Investigating Compassion-Based Guided Self-Help for Depression in People with Skin Conditions

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An Acceptability and Feasibility Study of a Compassion-Based Guided Self-Help Intervention for Depression in People with Skin Conditions

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Skin conditions are among the most common health complaints in the world: skin disease is the fourth leading cause of nonfatal disease burden (Hay et al., 2013). In the UK, an estimated 54% of the population experience a skin condition each year. While the majority (69%) of these people self-care, almost 13 million people in England and Wales visit their GP each year for skin complaints, with 0.8 million people being referred on for specialist care (All Party Paliamentary Group on Skin, 2013). While some skin conditions are resolved relatively quickly, others are life-long conditions. The impact of skin conditions can be considerable, for example, psoriasis has been found to have a similar impact on health-related quality of life as diseases such as cancer, arthritis, and heart disease (Rapp, Feldman, Exum, Fleischer, & Reboussin, 1999). As well as causing symptoms that are difficult to live with, skin conditions can impact other areas of individuals' lives, including work/school, daily activities, leisure, personal relationships and socialising (de Aruda & de Moraes, 2001; Dures, Morris, Gleeson, & Rumsey, 2011; Sampogna, Tabolli, & Abeni, 2012). A further, related, impact of skin conditions is on mental health. Living with a chronic skin condition can involve ongoing difficulties in the aforementioned areas, which can be sources of stress. In addition, people with skin conditions may experience appearance concerns and self-criticism if they perceive themselves to be falling short of their ideal standards due to their skin condition. This may lead to feelings of shame and anxiety. Indeed, skin conditions have been found to be associated with higher than average levels of psychological distress. Studies have found overall psychiatric morbidity among dermatology patients of 25.2% (Picardi, Abeni, Melchi, Puddu, & Pasquini, 2000), and significantly higher rates of depression, anxiety and suicidal ideation than people without skin conditions (Dalgard et al., 2015).

Psychological treatments for people with skin conditions

There are few psychological treatments available specifically for people with skin conditions: the ones most used are habit reversal, cognitive behavioural therapy (CBT), arousal reduction and combined techniques (Lavda, Webb, & Thompson, 2012). Habit

reversal focuses on reducing itch/scratch cycles, to improve the condition of the skin in pruritic conditions. CBT focuses on changing unhelpful thoughts and behaviours associated with the skin condition while arousal reduction focuses on reducing physiological arousal through techniques such as relaxation or meditation.

Psychological treatments for people with skin conditions often focus on anxiety rather than depression (for example, A. Clarke, Thompson, Jenkinson, Rumsey, & Newell, 2014), as it has been noted that people with conditions that alter their appearance can experience similar difficulties to people with social anxiety disorder, such as fear/avoidance cycles about public scrutiny (Bessell & Moss, 2007). However, not all people with skin conditions experiences difficulties with (social) anxiety as their primary psychological problem. Clinical depression has been found to be present in 10.1% of dermatology patients (Dalgard et al., 2015). Although anxiety problems were more common in this population (17.2%), the odds ratio for depression was higher (Dalgard et al., 2015). Furthermore, depression is associated with a higher average level of disability than anxiety disorders (World Health Organisation, 2017), and so there is a need to develop psychological interventions for people with skin conditions that focus on depression.

Guidelines for the treatment of depression recommend using a stepped care approach (National Institute for Health and Clinical Excellence [NICE], 2009; NICE, 2010), in which the least restrictive treatment that is likely to improve health is first recommended, and then more intensive treatment is provided as necessary if the patient fails to improve with the lower intensity treatment (Bower & Gilbody, 2005). Low intensity interventions require the least resources and so can be provided to more patients than the higher intensity interventions. One type of low intensity intervention is ‘guided self-help’, in which patients receive self-help materials and limited support from a trained practitioner. Research has shown that guided self-help is more effective for depressive symptoms than ‘pure’ self-help (without support), and that different modes of guidance (face-to-face support and other methods such as email) are equally effective (Gellatly et al., 2007). As well as being cost-effective, guided self-help can

enable patients to access an intervention despite geographic or time restrictions, particularly if the guidance is provided remotely, for example, by telephone or email.

