Data will be collected using online self-report measures with the Qualtrics platform at the four measurement points; baseline, mid-intervention, post-intervention, and 6-months follow-up.

Recruitment

General Practitioners and psychiatrists practicing in the local area will be mailed recruitment letters and information flyers about the study together with referral forms and an explanation of the project eligibility criteria all of which are approved by the Monash University Human Research Ethics Committee. Referring medical practitioners are requested to provide a K10 score for each potential participant to determine eligibility as part of their referral.

Mail-outs to medical practices will be repeated to maintain the flow of participants to meet the required numbers. Applicants are subsequently screened at initial face-to-face or telephone interview by the researcher. Participants are then provided with an explanatory statement describing the project and after reading it through, those who wish to participate in the study are invited to sign the consent to participate form.

Randomization

All subjects will be allocated an identification number and then randomly allocated to either the MiCBT group or the control group. Randomization is stratified based on the K10 scores (Levels of psychological distress: mild and moderate K10 score < 30; severe, K10 score ≥ 30), antidepressant or mood stabilizer medication (yes/no) and gender. The randomization procedure is conducted using Stata Version 14 SE by a researcher independent from all other aspects of project implementation, including group facilitation and data collection, using random allocation of treatments balanced in blocks. A sequence of treatments (test or control) are randomly permuted in blocks of size 4. Blocks of size 4 were chosen to ensure a balance of treatments in all group sessions, because groups of size 8 could begin as soon as 16 participants are recruited. Allocation is stratified by three stratification variables, each having

two values: gender (M/F), antidepressants (Y/N), K10 score (20+/30+). Therefore a randomization schedule is generated for each of the 8 strata: F N 20+; F N 30+; F Y 20+; F Y 30 + M N 20+; M N 30+; M Y 20+; M Y 30+.

Blindness

With the exception of meditation practice data, which is collected as described, all other assessments are conducted online, thus minimizing the possibility of researcher bias. Analysis of results will not be blinded.

Data collection

In addition to the quantitative measures previously described participants in the MiCBT group will be asked some additional qualitative questions at the end of the 8-week program evaluating the program and asking about any adverse events they may experience with their meditation practices during the MiCBT program. Additionally, at the 6-month follow up, participants in the MiCBT group will be asked questions relating to adherence to meditation practices and any changes to treatment. Participants in the control condition will complete all measures at the same four time points as the treatment group and receive treatment as usual during this time.

Data management

Results of the assessments will be kept confidential. Participants are allocated a unique identifier to be used when processing and communicating results. Personal details and results will be kept in separate databases and stored in accordance with Australian Psychological Society Ethical Standards and as outlined in the approved ethics application. Any publication of the results will not be published in a manner that would reveal the identity of any participants. The research dataset, de-identified, may be made publicly available.

Research ethics approval

The project has approval from Monash University Human Research Ethics Committee (Approval Number CF16/2278–2,016,001,131). This ethics approval addresses issues of confidentiality as described above, consent of participants, access to data, ancillary and post-trial care and limitations of dissemination to thesis transcript, journal articles/book chapters, conference papers.

Statistical analysis

Statistical analysis will be conducted using SPSS version 24 statistical software package. The dependent variables are scores on the two primary outcomes (DASS-21 and the K10), the secondary outcomes (SWLS and FS) and the other mediators (EQ, the MSES-R, the MAIA, and the NAS). The expected outcomes are that the MiCBT group will show significantly changed scores as compared to the wait-list control group, with lower scores on the DASS-21, the K10 and higher scores on the SWLS, FS, the MSES-R, the MAIA, the EQ, and the NAS.

The differential changes in the MiCBT group compared to the control group is the primary focus of the analysis. Analysis will use mixed-model repeated measures (MMRM), the method recommended for clinical trial data [77]. Evidence for the effectiveness of MiCBT will be demonstrated by a significant two-way interaction demonstrating greater change in the outcome measures in the MiCBT group from the control group pre to post intervention. Baseline to follow-up interactions for the MiCBT group will also be examined and changes compared with post intervention data. Results of the trial will be made available to referring clinicians and to participants in the form of a summarized report. Results may be published in journal articles, student thesis and conference presentations.

Intention-to-treat (ITT) analysis will be used because this approach uses all available information. Subjects with incomplete data are not discarded and missing data are not replaced with estimated values. Missing data will be examined and if found to be missing completely at random (MCAR) then the analysis will proceed without replacing missing data with estimated values. If pattern of missingness is not MCAR then multiple imputation will be applied using the strata that defined the non-random missingness.

This is consistent with the CONSORT standard [78]. If data are non-normal, then it will be analyzed using generalized linear MMRM. The mediational impact of pre to post MAIA, MSES, EQ and NAS will be assessed using the Sobel test, a method for measuring indirect effects [79]. The test assesses the significance of the product of the coefficients for treatment-mediator and mediator-outcome effects. A bootstrapped multivariate extension of the Sobel test will be used to examine both the total indirect effect and the individual effect and the effect of each mediator. The first model will comprise: group (MiCBT vs wait-list control) as the independent variable; clinical DASS-21 and K10 measures as the dependent variables; and MAIA (interoceptive awareness), EQ (metacognitive awareness), MSES-R (Emotion Regulation, Distress Tolerance, Equanimity subscales and total) and NAS (equanimity), scales that reveal significant group x time interactions, as mediators. Two time-frames will be tested for changes over the course of the program itself (mediators measured at 4 weeks; outcomes at 8 weeks) and in the longer term (mediators measured at 8 weeks, outcomes at 6 months). The second model will comprise: group (MiCBT vs wait-list control) as the independent variable: psychological well-being SWLS and FS measures (measured at 6 months) as the dependent variables; and MSES-R subscales of Taking

Responsibility, Social Skills, Interpersonal Effectiveness and total score (measured at 8 weeks), MAIA (interoceptive awareness), EQ (metacognitive awareness), MSES-R (Emotion Regulation, Distress Tolerance, Equanimity subscales and total) and NAS (equanimity) scales that reveal significant group x time interactions, as mediators.

Discussion

MiCBT is a potentially important addition to the suite of mindfulness-based interventions because of its trans-diagnostic applicability and the comprehensive nature of the intervention that seeks to directly address fundamental processes underpinning suffering, described by the co-emergent model of reinforcement. It employs a sophisticated integration of traditional mindfulness meditations including loving kindness, cognitive behavioral techniques as well as its consideration of personal ethics as an aspect of psychological well-being. This study aims to investigate the effectiveness of MiCBT as a group intervention with a transdiagnostic population. It will explore if participants who engaged in the MiCBT program show improvement in anxiety, depression, stress, well-being and flourishing compared to a treatment as usual control group. The study will also explore some of the putative underlying mechanisms of action, notably interoceptive and metacognitive awareness and equanimity, but also interpersonal effectiveness.

Study participants represent the population of mild to moderately psychologically unwell individuals whose mental health has considerable impact on their flourishing. This contributes to negative impacts on family well-being and community costs in terms of lost work days and costs associated with medical treatments [80]. The availability of treatment options is frequently limited with long wait times to join the MBIs that are offered through community mental health services while patients continue to consume valuable medical and psychiatric resources. The ability of MiCBT to be delivered trans-diagnostically means that it is much easier to recruit groups of a viable size without having a long waiting period. Delivery through private psychology practices utilizes the well-established therapeutic collaboration in Australia between general medical practitioners and psychologists in private practice, which is supported by the National Health Insurance Scheme (Medicare). While the intervention is of short duration, it comprehensively teaches specific self-regulation skills, both in personal and interpersonal contexts. Its short duration enables the program to be cost-efficient, and in Australia, to be delivered within the limits of government-subsidized group psychological treatments.

The datasets used and analyzed during the current study will be available from the corresponding author on reasonable request.

Abbreviations

CBT: Cognitive Behavior Therapy; DASS 21: Depression, Anxiety and Stress Scale; EQ: Experiences Questionnaire; FS: Flourishing scale; ITT: Intention to treat; K10: Kessler Psychological Distress Scale; MAIS: Multidimensional Assessment of Interoceptive Awareness; MB-EAT: Mindfulness-based Eating Program; MBI: Mindfulness-based Intervention; MBRE: Mindfulness-based Relationship Enhancement; MBSR: Mindfulness-based Stress Reducyion; MiCBT: Mindfulness integrated Cognitive Behavior Therapy; MMRM: Mixed Model Repeated Measures; MSES: Mindfulness-based Self-efficacy Scale; NAS: Non-attachment Scale; NICE: National Institute for Health and Care Excellence; SWLS: Satisfaction with Life Scale

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Authors' contributions

As the project supervisor, FS was the Chief Investigator, SF was the Principal Student Investigator, BC and GM were co-supervisors. The MiCBT implementation protocol was adapted from the program developed by BC who also gave permission for the use of audio materials for the study. FS had oversight of the project design which was developed jointly with SF with advice from GM and BC. JE provided statistical advice and for the design of the data collection and analysis and randomization. GM provided overall advice and support for the project. All authors read, amended and approved the manuscript.

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Availability of data and materials

The individual deidentified participant datasets generated and/or analysed during the current study will be made available in Monash University's institutional data repository, Monash.figshare (https://monash.figshare.com/).

Ethics approval and consent to participate

Research ethics approval for the project was granted by the Human Research Ethics Committees at Monash University (project approval number Approval Number CF16/2278–2016001131; approved 7th September 2016). All participants in the study must sign a written consent form after reading the explanatory statement describing the study.

Consent for publication

Not applicable.

Competing interests

Dr. Cayoun receives royalties from Wiley Blackwell Press for MiCBT publications outside the submitted work and fees for MiCBT professional training workshops. Sarah Francis receives royalties from Wiley Blackwell Press for MiCBT publications outside the submitted work.

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References

1. Bhar SS, Gelfand LA, Schmid SP, Gallop R, DeRubeis RJ, Hollon SD, Amsterdam JD, Shelton RC, Beck AT. Sequence of improvement in depressive symptoms across cognitive therapy and pharmacotherapy. J Affect Disord. 2008;110(1):161–6.
2. Churchill R, Moore TH, Davies P, Caldwell D, Jones H, Lewis G, Hunot V. Mindfulness-based'third wave'cognitive and behavioural therapies versus treatment as usual for depression. Cochrane Libr. 2010, Issue 9. Art. No.: CD008705. https://doi.org/10.1002/14651858.CD008705.
3. DeRubeis RJ, Hollon SD, Amsterdam JD, et al. Cognitive therapy vs medications in the treatment of moderate to severe depression. Arch Gen Psychiatry. 2005;62(4):409–16.
4. Olatunji BO, Cisler JM, Deacon BJ. Efficacy of cognitive behavioral therapy for anxiety disorders: a review of meta-analytic findings. Psychiatr Clin N Am. 2010;33(3):557–77.
5. Barrett P, Farrell L, Dadds M, Boulter N. Cognitive-behavioral family treatment of childhood obsessive-compulsive disorder: long-term follow-up and predictors of outcome. J Am Acad Child Adolesc Psychiatry. 2005; 44(10):1005–14.
6. Park HS, SHIN YW, Ha TH, Shin MS, Kim YY, Lee YH, Kwon JS. Effect of cognitive training focusing on organizational strategies in patients with obsessive-compulsive disorder. Psychiatry Clin Neurosci. 2006;60(6):718–26.
7. Siev J, Chambless DL. Specificity of treatment effects: cognitive therapy and relaxation for generalized anxiety and panic disorders. Journal of consulting and clinical psychology. 2007;75(4):513.
8. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy: a review of meta-analyses. Clin Psychol Rev. 2006;26(1):17–31.
9. Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: a meta-analytic review. J Consult Clin Psychol. 2010;78(2):169.
10. Sacco WP, Beck AT. Cognitive theory and therapy; 1995.
11. Hayes SC, Strosahl KD, Wilson KG. Acceptance and commitment therapy, second edition: the process and practice of mindful change. New York: Guilford Publications; 2011.
12. Segal Z, Williams J, Teasdale J. Mindfulness-based cognitive therapy for depression: a new approach to relapse prevention. New York: Guilford; 2002.
13. Meadows G, Singh B, Grigg M. Mental health in Australia : collaborative community practice. South Melbourne: Oxford University Press; 2007.
14. Kahl KG, Winter L, Schweiger U. The third wave of cognitive behavioural therapies: what is new and what is effective? Curr Opin Psychiatry. 2012; 25(6):522–8.
15. Kabat-Zinn J, Wheeler E, Light T, Skillings A, Scharf M, J. Cropley T, Hosmer G, Bernhard JD. Influence of a mindfulness meditation-based stress reduction intervention on rates of skin clearing in patients with moderate to severe psoriasis undergoing photo therapy (UVB) and photochemotherapy (PUVA). Psychosom Med. 1998;60(5):625–32.
16. Segal ZV, Williams JMG, Teasdale JD. Mindfulenss-based cognitive therapy for depression. 2nd ed; 2013.
17. Kabat-Zinn J, Lipworth L, Burney R. The clinical use of mindfulness meditation for the self-regulation of chronic pain. J Behav Med. 1985;8(2): 163–90.
18. Kabat-Zinn J, Lipworth L, Burney R, Sellers W. Four year follow-up of a meditation-based program for the self-regulation of chronic pain: treatment outcomes and compliance. Clin J Pain. 1986;2:159–73.
19. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. Gen Hosp Psychiatry. 1982;4(1):33–47.
20. Campbell TS, Labelle LE, Bacon SL, Faris P, Carlson LE. Impact of mindfulness-based stress reduction (MBSR) on attention, rumination and resting blood pressure in women with cancer: a waitlist-controlled study. J Behav Med. 2012;35(3):262–71.
21. Speca M, Carlson LE, Goodey E. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. Psychosom Med. 2000;62:613–22.
22. van Son J, Nyklíček I, Pop VJ, Pouwer F. Testing the effectiveness of a mindfulness-based intervention to reduce emotional distress in outpatients with diabetes (DiaMind): design of a randomized controlled trial. BMC Public Health. 2011;11(1):131.
23. Lenz AS, Hall J, Bailey Smith L. Meta-analysis of group mindfulness-based cognitive therapy for decreasing symptoms of acute depression. J Spec Group Work. 2016;41(1):44–70.
24. Cheisa A, Malinowski P. Mindfulness-based approaches: are they all the same? J Clin Psychol. 2011;67:404–24.
25. Alfonso JP, Caracuel A, Delgado-Pastor LC, Verdejo-García A. Combined goal management training and mindfulness meditation improve executive functions and decision-making performance in abstinent polysubstance abusers. Drug Alcohol Depend. 2011;117(1):78–81.
26. Roemer L, Lee JK, Salters-Pedneault K, Erisman SM, Orsillo SM, Mennin DS. Mindfulness and emotion regulation difficulties in generalized anxiety disorder: preliminary evidence for independent and overlapping contributions. Behav Ther. 2009;40(2):142–54.
27. Kristeller JL. Mindfulness, wisdom and eating: applying a multi-domain model of meditation effects. J Construct Human Sci. 2003;8(2):107–18.
28. Kristeller JL, Hallett CB. An exploratory study of a meditation-based intervention for binge eating disorder. J Health Psychol. 1999;4(3):357–63.
29. Carson JW, Carson KM, Gill KM, Baucom DH. Mindfulness-based relationship enhancement. Behav Ther. 2004;35:471–94.
30. Abraham C, Kelly MP, West R, Michie S. The UK National Institute for health and clinical excellence public health guidance on behaviour change: a brief introduction. Psychol Health Med. 2009;14(1):1–8.
31. Goyal M, Singh S, Sibinga EM, Gould NF, Rowland-Seymour A, Sharma R, Berger Z, Sleicher D, Maron DD, Shihab HM. Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. JAMA Intern Med. 2014;174(3):357–68.
32. Cayoun BA. Mindfulness-integrated CBT: principles and practice. New York: Wiley; 2011.
33. Eraslan-Capan B. Social connectedness and flourishing: the mediating role of hopelessness. Univ J Educ Res. 2016;4(5):933–40.
34. Saeri AK, Cruwys T, Barlow FK, Stronge S, Sibley CG. Social connectedness improves public mental health: investigating bidirectional relationships in the New Zealand attitudes and values survey. Aust & New Zealand J Psych. 2018;52(4):365–74.
35. Pollatos O, Traut-Mattausch E, Schroeder H, Schandry R. Interoceptive awareness mediates the relationship between anxiety and the intensity of unpleasant feelings. J Anxiety Disord. 2007;21(7):931–43.
36. Khalsa SS, Adolphs R, Cameron OG, Critchley HD, Davenport PW, Feinstein JS, Feusner JD, Garfinkel SN, Lane RD, Mehling WE *et al*: Interoception and mental health: a roadmap. Biological Psychiatry: Cognitive Neuroscience and Neuroimaging 2017.
37. Sterling P. Homeostasis vs allostasis: implications for brain function and mental disorders. JAMA Psychiat. 2014;71(10):1192–3.
38. Paulus MP, Stein MB. Interoception in anxiety and depression. Brain Struct Funct. 2010;214(5):451–63.
39. Füstös J, Gramann K, Herbert BM, Pollatos O. On the embodiment of emotion regulation: interoceptive awareness facilitates reappraisal. Soc Cogn Affect Neurosci. 2013;8(8):911–7.
40. Brewer JA, Worhunsky PD, Gray JR, Tang YY, Weber J, Kober H. Meditation experience is associated with differences in default mode network activity and connectivity. Proc Natl Acad Sci U S A. 2011;108:20254–9.
41. Hölzel BK, Carmody J, Evans KC, Hoge EA, Dusek JA, Morgan L, Pitman RK, Lazar SW. Stress reduction correlates with structural changes in the amygdala. Soc Cogn Affect Neurosci. 2010;5(1):11–7.
42. Segal Z, Williams M, Teasdale J. Mindfulness-based cognitive therapy for depression. 2nd revised ed. New York: Guilford Publications; 2013.
43. Williams JMG. Mindfulness, depression and modes of mind. Cogn Ther Res. 2008;32(6):721.
44. Mehling WE, Price C, Daubenmier JJ, Acree M, Bartmess E, Stewart A. The multidimensional assessment of interoceptive awareness (MAIA). PLoS One. 2012;7(11):e48230.
45. Cayoun BA, Sauvage V, Van Impe M. A non diagnosis-specific application of mindfulness-based cognitive-behaviour therapy (MCBT): a pilot study. Rokeby: The Hobart Clinic; 2004.
46. Sohrabi F, Sohrabi A, Shams-Alizadeh N. Effects of mindfulness-integrated cognitive behaviour therapy (MiCBT) on depression, adherence and blood glucose control of patients with type 2 diabetes mellitus; 2014.

47. Farzinrad B, Kamal MN. Comparison between Effectiveness of Mindfulness integrated Cognitive Behavioral Therapy (MiCBT) and Rational Emotional Behavior Therapy (REBT) on procrastination, perfectionism and worry in students. In: 6th International Congress on Child and Adolescent Psychiatry. East Azarbaijan: Tabtiz university of medical sciences; 2013.
48. Bahrani S, Zargar F, Yousefipour G, Akbari H. The effectiveness of mindfulness-integrated cognitive behavior therapy on depression, anxiety, and stress in females with multiple sclerosis: a single blind randomized controlled trial. Iran Red Crescent Med J. 2017;19(4):p1–8.
49. Yazdanimehr R, Omidi A, Sadat Z, Akbari H. The effect of mindfulness-integrated cognitive behavior therapy on depression and anxiety among pregnant women: a randomized clinical trial. J Caring Sci. 2016;5(3):195–204.
50. Cayoun BA, Simmons A, Shires A. Immediate and lasting chronic pain reduction following a brief self-implemented mindfulness-based interoceptive exposure task: a pilot study. Mindfulness. 2017:1–13.
51. Scott-Hamilton J, Schutte NS, Brown RF. Effects of a mindfulness intervention on sports-anxiety, pessimism, and flow in competitive cyclists. Appl Psychol Health Well Being. 2016;8(1):85–103.
52. Francis SEB. A preliminary study of mindfulness-integreatd cognitive behaviour therapy: results from a series of group interventions. Rome: First International Conference on Mindfulness; 2013.
53. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand S-L, Walters EE, Zaslavsky AM. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med. 2002;32(06):959–76.
54. Lovibond SH, Lovibond PF. Manual for the depression anxiety stress scales. 2nd ed. Psychology Foundation: Sydney; 1995.
55. Henry JD, Crawford JR. The 21-item version of the depression anxiety stress scales (DASS–21): normative data and psychometric evaluation in a large non-clinical sample. Br J Clin Psychol. 2005;44:227–39.
56. Crawford JR, Henry JD. The depression anxiety stress scales (DASS): normative data and latent structure in a large non-clinical sample. Br J Clin Psychol. 2003;42(2):111–31.
57. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. J Pers Assess. 1985;49(1):71–5.
58. Lawton MP. The Philadelphia geriatric center morale scale: a revision. J Gerontol. 1975;30(1):85–9.
59. Diener E, Wirtz D, Tov W, Kim-Prieto C, Choi D, Oishi S, Biswas-Diener R. New well-being measures: short scales to assess flourishing and positive and negative feelings. Soc Indic Res. 2010;97(2):143–56.
60. Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the depression anxiety stress scales (DASS) with the Beck depression and anxiety inventories. Behav Res Ther. 1995;33(3):335–43.
61. Wallach H, Buchheld N, Buttenmuller V, Kleinknecht N, Schmidt S. Measuring mindfulness. The Freiburg mindfulness inventory. Personal Individ Differ. 2006;40:1543–55.
62. Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. J Pers Soc Psychol. 2003;84(4):822.
63. Baer RA, Smith GT, Allen KB. Assessment of mindfulness by self-report: the Kentucky inventory of mindfulness skills. Assessment. 2004;11(3):191–206.
64. Armijo-Olivo S, Warren S, Magee D. Intention to treat analysis, compliance, drop-outs and how to deal with missing data in clinical research: a review. Phys Ther Rev. 2009;14(1):36–49.
65. Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. Assessment. 2006; 13(1):27–45.
66. Kasselis N. A psychometric analysis of the mindfulness-based self efficacy scale (MSES): Honours Bachelor of Arts. Australia: University of Tasmania; 2011.
67. Fresco DM, Moore MT, van Dulmen MH, Segal ZV, Ma SH, Teasdale JD, Williams JMG. Initial psychometric properties of the experiences questionnaire: validation of a self-report measure of decentering. Behav Ther. 2007;38(3):234–46.
68. Bernstein A, Hadash Y, Lichtash Y, Tanay G, Shepherd K, Fresco DM. Decentering and related constructs:a critical review and metacognitive processes model. Perspect Psychol Sci. 2015;10(5):599–617.
69. Wells A. Cognition about cognition: metacognitive therapy and change in generalized anxiety disorder and social phobia. Cogn Behav Pract. 2007; 14(1):18–25.
70. Teasdale J, Moore R, Hayhurst H, Pope M, Williams S, Segal Z. Metacognitive awareness and prevention of relapse in depression: empirical evidence. J Consult Clin Psychol. 2002;70(2):275.
71. Soler J, Franquesa A, Feliu-Soler A, Cebolla A, García-Campayo J, Tejedor R, Demarzo M, Baños R, Pascual JC, Portella MJ. Assessing decentering: validation, psychometric properties, and clinical usefulness of the experiences questionnaire in a Spanish sample. Behav Ther. 2014;45(6):863–71.
72. Gueorguieva R, Krystal JH. Move over anova: Progress in analyzing repeated-measures data andits reflection in papers published in the archives of general psychiatry. Arch Gen Psychiatry. 2004;61(3):310–7.
73. Sahdra BK, Shaver PR, Brown KW. A scale to measure nonattachment: a Buddhist complement to Western research on attachment and adaptive functioning. J Pers Assess. 2010;92(2):116–27.
74. Lindahl JR, Fisher NE, Cooper DJ, Rosen RK, Britton WB. The varieties of contemplative experience: a mixed-methods study of meditation-related challenges in Western Buddhists. PLoS One. 2017;12(5):e0176239.
75. Eisendrath SJ, Gillung EP, Delucchi KL, Chartier M, Mathalon DH, Sullivan JC, Segal ZV, Feldman MD. Mindfulness-based cognitive therapy (MBCT) versus the health-enhancement program (HEP) for adults with treatment-resistant depression: a randomized control trial study protocol. BMC Complement Altern Med. 2014;14(1):95.
76. Fritz MS, Mackinnon DP. Required sample size to detect the mediated effect. Psychol Sci. 2007;18(3):233–9.
77. Lau MA, Bishop SR, Segal ZV, Buis T, Anderson ND, Carlson L, Shapiro S, Carmody J. The Toronto mindfulness scale: development and validation. J Clin Psychol. 2006;62(12):1445–67.
78. Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RTCs) published in mendical journals, reprint of a Cochrane review. Cochrane Libr. 2012;11:p1–10.
79. Sobel ME. Asymptotoc confidence intervals for indirect effects in structural equations models. Sociol Methodol. 1982;13:290–312.
80. Birnbaum HG, Kessler RC, Kelley D, Ben-Hamadi R, Joish VN, Greenberg PE. Employer burden of mild, moderate, and severe major depressive disorder: mental health services utilization and costs, and work performance. Depress Anxiety. 2010;27(1):78–89.

Publisher's Note

3.3 Correction to Protocol Paper

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BMC Psychiatry

CORRECTION Open Access

Correction to: Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients

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Correction to: BMC Psychiatry
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After publication of our article [1] the authors have notified us that one of the names has been incorrectly spelled.

- Original name spelling:
  Sarah Frances
- Correct name spelling:
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4 CHAPTER FOUR: Results of the MiCBT Randomised Controlled Study

4.1 Rationale of research paper

The third paper describes the results of the RCT comparing MiCBT with a treatment-as-usual waitlist control. Due to the requirement to recruit 120 participants and the fact that it was to be conducted as a part-time PhD project, the final 8-week intervention program finished in December 2018. Recruitment was ongoing over a two-year period with rolling referrals from general medical practitioners and mental health professionals. Data analysis commenced in July 2019 after the 6-month follow up period for the final group intervention concluded. Thirty-two of the control group participants took up the offer to receive the 8-week program. The candidate was therefore engaged in program delivery until July 2019 while concurrently engaging in the data analysis. The results paper is currently under review with the journal *Mindfulness,* which has an impact factor of 3.10.

4.2 Manuscript submitted for review

Francis, S.E.B., Shawyer, F., Cayoun, B.A., Enticott, J., Meadows, G. Group mindfulness-integrated cognitive behavior therapy (MiCBT) reduces depression and anxiety and improves flourishing in a transdiagnostic primary care sample compared to a treatment-as-usual waitlist control. Submitted to *Mindfulness which has an Impact factor of 3.581.*

Group mindfulness-integrated cognitive therapy (MiCBT) reduces depression and anxiety and improves flourishing in a transdiagnostic primary care sample compared to a treatment-as-usual waitlist control.

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This project was undertaken through Monash University.

Clinical Trial Registration

This trial is registered with the Australian and New Zealand Clinical Trial Registry: ACTRN12617000061336; Registration date: 11th January 2017.

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We thank Shrinkhala Dawadi for assistance with the data analyses. We thank our project participants who, in sharing their time and experience, made this study possible.

Contributions

SF conducted the research and led the writing of this paper as part of a PhD thesis. FS was the primary supervisor and BC, and GM were co-supervisors. JE and FS devised and guided the statistical analyses. FS, BC, and GM contributed to the writing, editing and critical revision of the intellectual content of the manuscript. All authors approved the final version of this manuscript.

Abstract

Objectives: There is developing interest in transdiagnostic interventions that focus on processes which are shared across mental health conditions rather than on a specific diagnosis. We sought to investigate the effectiveness of a transdiagnostic intervention, Mindfulness-integrated Cognitive Behavior Therapy (MiCBT), which utilizes interoceptive awareness and equanimity processes, underpinned by the co-emergence model of reinforcement, which proposes interoception as the locus of reinforcement.

Methods: This study investigated the effectiveness of a group-based eight-week MiCBT intervention to decrease depression and anxiety symptoms and increase well-being in a transdiagnostic population in primary health care delivered by an expert therapist. Participants (N = 118, aged 20-72) were randomised to two groups (MiCBT, TAU). Outcomes were assessed at pre-, mid- and post-treatment and at 6-month follow-up. The primary outcome was psychological distress, measured by the Depression, Anxiety and Stress Scale-21 (DASS-21). Secondary outcome measures were the Kessler Psychological Distress Scale-10 (K10), Satisfaction with Life Scale (SWLS), and Flourishing Scale (FS). Process measures of

interoceptive awareness, metacognitive awareness (decentering), equanimity, and social functioning were included to investigate putative mediators.

Results: The MiCBT intervention significantly reduced depression, anxiety and stress at post-treatment. Gains were maintained at 6-month follow-up (*p < .000, d < .38,)* and had positive effects on flourishing (*d <.24, p <.000)*. Mediation analysis suggested equanimity to be the most influential mediator of the primary outcome.

Conclusions: The results support the transdiagnostic effectiveness of MiCBT in a primary mental health care with heterogenous groups. These promising results support the scaled-up implementation of this intervention.

Key words: mindfulness, equanimity, transdiagnostic treatment, mental health, interoception, mindfulness-integrated cognitive behaviour therapy (MiCBT).

