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Running Head: COMPASSION-FOCUSED SELF-HELP FOR SKIN CONDITIONS

Compassion-Focused Self-Help for Psychological Distress Associated with Skin Conditions: A Randomized Feasibility Trial

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Abstract

Objective: This study tested the feasibility of a self-help intervention based on Compassion-Focused Theory (CFT), and estimated treatment effects in a population of adults with skin conditions and associated psychological distress.

Design: A randomized-controlled design was used, with 176 participants being allocated to either CFT-based self-help or a waitlist control group, who received usual medical care. The two-week intervention was provided by email.

Main Outcome Measures: Treatment adherence and attrition rates were calculated, and effectiveness was estimated using measures of perceived stress, anxiety, depression, dermatology-specific quality of life and self-compassion.

Results: Eighty-seven participants completed the post-intervention questionnaires (51%), and practiced on a median of 9/14 days. Study completers demonstrated significant, moderate improvements on measures of stress, anxiety, depression, self-compassion and dermatology-specific quality of life, relative to controls. In intention-to-treat (ITT) analyses, these findings remained significant, however effect sizes reduced from moderate to small.

Conclusions: The findings indicate that CFT self-help shows promise in the treatment of psychological distress associated with skin conditions, however further testing of the intervention is not feasible without significant methodological changes, including the method of treatment delivery. Future studies should also include a follow-up period, as the duration of treatment effects could not be shown.

Keywords: mindfulness, compassion, self-help, psychodermatology, skin conditions

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Conditions affecting the skin are ranked among the 10 most prevalent diseases worldwide and represent the fourth leading cause of non-fatal disease burden globally (Hey et al., 2014). Visible health conditions can have a significant impact on psychological functioning (Clarke, Thompson, Jenkinson, Rumsey, & Newell, 2012; Rumsey & Harcourt, 2004), with as many as 30% of dermatology patients showing clinically significant levels of psychological distress, including depression, anger, anxiety, shame, increased risk of suicide, impaired body image, and decreased social support (Dalgard et al., 2015; Schofield, Grindlay, & Williams, 2009; Thompson, 2009, 2012, 2014a). There is evidence that negative emotional states can elicit or exacerbate skin disease either directly via psychoneuroimmunological pathways, or via behavioral reactions, which can set up vicious cycles of stress and impaired skin functioning (Thompson, 2005, 2009; Yan, 2016). Skin conditions also lead to loss of earnings and impaired quality of life, which at times can be greater than for individuals with cancer (All Party Parliamentary Report on Skin, 2013; Schofield et al., 2009). Given the substantial impact of skin conditions, there is a need to develop psychological interventions that are specific to this population.

A limited number of psychological interventions have been developed and evaluated for people with visible or/and potentially disfiguring conditions (Muftin & Thompson, 2013; Norman & Moss, 2015). Psychological inventions tested specifically with skin conditions include group therapy, meditation, cognitive-behavioural therapy (CBT), biofeedback and relaxation, and emotional disclosure (Lavda, Webb, & Thompson, 2012). Currently there is insufficient evidence to recommend the use of any particular approach across conditions (Pickett, Loveman, Kalita, Frampton, & Jones, 2015), although interventions based on CBT have shown greater effectiveness in reducing psoriasis severity when compared to other psychological approaches (Xiao et al., 2019). In addition, specialist training is normally required to deliver psychological interventions, and a recent survey of dermatologists in the

UK indicated that only eight percent were able to refer directly to a psychologist or psychotherapist (Lowry, Shah, Fleming, Taylor, & Bewley, 2014). Therefore, psychological self-help interventions, which have shown effectiveness in people with depression (Gellatly et al., 2007), anxiety (Hirai & Clum, 2006) and other chronic health conditions (Beatty & Lambert, 2013), may hold potential for this population.

Psychological self-help interventions, such as psychoeducation, are typically single-strand interventions, that are less complex and briefer than formal psychotherapy (Baguley et al., 2010). There is emerging evidence that self-help is viewed as acceptable by people with appearance altering conditions, and shows promise in reducing stress and appearance related concerns (Muftin & Thompson, 2013). However, there remains a paucity of research into psychological self-help designed specifically for people with skin conditions (Thompson, 2014b).

