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A randomized trial of Mindfulness-based cognitive therapy with psoriasis patients.

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Abstract

Objectives

The objective of the present study was to investigate the effect of mindfulness-based cognitive therapy (MBCT) on psoriasis patients' symptoms, anxiety, depression, and psychological wellbeing. The study also examined if MBCT significantly impacted the domain and mediating variables of a clinically modified Buddhist psychological model (CBPM), which are acceptance, mindfulness, self-compassion, aversion, non-attachment, attention, rumination and worry.

Methods

One hundred and one participants were randomly allocated to MBCT ($n = 51$) or TAU ($n = 50$).

Participants were measured pre-treatment, post-treatment and after a 3-month follow up period.

Results

Analyses revealed that when baseline variables were controlled, there was a significant reduction or increase in the hypothesised direction for each variable over time in the MBCT group, but not in the treatment as usual group.

Conclusions

The results suggest that MBCT may be a useful adjunct therapy for those suffering from psoriasis and the associated psychological symptoms relating to the condition.

Keywords Mindfulness: Psoriasis: Randomized trial: Buddhist: CBPM

Psoriasis is a chronic, noncommunicable, painful, debilitating and disfiguring autoimmune inflammatory skin disease characterised by an accelerated rate of turnover of the top layer of the skin (Irish Skin Foundation [ISF] 2015; World Health Organisation [WHO] 2017). Kelly-Sell and Gudjonsson (2017) estimate that psoriasis affects 125 million people across the world. The ISF (2015) estimated that 1.6% of the population of Ireland is affected by psoriasis. Psoriasis can affect all aspects of a patient's life, including physical, psychological, social, sexual and occupational elements (Kimball et al. 2005). Patients can experience a range of psychosocial difficulties including problems in body image, self-esteem, self-consciousness, embarrassment, shame, helplessness, stigmatization, rejection, social discomfort, isolation, sexual dysfunction, anger and frustration (Armstrong et al. 2012; Hayes and Koo 2010; Kimball et al. 2005). These difficulties can lead to a significant proportion of psoriasis patients suffering from anxiety (7% to 48%; Fleming et al. 2017), depression (6% to 62%; ISF 2015; Kimball et al. 2005) and poorer psychological wellbeing (80% report their psoriasis as being a moderate to large problem in their everyday life; Kurd et al. 2010).

In a meta-analysis of 22 intervention studies (only 8 of which were controlled trials) on the effectiveness of psychological interventions for adults with skin conditions, Lavda et al. (2012) found that the psychological interventions investigated had a medium-sized effect on psoriasis ($g = 0.51$). Even though specific psychological interventions, such as habit reversal, relaxation and CBT, have been developed and received support for their effectiveness in reducing psoriasis, this evidence base has limitations (Shah and Bewley 2014). Studies have included small samples, contained no control groups, no follow-up data and/or high levels of missing data (Lavda et al. 2012; Shah and Bewley 2014). It is clear that psychological interventions could be beneficial to people with skin conditions, but there is also a need to develop a broader evidence base.

Psychological and emotional stress can have the potential to regulate the immune response (Chapman and Moynihan 2009; Morey et al. 2015). Psychological and emotional stress have been consistently implicated by patients as a potential trigger in the onset and exacerbation of and causative or maintaining factor in psoriasis disease expression (ISF, 2015; O'Leary et al. 2004). Psoriasis itself also causes stress, with the bi-directionality of these interactions, in turn, exacerbating levels of depression and anxiety in the patient (Chapman and Moynihan 2009). Teaching patients how to relate differently to and reduce stress through Mindfulness-based programs (MBPs), such as Mindfulness-based cognitive therapy (MBCT), may help to dampen this cycle and the body's inflammatory

response, while also supporting the bio-psycho-social adjustment of psoriasis patients (Fordham et al. 2015; Grossman et al. 2004). MBCT, derived from Mindfulness-based stress reduction (MBSR), is an evidence-based 8-week systematic psychotherapeutic intervention that integrates selected elements of CBT for depression, with the clinical application of mindfulness meditation (Segal et al. 2002). Meta-analyses have found that MBPs such as MBCT have positive effects on mental health issues such as anxiety, depression and wellbeing with a range of clinical and non-clinical samples across age groups (Grossman et al. 2004; Hofmann et al. 2010; Ludwig and Kabat-Zinn 2008). This literature has typically found that MBCT has a small to medium effect on wellbeing (Bolier et al. 2013; Pots et al. 2014), anxiety (Bohlmeijer et al. 2010; Goyal et al. 2014; Hofman et al. 2010; Pots et al. 2014) and depression (Bolier et al. 2013; Goyal et al. 2014; Hofman et al. 2010; Pots et al. 2014).

There have only been three RCT studies published on the use of MBPs with psoriasis patients. Kabat-Zinn et al. (1998) recruited 37 adult patients to investigate the efficacy of a brief MBSR audio-tape intervention in increasing skin clearing rates among individuals with moderate to severe psoriasis who were candidates for treatment with phototherapy (UVB) or photochemotherapy (PUVA). Patients who were meditating reached skin clearance significantly more rapidly than the control group, clearing at about four times the rate of subjects who received the UVB or PUVA. No statistically significant differences in anxiety or psychological distress were found.

Fordham et al. (2015) conducted a small-scale pilot study ($n = 29$) on the impact of an 8-week MBCT course versus treatment as usual (TAU) on perceived stress, anxiety, depression, QoL and psoriasis severity. The MBCT group reported a significant improvement in both psoriasis severity and quality of life. They did not find significant changes in anxiety or depression, which may be due to the small sample size ($n = 19$; 6 in intervention and 13 in the control group), or the low levels of anxiety and depression existing within the study population, demonstrating a floor effect.