Over the last few years, there has been an increasing interest in transdiagnostic therapies, which are interventions that focus on underlying causal processes common to many conditions rather than targeting specific symptoms or particular diagnoses (Sauer-Zavala et al., 2017). Transdiagnostic therapies that target common processes such as attention regulation, metacognitive awareness and avoidance can treat multiple conditions, both within and across individuals, which is advantageous for both group-based and individual therapies and obviates the need to tailor the content to particular diagnostic groups. It is valuable to have therapies that can accommodate comorbidities that are so common in mental health conditions (Kessler et al., 2002; Pollack, 2005; Sekula et al., 2003) and which have been associated with greater service use but worse outcomes and greater unmet need (Chen et al., 2013). Nevertheless, psychological therapies including traditional cognitive-behavioral therapies (CBT), and more recently mindfulness-based therapies are, in the main, disorder specific following a medical model in which patients are diagnosed with a primary presenting problem that is targeted for treatment.

Recently, interest in transdiagnostic therapies appears to be growing in both first and second wave cognitive-behavioral therapies and in the more recent third wave CBT approaches (Farchione et al., 2012) (Hayes, 2017), although initial evidence does not indicate improved therapeutic outcomes in the latter (Craske, 2012). Nevertheless, mindfulness-based therapies have placed more emphasis on targeting underlying behavioral and cognitive processes associated with distress, such as the lack of mindfulness, acceptance, and attentional flexibility (Newby, 2015). A recent review of implementation of Mindfulness-Based Cognitive Therapy for depression (MBCT; Segal et al., 2002, 2013) in the United Kingdom found that although the program was specifically designed for relapse prevention in recurrent depression, it was being widely offered for a variety of conditions that included depression, anxiety and chronic pain/fatigue (Crane and Kuyken, 2013). The expansion and popularity of MBCT demonstrates the need for evidence-based transdiagnostic interventions that can be flexibly applied to a range of conditions as well as their comorbidities.

MiCBT, a third wave cognitive behavioural therapy, draws on both CBT and mindfulness techniques. MiCBT can be differentiated from its apparent nearest relation, MBCT in that MiCBT: a) is designed for acute transdiagnostic mental health conditions; b) is aligned with behavioral aspects of CBT especially exposure therapy utilizing interoceptive and exteroceptive desensitization, and equanimity as its core processes; and c) integrates a Buddhist psychological approach that includes mindfulness, various meditations, explicit ethics and loving kindness meditation into the therapy model. The meditation skills are adopted from the Vipassana (insight) tradition taught by U Ba Khin and Satya Narayan Goenka (Cayoun, 2011). Accordingly, MiCBT provides a structured sequence of mindfulness practices: 1) body awareness through progressive muscle relaxation and attention to posture and movement in daily activity, followed by 2) mindfulness of breath to increase attention regulation, through metacognitive awareness and response inhibition, 3) various body-scanning methods to develop interoceptive awareness and equanimity (body-scanning methods comprise 75% of the meditations in MiCBT), and 4) loving

kindness meditation to increase empathy and compassion for self and others. MiCBT incorporates exposure methods, such as graded imaginal and *in vivo* exposure, to increase tolerance of interoceptive signals while reducing reactivity to avoided situations. Exposure is applied to potential harmful behaviors which patients learn to prevent out of compassion for themselves and others. These include behaviors in interpersonal contexts, thus improving interpersonal skills and social functioning. Improved social functioning and connectedness with others tends to enhance well-being and flourishing (Eraslan-Capan, 2016; Saeri et al., 2018) which in turn helps prevent relapse (Cayoun, 2017).

The rationale for MiCBT is described in detail in the protocol paper for the current study (Francis et al., 2020; Francis, 2020) and elsewhere (Cayoun, 2011, 2015; Francis et al., 2019). Briefly, the rationale is based on the co-emergence model of reinforcement (Cayoun, 2011), which is explicitly taught in the program (see Francis et al., 2020, Figure 1, p. 3). The model proposes that following a sensory stimulus (either from external sources through sight, smell, touch, taste, hearing or from internal sources through thinking, remembering or interoception) an evaluative process takes place, in which the sensory event is contextualized in terms of its personal relevance. Identifying with the stimulus results in spontaneous co-emerging interoception which directs behavior. According to the co-emergence model behavior is moderated by the quality and strength of co-emerging interoceptive experience, where unpleasant body sensations are more likely to be the antecedents of avoidant behavior, while pleasant sensations are more likely to generate seeking behaviors. This approach to reinforcement therefore advances that behavior is prescribed by interoceptive cues, rather than its consequence on the environment.

An important underlying mechanism of psychological conditions, namely over-reactivity to unpleasant interoceptive signals, is based on this principle of reinforcement. According to the MiCBT rationale, behavior modification is brought about through the development of equanimity towards interoceptive signals. Equanimity is achieved through a process of gentle and systematic

exposure during body scanning to practice and cultivate non-reactivity to body sensations. Since habitual reactivity is a common factor shared by numerous mental health conditions (Vøllestad et al., 2011), treatments which address these underlying processes, such as MiCBT, are more likely to have transdiagnostic effects. It is now established that interoceptive awareness is impaired in mental health disorders (Khalsa et al., 2018) and as MiCBT puts a great emphasis on increasing interoceptive awareness and desensitization, it is expected to improve emotion regulation across a range of emotional disorders, including those with complex comorbidities.

There is growing evidence supporting the efficacy of MiCBT in different contexts, including depression, anxiety and depression in multiple sclerosis (Bahrani et al., 2017; Pouyanfard et al., 2020), anxiety and depression during pregnancy (Yazdanimehr et al., 2016), sports anxiety, (Scott-Hamilton et al., 2016), pain and pain self-efficacy in patients with breast cancer (Mozafari-Motlagh et al. 2019), and chronic pain in the general population (Cayoun, Simmons, et al., 2019). A preliminary pilot study was conducted in a private psychology practice setting where MiCBT was implemented in eight groups of participants ($N = 69$) with mixed diagnoses (Francis, 2013). Although the study was uncontrolled, the results were promising including significant reductions in the depression, anxiety and stress across disorders.

The aim of the current study was to investigate the effectiveness of MiCBT as a transdiagnostic group-based therapy to decrease depression, stress and anxiety for patients with a range of mild to severe mental health conditions in a primary health care setting. The hypotheses were that, compared to the control group, the MiCBT group would show a greater decrease in self-report assessments of depression, anxiety and stress and improvements in life satisfaction and flourishing. It was also hypothesized that the improvements would be maintained over a six-month follow-up period. Additionally, it was hypothesized that improvements in the clinical measures as a function of MiCBT relative to the control group would be mediated by a) improvements in awareness (metacognitive and interoceptive awareness) and b) equanimity. We

also hypothesized that changes in life satisfaction and flourishing scores would be mediated by improvements in interpersonal skills compared to awareness and equanimity.

Method

Participants were randomised to either the MiCBT or the treatment-as-usual (wait-list) control condition. Participants on both conditions continued with treatment-as-usual (TAU) including medications and/or psychological therapy. The MiCBT intervention was offered to control group participants following the completion of the 6-month follow-up assessment.

Recruitment

Information about the study was circulated to medical and psychology clinics in the city and inner suburbs of Melbourne and rolling recruitment took place over two years through referrals from general medical practitioners, psychiatrists and psychologists in Melbourne. Inclusion criteria were: age 18-75; fluent in English; and with a Kessler Psychological Distress Scale-10 (K10) score of 20 or more. Exclusion criteria included: less than 18 years; non-English speakers; current psychotic symptoms, current drug or alcohol dependency, current diagnosis of borderline or antisocial personality disorder, pervasive developmental delay, organic mental disorder, or prescribed more than 20mg diazepam equivalent per day. Patients who were referred to the study were interviewed to confirm eligibility and to gain written consent. A total of 206 patients expressed interest in the study and were assessed. Of the 80 participants excluded from the study, 6 did not meet criteria and 74 declined to participate (see Figure 1).

Randomization

Participants were allocated a unique identification number and randomised to either the control or the MiCBT group. Randomization was stratified based on K10 psychological distress: K10 score <30; mild to moderate; ≥ 30; severe; psychotropic medication (yes/no) and gender. Randomization was conducted by a researcher who was independent from the recruitment,

assessment and treatment of participants using Stata version 14SE by means of random allocation of treatments balanced in blocks.

Participants

In total, 118 participants were included in the study (aged 20 -72 years), of whom 86 identified as female (72.9%) and 31 as male (26.3%) and one as "other" (0.8%). As per inclusion criteria, all participants had a K10 score of ≥ 20 on referral and this was administered again at the start of the study. Demographic characteristics and baseline clinical characteristics are shown in Table 1.

Table 1: Participant characteristics

Variable	MiCBT group	Control group
Gender: n (%)		
Male,	15 (24.6)	16 (28.1)
Female	46 (75.4)	40 (70.2)
Other		1 (1.8)
Age: n (%)		
18-34	21 (34.4)	18(31.6)
35-49	15 (24.6)	24 (42.1)
50-75	25 (41.0)	15 (26.3)
Nationality: n (%)		
Born in Australia	49 (80.3)	47 (82.5)
Born outside Australia	12 (19.7)	10 (17.5)
Marital status: n (%)		
Married/in a relationship	25 (55.7)	32 (56.1)
Single/divorced/separated	34 (41)	23 (40.4)
Other	2 (3.3)	2 (3.5)
Education: n (%)		
High school education only	12 (19.7)	4 (7)
Post high school education	49 (80.3)	53 (93)
Taking medications for psychological conditions n (%)	26 (70)	35 (66.7)
Practice meditation n (%)	18(30)	19(33.3)
K10 score at referral: mean (SD)	29.4 (6.1)	29.3 (5.6)
K10 score T0	27.7 (7.0)	29.0 (6.3)
K10 score at referral n (%)		
< 30 (mild-moderate)	30 (49.2)	30 (52.6)
≥ 30 (severe)	31 (50.8)	27 (47.4)
K10 score T0 n (%)		
< 30 (mild-moderate)	38 (62.3)	28 (49)
≥ 30 (severe)	23 (37.7)	29 (51)

Participants tended to be well educated, 87% having tertiary education. In both groups approximately 70% were taking some form of psychotropic medication; 30% had some meditation experience and/or currently had some meditation practice.

Participant timeline

Referring General Medical Practitioners administered an initial K10 as part of the referral process. Participants were interviewed for eligibility and those who were eligible were randomised to either the control or MiCBT condition. Baseline assessments were administered post-randomization, 1 week before the commencement of the program so that the assessment

timeframe could be standardized across participants and to address the variation in the period between recruitment and the start of the intervention. This was expected to achieve maximum sensitivity to change taking account of fluctuating mental health conditions. The flow of participants through the study is outlined in Figure 1.

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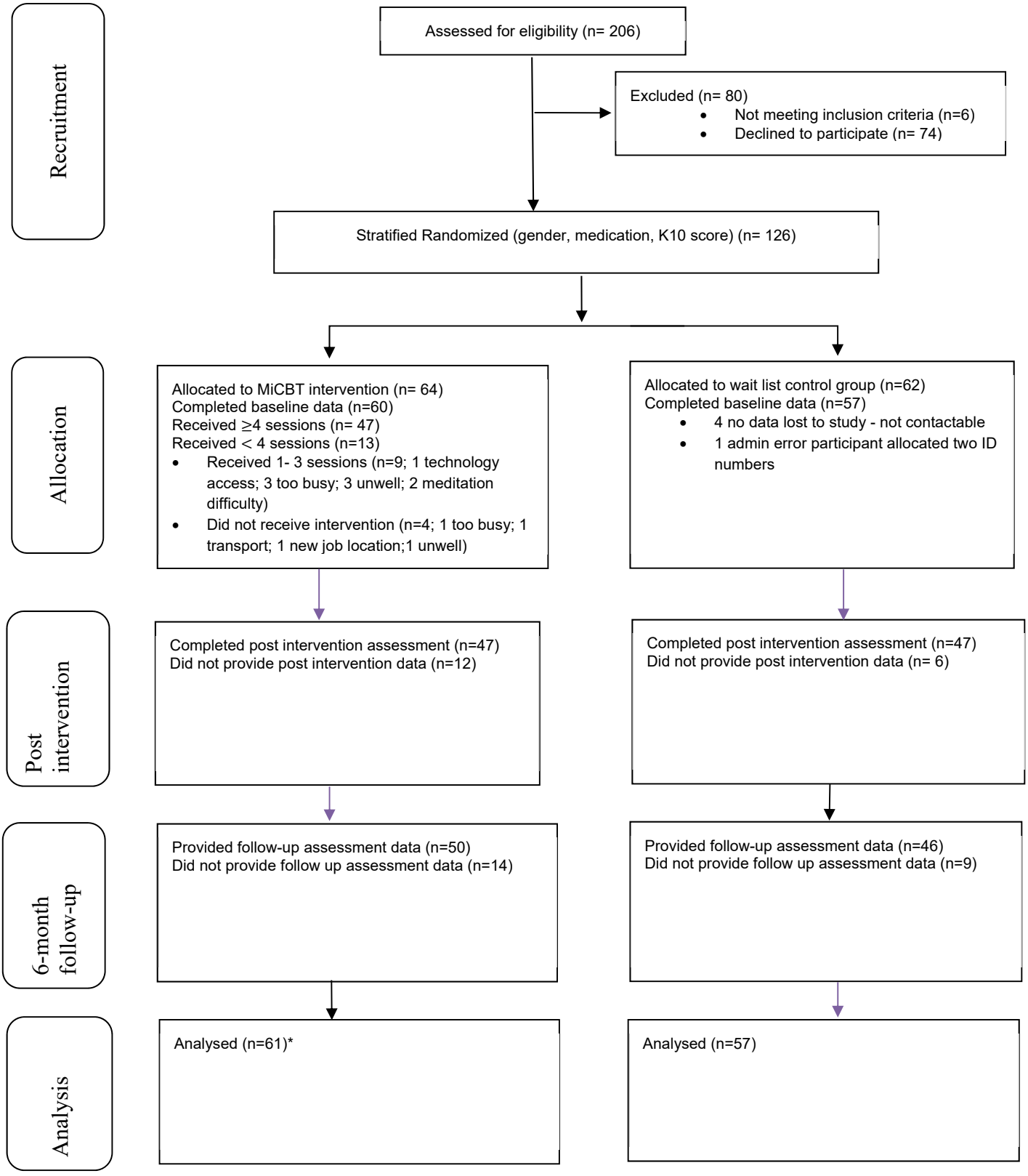
Figure1: CONSORT flow diagram



*one participant provided data at post and follow up only

Measures

The measures are described fully in the protocol paper (Frances et al., 2020) and all exhibit satisfactory psychometric properties. Both the K10 and DASS-21 are used in the current study and they both measure psychological distress. The DASS-21 however provides both a global measure (total score) and measures of depression, anxiety and stress as separate subscales. The DASS-21 scores were the prime focus of the analysis.

Primary outcome measure

Depression, Anxiety, and Stress Scale (DASS-21). The DASS-21 is a 21-item self-report questionnaire designed to measure three domains: depression, anxiety and stress (Lovibond & Lovibond, 1995). In accordance with the Lovibond Manual for the Depression Anxiety and Stress Scales, the scores on the DASS-21 are doubled to align with the norms for the DASS-42. Higher scores indicate more severe symptoms. Scores may be classified in terms of ranges of clinical significance; normal, mild, moderate, severe or extreme range.

Secondary outcome measures

Kessler Psychological Distress Scale (K10). The K10 is a 10-item scale for the screening of psychological distress with a focus on anxiety and depressive symptoms over the last 4 weeks (Kessler et al., 2002). This measure is commonly used as a screening tool by general practitioners in Australia to identify people eligible for a Mental Health Care Plan, a Medicare scheme for subsidized psychological treatment in Australia.

Satisfaction with Life Scale (SWLS). This is a 5-item self-report measure of global judgement of life satisfaction (Diener et al., 1985).

The Flourishing Scale (FS). The FS is an 8-item self-report measure of psychological well-being, designed to tap self-perception of aspects of well-being such as optimism, positive relationships and self-esteem (Diener et al., 2010).

Process measures reflecting the aspects of mindfulness which are the focus of MiCBT

Multi-dimensional Assessment of Interoceptive Awareness (MAIA). The MAIA is a 32-item self-report measure of interoceptive awareness (Mehling et al., 2012). The MAIA has eight subscales, all of which reflect aspects of interoception. We therefore decided to use total MAIA scores in the current study.

The Nonattachment Scale (NAS). The NAS is a 30-item self-report scale. It is a unidimensional measure of attachment as the term is used in Buddhism tapping the construct of being equanimous, flexible and receptive (Sahdra et al., 2010).

The Experiences Questionnaire (EQ). This is a 20-item self-report measure of decentering; the ability to observe thoughts and feelings with objectivity rather than identifying with experiences (Fresco et al., 2007). Metacognitive awareness is a key element of decentering conceptualized as a protective factor assisting with resilience to depressive relapse (Bernstein et al., 2015; Wells, 2007). For the purposes of this paper metacognitive awareness and decentering are used interchangeably.

Mindfulness-based Self-Efficacy Scale-Revised (MSES–R). The MSES is a 22-item self-report measure designed to assess the changes in levels of perceived self-efficacy as a result of mindfulness-based therapy (Cayoun, 2011). The six subscales taken in two clusters are, Emotion Regulation, Distress Tolerance, Equanimity (considered here as measuring aspects of equanimity; MSES-R-E), and Taking Responsibility, Social Skills, and Interpersonal effectiveness (considered here as measuring aspects of interpersonal skills; MSES-R-I).

Meditation practice. Participants recorded daily meditation practice on a prescribed form in the program notes and the weekly total was collected at each session on an individual form not visible to other participants.

Adverse effects. Each week participants were asked about their practice so that any issues raised could be addressed. In a few instances minor modifications to practice were recommended such as continuing with an exercise a little longer before moving to the next exercise. At the 6-month follow-up questions were included regarding any adverse or unexpected difficult experiences believed to be as a result of meditating. We took these questions from a recent study about the of experiences that occur in association with meditation practices (Lindahl et al., 2017). The questions were:

1. "Did you have any unexpected, challenging, or difficult experiences that you associate with your practice of meditation?"
2. "How did these experiences impact your life"?

Procedure

All participants completed all measures one week before the start of the MiCBT group intervention (T0), after week 4 (T1), at week 8 (T2, post-intervention), and then again after a 6-month follow up period (T3). Demographic questions were included at T0, program evaluation questions at T2, and at T3 there were questions about meditation practice in the last 6 months as well as about any adverse effects. Measures were administered online using Qualtrics survey software, with the exception of the amount of meditation practice which was recorded by participants as described above. Participants were emailed a link to the online measures utilizing their unique identification number. All data was collected online (except meditation practice hours) thus minimizing researcher bias.

Intervention

The intervention protocol was adapted from the published protocols (Cayoun, 2011, 2015) and consisted of eight weekly two hour classes. Adaptations from the original 8-week protocol included: a) using the most recent publicly available audio instructions from Cayoun (2015; used with permission) and b) individual sessions between groups were not routinely offered. In accordance with the protocol, a guided meditation was conducted at each session to introduce the practice required for the following week. The remainder of the time in the sessions was used for a review and discussion about practice experiences and psychoeducation, including the rationale for practices and homework tasks. Weekly homework tasks included two half-hour meditation sessions per day. Intervention group sizes varied between 8 and 13 participants. The intervention was delivered by a registered psychologist trained in MiCBT who had been implementing MiCBT regularly over the past 10 years. Handouts for each session were provided as a workbook at the start of treatment. The handouts included practice record sheets, worksheets and a list of homework tasks. The treatment outline is briefly depicted in Figure 2.

Figure 2: Four stage model of MiCBT 8-week program

1. Personal stage: Weeks 1, 2 and 3	**2. Exposure stage: Weeks 4 and 5**	**3. Interpersonal stage: Week 6**	**4. Empathic stage: Weeks 7 and 8**
• Progressive muscle relaxation and attention to body posture • Mindfulness of breath (attending to breath) • Body scanning (Burmese Vipassana tradition) • Co-emergence model of reinforcement	• Advanced body scanning • Overcoming avoidance • Integrating mindfulness and CBT - exposure tasks to address avoidance	• Advanced body scanning • Moving from focus on self to others; exposure to interpersonal difficulties • Mindful assertiveness • Taking responsibility for own experience in interpersonal situations; exposure tasks for interpersonal avoidance	• More advanced and flowing body scanning • Empathy and compassion with loving kindness meditation • Non-attachment to sense of self • Ethics – minimizing harm to self and others

Statistical analyses

For the main analyses we used mixed-model repeated measures using Stata version 16 to examine the effects of the MiCBT intervention on outcomes. The effect of MiCBT on each outcome measure was tested using a mixed effects REML regression for each outcome variable with participants included as random effects and group and time as fixed effects. Mixed methods repeated measures (MMRM) was used because mixed methods account for the correlations between repeated measurements within each participant.

An intention-to-treat (ITT) analysis was used so that incomplete data was not discarded. Missing data was not imputed. We analysed all available data. Therefore, if a participant did not provide data at all time-points we included the data sets that they provided. Because of the set-up of the online questions preventing missed questions, missing data was for all data at a particular time point. While this was usually because a participant had dropped out of the study, there are a small number of instances where T1 or T2 data was missing but the follow up data was completed. Missing data for the DASS-21 scores across timepoints were: T0=1; T1=13; T2=24; T3=20. An overview of the two planned mediation models is described in Francis et al., (2020). The first planned model comprised: group (MiCBT vs TAU-wait-list control) as the independent variable (IV); clinical and wellbeing measures as the dependent variable(s) (DV); and awareness (metacognitive and interoceptive) and equanimity measures that revealed significant group x time interactions as mediators. It was intended to test changes occurring both during the program and during the follow-up phase. The second planned model comprised: group as the independent variable; T3 psychological wellbeing as the dependent variable; and T2 social functioning, awareness and equanimity measures that revealed significant group x time interactions as mediators.

Following correlation analysis of the model variables using Pearson's correlation coefficients, model building commenced with a series of single mediation models to identify relevant mediators for the final model (MacKinnon & Luecken, 2011; van Kesteren & Oberski, 2019). To take into account changes over time, baseline (pre-intervention period) measures of the outcome and mediator ("lags") were included in the modelling as covariates in preference to difference scores, as recommended by Valente and MacKinnon (2017) and Hayes (2018). Analyses for the two planned multiple mediation models used standardized residualized change scores for mediator and outcome variables. Standardized residuals were calculated using linear regression in which baseline scores predicted post-intervention scores for mediators and baseline scores predicted follow-up scores for the outcome variable.

Using the PROCESS macro version 3.5 for SPSS (Hayes, 2018), point estimates of each indirect effect (ab) were computed by averaging the ab product from 5000 random samples of the original data. Indirect effects are significant if the lower and upper boundaries of the bootstrapped 95% confidence intervals (CIs) do not include zero. Path coefficients were also computed in PROCESS for: path a, the effect of the IV on the mediator; path b, the effect of the mediator on the DV controlling for the IV; and path c', the direct effect of the IV on the DV controlling for the mediator. Unstandardized regression coefficients are reported (Hayes, 2018). Data were analyzed using the Statistical Package for Social Sciences (SPSS) Version 26.0 software (Corp. 2019). An alpha level of .05 was set for the main inferential tests.

Results

Data from 118 participants were analyzed. The MiCBT and control groups were compared at time points: pre- (T0), mid- (T1), post- (T2) and at follow-up (T3). The MiCBT group improved significantly more that the control group across T1-T3. Of the 47 participants who completed 4

or more sessions of 8-week MiCBT intervention, the average attendance was 6.0 sessions (SD 2.0) and 18 participants attended all 8 sessions. Control group participants received treatment as usual during the 8-week intervention period and until the end of the 6-month follow up at which time the MiCBT intervention was offered. There was no significant difference in K10 change scores from referral to baseline between the control group (M = -.28, SD = 5.58) and MiCBT group (M = -2.03, SD = 5.68; t (115) = 1.68, p = .10, two-tailed). Although more participants in the MiCBT group reported a reduction in symptoms in the waiting period before the program commenced the mean difference = 1.75 (CI -.31 to 3.82) was small (eta squared = .02).

The mean number of meditation practice hours across the 8-week program was 27.25 (13.70) median = 30 hours; range = 0 - 49. The mean weekly practice hours were 4.47 hours. The mean number of classes attended was 6.22 (1.87); median 7.0; range = 1-8. The dropout rate for the control and MiCBT groups was 19% and 18% respectively. Information about medications at follow up was collected from the MiCBT group. The majority of participants (78%) reported no change to their medications at the 6-month follow-up. For the remaining 22%, three people lowered the dose, two ceased medication, three changed type of medication and one person increased the medication dose. Table 2 presents the responses to questions regarding any challenging (adverse) effects that MiCBT participants may have experienced.

Preliminary analysis using binary logistic regression indicated that missing data for the primary outcome variable, the DASS-21, across the four data collection points was not associated with age, gender, education, baseline K10 and medication.

Main analysis

Supplementary Table 1 presents the means, standard deviations and medians of all measurement instruments at the four time points for each group. Table 3 presents the effect

sizes and Table 4 and Supplementary Table 2 present the intervention differences estimated by the regression model for the effects of time (i.e., model adjusted intervention difference) for the outcome and mediator measures respectively. Timepoints T1-T3 are all compared to baseline T0. Intervention status is MiCBT compared to control. Results showed that all outcome and mediation measures showed significant improvement over time compared to baseline. The primary outcome measure (DASS-21) demonstrated significant differences between the MiCBT and the control groups (p <.000), as did the K10 and the FS. Only the SWLS failed to reach significance (p = 0.177). The differences between the MiCBT and control groups adjusting for the effects of time were as follows: DASS-21 -9.17, (95% CI -12.32 - 6.01); K10 -3.54, (95% CI -4.62 - 2.47); SWLS 0.59, (95% CI -0.27 - 1.45); FS 2.17 (95% CI 1.03-3.30). All mediation measures demonstrated significance (p < .000). The differences between the MiCBT and control groups adjusting for the effects of time were as follows: MSES-R-E (Equanimity) 3.79, (95% CI 2.71, 4.88); MSES-R-I (Interpersonal skills) 1.79, 95% (CI 1.07, 2.51); MAIA (12.23, 95% CI 10.09 - 14.38); NAS was 11.47, 95% (CI 8.73-14.21); Decentering was 3.83, (95% CI 2.95 – 4.71). Because all the measures at baseline were similar in both groups (Supplementary Table 1), and improved over time following baseline, the intervention status results provide evidence that MiCBT improved participant outcomes on the DASS-21, K10, FS compared to controls along with all mediation measures.

Table 2: Unexpected challenging or difficult effects

1. *Did you have any unexpected, challenging or difficult experiences that you associate with your practice of meditation?*
   - 19 participants responded "yes" (31%)

2. *How did* these *experiences impact your life?*
   - 12 of the 19 of those who responded "yes" to the previous question provided a description of adverse experiences.

Below is the list of responses that described effects that may be considered adverse: n=12

1. They caused mood swings and changed the way some of my relationships progressed
2. I needed to rest a lot
3. Limited time to practice
4. Not to such a great extent but I can become irritable
5. Some positive, some negative
6. Hard to explain but affected my anxiety
7. Made me want to avoid meditating
8. In the beginning there were extremely intense sensations that were really, really distracting, particularly at work. I spent my first week constantly feeling as though I would have a panic attack, along with intense pain throughout my body. I had to remind myself it was just part of the process. With a difficult first week and a few moments of intense memories throughout body scanning, the results were incredible. I never anticipated to feel 'at peace', or 'content' in my life... I think that's getting closer to happiness? Relationships in my life have improved dramatically, and the ruminating over this person and that person, this situation or that, wasn't an issue – it's like a happy oblivion, but still aware of all the craziness.
9. They brought unprocessed trauma closer to the surface
10. The body scanning brought up some issues that I had placed on emotional lockdown and I went through a period of intense healing and rest after doing the course
11. For the first two weeks meditation felt great, around four to six weeks I noticed that I was becoming more aware of challenging emotions in my body, that were perhaps previously ignored.
12. Some PTSD triggers

Table 3: Outcome effect sizes

Model Calculated (95% CI)				Estimated Cohen's d
	Control	Intervention	Difference	
Outcome Variables				
DASS-21	47.12 (44.97, 49.27)	37.95 (35.82, 40.08)	-9.17 (-12.32, -6.01)	0.38
K10	27.19 (26.43-27.95)	23.65 (22.96-24.34)	-3.54 (-5.81, -1.27)	0.45
SWLS	18.95 (18.36, 19.54)	19.55 (18.98, 20.11)	.59 (-.27, 1.45)	0.08
FS	37.35 (36.64, 38.06)	39.51 (38.68, 40.34)	2.17 (1.02, -3.30)	0.24
Mediator variables				
MAIA	62.38 (61.02-63.73)	74.61 (72.81-76.40)	12.23 (10.09, 14.38)	0.67
NAS	108.41 (106.62-110.22)	119.89 (117.70-122.07)	11.47 (8.72, 14.21)	0.48
EQ (decentering)	30.10 (29.57, 30.64)	33.93 (33.24, 34.62)	3.83 (2.95, 4.71)	0.16
MSES-R-E (Equanimity)	26.29 (25.67, 26.92)	30.09 (29.21, 30.97)	3.80 (2.71, 4.88)	0.50
MSES-R-I (Interpersonal)	22.28 (21.78, 22.77))	24.07 (23.56, 24.58)	1.79 (1.07,2.51)	0.34

Notes. DASS-21 = Depression, Anxiety, and Stress Scale-21; K10 = Kessler Psychological Distress Scale; SWLS = Satisfaction with Life Scale; FS = Flourishing Scale; MAIA = Multi-dimensional Assessment of Interoceptive Awareness; NAS = Nonattachment Scale; EQ = Experiences Questionnaire; MSES-R-E = Mindfulness-based Self-Efficacy Scale-Revised-Equanimity subscales; MSES-R-I = Mindfulness-based Self-Efficacy Scale-Revised-Interpersonal skills subscales.