One such approach has been evaluated by Shah, Hunt, Webb, and Thompson (2014), who developed a CBT-based intervention for people with vitiligo, which included psychoeducation, relaxation and attentional refocusing. Participants were randomized to receive either standard self-help, self-help enhanced by implementation intentions (a planning exercise), or to a waitlist control group. A greater proportion of participants in the enhanced self-help condition showed reliable and clinically significant change in social anxiety; however, no differences were found in levels of depression, anxiety, or appearance concerns. The lack of treatment effects may be attributed to the CBT-based intervention not being specifically designed to alleviate shame, which has featured heavily in attempts to understand the process of adjustment to skin conditions.

Kent and Thompson (2002) developed a model of shame-proneness in individuals distressed by disfigurement, which suggests that repeated experiences of stigmatisation and poor psychological support, can lead to body shame and low self-worth in relation to

appearance. The resulting negative 'self-schema' are in turn associated with anxiety regarding social situations, sensitivity to rejection, and can lead to sufferers adopting unhelpful coping strategies, such as avoidance (Kellett & Gilbert, 2001; Thompson, 2009). As a result, self-help interventions aimed at increasing mindfulness and self-compassion might be particularly appropriate for this group.

Mindfulness meditation has been described as 'Paying attention in a particular way: on purpose, in the present moment, and non-judgementally' (Kabat-Zinn, 1994). In Buddhism, mindfulness and compassion are thought of as 'the two wings of a bird', with mindfulness providing the context for the further development of compassion (Kraus & Sears, 2008). Compassion has been described as 'a multidimensional process comprised of four key components: (1) an awareness of suffering (cognitive/empathic awareness), (2) sympathetic concern related to being emotionally moved by suffering (affective component), (3) a wish to see the relief of that suffering (intention), and (4) a responsiveness or readiness to help relieve that suffering (motivational; Jazaieri et al., 2012). HERE CAN YOU ADD SOMETHING ABOUT HOW MINDFULNESS IS REFLECTED IN THIS DEFINITION? IE,

Compassion focused therapy (CFT) was based on CBT and designed for people with high levels of shame and self-criticism, making it particularly relevant to people with skin conditions. CFT aims to change the way people relate to themselves and others by cultivating compassionate attributes such as empathy, distress-tolerance, and a non-judgmental attitude. The CFT model highlights the importance of mindful breathing as a way of stimulating the soothing/affiliative system in the brain, and increasing tolerance of threat-based emotions such as shame or anxiety (Gilbert, 2010, 2014).

The association between mindfulness and psychosocial distress has been examined in a range of visible skin conditions, and specific facets of mindfulness, particularly acting with

awareness, have been found to be associated with reduced depression and anxiety symptoms, after controlling for subjective severity (Montgomery, Norman, Messenger, & Thompson, 2016). The role of stress in particular has been identified as a precursor to exacerbation in skin problems, particularly in psoriasis, where perceived stress is proposed to modulate HPA axis function, cortisol release and the production of inflammatory cytokines (Fordham, 2012). In a review, Carlson (2012) reported beneficial effects of mindfulness-based interventions (MBIs) on physical health problems and found that mindful attention and exposure are likely mechanisms of change for physical symptoms that are exacerbated by stress, or avoided if paying attention to them causes anxiety. Bringing mindful attention and acceptance to the physical sensations associated with skin conditions may therefore reduce the avoidance reported in this population.

Mindfulness-based interventions are usually delivered in a group format, and facilitated by a teacher, which has benefits in relation to providing a supportive community and role model due to the teacher's facilitation (Imel et al., 2008). However, MBIs have been increasingly applied in self-help and online format for a range of difficulties. Recent meta-analyses have concluded that online and self-help approaches are effective at increasing mindfulness and acceptance skills, and reducing mental health difficulties (Cavanagh, Strauss, Forder & Jones, 2014; Spijkerman, Pots, & Bohlmeijer, 2016), There is also some emerging research suggesting the potential effectiveness of self-help MBIs for people with skin conditions (Montgomery & Thompson, 2018).

Kabat-Zinn (1998) randomly allocated 37 patients with moderate-severe psoriasis to receive either usual dermatological care alone, or alongside a Mindfulness-Based Stress Reduction audiotape, and it was reported that skin lesions cleared significantly more quickly for those in the mindfulness condition. Furthermore, Kelly, Zuroff, and Shapira (2009) conducted an experimental study with chronic acne sufferers, in which participants were

assigned to a self-help condition that involved practicing compassion-focused imagery, letter writing, and self-statements over a two-week period. At the end of the study, participants in the self-help condition reported less shame and skin complaints relative to controls, but the intervention had no effect on depression symptoms. Finally, a pilot study of a compassion-focused self-help intervention for people with psoriasis reported no difference between two different techniques, mindful soothing rhythm breathing and compassionate imagery, both of which had a medium effect on dermatology-related quality of life and a small effect on shame (Muftin, 2012).