D'Alton et al. (2018) ($n = 94$) examined the comparative efficacy of MBCT, Mindfulness-based Self-Compassion therapy (MBSCT), and self-help MBSCT relative to treatment-as-usual (TAU) in improving the long-term psychological and physical outcomes of individuals with psoriasis. This study found no statistically significant differences on the effects of the MBIs on psychological wellbeing, anxiety, depression, psoriasis symptoms, quality of life, worry, mindfulness or self-compassion relative to TAU alone at post-treatment, 6- or 12-month follow-up. The authors identified floor effects as being a potential factor in the inefficacy of the MBIs in this study. The sample in this

study had mild-to-moderate severity of psoriasis and was in the normal ranges for anxiety, depression and worry in the intervention groups at baseline, thus participants with low baseline scores had little room for improvement. As highlighted earlier, the literature on MBPs has typically found that MBCT has a small to medium effect on anxiety, depression and wellbeing. The mixed results and methodological limitations of these studies indicate that it is still unclear if MBPs are effective or not at improving the psoriasis symptoms, anxiety, depression and psychological wellbeing of psoriasis patients. Thus, further research using RCT designs is clearly needed.

The change process involved with mindfulness is a complex one and it remains unclear what the underlying mechanisms are (Montgomery et al. 2016). Identifying the mechanisms of action in MBPs and enhancing the theoretical understanding of how this treatment may work for psoriasis patients could facilitate the development of more potent programs through the enhancement of the active components (Kazdin 2007; Svendsen et al. 2017; Van der Velden et al. 2015). To this end, the development of testable theories is important to the advancement of our understanding of how MBPs lead to beneficial outcomes in clinical settings (Van der Velden et al. 2015).

One such promising integrative testable model comes from Grabovac, Lau and Willett's (2011) Buddhist Psychological Model (BPM). In an attempt to address the lack of clarity in the understanding of the mechanistic change processes in MBPs, Grabovac et al. (2011) proposed a psychological model derived from Buddhist contemplative traditions. Grabovac et al. (2011) outlined that by engaging in meditation, the participant develops an improved ability for attentional regulation and a greater accepting quality of awareness towards emotional content (thoughts, feeling and emotions). Secondly, this attentional awareness brings less need of emotional control, clinging and mental fixation and thereby reduced rumination, which in summary, represents the main object of the BPM, decreased mental proliferation. And thirdly, this overall decrease in mental proliferation, and in conjunction with a Buddhist loving, kind and ethical predisposing towards others, results in an increased sense of (psychological wellbeing and symptom reduction (Grabovac et al. 2011). In the BPM, mindfulness practice leads to decreases in the domains of attachment and aversion, and increases in the domains of acceptance, concentration/attentional regulation and ethical practices (Grabovac et al. 2011). The term domain refers to specific conceptual areas of growth and change in emotional and cognitive development after mindfulness practice (Ryff and Keyes 1995). In the BPM, changes in these domains (increases or decreases) after mindfulness practice leads to reductions in mental proliferation

(Grabovac et al. 2011). A mediation effect occurs when a third variable explains the relationship between two other variables (Hayes 2018). This reduction in mental proliferation then has a mediating effect on the relationships between the changes in BPM domains (attachment, aversion, acceptance, concentration/attentional regulation and ethical practices) and the mental and physical health outcomes of well-being and symptom reduction.

One of the potential weaknesses of the BPM (Grabovac et al., 2011) as well as any other model, is how it may fail to account for other potentially important predictor and/or mediating variables that could potentially have an important impact on the way in which mindfulness training may impact participant wellbeing and symptom reduction. In order to ameliorate this potential weakness, the domains of self-compassion and mindfulness were added and ethical practices omitted as part of an enhanced model, which will hereto for be referred to as the ‘clinically modified BPM model’ or CBPM. These domains have been added due to the empirical support for their potential utility in supporting the improvement of the anxiety, depression and psychological wellbeing of clinical populations (Gu et al. 2015; Hölzel et al. 2011; Kuyken et al. 2010; Neff 2003; O’Doherty et al. 2015; Vøllestad et al. 2011). Mental proliferation is not clearly defined by Grabovac et al. (2011) as a measurable psychological construct but it would appear to most resemble repetitive negative thinking (RNT), which is a style of repetitive thinking about negative experiences that is difficult to disengage from and at least partly intrusive (Ehring et al. 2011). The two most common forms of RNT are rumination and worry, and these two variables represent mental proliferation in the CBPM (Fresco et al. 2002; Gu et al. 2015).

No empirical research has attempted to test how MBPs may impact these potentially important domain and mediating variables of an integrative model such as the CBPM in the same study. There are only a few small scale RCTs that have investigated the impact of MBPs on these CBPM domain and mediating variables in studies of patients with depression. These studies found that MBCT has medium to large effect on the mindfulness (Kuyken et al. 2008; Labelle et al. 2010; van Aalderen et al. 2012); a medium sized effect on self-compassion (Kuyken et al., 2008); medium to large effects on attention regulation (Bieling et al. 2012; Hargus et al. 2010); small to medium effects on acceptance (Bedard et al. 2014); a medium to large effect on rumination (Labelle et al. 2010; van Aalderen et al. 2012) and medium effects on the worry levels of these participants (Batink et al. 2013; van Aalderen et al. 2012).

This study has two aims: (1) to investigate the effectiveness of MBCT on psoriasis symptoms, anxiety, depression and wellbeing, and (2) examine if MBCT is effective in improving the six CBPM domains (mindfulness, attention regulation, acceptance, self-compassion, non-attachment and aversion) and two mediating variables (worry and rumination) of the CBPM theory. Consequently, this study will test the following hypotheses: H₁: self-reported psoriasis, depression, anxiety, psychological wellbeing, acceptance, mindfulness, self-compassion, aversion, non-attachment, attention, rumination and worry for psoriasis patients who engage in an MBCT program will improve significantly after program (post program and 3 months hence) when compared to a group of psoriasis patients who engage in treatment as usual (TAU).

Method

Participants

Inclusion criteria for this study were: adults over 18 years of age with a diagnosis of mild to severe psoriasis. Exclusion criteria were: patients deemed unsuitable for MBCT after psychological assessment by the trial administrator due to recent bereavement, experiencing current psychotic symptoms or having a diagnosis of Bipolar Disorder, and patients who had previously participated in a formal 8-week mindfulness programme. An a priori power calculation using G-Power identified that a sample of 92 (46/46) would be required to have 95 % power in detecting the small to medium effect sizes ($f = .17$) suggested by the literature on the impact of MBPs on the variables of interest (e.g. Bedard et al. 2014; Kuyken et al. 2008). As there was potential for participant attrition across the repeated measures design of this study, a sample of 101 psoriasis patients were recruited through purposive sampling.