Although evidence-based interventions for depression already exist (NICE, 2009), it is recognised that depression and chronic physical health problems can adversely affect each other: the impacts of chronic physical health problems increase the risk of depression, while depression can exacerbate pain and distress in people with physical illnesses (NICE, 2010). Given the relationship between depression and chronic physical health problems, interventions for depression should acknowledge the presence and impact of chronic physical health conditions. Previous qualitative research has noted that generic computerised interventions for depression need to be adapted for people with chronic physical conditions (Hind et al., 2010). Skin-specific self-help for depression is likely to be a valuable resource as many people with skin conditions manage alone or with the help of their GP only, and even for people who are referred to dermatology services, access to psychological support is limited (All Party Paliamentary Group on Skin, 2013).

In a review of self-help for people with visible differences, Muftin and Thompson (2013) identified five studies with people with skin conditions. The only study that used an intervention specifically developed for people with a skin condition (psoriasis) found that it was not effective for depression (Bundy et al., 2013). This intervention was a computerised CBT programme designed for people with psoriasis. The authors suggested that the relatively low level of depression in the sample could have contributed to the lack of significant effect on depression. In addition, the study suffered from a high attrition rate (43% in the intervention arm), which suggests a problem with acceptability of the intervention. Two further studies investigated interventions designed for people with visible differences, which could potentially be used by people with skin conditions (Bessell et al., 2012; Newell & Clarke, 2000). Both interventions focused on addressing social anxiety, and while some improvements in depression were also found, most of the interventions' content would not be relevant for individuals with skin conditions for whom depression was the primary psychological

problem. Two other studies in the review investigated the effect of generic self-help interventions for depression in samples of people with skin conditions. One of these studies found that Mindfulness-Based Stress Reduction did not reduce depression among people with psoriasis (Jackson, 2006). In the other study, two techniques based on Compassionate Mind Training (Gilbert & Irons, 2005) were investigated with people with acne (Kelly, Zuroff, & Shapira, 2009). Both self-soothing and attack-resisting self-help reduced shame at two weeks compared to the control, but only the attack-resisting intervention reduced depression. The results of this review indicate that there is a need to develop interventions for depression in people with skin conditions.

The development of compassion-based self-help

In recent years there has been increasing interest in the use of compassion as a therapeutic tool, with several compassion-based interventions having been developed (see Kirby, 2017, for a review). Being self-compassionate may be a particularly adaptive strategy for people with skin conditions, as for some people, skin symptoms can trigger negative self-evaluations (Thompson, Clarke, Newell, Gawkrodger, & the Appearance Research Collaboration [ARC], 2010; Wahl, Gjengedal, & Hanestad, 2002). A meta-analysis of compassion-based interventions ($n = 470$) reported that compassion-based interventions are effective for treating depression, with an average effect size of $d = 0.64$ (Kirby, Tellegen, & Steindl, 2017). Of the various interventions that have been investigated, Compassion Focused Therapy (CFT; Gilbert, 2010) is the only intervention that was specifically developed for use in clinical populations, and therefore self-help based on this may be particularly beneficial for people with depression. In particular, CFT was developed for people with problems with shame and self-criticism, which are known to contribute to depression (Gilbert & Irons, 2005). In CFT, compassion is described as "a sensitivity to suffering in self and others, with a commitment to try to alleviate and prevent it" (Gilbert, 2014, p. 19). CFT is an adaptation of CBT that focuses on learning to be compassionate to oneself as a therapeutic response to one's suffering (Gilbert, 2010). Within CFT, 'Compassionate Mind Training' (CMT) is used to refer to the exercises that patients practise to increase

their abilities to be compassionate.

While there are many published studies on CFT (see Beaumont & Hollings Martin, 2015; Leaviss & Uttley, 2015, for reviews), research on self-help based on CFT is in its infancy. Despite this, CFT-based self-help has been shown to improve depression in a variety of populations: students (McEwan & Gilbert, 2016), self-critical people (Krieger, Martig, van der Brink, & Berger, 2016; Krieger et al., 2018)[1], people with low–moderate wellbeing (Sommers-Spijkerman, Trompetter, Schreurs, & Bohlmeijer, 2018) and perinatal and intending-to-become-pregnant women (Kelman, Evare, Barrera, Muñoz, & Gilbert, 2018). Furthermore, two of these studies found that treatment gains were maintained at six-month follow-up (McEwan & Gilbert, 2016; Krieger et al., 2018), and one found that online CMT was superior to online CBT for depression (Kelman et al., 2018).

