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Online mindfulness-enhanced cognitive behavioural therapy for anxiety and depression: Outcomes of a pilot trial

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ABSTRACT

Transdiagnostic internet-delivered cognitive behavioural therapies (iCBT) are effective for treating anxiety and depression, but there is room for improvement. In this study we developed a new Mindfulness-Enhanced iCBT intervention by incorporating formal and informal mindfulness exercises within an existing transdiagnostic iCBT program for mixed depression and anxiety. We examined the acceptability, feasibility, and outcomes of this new program in a sample of 22 adults with anxiety disorders and/or major depression. Participants took part in the 7-lesson clinician-guided online intervention over 14 weeks, and completed measures of distress (K-10), anxiety (GAD-7), depression (PHQ-9), mindfulness (FFMQ) and well-being (WEMBWS) at pre-, mid-, post-treatment, and three months post-treatment. Treatment engagement, satisfaction, and side-effects were assessed. We found large, significant reductions in distress (Hedges $g = 1.55$), anxiety ($g = 1.39$), and depression ($g = 1.96$), and improvements in trait mindfulness ($g = 0.98$) and well-being ($g = 1.26$) between baseline and post-treatment, all of which were maintained at follow-up. Treatment satisfaction was high for treatment-completers, with minimal side-effects reported, although adherence was lower than expected (59.1% completed). These findings show that it is feasible to integrate online mindfulness training with iCBT for the treatment of anxiety and depression, but further research is needed to improve adherence. A randomised controlled trial is needed to explore the efficacy of this program.

1. Introduction

Anxiety and depressive disorders are two of the largest causes of disability worldwide (Mathers et al., 2008). Given the high lifetime prevalence rates (Kessler et al., 2005) and the low proportion receiving evidence-based treatment (Harris et al., 2015) it is essential that effective, efficient, and cost-effective interventions for these disorders become widely available. Internet-delivered cognitive behavioural therapy (iCBT) addresses many barriers to accessing face-to-face CBT, and is an effective and affordable treatment for people with depression and anxiety disorders (Newby et al., 2016; Olthuis et al., 2016; Carlbring et al., 2018). Meta-analyses show that iCBT achieves comparable outcomes to face-to-face CBT (Carlbring et al., 2018) and that iCBT is effective for the treatment of a range of anxiety and depressive disorders (Olthuis et al., 2016).

Research into iCBT interventions has closely mirrored the shift in the face-to-face treatment literature (e.g., Barlow et al., 2004) away from disorder-specific treatments to transdiagnostic protocols. Transdiagnostic, or unified, CBT interventions are argued to be efficient treatments that target shared cognitive and behavioural processes implicated in the development and maintenance of psychopathology across disorders (Titov et al., 2015; Barlow et al., 2004). Transdiagnostic iCBT programs have been shown to be effective in the treatment of mixed and comorbid anxiety disorders (Johnston et al., 2011; Titov et al., 2010; Nordgren et al., 2014), as well as anxiety co-morbid with depression (Titov et al., 2011b; Newby et al., 2016; Newby et al., 2013; Titov et al., 2012), and achieve comparable outcomes to disorder-specific iCBT programs (Dear et al., 2015; Berger et al., 2014; Titov et al., 2015).

Despite these promising results, there remains room for improvement, as only half of those who complete iCBT achieve full recovery, leaving 30% with residual symptoms that place them at high risk of relapse, and 20% who do not improve (Sunderland et al., 2012; Newby et al., 2013). In addition, between 45 and 60% of participants do not demonstrate clinically reliable change in either the core symptoms of depression and anxiety, or the transdiagnostic factors, such as repetitive

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negative thinking, that cause and maintain symptoms (Newby et al., 2014). Therefore, continuing to refine existing transdiagnostic treatment protocols is essential to improving patient outcomes.

In this study we explored whether it was feasible to augment an existing iCBT program with mindfulness. Mindfulness is a skill of purposely bringing attention to and observing the ongoing stream of internal and external stimuli, such as physical sensations, thoughts, emotions, and environmental stimuli, with an attitude of non-judgmental acceptance (Kabat-Zinn, 2003; Marlatt and Kristeller, 1999). Developed through mindfulness meditation exercises, which promote the intentional self-regulation of attention (Goleman and Schwartz, 1976; Kabat-Zinn, 1982), mindfulness has been shown to improve adaptive functioning (see Brown et al., 2007 for a review). In the context of mental health, mindfulness training encourages individuals to develop awareness of the fleeting nature of cognitive-emotional phenomena, thereby developing a more compassionate and accepting relationship with their thoughts and feelings, as well as learning to suspend habitual, maladaptive behaviours (Segal et al., 2004).

There are several reasons why mindfulness may be a useful adjunct to iCBT. First, CBT and mindfulness-based interventions aim to reduce symptoms in different but complementary ways. For instance, while traditional CBT teaches adaptive emotion regulation strategies of problem-solving and cognitive reappraisal (Beck, 1979), mindfulness training teaches individuals to allow their repetitive cognitive-emotional experiences to occur without trying to control them (Kabat-Zinn, 1990), thereby discouraging experiential avoidance (i.e., a tendency to supress or avoid thoughts, images, emotions, memories, or physical sensations) and over-engagement with internal experiences (Hayes and Feldman, 2004), both of which are seen as maladaptive forms of emotion regulation (Sloan et al., 2017). Hayes and Feldman (2004), for example, refer to mindfulness training as a tool that facilitates the process of change in therapy, because by fostering adaptive emotion regulation, mindfulness helps individuals confront, work through, and transform painful cognitive-emotional experiences without becoming over-absorbed in them. To this end, mindfulness training can be seen as a facilitator of exposure-based work characteristic of CBT.