Mediation analyses

Correlations between model variables are shown in Supplementary Tables 3.1 and 3.2. T1 correlations were substantially lower than at T3-4 and therefore the strength of correlation changes as a function of the intervention. Because all mediators showed significant group x time interactions in the main analyses, we constrained the number of analyses by limiting the DV to the primary outcome (rather than including both the DASS-21 and the K10), and the time frame to the follow-up (rather than both the follow-up and treatment period). Focusing on mediators measured at the end of treatment affecting outcome measured at 6-month follow-up enabled the

examination of mechanisms related to the full effects of treatment and their sustainability over time, which we considered to be of most interest. This timeframe allowed for changes in the mediator during the treatment phase to be measured prior to the change in outcome.

The single mediation analyses included four independent variable mediation models (MAIA, EQ, NAS, MSES-R-E, MESS-R-S) to assess symptom change in the DASS-21 as a function of MiCBT versus control during the timeframe of the follow-up period (mediators measured at post-intervention; outcomes at 6 months) and five independent variable mediation models (MAIA, EQ, NAS, MSES-R-E, MSES-R-S) assessing change in the FS as a function of treatment condition during the same timeframe. The MAIA, EQ, NAS and MSES-E were each significant mediators between treatment and outcome as measured by DASS. In addition, the MAIA, EQ, NAS and MSES-E and MSES-S were significant mediators between intervention and outcome as assessed by FS. The results of the single mediation pathways suggested overlap in the mediation effects since the sum of their proportions add up to more than 100%. This indicates certain paths are being counted twice - they affect each other or there are other interactions between them affecting the outcome (VanderWeele & Vansteelandt, 2014).

Model 1

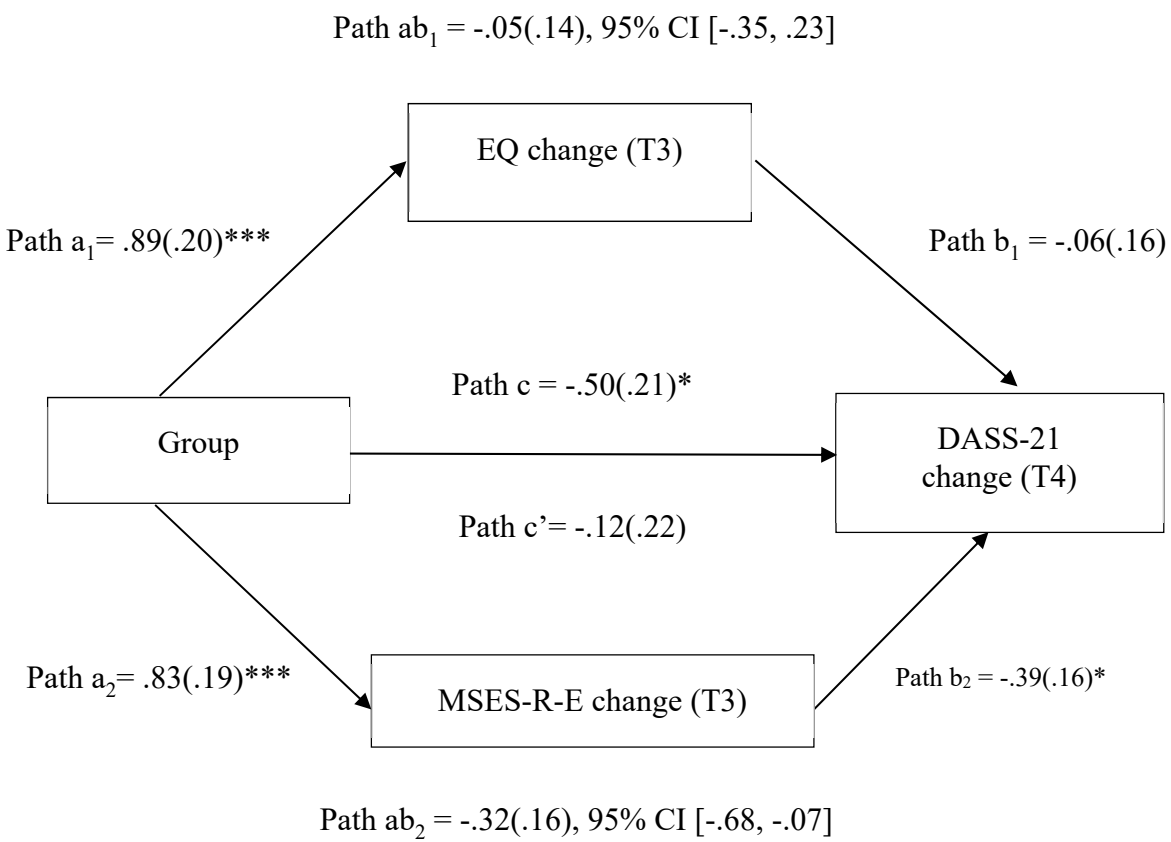
Awareness (interoceptive awareness measured by the MAIA and metacognitive awareness measured by EQ) and equanimity (measured by the MSES-R-E and NAS) are considered to be the two core abilities developed in MiCBT, which are developed independently and simultaneously (Zeng et al., 2015). The relative influence of awareness and equanimity on outcomes was examined in the first (parallel) multiple mediation model. Given theoretical overlap and large correlations between the mediators (r = 0.45 - 0.85) one candidate variable was selected from each construct based on having the strongest correlation with the DASS-21 at time 4 (see Supplementary Table 3.2). These were MSES-R-E and EQ. Results are shown in Figure 4. While 65.3% of the total effect of MiCBT relative to control on the DASS-21 at time 4 was

due to the indirect effect of MSES-R-E measured at time 3, only 10.8% of total effect was due to the indirect effect of EQ at time 3. While only MSES-R-E had a significant indirect effect on the DASS-21 at time 4, the difference between the two indirect effects was not significant (B =

Model 2

In a second parallel model (Figure 5), we examined whether the effect of MiCBT versus control on flourishing scale scores are mediated more by improvements in interpersonal skills compared to awareness and equanimity. Results are shown in Figure 5. While the total indirect effect of EQ, MSES-R-E and MSES-R-S was significant, B = .43(.15) 95% CI [.19, .75], and accounted for 64.8% of the total effect of Group on FS at time 4, none of the individual mediators when combined had a significant indirect effect.

Figure 3: Path diagram depicting model 1, testing whether changes in equanimity and awareness mediate the effects of MiCBT versus control on improvements in the DASS-21. Unstandardized path coefficients are displayed



Notes. *<.05; ** <.01; ***<.001.
EQ = Experiences Questionnaire; MSES-R-E = Mindfulness-based Self-Efficacy Scale-Revised-Equanimity subscales; DASS-21 = Depression, Anxiety, and Stress Scale-21.
a, b, c' and c are unstandardized regression coefficients (with standard errors) which represent predicting the mediator from group (a), DASS-21 change from M controlling for group (b), DASS-21change from group controlling for both mediators (direct effect, c'), and DASS-21 change from group *not* controlling for the mediators (total effect, c). The product of a and b paths, ab, represents the mediated or indirect effect. Change refers to standardised residualized change scores

Exploratory analyses to investigate each of the three DASS-21subscales (Depression, Anxiety and Stress) indicate that there was a similar pattern of improved scores across each subscale. The level of symptom severity was spread across the three subscales and, across the sample, more participants had severe stress compared to severe anxiety and depression.

Analysis was conducted using an adaptation of the Ronk et al. classification system (Ronk 2013) for indicating recovery (deteriorated, improved, recovered). For the DASS-21 we used the following categories to define clinical significance: normal range; mild-moderate range (collapsing mild and moderate together) and severe-extreme range (collapsing severe and extreme categories together). We define deteriorated as making no clinically significant change (i.e. did not move to a less severe category). Improved is defined as moved to a less severe range and recovered is defined as moved to normal range. Results indicated that in the control group, 40.5% (17/42) of participants deteriorated and 21.4% (9/42) recovered at follow up. Participants in the MiCBT group showed significantly greater clinical improvement compared to controls with just 16.7% (8/48) deteriorating and 41.7% (20/48) recovering. Overall, 59.5% (25/42) of participants in the control group showed improvement or recovery compared to 83.3% (40/48) of participants in the MiCBT group ($p < 0.05$).

If treatment success is defined as the sum of the cases that improved or recovered then was 4.2 meaning that on average, 4.2 patients would have to receive MiCBT (instead of the control) for one patient to improve or recover who would not have got better without MiCBT. The incidence of improvement or recovery in the control group was: 59.5% (25/42) and in the MiCBT group it was 83.3% (40/48). Individuals in the MiCBT group had higher odds of a successful treatment (OR: 3.4, 95% CI: 1.3 - 9.0; $p = 0.01$) and their relative risk for deterioration was 0.4 (95%CI: 0.2 -0.9). Chi-square for group differences: 6.3, $p = 0.01$.

If treatment success is defined as the sum of the cases that recovered, the number needed to treat (NNT) was 2.7 meaning that on average, 2.7 patients would have to receive MiCBT

(instead of the control) for one patient to recover who would not have got better without MiCBT. The incidence of recovery in the control group was: 34.6% (9/26) and in the MiCBT group it was 71.4% (20/28). Individuals in the MiCBT group had higher odds of a successful treatment (OR: 4.7, 95% CI: 1.5 - 14.9; p = .008) and their relative risk for deterioration was 0.4 (95%CI: 0.2 -0.8). Chi-square for group differences: 7.4, p = 0.007.

74% of participants who improved or recovered did at least 20 hours of meditation practice (i.e. 2.5 hours per week) while 26% improved or recovered with less than 20 hours. 52% of those who recovered or improved attended all 8 sessions and 94% if improved/recovered group attended at least 5 sessions.

Exploratory analysis of the data from those who had severe levels of distress at T0 suggests that the MiCBT intervention was effective for severe anxiety with 77% recovered or improved (13/17) compared to 33% (4/12) recovered or improved in the control group. For those with severe levels of stress at T0 81% recovered or improved (13/19) compared to 40% (6/15) in the control group. MiCBT was no better than usual treatment in the severely depressed group (50% improved or recovered- 5/10), compared to 57% (8/14) of the control group.

Discussion

The findings support our hypotheses that MiCBT would a) reduce symptoms of depression, anxiety and stress as measured by the total DASS-21 scores and b) improved flourishing significantly more than TAU, and c) that such differential improvements would be sustained over a 6-month follow-up period. The findings did not, however, support our hypothesis of improved life satisfaction. Findings also showed that all the putative mediating measures improved in the MiCBT group relative to controls and single mediation models indicated that equanimity, interoceptive awareness, decentering and interpersonal skills were all significant mediators of symptom reduction, as measured by the DASS-21. Results of parallel mediation models suggested that equanimity was the most important change variable for symptom reduction,

whereas interpersonal skills did not show a significant mediation effect for flourishing when compared to awareness (decentering) and equanimity.

The severity of clinical symptoms (mild to severe) was reflective of presentations in primary health care. The rate of adherence to treatment is consistent with other studies (e.g. Piet, 2010; King, 2013) with 78% of participants receiving four or more sessions. The mean practice hours over the 8 weeks was 4.5 hours per week (SD 13.4) which was considerably less than the recommended 7 hours per week. Adherence to standard program delivery was supported by the use of audio instructions that provide the rationale for each exercise as well as guidance for each meditation.

A strength of the current study is that data about adverse (difficult unexpected) effects was actively collected. In MiCBT trainees are explicitly forewarned that both pleasant and unpleasant body sensations are to be expected during practice and to remain equanimous to whatever arises. The data indicated that for 31% of participants there were unexpected experiences. Different frequencies of unexpected difficult effects from meditation in a mindfulness-based intervention (MBI) have been reported dependent on methodological approach ranging from 3.7% to 33.2% (Farias & Wikholm, 2016). Furthermore, it is recognized that in the Buddhist Vipassana tradition there are stages of development of insight or knowledge some of which involve negative experiences such as fear, dissolution, disgust which may result in potential clinical effects (Grabovac, 2014). Challenges and difficulties in MiCBT are to be expected because the therapeutic strategy is fundamentally exposure based: by developing equanimity towards sensations, a desensitization process takes place enabling tolerance of previously intolerable experience. For many people the experience of physical pain and psychological distress is deemed intolerable and pharmaceutical pain-relieving interventions are readily available in contemporary affluent communities with sophisticated medical systems. This biopsychosocial context means that many of the traditionally expected experiences of pain and distress may be

unacceptable, and therefore the instruction to sit with discomfort non-reactively may be very challenging for some people, especially when the level of equanimity is not yet well developed. However, a recent study demonstrated that there was no relationship between emotional responding early in a mindfulness intervention and adverse outcomes or drop-out rate (Harel et al., 2019). It is interesting to note that participants in some instances clearly understand that any difficulties were a natural part of the process and that the development of equanimity enabled a transformation of attitude to difficulties (e.g. Table 2, response 8).

Despite the reporting of some unexpected effects, the dropout rate of 19% was consistent with other studies which reported between 14% and 25% drop out rates (Gárriz et al., 2020). While most of those who discontinued the program provided reasons such as changed personal circumstances, it is possible that some people dropped out due to unpleasant effects. Unexpected effects data was only collected at follow-up.

Results indicate a significant symptom reduction after week 4 of the program. There was further symptom reduction between weeks 4 and 8 and at follow up the changes were mostly maintained or enhanced. It is of interest that this pattern was consistent across all measures, both clinical and wellbeing measures as well as the mediator measures (Table 1) and Supplementary Table 2. Interestingly, although the interpersonal skills are not explicitly taught until the second half of the program, the pattern of change was the same for the interpersonal skills measures with an increase in scores between weeks 1 and 4. It appears that in the current study, much of the change that occurred with the MiCBT training was in the first 4 weeks, generalized across both clinical and non-clinical measures and was maintained at 6-month follow-up. Thus, it may be that increasing awareness and equanimity towards interoceptive cues is a process that impacts all domains of functioning. A relevant factor may also be the impact of presenting the co-emergence model as a coherent psychological model that clearly describes the relationship between evaluative thinking, co-emerging body sensations and

resulting reactivity. The model is presented as a worksheet ("Diary of Reactive Habits") to demonstrate the relationship between the processing of information during emotional distress. Thus, the integration of a clear cognitive-behavioral framework with metacognitive and interoceptive awareness and equanimity is proposed to decondition reactivity and restore equilibrium among the four components of the co-emergence model, i.e. perception, evaluation, interoception and reaction, as suggested by (Cayoun, Francis, et al., 2019).

Limitations and Future Research

This study has several limitations. Firstly, the lack of an active control precludes being able to distinguish between improvements that may be due to generic group processes as opposed to the MiCBT skill acquisition. However, the findings from the mediation analysis provide some evidence that the effects of MiCBT operated through its hypothezised mechanisms, especially equanimity. Secondly, the sample was not representative of the general Australian population. Specifically, there was low representation of participants born outside Australia (12%) compared to 30% in the general population (SBS, 2019) and our sample was also more highly educated than the general population with over 80% of participants with post school education compared to 56% for the general population (ABS, 2017). It is possible that the population willing to engage in meditation-based therapies tend to be more educated as there is some requirement for homework and effortful meditations. It is noteworthy that the the amount of meditation practice was considerably less than prescribed which may indicate that the twice daily practice requirement is a possible barrier to the applicability of MiCBT with those not willing to commit to this amount of home practice. However, no participant recovered who practiced less than 10 hours per week.

Thirdly, while we collected information on medications, we did not collect data on any other therapeutic interventions that participants may have been offered. Also, although we asked

MiCBT group participants at follow up if there had been any changes to medications, we did not collect this data from the control group. Fourthly, the fact that the same therapist (the first author) conducting all the group training is a significant limitation of the study and generalizability can be examined in future scaled up implementation of this promising intervention. The use of the most recent audio instructions recorded by the developer of the program (BC) would support consistency in delivery, as mentioned earlier. Future research could replicate the study with different facilitators including, potentially, at different skill levels as this has implications for treatment dissemination (Meadows et al., 2014).

Another limitation to note was that the baseline measures for the study were administered post-randomization, one week prior to the start of the program. While this had the advantage of accounting for the delay in recruitment for some groups to maximize sensitivity to change in the context of fluctuating mental health conditions, it also had the potential to produce a systematic observer or participant bias. However, we consider this to be unlikely. Observer bias is unlikely because the main measures were administered online. Participant bias is still possible but perhaps minimal because there were no significant group differences between the (pre-randomization) medical practitioner administered K10 and the (post-randomization) baseline K10 that would suggest, for example, demoralization in the control group. All participants were aware from the commencement of the study that they would be offered MiCBT within a reasonable time frame.

The current study did not directly measure the specific behavior changes that typically take place through exposure interventions in the second half of MiCBT. Future studies could investigate if the gains at four weeks can be maintained even without receiving the remaining four weeks of the program or whether the second half of the program is essential for long-term change. Notwithstanding the positive mediation findings, the comparative effectiveness of MiCBT should be tested against an active control including, potentially CBT, MBCT or other third wave therapies. Future studies might also investigate the possibility of reductions of medication needs

in patients whose depression, anxiety and stress scores improve following the MiCBT intervention.

As well as the limitations discussed above, this study also had some key strengths. The use of a randomised controlled trial in a naturalistic private psychology clinic setting with a transdiagnostic population is a contribution to this under-researched area. The collection of data at the mid-point as well as at 8 weeks and 6-month follow up provides useful information about timelines for change. The study was designed using K10 scores as inclusion criteria rather than diagnosis, which is in line with naturalistic clinical settings, where general practitioners in Australia tend to refer patients on the basis of K10 evaluation. This was also consistent with the notion that MiCBT is suitable across a broad range of psychological conditions.

In summary, the present results provide additional evidence to previous research relating to the effectiveness of the MiCBT intervention. Importantly, the results support the transdiagnostic applicability of MiCBT, demonstrating significant improvements in clinical outcomes in the first four weeks of treatment. The benefits were maintained over a six-month period across the population with a range of disorders and levels of distress severity.

Ethics approval

This study was granted ethical approval by the Monash University Human Research Ethics Committee (Project number: CF16/2278 - 2016001131). All participants provided written informed consent prior to their inclusion in the study.

Conflict of interest statement

SF and BC have been paid for developing and delivering educational presentations, workshops and professional training programs for the MiCBT Institute in Australia and North America.

References

Australian Bureau of Statistics. (2017). *Australians pursuing higher education in record numbers*. ABS. Retrieved 12th May 2020 from https://www.abs.gov.au/Ausstats/abs@.nsf/dd0ca10eed681f12ca2570ce0082655d/1533fe5a8541d66cca2581bf00362d1d!OpenDocument

Bahrani, S., Zargar, F., Yousefipour, G., & Akbari, H. (2017). The Effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy on Depression, Anxiety, and Stress in Females with Multiple Sclerosis: A Single Blind Randomized Controlled Trial. *Iranian Red Crescent Medical Journal*, *19*(4).

Bernstein, A., Hadash, Y., Lichtash, Y., Tanay, G., Shepherd, K., & Fresco, D. M. (2015). Decentering and Related Constructs:A Critical Review and Metacognitive Processes Model. *Perspectives on Psychological Science*, *10*(5), 599-617. https://doi.org/10.1177/1745691615594577

Cayoun, B. A. (2011). Mindfulness-integrated CBT: Principles and practice. John Wiley & Sons.

Cayoun, B. A. (2015). Mindfulness-integrated CBT for well-being and personal growth : four steps to enhance inner calm, self-confidence and relationships. Wiley/Blackwell.

Cayoun, B. A. (2017). The purpose, mechanisms and benefits of cultivating ethics in Mindfulness-integrated Cognitive Behavior Therapy. In C. M. Monteiro (Ed.), *Practitioner's Guide to Ethics and Mindfulness-Based Interventions* (pp. 163-192). Springer.

Cayoun, B. A., Francis, S., & Shires, A. G. (2019). *The Clinical Handbook of Mindfulness-integrated Cognitive Behavior Therapy: A Step-by-step Guide for Therapists*. John Wiley & Sons. https://doi.org/ISBN: 978-1-119-38963-7

Cayoun, B. A., Simmons, A., & Shires, A. (2019). Immediate and Lasting Chronic Pain Reduction Following a Brief Self-Implemented Mindfulness-Based Interoceptive

Exposure Task: a Pilot Study. Mindfulness, 1-13. https://doi.org/10.1007/s12671-017-0823-x

Chen, L.-Y., Crum, R. M., Martins, S. S., Kaufmann, C. N., Strain, E. C., & Mojtabai, R. (2013). Service use and barriers to mental health care among adults with major depression and comorbid substance dependence. Psychiatric Services, 64(9), 863-870.

Craske, M. G. (2012). Transdiagnostic treatment for anxiety and depression. Depression and Anxiety.

Diener, E., Emmons, R. A., Larsen, R. J., & Griffin, S. (1985). The satisfaction with life scale. Journal of personality assessment, 49(1), 71-75.

Diener, E., Wirtz, D., Tov, W., Kim-Prieto, C., Choi, D., Oishi, S., & Biswas-Diener, R. (2010). New well-being measures: Short scales to assess flourishing and positive and negative feelings. Social Indicators Research, 97(2), 143-156.

Eraslan-Capan, B. (2016). Social Connectedness and Flourishing: The Mediating Role of Hopelessness. Universal Journal of Educational Research, 4(5), 933-940. https://doi.org/DOI: 10.13189/ujer.2016.040501

Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Thompson-Hollands, J., Carl, J. R., Gallagher, M. W., & Barlow, D. H. (2012). Unified protocol for transdiagnostic treatment of emotional disorders: a randomized controlled trial. Behavior therapy, 43(3), 666-678. https://doi.org/10.1016/j.beth.2012.01.001

Farias, M., & Wikholm, C. (2016). Has the science of mindfulness lost its mind? BJPsych Bulletin, 40(6), 329-332. https://doi.org/10.1192/pb.bp.116.053686

Frances, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020). Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry, 20(1), 7. https://doi.org/10.1186/s12888-019-2411-1

Francis, S. (2013). A preliminary study of Mindfulness-integreatd Cognitive Behaviour Therapy: Results from a series of group interventions First International Conference on Mindfulness, Rome, Italy.

Francis, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020). Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry, 20(1), 7. https://doi.org/10.1186/s12888-019-2411-1

Francis, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G (2020) Correction to: Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. BMC Psychiatry, 20(1), 1-1. https://doi.org/10.1186/s12888-019-2411-1

Fresco, D. M., Moore, M. T., van Dulmen, M. H., Segal, Z. V., Ma, S. H., Teasdale, J., & Williams, J. M. G. (2007). Initial psychometric properties of the experiences questionnaire: validation of a self-report measure of decentering. Behavior therapy, 38(3), 234-246.

Gárriz, M., Elices, M., Peretó, M., Martín-López, L. M., Justicia, A., & Pérez, V. (2020). Mindfulness-Based Cognitive Therapy Delivered in Primary Care: a Naturalistic, Mixed-Methods Study of Participant Characteristics and Experiences [journal article]. Mindfulness, 11(2), 291-302. https://doi.org/10.1007/s12671-019-01166-y

Grabovac, A. (2014). The Stages of Insight: Clinical Relevance for Mindfulenss-Based Interventions [online]. Mindfulness. https://doi.org/10.1007/s12671-014-0294-2

Gustafsson, J.-E., & Åberg-Bengtsson, L. (2010). *Unidimensionality and interpretability of psychological instruments.* In S. E. Embretson (Ed.), *Measuring psychological*

constructs: Advances in model-based approaches (p. 97–121). American Psychological Association. https://doi.org/10.1037/12074-005

Harel, O., Hadash, Y., Levi-Belz, Y., & Bernstein, A. (2019). Does Early Emotional Responding to Initial Mindfulness Training Impact Intervention Outcomes? Mindfulness, 10(4), 616-626. https://doi.org/10.1007/s12671-018-1018-9

Hayes, A. F. (2018). Introduction to Mediation, Moderation and Conditional Process Analysis: A Regression-based Approach (Second ed.). The Guilford Press.

Hayes, S. C. (2017). The third wave of CBT and the rise of process--based care. World Psychiatry.

Kessler, R. C., Andrews, G., Colpe, L. J., Hiripi, E., Mroczek, D. K., Normand, S.-L., Walters, E. E., & Zaslavsky, A. M. (2002). Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychological medicine, 32(06), 959-976. https://doi.org/DOI: 10.1017}S0033291702006074

Lindahl, J. R., Fisher, N. E., Cooper, D. J., Rosen, R. K., & Britton, W. B. (2017). The varieties of contemplative experience: A mixed-methods study of meditation-related challenges in Western Buddhists. PLoS One, 12(5), e0176239. https://doi.org/10.1371/journal.pone.0176239

Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behaviour research and therapy, 33(3), 335-343.

MacKinnon, D. P., & Luecken, L. J. (2011). Statistical analysis for identifying mediating variables in public health dentistry interventions. Journal of public health dentistry, 71 Suppl 1(Suppl 1), S37-S46. https://doi.org/10.1111/j.1752-7325.2011.00252.x

Meadows GN, Shawyer F, Enticott JC, Graham AL, Judd F, Martin PR, Piterman L, Segal Z. Mindfulness-based cognitive therapy for recurrent depression: A translational research

study with 2-year follow-up. Aust N Z J Psychiatry. 2014 Aug;48(8):743-55. doi: 10.1177/0004867414525841. Epub 2014 Mar 4. PMID: 24595511.

Mehling, W. E., Price, C., Daubenmier, J. J., Acree, M., Bartmess, E., & Stewart, A. (2012). The multidimensional assessment of interoceptive awareness (MAIA). PLoS One, 7(11), e48230. https://doi.org/https://doi.org/10.1371/journal.pone.0048230

Newby, J., Mckinnon, A., Kuyken, W., Gilbody, S., & Dalgleish, T. (2015). Systematic review and meta-analysis of transdiagnostic psychological treatments for anxiety and depressive disorders in adulthood. . Clinical psychology review(40), 91. https://doi.org/https://doi.org/10.1016/j.cpr.2015.06.002

Pollack, M. H. (2005). Comorbid anxiety and depression. The Journal of Clinical Psychiatry, 66 Suppl 8, 22.

Pouyanfard, S., ParviziFard, A. A., Mohammadpour, M., & Sadeghi, K. (2020). Effectiveness of mindfulness-integrated cognitive behavior therapy on anxiety, depression and hope in multiple sclerosis patients: a randomized clinical trial. Trends in Psychiatry and Psychotherapy, 42(1), 55-63.

Reise, S. P., Moore, T. M., & Haviland, M. G. (2010). Bifactor models and rotations: Exploring the extent to which multidimensional data yield univocal scale scores. *Journal of personality assessment*, *92*(6), 544-559.doi: 10.1080/00223891.2010.496477

Reise, S. P., Bonifay, W. E., & Haviland, M. G. (2013). Scoring and modeling psychological measures in the presence of multidimensionality. *Journal of personality assessment*, *95*(2), 129-140. https://doi.org/10.1080/00223891.2012.725437

Ronk, F. R., Korman, J. R., Hooke, G. R., & Page, A. C. (2013). Assessing clinical significance of treatment outcomes using the DASS-21. *Psychological Assessment, 25*(4), 1103–1110. https://doi.org/10.1037/a0033100\

Saeri, A. K., Cruwys, T., Barlow, F. K., Stronge, S., & Sibley, C. G. (2018). Social connectedness improves public mental health: Investigating bidirectional relationships in

the New Zealand attitudes and values survey. Australian & New Zealand Journal of Psychiatry, 52(4), 365-374. https://doi.org/10.1177/0004867417723990

Sahdra, B. K., Shaver, P. R., & Brown, K. W. (2010). A scale to measure nonattachment: A Buddhist complement to Western research on attachment and adaptive functioning. Journal of personality assessment, 92(2), 116-127. https://doi.org/https://doi.org/10.1080/00223890903425960

Sauer-Zavala, S., Gutner, C. A., Farchione, T. J., Boettcher, H. T., Bullis, J. R., & Barlow, D. H. (2017). Current definitions of "transdiagnostic" in treatment development: A search for consensus. Behavior therapy, 48(1), 128-138. https://doi.org/https://doi.org/10.1016/j.beth.2016.09.004

SBS. (2019). Almost 30 per cent of the Australian population was born overseas. SBS. Retrieved 12th May 2020 from https://www.sbs.com.au/news/almost-30-per-cent-of-the-australian-population-was-born-overseas

Scott-Hamilton, J., Schutte, N. S., & Brown, R. F. (2016). Effects of a mindfulness intervention on sports-anxiety, pessimism, and flow in competitive cyclists. Applied Psychology: Health and Well-Being, 8(1), 85-103. https://doi.org/https://doi.org/10.1111/aphw.12063

Segal, Z., Williams, M., & Teasdale, J. (2002). Mindfulness-based cognitive therapy for depression : a new approach to preventing relapse. New York : Guilford Press.

Segal, Z., Williams, M., & Teasdale, J. (2013). Mindfulness-Based Cognitive Therapy for Depression (2nd revised ed. ed.). Guilford Publications.

