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A randomized controlled feasibility trial of online compassion-focused self-help for psoriasis

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Summary

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The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Background People with psoriasis can experience psychological distress that might be amenable to psychosocial self-help.

Objectives This study tested the feasibility and acceptability of two theoretically developed self-help interventions designed to reduce feelings of shame and improve quality of life.

Methods A randomized controlled feasibility trial was conducted comprising 130 participants with psoriasis who were randomly allocated to receive either compassion-based self-help (n = 65) or mindfulness-based self-help (n = 65), over a 4-week period. Both interventions were provided online.

Results The interventions were found to be acceptable, with over 70% of study completers reporting that they found the materials helpful. Of the 130 participants, 92 completed the study, with attrition at 29%. Both interventions showed modest yet statistically significant reductions in shame (Cohen's d = 0.20) and improvements in quality of life (Cohen's d = 0.40).

Conclusions Self-help based on compassion and mindfulness is acceptable to users, and can reduce feelings of shame and improve quality of life for people living with psoriasis.

Psoriasis is a chronic inflammatory skin condition, affecting 1-3% of the general population. 1 It tends to be highly visible to others, and can be associated with elevated distress in social contexts and the presence of a range of uncomfortable feelings, including stigma.^{2,3} Perceived stigmatization associated with psoriasis has been found to be a predictor of psychosocial distress 4-6 over and above disease severity, and an important factor in treatment adherence.⁷ The increased prevalence of psychological distress in patients with psoriasis indicates the need to provide access to psychological interventions,8 yet a recent systematic review found that the existing interventions for psoriasis have only small to medium effects in reducing psychological distress and improving quality of life. Moreover, these interventions are beset with methodological weaknesses, such as small sample sizes and heterogeneous outcomes.9 The findings of Zill et al.9 agree with earlier reviews, indicating that while psychological interventions show promise, further research with theoretically underpinned interventions and robust methods is urgently needed. 10-12

To ensure that psychological interventions are effective for patients with psoriasis, some researchers have recently investigated the value of adding into stress-reduction interventions some techniques that also seek to develop mindfulness and selfcompassion.¹³ Mindfulness-based interventions might be particularly appropriate for patients with psoriasis, as they can help people to increase their awareness of the present moment and as such reduce excessive preoccupation with bodily symptoms (such as itching). 14 Heightened levels of mindfulness and selfcompassion could also help patients to deal with the negative reactions of others and self-stigmatization that may perpetuate avoidant behavioural responses. 15 Indeed, existing evidence shows that patients with psoriasis might benefit from mindfulness-based interventions. 16-18 For example, an initial pilot study of a mindfulness-based stress-reduction intervention with patients receiving phototherapy showed improvements in skin clearance for the treatment group when compared with the active control, but not in anxiety or depression. 18 Similarly, other studies combining mindfulness-based interventions found no benefits on any of the psychosocial outcomes, including depression and anxiety. 19 The mixed results of studies examining mindfulness-based interventions for psoriasis show it is still unclear whether or not these interventions alleviate psychological distress, emphasizing the need for further research using more methodologically robust designs.

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Indeed, the mechanism behind the process of change in mindfulness is theorized to be complex, and the exact process of therapeutic change is not fully understood. Mindfulness consists of many facets, including fostering a self-compassionate stance and compassionate mind training (CMT), large emphasis on the development of self-compassion or self-soothing to help patients with psoriasis cope with the shame and self-criticism. Some researchers believe that combining mindfulness and self-compassion can target shame and self-criticism, those core problematic responses to psoriasis. However, there are only three small-scale randomized controlled trials investigating the impact of compassion-focused approaches with skin conditions, and all have shown promising results, particularly in lowering shame, depression, and skin complaints.

One way to further increase knowledge about the combined role of mindfulness and self-compassion is by testing these processes as an adjunct programme for patients with psoriasis, delivered in a form of self-help intervention. Self-help interventions can be particularly important as a first-step approach for individuals with mild level of distress. Thompson²⁶ has presented a model of stepped psychosocial care for skin conditions, with early steps focusing on the delivery of self-help interventions. These types of interventions allow an ongoing assessment of patients' needs and can motivate individuals who need it to seek further psychological intervention.²⁶ Hence, self-help interventions have the potential to provide a cost-effective first-line intervention, ^{16,17} yet very limited programmes exist for patients with psoriasis.