Second, emerging evidence from the face-to-face treatment literature suggests that mindfulness training may be particularly useful in directly addressing the transdiagnostic mechanisms underlying depression and anxiety such experiential avoidance (Hayes et al., 1996; Roemer and Orsillo, 2002; Roemer et al., 2013), repetitive negative thinking (Watkins et al., 2007; Kingston et al., 2007), and emotion regulation (Chambers et al., 2009; Berking et al., 2008; Teper et al., 2013), which may not be adequately targeted by CBT on its own, but are simultaneously tragetted during mindfulness training and practice (Baer, 2003; Hofmann et al., 2010). Third, preliminary evidence from face-to-face CBT studies suggests that adding mindfulness instruction to standard CBT results in greater effects on depression and anxiety symptoms compared to CBT alone. For example, Berking et al. (2013) found that standard CBT was inferior to CBT containing additional mindfulness instruction, which demonstrated greater reductions in depression and improvements in emotion regulation.

Although the majority of the evidence in support of mindfulness stems from programs that are taught in face-to-face groups and by experienced mindfulness teachers (Kabat-Zinn, 1990), mindfulness is increasingly being taught online. Numerous self-help online courses and mobile phone applications are becoming available, which are said to reduce stress and anxiety, and improve mood (e.g., Sucala et al., 2017), yet have not been evaluated in controlled trials. While emerging evidence supports the feasibility of online self-help mindfulness training in non-clinical populations (Glück and Maercker, 2011; Krusche et al., 2012), there is a severe lack of research to support such interventions for those with clinical levels of depression and anxiety. Further research is needed to understand whether online mindfulness-based interventions are associated with side-effects or adverse events (Rozental et al., 2015), or whether there are any contraindications for self-guided mindfulness practice over the internet (Dobkin et al., 2012; Lustyk et al., 2009).

With these issues in mind, we developed a new online program that incorporated mindfulness training with transdiagnostic iCBT. Rather than adding mindfulness as a separate module, we incorporated mindfulness training, including psychoeducation about mindfulness, informal mindfulness exercises (e.g., bringing mindful awareness to everyday activities), and formal mindfulness meditation instruction (e.g., mindfulness of breath) adapted from the mindfulness based cognitive therapy (MBCT) protocol (Segal et al., 2012), into an existing transdiagnostic iCBT program for depression and anxiety developed by Newby et al. (2013). The original iCBT program consisted of classic CBT strategies such as behavioural activation, activity scheduling, structured problem solving, cognitive restructuring, graded exposure, and relapse prevention. Mindfulness exercises were incorporated into the program both to teach additional skills as well as to assist with the use and practice of the CBT skills. For instance, the concept of being mindful and engaged in everyday activities was taught alongside behavioural activation and activity scheduling. The skill of noticing and letting go of thoughts (e.g., during Mindfulness of the Breath and Body Scan) was taught alongside psychoeducation about the fight-or-flight response with the aim of reducing reactivity to bodily cues, as well as throughout cognitive restructuring to enhance recognition of maladaptive thoughts and disengagement from worry and rumination. Mindfulness and acceptance of unpleasant experiences (e.g., Mindfulness of Physical Discomfort and Mindfulness of a Difficulty) was taught alongside graded exposure to facilitate emotion regulation and to reduce experiential and behavioural avoidance. Psychoeducation about the use of mindfulness practice in daily life was also incorporated into relapse prevention both to increase recognition of early warning signs, as well as to reduce reactivity to and catastrophic interpretations of symptom lapses.

In the current study we explored the feasibility, acceptability, adherence, and preliminary outcomes of this new 7-lesson *Mindfulness-Enhanced iCBT program* in a sample of participants with depression and/or anxiety disorders. We explored the effect of this program on symptom severity, functional impairment and wellbeing, as well as the transdiagnostic process variables that the program was designed to target (e.g., experiential avoidance, negative repetitive thinking in the form of rumination and worry, and emotion regulation). We also examined participant feedback and possible unwanted side effects of this program, with the view to evaluating it in a future RCT. This study is the first to evaluate a mindfulness-enhanced transdiagnostic iCBT program, the first to explicitly assess the side-effects associated with an online self-help program that involves mindfulness training, as well as the first to gain participants' feedback on the perceived usefulness of mindfulness training within iCBT. We hypothesised that this program would be acceptable to participants with clinical levels of anxiety and depression, and lead to significant reductions in symptoms, as well as increases in mindfulness and well-being.

2. Method

2.1. Design

This study was an open trial. Participants were assessed at pre-treatment, mid-treatment (prior to starting Lesson 5), post-treatment, and at 3-month follow-up.

2.2. Inclusion/exclusion criteria

Inclusion criteria were: (i) aged over 18, (ii) self-identified as experiencing symptoms of depression and/or anxiety and met criteria for a DSM-IV diagnosis of one or more of the following: generalized anxiety disorder (GAD), social phobia, panic disorder, agoraphobia, obsessive compulsive disorder (OCD), and/or major depressive disorder (MDD),

(iii) prepared to provide name, phone number and address, and the name and address of their local general practitioner, (iv) had access to a phone, computer and printer, and (vi) if in treatment, were on a stable dose of antidepressant medication for at least two months prior to assessment, and/or a stable dose of psychotherapy for at least one month prior to assessment. Exclusion criteria included psychosis or bipolar disorder, drug or alcohol dependence, current and/or recent (< 12 months) suicidality and/or self-harm, current use of antipsychotic or regular benzodiazepine medications, severe depression (PHQ-9 total score > 23), or completion of an online program for anxiety or depression in the past year.

2.3. Procedure

The study was advertised on social media and to a waiting list of individuals interested in participating in research evaluating online treatment for depression or anxiety. Individuals applied online at www.virtualclinic.org.au after reading details about the study. The online screening assessment comprised of demographic questions (including symptoms and treatment history), the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) to assess depression severity and suicidal ideation, and the Generalised Anxiety Disorder 7-item scale (GAD-7; Spitzer et al., 2006) to assess severity of anxiety symptoms. Applicants who met the online screening criteria then participated in a brief phone interview with a trained Clinical Psychologist with either a Masters level qualification (NK) or PhD Qualification (JN) in Clinical Psychology. The interviewer administered a structured diagnostic interview that consisted of a Mini International Neuropsychiatric Interview Version 5.0.0 (Sheehan et al., 1998) to assess for the presence of one of more of the DSM-IV diagnoses of current panic disorder, social phobia, agoraphobia, GAD, OCD and/or MDD. Participants completed the 7-lesson Mindfulness-Enhanced iCBT Program over a 14-week period (between 23rd March 2015 and 14th of June 2015).