Procedure

An RCT was conducted in Ireland. Ethical approval was sought and granted from the ethics committees of the University and the hospital involved in the study. These study procedures were performed in accordance with the Declaration of Helsinki (World Medical Association, 2013). All patients provided informed consent prior to their inclusion in the study. The trial is reported in accordance with the CONSORT guideline (Schulz et al. 2010).

Participants were recruited from August 2016 to January 2017. The study population consisted of psoriasis patients recruited from an outpatient clinic in a general hospital in Ireland, and through advertisements in a national newspaper and the Irish Skin Foundation's website. Patients who expressed an interest in the study were contacted via telephone for assessment to check for availability during the study period and likelihood of meeting the inclusion and exclusion criteria outlined above. Following screening, participants were randomised to continue with their usual psoriasis treatment (treatment as usual - TAU) or to receive 8 weeks of MBCT in addition to their usual psoriasis treatment in a 1:1 ratio. The randomization sequence was generated in blocks as participants entered the study using computer-generated numbers. Randomisation was stratified according to gender. Participants completed self-report scales pre-program (t1), post-program (t2) and 3 months later (t3).

Intervention The MBCT classes were run in 2 groups of 25-26 participants who met for 2 hours per week over 8 weeks. Each session included guided meditation, experiential exercises and discussion. In addition to the weekly group sessions, participants received CDs with guided exercises and were asked to complete daily homework exercises (including meditation practices and exercises to integrate the awareness skills into daily life) for at least 45 min per day, 6 days per week. These sessions were facilitated by formally trained MBCT facilitators with a number of years of MBCT facilitation experience. The programme followed the protocol for MBCT as outlined by Segal et al. (2002).

TAU consisted of any treatment the participant, their dermatologist or mental health care specialist regarded as necessary. Participants were encouraged to continue treatment they followed prior to enrolling in the study and advised that they were free to remain on or receive additional treatment or to change their (dose of) pharmacological medication during the study period.

Measures

Hospital Anxiety and Depression Scale The Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith 1983) is a self-report rating scale of 14 items, designed to measure anxiety (HADS-A) and depression (HADS-D), with each subscale consisting of 7 items. Higher scores on each scale indicate higher levels of anxiety or depression. These are categorized as normal (0-7), borderline abnormal (8-10) and abnormal (11-21). The scale has been validated against interview ratings and has good internal reliability (Zigmond and Snaith 1983). Lewis and Wessley (1990) found that the HADS was comparable to the General Health Questionnaire (Goldberg and Williams 1988) in its ability to

detect cases of minor psychiatric disorder in dermatology patients. The Cronbach's alpha for this study for HADS-A was .86 and .78 for HADS-D.

Ryff's Psychological Wellbeing Scales The Ryff's Psychological Wellbeing Scales (Ryff 1989) includes 6 domains each containing 9 items: 1) self-acceptance, 2) purpose in life, 3) environmental mastery, 4) personal growth, 5) positive relations with others, and 6) autonomy (Ryff 1989). Higher scores on this scale indicate higher levels of wellbeing, with scores ranging from 42-252. The psychometric properties for this scale were originally tested on a sample of 321 healthy men and women (Ryff 1989). Findings included high internal consistency for the 6 domains (Cronbach's alpha's from .86-.93), and good test-retest reliability with Pearson product moment coefficients over a six-week period ranging from .81-.88. The Cronbach's alpha for this study was .95.

SAPASI The self-administered psoriasis area and severity index (SAPASI) is a structured instrument for measuring the severity of psoriasis (Feldman et al. 1996). The instrument consists of a silhouette of a body for patients to shade in affected areas and of three modified visual analog scales for recording the redness, thickness, and scaliness of an average lesion (Fleischer et al. 1994). The SAPASI scores the body surface area coverage scores (no shading = 0), (<10% = 1), (11-30% = 2), (31-50% = 3), (51-70% = 4), (71-90% = 5) and (91-100%). The score allocated to each body area is weighted (head x 0.1; upper extremities x 0.2; trunk x 0.3; lower extremities x 0.4). These weighted scores were summed to produce the total area of active psoriasis score. The SAPASI's psychometric properties have assessed by comparison with the PASI, which has been used extensively in both clinical and research dermatology settings. The SAPASI has demonstrated high criterion validity by correlating significantly with all components of the PASI with an overall correlation of $r = .59, p = .0001$. Test re-test reliability found a correlation between the two time points of $r = .82, p < .0001$ and inter-rater reliability between five raters was $r = .95, p < .001$ (Feldman et al. 1996). Research has replicated the correlation between the SAPASI and PASI (Feldman et al. 1996).

Philadelphia Mindfulness Scale The Philadelphia Mindfulness Acceptance sub scale (PHLMS; Cardaciotto et al. 2008) is a 10-item questionnaire that measures acceptance. Scores on this measure range from 10-50, with lower scores indicating higher levels of acceptance. Cardaciotto et al. (2008) reported very good internal consistency ($\alpha = .91$) for the acceptance sub-scale with a population of undergraduates. In terms of construct validity, Cardaciotto et al. (2008) reported that the acceptance

subscale was strongly correlated with the KIMS Accept (Baer et al. 2004) without Judgment subscale ($r = .79$). The Cronbach's alpha for this study for PHLMS-acceptance was .9.

Southampton Mindfulness Scale The Southampton Mindfulness Questionnaire (Chadwick et al. 2008) is a 16-item instrument designed to measure elements of mindfulness when unpleasant thoughts and images arise (Chadwick et al. 2008; 2005). High scores on this measure indicate higher levels of mindfulness, with scores ranging from 0-96. Chadwick et al. (2008) examined the SMQ's reliability, concurrent validity, factor structure, and clinical sensitivity. The SMQ had a Cronbach's alpha of .89. For 197 participants involved in assessing concurrent validity, SMQ and Mindful Attention Awareness Scale (MAAS; Brown and Ryan 2003) scores correlated significantly ($r = .61$, $p < .001$). The Cronbach's alpha for the present study was .74.

Experiences Questionnaire The Experiences Questionnaire – Decentering is an 11-item self-report measure of the capacity to regulate attention through decentering (Fresco et al. 2007). Higher scores on the EQ indicate higher levels of attention regulation, with scores ranging from 11-55. The EQ Decentering scale has shown high internal reliability: Cronbach's alpha = .90 (Fresco et al. 2007). Concurrent validity of this measure was supported with a non-patient sample by significant positive correlations with cognitive appraisal ($r = .25$), and significant negative correlations with experiential avoidance, brooding rumination, emotional suppression, current depression, and anxiety symptoms (r 's = .31 to .49). The Cronbach's alpha for the present study was .89.