The previous compassion-focused self-help studies by Muftin (2012) and Kelly et al. (2009) are limited by not using any form of guided support, or a no treatment control group. The absence of a no treatment control group means that it is not possible to conclude whether the interventions were more effective than the passage of time alone. There is also evidence that self-help materials which include guided support lead to significantly higher effect sizes than those which examine pure self-help (Gellatly et al., 2007). As a result, further testing of compassion-focused self-help for people with skin conditions is needed, which utilizes a support mechanism and controls for the effect of history.

The current study reports on a randomized controlled feasibility trial, in which the primary aim was to examine the attrition and adherence rates of a heterogeneous population of adults with skin conditions to a compassion-focused self-help intervention. The Medical Research Council (MRC) guidelines on complex interventions support the use of feasibility studies as part of a phased approach to the development, testing, and evaluation of healthcare interventions (Craig et al., 2008). The secondary aims of this study were to estimate whether the intervention has the potential to reduce levels of anxiety, depression, and stress, and increase dermatology-specific quality of life and self-compassion in this population. In addition, this study investigated whether baseline demographic variables or outcome

measures have an impact on drop-out. It was hypothesized that participants who completed the intervention would demonstrate reduced levels of anxiety, depression, and stress; and increased levels of dermatology-specific quality of life and self-compassion, relative to controls. It was also hypothesized that participants with high levels of self-compassion at baseline would be more likely to complete the intervention than participants with low levels of self-compassion.

Method

Design

A parallel group randomized controlled feasibility trial was used to examine the preliminary effectiveness of a CFT-based self-help intervention, for adults with heterogeneous skin conditions. A waiting-list control design was used, whereby participants were randomized to the intervention condition either immediately, or after a two week delay. An independent doctoral researcher assigned participants to each condition using simple randomization, with a computer-generated random number schedule.

The study had two independent variables: one between-subjects variable with two levels, treatment condition (CFT-based self-help vs. usual dermatological care); and one within-subjects variable with three levels, time (time points one, two, and three). The dependent variables were perceived stress, anxiety, depression, dermatology-specific quality of life and self-compassion.

Participants

The inclusion criteria included being aged 16 years or above, English-speaking, having a diagnosis of a skin condition from a general practitioner or hospital doctor, and experiencing skin-related psychological distress, such as low mood, anxiety, or stress. No skin conditions

were excluded from the study and participants were accepted regardless of skin condition severity, which was not assessed. Participants were excluded if they had been diagnosed with a psychotic illness or drug/alcohol addiction, were engaged in any concurrent pharmacological or psychological treatment for a mental health condition, or reported any current thoughts of deliberate self-harm or suicide.

Participants were recruited via links posted on the websites, online forums and social media pages of UK-based and international skin charities, service user-led online forums, social media, and an email advertisement at two Universities in northern England. Snowball sampling was utilized by asking potential participants to forward the study information to friends or family who might be eligible. All participants who returned post-intervention questionnaires were entered into a prize draw to receive a voucher worth £50.00.

Given that our study was a feasibility trial, and the primary aim was to estimate attrition, a confidence intervals approach was used to estimate the required sample size, as recommended by Thabane et al. (2010). The calculation for this was taken from Hertzog (2008), who showed that with an attrition rate of 30% in a study with 80 participants, we can be 90% confident that this estimate is accurate within eight percentage points. Therefore the study aimed to recruit 80 participants (40 per group).

A total of 326 people consented to participate and were assessed for eligibility. This left 176 remaining participants that were eligible for the study. Of these, 137 (77.84%) were from a white background, 5 were mixed ethnicity, 6 were Indian, 5 were Chinese, 3 were Caribbean, and 19 had another ethnicity. One participant did not record their ethnic background. Following randomization, 91 participants were allocated to the control condition and 85 to the intervention condition. The demographic characteristics of the overall sample and each group are shown in Table 1. The flow of participants through the study is shown in a CONSORT diagram (Schulz, Altman, & Moher, 2010) in Figure 1.