2.4. Description of treatment

The 7-lesson Mindfulness-Enhanced iCBT Program[1], described in Table 1, was based on our existing transdiagnostic iCBT program for depression and anxiety (Newby et al., 2013). The program consisted of traditional CBT strategies, such as behavioural activation, cognitive restructuring, and graded exposure, which were supplemented by mindfulness instruction and practice exercises, including seven audio guided meditations adapted from the Mindfulness-Based Cognitive Therapy (MBCT) protocol (Segal et al., 2004) and provided to participants on a CD. The program was self-paced, with one lesson becoming available each week during the first 7 weeks of the study. It was delivered via the Virtual Clinic website (www.virtualclinic.org.au) in the form of an illustrated story about two people who experience anxiety and depression, and gain mastery over their symptoms using mindfulness and CBT skills. Following each lesson, participants were encouraged to download and print out a lesson summary, which included an overview of the key concepts and practical homework activities. Participants had access to (i) frequently asked questions for each lesson, (ii) common difficulties with mindfulness practice, and (iii) extra resources (see Table 1 for details).

2.5. Clinical contact with a psychologist

After the completion of the first two lessons, participants received e-mail contact from their clinician (NK or JN) to enquire about their experience with the lessons, and to offer an opportunity to ask questions or request a phone consultation. From then on, e-mail and/or phone contact was made in response to a patient request, if a participants' score triggered an alert, or if a participant failed to log-in and complete a lesson in more than 10 days. Alerts were triggered within the online participant management system by K10 total scores above 30 (indicating severe distress); PHQ-9 total scores above 23 (indicating severe depression), and PHQ9 Question 9 score of 2 and above (indicating the presence of suicidal thoughts). Alerts were also triggered if a K10, PHQ9 or GAD7 score increased more than 0.5SD from the previous lesson. Clinician-initiated contact in response to alerts was for the purposes of risk monitoring.

2.6. Participant flow

See Figure Fig. 1 for participant flow. A total of 88 individuals started an application to the study (recruitment occurred between 5th and 9th of March 2015). Of the 61 who completed their online application, 37 met online screening criteria, and were eligible for a further phone interview. Five individuals were excluded during the phone interview and five could not be contacted, leaving 27 applicants who met all inclusion criteria. Twenty two participants started the program, had baseline data, and were included in the analysis (4 did not start and had no baseline data, and one withdrew). Data were collected from 16/22 participants at post-treatment, and 14/22 at follow-up. The study was approved by the Human Research Ethics Committee (HREC) of St Vincent's Hospital (Sydney, Australia) (HREC/14/SVH/170), and the trial was registered with the Australian and New Zealand Clinical Trials Registry ACTRN12616000258459.

2.7. Measures

2.7.1. Diagnostic interview

The Mini International Neuropsychiatric Interview Version 5.0.0 (MINI; Sheehan et al., 1998). GAD, panic disorder (PD), agoraphobia (Ag), social phobia (SP), OCD, MDD and risk assessment modules were administered to assess current DSM-IV diagnoses. The MINI possesses excellent inter-rater reliability (k = 0.88–1.00) and good concurrent validity with the Composite International Diagnostic Interview (CIDI, Kessler and Üstün, 2004).

2.7.2. Outcome measures

The Kessler 10-item Psychological Distress Scale (K-10; Kessler et al., 2002) is a 10-item measure of non-specific psychological distress. The total score ranges from 10 to 50, with higher scores indicating increased distress, and those above 20 indicating clinically significant levels of distress. The K-10 has excellent psychometric properties (Andrews and Slade, 2001), including high internal consistency (α = 0.93; Kessler et al., 2002) and discriminant validity (Furukawa et al., 2003).

The Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) is a 9-item measure of depression symptoms experienced over the past two weeks. Scores range from 0 to 27, and a score ≥ 10 is used as a clinical cut-off for probable MDD (Zuithoff et al., 2010). The measure has good internal consistency (α = .86 – .89), test-retest reliability (r = 0.84 over 48 h), and construct validity (Kroenke et al., 2001). It is also sensitive to change across internet-delivered CBT (Titov et al., 2011a).

The Generalised Anxiety Disorder 7-item Scale (GAD-7; Spitzer et al., 2006) is a 7-item measure of generalised anxiety symptoms (e.g., "Not being able to stop or control worrying"). It assesses symptoms over the past fortnight. Scores range from 0 to 21, and a score ≥ 10 is used as a clinical cut-off for probable GAD. The scale has good reliability (r = 0.85) and validity (Kroenke et al., 2007).

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007) is a 14-item scale measuring subjective well-being and positive psychological functioning. Scores range between 14 and 70, with higher scores indicating higher levels of well-being. The measure

[1] Clinicians are able to access and use the updated version of this program with their clients at www.thiswayup.org.au

Table 1
Lesson-by-lesson structure of the mindfulness-enhanced iCBT program.