Although psychological interventions are intended to improve people's lives, negative emotions and distress are common side effects, for example, affecting around 27% of CBT patients (Schermuly-Haupt, Linden, & Rush, 2018). As well as demonstrating benefits from their self-help interventions, three of the above studies investigated negative effects. McEwan and Gilbert (2016) concluded that compassion-focused imagery could safely be practised using online instructions without clinical supervision, as only two participants (4.4%) reported experiencing negative emotions (pity and sadness) while trying to feel compassion. Contrary to concerns that people who were highly self-critical might show adverse responses, the higher self-critics showed the largest improvements. Similarly, in Krieger et al.'s (2016) pilot study only four participants (10.3%) experienced negative emotions (sadness and shame) during the programme—but the three people who felt sadness said that this then helped them to become more self-compassionate. In the subsequent randomised trial, four participants (6.8%) in the compassion group experienced negative emotions during the intervention (loneliness, impatience, anxiety, sadness and emotional instability), most of

[1] Krieger et al. (2016) and Krieger et al. (2018) investigated an online version of the 'Mindfulness-Based Compassionate Living' programme, which, although not explicitly based on CFT, also uses Gilbert's (2010) theoretical framework of three affect regulation systems.

which were perceived as transient (Krieger et al., 2018). These findings suggest that compassion-based self-help interventions can be used with few adverse effects for participants.

Compassion self-help for skin conditions

In addition to the Kelly et al. (2009) study that was included in Muftin and Thompson's (2013) review, four studies have investigated compassion-based self-help for people with skin conditions to date. Muftin, Gilbert, and Thompson (2018) compared the use of compassionate imagery and soothing breathing self-help materials with people with psoriasis. Depression was not measured, but both interventions were effective in reducing shame over four weeks. Hudson (2015) later compared the soothing breathing self-help with a wait list control among people with heterogenous skin conditions, finding that the soothing breathing led to reduced depression two weeks later. Similarly, a recent study found that, compared to an expressive writing control, a single-dose compassionate writing intervention led to immediate improvements in negative affect in people with visible skin conditions (Sherman, Roper, & Kilby, 2019). In contrast, D'Alton et al. (2019) found that a self-help version of mindfulness-based self-compassion therapy had no significant effect on depression over eight weeks among people with psoriasis. However, neither of the other interventions in this study (mindfulness-based cognitive therapy and mindfulness-based self-compassion therapy) were effective for depression, contrary to expectations, and the authors suggested that a floor effect may have prevented significant results from any of the interventions. Despite this, participants reported finding all of the interventions satisfactory and beneficial, and that they would recommend them to others. Overall, evidence suggests that compassion-based techniques hold promise as a self-help treatment for depression in people with skin conditions, but that further research is needed.

One key area for futher research is intervention development. In the studies that tested the effects of compassion self-help on depression (D'Alton et al., 2019; Kelly et al., 2009; Hudson, 2015), the interventions suffered from a number of shortcomings. Firstly, D'Alton et al. (2019) excluded people with suspected depressive disorders,

which may have led to a floor effect, and the authors suggested that future studies consider only including participants who score above clinical cutoffs on psychopathology measures. Secondly, Kelly et al.'s (2009) self-soothing intervention comprised compassionate imagery, letter writing and self statements over only two weeks. It is possible that a multi-component compassion intervention cannot affect depression in so short a time, as participants have not had the chance to practise any of the techniques sufficiently. Thirdly, participant retention and adherence to the intervention were lower than expected in Hudson's (2015) study. The self-help booklet, while designed for people with skin conditions, focused on appearance-related distress and did not mention other common impacts of skin conditions, such as pain, itch, treatment burden and restriction of valued activities. Only 35% of participants agreed that they would recommend the self-help materials to a friend or family member, which indicates that there is scope to improve the materials themselves. In addition, one of the problems noted in the study was that some participants had trouble accessing the materials. This was resolved by putting the materials online, but this only happened towards the end of recruitment and so may have reduced participant engagement in the study.