Sekula, L. K., Desantis, J., & Gianetti, V. (2003). Considerations in the Management of the Patient with Comorbid Depression and Anxiety. Journal of the American Academy of Nurse Practitioners, 15(1), 23-33. https://doi.org/10.1111/j.1745-7599.2003.tb00251.x

Valente, M. J., & MacKinnon, D. P. (2017). Comparing models of change to estimate the mediated effect in the pretest-posttest control group design. Struct Equ Modeling, 24(3), 428-450. https://doi.org/10.1080/10705511.2016.1274657

van Kesteren, E.-J., & Oberski, D. L. (2019). Exploratory Mediation Analysis with Many Potential Mediators. Structural Equation Modeling: A Multidisciplinary Journal, 26(5), 710-723. https://doi.org/10.1080/10705511.2019.1588124

VanderWeele, T. J., & Vansteelandt, S. (2014). Mediation Analysis with Multiple Mediators. Epidemiologic methods, 2(1), 95-115. https://doi.org/10.1515/em-2012-0010

Vøllestad, J., Sivertsen, B., & Nielsen, G. H. (2011). Mindfulness-based stress reduction for patients with anxiety disorders: Evaluation in a randomized controlled trial. Behaviour research and therapy, 49(4), 281-288.

Wells, A. (2007). Cognition About Cognition: Metacognitive Therapy and Change in Generalized Anxiety Disorder and Social Phobia. Cognitive and Behavioral Practice, 14(1), 18-25. https://doi.org/https://doi.org/10.1016/j.cbpra.2006.01.005

Yazdanimehr, R., Omidi, A., Sadat, Z., & Akbari, H. (2016). The effect of mindfulness-integrated cognitive behavior therapy on depression and anxiety among pregnant women: a randomized clinical trial. Journal of Caring Sciences, 5(3), 195.

Zeng, X., Oei, T. P., Ye, Y., & Liu, X. (2015). A critical analysis of the concepts and measurement of awareness and equanimity in Goenka's Vipassana meditation. J Relig Health, 54(2), 399-412. https://doi.org/10.1007/s10943-013-9796-9

Table 1: Mixed REML regression models for outcome variables with fixed factors of time and intervention status, and participants as random

DASS-21	b	se	z	p value	[95%Conf.	Interval]
Timepoint						
T1	-7.46	2.12	-3.51	0.000	-11.61	-3.29
T2	-12.08	2.04	-5.92	0.000	-16.08	-8.08
T3	-10.38	2.14	-4.86	0.000	-14.57	-6.19
Intervention status						
1	-9.17	1.61	-5.69	0•000	-12.33	-6.01

Number of obs=413, Number of groups = 118, Bootstrap replications = 50

K10	b	se	z	p value	[95%Conf.	Interval]
Timepoint						
T1	-3.60	0.78	-4.63	0.000	-5.13	-2.08
T2	-4.42	0.80	-5.51	0.000	-6.00	-2.85
T3	-4.79	0.86	-5.57	0.000	-6.48	-3.11
Intervention status						
1	-3.54	0.55	-6.48	0•000	-4.62	-2.47

Number of obs=405, Number of groups = 118, Bootstrap replications = 50

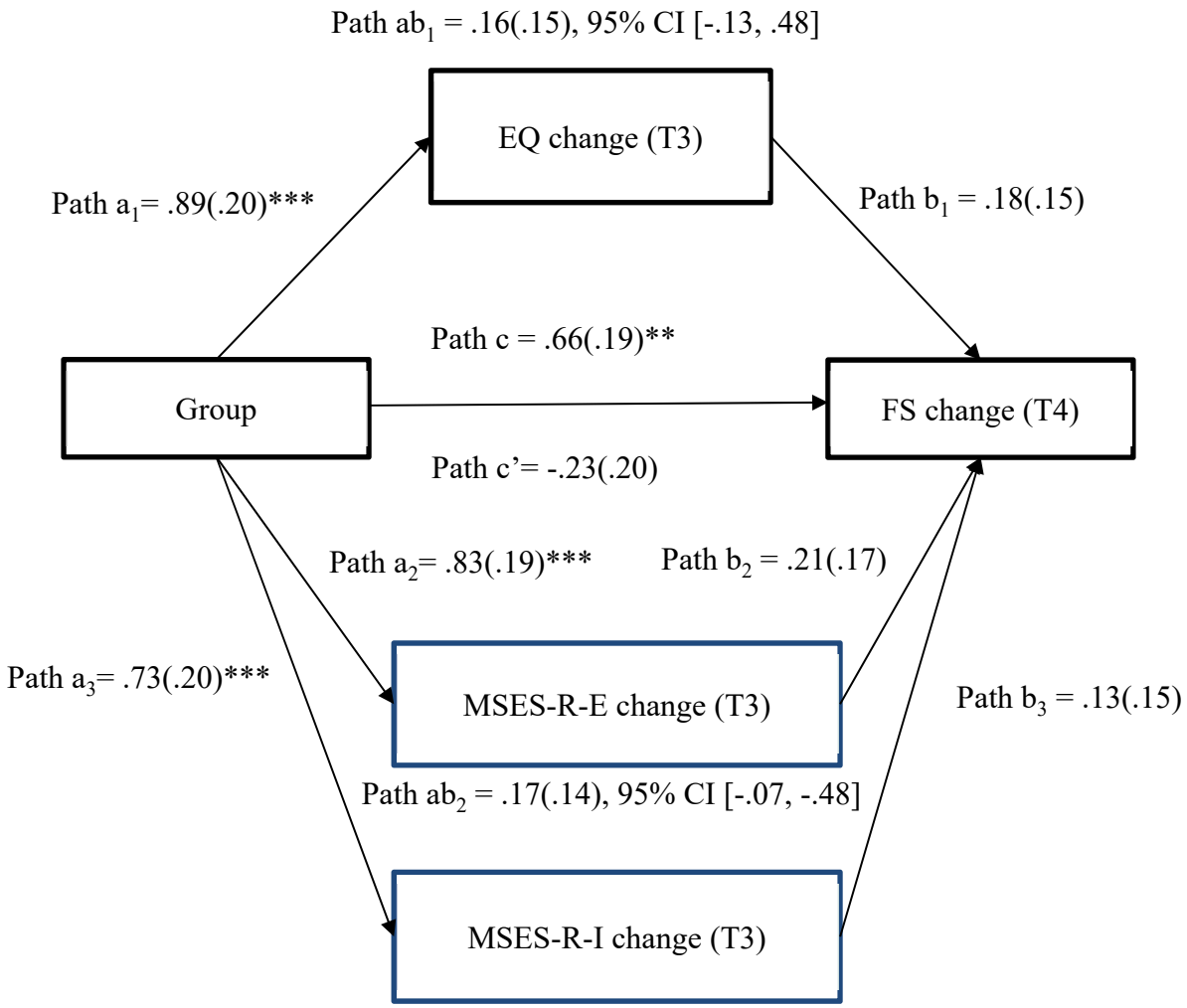
SWLS	b	se	z	p value	[95%Conf.	Interval]
Timepoint						
T1	2.12	.60	3.50	0.000	0.93	3.30
T2	2.96	.57	5.22	0.000	1.85	4.07
T3	3.08	.53	5.78	0.000	2.03	4.12
Intervention status						
1	.59	.44	1.35	0.177	-.27	1.45

Number of obs=411, Number of groups = 118, Bootstrap replications = 50

FS	b	se	z	p value	[95%Conf.	Interval]
Timepoint						
T1	2.86	.63	4.52	0.000	1.62	4.10
T2	3.84	.74	5.17	0.000	2.39	5.30
T3	4.26	.75	5.70	0.000	2.80	5.72
Intervention status						
1	2.17	.58	3.74	0.000	1.03	3.30

Notes. Number of obs=411, Number of groups = 118, Bootstrap replications = 50
DASS-21 = Depression, Anxiety, and Stress Scale-21; K10 = Kessler Psychological Distress Scale; SWLS = Satisfaction with Life Scale; FS = Flourishing Scale.

Figure 4: Path diagram depicting model 2, testing whether changes in equanimity, awareness and interpersonal skills mediate the effects of MiCBT versus control on improvements in flourishing. Unstandardized path coefficients are displayed



Notes. *<.05; **<.01; ***<.001.

EQ = Experiences Questionnaire; MSES-R-E = Mindfulness-based Self-Efficacy Scale-Revised-Equanimity subscales; MSES-R-I = Mindfulness-based Self-Efficacy Scale-Revised-Interpersonal skills subscales; DASS-21 = Depression, Anxiety, and Stress Scale-21.
a, b, c' and c are unstandardized regression coefficients (with standard errors) which represent predicting the mediator from group (a), DASS-21 change from M controlling for group (b), DASS-21change from group controlling for the mediators (direct effect, c'), and DASS-21 change from group *not* controlling for the mediators (total effect, c). The product of a and b paths, ab, represents the mediated or indirect effect. Change refers to standardised residualized change scores.

4.3 Supplementary Materials

Supplementary Table 1

Mean (SD, 95%CI) and median values of outcome and mediator variables for MiCBT and control groups from baseline (T0) to mid-treatment (T1), and of treatment (T2) and 6-month follow-up (t3)

	Measure	T0			T1			T2			T3		
		Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N
DASS	MiCBT	48.5 (23.1) (42.5, 54.5)	46	60	35.44 (17.51) (30.46, 40.42)	35	50	30.13 (20.62) (24.07, 36.18)	24	47	34.73(22.83) (28.18,41.29)	30	49
	Control	50.2 (22.0) (44.4, 56.0)	46	57	48.33 (27.5) (48.33, 40.89)	46	55	45.62(23.63) (38.68, 52.56)	44	47	44.67 (25.22) (37.34, 51.99)	40	48
K10	MiCBT	27.75 (6.99) (25.96, 29.54)	28	61	23.02 (6.8) (21.09, 24.95)	21	50	21.58 (7.90) (19.2, 23.95)	20	45	21.56 (7.06) (19.52, 23.67)	20	47
	Control	29.04 (6.25) (27.34, 30.69)	30	57	26.77 (7.93) (24.59, 28.96)	26	53	27.2 (8.11) (24.76, 29.64)	27	45	26.26 (8.13) (23.87, 28.64)	26	47
SWLS	MiCBT	17.08 (7.04) (15.26,18.9)	17	60	20.36 (6.63) (18.48, 22.24)	21.5	50	21.49 (6.65) (19.54, 23.44)	22	47	21.81(6.45) (19.94, 23.69)	22	48
	Control	17.66 (6.8) (15.86, 19.47)	17	57	19.20 (7.79) (17.08, 21.33)	19	54	19.66 (7.4) (17.49, 21.83)	20	47	18.88 (7.47) (16.7, 21.05)	19	48
FS	MiCBT	36.65 (9.23)	36	60	40.44 (8.08)	42	50	42.43 (7.67)	43	47	42.63 (7.02)	43	48

	Measure	T0			T1			T2			T3		
		Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N	Mean (SD) (95% CI)	Median	N
MAIA	Control	36.09(8.55) (33.26, 38.04)	36	57	37.74 (8.69) (35.37, 40.11)	37	54	37.23 (10.04) (34.29, 40.18)	39	47	37.4 (9.65) (34.59, 40.2)	39.5	48
	MiCBT	65.16 (17.18) 60.73, 69.60)	63.93	60	75.17 (14.88) (75.17, 83.63)	81.72	50	83.21 (18.15) (77.76, 88.66)	86.9	45	77.08 (17.58) (71.92, 82.25)	75.45	47
	Control	62.0 (15.1) (57.98, 65.99)	63.53	57	61.59 (15.06) (57.44, 65.74)	60.83	53	61.7 (16.79) (56.65, 66.74)	62.23	45	62.29 (17.06) (57.28, 67.30)	61.96	47
NAS	MiCBT	3.53 (.81) (3.33, 3.74)	3.6	60	4.02 (.72) (3.82, 4.22)	4.17	52	4.27 (.79) (4.04, 4.50)	4.47	45	4.3 (.68) (4.10, 4.50)	4.3	47
	Control	3.57 (.79) (3.36, 3.79)	3.6	57	3.54(.68) (3.36, 3.73)	3.63	54	3.55 (.68) (3.35, 3.76)	3.63	45	3.72 (.79) (3.49, 3.95)	3.7	47
EQ (decentering)	MiCBT	30.55 (5.79) (29.06, 32.04)	31	60	34.6 (4.96) (33.19, 36.01)	35	50	36.04 (6.43) (34.15, 37.93)	37	47	36.35 (5.84) (34.66, 38.05)	37	48
	Control	29.19 (5 .29) (27.79, 30.6)	28	57	29.74 (5.8) (28.14, 31.33)	30	53	30.04 (6.0) (28.26, 31.83)	29	46	30.92 (6.69) (29.0, 32.83)	31	48

Supplementary Table 2 Mixed REML regression models for mediator variables with fixed factors of time and intervention status, and participants as random

MAIA Timepoint	b	se	z	p value	[95%Conf.	Interval]
Timepoint (compared to baseline)						
T1	6.67	1.52	4.38	0.000	3.69	9.64
T2	9.14	1.89	4.92	0.000	5.50	12.78
T3	6.06	1.80	3.36	0.001	2.52	9.60
Intervention status						
MiCBT compared to control	12.23	1.09	11.17	0.000	10.09	14.38

Number of obs=404, Number of groups = 118

NAS Timepoint	b	se	z	p value	[95%Conf.	Interval]
Timepoint (compared to baseline)						
T1	6.93	2.18	3.18	0.001	2.66	11.20
T2	12.28	2.05	6.0	0.000	8.25	16.30
T3	13.65	2.24	6.10	0.000	9.26	18.04
Intervention status						
MiCBT compared to control	11.47	1.40	8.21	0.000	8.23	14.21

Number of obs=404, Number of groups = 118

EQ Timepoint	b	se	z	p value	[95%Conf.	Interval]
Timepoint (compared to baseline)						
T1	2.18	.51	4.29	0.000	1.18	3.18
T2	3.40	.61	5.54	0.000	2.19	4.60
T3	3.83	.58	6.65	0.000	2.70	4.96
Intervention status						
MiCBT compared to control	3.83	.45	8.55	0.000	2.95	4.71

Number of obs=409, Number of groups = 118, Bootstrap replications = 50

MSES - E Timepoint	b	se	z	p value	[95%Conf.	Interval]
Timepoint (compared to baseline)						
T1	2.36	.56	4.24	0.000	1.27	3.45
T2	4.24	.62	6.76	0.000	3.01	5.47
T3	4.81	.68	7.08	0.000	3.48	6.14
Intervention status						
MiCBT compared to control	3.79	.56	6.83	0.000	2.71	4.88

Number of obs=412 , Number of groups = 118

MSES - S Timepoint	b	se	z	p value	[95%Conf.	Interval]
Timepoint (compared to baseline)						
T1	1.79	.36	4.99	0.000	1.09	2.49
T2	2.90	.44	6.58	0.000	2.04	3.77
T3	2.39	.49	4.84	0.000	1.42	3.35
Intervention status						
MiCBT compared to control	1.79	.37	4.88	0.000	1.07	2.51

Number of obs=412 , Number of groups = 118

Supplementary Table 3.1
Correlation between Mediation Model Variables at Time 1 (sample size in parentheses)

	NAS T1	MSES-E T1	EQ T1	MAIA T1	MSES-S T1	DASS-21 T1	FS T1
Group	—						
NAS T1	1.00	—					
MSES-E T1	.35** (117)	1.00 (117)	—				
EQ T1	.55** (117)	.30** (117)	1.00 (117)	—			
MAIA T1	.49** (117)	.30** (117)	.72** (117)	1.00 (117)	—		
MSES-S T1	.40** (117)	.24* (117)	.22* (117)	.25** (117)	1.00 (117)	—	
DASS-21 T1	-.35** (117)	-.09 (117)	-.28** (117)	.28 (117)	-.36** (117)	1.00 (117)	—
FS T1	.46** (117)	.26** (117)	.44** (117)	.38** (117)	.53** (117)	-.44** (117)	1.00 (117)

Note. Pearson's *r* correlation coefficients, with sample size (*n*) in parentheses.
*$p < 0.05$; ** $p < 0.01$; *** $p < 0.00$

Supplementary Table 3.2
Correlation between Mediation Model Variables (sample size in parentheses)

	NAS T3	MSES-E T3	EQ T3	MAIA T3	MSES-S T3	DASS-21 T4	FS T4
NAS T3	1.00 (90)	—					
MSES-E T3	.75*** (90)	1.00 (94)	—				
EQ T3	.73*** (90)	.78*** (93)	1.00 (93))	—			
MAIA T3	.67*** (90)	.67*** (90)	.85*** (90)	1.00 (90)	—		
MSES-S T3	.65*** (90)	.71*** (94)	.56*** (93)	.45*** (90)	1.00 (94)	—	
DASS-21 T4	-.39*** (87)	-.54*** (89)	-.41*** (89)	-.34** (87)	-.57*** (89)	1.00 (97)	—
FS T4	.45*** (87)	.46*** (89)	.46*** (89)	.40*** (87)	.62*** (89)	-.58*** (96)	1.00 (96)

Note. Pearson's *r* correlation coefficients, with sample size (*n*) in parentheses.
*$p < 0.05$; ** $p < 0.01$; *** $p < 0.00$

Supplementary Table 4

Unstandardized regression coefficients, their standard errors (SEs) and significance values, and bootstrapped unstandardized point estimates and their SEs and 95% confidence intervals, for the five independent variable mediation models assessing change in the primary outcome (DASS) during the follow-up period (mediators measured at 8 weeks; outcomes at 6 months)

Model	B	SE	t	p	Indirect effect point estimate (SE) [95% CIs][a]	Percentage of total effect that operates indirectly
Model 1: with MAIA as the mediator (*n* = 86)					-9.54 (3.07) [-16.26, -4.18]	85.8%
a_1 path: Group - MAIA	19.17	3.31	5.80	.00		
b_1 path: MAIA - DASS-21	-.50	.14	-3.55	.00		
c_1 path: Group - DASS-21(total effect)	-11.12	4.49	-2.48	.02		
c'_1 path: Group - DASS-21(direct effect)	-1.58	4.99	-.32	.75		
Model 2: with EQ as the mediator (*n* = 88)					-6.87 (3.41) [-14.29, -1.04]	67.6%
a_1 path: Group - EQ	5.28	1.15	4.59	.00		
b_1 path: EQ - DASS-21	-1.30	.40	-3.24	.00		
c_1 path: Group - DASS-21(total effect)	-10.17	4.46	-2.28	.03		
c'_1 path: Group - DASS-21(direct effect)	-3.30	4.73	-.70	.49		
Model 3: with NAS as the mediator (*n* = 86)					-10.05 (2.99) [-16.46, -4.59]	93.3%
a_1 path: Group - NAS	21.02	3.60	5.84	.00		
b_1 path: NAS - DASS-21	-.48	.13	-3.79	.00		
c_1 path: Group - DASS-21(total effect)	-10.77	4.43	-2.43	.02		
c'_1 path: Group - DASS-21(direct effect)	-.71	4.89	0.15	.88		
Model 4: with MSES-E as the mediator (*n* = 88)					-7.90 (3.34) [-15.37, -2.41)	75.2%
a_1 path: Group - MSES-E	5.93	1.38	4.30	.00		
b_1 path: MSES-E - DASS-21	-1.33	.32	-4.15	.00		
c_1 path: Group - DASS-21(total effect)	-10.50	4.42	-2.37	.02		
c'_1 path: Group - DASS-21(direct effect)	-2.60	4.47	-.58	.56		

[a]Bootstrapped 95% BC CIs for the ab (indirect) effect; a significant indirect effect is indicated where these do not cross zero ($p < .05$).
DASS-21- Depression, Anxiety and Stress Scale; MAIS - Multidimensional Assessment of Interoceptive Awareness; EQ - Experiences Questionnaire; NAS - Non-attachment Scale; MSES-E - Mindfulness-based Self-efficacy Scale (Equanimity subscales)

Supplementary Table 5
Unstandardized regression coefficients, their standard errors (SEs) and significance values, and bootstrapped unstandardized point estimates and their SEs and 95% confidence intervals, for the five independent variable mediation models assessing change in the Flourishing Scale during the follow-up period (mediators measured at 8 weeks; outcomes at 6 months)

Model	B	SE	t	p	Indirect effect point estimate (SE) [95% CIs][a]	Percentage of total effect that operates indirectly
Model 1: with MAIA as the mediator (n = 86)					2.69 (1.00) [.82, 7.72]	57.2%
a_1 path: Group - MAIA	19.10	3.29	5.80	.00		
b_1 path: MAIA - FS	.14	.04	3.30	.00		
c_1 path: Group - FS (total effect)	4.70	1.35	3.48	.00		
c'_1 path: Group - FS (direct effect)	2.01	1.52	1.32	.19		
Model 2: with EQ as the mediator (n = 88)					2.57 (.89) [1.02, 4.51]	57.1%
a_1 path: Group - EQ	5.27	1.16	4.56	.00		
b_1 path: EQ - FS	.49	.11	4.27	.00		
c_1 path: Group - FS (total effect)	4.50	1.33	3.38	.00		
c'_1 path: Group - FS (direct effect)	1.93	1.35	1.42	.16		
Model 3: with NAS as the mediator (n = 86)					3.68 (.95) [1.94, 5.61]	79.3%
a_1 path: Group - NAS	21.20	3.60	5.90	.00		
b_1 path: NAS - FS	.17	.04	4.75	.00		
c_1 path: Group - FS (total effect)	4.64	1.34	3.47	.00		
c'_1 path: Group - FS (direct effect)	.96	1.42	.68	.50		
Model 4: with MSES-E as the mediator (n = 88)					2.51 (.91) [1.02, 4.51]	56.8%
a_1 path: Group - MSES-E	5.93	1.39	4.26	.00		
b_1 path: MSES-E - FS	.42	.09	4.56	.00		
c_1 path: Group - FS (total effect)	4.42	1.31	3.37	.00		
c'_1 path: Group - FS (direct effect)	1.92	1.30	1.47	.14		
Model 5: with MSES-S as the mediator (n = 88)					2.05 (.90) [.58, 4.02]	54.4%
a_1 path: Group - MSES-S	3.13	.88	3.56	.00		
b_1 path: MSES-S - FS	.66	.14	4.53	.00		
c_1 path: Group - FS (total effect)	4.50	1.29	3.49	.00		
c'_1 path: Group - FS (direct effect)	2.45	1.25	1.97	.05		

[a]Bootstrapped 95% BC CIs for the ab (indirect) effect; a significant indirect effect is indicated where these do not cross zero ($p < .05$).
FS - Flourishing Scale; MAIS - Multidimensional Assessment of Interoceptive Awareness; EQ - Experiences Questionnaire; NAS - Non-attachment Scale; MSES-E - Mindfulness-based Self-efficacy Scale (Equanimity subscales); MSES-S - Mindfulness-based Self-efficacy Scale (Social skills subscales).

4.4 Data Availability Statement:

Study Data are stored in and available from Monash University's research repository:

https://www.monash.edu/library/researchers/researchdata/bridges: DOI 10.26180/13240304

5 CHAPTER FIVE: Findings, Concluding Remarks and Future Research

This chapter discusses the contributions and limitations of the body of work presented in this thesis as well as future research possibilities.

5.1 Comparison paper

The detailed comparison of MiCBT with MBCT, the program to which it is most similar, enabled close scrutiny of the similarities, differences and clinical implications for the application of both interventions. The work seeks to highlight the significance of the differences between the rationales of each program, the particular meditation practices, and the manner of application for symptom reduction. The transdiagnostic applicability of MiCBT was considered to be a significant feature and this paper highlights the utility of therapies that operate on underlying psychological processes shared across different diagnoses. This paper provides an analysis of both MiCBT and MBCT that elucidates therapeutic mechanisms and may assist guiding clinicians referring patients for treatment and in the future training of mental health professionals who are interested in mindfulness-based therapies. MiCBT has the potential to make a valuable contribution to the crowded field of MBIs in particular because it targets transdiagnostic populations. Further empirical work is required to be conducted in evaluating its effectiveness in this population.

5.2 RCT

The randomised controlled trial was the central study undertaken in this program of work. The aim of this trial was to investigate the effectiveness of MiCBT in improving clinical psychological symptoms and wellbeing in a heterogeneous patient population in a primary healthcare setting. The findings support the hypothesis that the 8-week MiCBT intervention would reduce clinical symptoms and improvement would be sustained at 6-month follow up. Support for the expected improvement in wellbeing was mixed, with significant effects seen in flourishing but no significant change in satisfaction with life, although the change was in the predicted direction. As well, all of

the mediation measures improved in the MiCBT group and, when considered individually in single mediation models, each measure significantly mediated symptom change on the primary outcome measure. Parallel mediation models suggested that equanimity accounted for the majority of mediational impact on symptom reduction. An interesting finding was that there was significant symptom reduction and improvement in mediating measures after just 4 weeks of the intervention. Further improvements occurred at the end of treatment and were maintained at 6-month follow-up.

The strengths and limitations are fully described in Paper three. Strengths include that the study is a randomised controlled study conducted in a naturalistic private psychology clinic setting. Randomization was stratified to ensure that treatment arms were balanced on important prognostic factors, including gender, medication status and severity of psychological distress at baseline. A number of limitations of the study were noted including that there was no active control and therefore it was not possible to account for the impact of group processes on the results. Other limitations were that the intervention was delivered by one experienced therapist, and the sample was not representative of the general Australian population. Additionally, no data was collected on other therapeutic interventions that may have occurred concurrently with the study.

5.3 General Discussion

The program of work examined the theoretical utility and empirical effectiveness of MiCBT as a broadly applicable intervention for a range of mental health conditions. MiCBT is differentiated by its integration of techniques to specifically target the commonalities of psychological disorders, enabling its use with current mild to severe psychological symptoms. An important advantage of this program is that it does not need to be modified to fit particular diagnostic groups.

Results from the RCT showed that attending the MiCBT group was associated with significant symptom and wellbeing improvement compared to the treatment-as-usual waitlist control. The RCT also demonstrated that all the mediating measures also showed significant changes at the 6-

month follow-up. The finding that equanimity appeared to be most impactful for symptom reduction is consistent with the underlying rationale of MiCBT and the original name for MiCBT being Equanimity Training. The roots of MiCBT in terms of the specific meditation approaches are in Buddhist psychology in the Vipassana tradition as taught by S.N Goenka. In that tradition, both equanimity and awareness are considered to be required to gain insight into the causes of suffering. The explicit emphasis on the development of equanimity (in particular towards body sensations) is one of the differences that is apparent when MiCBT is compared to seemingly similar interventions. Developing the capacity for equanimity towards distressing situations (distress being experienced somatically) addresses reactivity, a core aspect of mental health conditions.

This research demonstrates that delivering an 8-week intervention in a naturalistic private practice setting is an acceptable form of treatment despite the fact that participants had to attend sessions in the evenings and for many of them this was at the end of the work day.

Clearly these results need to take account of the limitations of the study noted above.

5.4 Conclusion

The program of work detailed in this thesis supports the theoretical utility and relevance of MiCBT as well as its effectiveness in reducing symptoms of depression, anxiety and stress and improving flourishing in transdiagnostic groups with mild-severe psychological distress. The comparison of MiCBT with MBCT facilitated a granular examination of both programs which may be useful in understanding how best to recommend particular treatments for particular patients. The study supports the application of MiCBT as a group intervention in which participants have a range of severity of diagnoses and symptom severity whether or not they are receiving ongoing treatments including pharmacotherapy. The referral process mirrored standard mental health care referral processes.

5.5 Future research

This research suggests a number of research directions including exploring further the relationship between the equanimity construct and the co-emergence model and outcomes, for example using qualitative methods. The study results suggested that improvement occurred in the first four weeks although the average amount of practice remained constant throughout the eight weeks of the intervention. This may merit further investigation using short-forms of the program including the robustness and longevity of the clinical changes. It also leads to speculation as to what the reasons for this observation may be. One possibility that was not specifically investigated is that the impact of introducing the co-emergence model of reinforcement in the second week may provide a significant cognitive shift that in turn acts to motivate continued mindfulness meditation practice. In the candidate's experience, this model is often experienced as an "aha" moment by participants. Future research is needed to investigate further the role of the theoretical framework in relation to the role of the meditation exercises. Future studies could also investigate possible differences in therapy process and outcomes between MBCT and MiCBT, as variables such as selection between MBCT and MiCBT may be influenced by the severity of psychological symptoms and the capacity of patients to engage with exposure methods.

The data collected regarding the amount of meditation practice that participants engaged in indicated that on average participants did not comply with the hour a day requirement. This is consistent with other studies in which participants practice less than the prescribed homework (Ribeiro et al., 2018). Further future research is required into the amount of practice that is needed to achieve significant and enduring clinical symptom improvement. Future research could also investigate the impact of implementing the program with therapist facilitators who have less meditation and group facilitation experience. Further support for the effectiveness of MiCBT even with reduced homework requirements and relatively inexperienced facilitators could enhance its dissemination (Meadows, et al., 2014). The wider availability of MiCBT as an evidence-based

transdiagnostic MBI has the potential to increase the accessibility of mindfulness-integrated techniques, which are often only available to patients in specific diagnostic categories.

CHAPTER SIX: Consolidated References

Abbott, R. A., Whear, R., Rodgers, L. R., Bethel, A., Coon, J. T., Kuyken, W., ... & Dickens, C. (2014). Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *Journal of psychosomatic research*, *76*(5), 341-351. doi: 10.1016/j.jpsychores.2014.02.012.

ABS. (2017). *Australians pursuing higher education in record numbers*. ABS. Retrieved 12th May 2020 from https://www.abs.gov.au/Ausstats/abs@.nsf/dd0ca10eed681f12ca2570ce0082655d/1533fe5a8541d66cca2581bf00362d1d!OpenDocument

Baeyens, F., Field, A. P., & Houwer, J. D. (2005). Associative learning of likes and dislikes: Some current controversies and possible ways forward. *Cognition & Emotion*, *19*(2), 161-174. https://doi.org/10.1080/02699930441000265

Bahrani, S., Zargar, F., Yousefipour, G., & Akbari, H. (2017). The Effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy on Depression, Anxiety, and Stress in Females with Multiple Sclerosis: A Single Blind Randomized Controlled Trial. *Iranian Red Crescent Medical Journal*, *19*(4).