The present parallel-group randomized controlled study examined the efficacy of mindfulness, compared with compassion-based self-help interventions, in patients with psoriasis. The study had three aims: (i) to examine shame as the primary outcome variable, (ii) to investigate secondary outcomes associated with shame, namely self-criticism, and (iii) to assess the impact of the self-help interventions on quality of life (QoL).

Patients and methods

The current study recruited a community-based psoriasis sample via web-based psoriasis organizations and the University of Sheffield mailing list. The study was a feasibility trial, evaluating the acceptability, adherence and efficacy of compassion-focused self-help interventions accessed via email. This involved assessing the two self-help interventions' acceptability and adherence while seeking to determine the extent to which the interventions can bring about changes in targeted therapeutic outcomes (detecting primary efficacy). Ethics approval was gained through the University of Sheffield ethics board.

Participant characteristics and sample size

As illustrated in Figure 1 (CONSORT flow diagram), 170 individuals were recruited and screened via telephone through local and national psoriasis organizations and associations, relevant forums, and the University of Sheffield mailing list (detailed below). Selection criteria included working age adults

(aged 16+ years) with a self-reporting diagnosis of psoriasis by a general practitioner or dermatologist, and an experience of emotional distress in managing psoriasis (e.g. low mood and anxiety). Participants were excluded if they were concurrently engaged in a psychological treatment or if they had done so within 6 months. A total of 142 individuals consented to take part in the study. Data were extracted for 130 participants who met the inclusion criteria and were invited to participate (Figure 1). Most study completers were recruited from the Psoriasis Association (80%), followed by the University of Sheffield volunteer emailing list, the Psoriasis Help Organization forum, and the Psoriatic Arthritis forum. Self-reported psoriasis severity was collected on a 0–9 scale (0 not severe, 9 very severe), and 79% of the sample reported a severity rating of between 5 and 9 on trial entry.

Procedure and randomization

Following screening, eligible candidates were sent a link with a survey (smartsurvey.co.uk), consisting of the study information sheet, consent form and demographics, along with pretreatment (T1) measures, and were requested to complete it. Participants had to consent and read the information sheet prior to filling out T1 measures. The survey included an inbuilt eligibility screen, allocating eligible participants to continue with the T1 measures, with ineligible people to be advised that they could seek further support in primary care services (general practitioners).

After eligibility assessment, participants were randomly assigned to receive either a mindfulness or a compassion self-help intervention. To ensure an equal group of participants, that is a 50% chance of participants allocated to either condition, a simple within-sample randomization technique was used, with participants being randomized in a single block. A block randomization schedule with two conditions was developed and held by an independent statistical consultant who randomly matched codes next to participants' identity codes in a participant workbook.

Following allocation, the study researcher informed participants via an email on how to gain access to the self-help book, and what they should do with each session per week. The email suggested that participants read carefully the self-help written material in each of the 4 weeks, prior to accessing the MP3-file recorded techniques. Participants were also encouraged to apply the material as often as they could. On completion of the 4-week trial, participants in both groups completed a second set of measures (T2), using the same survey method. Overall, completion of each set of measures took approximately 10-15 min, and the survey was designed to be easy to read, navigate and complete with simple button responses.

Measures

Demographic variables

Information on gender, age, ethnicity and education was collected. In addition, participants were asked to record whether