The Current Study

The Medical Research Council (MRC) recommends the use of feasibility studies as part of a systematic approach to developing, evaluating and implementing complex interventions (Craig et al., 2008). Feasibility studies are preliminary pieces of research that aim to explore certain aspects of the intervention that will inform future clinical trials (Arain, Campbell, Cooper, & Lancaster, 2010; Donald, 2018). As such, feasibility studies can have many different aims, depending on existing research, such as exploring acceptability or testing viability of the study protocols. The MRC also recommends that feasibility studies focus on issues relating to the development of the intervention, rather than outcomes (Craig et al., 2008). The current study will seek to build on previously researched compassion-based self-help interventions for people with skin conditions (D'Alton et al., 2019; Hudson, 2015; Kelly et al., 2009), by addressing their limitations of including only participants who were not depressed, using self-help over a

short (two-week) intervention period, and using self-help materials that were difficult to access and not perceived as acceptable to many participants. The study will therefore investigate an online self-help intervention with email guidance with people who are experiencing depressive symptoms. Based on the researcher's clinical experience of providing guided self-help to people with depression, it was decided that the intervention in the current study would be six weeks in duration. It is hoped that a six-week intervention will strike a balance between allowing time for participants to learn and practice a number of different techniques, and limiting participant burden and attrition. The self-help exercises in the current study will consist of a number of exercises derived from CFT/CMT (Gilbert & Irons, 2005; Gilbert, 2010), such as using soothing rhythm breathing, compassionate imagery and compassionate writing.

Aims

The study aims to explore whether the online compassion-based guided self-help is perceived as acceptable to people with heterogeneous skin conditions, in terms of retention rates and explicit feedback. The study also aims to investigate the feasibility of providing online compassion-based self-help and email guidance. Changes in depression, self-compassion and skin-related distress will be assessed to give an estimate of likely effect sizes for future research.

Acceptability and feasibility criteria

Acceptability of intervention overall: The percentage of eligible participants who access the webpages will be calculated using Qualtrics data and user logins to the website. The intervention will be considered acceptable if at least 66% of eligible participants log into the website during their sixth week of the study. This criterion was chosen as a recent meta-analysis of computerised CBT for depression and anxiety disorders reported a median retention rate of 66% (Andrews et al., 2018).

Feasibility of providing online self-help: All eligible participants should be able to access the website, so if less than 90% of eligible participants log into the website during their first week of the study, this may suggest that there were problems with accessing the self-help website. This criterion was chosen as more than one in ten people having

difficulty accessing the website is analogous to experiencing a 'very common' side effect of a medication (NHS, 2018). User logins for subsequent weeks of the intervention will also be recorded.

Feasibility of providing guidance: Researcher time spent providing email guidance will be recorded, and will be considered feasible if this takes 120 minutes or less per patient over the study period. This criterion is derived from guidance on individual guided self-help interventions for people with depression, which typically consist of up to 240 minutes overall (up to eight sessions at 30 minutes each; NICE, 2010; National IAPT Programme, n.d.): if providing email guidance takes over half the amount of time needed for individual guided self-help programmes, then it cannot reasonably be argued to be "limited facilitation" (NICE, 2010, p. 23). The percentage of participants who requested additional support via email will also be recorded. These figures will inform future trials and implementation of guided self-help for people with skin conditions within health services.

Method

Design

Given that the current study aims to investigate a novel intervention, the study will be an acceptability and feasibility study that uses a pre–post design.