[Insert Table 1 here]

[Insert Figure 1 here]

Baseline Comparisons

A series of independent samples *t*-tests and chi square tests confirmed that there were no significant differences between the intervention and control groups on the baseline demographic variables (see Table 1). A series of independent samples *t*-tests also showed no significant between-groups differences on the baseline outcome measures (see Table 2).

[Insert Table 2 here]

Intervention

An adapted version of the CFT-based self-help intervention piloted by Muftin (2012) was utilized in the current study, which involved daily practice of a mindful soothing rhythm breathing exercise, lasting approximately eight minutes, over a two-week period (see supplementary files for the TIDIER checklist and intervention materials). The two-week intervention period was chosen because this duration was sufficient to significantly reduce levels of stress, anxiety and depression in a previous study of brief online mindfulness-based self-help (Cavanagh et al., 2013). Mindful soothing rhythm breathing is a form of meditative breathing, with an emphasis on cultivating self-compassion. The intervention was comprised of a written booklet and an audio Mp3. The materials were written by three Clinical Psychologists with experience of working with long term health conditions and in one case with considerable theoretical expertise of the compassion-focused model (Dr Zina Muftin, Dr Andrew Thompson, and Professor Paul Gilbert). Initial service user feedback on the usability of the draft interventions was also sought from the Psoriasis Association in the UK. Feedback indicated that the materials were understandable and appeared useful, however questions surrounding the terminology and tone of the materials led to a greater focus on positive

adjustment and the addition of the audio file, to make them more personable. For the present study, the materials were modified slightly, essentially replacing 'psoriasis' with 'skin conditions', so as to make them applicable to people living with a range of visible skin conditions. The written materials followed a three-step format. Step 1 introduced the rationale for developing a skill in mindful soothing rhythm breathing. Step 2 explored ways to prepare for practice and overcome barriers such as a 'wandering mind' or time constraints. Finally, Step 3 contained a script for practicing mindful soothing rhythm breathing. The accompanying MP3 also contained instructions for the technique. Participants also received automated reminder emails at three-day intervals, to encourage them to continue practicing, which acted as a form of minimal contact support.

Procedure

Data was collected using the online survey provider 'www.qualtrics.com', where participants could view and complete the information sheet, consent form, demographic questionnaires and time one (T1) measures. Prior to the start of data collection, this study was reviewed and passed by the University ethics committee.

The intervention group were sent the self-help materials immediately as an email attachment, and were asked to begin practicing the technique. After one week, they were contacted again and asked to repeat the questionnaire battery (time two). They were then contacted for a final time and asked to complete the questionnaires at the end of the two-week intervention period (time three).

The control group received the same self-help materials after a waiting period of two weeks. After this, they began using the intervention and completed questionnaires in the same manner as the intervention group, however the outcome data returned by the control group after they started using the intervention were not included in the analyses. Participants whom had not returned measures at time three (T3), or time five (T5) in the control group, were sent

a reminder email after five days. Following the start of data collection, a hyperlink to an online storage facility was added to the email containing the self-help materials, which allowed an alternative method of downloading the intervention.

Measures

Feasibility. The intervention was considered to be feasible if the following criteria were met:

1. The study would retain 70% of participants at follow-up. This criterion was based on the reported completion rate found by Muftin (2012).

The compassion-focused self-help technique was practiced by at least 68% of participants on 11/14 days (80%). This criterion was chosen as a meta-analysis of adherence to internet-delivered CBT defined completing 80% of an intervention as having been exposed to a substantial part of the treatment content, and 67.5% of participants met this criterion (van Ballegooijen et al., 2014). This was measured using a single question about the number of days that participants had practiced the intervention in the last week. Prior to the intervention, participants were also asked to complete a series of four questions enquiring about the extent of their past experience of practicing mindfulness. This was based on similar questions presented by Baer et al. (2008).

Effectiveness. The primary outcome was perceived stress, as measured using the 10-item Perceived Stress Scale (PSS: Cohen & Williamson, 1988). This was chosen as the sample may have included participants who were not showing clinical levels of distress, and the PSS has been frequently used in other studies of mindfulness-based self-help. On this scale, respondents are asked to indicate how often they have felt or thought a certain way in the last month, using a five-point Likert scale where 0 = Never and 4 = Very Often. The total score is from 0-40 and higher scores indicate greater levels of perceived stress. Numerous studies have examined the internal reliability and temporal stability of the PSS-10 and

reported correlations greater than the recommended value of .70 (Field, 2009; Lee, 2012). The PSS-10 has been compared to the Hospital Anxiety and Depression Scale (HADS: Zigmond & Snaith, 1983), and found to have correlations of .632 and .619 with the anxiety and depression sub-scales, respectively (Fordham, 2012). Several studies using mindfulness interventions have shown a reduction in PSS scores (Krusche et al., 2012).