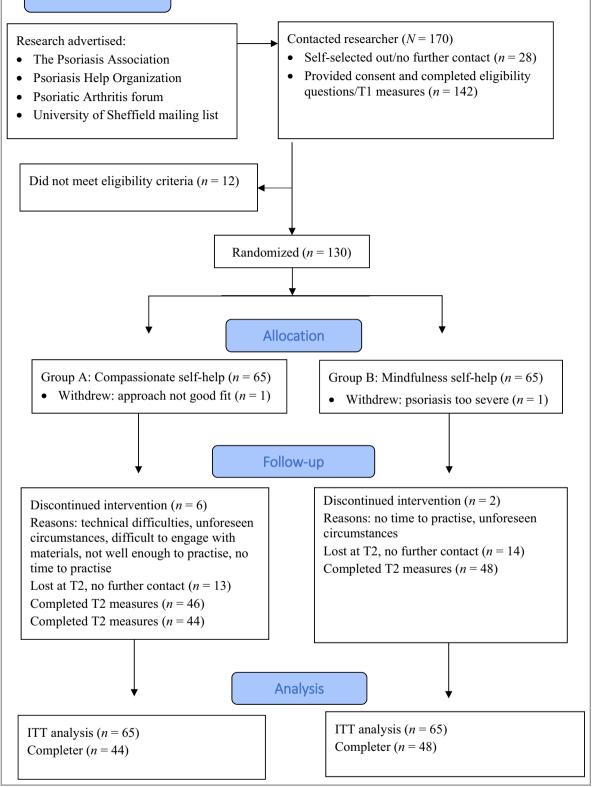


Figure 1 CONSORT flow diagram: participant flow through key study stages. T1, pretreatment; T2, post-treatment; ITT, intention to treat. Figure adapted from Schulz, 2010.38

Enrolment

or not (i) they get access to emotional support, (ii) they have any comorbid psychological and physical health conditions (including psoriatic arthritis), and (iii) they use any antidepressant medication.

Primary outcome

External shame The primary outcome measure was external shame as measured by the Other as Shamer Scale (OAS).²⁷ It measures negative self-beliefs held about other people's perceptions of the self through 18 items, rated on a 5-point Likert-type scale (0 = never to 4 = almost always). Cronbach's alpha showed a good internal consistency at 0.92.

Secondary outcomes

The Forms of Self-Criticizing/Attacking & Self-Reassuring Scale The Forms of Self-Criticizing/Attacking & Self-Reassuring Scale (FSCRS)²⁸ measures critical and reassuring self-evaluative responses in 22 items, separated into three subfactors: Inadequate-Self, Hated-Self and Reassured-Self. The Cronbach's alpha value for Hated-Self and Reassured-Self is 0.86.

The Dermatology Life Quality Index The Dermatology Life Quality Index (DLQI)²⁹ is a widely used QoL measure within dermatology research, with a Cronbach's alpha value of 0.78–0.79. It measures the extent to which the dermatological condition impacts on symptoms, daily activity, leisure, work and education and personal relationships, and impact of physical treatment. It comprises 10 items that are responded to on a 4-point Likert-type scale and the scores are summed to provide an impact of the condition on the patient's QoL.

Acceptability and use Following the end of the intervention period, participants also completed a self-help evaluation measure. This examined compliance, perceived acceptability and usefulness of the interventions on a 1-5 Likert-type scale (1 = strongly agree to 5 = strongly disagree).

Intervention development

The self-help materials were written by the authors, who have experience in providing one-to-one therapy using this model. Service user feedback was sought from the Psoriasis Association (UK). The two self-help interventions that were developed for the trial (one for mindfulness and another for compassion) were components of CMT. The first, compassionate self-help, is designed to strengthen compassionate intention and competencies. This intervention aims to teach patients with psoriasis how to react in a kind, caring and compassionate way to the experience of psoriasis, both through physically saying and doing things to alleviate psoriasis-related distress (e.g. by holding pain or itchy experiences gently, as if they were a crying baby or a priceless, fragile work of art), and by internally working with themselves through guided exercises (e.g. empathizing and thinking kindly about the experience they have gone through).

The second self-help intervention focused on developing mindfulness via a guided breathing exercise. This intervention focuses on cultivating a soothing rhythm of breathing. It focuses on fostering flexible attention to the psoriasis experience, and instead of cutting off or getting caught up in self-defeating thoughts and behaviours, engaging fully in more productive and valuebased activities by narrowing, focusing and sustaining attention on these activities. This can be cultivated via breathing exercises in which individuals are instructed to pay attention to and refocus on experiences they can control, as opposed to the itchy and uncomfortable sensations from psoriasis they cannot.

The final set of the two self-help interventions each comprised written materials and an audio MP3 file with exercises. The main written material followed a four-step format. In step 1, participants are introduced to the rationale of the two concepts examined, either developing a skill in compassionate self-imagery or a mindful breathing technique. In step 2, participants were prepared to overcome challenges in practising the exercises (such as emotional/cognitive barriers, e.g. 'I can't do this' or time constraints). In step 3, participants were introduced to the main techniques (developing compassionate self-imagery or mindful soothing rhythm breathing) through an accompanying audio MP3. In the final step 4, participants were invited to put together a plan to practise the newly acquired skills. The goal planner used in this step was based on implementation intention theory.30 Implementation intentions are specific plans of action, which specify exactly where and how to act in future situations.³¹ In a meta-analysis of 94 studies, implementation intentions had a medium-to-large effect on achievement of intended goals.³² A study investigating self-help for vitiligo augmented through implementation intentions showed enhanced self-help to be more effective than standard self-help.³³ Therefore, an implementation intention was embedded within both self-help interventions to enhance use of materials.