Participants

Participants will be adults who are currently living with a skin condition and who are experiencing symptoms of depression, as identified by scoring 10–20 on the depression subscale of the Depression Anxiety Stress Scales (DASS; Lovibond & Lovibond, 1995), which represents mild–moderate levels of depressive symptomatology. The stepped care model expects that people with mild–moderate depression will benefit from guided self-help (NICE, 2009), whereas people with more severe depression may require more intensive interventions. Participants will be recruited online, in line with the format of the intervention. The following skin charities/organisations have already agreed to advertise the study on their websites and/or their social media channels when ethical approval has been granted:

- British Skin Foundation
- British Association of Dermatologists
- DEBRA (epidermolysis bullosa)
- Lupus UK
- National Eczema Society
- Pem Friends (pemphigus and pemphigoid)
- Psoriasis Association

If it is necessary to recruit more participants after skin condition organisations have advertised the study, email advertisements will be sent to an existing volunteer list from a previous study (E. Clarke, Thompson, & Norman, 2019), to members of the University of Sheffield's volunteers lists, and to students at Sheffield Hallam University's Psychology department. Snowball sampling will be used, where potential participants will be asked to forward the study advert to family and friends who might be interested in participating.

Inclusion criteria

- Self-reported as currently experiencing a skin condition that has been diagnosed by a medical professional.
- Scored between 10 and 20 (inclusive) on the depression scale of the DASS at baseline.
- Age 18 or over.
- Sufficient English language ability to read self-help materials and complete self-report questionnaires.

Exclusion criteria

- Currently having psychological treatment for a mental health condition.

- Diagnosis of a serious mental illness (e.g. bipolar disorder or psychosis).
- Diagnosis of a drug/alcohol addiction.

Procedure

Data will be collected using Qualtrics, an online survey provider. In the study advert, participants will be provided with a link to the Qualtrics survey page, where they will read the participant information sheet and complete an online consent form (see Appendices A and B). Screening questions relating to the exclusion criteria will be asked before participants complete the demographic questions, clinical information, and baseline measures (see Appendices C–H). Baseline DASS depression scores will be calculated automatically by Qualtrics. Any participants who disagree with the consent statement or who are ineligible for the study will be re-directed to an 'end of study' webpage. This will explain that they are not able to continue with the study and recommend that they contact their GP if they need further support. Signposting information about mental health resources and emotional support for skin conditions will also be provided to all participants.

Qualtrics will notify the lead researcher when an eligible participant has completed the baseline survey. Eligible participants will be registered as users on the study website by the researcher and then sent an email with their login details and a link to the study website, with instructions to access the first session of the intervention. Anyone that attempts to access the intervention webpages without logging in will be redirected to the login page—the only exceptions to this are the homepage and the contact page. Requiring participants to log in means that engagement with the intervention can be monitored without involving any third parties for website traffic statistics (for example, Google Analytics), and also means that each participant's use of the website can be accurately tracked no matter what devices they use. At the end of the first session, participants will be asked to provide feedback on the first session, which will be collected using Qualtrics. Participants will receive an automated email three days after completing the baseline measures to remind them to practise the homework exercise (or go through the session if they haven't already done so). One

week after completing the baseline measures participants will receive an automated email inviting them to access the second session of the intervention. Automated emails will continue to be sent in this way, with homework reminders and links to subsequent sessions. The emails will also invite the participant to contact the researcher if they require further support with the self-help materials. The researcher will respond to any such emails individually. One week after the last session participants will be invited to provide feedback via Qualtrics about the guided self-help intervention overall, and to complete the outcome measures again.

Intervention

The guided self-help intervention will consist of six online sessions of self-help information for participants to work through, plus activities to carry out in-between sessions. The intervention will consist of psycho-education material, self-monitoring, and compassion-inducing exercises from CFT (Gilbert, 2010). The self-help exercises in the intervention will be evidence-based as being effective for depression: the compassion-focused imagery exercises will be those used by McEwan and Gilbert (2016) and the letter-writing exercise will be based on the one used by Shapira and Mongrain (2010). Other exercises, such as thought monitoring and relapse prevention planning, are commonly used in CBT and, as CFT is an adapted form of CBT, will be included in the current self-help intervention. The session content and homework exercises will build on previous sessions and homework, so there will be a clear sense of progression through the intervention. In addition, imagery and written homework exercises will be alternated, to provide variety and keep participants engaged in the intervention.[2] A breakdown of the intervention is shown in Table 1. Examples relating to skin conditions will be given throughout the self-help materials.