Secondary outcomes were psychological distress, dermatology-specific quality of life and self-compassion. Psychological distress was measured using the HADS (Snaith & Zigmond, 1994, as cited in Crawford, Henry, Crombie, & Taylor, 2001). Each item is rated from 0 to 3 according to the severity of the symptoms experienced. Eight items are reverse scored, after which they can be summed to produce subscale scores from 0-21, with higher scores indicating greater distress. Two review papers have established the internal consistency, test-retest reliability, and convergent validity of the HADS (Bjelland, Dahl, Haug, & Neckelmann, 2002; Herrmann, 1997).

Dermatology-specific quality of life was measured with the Dermatology Life Quality Index (DLQI; Finlay & Khan, 1994). Each item is rated on a four point scale from 0 (Not at all/not relevant) to 3 (very much). Scores are summed to produce a total from 0-30, with higher scores indicating greater impairment of quality of life. Good internal consistency and test-retest reliability has been shown in a range of studies (Basra, Fenech, Gatt, Salek, & Finlay, 2008). The DLQI has demonstrated responsiveness to change in two randomized controlled trials of drug treatment for psoriasis, where it showed significant moderate correlations with the Psoriasis Area and Severity Index, which assesses the severity of Psoriasis, and how much of the body is affected (Shikiar et al., 2003).

Self-compassion was assessed using the Self-Compassion Scale – Short Form (SCS-SF; Raes, Pommier, Neff, & Van Gucht, 2010). Participants are instructed to respond according to how much they act in accordance with the manner stated in each item, which are scored

from one (almost never) to five (almost always). Six items are reverse-scored and a total self-compassion score of 12-60 is computed by summing the items. The SCS-SF has a very strong correlation of .98 with the longer version of the scale. It has also shown good internal consistency and test-retest reliability, with a Cronbach's alpha coefficient of .86 and a correlation of .71 over a five-month period (Raes, 2011; Raes et al., 2010).

Data Analyses

Descriptive statistics were first calculated for the demographic variables, participants' adherence ratings, the measure of past meditation experience, and the five outcome measures. A representativeness check was carried out using a MANOVA on the data from each of the T1 outcome measures, to examine whether there were differences between those who filled out the T1 measures only (non-completers) and those who completed the T3 measures (completers). MANOVA was chosen as the scales were conceptually related, and to reduce the risk of a Type 1 error from multiple comparisons. An ANCOVA of those completing the study tested for differences between the intervention and control groups at T3, on the PSS, HADS, and SCS-SF. This method was chosen as ANCOVA has been found to yield greater statistical power than repeated measures ANOVA (Van Breukelen, 2006). Data from the DLQI violated the assumptions of normality, therefore, in accordance with recommended alternatives (Tabachnick & Fidell, 2001), an independent samples *t*-test was used to examine change scores (T3-T1).

The ANCOVAs were repeated in intention to treat (ITT) analyses, using a last observation carried forward method of imputation. In the ITT analyses, ANCOVA was used to test for between-groups differences at T3 on the DLQI, as the data now met the necessary assumptions. An independent samples *t*-test was performed on the data for the SCS-SF, as the data violated the assumption of homogeneity of regression slopes. Out of the non-completers at T3, nine were able to provide T2 data, with the remainder having their baseline scores

carried forward. Partial missing survey data was prevented by the survey software requiring a response prior to moving on.

Pearson's product-moment correlations were conducted to investigate whether the amount of mindfulness practice in the treatment period was associated with change scores on the outcome measures. Preliminary analyses were carried out to check the assumptions of normality, linearity, and homoscedasticity, and no violations were found. All scale measures were treated as interval level data in the analyses. All statistical analyses are reported with two-tailed levels of significance, and with alpha set at .05.

Results

Feasibility

Attrition. Overall, 87 participants completed the T3 outcome measures, resulting in a completion rate of 49.43 percent. There was also differential attrition across the groups, with 61 participants (67.03%) completing the T3 measures in the control group and 26 (30.59%) completing them in the intervention group.