Lesson title	Lesson content	Audio guided mindfulness exercises	Homework activities
1 *About Depression and Anxiety*: Learning about your symptoms and what to expect	• Psychoeducation about depression and anxiety • Socialization to the CBT model • Goal setting using SMART goals principle • Identifying own symptoms of depression and anxiety • Psychoeducation about mindfulness • Instruction about noticing and attending to senses • Psychoeducation about the fight-or-flight response • Instruction about attending to the breath and noticing thoughts arising • Psychoeducation about rumination and worry • Psychoeducation about the principles of CBT	The Raisin Exercise Mindfulness of the Breath	Set SMART goals for the Program Practice mindful eating Practice mindfulness of the breath once per day
2 *Getting Back on Track*: Learning to tackle physical symptoms and low activity	• Instruction about noticing and observing bodily sensations • Behavioural activation strategies: tackling low activity and avoidance using activity planning (pleasure and achievement) • Instruction about mindfulness during daily activities • Structured problem-solving	Body scan	Practice mindfulness of the breath for at least 5 minutes per day Practice body scan at least 3 times per week Use activity planning Practice mindfulness during daily tasks Practice structured problem-solving
3 *Learning about your Mind*: Learning about thoughts and unhelpful thinking patterns	• Psychoeducation about thoughts and thought distortions • Instructions for identifying thoughts and thought distortions • Instruction in noticing and observing thoughts using the 3-Minute Breathing Space exercise • Identifying worry and rumination	The 3-minute breathing space	Complete thought monitoring sheets Practise the 3-minute breathing space at least 3 times per day Continue skill practice from previous lesson
4 *Tackling Negative Thoughts*: Learning to tackle negative thinking habits	• Instructions for thought challenging of unhelpful thoughts • Identifying positive and negative beliefs about worry and rumination • Challenging unhelpful beliefs • Tackling unhelpful thinking step-by-step • Choosing your strategy • Hunt for positives • Using mindfulness to pause in the moment and select an optimal strategy		Thought and belief challenging sheets Continue mindfulness practice from previous lessons
5 *Learning to Face your Fears*	• Psychoeducation about avoidance and safety behaviours • Noticing the urge to avoid using mindfulness of physical discomfort exercise • Urge surfing • Rationale for exposure • Building exposure hierarchy and step ladders • Facing your emotions using the extended 3-minute breathing space	Mindfulness of Physical Discomfort The Extended 3-Minute Breathing Space	Practice exposure step-ladders Continue mindfulness practices from previous lesson
6 *Overcoming Your Fears*: Mastering your skills and overcoming your fears	• Troubleshooting difficulties with exposure • Mindfulness of difficult thoughts and emotions using the mindfulness of a difficulty exercise • Exposure to thoughts and emotions	Mindfulness of a difficulty	Graded exposure practice Mindfulness of a difficulty exercise Continue mindfulness practice from previous lessons
7 *Staying Well*: Staying well in the long term and getting even better	• Review of the skills covered • Psychoeducation about lases and relapses • Review of mindfulness skills and exercises • Relapse prevention plan • How to get further help for anxiety and depression		Relapse prevention plan How to incorporate mindfulness in daily life
Extra resources	Good sleep guide Medication information 100 things to do About assertiveness About panic attacks Boosting motivation Conversation skills In case of emergency Labelling emotions Worry stories Worry time Common difficulties with mindfulness 50 daily activities to do mindfully	*Worksheets*	Activity planning monitor Challenging beliefs about worry and rumination Exposure planner Exposure stepladder form Facing your fears worksheet Positives hunt worksheet Structured problem solving worksheet Thought challenging worksheet Thought monitoring form Mindfulness practice diary

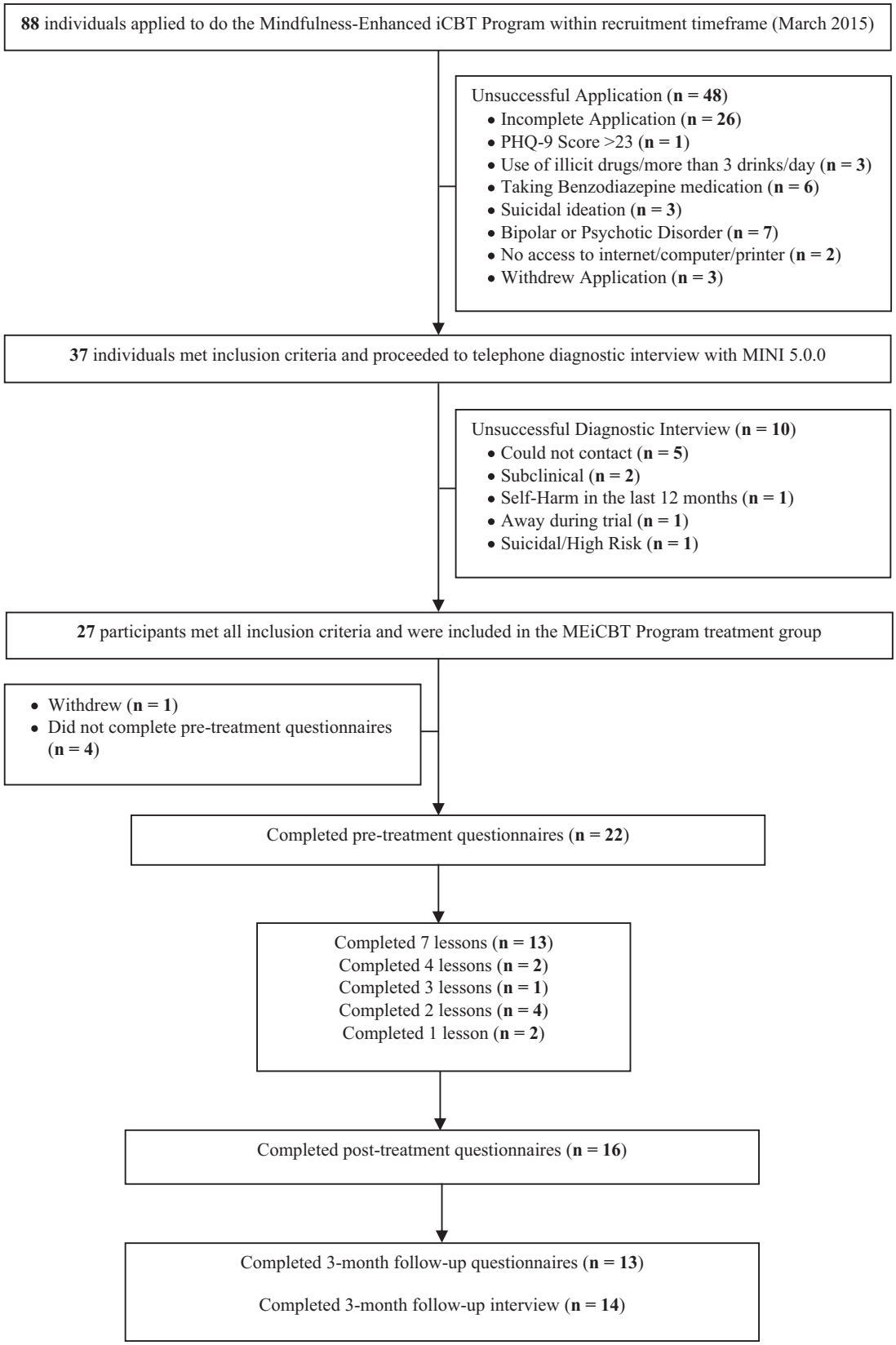

Fig. 1. Participant flow diagram.

demonstrates good psychometric properties, including internal consistency ($\alpha = 0.89$) (Stewart-Brown et al., 2011).