Non-Attachment Scale The Non-Attachment Scale (NAS; Sahdra et al. 2010) is a 30-item questionnaire. Higher scores on the NAS indicate higher levels of non-attachment, scores of this measure range from 30-180. The NAS has shown high internal reliability; Cronbach's alpha = .92, in a study of 382 undergraduate sample (Sahdra et al. 2010). In Sahdra et al. (2010), the NAS was moderately to highly correlated (r 's = .35–.60) negatively with anxious attachment (Experiences in Close Relationships (ECR; Brennan et al. 1998) and nonreactivity (Nonreactivity to Internal Experience subscale of the Five Facet Mindfulness Questionnaire (Baer et al. 2006). The Cronbach's alpha for this study was .92.

Acceptance and Action Questionnaire –II Aversion was measured with the 7-item Acceptance and Action Questionnaire-II (AAQ-II; Bond et al. 2011). High scores on the AAQ-II are reflective of greater experiential avoidance and immobility, while low scores reflect greater acceptance and action. Scores on this measure range from 7-49. Results from 2,816 participants across 6 samples

(3 different samples of undergraduate students in USA, 2 UK bank employee samples and 1 group of drug users seeking psychological treatment in a New York University hospital) indicate satisfactory structure, reliability, and validity of this measure. For example, the mean alpha coefficient was .84 (.78-.88), and the 3 month and 12 month test-retest reliability was .81 and .79 respectively (Bond et al. 2011). The Cronbach's alpha for present study was .94.

Self-Compassion Scale The 26-item Self-Compassion Scale (SCS: Neff 2003) includes dimensions (awareness, self-kindness, self-judgment and common humanity) thought to be important to the change process in mindfulness variables (Feldman and Kuyken 2011). Higher scores on the SCS indicate higher levels of self-compassion, scores range from 26-130. The internal reliability of the SCS has been found to be consistently high in studies across a wide variety of populations suggesting that all SCS items are inter-correlated in a satisfactory manner (Allen et al. 2012; Neff and Pommier 2013; Werner et al. 2012). The large body of research (e.g., systematic review carried out by Zessin et al. 2015) indicating that scores on the SCS predict wellbeing constitutes strong predictive validity. The Cronbach's alpha for the present study was .89.

Rumination Reflection Questionnaire Rumination was measured using the 12-item subscale from the Rumination Reflection Questionnaire (Trapnell and Campbell 1999) which measures the extent to which participants are disposed to engage in repetitive thinking about their past. Higher scores on the RRQ-rumination indicate higher levels of rumination. Scores on this measure range from 12-60. Trapnell and Campbell (1999) reported a high coefficient alpha for the rumination subscales (.90). The rumination subscale also showed good convergent validity, as it correlated highly with its respective factor predicted from the Big Five factor model of personality (Trapnell and Campbell 1999). The Cronbach's Alpha for the present study was .93.

Penn State Worry Questionnaire The 16-item Penn State Worry Questionnaire (PSWQ; Meyer et al. 1990) assesses the extent to which worry is pervasive, excessive, and difficult to control. Higher scores on the PSWQ scale indicate higher levels of worry, with a (<45) being deemed as high worry (Meyer et al. 1990). The PSWQ has been shown to have excellent internal consistency ($\alpha = .91$; Meyer et al. 1990) and good convergent and discriminant validity for Generalised Anxiety Disorder when compared to other anxiety disorders and community controls (Brown et al. 1992). The Cronbach's alpha for this study was .94.

Data Analyses

The data were screened for missing values and any error cases, such as extreme outliers. There were no missing values on any of the primary outcomes. There were a maximum of two cases missing on some subscales for individual participants on the secondary outcomes. As these were such a small proportion of the overall dataset ($n=101$) and not from the primary variables of interest, mean replacement was used for the missing items. This study used analysis of covariance (ANCOVA), as this method increases the power of RCTs by reducing any unintentional baseline differences due to random allocation, which increases a study's capacity to obtain a valid estimation of the intervention effect between groups (Fitzmaurice et al. 2011; Senn 1994). In order to retain balance in prognosis created by the random allocation outlined above, intention-to-treat analysis was also employed (Gupta 2011). Effect size interpretation was based on Cohen (1988) who identified a partial $\eta^2 = .01$ as a small effect, $.06 =$ as a medium effect and $.14 =$ as a large effect size. No p -value adjustment was made for multiple comparisons, as controlling for Type 1 error in this manner is likely to increase the chances of Type 2 error (Rothman 1990).

Results

The demographic and clinical characteristics of each group are shown in Table 1 below. Chi-squared tests found that the percentage of females ($\chi^2(1, N= 51) = .22, p = .64$), males ($\chi^2(1, N= 51) = .22, p = .64$), those receiving topical treatment ($\chi^2(1, N= 51) = .12, p = .73$), sytematic treatment ($\chi^2(1, N= 51) = .01, p = .94$), those receiving phototherapy ($\chi^2(1, N= 51) = .28, p = .6$), biologics ($\chi^2(1, N= 51) = .04, p = .39$), psychothropic mediation ($\chi^2(1, N= 51) = .04, p = .39$) and those who have a diagnosis of psoriatic arthritis ($\chi^2(1, N= 51) = .01, p = .94$) did not differ between the program group trial completers and non completers. This was also the case for the groups of participants in the TAU group who completed the trial and those that did not. The percentage of females ($\chi^2(1, N= 50) = .29, p = .51$), males ($\chi^2(1, N= 50) = .29, p = .51$), those receiving topical treatment ($\chi^2(1, N= 50) = .01, p = .95$), sytematic treatment ($\chi^2(1, N= 50) = .38, p = .54$), those receiving phototherapy ($\chi^2(1, N= 50) = .001, p = .98$), biologics ($\chi^2(1, N= 50) = .08, p = .78$), psychothropic mediation ($\chi^2(1, N= 50) = .08, p = .78$) and those who have a diagnosis of psoriatic arthritis ($\chi^2(1, N= 51) = .99, p = .32$) did not differ

between these two groups. There were no significant differences on any psychological variable between those that stayed in the trial and those who dropped out in either group.