A one-way between groups MANOVA was performed to investigate differences between completers (n = 87) and non-completers (n = 89) on the five outcome measures at T1. No statistically significant differences were found, F (6, 169) = .93, p = .47, Wilk's Lambda = .97, partial $\eta^2 = .03$. It can therefore be concluded that study completers were representative of the overall sample at T1, in terms of levels of stress, anxiety, depression, self-compassion, and dermatology-specific quality of life. A series of Chi-square tests for independence confirmed that there were also no differences between completers and non-completers in terms of gender, ethnicity, marital status, employment, education, type of skin problem, and previous meditation experience, p > .05.

An independent samples t-test was conducted to compare the age of completers and non-completers. There were no significant differences between completers (M = 35.67, SD =

13.20) and non-completers (M = 31.75, SD = 12.20); t (143) = 1.85, p = .07. A further independent samples t-test was performed to examine whether completers and non-completers differed according to the time since they were first diagnosed with a skin condition. No significant differences were found between completers (M = 7.89, SD = 3.55) and non-completers (M = 7.66, SD = 3.69); t = .41, p = .68.

Adherence. Nineteen participants in the CFT self-help group reported their total level of practice over the two-week intervention period. Only three (15.79%) of these participants reported using mindful soothing breathing on 11 or more days, which is less than the 68 percent criterion which was set at the study outset. However, 78.95 percent of participants reported using the technique on at least half of the days, and the median number of practice days was nine.

In the waitlist control group, 30 participants provided adherence data from both weeks. A total of 28 percent reported using the self-help materials on at least 11/14 days and 83.3 percent of participants used the self-help materials on at least half of the days. The median number of practice days was also nine.

Past mindfulness experience. In the intervention group, 12 participants (14.10%) reported having practiced mindfulness prior to the study outset, eight of whom had practiced for less than six months (66.0%). The majority of participants (57.10%) reported practicing once or twice a week, for periods lasting up to 10 minutes (58.30%).

In the control group, 14 participants (15.40%) reported past mindfulness experience, with eight having practiced for six months or less (57.10%). Once again, the majority of participants practiced once or twice per week (78.60%), for periods of 10 minutes or less (58.30%).

Effectiveness

A series of one-way, between groups ANCOVAs compared T3 scores for stress (PSS), anxiety (HADS-A), depression (HADS-D) and self-compassion (SCS-SF) between study completers in the intervention group (n = 26) and control group (n = 61). Scores at T1 were used as covariates. The mean scores by group at T1 and T3 and the results of the statistical tests can be seen in Table 3.

There was a significant effect of the CFT self-help intervention on levels of stress, self-compassion, anxiety, and depression, with participants in the intervention group showing greater improvements than those in the control group. This resulted in moderate effect sizes, and accounted for between six and twelve percent of the variance in outcome. There were also strong relationships between baseline scores and scores at T3 on each outcome measure.

[Insert Table 3 here]

An independent samples t-test was performed to compare the — scores on the DLQI between the CFT self-help group and the control group. As shown in Table Four, participants in the CFT self-help group showed greater improvement in quality of life (M = -4.23, SD = 4.24), compared to those in the control group (M = -.98, SD = 3.65). The magnitude of the differences in the means was moderate. Effect sizes were determined using the recommendations provided by Cohen (1988, as cited in Pallant, 2007). Eta squared and partial eta squared values of .01 were considered small, .06 were considered medium, and .138 were considered large.

Intention to treat analyses were conducted to account for potential bias (e.g. non-random attrition of participants), due to factors which were not accounted for in the study.

ANCOVAs were repeated for the PSS, HADS and DLQI scores at T3, after baseline or time T2 values had been imputed for participants who had dropped out. The mean scores by group at T1 and T3 and the results of the statistical tests can be viewed in Table 4.

After adjusting for T1 scores, there was still a significant effect of the CFT self-help intervention on levels of stress, anxiety, and depression. However, the effect sizes were small, and accounted for between two and four percent of the variance in outcome. The baseline scores still showed a strong relationship with the scores at T3.

An independent samples t-test compared change scores on the SCS-SF between the CFT self-help group and the control group. Participants in the CFT self-help group showed greater change in self-compassion (M = -1.28, SD = 4.91) than participants in the control group (M = -.47, SD = 6.48). This was statistically significant, and the magnitude of the differences in the means was small (see Table 4).