Expert feedback regarding the content of the website has been sourced through personal contacts and social media. Feedback has already been gathered from three people with skin conditions. Changes to the website deemed necessary based on their

[2] Some participants may struggle with imagery exercises (Naismith, Mwale, & Feigenbaum, 2018) while others may prefer imagery to written exercises. Alternating these types of homework task ensures that participants are never asked to do their less-preferred type of task for two consecutive weeks.

feedback have been made (see Appendix K for anonymised email exchanges with expert patients). In addition, a clinician with expertise in CFT has agreed to provide feedback on the intervention, and any minor amendments (e.g. re-phrasing items) recommended to keep the intervention in line with CFT principles will be made. The Psychology DESC will be informed if any substantial amendments (e.g. changes to the format of the intervention) are recommended.

Measures

Demographics. As part of the baseline measures, participants will be asked to provide demographic information about their age, gender, ethnicity, country of residence, employment status and education level.

Clinical information. Participants will be asked to state the name of their skin condition(s) and how long they have had the condition. Participants will also be asked to indicate whether they are currently taking any medication for a mental health condition, and if 'yes', what medication(s) they are taking and how long they have been taking it.

Acceptability measures. Overall acceptability: At the end of the intervention, participants will be asked to provide feedback via Qualtrics about which aspects of the intervention were helpful or unhelpful for them and if they can identify any areas for improvement. Open questions with spaces for text responses will be used to collect this feedback, as well as an adapted version of the 'Friends and Family Test' used in the NHS (see Appendix J). In line with recommendations that internet interventions monitor negative effects (Rozental et al., 2014), participants will also be asked whether the intervention exacerbated any existing symptoms or caused any novel symptoms to arise.

Acceptability of intervention components: Participants will be asked for their feedback on each weekly session of the intervention. Weekly feedback measures avoid retrospective bias and responses will be used to identify helpful/unhelpful aspects of the self-help intervention for further intervention development. Likert scales will be used to ask participants for feedback on the usability of the webpage and the impact of the self-help session. Relevant items from the Website Evaluation Questionnaire (Elling,

2012) and the Session Impacts Scale (Elliott & Wexler, 1994) will be adapted to form these Likert scales (see Appendix I). In addition, participants will have the opportunity to make other comments on the weekly sessions via open text responses. Self-reported adherence to the homework exercises will not be assessed, as the activities will differ from session to session, so it will not be possible to calculate overall adherence with the homework exercises.

Outcome measures. The depression subscale of the DASS (DASS–DEP; Lovibond & Lovibond, 1995) will be used to measure participants' levels of depression. This consists of 14 items. Participants are asked to rate how much statements applied to them over the past week on a four-point scale from 'did not apply to me at all' (0) to 'applied to me very much, or most of the time' (3), for example, 'I couldn't seem to experience any positive feeling at all'. Higher scores indicate higher levels of depression. Internal consistency of the DASS–DEP is excellent, with Cronbach's alpha of .95 (Crawford & Henry, 2003).

The Self-Compassion Scale (SCS; Neff, 2003) is a 26-item scale that will be used to measure participants' levels of self-compassion. Participants are asked to rate how often they behave in the manner described in the statements on a five-point scale from 'almost never' (1) to 'almost always' (5), for example, 'When I'm going through a very hard time, I give myself the caring and tenderness I need'. Half the items are negatively worded, and the total self-compassion score is obtained by reverse coding the negative items. Higher scores indicate higher levels of self-compassion. The SCS has been shown to have excellent internal consistency, with a Cronbach's alpha of .93 (Neff & Pommier, 2013). The SCS can also be used to give subscale scores for its six components: self-kindness, self-judgement, common humanity, isolation, mindfulness and over-identification. The subscale scores have acceptable internal consistencies, with Cronbach's alphas between .75 and .81 (Neff, 2003).

The Dermatology Life Quality Index (DLQI; Finlay & Khan, 1994) will be used to measure the impact of participants' skin conditions. Participants are asked to rate how much their skin condition has affected different areas of their life over the last week on a

four point scale from 'not at all/not relevant' (0) to 'very much' (3), for example, 'Over the last week, how much has your skin affected any social or leisure activities?' Higher scores indicate more impaired quality of life. A review of studies that used the DLQI found Cronbach's alpha ranged from 0.75 to 0.92 (Basra, Fenech, Gatt, Salek, & Finlay, 2008).