Overall both group averages were in the normal range for HADS-D so the sample can be described as a sample with low levels of depression at baseline. The overall sample had reasonably high levels of anxiety, which is quite evenly matched across each group, with both groups averaging in the borderline abnormal anxiety range for the HADS-A measure. The MBCT group reported experiencing higher levels of psoriasis and lower levels of psychological wellbeing at baseline after random allocation. The means and standard deviations for the CBPM domain, mediating and outcome variables for both the MBCT and TAU groups, the results of the ANCOVA and the effect sizes are presented in Table 2 below.

CBPM outcomes

Psoriasis: The MBCT group reported a large significant reduction in SAPASI scores when compared to the TAU group when baseline scores were controlled for at t2, ($\eta^2 = .17$). There was no significant group differences at t3. *Post-hoc* tests showed a significant reduction of SAPASI scores from t1 to t2 in the MBCT group (M difference = 3.2 (95% CI = 0.81, 5.59), $p = .01$) but not in the TAU group (M difference = 1.89 (95% CI = -0.116, 3.89), $p = .07$).

Anxiety: The MBCT group reported a small to medium significant reduction in HADS-A scores when compared to the TAU group when baseline scores were controlled at t2, ($\eta^2 = .05$). There was no significant group differences between the MBCT and TAU groups at t3. The HADS-A scores were significantly reduced from t1 to t2 in the MBCT group (M difference = 1.49 (95% CI = .67, 2.31) $p = 0.001$) but not in the TAU group (M difference = 0.26 (95% CI = -0.46, 0.98), $p = .48$).

Depression: When compared to the TAU group, the MBCT group showed medium significant reductions in HADS-D scores when baseline scores were controlled at t2, ($\eta^2 = .06$) and t3 ($\eta^2 = .08$). The HADS-D scores from t1 to t2 (M difference = 1.21 (95% CI = .33, 2.09) $p = .008$) and from t1 to t3 post program reduced significantly in the MBCT group (M difference = 1.47 (95% CI = .56, 2.38), $p = .001$). The TAU group HADS-D scores from t1 to t2 (M difference = -0.2 (95% CI = -0.81, 0.41), $p = 1.00$) and from t1 to t3 (M difference = -0.001 (95% CI = -0.81, 0.81), $p = 1.00$) did not change significantly.

Wellbeing: The MBCT group reported a small to medium significant increase in PWBS scores when compared to the TAU group when baseline scores were controlled at t2, ($\eta^2 = .05$) but not at t3, ($\eta^2 = .03$). *Post-hoc* tests showed a significant increase in PWBS scores from t1 to t2 in the MBCT group (M difference = 6.39 (95% CI = 2, 10.78), $p = <.001$) but not in the TAU group (M difference = -0.04 (95% CI = -0.81, 0.73), $p = 1.00$).

CBPM mediating variables

Rumination: When compared to the TAU group, the MBCT group showed medium to large significant reductions in rumination scores when baseline scores were controlled at t2, ($\eta^2 = .12$), and large significant reductions at t3, ($\eta^2 = .17$). *Post-hoc* tests showed a significant reduction of rumination scores from t1 to t2 in the MBCT group (M difference = 5.31 (95% CI = 3.50, 7.16), $p <.001$) and from t1 to t3 (M difference = 5.22 (95% CI = 3.35, 7.09), $p <.001$). The TAU group rumination scores did not change significantly from t1 to t2 (M difference = 1.42 (95% CI = -0.10, 2.94), $p = .08$) or t1 to t3 (M difference = 0.44 (95% CI = -0.92, 1.8), $p = 1.00$).

Worry: The MBCT group showed a medium significant reduction in worry when compared to the TAU group when baseline scores were controlled at t2 ($\eta^2 = .08$), and t3, ($\eta^2 = .07$). *Post-hoc* tests showed a significant reduction in worry scores from t1 to t2 in the MBCT-group (M difference = 4.55 (95% CI = 2.07, 7.03), $p = .001$) and from t1 to t3 (M difference = 5.14 (95% CI = 2.63, 7.64), $p = 0.001$) but not in the TAU group from t1 to t2 (M difference = 0.56 (95% CI = -1.42, 2.53), $p = 1.00$) or t1 to t3 (M difference = 1.14 (95% CI = -1.16, 3.44), $p = .68$).

CBPM domains

Acceptance: When compared to the TAU group, the MBCT group experienced medium significant reductions in acceptance scores on the PMS (indicating an increase in acceptance) when baseline scores were controlled at t2, ($\eta^2 = 0.08$). There was no significant group differences between the MBCT and TAU groups at t3, ($\eta^2 = .02$). The MBCT group showed significant reductions in acceptance scores from t1 to t2 in the MBCT group (M difference = 3.43 (95% CI = 1.64, 5.22), $p <.01$) but not in the TAU group (M difference = 0.46 (95% CI = -1.03, 1.95), $p = 1.00$).

Mindfulness: The MBCT group showed a large significant increase in SMS scores when compared to the TAU group when baseline scores were controlled at t2, ($\eta^2 = .18$), and a medium significant increase at t3, ($\eta^2 = 0.1$). *Post-hoc* tests showed a significant reduction of SMS scores from t1 to t2 in the MBCT group (M difference = 10.63 (95% CI = 6.74, 14.52), $p <.01$) and from t1 to t3 (M

difference = 8.14 (95% CI = 4.4, 11.88), $p < .01$) but not in the TAU group from t1 to t2 (M difference = 1.6 (95% CI = -1.528, 4.73), $p = .63$) or t1 to t3 (M difference = 1.32 (95% CI = -2.47, 5.11), $p = 1.00$).

Self-Compassion: When compared to the TAU group, the MBCT group showed medium significant increases in SCS scores when baseline scores were controlled at t2, ($\eta^2 = 0.07$), and t3, ($\eta^2 = 0.14$). The MBCT group showed a significant increase in SCS scores from t1 to t2 (M difference = 5.98 (95% CI = 2.72, 9.24), $p < .01$) and t1 to t3 (M difference = 7.4 (95% CI = 4.24, 10.54) $p < .01$). The TAU group t1 to t2 SCS scores did not change significantly (M difference = 0.8 (95% CI = 1.42, -3.02), $p = 1.00$) or from t1 to t3 (M difference = -0.14 (95% CI = -2.16, 2.44) $p = 1.00$).