The 12-item World Health Organisation Disability Assessment Schedule (WHODAS-II; Rehm et al., 1999) is a short self-report measure of functional impairment over the past month, including restriction of and participation in six life tasks (e.g., learning, maintaining a friendship, joining in community activities), resulting from a health condition. Higher scores indicate more impairment. The questionnaire yields

a global disability score and has good psychometric properties (Rehm et al., 1999; Andrews et al., 2009).

The Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990) is a 16-item scale measuring aspects of worry, including the frequency, intensity, and perceived uncontrollability. The total score ranges between 16 and 80, with higher scores indicating higher trait worry. The questionnaire has good psychometric properties, including high internal consistency (α = 0.86–0.95) and test-retest reliability (r = 0.74–0.93) (Molina and Borkovec, 1994), which are maintained when it is delivered online (Zlomke, 2009).

The Ruminative Responses Scale (RRS; Treynor et al., 2003) is a 22-item scale that measures frequency of ruminative thinking and behaviour in response to dysphoric mood, with higher scores indicating more frequent rumination. The measure has good psychometric properties including internal consistency (α = 0.72–0.79) and test-retest reliability (r = 0.60–0.62) (Roelofs et al., 2006; Treynor et al., 2003).

Brief Experiential Avoidance Questionnaire (BEAQ; Gámez et al., 2014) is a 15-item measure assessing avoidance of unpleasant experiences, such as pain, uneasiness, and unpleasant emotions and memories. The total score ranges between 15 and 90 with higher scores indicating more avoidance. The measure demonstrates good internal consistency (α = 0.86), which replicates across community, student, and patient samples (Gámez et al., 2014).

Difficulties with Emotion Regulation Scale (DERS; Gratz and Roemer, 2004) is a 36-item scale that measures emotion regulation deficits across four domains, (a) understanding and awareness of emotions, (b) acceptance of emotions, (c) ability to refrain from impulsive behaviour and persist with goal-directed behaviour when experiencing negative emotions, and (d) ability to access effective emotion regulation strategies. Higher scores indicate poorer emotion regulation. The DERS has been shown to have high internal consistency (α = 0.93), good test-retest reliability (r = 0.88), and construct validity (Gratz and Roemer, 2004).

Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) is a 39-item measure of mindfulness skills, which consists of five subscales hypothesised to map onto the facets of the mindfulness construct, (a) non-reactivity to internal experiences, (b) noticing and observing, (c) acting with awareness, (d) describing, and (e) non-judging of internal experiences. Higher scores indicate higher trait mindfulness. The FFMQ has adequate psychometric properties, including high internal consistency (α = 0.77–0.93; Williams et al., 2014), and has been shown to be valid, reliable, and sensitive to change in clinical populations (Bohlmeijer et al., 2011).

2.8. Outcome measurement

The MINI was administered to all participants at baseline and at 3-month follow-up to assess diagnostic status. All participants completed the K-10 and WEMWBS before they commenced each lesson. The K-10 was used to alert the clinician if participants' scores rose by more than 0.5SD between lessons, indicating a significant increase in distress, or if their scores rose above 30 (severe range). The remaining outcome measures were administered at pre-treatment (prior to Lesson 1), before Lesson 5 (mid-treatment), at post-treatment (one week after the treatment finished) and at 3-month follow-up.

2.9. Treatment satisfaction

At post-treatment, participants were asked to rate how satisfied they were with the program on a 5-point scale ranging from 0 = "very dissatisfied" to 5 = "very satisfied". They were also asked to rate how logical the program was, and how successful it was in teaching them skills to manage their anxiety and/or depression, on a scale from 1–10 (where 1 = "not very", and 10 = "very"). Finally, participants were asked about the impact their participation in the program had on their confidence to manage their symptoms going forward (on a 5-point scale: 1 = "significantly reduced", 5 = "significantly increased").

2.10. Engagement with the program, skill practice, and acceptability of the mindfulness components

To assess the frequency and amount of mindfulness practice between lessons, and participants' overall engagement with the program we asked participants (from Lesson 2 onwards) (i) how long they spent reading (and re-reading) the previous lesson and practicing what they had learnt over the past week in minutes, (ii) how many days over the past week they practiced mindfulness and how long on average they spent practicing (in minutes) on those days.

At post-treatment, participants were asked to rate how helpful they found the audio mindfulness exercises (on a 10-point scale: 1 = "not very helpful", 10 = "very helpful") and how important they were to the program (on a 4-point scale: 1 = "not important", 4 = "extremely important"). They also rated how helpful mindfulness practice was "In relation to other skills taught in this Program (e.g., structured problem-solving, thought challenging)" on a 5-point scale (0 = "not at all helpful", 1 = "less helpful than other skills", 2 = "as helpful as other skills", 3 = "more helpful than other skills", 4 = "most helpful").

2.11. Side effects

At post-treatment, participants were asked an open ended question to describe any unwanted side effects or negative events that occurred because of the program.

2.12. Statistical analyses

All analyses were conducted using SPSS v. 23. For each of the primary and secondary outcome measures, a linear mixed model was constructed using the MIXED procedure with a random intercept for subject, to investigate reductions between pre- and post-treatment, and pre-treatment and follow-up. Linear mixed models analyses using maximum likelihood estimation were performed to account for incomplete data in a way that does not bias the parameter estimates (West et al., 2014). For each model, time was entered as a categorical variable; with an identity covariance structure specified to model the covariance structure of the random intercept. Initial model building focused on the selection of the most appropriate covariance structure for the residual correlation matrix. Model fit indices and inspection of the variance-covariance matrix supported the selection of the diagonal covariance structure for each of the outcome measures, with the exception of RRS and BEAQ scores in which the unstructured covariance structure provided the best fit. Effect sizes (Hedges g, adjusted for sample size) were calculated to determine the magnitude of within-group reduction in scores between pre-treatment to post-treatment, and between pre-treatment to 3-month follow-up.