Effect of Mindfulness Practice

The relationship between the total amount of mindfulness practice and post-intervention scores on the PSS, DLQI, SCS-SF, HADS-A, and HADS-D was investigated using a series of Pearson product-moment correlations. There was a large, negative correlation between the amount of practice and scores on the HADS-A, r = -.62, n = 19, p < .05, with greater practice associated with lower anxiety scores. There was also a medium, negative correlation between the amount of practice and scores on the DLQI, r = -.46, n = 19, p < .05, with greater practice associated with increased quality of life. Outcomes on the other measures were not found to be significantly associated with meditation practice.

[Insert Table 4 here]

Discussion

The current study tested the feasibility and estimated the effectiveness of a CFT-based self-help intervention for people with a range of visible skin conditions. Participants were randomly assigned either to practice daily mindful soothing rhythm breathing over a two-

week period, or to a waiting list control condition. Consistent with our expectations, the results showed that the CFT self-help intervention was effective in reducing levels of stress, anxiety, depression, and dermatology-specific quality of life. Importantly in terms of theoretical proof of concept, the intervention also improved levels of self-compassion.

The levels of attrition and treatment adherence were poorer than expected, and did not meet the feasibility criteria that were set for the study. Contrary to our expectation, self-compassion did not have a significant effect on levels of attrition. The level of attrition overall, and in the intervention group in particular, was high in this study, with just over 49 percent of participants completing the post-intervention measures. A review by Cavanagh et al. (2014) found that across a range of mindfulness and acceptance-based self-help interventions, the number of randomized participants completing post-intervention measures ranged from 48 percent to 98 percent. The data from the current study are therefore comparable with the relatively high attrition rates found in other studies of psychological self-help interventions. Cavanagh et al. (2014) reported that attrition was higher in two large pure self-help studies, with almost half of participants not returning post-intervention measures. This reflects the wider self-help literature (Gellatly et al., 2007), and suggests that the automated reminders may not have been sufficient to improve completion rates.

To account for the high level of attrition, the data were analyzed on an intention to treat basis, using a conservative last observation carried forward imputation method. In addition, demographic variables and baseline outcome measures were compared between study completers and non-completers, and no significant differences were found. It is possible that differences might have existed between groups in variables that were not measured, such as expectancy and locus of control, as having a higher expectation of beneficial outcome and an internal locus of control have been shown to predict attrition in a previous study of self-help for body dissatisfaction (Geraghty, Wood, & Hyland, 2010). Yardley et al. (2016) describe

the concept of 'effective engagement' to explain the need for treatment benefits to outweigh the costs. It is possible that participants did not see the benefits of practicing mindfulness as outweighing other valued pursuits. Yardley describes the importance of carrying out in-depth qualitative analysis to explore a range of factors which may impact on engagement, which is important for future studies. This could include the degree of tailoring which the intervention might need for specific skin populations, as well as the right level of practitioner involvement, and the best way to include people from lower socioeconomic groups, who may face more barriers to accessing digital interventions.

The differential attrition between groups could be partially explained by some participants finding the self-help materials difficult to tolerate, or not finding them to be usable or helpful. For instance, interventions that involve relaxation are known to have the potential to trigger anxiety (Heide & Borkovec, 1984), and participants in this study did report mild-moderate anxiety on average. However, the likelihood of these factors significantly influencing the attrition rate is reduced by the fact that in a pilot study, 88 percent of participants reported finding the self-help information helpful, and 96 percent reported that the audio was easy to follow (Muftin, 2012). Furthermore, no reports of adverse events were made to the researcher in the current study, and of those participants in the waitlist control group who received the intervention, 82% completed their final outcome measures.

A number of participants were not able to access the self-help materials due to technical problems, including a lack of space in their email inbox, or download restrictions on their workplace computers. The addition of a hyperlink to the online storage facility was made towards the end of the recruitment period, and so would have disproportionately advantaged the waitlist control group. This is considered the main reason for the high level of differential attrition, and accounts for why participants appeared to be missing at random. As a result, the level of attrition observed in this study may not be an accurate reflection of participants'

engagement, and may instead reflect an access issue. Despite this setback in the administration of this intervention, the sample size was sufficient to find significant effects.

Lower adherence was observed in the current study than was expected based on the criterion taken from a review of internet-based CBT for depression by van Ballegooijen et al. (2009). However, on the basis of the adherence data, it might be premature to conclude that the mindful soothing breathing technique is not feasible, given that the criterion used was stringently defined. There is a paucity of research into what constitutes an adequate 'dose' of mindfulness or CFT-based self-help. A study of online mindfulness-based self-help defined practicing on 6/12 days as being adequate and 64 percent of the treatment group met this criterion (Gluck & Maerker, 2011). Furthermore, a study of book-based MBCT reported a median practice frequency of two to three times per week (Lever Taylor, Strauss, Cavanagh, & Jones, 2014). The findings of the present study compare favourably to this, as 79 percent of participants in the intervention condition used the self-help technique on at least half of the days, and the median number of practice days was 9/14.