Aversion: The MBCT group showed medium but significant reductions in aversion scores when compared to the TAU group when baseline scores were controlled at t2, ($\eta^2 = .09$), but not at t3, ($\eta^2 = .03$). *Post-hoc* tests showed a significant reduction of aversion scores from t1 to t2 in the MBCT group (M difference = -2.84 (95% CI = -1.42, -4.26) $p < .001$) but not in the TAU group (M difference = -0.14 (-1.88, 1.6), $p = 1.00$).

Non-attachment: When compared to the TAU group, the MBCT group showed large significant increases in NAS scores when baseline scores were controlled at t2, ($\eta^2 = .16$), and medium to large increases at t3, ($\eta^2 = .13$). *Post-hoc* tests showed a significant increase in non-attachment scores from t1 to t2 in the MBCT group (M difference = 10.5 (95% CI = 6.67, 14.32), $p = .00$) and from t1 to t3 (M difference = 8.53 (95% CI = 4.99, 12.07), $p < .001$) but the TAU group did not experience this increased non-attachment from t1 to t2 (M difference = -0.44 (95% CI = 2.97, -3.9), $p = 1.00$) or from t1 to t3 (M difference = -1.08 (95% CI = 2.94, -5.1), $p = 1.00$).

Attention: The MBCT group showed a large significant increases in attention regulation scores when compared to the TAU group when baseline scores were controlled at t2, ($\eta^2 = .17$), and medium significant increases at t3, ($\eta^2 = .09$). The MBCT group showed significant increases in attention regulation scores from t1 to t2 (M difference = 6.82 (95% CI = 4.55, 9.1), $p < .01$) and from t1 to t3 (M difference = 6.8 (95% CI = 4.04, 9.57), $p < .01$). The TAU group attention regulation scores from t1 to t2 (M difference = -0.10 (95% CI = -1.50, 1.7), $p = 1.00$) and from t1 to t3 did not change significantly (M difference = -0.26 (95% CI = -1.69, 2.21), $p = 1.00$).

Discussion

The results from this RCT indicate that MBCT may be an effective program for improving psoriasis symptoms, anxiety and wellbeing in the immediate term, and may also be effective for improving depression in the short term. The small to medium significant effects found on the anxiety, depression and wellbeing of the psoriasis patients in this study are consistent with the findings of a number of RCTs, systematic reviews and meta-analyses on the impact of MBPs (either MBCT or MBSR) on these outcomes with other clinical and non-clinical populations (e.g., Bohlmeijer et al. 2010; Bolier et al. 2013; Goyal et al. 2014; Hofman et al. 2010; Pots et al. 2014).

In this study, the MBCT group showed 1.2 and 1.5-point decreases in depression and anxiety respectively on the HADS-D and HADS-A at t2. These appear to be minimal clinically important differences (MCID), as these changes in measure scores are both in line with the recommendations of Puhan et al. (2008), who in a study of patients with chronic obstructive pulmonary disease patients identified a 1.5-point decrease as an MCID. The MBCT group also showed a 55% decrease in self-reported psoriasis severity at t2, which is in line with the 50% MCID adopted for pharmaceutical trials using the PASI (Carlin et al. 2004).

The statistically significant differences between the groups on the outcomes remained for depression at t3 but did not remain for self-reported psoriasis, anxiety and psychological wellbeing. This prolonged effect may be due to the fact that MBCT is specifically designed to support depression (Segal et al. 2002). In order to prolong the impact of MBPs on the self-reported psoriasis, anxiety and psychological wellbeing of psoriasis patients, the MBCT protocol could be changed to fit this patient population, or new MBPs could be developed which may more specifically target these outcomes.

The findings that MBCT had significant small to medium effects on the anxiety and psychological wellbeing, a significant medium effect on depression and worry, and a large significant effect on the mindfulness of psoriasis patients differs from the results of D'Alton et al. (2018). They reported that MBCT had a small effect on these variables and found no statistically significant differences on the effects of a number of MBPs (including MBCT) on these variables relative to TAU alone at post-treatment, 6- or 12-month follow-up. The differences between this study's results and D'Alton et al. (2018) on the effects of MBCT on these variables may have been due to the differences in the severity of psoriasis and the levels of worry, anxiety and depression experienced by both samples at baseline. D'Alton et al. (2018) also used the HADS to measure anxiety and depression, and the PSWQ to measure worry. Of note, D'Alton et al. (2018) differed in its exclusion criteria, in that any

person with a score greater than 10 (>10 = abnormal range on the HADS: Zigmond & Snaith, 1983) on both subscales was not permitted entry to their trial. This criterion led to the participants in D'Alton et al. (2018) having lower levels of anxiety and depression compared to the samples in the present study, potentially leading to a floor effect being present in D'Alton et al. (2018). The present study used more liberal exclusion criteria. For example, 21 participants in the MBCT group were in the abnormal range for anxiety on the HADS-A in the present study at baseline. These participants would have been excluded from D'Alton et al. (2018). This meant the present sample as a whole were in the borderline abnormal range for anxiety at baseline, which allowed more room from MBCT to be effective at improving the anxiety symptoms of this group. The sample in D'Alton et al. (2018) at baseline was in the normal range for worry on the PSWQ; the sample in the present study was in the high worrier category on this measure at baseline (PSWQ >45) (Meyer et al. 1990). The higher worry levels experienced by participants in the current study may have allowed more room for MBCT to be effective. D'Alton et al. (2018) used a different measure of mindfulness (Five Facet Mindfulness Questionnaire; Baer et al. 2006) than was used in the present study and they noted that the FFMQ may be an insensitive outcome measure (Malinowski et al. 2017).

The present study's results also differ from Fordham et al. (2015), who carried out the only other RCT examining the effectiveness of MBCT on psoriasis patients distress scores, using the HADS-A and HADS-D as a single score. In this pilot RCT ($n = 29$), Fordham et al. (2015) found that MBCT did not improve psychological distress in psoriasis patients; however the study was not sufficiently powered to detect small to medium effects. Their study also suffered from a very high attrition rate (45% versus 7% in the present study) with only six participants completing the MBCT program. Of note, Fordham et al.'s sample, similar to that of D'Alton et al., was characterized by low levels of psychological distress at baseline, which may have resulted in a floor effect.