3. Results

3.1. Demographic characteristics

The majority of participants were female (90.9%) ranging in age between 18 and 66 (mean age: 36.5, SD = 12.96) and born in Australia (91%). Sixteen participants were either in full-time (54.5%) or part-time (18.2%) paid employment, four (18.1%) were studying, one (4.5%) was a stay-at-home parent, and one participant (4.5%) was retired. At pre-treatment, the mean scores on the self-report measures of depression (PHQ-9: M = 13.31, SD = 5.05) and anxiety (GAD-7: M = 12.06, SD = 5.27) fell in the moderate range (Kroenke et al., 2001). Of the 22 participants, 17 participants (77.3%) met DSM-IV diagnostic criteria for GAD, 15 participants (68.2%) met criteria for MDD, 12 (54.5%) had social phobia, nine (40.9%) had agoraphobia, 5 (22.7%) met criteria for panic disorder, and three (13.6%) had OCD.

Participants met criteria for an average of 2.7 diagnoses (*SD* = 1.48, range = 1–6). Eleven participants (50%) met criteria for both MDD and an anxiety disorder, seven participants (31.8%) met criteria for two or more anxiety disorders without MDD, and four (18.2%) participants met criteria for MDD only.

The average age of onset of symptoms of depression and anxiety was 21 years (*SD* = 9.52, range = 9–50). Most participants (n = 21, 95.4%) reported having more than one previous episode, of which nine (40.9%) reported having more than seven "different spells of persistent low mood and/or anxiety" over their lifetime. Nine participants (40.9%) reported feeling "persistently low and/or anxious" for more than two years during their lifetime, seven (31.8%) for one to two years, and six (27.2%) reported feeling this way for less than 12 months. Six participants (27.2%) were taking antidepressant medication, including SSRIs (n = 4), MAOIs (n = 1), and TCA (n = 1), and four (18.2%) were receiving non-CBT based psychotherapy or counselling. Fifteen participants (68.2%) reported having received treatment for their depression and/or anxiety in the past, and sixteen participants (72.7%) reported having previous experience with mindfulness.

3.2. Adherence and engagement with the program

Out of the 22 participants who started the online program, 13 completed all seven lessons at the end of the 14-week treatment period (59.1% completion rate). Of the non-completers, two did not progress past the first lesson, four completed the second lesson, one completed three lessons, and two completed four lessons of the program.

3.3. Primary and secondary outcomes at post-treatment

Table 2 shows the linear mixed model results, including the estimated marginal means for each of the outcome measures at pre-, post- and 3-month follow-up time points. We found statistically significant improvements between pre- and post-treatment on all of the symptom outcome measures, including the K-10, PHQ-9, GAD-7, and WHODAS, with scores on average falling within the normal range at post-treatment on each of these measures: K-10 (*M* = 18.65, *SD* = 5.16), PHQ-9 (*M* = 5.14, *SD* = 2.65), GAD-7 (*M* = 5.34, *SD* = 4.16), and WHODAS-II (*M* = 18.44, *SD* = 4.80). The within-group effect sizes from pre to post treatment were large for all of these measures (Hedges *gs* = 1.55, 1.96, 1.39, and 1.69 for K-10, PHQ-9, GAD-7 and WHODAS-II scores respectively). Participants' well-being on the WEMWBS and mindfulness scores on the FFMQ also improved significantly from pre- to post-treatment. These effect sizes were large (Hedges *gs* = 1.26 and 0.98 respectively). Finally, we found significant reductions on all of the secondary outcome measures including PSWQ, RRS, BEAQ, and DERS, with a medium effect size for BEAQ (Hedges *g* = 0.57) and large effect sizes for the others (Hedges *gs* = 1.07 (PSWQ), 0.76 (RRS), and 0.95 (DERS)).

3.4. Primary and secondary outcomes at 3-Month follow-up

A similar pattern of results was evident at follow-up, with all of the symptom score reductions and cognitive and behavioural process variables (e.g., rumination, worry, emotion regulation) between pre-treatment to 3-month follow-up being significant at $p < 0.01$ level. Pre-treatment to follow-up effect sizes ranged from medium (*g* = 0.58 for BEAQ scores) to large (*g* = 1.70 for PHQ-9 scores).

3.5. Diagnostic status at follow-up

At the 3-month follow-up, 11 (78.6%) of the 14 participants who completed the follow-up diagnostic interviews no longer met criteria for a depressive or anxiety disorder. Only three participants continued to meet DSM-IV diagnostic criteria – two participants continued to meet criteria for GAD (14.3%) and one for social phobia (7.1%).

3.6. Clinician contact

The clinicians (NK and JN) spent an average of 26 minutes per participant (SD = 18.36, range = 11–97) in e-mail or phone contact with participants over the course of treatment. Clinician contact focused primarily on adherence and risk monitoring.

3.7. Treatment satisfaction

Of the 16 participants who completed the post-treatment ratings, most reported being either "very satisfied" (n = 11, 68.8%) or "mostly satisfied" (n = 4, 25%) with the online program, with one participant being "neutral". On average, participants found the program very logical (*M* = 9, *SD* = 1.46, range = 5–10) and successful (*M* = 8.75, *SD* = 1.13, range = 7–10) at teaching them techniques to manage their

Table 2
Estimated marginal means at pre- and post-treatment, and three months following mindfulness-enhanced iCBT program.