Barlow, D. H., Allen, L. B., & Choate, M. L. (2004). Toward a unified treatment for emotional disorders. *Behavior therapy*, *35*(2), 205-230. https://doi.org/10.1016/S0005-7894(04)80036-4

Barrett, L. F. (2006). Valence is a basic building block of emotional life. *Journal of Research in Personality*, *40*(1), 35-55.

Bernstein, A., Hadash, Y., Lichtash, Y., Tanay, G., Shepherd, K., & Fresco, D. M. (2015). Decentering and Related Constructs:A Critical Review and Metacognitive Processes Model. *Perspectives on Psychological Science*, *10*(5), 599-617. https://doi.org/10.1177/1745691615594577

Brown, T., Antony, M., & Barlow, D. (1995). Diagnostic comorbidity in panic disorder: effect on treatment outcome and course of comorbid diagnoses following treatment. *Journal of consulting and clinical psychology, 63 3*, 408-18 . DOI: 10.1037/0022-006x63.3.408

Brown, T. A., Campbell, L. A., Lehman, C. L., Grisham, J. R., & Mancill, R. B. (2001). Current and lifetime comorbidity of the DSM-IV anxiety and mood disorders in a large clinical sample. *Journal of Abnormal Psychology, 110*(4), 585–599. https://doi.org/10.1037/0021-843X.110.4.585

Cayoun, B. A. (2004). Advances in mindfulness training integration: towards a non-dualistic cognitive-behaviour therapy. biennial conference of the Australian Psychological society's Buddhism and Psychology Group, Deakin University, Melbourne, Australia. http://www. mindfulness. info/Publications/Articles/Towards% 20a% 20Non-Dualistic% 20CBT_APS-B&P-IG. pdf,

Cayoun, B. A. (2011). Mindfulness-integrated CBT: Principles and practice. John Wiley & Sons.

Cayoun, B. A. (2015). Mindfulness-integrated CBT for well-being and personal growth : four steps to enhance inner calm, self-confidence and relationships. Wiley/Blackwell.

Cayoun, B. A. (2017). The purpose, mechanisms and benefits of cultivating ethics in Mindfulness-integrated Cognitive Behavior Therapy. In C. M. Monteiro (Ed.), *Practitioner's Guide to Ethics and Mindfulness-Based Interventions* (pp. 163-192). Springer.

Cayoun, B. A., Francis, S., & Shires, A. G. (2019). *The Clinical Handbook of Mindfulness-integrated Cognitive Behavior Therapy: A Step-by-step Guide for Therapists*. John Wiley & Sons. https://doi.org/ISBN: 978-1-119-38963-7

Cayoun, B. A., Simmons, A., & Shires, A. (2020). Immediate and Lasting Chronic Pain Reduction Following a Brief Self-Implemented Mindfulness-Based Interoceptive Exposure Task: a Pilot Study. *Mindfulness*, *11*,112-124. https://doi.org/10.1007/s12671-017-0823-x

Chen, L.-Y., Crum, R. M., Martins, S. S., Kaufmann, C. N., Strain, E. C., & Mojtabai, R. (2013). Service use and barriers to mental health care among adults with major depression and comorbid substance dependence. *Psychiatric Services*, *64*(9), 863-870.

Craske, M. G. (2012). Transdiagnostic treatment for anxiety and depression. *Depression and Anxiety*.

Creswell, D. J. (2017). Mindfulness Interventions. *Annual Review of Psychology*, *68*(1), 491-516. https://doi.org/10.1146/annurev-psych-042716-051139

Desbordes, G., Gard, T., Hoge, E. A., Hölzel, B. K., Kerr, C., Lazar, S. W., Olendzki, A., & Vago, D. R. (2015). Moving beyond mindfulness: defining equanimity as an outcome measure in meditation and contemplative research. *Mindfulness*, *6*(2), 356-372.

De Houwer, J., Thomas, S., & Baeyens, F. (2001). Associative learning of likes and dislikes: A review of 25 years of research on human evaluative conditioning. Psychological Bulletin, 127, 853-869. DOI: 10.1037//033-2909.127.6.853

De Houwer, J. (2007). A conceptual and theoretical analysis of evaluative conditioning. *The Spanish journal of psychology*, *10*(2), 230. DOI: 10.1017/s1138741600006491

Diener, E., Emmons, R. A., Larsen, R. J., & Griffin, S. (1985). The satisfaction with life scale. *Journal of personality assessment*, *49*(1), 71-75.

Diener, E., Wirtz, D., Tov, W., Kim-Prieto, C., Choi, D., Oishi, S., & Biswas-Diener, R. (2010). New well-being measures: Short scales to assess flourishing and positive and negative feelings. *Social Indicators Research*, *97*(2), 143-156.

Eraslan-Capan, B. (2016). Social Connectedness and Flourishing: The Mediating Role of Hopelessness. *Universal Journal of Educational Research*, *4*(5), 933-940. https://doi.org/DOI: 10.13189/ujer.2016.040501

Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Thompson-Hollands, J., Carl, J. R., Gallagher, M. W., & Barlow, D. H. (2012). Unified protocol for transdiagnostic

treatment of emotional disorders: a randomized controlled trial. *Behavior therapy*, *43*(3), 666-678. https://doi.org/10.1016/j.beth.2012.01.001

Farias, M., & Wikholm, C. (2016). Has the science of mindfulness lost its mind? *BJPsych Bulletin*, *40*(6), 329-332. https://doi.org/10.1192/pb.bp.116.053686

Flett, J. A. M., Hayne, H., Riordan, B. C., Thompson, L. M., & Conner, T. S. (2019). Mobile Mindfulness Meditation: a Randomised Controlled Trial of the Effect of Two Popular Apps on Mental Health. *Mindfulness*, *10*(5), 863-876. https://doi.org/10.1007/s12671-018-1050-9

Frances, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020). Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. *BMC Psychiatry*, *20*(1), 7. https://doi.org/10.1186/s12888-019-2411-1

Francis, S. (2013). A preliminary study of Mindfulness-integreatd Cognitive Behaviour Therapy: Results from a series of group interventions First International Conference on Mindfulness, Rome, Italy.

Francis, S., Shawyer, F., Cayoun, B., Enticott, J., & Meadows, G. (2020). Study protocol for a randomized control trial to investigate the effectiveness of an 8-week mindfulness-integrated cognitive behavior therapy (MiCBT) transdiagnostic group intervention for primary care patients. *BMC Psychiatry*, *20*(1), 7. https://doi.org/10.1186/s12888-019-2411-1

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Fresco, D. M., Moore, M. T., van Dulmen, M. H., Segal, Z. V., Ma, S. H., Teasdale, J., & Williams, J. M. G. (2007). Initial psychometric properties of the experiences questionnaire: validation of a self-report measure of decentering. *Behavior therapy*, *38*(3), 234-246.

Gárriz, M., Elices, M., Peretó, M., Martín-López, L. M., Justicia, A., & Pérez, V. (2020). Mindfulness-Based Cognitive Therapy Delivered in Primary Care: a Naturalistic, Mixed-

Methods Study of Participant Characteristics and Experiences [journal article]. *Mindfulness*, *11*(2), 291-302. https://doi.org/10.1007/s12671-019-01166-y

Grabovac, A. (2014). The Stages of Insight: Clinical Relevance for Mindfulenss-Based Interventions [online]. *Mindfulness*. https://doi.org/10.1007/s12671-014-0294-2

Harel, O., Hadash, Y., Levi-Belz, Y., & Bernstein, A. (2019). Does Early Emotional Responding to Initial Mindfulness Training Impact Intervention Outcomes? *Mindfulness*, *10*(4), 616-626. https://doi.org/10.1007/s12671-018-1018-9

Hayes, A. F. (2018). Introduction to Mediation, Moderation and Conditional Process Analysis: A Regression-based Approach (Second ed.). The Guilford Press.

Hayes, S. C. (2017). The third wave of CBT and the rise of process--based care. *World Psychiatry*.

Hudson, J. I., & Pope, H. G. (1990). Affective spectrum disorder: does antidepressant response identify a family of disorders with a common pathophysiology?. *The American journal of psychiatry*. https://doi.org/10.1176/ajp.147.5.552

Juneau, C., Pellerin, N., Elliott, T., Ricard, M., Shankland, R., & Dambrun, M. (2019). Reliability and Validity of an Equanimity Questionnaire: The Two-factor Equanimity Scale (EQUA-S).

Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General hospital psychiatry*, *4*(1), 33-47.

Kabat-Zinn, J. (1990). *Full Catastrophe Living*. Delacorte.

Kabat-Zinn, J. (1994). Wherever you go there you are: Mindfulness meditation in everyday life. Piatkas.

Kessler R.C., Stang P.E., Wittchen H., Ustun TB, Roy-Burne P.P., Walters EE. Lifetime Panic-Depression Comorbidity in the National Comorbidity Survey. *Arch Gen Psychiatry.* 1998;55(9):801–808. doi:10.1001/archpsyc.55.9.801

Kessler, R. C., Andrews, G., Colpe, L. J., Hiripi, E., Mroczek, D. K., Normand, S.-L., Walters, E. E., & Zaslavsky, A. M. (2002). Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological medicine*, *32*(06), 959-976. https://doi.org/DOI: 10.1017}S0033291702006074

Levenson, R.W., Blood, Sweat and Fears. (2003) Annals of New York Academy of Sciences 1000: 348–366 (2003). doi: 10.1196/annals.1280.016

Lindahl, J. R., Fisher, N. E., Cooper, D. J., Rosen, R. K., & Britton, W. B. (2017). The varieties of contemplative experience: A mixed-methods study of meditation-related challenges in Western Buddhists. *PLoS One*, *12*(5), e0176239. https://doi.org/10.1371/journal.pone.0176239

Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behaviour research and therapy*, *33*(3), 335-343.

MacKinnon, D. P., & Luecken, L. J. (2011). Statistical analysis for identifying mediating variables in public health dentistry interventions. *Journal of public health dentistry*, *71 Suppl 1*(Suppl 1), S37-S46. https://doi.org/10.1111/j.1752-7325.2011.00252.x

Meadows, G. N., Shawyer, F., Enticott, J. C., Graham, A. L., Judd, F., Martin, P. R., Piterman, L., & Segal, Z. (2014). Mindfulness-based cognitive therapy for recurrent depression: a translational research study with 2-year follow-up. *Australian & New Zealand Journal of Psychiatry*, *48*(8), 743-755.

Mehling, W. E., Price, C., Daubenmier, J. J., Acree, M., Bartmess, E., & Stewart, A. (2012). The multidimensional assessment of interoceptive awareness (MAIA). *PLoS One*, *7*(11), e48230. https://doi.org/https://doi.org/10.1371/journal.pone.0048230

Moses, E. B., & Barlow, D. H. (2006). A new unified treatment approach for emotional disorders based on emotion science. *Current directions in psychological science*, *15*(3), 146-150. https://doi.org/10.1111/j.0963-7214.2006.00425.x

Newby, J., Mckinnon, A., Kuyken, W., Gilbody, S., & Dalgleish, T. (2015). Systematic review and meta-analysis of transdiagnostic psychological treatments for anxiety and depressive disorders in adulthood. . *Clinical psychology review*(40), 91. https://doi.org/https://doi.org/10.1016/j.cpr.2015.06.002

Pollack, M. H. (2005). Comorbid anxiety and depression. *The Journal of Clinical Psychiatry*, *66 Suppl 8*, 22.

Pouyanfard, S., ParviziFard, A. A., Mohammadpour, M., & Sadeghi, K. (2020). Effectiveness of mindfulness-integrated cognitive behavior therapy on anxiety, depression and hope in multiple sclerosis patients: a randomized clinical trial. *Trends in Psychiatry and Psychotherapy*, *42*(1), 55-63.

Ribeiro, L., Atchley, R. M., & Oken, B. S. (2018). Adherence to Practice of Mindfulness in Novice Meditators: Practices Chosen, Amount of Time Practiced, and Long-Term Effects Following a Mindfulness-Based Intervention [journal article]. *Mindfulness*, *9*(2), 401-411. https://doi.org/10.1007/s12671-017-0781-3

Rogers, H. T., Shires, A. G., & Cayoun, B. A. (2020). Development and Validation of the Equanimity Scale-16. *Mindfulness*. https://doi.org/10.1007/s12671-020-01503-6

Saeri, A. K., Cruwys, T., Barlow, F. K., Stronge, S., & Sibley, C. G. (2018). Social connectedness improves public mental health: Investigating bidirectional relationships in the New Zealand attitudes and values survey. *Australian & New Zealand Journal of Psychiatry*, *52*(4), 365-374. https://doi.org/10.1177/0004867417723990

Sahdra, B., Ciarrochi, J., & Parker, P. (2016). Nonattachment and mindfulness: Related but distinct constructs. *Psychological assessment*, *28*(7), 819.

Sahdra, B. K., Shaver, P. R., & Brown, K. W. (2010). A scale to measure nonattachment: A Buddhist complement to Western research on attachment and adaptive functioning. *Journal of personality assessment*, *92*(2), 116-127. https://doi.org/https://doi.org/10.1080/00223890903425960

Sauer-Zavala, S., Gutner, C. A., Farchione, T. J., Boettcher, H. T., Bullis, J. R., & Barlow, D. H. (2017). Current definitions of "transdiagnostic" in treatment development: A search for consensus. *Behavior therapy*, *48*(1), 128-138. https://doi.org/https://doi.org/10.1016/j.beth.2016.09.004

SBS. (2019). *Almost 30 per cent of the Australian population was born overseas*. SBS. Retrieved 12th May 2020 from https://www.sbs.com.au/news/almost-30-per-cent-of-the-australian-population-was-born-overseas

Scott-Hamilton, J., Schutte, N. S., & Brown, R. F. (2016). Effects of a mindfulness intervention on sports-anxiety, pessimism, and flow in competitive cyclists. *Applied Psychology: Health and Well-Being*, *8*(1), 85-103. https://doi.org/https://doi.org/10.1111/aphw.12063

Segal, Z., Williams, M., & Teasdale, J. (2002). Mindfulness-based cognitive therapy for depression : a new approach to preventing relapse. New York : Guilford Press.

Segal, Z., Williams, M., & Teasdale, J. (2013). *Mindfulness-Based Cognitive Therapy for Depression* (2nd revised ed. ed.). Guilford Publications.

Sekula, L. K., Desantis, J., & Gianetti, V. (2003). Considerations in the Management of the Patient with Comorbid Depression and Anxiety. *Journal of the American Academy of Nurse Practitioners*, *15*(1), 23-33. https://doi.org/10.1111/j.1745-7599.2003.tb00251.x

Valente, M. J., & MacKinnon, D. P. (2017). Comparing models of change to estimate the mediated effect in the pretest-posttest control group design. *Struct Equ Modeling*, *24*(3), 428-450. https://doi.org/10.1080/10705511.2016.1274657

van Kesteren, E.-J., & Oberski, D. L. (2019). Exploratory Mediation Analysis with Many Potential Mediators. *Structural Equation Modeling: A Multidisciplinary Journal*, *26*(5), 710-723. https://doi.org/10.1080/10705511.2019.1588124

VanderWeele, T. J., & Vansteelandt, S. (2014). Mediation Analysis with Multiple Mediators. *Epidemiologic methods*, *2*(1), 95-115. https://doi.org/10.1515/em-2012-0010

Vøllestad, J., Sivertsen, B., & Nielsen, G. H. (2011). Mindfulness-based stress reduction for patients with anxiety disorders: Evaluation in a randomized controlled trial. *Behaviour research and therapy*, *49*(4), 281-288.

Wells, A. (2007). Cognition About Cognition: Metacognitive Therapy and Change in Generalized Anxiety Disorder and Social Phobia. *Cognitive and Behavioral Practice*, *14*(1), 18-25. https://doi.org/https://doi.org/10.1016/j.cbpra.2006.01.005

Yazdanimehr, R., Omidi, A., Sadat, Z., & Akbari, H. (2016). The effect of mindfulness-integrated cognitive behavior therapy on depression and anxiety among pregnant women: a randomized clinical trial. *Journal of Caring Sciences*, *5*(3), 195.

Zeng, X., Oei, T. P., Ye, Y., & Liu, X. (2015). A critical analysis of the concepts and measurement of awareness and equanimity in Goenka's Vipassana meditation. *J Relig Health*, *54*(2), 399-412. https://doi.org/10.1007/s10943-013-9796-9

6 CHAPTER SEVEN: Appendices

6.1 Appendix 1

7.1.1 Ethics approval

7.1.2 Risk assessment

Ethics approval
Monash University Human Research Ethics Committee

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project Number:	CF16/2278 - 2016001131	
Project Title:	Randomised controlled trial of MiCBT compared to control group	
Chief Investigator:	Dr Frances Shawyer	
Approved:	**From:** 19 September 2016	**To:** 19 September 2021

Terms of approval - ***Failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.***

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must include your project number.
6. **Amendments to the approved project (including changes in personnel):** Require the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

Professor Nip Thomson
Chair, MUHREC

cc: Dr Bruno Cayoun, Ms Sarah Francis

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ABN 12 377 614 012 CRICOS Provider #00008C

Risk assessment

NUMBER	RISK DESCRIPTION	TREND	CURRENT	RESIDUAL
1473	Randomised control trial of group mindfulness intervention	↓	Low	Not Assessed

RISK OWNER	RISK IDENTIFIED ON	LAST REVIEWED ON	NEXT SCHEDULED REVIEW
SARAH ELIZABETH FRANCIS	29/08/2016	29/08/2016	29/08/2019

RISK CONSEQUENCE	RISK FACTOR(S)	EXISTING CONTROL(S)	PROPOSED CONTROL(S)	OWNER	DUE DATE
	Potential discomfort of researcher during group session.	**Control**: Researcher is a registered psychologist. Uses professional expertise to manage situation. Access to supervisor and co-supervisor to debrief if required. **Control**: Participants are screened by GP and researcher prior to invitation to take part in study. If not suitable for group session, referred for one-on-one therapy.			
	Potential discomfort of participants during group session.	**Control**: Researcher is a registered psychologist. Uses professional expertise to manage situation. **Control**: Security guards patrol the building. Advise security of sessions being run.			

6.2 Appendix 2: Recruitment information

7.2.1 Information for referring General Medical Practitioners

7.2.2 Email information for Health Professional

7.2.3 Information for Participants

Information for referring General Medical Practitioners

MONASH University

MONASH MEDICINE NURSING AND HEALTH SCIENCES

MINDFULNESS-INTEGRATED COGNITIVE BEHAVIOUR THERAPY (MiCBT)

Information for referring Health Practitioners

Is your patient struggling with anxiety, depression, stress, trauma, anger, pain or psychological issues? You may like to refer them to a research project about using a mindfulness-based therapy.

ABOUT MiCBT

MiCBT is a skills training program integrating specific meditation techniques with aspects of CBT. It involves groups of about 10-15 people attending one 2-hour session per week for 8 weeks with a requirement for daily mindfulness practice.

The program teaches how to use mindfulness skills to notice and detach from unhelpful thoughts and how to manage emotional reactivity. There is no cost to patients.

THE MiCBT FACILITATOR

Sarah Francis is an experienced registered psychologist trained in MiCBT who has been working with this approach for over 6 years. She has researched the efficacy of MiCBT in a pilot study in her private practice.

THE MiCBT RESEARCHERS

Principal researcher
Dr Frances Shawyer
BBSc(Hons), PhD, MAPS, MCCLP

Co-researcher
Dr Bruno Cayoun
D Psych(Clin), MAPS

Student researcher
Sarah Francis
MPsych, MA, BEd, MAPS

WHAT IS INVOLVED FOR PATIENTS?

Following initial assessment participants are randomised to one of two treatment conditions.

The treatment group will participate in an 8 week MiCBT program and complete assessment questionnaires on three occasions over around 9 months.

The control group will receive their usual treatment, complete assessment questionnaires on three occasions over 9 months, then have the opportunity to participate in the MiCBT program at the end of the trial.

Participants will receive a $20 gift voucher on completion of the final assessment.

INCLUSION CRITERIA

- Aged 18-75 years
- Fluent in english
- K10 score ≥ 20

EXCLUSION CRITERIA

- Current psychotic symptoms
- Current borderline or antisocial personality disorder
- Current significant eating disorder
- Current alcohol/drug dependency
- ≥ than 20mg diazepam equivalent/day
- Pervasive development delay
- Organic mental disorder

REFERRING PATIENTS

If you have a patient who you think is eligible and interested in participating, please provide them with the research information brochure or the following contact details:

Sarah Francis
M 0409 669 668
E sefra@student.monash.edu

This is a PhD research project conducted through the Department of Psychiatry, Faculty of Medicine, Nursing and Health Sciences at Monash University. Approval to conduct the project has been granted by the Monash University Human Research Ethics Committee.

Is your patient struggling with anxiety, depression, stress, trauma, anger, pain or psychological issues? You may like to refer them to a research project about using a mindfulness-based therapy.

REFERRING HEALTH PRACTITIONER (GP OR PSYCHIATRIST)

Referrer Name:

Address:

State: Postcode:

Telephone: Mobile:

Email:

PATIENT DETAILS

Patient Name: Date of Birth: / /

Address:

State: Postcode:

Telephone: Mobile:

Email:

Presenting problem:

K10 Score:

Please email this form to:
melbournemindfulness.melbourne@gmail.com

This is a PhD research project conducted through the Department of Psychiatry, Faculty of Medicine, Nursing and Health Sciences at Monash University. Approval to conduct the project has been granted by the Monash University Human Research Ethics Committee.

Email information for Health Professional

7.2.2

Sarah Francis, Psychologist.

M.Psych.M.A.,B.Ed.,Diploma in Psychodynamic Psychotherapy, Voc Dip in MiCBT; M.A.P.S.

Level 3, 530, Little Collins Street, Melbourne 3000

Provider no: 4148837A

contact@melbournemindfulness.com

www.melbournemindfulness.com

Telephone: 9629 3869; **Mobile:** 0409 669 688

Research Trial - Information for Health Professionals

Randomised controlled trial of MiCBT compared to control group

Principal Researcher: Sarah Francis

I am conducting a research project, as part of a Ph.D. degree at Monash University.

Participants need to meet the selection criteria which include having a K10 score of 20 or above. I attach a referral form and flyer for patients in case you have any patients who may benefit from this program and are interested in volunteering to contribute to mental health research and being part of a randomised controlled trial. This means that patients may be offered the program (of course this is free of charge) first or they may be randomly allocated to the control, wait list group and not receive the program until the 6-month follow up is complete.

Mindfulness-Integrated Cognitive Behaviour Therapy (MiCBT) is a sophisticated integration of CBT with very specific mindfulness exercises. The program develops non-reactive awareness of both thinking patterns and co-arising body sensations and provides psycho-education about the neurophysiology of mindfulness as well as techniques to apply skills to daily life. This provides a powerful platform for change and psychological well-being. This therapy is used across a range of psychological diagnoses including anxiety, depression, stress related conditions, attentional issues and pain.

There are two publications describing the program, Mindfulness-Integrated CBT: Principles and Practice (Cayoun, 2011) and Mindfulness-Integrated CBT for Well-being and Personal Growth, Cayoun, (2015). MiCBT is used in both group programs and individual therapy – the current research project is using a group based intervention.

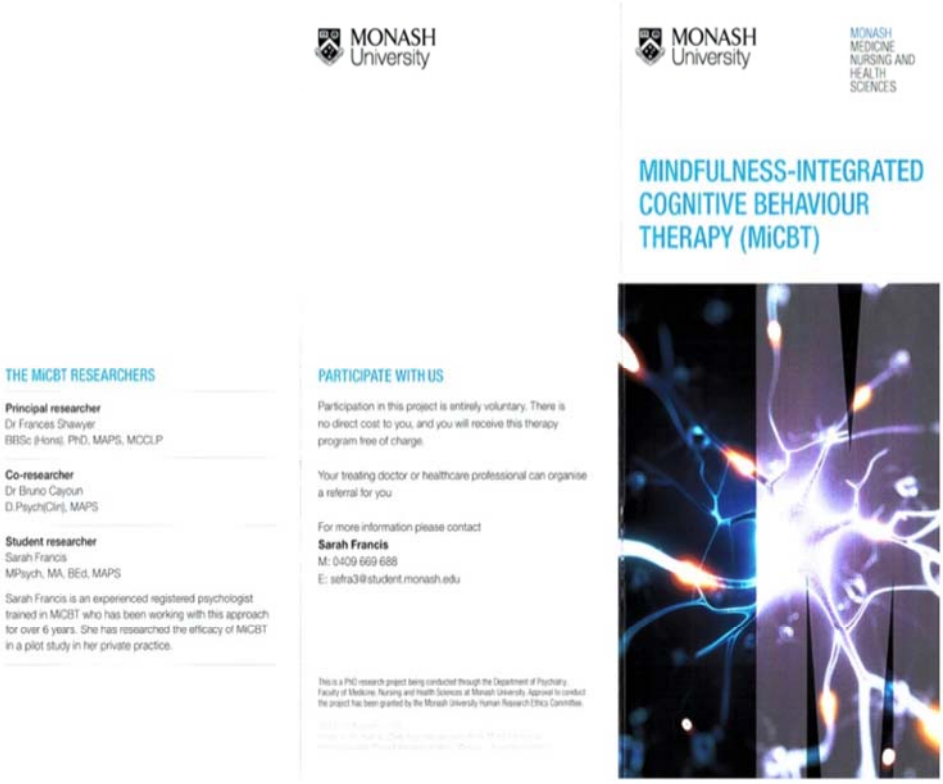
We believe it is important to gather robust research data about the efficacy of programs such as the MiCBT program and would appreciate your support. The project has ethical approval from the Monash University Human Research Ethics Committee (CF16/2278 – 2016001131) and is registered with the ANZ Registered Controlled Trial Register (Ref. 12617000061336).

I would be happy to provide any additional information that may be useful and would be happy to provide a briefing to clinic staff.

Sarah Francis

Sarah Francis, Principal Psychologist
M.A., M. Psych,. B.Ed., Dip. Psychodynamic Psychotherapy, Grad. Dip. MiCBT, MAPS.
9629 3869
0409 669 688
www.melbournemindfulness.com.

Information for Participants



MONASH University

MONASH University

MONASH MEDICINE NURSING AND HEALTH SCIENCES

MINDFULNESS-INTEGRATED COGNITIVE BEHAVIOUR THERAPY (MiCBT)

THE MiCBT RESEARCHERS

Principal researcher
Dr Frances Shawyer
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Co-researcher
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D.Psych(Clin), MAPS

Student researcher
Sarah Francis
MPsych, MA, BEd, MAPS

Sarah Francis is an experienced registered psychologist trained in MiCBT who has been working with this approach for over 6 years. She has researched the efficacy of MiCBT in a pilot study in her private practice.

PARTICIPATE WITH US

Participation in this project is entirely voluntary. There is no direct cost to you, and you will receive this therapy program free of charge.

Your treating doctor or healthcare professional can organise a referral for you

For more information please contact
Sarah Francis
M: 0409 669 688
E: sefra3@student.monash.edu

This is a PhD research project being conducted through the Department of Psychiatry, Faculty of Medicine, Nursing and Health Sciences at Monash University. Approval to conduct the project has been granted by the Monash University Human Research Ethics Committee.

STRUGGLING WITH ANXIETY, DEPRESSION, STRESS, TRAUMA, ANGER, PAIN OR OTHER PSYCHOLOGICAL ISSUES? CONSIDER JOINING THIS MiCBT RESEARCH TRIAL

This project is investigating a Mindfulness Therapy called Mindfulness Integrated Cognitive Behaviour Therapy (MiCBT).

ABOUT MiCBT

Mindfulness Integrated Cognitive Behaviour Therapy (MiCBT) aims to help people find new ways to deal with psychological issues such as anxiety, depression, stress, trauma, attention issues. It involves groups of about 10-15 people attending one 2-hour session per week for 8 weeks. The MiCBT program teaches skills in managing mind-wandering and emotions, awareness of thinking processes, body sensations and self-compassion. Mindfulness meditation practices are central to the program.

The project involves comparing usual treatment with MiCBT. All participants will be offered the MiCBT program; one group will be offered the program first and the remaining participants (the control group) will be offered the MiCBT around eight months later, at the end of the project.

WHAT IS INVOLVED

If you take part, you will be asked to complete an assessment interview with questionnaires and then you will be randomly placed in one of two groups (by chance, like tossing a coin). One group will complete the MiCBT program first and the other group will be offered MiCBT at the end of the project.

Participants in both groups will be asked to complete further questionnaires around 4 and 8 weeks into the project then after a further 6 months to see how you are getting on.

In both groups you will be free to visit any doctor or any health professional as you see fit. **All material is treated as private and confidential.**

REMUNERATION

You will receive MiCBT free of charge.

To acknowledge your contribution, you will be given a gift voucher to the value of $20 following the final assessment.

INCLUSION CRITERIA

To participate you need to be:

- Aged between 18-75 years;
- Interested in taking part in this treatment trial
- Willing to get a referral from your GP (no Mental Health Care Plan required)
- Interested in making a contribution to mental health research
- Willing to engage with daily mindfulness practice
- Fluent in english

If you are interested in participating then please take this brochure along to your treating doctor or healthcare professional to discuss.