Data analysis strategy

Text responses from participants' feedback on the intervention overall will be analysed using content analysis to identify helpful aspects of the intervention and areas for improvement.

Quantitative data (outcome measures and acceptability ratings) will be screened for outliers and missing values, and descriptive statistics will be conducted for all variables. The data will be tested for the assumption of normality. Paired t-tests will be used to test for differences in participants' psychological outcome measures before and after the intervention. This information will also be used to calculate effect sizes (d_z) for changes in scores on each outcome measure. Intention-to-treat and completer analyses will be carried out.

Sample size

Although all clinical trials require sample size justification, formal sample size calculations are not necessarily appropriate for feasibility trials (Billingham, Whitehead, & Stevens, 2013). In this study, qualitative acceptability data will be used for further development of the intervention as necessary. Quantitative data (such as feedback ratings and changes in depression) will inform future research about the acceptability of the intervention in its current form and provide an estimate of the effect size for depression. A minimum sample size of 12 can be justified based upon precision of the estimates to be used in future research (Julious, 2005), although extra participants need to be recruited to allow for attrition. A meta-analysis of internet-based CBT found that attrition was 48% at the 75th percentile of studies (Andrews et al., 2018). To allow for up to 48% attrition, it will be necessary to recruit 23 participants to provide the minimum sample size of 12.

The maximum sample size is dictated by the available resources to facilitate the intervention. Based on clinical experience of providing email and telephone guidance to patients undertaking cCBT, it is expected that providing email support will take around 10 minutes per week per patient on average. Given the researcher's working pattern, up to nine hours per week could be allocated for directly facilitating the intervention (approximately half of the researcher's part-time hours). This leads to a maximum of 54 ([9 x 60]/10) participants that can be provided with email support at any one time. Although it would be possible to include more participants in the study due to the rolling nature of recruitment, there are diminishing returns on the value of increasing the sample size, as gains in the precision of estimates become less pronounced (Hertzog, 2008; Julious, 2005). It therefore seems logical to set 54 participants as the maximum sample size for the study.

Estimated timescale

A previous study of an online intervention for people with heterogeneous skin conditions recruited 176 eligible participants over approximately three months (Hudson, 2015), using similar recruitment techniques. This equates to recruitment of 59 participants per month. The current study has one additional exclusion criterion (mild–moderate level of depressive symptoms) compared to Hudson's (2015) study, so recruitment rates may be somewhat lower. Accordingly, it is expected that recruitment will be completed within 6 weeks. In the current study it is hoped to recruit participants primarily from skin condition charities/organisations so that university students are not over-represented in the sample. However, if less than half of the minimum sample required (n = 12) have been recruited three weeks after the study has been advertised by skin condition organisations, the study will be subsequently advertised using the researcher's and the University of Sheffield's volunteer lists. Recruitment will be closed after six weeks if the minimum sample size has been achieved or earlier if the maximum sample size has been achieved. Once recruited, participants will remain in the study for seven weeks (six weeks of the intervention plus follow-up one week later). It is therefore expected that the study overall will be completed in 13 weeks.

Ethical issues

Ethical approval. The proposal, information sheet, consent form, measures and intervention exercises for the current study will be sent to the University of Sheffield Department of Psychology Research Ethics Sub-Committee for approval through the online ethics application system. In addition, the University of Sheffield's research governance procedure will be followed, including completion of the 'Risk Assessment Checklist for University Sponsored Human-Interventional Studies' and public registration of the study on 'ClinicalTrials.gov'.

Informed consent. All potential participants will read an information sheet (see Appendix A) and complete a consent form (see Appendix B) online prior to taking part in the study. They will have the opportunity to ask the researcher any questions about their participation in the study via email. The researcher's email address will be provided on the information sheet.

Participant withdrawal. Participants will be able to withdraw from the study at any point until their data are anonymised. Participants will be informed of this on the information sheet and may contact the researcher by email to request that their data is destroyed should they subsequently wish to withdraw from the study.