	Pre-treatment	Post-treatment	3-Month follow-up	Statistic	Pre- to post-treatment	Pre- to follow-up
	Mean (*SD*) n = 22	Mean (*SD*) n = 16	Mean (*SD*) n = 13	*F*(df)	Effect size: Hedges g (95% CI)	Effect size: Hedges g (95% CI)
Symptoms and well-being						
Distress (K-10)	30.14 (7.14)	18.65 (5.16)	19.47 (7.63)	*F*(8, 18.07) = 13.68***	1.55 (0.82-2.28)	1.09 (0.35-1.82)
Depression (PHQ-9)	13.73 (4.93)	5.14 (2.65)	6.36 (4.36)	*F*(3, 116.45) = 16.86***	1.96 (1.18-2.74)	1.70 (0.91-2.50)
Anxiety (GAD-7)	12.50 (5.47)	5.34 (4.16)	5.56 (4.80)	*F*(3, 18.82) = 9.22**	1.39 (0.68-2.11)	1.19 (0.45-1.93)
Well-being (WEMWBS)	36.05 (7.76)	47.69 (7.23)	49.76 (8.81)	*F*(3, 17.82) = 10.77***	1.26 (0.55-1.96)	1.27 (0.52-2.01)
Functional impairment (WHODAS-II)	27.68 (6.48)	18.44 (4.80)	18.81 (5.99)	*F*(2, 32.56) = 17.02***	1.69 (0.90-2.48)	1.18 (0.44-1.92)
Cognitive and behavioural processes						
Worry (PSWQ)	62.77 (12.62)	49.90 (9.70)	47.56 (9.81)	*F*(3, 41.62) = 13.88***	1.07 (0.38-1.76)	1.12 (0.39-1.86)
Rumination (RRS)	57.14 (12.27)	46.88 (11.73)	46.09 (11.43)	*F*(3, 40.54) = 6.79**	0.76 (0.09–1.43)	0.91 (0.20–1.63)
Experiential avoidance (BEAQ)	54.50 (9.45)	47.06 (9.15)	45.78 (9.45)	*F*(3, 43.42) = 5.37*	0.57 (−0.08–1.23)	0.59 (−0.11–1.29)
Emotion regulation (DERS)	103.91 (20.83)	83.05 (18.24)	77.72 (19.33)	*F*(3, 14.55) = 9.06**	0.95 (0.27–1.63)	1.24 (0.49–1.98)
Mindfulness (FFMQ)	107.18 (16.68)	130.27 (20.71)	132.96 (17.92)	*F*(3, 16.06) = 11.01***	0.98 (0.30–1.66)	1.38 (0.63–2.14)

Note. PHQ9 = Patient Health Questionnaire – 9 item; GAD-7 = The Generalised Anxiety Disorder 7-item scale; K-10 = Kessler Distress Scale – 10 item; WEMWBS = Warwick-Edinburgh Mental Well-Being Scale; WHODAS-II = The 12-item World Health Organisation Disability Assessment Schedule; PSWQ = Penn State Worry Questionnaire; RRS = Ruminative Response Scale; BEAQ = Brief Experiential Avoidance Questionnaire; DERS = Difficulties in Emotion Regulation Scale; FFMQ = Five Facet Mindfulness Questionnaire; ***p < 0.001; **p < 0.01; *p < 0.05

Table 3
Time spent completing the program and practising new skills.

	Time spent reading lesson		Time spent practicing skills		Frequency of practicing mindfulness*		Duration of practicing mindfulness*	
	Time in minutes M (SD)	Range in minutes	Time in minutes M (SD)	Range in minutes	Days per week M (SD)	Range in days	Time in minutes M (SD)	Range in minutes
Lesson 1	77.78 (51.51)	0–180	79.17 (53.20)	10–210	4	2–7	17.89 (14.62)	2–60
Lesson 2	62.19 (40.86)	15–180	87.19 (86.70)	30–300	5	3–7	22.00 (15.56)	5–60
Lesson 3	67.14 (37.71)	20–160	73.93 (52.56)	15–200	5	2–7	22.43 (15.94)	5–60
Lesson 4	87.08 (66.55)	30–280	87.50 (89.07)	20–270	5	3–7	21.58 (18.19)	4–60
Lesson 5	87.08 (58.91)	5–180	70.83 (63.06)	20–240	5	1–7	28.55 (23.56)	4–60
Lesson 6	62.08 (50.34)	0–180	57.50 (55.98)	0–180	4	0–7	22.42 (18.37)	0–60

Note. Frequency of mindfulness practice refers to: "On how many days over the past week did you practise mindfulness (days per week)?". Duration of mindfulness practise refers to "On the days when you practised mindfulness, how long on average did you spend practising (minutes per day)?". One participant's data were excluded from the Time Spent analysis due to ambiguity in the responses.

depression and/or anxiety. The majority of the participants reported that their participation in the program increased or significantly increased their confidence in being able to manage their symptoms going forward (n = 14, 87.6%). On average, participants found the guided mindfulness exercises on audio helpful ($M = 7.25$, $SD = 2.79$, range = 2–10), and the majority rated them as either an "important" (n = 6, 37.5%) or an "extremely important" (n = 7, 43.8%) part of the program.

3.8. Amount of skill practice

The average time spent working on each lesson as well as the frequency and duration of CBT and mindfulness skills practice is detailed in Table 3. On average throughout the program, participants reported spending 77.4 minutes per week ($SD = 35.22$, range = 31.67–131.67 min) reading the lessons, and 79.1 min per week ($SD = 59.89$, range = 25.83–218.33 min) practising new skills. Participants reported practising mindfulness on average 4 out of 7 days per week ($M = 4.7$, $SD = 1.49$, range = 2.50 – 6.67) for approximately 20 min per day ($M = 23.95$, $SD = 16.7$, range = 5.33–56.67).

At post-treatment, out of the 16 participants who completed the questionnaires, nine participants (56.25%) reported practising mindfulness daily, six (37.5%) reported practising several times per week, and one participant (6.25%) reported practicing less than once per week. When asked how helpful mindfulness skills were compared to CBT, eight participants (50%) described it "as helpful as other skills", five (31.3%) found it to be "more helpful than other skills", and three participants (18.8%) found mindfulness practise to be "most helpful". Finally, at the 3-month follow-up, out of the participants who completed the follow-up questionnaires, all reported continuing to practise formal mindfulness meditation and 10 reported continuing to practise CBT skills after the completion of the program.

3.9. Self-reported side effects attributed to the program

Of the 16 participants who completed the ratings at post-treatment, most (n = 13, 81.3%) did not report experiencing any unwanted side effects resulting from the program. Out of the three participants who reported unwanted effects, one reported having difficulty coping with multiple life stressors which were not attributed to the program; a second participant noticed using mindfulness as a distraction from difficulties, and the third reported a brief increase in anxiety shortly after starting the program, and then again when tackling avoidance (although they stated they used their new skills to manage their symptoms and ride them out).