Your treating doctor or healthcare professional can refer you to the project by contacting:

Sarah Francis
M: 0409 669 688
E: sefra3@student.monash.edu
or downloading referral information form:
melbournemindfulness.com

6.3 Appendix 3: Explanatory Statement and Consent Form

MONASH University

Explanatory Statement and Consent Form

September 2016

Full Project Title: ***Randomised controlled trial of MiCBT compared to control group.***

Principal Researchers: Dr Frances Shawyer, Sarah Francis

This Explanatory Statement and Consent Form is six pages long. Please make sure you have all the pages.

Your Consent

This Explanatory Statement and Consent Form contains detailed information about the research project. Its purpose is to explain to you as clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Explanatory Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker before deciding whether or not to participate. If you do not want to participate you do not have to.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Explanatory Statement and Consent Form (Client) to keep as a record.

This information sheet is for you to keep.

My name is Sarah Francis and I am conducting a research project under the supervision of Dr. Frances Shawyer, a Research Fellow in the School of Clinical Sciences at Monash Health, as part of a Ph.D. degree at Monash University, and Dr Bruno Cayoun, Clinical Psychologist and creator of MiCBT.

Purpose and Background:

Many people experience a wide range of psychological conditions across their lifetime. The need to develop effective short-term therapy that can be applied broadly makes mindfulness-based therapy an attractive possibility for individuals who wish to explore new therapies or to enhance the impact of medication. There is an increasing amount of research emerging into mindfulness-based therapies with promising results but more robust research is needed. Mindfulness-integrated cognitive behaviour therapy (MiCBT) is a relatively new therapy that is starting to show some promising results in clinical practice. The purpose of the study is to investigate the capacity of MiCBT group interventions to improve a range of psychological symptoms such as depression and anxiety.

MiCBT aims to help people to learn new ways to handle anxiety depression, stress and other psychological problems. It focuses on understanding how we process thoughts and manage body sensations and our reactivity.

In order to test if MiCBT is an effective psychological treatment, the results of the MiCBT treatment will be compared to the results of people who are not given MiCBT but who receive their usual treatment.

A total of 120 people will participate in this study.

Procedures

You have expressed interest in this research project through our advertising or through your General Practitioner or another health professional who believes that you may be eligible to participate. We are inviting you to participate in this randomised controlled treatment study using Mindfulness-integrated Cognitive Behaviour Therapy (MiCBT) in a group format. This means the delivery of this Mindfulness-based program (MiCBT) to groups of 8-12 participants in 8 two-hour training sessions as well as a pre- mid-end and post-program assessment. The program requires regular daily mindfulness exercises. To be included in this study you must be age 18-75; fluent in English and have a referral to the study from your GP who has been provided with the eligibility criteria for selection to the study.

The purpose of the study is to investigate whether MiCBT reduces symptoms of depression and anxiety and improves overall well-being. If you agree to take part in the study to you will be randomly allocated to either a treatment or a control group. If you are allocated to the treatment group you will participate in an 8-week MiCBT treatment program and complete the survey questionnaires at the start, middle and end of the program and again after 6 months. You will be expected to attend the eight training sessions (each session is 2 hours) as well as completing the measures pre and post the training.

If you are allocated to the control group you will receive your usual treatment, complete all the survey questionnaires on four occasions and will be invited to attend the treatment program approximately 6 months after the start of the study. Therefore all participants are able to attend the program.

If you decide to participate in this project, you will be contacted via email or telephone and invited to attend an interview and complete some survey questions. These include the Depression Anxiety and Stress Scale (DASS 21), the Mindfulness Self Efficacy Scale, and the Satisfaction with Life Scale, the Experiences Questionnaire, the Multidimensional Assessment of Interoceptive Awareness (MIAI) and the Non-attachment scale (NAS), The Flourishing Scale (FS) and the K10. You will be asked if you would like to receive information about the results of this study and arrangements will be made to provide you with this information if requested.

It is possible that not all those who are referred to this project will be able to take part. The following groups will not be eligible to participate in this research study: people less than 18 years of age, non-English speakers, those with intellectual disability, psychotic symptoms, a current diagnosis of borderline or antisocial personality disorder, current significant obsessive compulsive disorder, current significant eating disorder, prescribed more than 20mg diazepam equivalent per day, and current treatment for active drug or alcohol abuse. If you are not able to take part in the study we can discuss alternative treatment options with you.

Possible benefits

Possible benefits include reductions in symptoms such as anxiety, depression and stress, an increased sense of being able to manage challenging situations with less emotional reactivity and improved life satisfaction. We cannot guarantee the benefits from this project.

Possible risks

It is possible that in the process of your participation you may experience feelings of emotional distress. If such concerns do arise, we encourage you to discuss them with the researcher, Sarah Francis. Alternatively, you should feel free to contact Dr. Frances Shawyer (see contact details below) who is the project supervisor, a registered clinical psychologist and experienced counsellor. You are free to discontinue form the study at any time. Any issues of concern can also be discussed with Lifeline or any of the other services listed below.

Privacy and confidentiality

If you were not referred to this project by your general practitioner or psychiatrist, we will ask you to attend your general practitioner or psychiatrist with a view to ensuring that your treating clinician is aware of and comfortable with your participation in MiCBT and, where your treating clinician is agreeable, being referred by your treating clinician. Your MiCBT instructor will provide your referring clinician with a report at the end of the course of treatment.

According to the ethical considerations of the Australian Psychological Society confidentiality may be breached if it considered that, by not doing so, you or others will be exposed to harm or for legal reasons.

With these exceptions, any information you give and the results of the assessments will be kept confidential. Participants will be allocated a unique identifier to be used when processing and communicating results. Personal details and results will be kept in separate databases and stored in accordance with Australian Psychological Society Ethical Standards. No information regarding your treatment, participation and progress will be divulged. The results of this project may be published in journal articles, student reports (i.e., thesis), and conference presentations, but they will not be published in a manner that would reveal your identity. The research dataset, de-identified may be made publically available.

Your participation in this project is voluntary and there is no obligation for you to take part. Your decision whether or not to take part or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with any hospital or mental health service. If you receive treatment from the person who introduced this project to you, a decision to participate or not to participate or to withdraw shall not affect your treatment by this person in any way.

Should you wish to participate please note that you can withdraw from the program at any time. If you decide to leave the research study, the researchers will not collect additional personal information from you. However personal information already collected will be kept to ensure that the results of the research project can be measured properly and to comply with the law. You should be aware that data collected up to the time you withdraw will form part of the research study results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research.

Further information or any problems

If you require further information or you have any problems concerning this project, you can contact the Principal Researcher, Frances Shawyer on telephone 99029696 or email frances.shawyer@monash.edu

Other issues
If you have a complaint concerning the manner in which this research (*Randomised controlled trial of MiCBT compared to control group*) is conducted, please contact:
Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building E
24 Sports Walk
Clayton Campus, Monash University
Wellington Rd
Clayton VIC 3800, Australia
Tel: +61 3 9905 2052
Fax: +61 3 9905 3831
Email: muhrec@monash.edu

Available services:
Lifeline: **13 11 14**
Turning Point (24 hour Alcohol and Drug **helpline): 1800 888 236 (Freecall)**
Beyond Blue Information & Referral Line (24 hour service) Ph: 1300224636

Australian Psychologists Referral Service Melbourne: 03 8662 3300 Outside Melbourne **1 800 333 497**
Email:referral@psychsociety.com.au (Cost Range: $80.00-$140.00)

Carlton Community Health Centre
622 Lygon Street
Carlton 3054
Ph: 03 9349 7333
Fax: 03 93497300

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Inner South Community Health - **9525 1300**
Prahran
240 Malvern Rd Prahran 3181
10 Inkerman St St Kilda 3182

Bentleigh Bayside Community Health Centre

Bentleigh East Site:
Gardeners Rd
Bentleigh East 3165
Ph: 03 9575 5333

Highett Site:
4 Livingstone Street
Highett
Ph: 03 9553 6033

MonashLink Community Health Service - Cost: Sliding scale dependent upon income.

Hughesdale Site:
568 Neerim Rd
Hughesdale 3166
Ph: 03 9568 2599

Ashwood Site:
219 High Street Rd
Ashwood 3147
Ph: 03 9809 5499

Waverley Site:
7 Dunscombe Ave
Glen Waverley 3150
Ph: 03 9803 0300

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Consent Form

Full Project Title: **Randomised controlled trial of MiCBT compared to control group.**

I have read and I understand the Explanatory Statement.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project according to the conditions and as set out in the Explanatory Statement which describes the group training program and the completion questionnaires on four occasions.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

I will be given a copy of the Explanatory Statement to keep.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's name (printed) .....

Signature ..... Date .....

Name of witness to participant's signature (printed) .....

Signature ..... Date .....

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed) .....

Signature ..... Date .....

**Note:* All parties signing the Consent form must date their own signature.

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Revocation of Consent Form

Full Project Title: **Randomised controlled trial of MiCBT compared to control group.**

I hereby with to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with any treatment provider.

☐ I wish to be kept informed of the progress and outcomes of the study.
☐ I wish to be offered MiCBT at the conclusion of the project

Participant's name (printed) .....

Signature ..... Date .....

6.4 Appendix 4: Measures

Data was collected using Qualtrics online software. Questions and measures are presented here as downloaded from Qualtrics.

6.5 Participant information pre-program

7.6. Scales

7.6.1 DASS21

7.6.2 MSES

7.6.3 SWLS

7.6.4 FS

7.6.5 EQ

7.6.6 MAIA

7.6.7 NAS

7.6.8 K10

7.6.9 Post-program questions

7.6.10 6-month follow-up questions

7.5 Participant information pre-program

1. Mindfulness integrated CBT (MiCBT): Pre-program Questionnaire

Start of Block: Default Question Block

Q1
Mindfulness integrated CBT (MiCBT): Pre-program Questionnaire

I have read the consent form and explanatory statement. I understand that my participation in this study is voluntary, and I wish to be involved with this research.

O Yes (1)

O No (2)

Skip To: End of Survey If Explanatory statement = No

Page Break

Q2 **Please enter your participant number:**
(This number was given to you at your interview with Sarah Francis and is written on your participant information sheet.)

_____

Page Break

Q3 **Let's begin...**

You will see a progress bar on the bottom of the page as you go through each of the questionnaires. This will let you know how much of the survey you have already completed.

The survey should take about 15-20 minutes.

In what month and year were you born? *(e.g. MM/YYYY)*

_____

Which gender do you identify with?

- O Male (1)
- O Female (2)
- O Other (3) _____

What is your country of birth?

- O Australia (1)
- O Other (2) _____

(If not born in Australia) In what year did you arrive in Australia?

_____

What is the main language spoken at home?

- O English (1)
- O Other (2) _____

What is your martial status?

O Single (1)

O Married (2)

O De facto (3)

O Separated (4)

O Divorced (5)

O Widowed (6)

O Other (7) _____

What education level did you complete in school? (i.e., fully completed – e.g., if primary school not completed tick none)

O None (1)

O Primary school (2)

O Secondary school – Year 10 or less (3)

O Senior Secondary school – Year 11 (4)

O Senior Secondary school – Senior Certificate of Education completed (e.g., HSC, VCE, VCAL) (5)

Have you completed any further qualifications since leaving school?

O Yes (1)

O No (2)

Skip To: medications If Have you completed any further qualifications since leaving school? = No

What is your highest qualification since leaving school? (i.e., fully completed)

- O Certificate I (1)
- O Certificate II (2)
- O Certificate III (3)
- O Certificate IV (4)
- O Diploma (5)
- O Advanced Diploma (6)
- O Associate Degree (7)
- O Bachelor Degree (8)
- O Bachelor Honours (9)
- O Degree Graduate (10)
- O Certificate Graduate (11)
- O Masters Degree (research) (12)
- O Masters Degree (coursework) (13)
- O Masters Degree (extended) (14)
- O Doctoral Degree (15)
- O Other (16) _____

Mental Health Medications

Please list any medications for your mental health that you take on a daily or regular basis. (Please include the dose and frequency of any medications, including those given by injection).

If you do not take any medications please write "none"

**Please provide dosage in units, such as milligrams (mg) or micrograms (mcg), as provided on the medication packaging, rather than number of pills. e.g. if you take a 10 mg pill once a day you would put 10 mg per day, not one pill. If you take a 5mg pill twice a day you would also put 10mg per day.*

_____

Do you practice meditation at the moment?

O Yes (1)

O No (2)

Display This Question:

If Do you practice meditation at the moment? = Yes

Please describe the type of meditation practice and how long and how often you practice.

_____

Q16 That is the end of the basic demographic questions.

We will move onto the questionnaires.

6.6 Scales

Depression, Anxiety and Stress Scale
DASS 21 Depression, Anxiety, Stress Scale (DASS - 21)
Lovibond, S.H.,& Lovibond, P.F., (1995)

Please read each statement and circle a number 0, 1, 2 or 3 that indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

	0. Did not apply to me at all (0)	1. Applied to me to some degree, or some of the time (1)	2. Applied to me to a considerable degree, or a good part of time (2)	3. Applied to me very much, or most of the time (3)
I found it hard to wind down (1)	O	O	O	O
I was aware of dryness of my mouth (2)	O	O	O	O
I couldn't seem to experience any positive feeling at all (3)	O	O	O	O
I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion) (4)	O	O	O	O
I found it difficult to work up the initiative to do things (5)	O	O	O	O
I tended to over-react to situations (6)	O	O	O	O
I experienced trembling (e.g., in the hands) (7)	O	O	O	O
I felt that I was using a lot of nervous energy (8)	O	O	O	O
I was worried about situations in which I might panic and make a fool of myself (9)	O	O	O	O

	0. Did not apply to me at all (0)	1. Applied to me to some degree, or some of the time (1)	2. Applied to me to a considerable degree, or a good part of time (2)	3. Applied to me very much, or most of the time (3)
I felt that I had nothing to look forward to (10)	O	O	O	O
I found myself getting agitated (11)	O	O	O	O
I found it difficult to relax (12)	O	O	O	O
I felt down-hearted and blue (13)	O	O	O	O
I was intolerant of anything that kept me from getting on with what I was doing (14)	O	O	O	O
I felt I was close to panic (15)	O	O	O	O
I was unable to become enthusiastic about anything (16)	O	O	O	O
I felt I wasn't worth much as a person (17)	O	O	O	O
I felt that I was rather touchy (18)	O	O	O	O
I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat) (19)	O	O	O	O
I felt scared without any good reason (20)	O	O	O	O
I felt that life was meaningless (21)	O	O	O	O

Mindfulness-based Self Efficacy Scale - R
MSES Mindfulness-Based Self Efficacy Scale – REVISED © (MSES-R)

Select one number in each row according to how much you now agree with each statement below. Try not to spend too much time on any one item. There are no right or wrong answers.

	0. Not at all (0)	A little (1)	Moderately (2)	A lot (3)	Completely (4)
I found it hard to wind down (1)	O	O	O	O	O
I get easily overwhelmed by my emotions (1)	O	O	O	O	O
I find it difficult to make new friends (2)	O	O	O	O	O
I try to avoid uncomfortable situations even when they are really important (3)	O	O	O	O	O
When I feel very emotional, it takes a long time for it to pass (4)	O	O	O	O	O
I feel comfortable saying sorry when I feel I am in the wrong (5)	O	O	O	O	O
It is often too late when I realise I overreacted in a stressful situation (6)	O	O	O	O	O
I get so caught up in my thoughts that I end up feeling very sad or anxious (7)	O	O	O	O	O
When I have unpleasant feelings in my body, I prefer to push them away (8)	O	O	O	O	O
I can resolve problems easily with my partner (or best friend if single) (9)	O	O	O	O	O

	0. Not at all (0)	A little (1)	Moderately (2)	A lot (3)	Completely (4)
I can face my thoughts, even if they are unpleasant (10)	O	O	O	O	O
My actions are often controlled by other people or circumstances (11)	O	O	O	O	O
I get caught up in unpleasant memories or anxious thoughts about the future (12)	O	O	O	O	O
I can deal with physical discomfort (13)	O	O	O	O	O
I feel I cannot love anyone (14)	O	O	O	O	O
I am often in conflict with one (or more) family member (15)	O	O	O	O	O
I avoid feeling my body when there is pain or other discomfort (16)	O	O	O	O	O
I do things that make me feel good straightaway even if I will feel bad later (17)	O	O	O	O	O
When I have a problem, I tend to believe it will ruin my whole life (18)	O	O	O	O	O
When I feel physical discomfort, I relax because I know it will pass (19)	O	O	O	O	O
I can feel comfortable around people (20)	O	O	O	O	O
Seeing or hearing someone with strong emotions is unbearable to me (21)	O	O	O	O	O
If I get angry or anxious, it is generally because of others (22)	O	O	O	O	O

Satisfaction with Life Scale - SWLS

Diener, E., Emmons, R.A., Larson, R.J. & Griffin, S. (1985) The Satisfaction with Life scale. Journal of Personality Assessment, 49, 71-76.

Please read each statement and indicate your agreement or disagreement by choosing a number from 1 to 7.

	1 Strongly disagree (1)	2 Disagree (2)	3 Slightly disagree (3)	4 Neither agree nor disagree (4)	5 Slightly agree (5)	6 Agree (6)	7 Strongly agree (7)
In most ways my life is close to ideal (1)	O	O	O	O	O	O	O
The conditions of my life are excellent (2)	O	O	O	O	O	O	O
I am satisfied with my life (3)	O	O	O	O	O	O	O
So far I have got the important things I want in life (4)	O	O	O	O	O	O	O
If I could live my life again, I would change almost nothing (5)	O	O	O	O	O	O	O

Short Flourishing Scale - FS
Diener, E., Wirtz, D., Tov, W., Kim-Prieto, C., Choi, D. W., Oishi, S., & Biswas-Diener, R. (2010). New well-being measures: Short scales to assess flourishing and positive and negative feelings. Social Indicators Research, 97(2), 143-156.

Please respond to each item by selecting one box per row.

	1 Strongly Disagree (1)	2 Disagree (2)	3 Slightly Disagree (3)	4 Mixed (4)	5 Slightly Agree (5)	6 Agree (6)	7 Strongly Agree (7)
I lead a purposeful and meaningful life … (1)	O	O	O	O	O	O	O
My social relationships are supportive and rewarding … (2)	O	O	O	O	O	O	O
I am engaged and interested in my daily activities … (3)	O	O	O	O	O	O	O
I actively contribute to the happiness and well-being of others… (4)	O	O	O	O	O	O	O
I am competent and capable in the activities that are important to me… (5)	O	O	O	O	O	O	O
I am a good person and live a good life… (6)	O	O	O	O	O	O	O
I am optimistic about my future… (7)	O	O	O	O	O	O	O
People respect me… (8)	O	O	O	O	O	O	O

Experiences Questionnaire

Instructions: We are interested in your recent experiences. Below is a list of things that people sometimes experience. Next to each item are five choices: “never”, “rarely”, “sometimes”, “often”, and “all the time”. Please select one of these to indicate how much you currently have experiences similar to those described.

Please do not spend too long on each item–it is your first response that we are interested in. Please be sure to answer every item.

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	All the time (5)
I think about what will happen in the future. (1)	O	O	O	O	O
I remind myself that thoughts aren't facts. (2)	O	O	O	O	O
I am better able to accept myself as I am. (3)	O	O	O	O	O
I notice all sorts of little things and details in the world around me. (4)	O	O	O	O	O
I am kinder to myself when things go wrong. (5)	O	O	O	O	O
I can slow my thinking at times of stress. (6)	O	O	O	O	O
I wonder what kind of person I really am. (7)	O	O	O	O	O
I am not so easily carried away by my thoughts and feelings. (8)	O	O	O	O	O
I notice that I don't take difficulties so personally. (9)	O	O	O	O	O
I can separate myself from my thoughts and feelings. (10)	O	O	O	O	O
I analyse why things turn out the way they do. (11)	O	O	O	O	O
I can take time to respond to difficulties. (12)	O	O	O	O	O
I think over and over again about what others have said to me. (13)	O	O	O	O	O
I can treat myself kindly. (14)	O	O	O	O	O
I can observe unpleasant feelings without being drawn into them. (15)	O	O	O	O	O
I have the sense that I am fully aware of what is	O	O	O	O	O

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	All the time (5)
going on around and inside me. (16)					
I can actually see that I am not my thoughts. (17)	O	O	O	O	O
I am consciously aware of a sense of my body as a whole. (18)	O	O	O	O	O
I think about the ways in which I am different from other people. (19)	O	O	O	O	O
I view things from a wider perspective. (20)	O	O	O	O	O

Multidimensional Assessment of Interoceptive Awareness
MAIA Multidimensional Assessment of Interoceptive Awareness (MAIA)

http://www.osher.ucsf.edu/maia/

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

The rating scale is as follows: 0 = Never, 5 = Always

	0. Never (1)	1 (2)	2 (3)	4 (5)	Always (6)
When I am tense I notice where the tension is located in my body. (1)	O	O	O	O	O
I notice when I am uncomfortable in my body. (2)	O	O	O	O	O
I notice where in my body I am comfortable. (3)	O	O	O	O	O
I notice changes in my breathing, such as whether it slows down or speeds up. (4)	O	O	O	O	O
I do not notice (I ignore) physical tension or discomfort until they become more severe. (5)	O	O	O	O	O
I distract myself from sensations of discomfort. (6)	O	O	O	O	O
When I feel pain or discomfort, I try to power through it. (7)	O	O	O	O	O
When I feel physical pain, I become upset. (8)	O	O	O	O	O

	0. Never (1)	1 (2)	2 (3)	4 (5)	Always (6)
I start to worry that something is wrong if I feel any discomfort. (9)	O	O	O	O	O
I can notice an unpleasant body sensation without worrying about it. (10)	O	O	O	O	O
I can pay attention to my breath without being distracted by things happening around me. (11)	O	O	O	O	O
I can maintain awareness of my inner bodily sensations even when there is a lot going on around me. (12)	O	O	O	O	O
When I am in conversation with someone, I can pay attention to my posture. (13)	O	O	O	O	O
I can return awareness to my body if I am distracted. (14)	O	O	O	O	O
I can refocus my attention from thinking to sensing my body. (15)	O	O	O	O	O
I can maintain awareness of my whole body even when a part of me is in pain or discomfort. (16)	O	O	O	O	O

	0. Never (1)	1 (2)	2 (3)	4 (5)	Always (6)
I am able to consciously focus on my body as a whole. (17)	O	O	O	O	O
I notice how my body changes when I am angry. (18)	O	O	O	O	O
When something is wrong in my life I can feel it in my body. (19)	O	O	O	O	O
I notice that my body feels different after a peaceful experience. (20)	O	O	O	O	O
I notice that my breathing becomes free and easy when I feel comfortable. (21)	O	O	O	O	O
I notice how my body changes when I feel happy / joyful. (22)	O	O	O	O	O
When I feel overwhelmed I can find a calm place inside. (23)	O	O	O	O	O
When I bring awareness to my body I feel a sense of calm. (24)	O	O	O	O	O
I can use my breath to reduce tension. (25)	O	O	O	O	O

	0. Never (1)	1 (2)	2 (3)	4 (5)	Always (6)
When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing. (26)	O	O	O	O	O
I listen for information from my body about my emotional state. (27)	O	O	O	O	O
When I am upset, I take time to explore how my body feels. (28)	O	O	O	O	O
I listen to my body to inform me about what to do. (29)	O	O	O	O	O
I am at home in my body. (30)	O	O	O	O	O
I feel my body is a safe place. (31)	O	O	O	O	O
I trust my body sensations. (32)	O	O	O	O	O

Approach to Life Questionnaire (Nonattachment Scale) - NAS
Baljinder, K.S., Shaver, P.R., Brown, K.W. (2010)

Instructions: To help understand your general approach to life and your views about yourself, others, and life in general, tell us the extent to which the following statements reflect your experiences at this point in your life. Select a number from 1 to 6 on the scale provided with each statement to rate the extent to which you agree with it.

Please answer according to what really reflects your experience rather than what you think your experience should be.

	1 Disagree strongly (1)	2 Disagree moderately (2)	3 Disagree slightly (3)	4 Agree slightly (4)	5 Agree Moderately (5)	6 Agree strongly (6)
I can accept the flow of events in my life without hanging onto them or pushing them away	O	O	O	O	O	O
I can let go of regrets and feelings of dissatisfaction about the past. (2)	O	O	O	O	O	O
I can find I can be calm and/or happy even if things are not going my way. (3)	O	O	O	O	O	O
I have a hard time appreciating others' successes when they outperform me. (4)	O	O	O	O	O	O
I can enjoy pleasant experiences without needing them to last forever. (6)	O	O	O	O	O	O

	1 Disagree strongly (1)	2 Disagree moderately (2)	3 Disagree slightly (3)	4 Agree slightly (4)	5 Agree Moderately (5)	6 Agree strongly (6)
I view the problems that enter my life as things/issues to work on rather than reasons for becoming disheartened or demoralised. (7)	O	O	O	O	O	O
I can enjoy my possessions without being upset when they are damaged or destroyed. (8)	O	O	O	O	O	O
The amount of money I have is not important to my sense of who I am. (9)	O	O	O	O	O	O
I do not go out of my way to cover up or deny my negative qualities or mistakes. (10)	O	O	O	O	O	O
I accept my flaws. (11)	O	O	O	O	O	O
I can enjoy my family and friends without feeling I need to hang onto them. (12)	O	O	O	O	O	O
If things aren't turning out the way I want, I get upset. (13)	O	O	O	O	O	O
I can enjoy the pleasures of life without feeling sad or frustrated when they end. (14)	O	O	O	O	O	O
I can take joy in others' achievements without feeling envious. (15)	O	O	O	O	O	O

	1 Disagree strongly (1)	2 Disagree moderately (2)	3 Disagree slightly (3)	4 Agree slightly (4)	5 Agree Moderately (5)	6 Agree strongly (6)
I find I can be happy almost regardless of what is going on in my life. (16)	O	O	O	O	O	O
Instead of avoiding or denying life's difficulties, I face up to them. (17)	O	O	O	O	O	O
I am open to reflecting on my past mistakes and failings. (18)	O	O	O	O	O	O
I do not get "hung up" on wanting an "ideal" or "perfect" life. (19)	O	O	O	O	O	O
I am comfortable being an ordinary, less than perfect human being. (20)	O	O	O	O	O	O
I can remain open to thoughts and feelings that come into my mind, even if they are negative or painful. (21)	O	O	O	O	O	O
I can see my own problems and short comings without trying to blame them on someone or something outside myself. (22)	O	O	O	O	O	O

	1 Disagree strongly (1)	2 Disagree moderately (2)	3 Disagree slightly (3)	4 Agree slightly (4)	5 Agree Moderately (5)	6 Agree strongly (6)
When pleasant experiences end, I am fine moving on to what comes next. (23)	O	O	O	O	O	O
I am often preoccupied by threats or fears. (24)	O	O	O	O	O	O
I am not possessive of the people I love. (25)	O	O	O	O	O	O
I do not have to hang on to the people I love at all costs; I can let go if they wish to go. (26)	O	O	O	O	O	O
I do not feel I need to escape or avoid bad experiences in my life. (27)	O	O	O	O	O	O
I can admit my shortcomings without shame or embarrassment. (28)	O	O	O	O	O	O
I experience and acknowledge grief following significant losses, but do not become overwhelmed, devastated, or incapable of meeting lifes other demands. (29)	O	O	O	O	O	O
I am not possessive of the things I own. (30)	O	O	O	O	O	O

Kessler Psychological Distress Scale (K10)

K10 Source: Kessler R. Professor of Health Care Policy, Harvard Medical School, Boston,USA.

These questions concern how you have been feeling over the past 30 days. Circle a box below each question that best represents how you have been. The rating scale is below.

	1 None of the time (1)	**2 A little of the time (2)**	**3 Some of the time (3)**	**4 Most of the time (4)**	**5 All of the time (5)**
1. During the last 30 days, about how often did you feel tired for no reason? (1)	O	O	O	O	O
2. During the last 30 days, about how often did you feel nervous? (2)	O	O	O	O	O
3. During the last 30 days about how often did you feel so nervous that nothing could calm you down? (3)	O	O	O	O	O
4. During the last 30 days, about how often did you feel hopeless? (4)	O	O	O	O	O
5. During the last 30 days, about how often did you feel restless or fidgety? (5)	O	O	O	O	O
6. During the last 30 days, about how often did you feel so restless you couldn't keep still? (6)	O	O	O	O	O
7. uring the last 30 days, about how often did you feel depressed? (7)	O	O	O	O	O
8. During the last 30 days, about how often	O	O	O	O	O

	1 None of the time (1)	2 A little of the time (2)	3 Some of the time (3)	4 Most of the time (4)	5 All of the time (5)
did you feel that everything was an effort? (8)					
9. During the last 30 days, about how often did you feel so sad that nothing could cheer you up? (9)	O	O	O	O	O
10. During the last 30 days, about how often did you feel worthless? (10)	O	O	O	O	O

Post-program questions

3. Mindfulness-integrated CBT (MiCBT) end of program questionnaire

Please enter your participant number: _____
(This number was given to you at your interview with Sarah Francis and is written on your participant information sheet.)

Have you just completed the 8 week MiCBT program?

O Yes (1)

O No (2)

Skip To: DASS 21 If Have you just completed the 8 week MiCBT program? = No

What were the most helpful things you have learned for the program?

_____

Describe how you have managed your daily routine to fit in practice?

_____

Do you expect to maintain a regular mindfulness practice?

_____

Do you feel that your ability to deal with life issues has changed at all? If you answer yes, please give examples.