Statistical analysis

Data were analysed with IBM SPSS Statistics, Version 19.0 (IBM Corp., Armonk, NY, USA) with alpha level set at 0.05 for statistical tests. Data underwent both intention-to-treat (ITT) analysis (n = 130) and completer analysis (n = 92). To evaluate the success in randomization at baseline, group comparisons were calculated with χ^2 -tests for categorical variables and through multivariate analysis of variance (MANOVA) for continuous variables. The same procedures were conducted to compare completers and those who dropped out.

Pre-post effect sizes were calculated using starting mean – end mean/starting SD for both ITT and completers. To evaluate the efficacy of the self-help interventions, a two-way mixed analysis of variance (ANOVA; group or time effects and interaction effects) was conducted for each measure.

To evaluate self-help acceptability, usability and frequency of use, participant responses on the feedback questionnaire were converted to percentages, and χ^2 -tests were also conducted to explore differences between treatment groups.

Results

Attrition

Of the 130 participants randomized, 38 participants dropped out, with overall attrition at 29%. A MANOVA test revealed no significant difference between completers (n = 92) and noncompleters (n = 38) on the outcomes of interest $[F(4,125) = 2.09, P = 0.086, \eta p^2 = 0.06]$. Reasons for dropping out included technical difficulties, difficulties engaging with the materials, time constraints and poor health. Of those that dropped out, 27 were completely lost at follow-up.

Baseline comparisons

Preintervention, 130 participants were randomized into either the compassionate or mindfulness intervention (n = 65 each). There were no significant differences found between the intervention groups on the preintervention measures $[F(4,125) = 0.81, P = 0.52, \eta p^2 = 0.03]$. A significant difference in the percentage of participants prescribed antidepressant medication was found, with more people in the mindfulness group reporting the use of antidepressant medication (20%) compared with those in the compassion group (8%) $[\gamma^2 (1, n = 130) = 3.16, P = 0.04]$. There were no other significant differences between the intervention groups on the demographic variables (Table 1).

Descriptive statistics and effect size

Table 2 presents the group means and SDs for shame (OAS), self-criticizing, attacking and self-reassuring (FSCRS) and for QoL (DLQI), pre- and post-intervention for ITT (n = 130) and completers (n = 92). The effects were larger for study completers with small-moderate effects, with QoL showing the largest effects (ranging from 0.43 to 0.68).

Intention-to-treat effects of interventions

A two-way mixed ANOVA revealed no significant interactions (time × treatment group) or main effect of group, indicating no difference in the effectiveness of the two treatment groups in reducing shame. However, there was a significant effect of time, indicating that both groups showed a statistically significant reduction in shame from T1 to T2. This pattern of results was found for the other measures (Table 3). Repeating the analysis for study completers (n = 92) revealed the same pattern in the outcomes (Table 4).

User feedback

Feedback on the usefulness and usability (compassion n = 44, mindfulness n = 48) of the self-help interventions revealed similar group experiences. There were no adverse reactions reported. There was high agreement that the audio techniques were 'easy to follow': compassion 86%; mindfulness 96%. There was high agreement about the helpfulness of the information specific to the respective technique: compassion 74%; mindfulness 88%. A χ^2 -test indicated that the percentage who found information helpful did not differ by treatment condition $[\chi^2 (1, n = 92) = 1.92, P = 0.166]$. The goal planner, intended to enhance use of the materials, did not appear to be successful within the current study: 45% (compassion) and 54% (mindfulness) were either unsure or disagreed that it was useful. Finally, the perceived usefulness of the audio exercise was 62% (compassion) and 60% (mindfulness). Data on the pattern of use of the interventions revealed wide variation both within and between groups. Participants were more likely to have used the audio than the written components; daily audio use was 52% (compassion) and 63% (mindfulness).