4. Discussion

The aim of this pilot study was to investigate the feasibility, acceptability, adherence, and preliminary outcomes of the *Mindfulness-Enhanced iCBT Program* - a new transdiagnostic, internet-delivered treatment for anxiety and depression, which combined mindfulness training with CBT skills. Overall, this new online program was well-regarded by participants who remained in treatment, which was evidenced by the high levels of treatment satisfaction and participants' confidence in being able to manage symptoms in the future, and all endorsed mindfulness training as important and at least "as helpful as" the other skills taught in the program.

Interestingly, despite the largely self-guided way in which participants progressed throughout this online program, with an average of only 26 minutes of clinician input throughout the entire 14-week treatment period, those who completed the program reported high levels of engagement and time spent working through the lessons, as well as a substantial amount of mindfulness practice. Not all participants, however, completed the entire program. This means that data on the participants who dropped out of the program or could not be reached for post-treatment or follow-up assessment were not available, and this is an important consideration with regards to the general acceptability and uptake of this treatment.

While adherence to the program (59%) was consistent with some previously reported adherence rates (Melville et al., 2010), it was lower than adherence to the original 6-lesson iCBT delivered over 10 weeks (89%) reported by Newby et al. (2013), despite comparable clinician time spent per participant. There are several possible reasons for this difference. First, the lower adherence may have been due to the difference in length of the treatment period (14 versus 10 weeks), sample characteristics (any anxiety and/or MDD was included in this study, versus GAD and/or MDD in the previous study), or the larger amount of content in the Mindfulness-Enhanced iCBT program. In essence, the program contained twice the content of the original iCBT, and would therefore benefit from additional measures to improve adherence, such better chunking of content, explicit guidance to overcome common barriers (e.g., time management), and a way to keep participants engaged over extended timeframes, such as additional and regular clinician contact.

A key consideration for implementing mindfulness training online, as well as studying novel, internet-delivered interventions more broadly, is safety. The literature on side-effects of online psychological treatments is in its infancy, and although studies are beginning to emerge documenting participants' difficulties during online CBT (Boettcher et al., 2014; Melville et al., 2010), it is not yet known whether online mindfulness interventions are associated with any adverse events or side effects, particularly when participants undergo mindfulness training without explicit guidance from a teacher. While no adverse events were reported in this study, a number of participants did report experiencing difficulties with mindfulness practice, including increased frustration and distress associated with ruminative thinking, which needs to be considered in future studies using online mindfulness

training. Further, we did not ask participants about any difficulties they experienced with applying and practising the CBT skills. It will be pertinent to evaluate the relative complexity of applying and practising both types of strategies when they are learnt without explicit clinician guidance, and to compare the side effects of online mindfulness-based interventions with those of iCBT.

Although the small sample size and a lack of a control group limits the inferences we can make with regards to the efficacy of the Mindfulness-Enhanced iCBT program, we observed large improvements in depression and anxiety, as well as significant reductions in experiential avoidance, worry, rumination, and emotion regulation difficulties, all of which are factors hypothesised to maintain symptoms across anxiety and depressive disorders (Harvey et al., 2004). Significant gains in mindfulness and well-being were also evident, and, in general, participants provided positive feedback about the online program. At 3-months follow-up, 80% of those interviewed no longer met criteria for an anxiety or depressive disorder.

Compared with previous studies, the within-group pre-post effect sizes for anxiety (Hedges $g = 1.39$) and depression ($g = 1.96$) appeared to be larger than those resulting from the original iCBT program (anxiety: $d = 0.96$, and depression: $d = 1.05$; Newby et al., 2013), as well as larger than the uncontrolled effect sizes for anxiety ($g = 0.78$) and depression ($g = 0.84$) found in a meta-analysis of computerised transdiagnostic iCBT (Newby et al., 2016). While it is not yet clear whether the larger improvements observed in the present study were related to the sample characteristics (e.g., severity, comorbidity), the dose of treatment (7 versus 6 lessons), or whether mindfulness does in fact augment the impact of iCBT, our preliminary findings suggest that a RCT is warranted to evaluate the program further.

Overall, given that this study represents the first attempt to formally combine online mindfulness training with an established transdiagnostic iCBT, the results of the pilot trial were encouraging, although a number of limitations exist and will need to be addressed in future studies. First, while recruitment for this study was aided by the current popularity of mindfulness, we only recruited a small, predominantly female sample to pilot test the program. This highlights the need to establish individual characteristics of people who seek and are likely to benefit from such online interventions. The small sample and substantial missing data may have also led to an overestimation of treatment effects, and the study lacked power to enable analysis of important moderators of treatment, such as adherence and baseline symptom severity. Second, because the study lacked a control group, the conclusions we can draw from the results are limited, and the improvements made during the program may have been due to other factors (e.g., spontaneous recovery, demand characteristics). We now need to evaluate this program in a RCT to determine whether it outperforms a control condition (e.g., usual care) and the original transdiagnostic iCBT program on which it was based. In addition, because a high proportion of participants reported past experience with mindfulness, the study may have been influenced by selection bias, and the generalisability of these findings to other samples needs further study. Finally, given the popularity of mindfulness, future studies would benefit from assessing the nature and the extent of participants' past experiences with mindfulness, as well as investigating whether past experience with mindfulness practice moderates treatment effects.

5. Conclusion

This study was the first to integrate online mindfulness training with an established transdiagnostic iCBT for depression and anxiety, and evaluate the feasibility and acceptability of this treatment approach in a clinical sample. For those who remained in the study, the Mindfulness-Enhanced iCBT program was well-received and regarded as helpful and acceptable. We found promising improvements in depression and anxiety symptoms, quality of life, as well as improved levels of mindfulness and well-being between pre and post-treatment, all of which were maintained at 3-month follow-up. However, adherence to the program was lower than previous studies, suggesting further improvements to the program are needed to encourage treatment completion. This program now needs to be evaluated in a RCT to determine its efficacy relative to existing transdiagnostic iCBT programs for depression and anxiety.

Conflict of Interest

All authors declare that they have no conflicts of interest.

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