The finding that MBCT had a large significant effect on psoriasis symptoms at t2 is in line with Fordham et al. (2015) who found that MBCT had a small significant effect on psoriasis severity (also using the SAPASI to measure psoriasis severity). The differences in effect sizes between Fordham et al. (2015) and the present study may be accounted for by the differences between psoriasis severity scores of the patients at baseline in the two studies. The baseline mean of patients in the MBCT group was 5.94 in Fordham et al. (2015) and 11.39 in the present study. The present finding that MBCT significantly affected psoriasis is also in line with Kabat-Zinn et al. (1998) who found that

MBSR statistically significantly improved skin clearing rates in psoriasis patients.

One of the most consistently articulated research priorities in the mindfulness literature is the need to identify what the most important mechanisms of MBPs are (Gu et al., 2015; Van der Velden et al., 2015). This study provides promising preliminary support to the CBPM as being a potentially useful theoretical model, which may enhance our understanding of how MBPs such as MBCT lead to beneficial outcomes in clinical settings (Van der Velden et al. 2015). By meditating and engaging in the mindfulness practices regularly, it appears that the MBCT participants in this study may have developed increased capacities in each CBPM domain, mediating and outcome variable post program. This indicates that each of the CBPM domain and mediating variables could be important mechanisms of action in line with the CBPM theory. This is evidenced by the small to large significant effects found across these variables in this study. These results are consistent with the findings of the aforementioned small scale RCTs, which found that MBCT has medium to large effect on the mindfulness (Kuyken et al. 2008; Labelle et al. 2010; van Aalderen et al. 2012); a medium sized effect on self-compassion (Kuyken et al. 2008); medium to large effects on attention regulation (Bieling et al. 2012; Hargus et al. 2010); small to medium effects on acceptance (Bedard et al. 2014); a medium to large effect on rumination (Labelle et al. 2010; van Aalderen et al. 2012) and medium effects on the worry levels of these participants (Batink et al. 2013; van Aalderen et al. 2012). No such studies have been carried out on attachment and aversion, as these are Buddhist constructs, which are quite new to the western psychological literature on mindfulness. The small to large effects found on these domains are supported by the original BPM theory (Grabovac et al. 2011), which hypothesised that mindfulness practice would improve these domains. A subsequent study undertaken by this paper's authors, which is currently under review, further supports the potential usefulness of the CBPM as useful theoretical framework.

This RCT study highlights the suitability of delivery of MBCT to psoriasis patients who were within this study's liberal inclusion and exclusion criteria. The majority of the psoriasis patients in the RCT study attended most of the mindfulness classes and the low attrition rate (7% at t2) is an indication of their relevance to the patients. This study's results mean that if replicated using independent samples in different contexts, then MBCT could be added to the set of clinical programs that mental health professionals use to support the physical and mental health of psoriasis patients, particularly those who suffer from anxiety and depression issues and poor psychological wellbeing.

Good quality research on the use of psychological interventions with psoriasis patients is sparse. This makes the direct comparisons of the effects of the MBCT with the effects found by psychological interventions such as CBT, on psoriasis symptoms, anxiety, depression and wellbeing more difficult. Based on the limited evidence against which to compare, the large significant effects of MBCT in this study on psoriasis symptoms were in line with Lavda et al. (2012) in a meta-analysis of the effect of psychological interventions including CBT, psychotherapy and behavioral interventions on psoriasis symptoms. These interventions had medium effects (Hedges $g = .51$) on psoriasis symptoms; however, the confidence interval for this estimate ranged from a low to a large effect size (95% CI: .25, .77). The studies reviewed by Lavda et al. (2012) used the PASI rather than the SAPASI as its measurement instrument, thus any differences between the present study and Lavda et al. (2012) may be due to the different measurements used.

The small to medium significant effects of the MBCT on anxiety and medium effects on depression were in line with, but smaller than the effects found by Fortune et al. (2002) ($N = 93$) in a case-control designed study, which is the highest quality study available to compare against. This study evaluated the effectiveness of a 6-week CBT programme on the anxiety and depression of patients using the HADS; they found that there was a net mean difference of a decrease in 3 points on the HADS-A and 4 points on the HADS-D (exact scores and effect sizes not reported) experienced by the program group versus a TAU group post program. This compares favorably with a 1.5 reduction in the HADS-A and a 1.2 decrease on the HADS-D experienced by the MBCT group versus the TAU group in this study. The difference in effects may be due to the higher anxiety levels (abnormal mean average on the HADS-A) and depression levels (borderline abnormal mean average on the HADS-D) experienced by the participants in Fortune et al. (2002) at baseline. This may have allowed a larger improvement in both to occur post CBT intervention, than was experienced by the MBCT group in the RCT which were experiencing borderline abnormal levels of anxiety and normal levels of depression at baseline. Conversely, it is also plausible that this study population may be more responsive to CBT than MBCT.

CBT has a far larger evidence base than MBCT, based on a larger number of RCTs of a higher methodological quality. Based on the limited nature of the research with which to compare, it is reasonable to conclude, that given the current evidence base, including the evidence found in this paper, that CBT should remain the front line psychological treatment for psoriasis, anxiety and

depression. However, MBCT does have promise and may be a useful adjunct program for psoriasis patients in improving their psoriasis, anxiety, depression and wellbeing. MBCT could be offered as an option in a stepped care treatment approach, where CBT therapists could refer clients to MBCT groups when a course of CBT has or is about to be completed (Vollestad et al. 2011). Given the fact that both depression and anxiety can both recur after recovery, there is also a potential that MBCT could constitute a relapse-prevention strategy, akin to what is suggested by the NICE guidelines that currently recommend MBCT against depressive relapse (National Institute for Clinical Excellence 2004).