Discussion

This is one of the first studies to provide support for the use of cognitive behavioural therapy self-help based on compassion and mindfulness in patients living with psoriasis. It is also one of only a few studies to examine the benefits such interventions might have on reducing skin-related feelings of shame and thoughts of self-criticism. Following the end of the intervention period, both treatment conditions showed modest yet statistically significant differences between the pre- and post-treatment group means on all the outcomes of interest including QoL. The present study findings differ from other recent studies insofar as finding positive benefits of

Table 1 Characteristics of sample by treatment group at baseline (n = 130)

	Compassion	Mindfulness	χ^2
Variable	(n = 65)	(n = 65)	P-valu
Gender			
Female	40	47	
Male	25	18	0.192
Age, years			
16-25	14	6	
26-35	19	17	
36-45	18	17	
46-55	8	16	
56–66	6	9	0.158
Ethnicity			
White	56	54	
Black, Asian & Mixed	9	11	0.627
Education			
Secondary	9	9	
Higher college	19	18	
University/postgraduate	37	38	0.980
Accessing emotional support	57	54	0.456
Comorbid health condition	12	12	1.0
Comorbid psychological	16	16	1.0
Psoriatic arthritis	12	17	0.292
Antidepressant medication	5	13	0.042

Table 2 Descriptive and pre-post effect sizes for intention to treat (ITT) (n = 130) and completers (n = 92)

Group	Mean intake	Mean end	Mean difference	SD intake	Cohen's d
Compassion ITT $(n = 65)$					
Shame (OAS)	28.95	26.09	2.86	12.66	0.23
Quality of life (DLQI)	14.63	11.38	3.25	7.19	0.45
Hated-Self (FSCRS)	5.95	5.26	0.69	4.64	0.15
Reassured-Self (FSCRS)	14.78	16.20	1.42	6.57	0.22
Mindfulness ITT $(n = 65)$					
Shame (OAS)	30.80	28.05	2.75	13.45	0.20
Quality of life (DLQI)	14.25	11.37	2.88	6.73	0.43
Hated-Self (FSCRS)	5.91	5.26	0.65	4.66	0.14
Reassured-Self (FSCRS)	15.49	17.08	1.59	6.11	0.26
Compassion completer ($n = 44$)				
Shame (OAS)	27.98	23.75	4.23	13.46	0.31
Quality of life (DLQI)	13.73	8.93	4.80	7.09	0.68
Hated-Self (FSCRS)	5.80	4.77	1.03	4.69	0.22
Reassured-Self (FSCRS)	15.34	17.43	2.09	7.06	0.30
Mindfulness completer ($n = 48$)				
Shame (OAS)	29.21	25.48	3.73	14.05	0.27
Quality of life (DLQI)	13.79	9.90	3.89	6.74	0.58
Hated-Self (FSCRS)	5.75	4.87	0.88	4.97	0.18
Reassured-Self (FSCRS)	16.42	18.56	2.14	6.53	0.33

OAS, Other as Shamer Scale; DLQI, Dermatology Life Quality Index; FSCRS, Forms of Self-Criticizing/Attacking & Self-Reassuring Scale.

Table 3 Intention-to-treat (ITT) analysis of variance (n = 130)

Measure	df	F	$\eta_p^{\ 2}$	P-value
Between subjects				
Shame (OAS)	1,128	0.72	0.01	0.398
Quality of life (DLQI)	1,128	0.03	0.00	0.866
Hated-Self (FSCRS)	1,128	0.00	0.00	0.977
Reassured-Self (FSCRS)	1,128	0.53	0.00	0.467
Within subjects				
Shame (OAS)	1,128	19.65	0.13	0.000
Time × group	1,128	0.01	0.00	0.932
Quality of life (DLQI)	1,128	40.71	0.24	0.000
Time × group	1,128	0.15	0.00	0.701
Hated-Self (FSCRS)	1,128	8.17	0.06	0.005
Time × group	1,128	0.01	0.00	0.922
Reassured-Self (FSCRS)	1,128	16.75	0.12	0.000
Time × group	1,128	0.05	0.00	0.818

df, degrees of freedom; OAS, Other as Shamer Scale; DLQI, Dermatology Life Quality Index; FSCRS, Forms of Self-Criticizing/ Attacking & Self-Reassuring Scale. P-values <0.05 (shown in bold) were considered statistically significant.