_____

Was the method of learning suitable for you?

_____

What was the most helpful aspect of the program?

_____

What, if anything, has been disappointing about the program?

_____

Have there been any changes to your medications since the program commenced?
If yes, please provide details.

_____

Is there any other feedback you would like to provide?

_____

4. Follow up Mindfulness integrated CBT (MiCBT): Follow-up Questionnaire

Start of Block: Default Question Block

Q1

4. Mindfulness integrated CBT (MiCBT): Follow-up Questionnaire

ID **Please enter your participant number:**
(This number was given to you by Sarah Francis, the researcher in the email called

"Participant number for MiCBT Questionnaires" e.g. 2015200)

_____ Q3 **Let's begin...**

You will see a progress bar on the bottom of the page as you go through each of the questionnaires. This will let you know how much of the survey you have already completed.

The survey should take about 15-20 minutes.

Completed program Have you completed the 8-week Mindfulness-integrated Cognitive Behaviour Therapy program?

O Yes (1) O No (2)

Page 1 of 5

MiCBT Program Evaluation
What type of mindfulness practice do you do? Select all that apply.

☐ Mindfulness of breath (2)

☐ Body scan (3)

☐ Loving kindness (4)

☐ Other -please specify (1) _____

☐ None (6)

On average, how often do you practice Mindfulness of Breath?

O Twice per day (14 times a week) (1) O Once per day (7 times a week) (2) O Every second day (3 times a week) (3) O Once per week (4)

O Other (5) _____

How long do you practice Mindfulness of Breath on average in a session? *Please answer in minutes.*

_____

Display This Question:
If MiCBT Program EvaluationWhat type of mindfulness practice do you do? Select all that apply. = Other -please specify

Page 2 of 5

During practice I attempted to notice when my mind wandered and bring it back to focussing on my breath. *(Use the slide bar below)*

0 1 2 3 4 5 6 7 8 9 10

Quality of practice ()

On average, how often do you practice Body Scan?

O Twice per day (14 times a week) (1) O Once per day (7 times a week) (2) O Every second day (3 times a week) (3) O Once per week (4)

O Other (5) _____

How long do you practice Body Scan on average in a session? *Please answer in minutes.*

_____

body scan quality **During practice I attempted to focus all my attention on feeling sensations in my body and to bring my mind back to this task when it wandered. *(Use the slide bar below).***

0 1 2 3 4 5 6 7 8 9 10

Display This Question:
If MiCBT Program EvaluationWhat type of mindfulness practice do you do? Select all that apply. = Mindfulness of breath

Page 3 of 5

Quality of practice ()

On average, how often do you practice Loving kindness?

O Twice per day (14 times a week) (1) O Once per day (7 times a week) (2) O Every second day (3 times a week) (3) O Once per week (4)

O Other (5) _____

How long do you practice Loving kindness on average in a session? *Please answer in minutes.*

_____

Do you feel that the skills learned in the MiCBT course have equipped you to deal more effectively with life's difficulties?

O Yes (1) O No (2)

Have you required additional professional support since completing the MiCBT program? *e.g. seen a counsellor/psychologist/psychiatrist.*

O Yes (1) O No (2)

Was this for a new or ongoing issue?

O A new issue (1) O An ongoing issue (2)

Have there been any changes to medications since the program? If "yes", please provide details.

O Yes (1) _____ O No (2)

What were the *most helpful* things about the MiCBT program?

_____

What were the *least helpful* things about the MiCBT program?

_____

Did you have any unexpected, challenging or difficult experiences that you associate with your practice of meditation?

O YES (1) O No (2)

How did these experiences impact your life?

_____

Are there practical ways that you apply your mindfulness skills in daily life?

_____

Please feel free to write any comments or suggestions.

_____

Now we will begin with the questionnaires.

6.7 Participant handouts

Mindfulness integrated Cognitive Behaviour therapy (MiCBT) Research Trial

Program worksheets

These program materials have been developed by Bruno Cayoun and adapted by Sarah Francis for use in a Research Trial. Cayoun's text "Mindfulness integrated CBT Principles and Practice" (Wiley 2011) describes the protocol for group program delivery.

Psychologist:
Sarah Francis, Provider no. 4148837A
MA, M Psych, B.Ed, Dip. Psychodynamic Psychotherapy, Grad. Dip. In MiCBT, MAPS

Session 1 – Introduction to MiCBT

In this session we will discuss:

- Principles of mindfulness
- Program expectations and goals
- Defining mindfulness
- The first mindfulness exercises: Progressive Muscle Relaxation and Mindfulness of the Breath, and their rationale and practice
- How to tackle home exercises

This "workbook" is a compilation of worksheets for each session of the program to provide support material for participants in an 8-week MiCBT research trial program. It is not intended to be a stand-alone manual on MiCBT. There are worksheets and templates to journal and reflect on your practice. For additional comprehensive support for the program content "Mindfulness Integrated Cognitive Behaviour Therapy for Well-being and Personal Growth" is recommended.

What is MiCBT

MiCBT is one of a growing number of mindfulness-based programs. It offers a skillful integration of cognitive behaviour therapy with mindfulness to address a range of psychological problems and to improve psychological well-being. Below is a brief overview of MiCBT.

However, while it is interesting to have a theoretical understanding – the experiential learning in this program is what will enable you to make significant changes to your behaviours.

What is mindfulness and how can it help me?

Mindfulness enables us to remember to stay fully aware of what is actually happening at the present moment both internally and externally – with no bias, no judgement and no reaction.

Mindfulness is the ability to be fully aware of what is happening as it happens, in contrast to our tendency to be "lost in thoughts" often about the past or the future, rarely present in the here and now. Mindfulness has roots in Eastern meditation techniques and MiCBT springs from the Vipassana tradition as taught by S.N. Goenka. **Equanimity** and **impermanence** are key principles. Equanimity is the ability to be unperturbed by events that arise – it is a state of awareness in which we are neither averse to unpleasant experiences nor do we crave pleasant ones – we accept our experiences with composure. This enables us to be less reactive in daily life and gives us self-control and composure. Impermanence refers to the idea that everything changes all the time – nothing is permanent including our own mental and emotional experience. Realising this helps us to have a more detached attitude to experiences because we know that they are not permanent and will pass away. We can look at them more objectively.

How do I learn mindfulness?

We can practice being more mindful as we go about our normal life by being more present but the most effective way to develop mindfulness is by formal sitting meditation practices. In this MiCBT program to learn mindfulness and experience its benefits, you must be prepared to commit to regular specific exercises. Our experience is that you are most likely to maximise the benefits of this program by a commitment to twice daily practice during the coming few weeks- the effort will pay off!

The practice

In MiCBT when we practice mindfulness we sit closed eyes and initially we use the breath as the focus to develop attention and concentration. We learn to decrease attention to intrusive thinking. We also learn to attend to body sensations non-reactively noticing them as "just sensations" whether pleasant or unpleasant. We come to see that body sensations cannot affect us unless we

react to them. Body sensations are important because they are the way we experience emotions and not reacting to them helps us to accept and let go of emotions.

The classes will teach you how to be more fully aware moment by moment and to see things as they really are, as they arise, so that you can find useful and effective ways to respond. These may be very different to habitual ways of reacting to problems.

Changing unhelpful or unwanted habits becomes easier as mindfulness skills are consolidated and integrated into daily life. We learn to understand and accept the process of thinking and sensing and to be able to understand the ever-changing nature of life.

CBT

CBT (Cognitive Behaviour Therapy) helps people to become aware of unhelpful thinking patterns and to change their thinking – to change the contents of unhelpful thoughts and behaviours.

Integrating mindfulness and CBT

MiCBT works on helping people to not only become aware of thinking patterns but also to be able to develop control over the processes that maintain unhelpful thinking; to change the process of thinking rather than the contents of thoughts.

Changing habitual behaviours

Both CBT and MiCBT use the principles of exposure and desensitisation to help us change unwanted behaviours. Unlike CBT however, MiCBT views reactivity as being to the sensations that result from our judgemental thinking. Learning to prevent reacting to body sensations creates the capacity for significant changes to our habitual feelings, emotions and behaviours.
The principles of MiCBT can be applied to interpersonal skills as we learn to be less reactive across all aspects of life. Finally, MiCBT teaches people to develop empathy to themselves and to others as they learn to reduce reactivity and realise that they are the first beneficiary of their emotions, whether positive or negative.

Program structure

MiCBT is delivered in 4-stages.

- Stage 1 teaches mindfulness skills to improve attention to and understanding of thoughts and body sensations.
- Stage 2 teaches how to apply these skills to the challenges of daily life helping us to tackle previously avoided situations.
- Stage 3 specifically engages the mindfulness skills in interpersonal communication and relationship issues.
- Stage 4 explores personal ethics from a mindfulness perspective and uses compassion training to develop empathic understanding of ourselves and others.

The group will meet for 8 two-hour sessions and classes will explore new ways of dealing with thoughts and feelings. Participants will be invited to review and share their own experience with the practice exercises.

These notes are designed to help with conceptual understanding – but the real understanding will happen through your own experience. This program guides participants through the various levels of experience of mindfulness exercises – do the practice and see for yourself!

Occasionally when people begin mindfulness exercises they may find that it stirs up disturbing material that they may have forgotten about. Participants will be offered access to individual counselling to assist them with this if they need it.

Audio instructions – available at www.melbournemindfulness.com
(ask your instructor for the current password)
Below is the usual sequence of exercises in MiCBT. Listen to the instructions to learn the exercise and then as soon as you are familiar with the exercise work on without the audio.

Part 1 –stage 1 **Practice instructions:** **Week 1** Tracks 1,2,3 and 4 for the first two days then track 4 for the rest of the week. **Week 2** Tracks 5&6 then add 10 more minutes without the audio instructions. After two days drop track 5 and continue with track 6 + 10 extra minutes in silence. **Week 3** Tracks 7&8 for the first two days then track 8 for the remainder of the week. **Week 4** Repeat week 3 exercises but without the audio instructions for 30 minutes twice daily. Do your best sit absolutely still during practice. Try to sustain awareness and equanimity during your day.	Tracks: Part 1- Stage 1 1. General introduction (1.13) 2. Rationale for Mindfulness Training (10.57) 3. Introduction to Progressive Muscle Relaxation (2.21) 4. Progressive Muscle Relaxation (14.01) 5. Introduction to Mindfulness of Breath (2.39) 6. Mindfulness of Breath (19.44) 7. Introduction to Body Scanning (1.41) 8. Body Scanning (31.34) 9. Withdrawing the Audio instructions (3.23)
Part 2 – stages 2,3 &4 **Practice Instructions:** **Week 5** Tracks 1 & 2 for the first 2 days and then continue with track 2 for the rest of the week. **Week 6** Track 3 & 4 for the first 2 days and then track 4 for the rest of the week. **Week 7** Tracks 5 & 6 for the first 2 days and then track 6 for the rest of the week. Add track 9 and 10 Loving Kindness at the end of each session. **Week 8** Tracks 7 &8 for the first two days then track 8 for the rest of the week. Loving Kindness Meditation in silence using your own words and style. **Post program:** Now that you have completed the program you have been introduced to a comprehensive set of mindfulness meditation practices. To maintain the gains you may wish to continue with a "maintenance" practice. You may be able to be self sufficient with this now, but Track 20 is provided as a guided meditation in case you feel that the guidance is helpful.	Tracks: Part - Stages 2,3,4 10. Introduction to Advanced Scanning (2.43) 11. Symmetrical Scanning (13.00) 12. Introduction to Partial Sweeping (1.35) 13. Partial Sweeping (14.25) 14. Introduction to Sweeping en Masse (1.46)) 15. Sweeping en Masse (13.30) 16. Introduction to Transversal Scanning (1.19) 17. Transversal Scanning (16.32) 18. Introduction to Loving Kindness (3.12) 19. Loving Kindness (8.11) 20. Maintenance Practice (44.55)

As described in the introduction, there are 4 stages to the MiCBT program and we will be working systematically through each stage.

Mindfulness exercises

The exercises for the first week are explained and experienced in class – they are:

- progressive muscle relaxation - to facilitate a relaxed body and posture for mindfulness meditation exercises and Mindfulness of Breath

Progressive Muscle Relaxation (PMR) has been shown to be effective as a relaxation and stress relieving technique. In this exercise we learn to relax muscle tension. You will learn to feel and let go of muscle tension in a simple practical way and this will help to make you feel more grounded, present and committed to self-care as you engage with the practice each day.

- We choose this technique in MiCBT because of its focus in the present reality of your experience rather than distracting you from it as some relaxation exercises do. PMR relaxes you while restoring the connection between mind and body
- mindfulness of breath – focussing on breath, noticing as the mind begins to wander and learning to quickly bring attention back to the breath.

For many people sitting entirely still and engaging your mind with nothing more interesting than your own breathing is an extremely simple but difficult task. It is made more difficult if you are already stressed and anxious when you begin. Consequently our first exercise is designed to be body aware and to relax the body so that it can engage better in the mindfulness exercises.

Summary

The aim of this program is to increase our awareness of what is actually occurring - what thoughts are arising and what is arising in the body. We learn to be able to manage our reactions - to know our internal reactions so that we can choose skillful behaviours and minimise harm to ourselves and to those with whom we interact.
We do this by practicing becoming aware of where our attention is and deliberately and repeatedly choosing to direct attention – to the breath. Developing the concentration needed to do this (learning to stop the mind "wandering") requires dedicated practice.
To begin with we start to learn how to relax and attend mindfully to the body.

Home Exercises:

We have practiced the home exercises this week in the class – the audio instructions are simply to support you as you learn to be independent of them.

1. Listen to the first 4 tracks and then practice PMR twice each day for the first 2 days. On day 3 listen to tracks 4, 5 &6 and then for the rest of the week use tracks 4 & 6 to guide your twice daily practice.
2. Reflect on your goals and refine them if you need to.

Goals for the program

List the things you would like to have improved or changed: (be quite specific – how will you know that this has changed?) For example "being more assertive" is too vague – you may want to be able to say "no" to a particular person for example.

Targeted issue/problem	**Success indicators**

Signed:_____Date:_____

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	**Practice y/n Length of time**		**Total daily practice time**
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

Session 2

Now that you have spent a week practicing Progressive Muscle Relaxation and Mindfulness of breath, you are ready to consolidate the mindfulness of breath practice before progressing to the next exercise. This week try to work unguided – maintaining your attention on the breath and catching yourself in mind-wandering mode so that you can re-focus on the breath.
In this session we will:

- Review practice and practice challenges
- Engage in practice
- Explore the mechanisms of MiCBT, namely reactivity and equanimity

We can notice our automatic or habitual thoughts. Often these are the judgements we make- " What's wrong with me? Why can't I do this mindfulness meditation? I must be stupid…"
We tend to fall into judgemental thinking. The mind then gets lost in thinking about the past or worrying about the future and this can set the ruminating or "mindfulness-wandering" thoughts going again.
Mindfulness of breath teaches how to observe normal breathing to gain some control over chattering thoughts. The breath is being used as a focus of attention and we start to notice how distractible the mind often is. We also notice that breathing patterns vary from moment to moment. We are gradually learning to be less distractible.
Physical discomfort during meditation can be very useful. Simply notice the discomfort –(try to think of it as "just sensations" – no labelling just noticing) and then return to your focus on the breath. This is an important skill – non-reactivity!
It is normal to be quite distractible at this stage in learning mindfulness skills – this will change in time and you will be able to sit for prolonged periods with less mind wandering and without needing to move.
We gradually learn to:

- Detect a thought as it arises
- Inhibit the response to the thought – in other words not to entertain the thought and just let it go
- Refocus attention to the breath

As we learn this skill, we notice more quickly when the mind starts to wander.

Mindfulness of breath - sitting

Choose a quiet and comfortable place to sit - Sit comfortably in a straight-backed chair. Try to sit away from the back of the chair and your knees a little lower than you buttocks – a cushion may help.
Make sure your back is straight and neck is straight.
Let your hands rest softly on your lap and simply breathe normally and as you do notice the sensation of the breath entering the body through the nostrils.
Aches and pains may arise – try to sit with them

– may be itching, heat, stiffness – just observe.
Simply be aware that air is flowing in and out.
There is no past or future when you are watching your breathing, only this present moment

Mindfulness Practice Challenges

Practicing without moving or shifting position will help to develop non-reactivity.
People typically report a number of challenges when learning to develop a regular mindfulness practice. These include:

Making a plan that will work – You may need to change your daily routine to make time for practice. The reward will be that you start to notice significant changes in how you feel.

Sticking to the plan – Once you have a plan stick to it! When things go wrong and you miss a practice just make sure you do the next one – be gentle with yourself!

Distractability – The intrusion of uninvited thoughts is usually a problem to begin with – this is normal! Simply bring your attention back to the breath over and over again! Your ability to control where you put your attention will start to improve little by little.

Pain – When you notice pain (remember that "pain" is sensations) first of all simply bring your attention back to your breath or to the part of the body you are scanning – if the pain seems to be too strong then direct your attention to the centre of the intense body sensation. You will notice that it may get stronger at first then it will begin to decrease. Curiously, trying to avoid the sensation (pain) will make it seem stronger – all experiences including body sensations are impermanent – they will pass away – "all things must pass" (George Harrison).

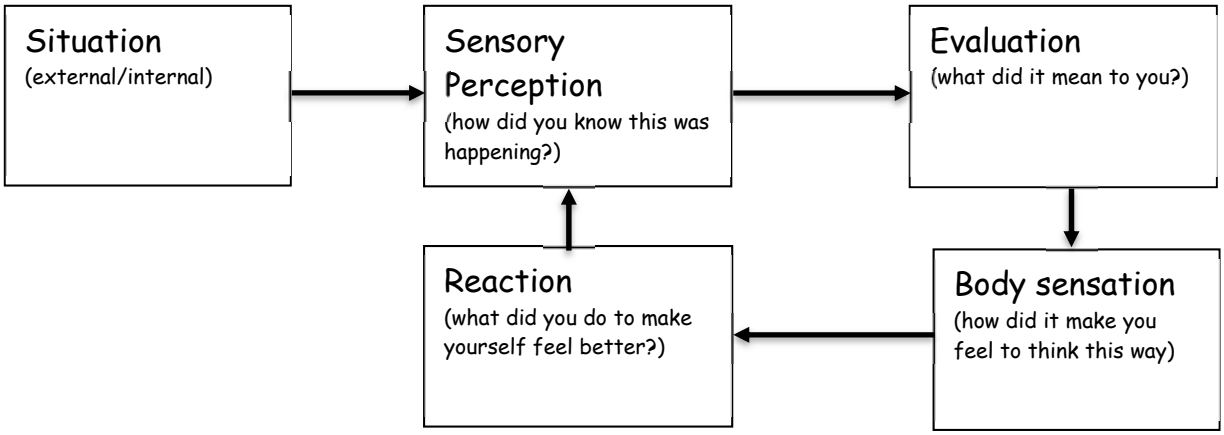
Feeling sleepy during practice – You can change a few things to assist with sleepiness - increase the light; decrease the temperature; modify posture – make sure back is straight – knees below the buttocks. It may help to open your eyes slightly to let a little light in. If you are still drowsy get up and go for a walk for a few minutes and then return to practice – this too will pass!

Trouble noticing sensations when doing the body scan – It is normal to have difficulty scanning the body at first – we are not used to this activity – the parts of the brain that are needed to feel the subtle sensations in the body are not well connected – this will happen with practice – like brain gym! It is important in body scanning to make sure posture is correct – as described above.

Trouble in being still during practice – There will be many distractions as you learn to sit still including external noise, feeling too hot or too cold. Intrusive thoughts may challenge the determination to practice – such as " I don't have time today", "this is boring", "maybe I'll do it later on", "I'm no good at this". All of this is experience that we can simply notice. Then we can return the focus of attention to the exercise.

Diary of reactive habits

Model of reactive habits – (Cayoun 2003)- the Co-emergence model



Our reaction can easily become a habitual behaviour. If we can separate out the steps from each other, we are able to understand our ***actual*** experience and therefore modify the reaction.
We experience how judging or evaluative thinking creates sensations - especially when we think this is very personal - (negative evaluation produces unpleasant sensations) and we can realise that our reactions are actually to our own sensations.

Home exercises:

1. PMR followed by Mindfulness of Breath twice daily – start by checking in on your body – make sure your posture is good and straight then use the track 4 exercises to loosen up. Then focus on the breath - track 6 for the remainder of the session.
2. Diary of reactive habits (co-emergence model) – use the template to map an example of two stressful events.
3. When you wake up and just before sleep take a moment to be aware of sensations in your body without reacting – just noticing what is going on.

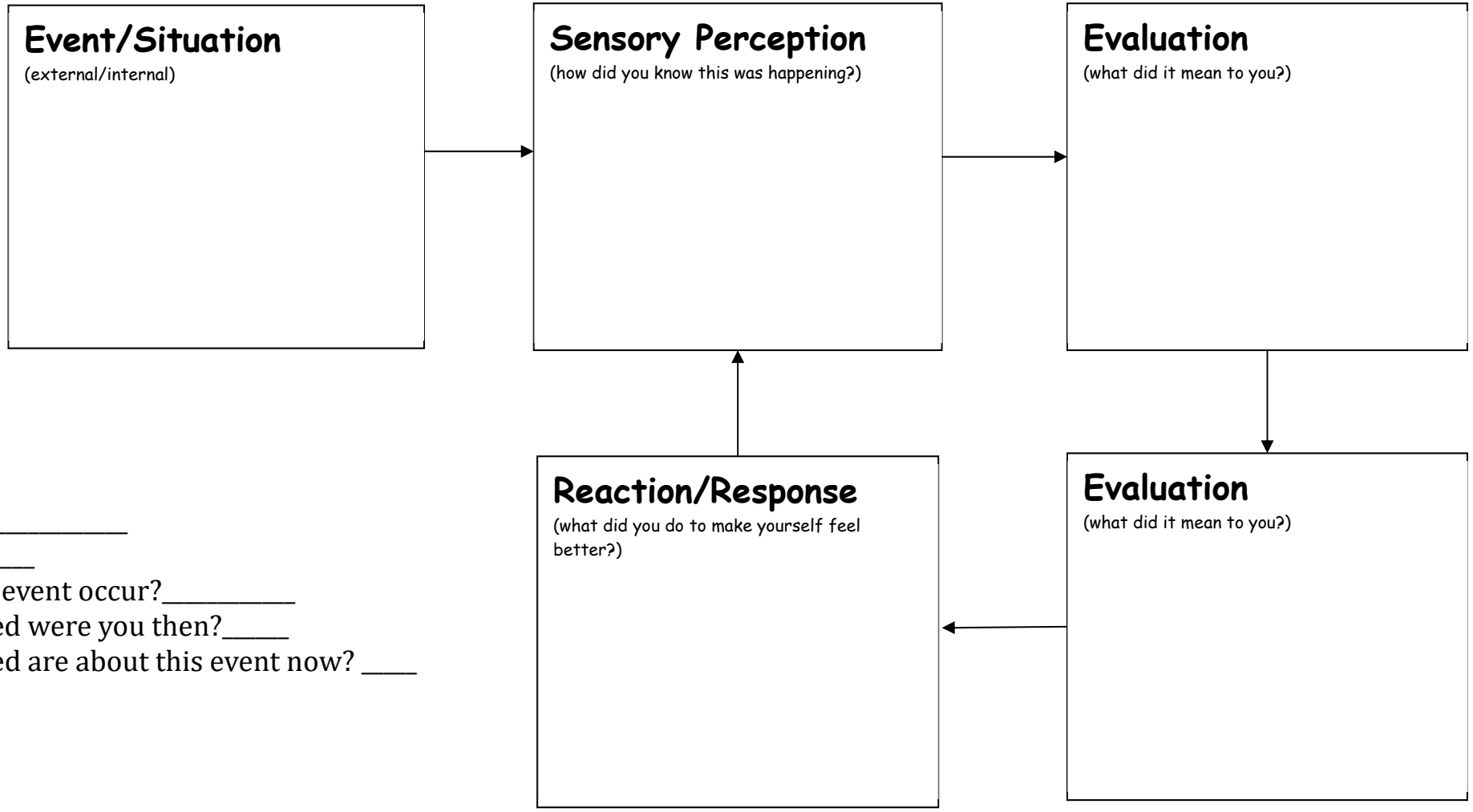
Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	**Practice y/n Length of time**		**Total daily practice time**
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

Diary of reactive habits (Cayoun 2003, 2011)- the Co-emergence model



Name:_____
Date:_____
When did the event occur?_____
How distressed were you then?_____
How distressed are about this event now? ____

Session 3

Having spent the week practicing mindfulness of breath you will be ready to start to practice body scanning.

In this session we will:
- Review practice
- Engage in practice
- Explore how body sensations work
- Practice Body scanning
- Explore a deeper understanding of interoception
- Discuss the difficulties encountered in practice

Body Scanning

This week we will learn a new skill – body scanning. This will help us to become aware of body sensations as they arise and pass moment by moment. We are able to experience the intimate relationship between thinking and body sensations, in particular when we take the thoughts very personally. We learn to survey the whole of the body part by part, noticing arising sensations without judgment, neutrally. As you do this you start to realise that sensations come and go all the time. Follow the instructions on the audio instructions as you scan the body.
We begin to experience that what we call an emotion is the result of the thinking and the body sensations that arise. For example with anger I may have the thought that "she shouldn't have spoken to me like that" while in my body I notice sensations that are hot, dense, and heavy and that move around. I have come to call this feeling "anger" and I may say "I am angry" and may react by shouting or speaking forcefully. If we are aware that body sensations are a key part of the emotional experience, we can simply observe the sensations and wait for them to change without having to DO anything and without identifying with them.
We tend to categorise experiences as pleasant, unpleasant or neutral. How we judge the experience will determine the sensations we experience.
When a difficult, challenging or threatening event is experienced there is a co-emerging body sensation that jogs the memory. The more difficult or distressing the situation, the stronger and more unpleasant will be the sensation. When an apparently similar event occurs, this may cause similar unpleasant sensations to arise that may trigger a similar reaction. This is how we develop habits.
We can observe that sensations can be perceived quite objectively in terms of Mass (light – heavy); Temperature (cold – hot); Motion (still - agitated); Cohesiveness or fluidity (loose – dense). Developing the ability to observe objectively what goes on in the body enables us to detach and not take everything personally.

Home exercises:

1. Body scan – part by part - the audio instructions are on tracks 7 and 8 – listen to the introduction then use track 8 for the rest of the week.
2. Informal practice – becoming more mindful in daily life
3. When noticing sensations arising – use the "interoceptive signature" (but not while you are doing the body scan)
4. Awareness of body sensations pre and post sleep

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

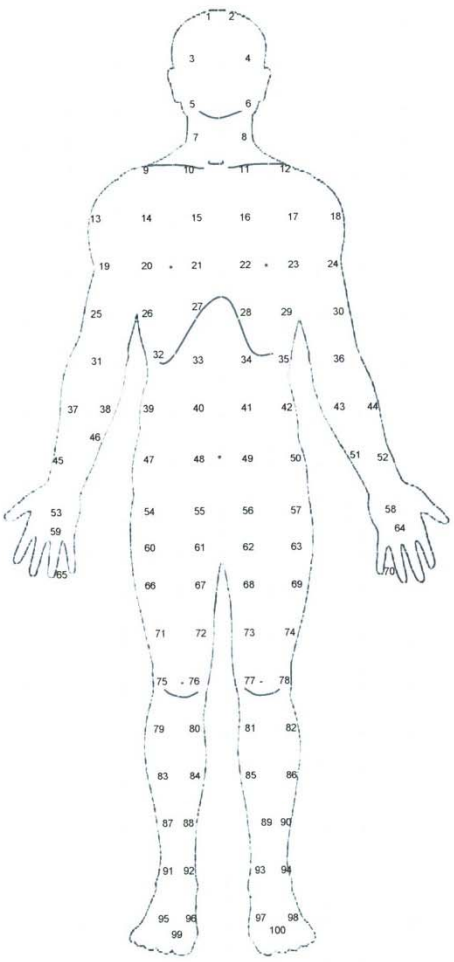
Day/date	Practice y/n Length of time		Total daily practice time
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

INTEROCEPTION FORM

Name:..... Age:.....Sex:..... Today's Date:.....

Date when training started:..... Scanning methods this week:.....

Please colour the parts in the silhouette where you can feel any type of body sensations. Try not to spend too long colouring the parts. It is OK if you go slightly over the silhouette edge.



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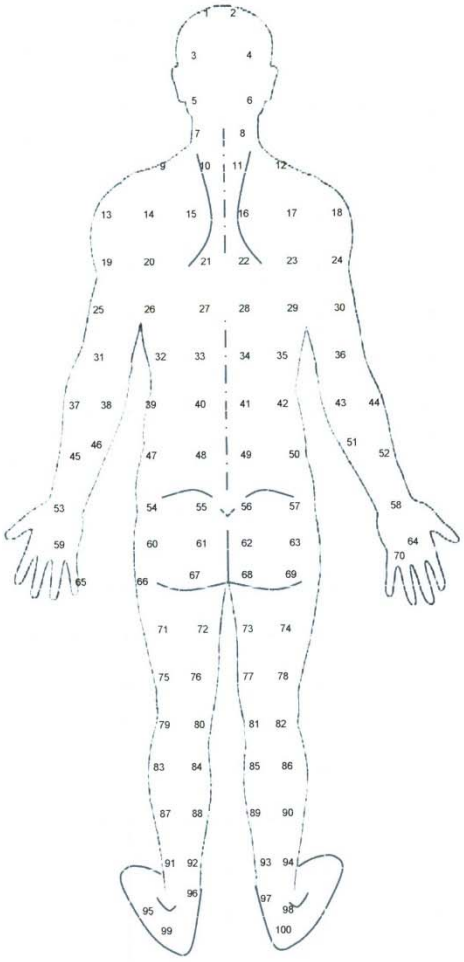

BACK

RESULTS

There are 100 numbered boxes (square and rectangular shapes) within or crossing the outline of the silhouette. To calculate the percentage of interoceptive awareness, count the total number of coloured boxes. A numbered box is counted as valid if at least half of its surface, which falls within the silhouette, is coloured.