The findings from the analyses of those completing the study suggest that the improvements observed in the CFT self-help group were unlikely to have occurred due to external events, the passage of time, or usual skin treatment. The moderate effect sizes were encouraging, particularly as the intervention was brief and comprised a single component. In the ITT analyses, the general reduction in effect sizes from moderate to small was unsurprising, as close to 50 percent of scores were being carried forward from either baseline or T2. The fact that the findings remained statistically significant is an indication of the robustness of the effects.

The findings of this study support theoretical predictions from Gilbert's CFT model (Gilbert, 2010, 2014), related to the role of mindful breathing in alleviating threat-based emotions, and cultivating a more compassionate style of self-to-self relating. The observed

outcomes also support the work of Muftin (2012) and Kelly et al. (2009), who reported that CFT self-help led to statistically significant improvements in dermatology-related quality of life in samples of people with psoriasis and acne. The current study also expanded on these results by finding additional significant changes in levels of anxiety and depression, which were either not measured or found to be non-significant in the previous studies. The present study adds to the growing field of mindfulness-based self-help interventions, which were recently found to have small to medium effects on mindfulness, anxiety and depression in a meta-analysis by Cavanagh et al. (2014).

Whilst the current findings cannot be generalized to clinical populations, this study suggests that CFT-based self-help has potential for use as a brief intervention in dermatology settings, or primary care services. CFT is often group-based and requires clinicians to have specific training, making it resource intensive to deliver. By comparison, the present self-help intervention is inexpensive and largely self-guided, meaning that it could be offered by professionals without specialist training in psychological interventions. CFT self-help may therefore play a role in addressing the treatment gap brought about by the lack of clinical psychologists available in dermatology settings (Thompson, 2014a). Given that the current sample consisted of participants with a range of skin conditions, this also lends support to the utility of CFT-based self-help as a transdiagnostic intervention.

This study builds upon earlier CFT-based self-help research for skin conditions in three ways: First, by including a measure of self-compassion; Second, by utilizing a dermatological treatment as usual control group; Finally, by investigating the usefulness of a minimal contact support mechanism. However, the findings are limited by the high degree of attrition and are less applicable to men, older people, and those who are economically disadvantaged, and do not have access to the internet. The study was further limited by the lack of a follow-up period, which would be important to measure over the longer term, as regular use of the

intervention is proposed to act as a preventative measure. Future studies of CFT self-help should consider different ways of offering access to the materials, for example via a mobile phone application, and consider including locus of control and outcome expectancy as potential moderators. The study could also have been strengthened by using measures of skin severity and collecting objective diagnoses of participants' skin conditions. Furthermore, although the number of participants that were recruited was adequate for estimating attrition, to gain an accurate understanding of treatment effects, a fully powered study would require at least 200 participants, taking into account the small effect sizes that were observed.

To further develop these self-help materials, it would be beneficial to test a mindful soothing breathing condition against mindful soothing breathing plus compassionate imagery. The addition of compassionate imagery may lead to better outcomes, as it would provide an additional technique to stimulate participants' ability to self-soothe. It would also be useful for future implementation to consider the dose-response effect. Given that this study demonstrates a potential effect following a two week intervention, the question of the ideal training period should be considered. It would be valuable to seek service user feedback as to whether further scaffolding or support over a longer period may improve attrition by increasing participants' expectation of gaining a beneficial outcome.

This study evaluated the feasibility of brief CFT-based self-help in a randomised controlled trial, and estimated its effectiveness for a heterogeneous population of adults with skin conditions and associated psychological distress. The feasibility criteria were not met, due to high levels of attrition, and lower than expected levels of adherence. The level of attrition was considered to be largely due to technical problems however, and the adherence rates did compare favorably with other studies of mindfulness-based self-help. Given that the study also found small-to-moderate effects on measures of stress, anxiety, depression, dermatology-specific quality of life, and self-compassion, the CFT-based self-help materials

are considered to warrant further development. Future research should determine how best to modify the current materials to improve their utility and effectiveness, and make them more applicable to clinical populations.

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