Table 4 Completer analysis of variance (n = 92)

Measure	df	F	$\eta_p^{\ 2}$	P-value
Between subjects				
Shame (OAS)	1,90	0.29	0.00	0.591
Quality of life (DLQI)	1,90	0.15	0.00	0.696
Hated-Self (FSCRS)	1,90	0.00	0.00	0.976
Reassured-Self (FSCRS)	1,90	0.68	0.01	0.413
Within subjects				
Shame (OAS)	1,90	20.94	19	0.000
Time × group	1,90	0.08	0.00	0.775
Quality of life (DLQI)	1,90	47.10	0.34	0.000
Time × group	1,90	0.51	0.01	0.479
Hated-Self (FSCRS)	1,90	8.38	0.09	0.005
Time × group	1,90	0.05	0.00	0.822
Reassured-Self (FSCRS)	1,90	17.53	0.16	0.000
Time × group	1,90	0.00	0.00	0.957

df, degrees of freedom; OAS, Other as Shamer Scale; DLQI, Dermatology Life Quality Index; FSCRS, Forms of Self-Criticizing/ Attacking & Self-Reassuring Scale. P-values < 0.05 (shown in bold) were considered statistically significant.

mindfulness- and compassion-based self-help. 23 We hypothesize that this is likely to be a result of our sample being selected so as to comprise a sufficient number of patients with psoriasis exhibiting some signs of significant distress, and thus our study avoided encountering the floor effects seen in some other studies.23

The perceived usefulness and acceptability of the interventions were examined at post-treatment through an evaluation questionnaire. Data available for 70% of the randomized sample for both treatment groups showed that the vast majority of participants reported finding the materials helpful and effective. The data examining the frequency of use of the interventions showed wide variations within both groups, with participants being more likely to use the audio than the written materials. This suggests that future development of self-help should utilize audio and video delivery formatting.

Both groups used the goal planner sporadically, and approximately half of the participants in each group reported feeling confused as to the usefulness of this part of the intervention. This is contrary to research that has found implementation intentions to promote compliance in a number of behavioural domains.³² While the current study did not intend to formally test the use of implementation intentions via the goal planner that was embedded in the materials of both groups, the use of implementation intentions in this form of self-help for psoriasis clearly requires further investigation.

The lack of an interaction effect between group and time may be attributed to the self-help interventions being components of single therapeutic modalities. In compassionate mind therapeutic approaches, mindful soothing rhythm breathing is used as a way to prepare one's mind for practice. Gilbert³⁴ has reflected that mindfulness allows for the ability to reflect on one's mental states and cultivate a calm mind. It could be argued that paying attention to the present moment, while letting go of preoccupations about the past or future, can in itself cultivate soothing and self-compassion. Thus, future randomized controlled trials would have to consider carefully the appropriateness of a chosen comparator. Future studies should attempt to evaluate each component separately with an additional group, targeted at compassionate and mindful techniques.

The study has several methodological limitations. Recruitment and delivery occurred completely online. This has enabled us to reach participants who might not be receiving active secondary dermatological care, but has also made the objective diagnosis of psoriasis difficult. For the same reasons, the online recruitment resulted in participation of younger in age female individuals who are usually open to new ideas and approaches. Most of the sample (80%) was recruited from the UK Psoriasis Association, and the participating group was well educated. This poses additional issues for generalization, particularly to older individuals or men. In the same vein, some of the patients were taking antidepressant medication, which might have affected the study findings, and also the overall sample size could be characterized as small for such a large community of patients with psoriasis. Future research should aim to recruit a larger and more heterogeneous group coming from dermatology clinics, who present with more medical and psychosocial challenges.35,36 Further, while current research supports the use of subjective disease severity ratings, as it has been found to be closely correlated with measures of distress,³⁷ the lack of an objective measure of psoriasis severity remains problematic and should be addressed in future studies. Additionally, information on age of onset, pruritus intensity, use of illegal substances or current treatment was not collected, and recording these types of data should be included in future studies. The study did not have the resources to conceal allocation or blind the research team. Effort was made to reduce bias through independent randomization and allocation.

In conclusion, the current study suggests that self-help interventions based on compassion-focused therapy have clinical relevance and are welcomed by a community psoriasis sample. This study demonstrated a respectable rate of recruitment over a 9-month period. The improvements were modest, yet demonstrate potential for the benefit of brief self-help

interventions. It is encouraging that, despite the limitations of unguided self-help, the study has shown self-help can reach a wide audience who do not have access to structured psychological support.

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