Eight of the guided self-help emails will be automatically sent from Qualtrics based on completion of the baseline measures. If any participants contact the researcher to withdraw from the study, that participant's Qualtrics data will be exported (for ITT analyses) and then the participant's contact details will be deleted from Qualtrics so that further automatic emails are not sent to that participant.

Adverse effects. As with all psychological interventions, there is a risk that taking part in this study may raise participants' awareness of pre-existing distressing thoughts and feelings, leading to some distress during or after taking part in the study. Participants will be made aware of this possibility prior to taking part in the study via the information sheet (see Appendix A). The information sheet will also provide participants with signposting information for mental health support (e.g. the Samaritans) and advise them to speak to their GP if necessary. In addition, if

participants advise the researcher of any adverse effects via email, the researcher will be able to re-iterate options for further support as appropriate. The researcher previously worked in primary care mental health services for five years, providing guided self-help to people with depression and anxiety disorders, and is therefore experienced in dealing with emotional distress and signposting appropriately. If necessary, the researcher will discuss concerns with her primary supervisor, who is a clinical psychologist.

Confidentiality. Participants will be informed that their data will be kept confidential and that they will not be personally identifiable in any results of the study. Unique identification numbers will be used throughout the data sets. A data file will be created to contain participants' details and their identification numbers, for matching up quantitative data over time and to allow the destruction of data should participants wish to withdraw from the study. This data file will be password-protected and kept separately from the rest of the participants' data.

Spreadsheets containing participants' names and email addresses will also be created in order to administer the study—for sending emails on the correct dates and tracking participants' logins. No sensitive quantitative data will be kept in these spreadsheets, only dates. These spreadsheets will also be password-protected and kept separately from outcome measures and feedback data. Once data collection is complete, participants' names and email addresses will be replaced with their unique identification numbers.

Participants will be required to log into the study website solely to track user logins for the purpose of monitoring participants' engagement with the intervention from week to week. Participants will log into the website with a username (usually their first name) and password that has been allocated to them by the researcher. Participants will not be asked to provide any data via the study website, nor will they be able to access any other participants' details. No-one except the researchers involved in the study will have access to participants' contact details.

Data protection. Personally identifiable digital data will be stored securely as described above, on the lead researcher's university filestore. The lead researcher will be

the only person with administrator access to the study website. The study website is hosted on the University of Sheffield's servers, and therefore participants' contact details (names and email addresses used to administer user memberships) that are visible to the administrator on the study website will also be stored securely within the university's firewalls. Administrator access to the website is protected by requiring the administrator to log in from within the University of Sheffield's virtual private network (VPN) and uses two factor authentication, requiring a code accessed from the administrator's mobile phone. Wordfence, a Wordpress security plugin, is also being used to provide protection from brute force attacks (malicious attempts to gain access using repeated guesses at user names and passwords) on the frontend of the website. Participants will be made aware of how their data will be protected in the information sheet (see Appendix A).

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Table 1

Compassion-based self-help intervention for people with skin conditions

Session number	Session content	Homework activity
1	Normalising the difficulties of living with skin conditions. Explanation of the three systems of emotions (threat/protection, drive/excitement, and soothing systems) and soothing system as regulator of threat/protection system. Audio recording (and text version) of soothing rhythm breathing practice.	Practise soothing rhythm breathing, e.g., five minutes daily.
2	Tricky brain explanation (emotions and cognitive abilities). Vicious cycle of thoughts and emotions. Example thought record.	Notice self-criticism: fill in own examples on thought record. Continue breathing practice.
3	Example of how emotional tone of self-talk can affect our feelings. Audio recording (and text version) of 'compassionate other' imagery.	Practise 'compassionate other' imagery, e.g. five minutes daily.
4	Compassionate writing instructions. Example compassionate letter to oneself.	Write compassionate letter (5–15 minutes).
5	Explanation of qualities of compassion (wisdom, strength/authority, and commitment). Audio recordings (and text versions) of 'building the compassionate self' imagery and 'addressing self-criticism'.	Practise 'compassionate self' imagery, e.g. five minutes daily.
6	Explanation of why a written relapse prevention plan (summary of learning points) is helpful. Example relapse prevention worksheet.	Complete relapse prevention worksheet.