Total interoceptive awareness = (%back + %front / 2) = ...%

INTEROCEPTION FORM

Name:..... Age:.....Sex:..... Today's Date:.....

Date when training started:..... Scanning methods this week:.....

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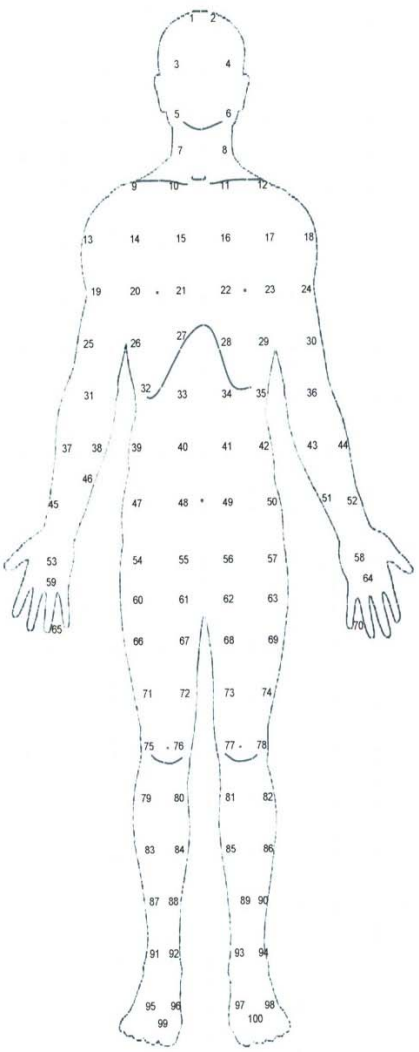

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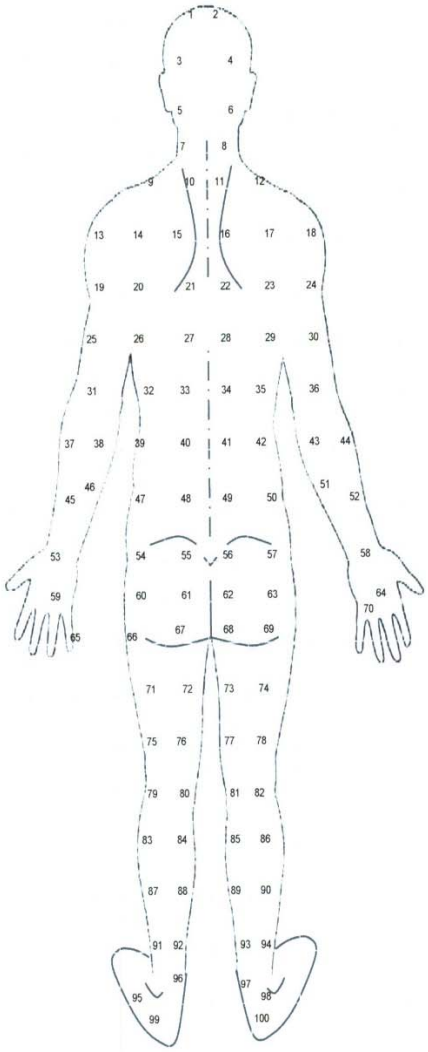

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Total interoceptive awareness = (%back + %front / 2) = ...%

Interoceptive Signature Scale

Instructions

Use one of the blank forms below to identify your experience of body sensations on each of the four categories (**Mass, Temperature, Motion, Cohesiveness**). When you experience a distressing event, notice the body sensations associated with it. Then, as soon as you can (either during or soon after), represent the strongest sensation in your body by placing a small dot on each of the four lines representing a category of body sensation. Then join each of the dots with a full line. This is the "distress line". After focusing on the sensation neutrally and with acceptance for half a minute, place another dot on each of the four categories to represent how you are experiencing body sensations after practice. Then join those dots with another line (a dotted line) to show any change. Record also the change in intensity by placing a small dot on the straight lines.

Date:	Time:	Brief event description:	
Mass	Lightest	Neutral	Heaviest
Temperature	Coldest	Neutral	Hottest
Motion	Stillest	Neutral	Most movement
Cohesiveness	Loosest	Neutral	Densest/tightest
Intensity before	Least		Most
Intensity after	Least		Most

Date:	Time:	Brief event description:	
Mass	Lightest	Neutral	Heaviest
Temperature	Coldest	Neutral	Hottest
Motion	Stillest	Neutral	Most movement
Cohesiveness	Loosest	Neutral	Densest/tightest
Intensity before	Least		Most
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Date:	Time:	Brief event description:	
Mass	Lightest	Neutral	Heaviest
Temperature	Coldest	Neutral	Hottest
Motion	Stillest	Neutral	Most movement
Cohesiveness	Loosest	Neutral	Densest/tightest
Intensity before	Least		Most
Intensity after	Least		Most

Session 4

In this session we will:

- Review practice
- Engage in body scanning practice
- Discuss brain structure and function, neuroplasticity, and the brain and mindfulness,
- Take a new look at things we tend to avoid – "exposure"

Practicing body scanning techniques strengthens our brain's nerve pathways in the somatosensory area. This makes us more aware of our sensations enabling us to notice subtle changes without reacting.
Re-visit the co-emergence (5-box) model. Think about how body sensations occur due to an evaluation, and how body sensations precede our reactions – sometimes habitually. The more we practice certain thoughts, such as negative intrusive thoughts, the more we consolidate the neural connection in our brains associated with these thoughts. This makes us more likely to have those thoughts again in the future; they start to become "automatic' – we quickly turn to them without a great deal of conscious thought. It is like being on automatic pilot when driving home. The route is so familiar and the habit is so strong that we can drive it without being consciously aware of how we got there.
As you develop a sense of responsibility for your own experiences you are moving to part 2 of the program, learning advanced scanning and applying skills to address specific internal and external stressors.
Advanced scanning methods increase the demands on the brain, which can only acquire skill by making new connections between neurons or strengthening weak existing connections.
In advanced scanning, we produce fast neuroplasticity effects, which will enable us to quickly feel very subtle sensations. Once we begin to feel very subtle sensations in the body, we can also notice the **early** signs of distress and choose to respond intentionally rather than react automatically. We can regulate emotions much better.
By developing advanced scanning we are able to attend to sensations that are not so intense. We are aware of the sensations as **we are becoming** anxious or angry. Thus we have lowered our threshold of awareness of sensations and can manage our actions more skillfully.
We are now applying what we have learned about our internal experiences to external experiences and events.

Home exercises:

1. Body scan – without audio instructions this week
2. Pre and post sleep body awareness
3. Use your SUDS (subjective units if distress) form. The SUDS scale ranges from 0 to 100 like a distress thermometer where 0 is least distressing and 100 is the worst distress imaginable.
4. Identify five distressing events and list them with the most distressing last. Choose something that you know will occur in the near future which is less than 50% on your SUDS scale.
5. Use the exposure procedure discussed in class – 5 minutes focussing on the worst possible scenario, 1 minute focussed on the breath and 5 minutes focussed on the best case scenario. Do this four times before you will encounter the situation for real. Observe how you experience the situation when it does occur.
6. Informal practice – mindfulness in daily life

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	Practice y/n Length of time		Total daily practice time
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

INTEROCEPTION FORM

Name:..... Age:.....Sex:..... Today's Date:.....

Date when training started:..... Scanning methods this week:.....

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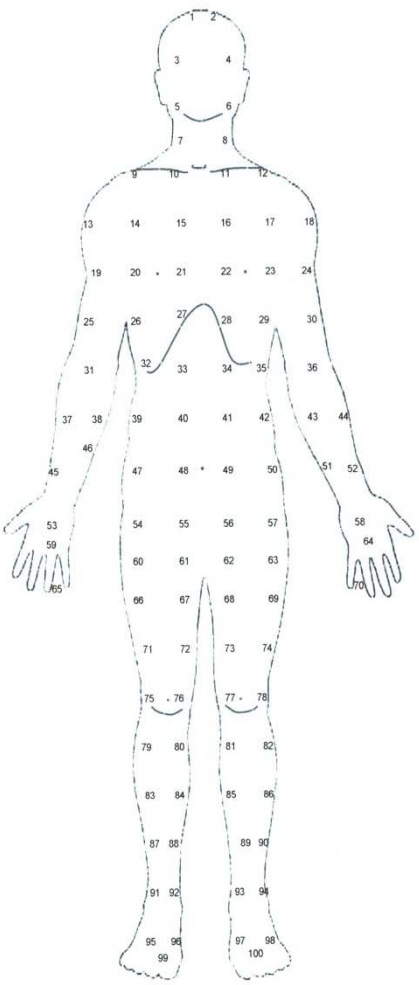

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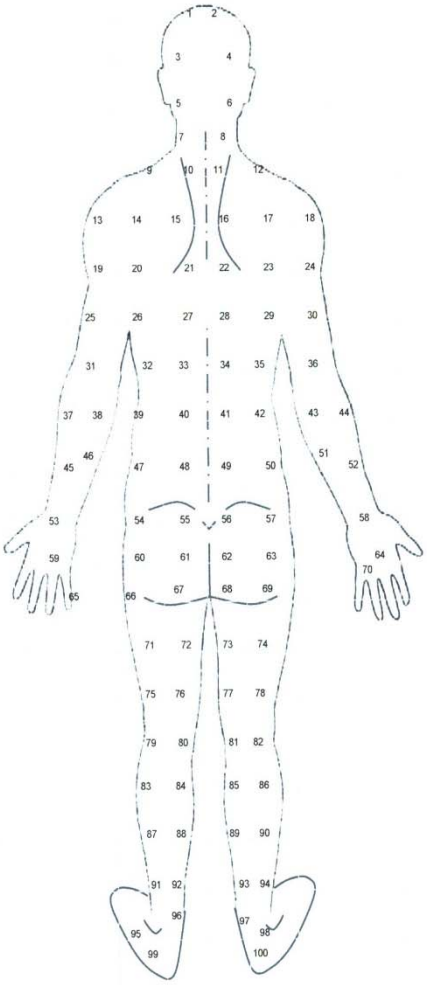

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Total interoceptive awareness = (%back + %front / 2) = ...%

INTEROCEPTION FORM

Name:..... Age:.....Sex:..... Today's Date:.....

Date when training started:..... Scanning methods this week:.....

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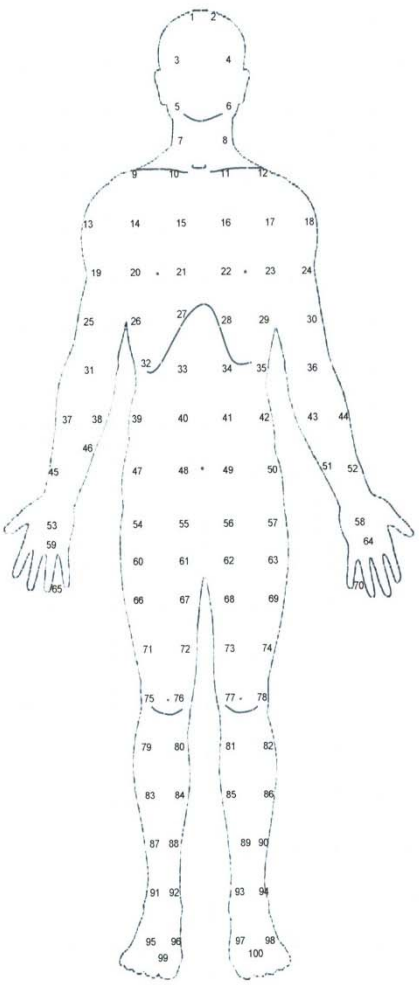

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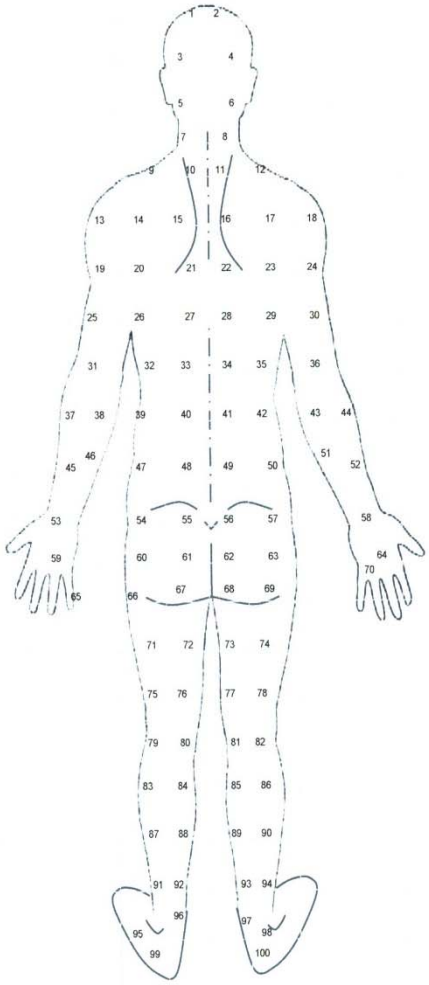

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Total interoceptive awareness = (%back + %front / 2) = ...%

Subjective Units of Distress (SUD) form

Week 4

<u>Exposure to distressing events</u>

Write down 5 events that you believe are distressing and that you are likely to avoid because they cause some level of distress/discomfort. List the events in reverse order of difficulty – the least difficult and manageable first and the most difficult last. Rate the amount of distress each causes you form 1- 100. You will learn to use "bipolar exposure" (see below) to reduce the % of distress.

Situation 1

_____

_____

Rating – what percentage of distress would this situation cause? .....%

Situation 2

_____

_____

Rating – what percentage of distress would this situation cause? .....%

Situation 3

_____

_____

Rating – what percentage of distress would this situation cause? .....%

Situation 4

_____

_____

Rating – what percentage of distress would this situation cause? .....%

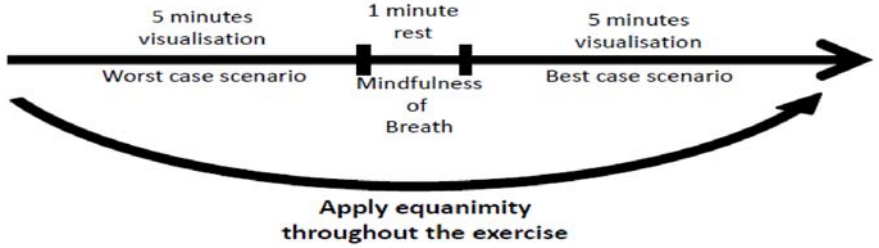
Situation 5

_____

_____

Rating – what percentage of distress would this situation cause? .....%

Bipolar exposure exercise:
Choose something from your list that you know will occur in the near future which is less than 50% distressing. Use the exposure procedure discussed in class – 5 minutes focussing on the worst possible scenario, 1 minute focussed on the breath and 5 minutes focussed on the best case scenario. Do this for four times before you will encounter the situation for real. Observe how you experience the situation when it does occur.



Session 5

In this session we will:

- Review practice
- Engage in practice symmetrical body scanning (scanning both sided together)
- Discuss taking responsibility for our own thought and sensations
- Discuss detaching for the experiences of others

Developing an attitude of noticing and accepting what is arising without reaction is a major part of this work. When there are very difficult thoughts, feelings or sensations, shine the spotlight on them – deliberately pay attention to them – not to try to change them but to look carefully at them while remaining calm and non-reactive. Allowing the unwanted has a strange effect of making it seem more bearable.

Another reason that this is a sensible thing to do is that it is actually very difficult – in fact impossible, to not experience what you are experiencing. Try this – think about a big bar of your favourite chocolate – imagine yourself eating it.

Now – do NOT think of chocolate …. how easy is this?

And yet this is what we try to do a lot in our daily lives – "I'll do anything to not have the experience I'm having – I'll have a drink, a cigarette, I'll turn on the television or go to a movie - I'll take drugs, go to the casino……anything to avoid experiencing what I am experiencing". In some cases these habits become addictions. Now with our new skill of observing what is going on including noticing sensations as simply sensations, we can take the time to just be with what is going on, losing the judgement; it is all just experience.

It is interesting to observe that when we are more able to stay calm (not reactive) while interacting with others who are distressed, we can empathise with their suffering and impact their level of arousal. Observe if you find this to be true.

Home exercises:

1. Symmetrical body scanning – tracks 10 & 11
2. Pre and post sleep body awareness
3. Informal practice – being mindful in daily life
4. Bi-polar exposure to more difficult items on your SUDS form

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	Practice y/n Length of time		Total daily practice time
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

Week 5

SUD FORM

Exposure to distressing events

Write down 5 events that you believe are distressing and that you are likely to avoid because they cause some level of distress/discomfort. List the events in reverse order of difficulty – the least difficult and manageable first and the most difficult last. Rate the amount of distress each causes you form 1- 100. Use "bipolar exposure" to reduce the % of distress.

Situation 1

_____

_____

Rating – how distressing was this – out of 100 - 1.....% 2. .....% 3.....% 4..... %

Situation 2

_____

_____

Rating – how distressing was this – out of 100 - 1.....% 2. .....% 3.....% 4..... %

Situation 3

_____

_____

Rating – how distressing was this – out of 100 - 1.....% 2. .....% 3.....% 4..... %

Situation 4

_____

_____

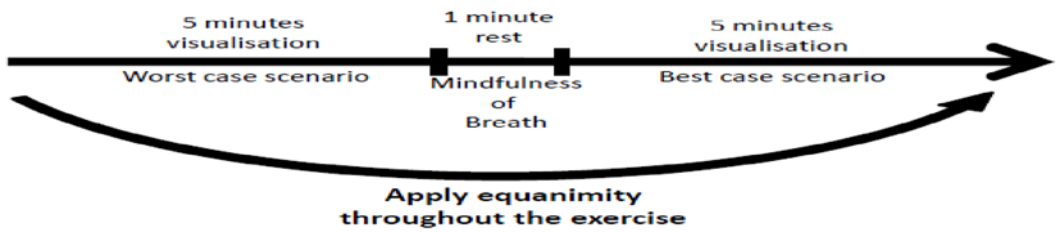
Rating – how distressing was this – out of 100 - ...1.....% 2. .....% 3.....% 4..... %

Situation 5

_____

_____

Rating – how distressing was this – out of 100 - 1.....% 2. .....% 3.....% 4..... %



Session 6

In this session we will:

- Review practice
- Engage in practice (partial sweeping/sweeping)
- Discuss applying MiCBT to relationships – assertiveness

Assertiveness

There are 3 predominant communication styles – passive, aggressive and assertive.
When people are stressed, anxious or depressed, they tend to be passive or aggressive rather than assertive.
Getting what you want comfortably with people at home, work, family, or in the community is difficult – our own reactivity is a major part of the problem
Being assertive is an "executive" task (frontal area of the brain) not an "emotional" task (limbic area of the brain).
We are using the skills learned already in the MiCBT training.

Action	Notes	Example
Ensure you have the others attention before you start		
State the facts	E.g. "for the last few weeks I have observed that….	*In the last 6 months I have washed the dishes nearly every night*
State how you feel (I statement)	I feel you….	*When you don't help me I feel that you don't care about how tired I am*
Take responsibility for your thoughts	I thought this way because it meant to me that…	*I think that this means we are not working as a team and that I come second in this relationship*
Acknowledge the other – possible error in judgement	This is what I thought; I may be wrong and it is possible that…	*I may be wrong in this – you are very good at fixing things and being social*
State what you want	What I want is a frank discussion about this…	*I would like you to co-operate with me more and help me with the cleaning up*
Thanks for listening (providing reward)	Show appreciation to the other for listening…	*I am glad you listened and seem to understand…. is there something you would like to say now?*
Negotiate win-win/compromise	If the other will not provide what you ask for then negotiate a win- win - compromise	*OK well if you are willing to help with the cleaning up three or four times a week, I will make an effort to be more social with our friends*

Home exercises:

1. Body Scan (sweeping) - tracks 14 &15
2. Bipolar and in vivo exposure to using assertiveness in two items from your SUD form.
3. Informal practice
4. Pre and post sleep body awareness

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	Practice y/n Length of time		Total daily practice time
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

Session 7

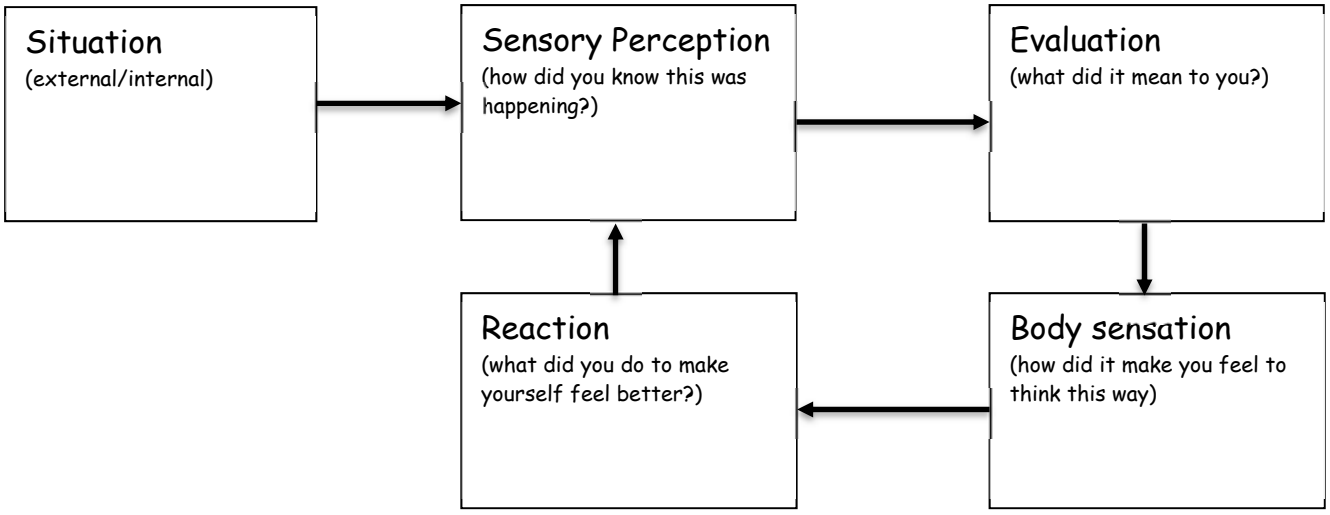
In this session we will:
- Review practice
- Engage in practice (transversal scanning)
- Discuss personal ethics and values and how contravening them makes us feel

Ethics in life

No matter what our cultural background we develop ethical frameworks by which to live. There exist many ethical frameworks.

From the MiCBT perspective we can consider what the impact is when we act in a way that is inconsistent with our own personal ethical framework e.g. how does it make me feel to prevent killing - eg a spider/mouse. How does it feel to perform the killing?

Reflect on acting in a way that is not true to your personal ethics using the co-emergence model:
Diary of reactive habits – the co-emergence model (Cayoun 2003)



Ethical Challenge:

This week try an experiment – be mindful of any situations in which you may be tempted to:
- Kill – e.g. a mosquito; a cockroach; a fish, an ant or a spider. Think about animals that have died to make something you eat or use.
- Steal – include things like making a personal phone call at work; using work stationery; taking a "sickie" when well – taking what is not freely given eg: taking up someone's time.
- Inappropriate sexual actions that may cause harm – unintended sexual activity
- False or harmful speech – including gossiping and lying.
- Taking intoxicants or mind altering substances – substances which may disinhibit - acknowledging the need to be in control of our actions if we are to be mindful.

Home exercise:

1. Transversal scanning – tracks 18 &19
2. Informal practice
3. Pre and post sleep body awareness
4. Ethical challenges
5. Add Loving kindness to twice daily practice (you may want to make up your own version)

Mindfulness practice record sheet

Week _____

Name: _____ **Date:** _____

Day/date	Practice y/n Length of time		Total daily practice time
Mon	am ☐ .....mins	pm ☐ ... ..mins	
Tues	am ☐ ... ..mins	pm ☐ ... ..mins	
Wed	am ☐ ... ..mins	pm ☐ ... ..mins	
Thurs	am ☐ ... ..mins	pm ☐ ... ..mins	
Fri	am ☐ ... ..mins	pm ☐ ... ..mins	
Sat	am ☐ ... ..mins	pm ☐ ... ..mins	
Sun	am ☐ ... ..mins	pm ☐ ... ..mins	
Informal	am ☐ ... ..mins	pm ☐ ... ..mins	
Total practice for the whole week			
Notes on this weeks practice:			

Session 8

In this session we will:

- Review practice
- Engage in practice – sweeping in depth
- Review the program and goals
- Check on progress
- Discuss maintaining the gains

In the 8 weeks of this program we have introduced a sequence of body scans. When you master transversal scanning you will probably notice some free-flowing sensations on the inside of the body. The final advanced body scan is to "sweep in depth"; sweeping so that your attention can be directed to the internal sensations as well as those on the surface of the body. There is no track for this scan; you will be able to engage with this exercise when your transversal scanning is sufficiently developed.

Now that you have developed your mindfulness skills you will benefit from continuing with a regular practice. You may choose to vary the type of body scan that you do to prevent habituation and to enable you to check that you are still detecting sensations across the whole body. Track 20 provides a guided track for maintenance practice or you may be self-sufficient by now. Start with a Mindfulness of Breath for about one third of your practice then practice Body Scanning and finish with Loving Kindness. For the loving kindness make up your own words around wishing for your happiness and ability to live peacefully and harmoniously.
Keeping up the practice!
Although you have been participating in a Research Trial, the Melbourne Mindfulness Institute is committed to offering ongoing support to those who have learned the skills taught in the MiCBT program. Free monthly mindfulness practice sessions are available. In addition we offer "mini-retreats" for a small charge – these are typically held on Saturdays.
For more information contact the Melbourne Mindfulness Institute www.melbournemindfulness.com.
The book "Mindfulness-integrated Cognitive Behaviour Therapy for Well-being and Personal Growth" by Bruno Cayoun (Wiley 2015) provides a comprehensive self-help guide to the program.

Further reading

- *Mindfulness-Integrated CBT Principles and Practice.* Cayoun, B. A. (2011). Chichester, UK: Wiley-Blackwell.
- Mindfulness-integrated CBT for Well-being and personal growth. Cayoun, B. A. (2015). Chichester, UK: Wiley- Blackwell.
- *Mindfulness in Plain English.* Gunaratana, B. H. (2002). Boston: Wisdom.
- *Eight Mindful Steps to Happiness* Gunaratana, B.H. (2001). Boston: Wisdom.
- *The miracle of mindfulness*. Hanh, T. N. (1975). Berkeley: Beacon Books.
- The art of living: Vipassana Meditation as taught by S. N. Goenka. Hart, W. (1987). New York: HarperCollins.
- *The psychology of awakening.* Eds Watson, G., Batchelor, S.,Claxton, G. (1999). Boston: Shambala.
- Towards the Psychology of Awakening: Buddhism, Psychotherapy and the Path of personal and spiritual Transformation. Welwood, J., (2002). Boston: Shambala
- Being Nobody, Going Nowhere: Meditations on the Buddhist Path. Khema, A., (1987). Boston: Wisdom.
- When the Iron Eagle Flies: Buddhism for the West. Khema, A., (2000). Boston: Wisdom.
- Mindsight - change your brain and your life.. Seigel, D.J. (2009). Melbourne: Scribe.
- The Mindfulness Solution: Everyday Practices for Everyday Problems. Siegel, R.D., (2010). New York: Guildford.
- Full catastrophe living: Using the wisdom of your body and mind to face stress, pain and illness. Kabat-Zinn, J. (1990). New York: Delacorte.
- Coming To Our Senses: Healing Ourselves and the World Through Mindfulness. Kabat-Zinn, J. (2005). New York: Hyperion.
- *The Brain That Changes Itself.* Doidge, N. (2010) Australia: Scribe

6.8 Appendix 6: Data Cleaning

Data Cleaning and checking

Data collected using Qualtrics software and downloaded to excel for Mac v16 and to SPSS v 26.

The following "fixes" were required to the time 0 (T0) data set.

1). checking the external data reference and the participant ID entered by participants matched and fixing any typographical errors (eg lower case instead of upper case)

2). deleting "false starts" - where a participant logged in but did not complete the questionnaire and subsequently logged in in later and completed the questionnaires

3). working datasets created at each time point:

- cleaning and screening including missing data, normality and linearity
- removal of all identifiers and irrelevant fields to ensure anonymity of participants including name, IP address
- create variable names for measures for time points
- create split file (age 18-34/35-49/50-75)
- create split file (medications y/n)
- create total for each scale including reverse score items where required

4). Files merged for all time points. To reduce the size of the SPSS file only the total scores from each time point were merged

5). created variables: program completion (y/n); medication change (y/n) education (post-secondary school y/n)

6). created long form of data set for analysis in stata

6.9 Appendix 7: Thank you email

Email accompanying gift voucher to participants who completed 6-month follow up questionnaires.

Dear (participant name)

Thank you so much for participation in the randomised controlled trial investigating the effectiveness of MiCBT. This gift voucher is a small token of our appreciation.

Thank you.