Limitations and Future Research

One limitation concerns the absence of an active control group, which means that we cannot exclude the possibility that the effects observed in this study may be due to non-specific factors, such as receiving attention, being part of a credible treatment programme, or group-related factors. This also means that the improvement experienced by the program group (who self-selected for inclusion to this study) may be in part due to the fact that they expected to improve, rather than due to the actual impact of the MBCT program. The MBCT program occurred in a supportive group environment with a trained MBCT facilitator. The impact of this environment, in which participants could share and learn from each other and have a positive social experience is another important confounding variable that can impact on MBCT's effect. In light of this study's results, in order to move the psychological literature on the use of mindfulness with psoriasis patients forward, further RCT research exploring the impact of MBCT on the CBPM variables using an active comparison control group e.g. versus a CBT intervention group, is thus needed. The limited nature of the assessment and reporting of MBCT treatment fidelity in this study limits the reliability and validity of its results (Carroll et al. 2007; Leeuw et al. 2009). Due to the nature of the program, both participants and assessors were not blind to treatment conditions. As a result, detection or performance biases could have affected the self-report outcome measures (Higgins et al. 2011). This study measured all of the CBPM variables and outcomes with self-report measures, thus common methods bias, which could have inflated the effects found in this study, cannot be ruled out (Podsakoff et al. 2003). The lack of objectively rated psoriasis measurement is also a study limitation; however, the good correlation between the PASI and SAPASI means that it is a minor limitation (Bundy et al. 2013).

Author Contribution

AM: Study design, program delivery, data collection, statistical analysis, and manuscript preparation. DH: Study design, statistical analysis, and manuscript preparation. PD: Study design, program delivery, and manuscript preparation. BK: Study design, and manuscript preparation.

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Compliance with Ethical Standards

Ethical Approval Ethical approval for the study was provided by St. Vincent's Healthcare Group Ethics and Medical Research Committee. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the Declaration of Helsinki (World Medical Association, 2013) or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare that they have no conflict of interest.

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Table 1.

Demographics and clinical characteristics.

	MBCT group (n = 51)	TAU Group (n = 50)
Age, years (<i>M</i> [<i>SD</i>]) min-max	(43.51 [16.96]) 18-82	(44.56 [16.36]) 19-73
	n (%)	n (%)
Female	38 (75)	38 (76)
Male	13 (25)	12 (24)
Topical treatment	35 (69)	26 (52)
Systemic treatment	8 (16)	3 (6)
Phototherapy	2 (4)	5 (10)
Biologics	4 (8)	4 (8)
Psychotropic medication	4 (8)	4 (8)
Psoriatic Arthritis	14 (19)	36 (17)

Table 2
Means, standard deviations (in parentheses) and ANCOVA test statistics

	MBCT (n=51)	TAU group (n=50)			
	M (SD)	M (SD)	F (df)	P	η^2
<i>CBPM outcomes</i>					
SAPASI					
Pre-treatment	11.39 (8.15)	10.22 (7.94)			
Post-treatment	5.14 (4.90)	8.34 (6.89)	19.59 (95)	<.01	.17
3 months post-treatment	5.79 (6.32)	6.83 (6.33)	1.73 (95)	.19	.02
PWBS					
Pre-treatment	178.29 (24.16)	186.72 (25.54)			
Post-treatment	184.69 (25.02)	184.94 (27.30)	5.64 (98)	.02	.05
3 months post-treatment	184.47 (23.32)	185.28 (27.08)	3.33 (98)	.07	.03
HADS-A					
Pre-treatment	9.02 (3.88)	8.68 (4.4)			
Post-treatment	7.51 (3.87)	8.42 (4.08)	5.17 (98)	.02	.05
3 months post-treatment	7.37 (3.86)	7.94 (4.29)	2.16 (95)	.15	.02
HADS-D					
Pre-treatment	4.45 (3.23)	4.1 (3.49)			
Post-treatment	3.31 (2.54)	4.12 (3.15)	5.95 (98)	.02	.06
3 months post-treatment	3.06 (2.57)	4.1 (3.03)	8.62 (98)	<.01	.08
<i>CBPM mediating variables</i>					
RRQ					
Pre-treatment	41.61 (9.69)	41.26 (10.03)			
Post-treatment	36.29 (9.21)	39.84 (10.85)	12.99 (98)	<.01	.12
3 months post-treatment	36.39 (9.48)	40.82 (10.07)	20.43 (98)	<.01	.17
PSWQ					
Pre-treatment	53.53 (13.84)	53.04 (14.85)			
Post-treatment	48.98 (12.22)	52.48 (14.35)	8.15 (98)	<.01	.08
3 months post-treatment	48.39 (13)	51.90 (14.63)	7.02 (98)	<.01	.07
<i>CBPM domains</i>					
PMS					
Pre-treatment	31.88 (7.22)	31.98 (7.52)			
Post-treatment	28.45 (7.67)	31.52 (7.40)	8.61 (98)	<.01	.08
3 months post-treatment	29.57 (7.29)	31.26 (7.65)	2.38 (98)	.13	.02
SMS					
Pre-treatment	44.02 (16.11)	50.80 (15.36)			
Post-treatment	54.65 (14.29)	49.20 (15.63)	21.79 (98)	< .01	.18
3 months post-treatment	52.16 (15.98)	49.48 (16.56)	10.79 (98)	< 0.1	.10
EQ					
Pre-treatment	40.57 (7.96)	44.08 (8.48)			
Post-treatment	47.39 (7.33)	44.18 (9.23)	20.56 (98)	< .01	.17
3 months post-treatment	47.37 (9.13)	44.34 (8.09)	9.86 (98)	< .01	.09
NAS					
Pre-treatment	125.35 (20.38)	126.68 (20.15)			
Post-treatment	135.84 (19.43)	127.12 (21.29)	8.70 (98)	< .01	.16
3 months post-treatment	133.88 (19.84)	127.76 (20.56)	9.86 (98)	<.01	.13
AAQ					
Pre-treatment	22.65 (8.83)	22.42 (9.96)			
Post-treatment	19.80 (8.42)	22.56 (9.05)	10.20 (98)	< .01	.09
3 months post-treatment	19.88 (8.17)	21.48 (9.41)	3.41 (98)	.07	.03
SCS					
Pre-treatment	77.41 (18.35)	80.64 (18.94)			
Post-treatment	83.39 (18.09)	81.44 (20.30)	6.97 (98)	.01	.07
3 months post-treatment	84.80 (18.14)	80.50 (20.03)	15.88 (98)	< .01	.14

Figure 1. Consort Diagram: enrollment and study flow in RCT of MBCT versus TAU.