Clinical feasibility and acceptability study of an online mindfulness and self-compassion integrated psychoeducation program for eczema in adults

Sanae Kishimoto (✉ sanae.kishimoto@post.harvard.edu)  
Kyoto University  https://orcid.org/0000-0002-2341-8931

Ryosuke Shimizu  
Shimizu Dermatology Clinic

Norio Watanabe  
Kyoto University Graduate School of Medicine Faculty of Medicine: Kyoto Daigaku Daigakuin Igaku Kenkyuka Igakubu

Yosuke Yamamoto  
Kyoto University Graduate School of Medicine Faculty of Medicine: Kyoto Daigaku Daigakuin Igaku Kenkyuka Igakubu

Christopher Germer  
Harvard Medical School

Masafumi Tada  
Kyoto University Graduate School of Medicine Faculty of Medicine: Kyoto Daigaku Daigakuin Igaku Kenkyuka Igakubu

Ethan Sahker  
Kyoto University: Kyoto Daigaku

Toshi A. Furukawa  
Kyoto University Graduate School of Medicine Faculty of Medicine: Kyoto Daigaku Daigakuin Igaku Kenkyuka Igakubu

Research Article

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Abstract

Objective

Although mindfulness and self-compassion programs have been applied in clinical settings, no studies have reported their benefits for atopic dermatitis (AD). The aim of the study was to evaluate the feasibility and acceptability of an online group format of 8 weekly 90-minute sessions of a mindfulness and self-compassion program for adults with AD.

Results

In this single-arm, open label pre-post comparison study design, 15 adults (10 women; mean age, 38.3 ± 8.98 years) completed the intervention and assessment. The primary outcome was disease-specific quality of life (QOL) (Dermatology Life Quality Index and Skindex-16) at the 20-week follow-up. The secondary outcomes were other self-reported questionnaires, and descriptive feedback of the program. Assessments were conducted at baseline, mid-treatment, post-intervention, and at follow-up. Overall, there were no significant improvements. However, of the four participants whose QOL was largely impacted due to AD, the scores improved significantly, with minimal clinically important difference or greater change. All participants were satisfied with the program. This program could benefit adults with AD by improving QOL. Randomized controlled trials are warranted to elucidate the efficacy of the program. This study has been registered at the UMIN Clinical Trials Registry (ID: UMIN000030484).

Introduction

Atopic dermatitis (AD) is a chronic relapsing inflammatory skin disorder associated with intense itching experienced by 10–20% of children [1] and 2–5% of adults [2]. Symptoms of AD significantly impact patients’ quality of life (QOL) [3]. AD is associated with the lowest QOL among skin diseases [4]. Furthermore, AD has the highest disease burden among skin diseases, as measured by disability-adjusted life-years (DALYs) [5]. Sleep difficulties, anxiety, and depression are reported as common comorbidities of AD, and it is responsible for significant work impairment [6]. While previous AD studies have highlighted the importance of psychological interventions, sample sizes were generally small, and very few investigated the QOL improvement [7, 8].

The Mindfulness-Based Stress Reduction (MBSR) was introduced in the 1970s for treating chronic pain [9, 10], and group programs have been increasingly applied to myriad clinical symptoms [11–18]. Self-compassion is a key factor in mindfulness-based interventions [19, 20]. The Mindful Self-Compassion (MSC) program was developed in 2010 [21] and has been applied to general and clinical populations [22]. While MBSR focuses on building a non-judgmental relationship with stress, MSC emphasizes a compassionate relationship with oneself when coping with a condition.
MBSR resolves symptoms four times faster than light treatments alone among patients with moderate to severe psoriasis [23]. No known studies have reported the benefits or efficacy of MBSR or MSC in AD patients. Thus, clinically relevant programs for AD are needed. We examined the feasibility and acceptability of a mindfulness and self-compassion integrated online intervention program as a single-arm pilot study for adults diagnosed with AD.

Main Text

Methods

Study design and participants

This single-arm, open-label pre-post study recruited participants from Kyoto University and Shimizu Dermatology Clinic, via posts on social media and word-of-mouth in December 2017. Participants were assessed for eligibility and were included in the study if they (1) were 18–59 years old, (2) self-reported an AD diagnosis obtained by a dermatologist, (3) received treatment/under observation for itchy skin, (4) could access the internet and participate in the online program, (5) could attend all sessions and complete home practice, and (6) could comprehend the purpose and risks of this study. Patients were excluded if they were (1) diagnosed with psychosis, personality disorders, post-traumatic stress disorder, or acute stress disorder, (2) receiving psychotherapy at the time of this study, (3) attending other mindfulness or compassion programs, (4) unable to understand Japanese, (5) related to the study researchers, or (6) deemed ineligible to participate in this study by the study researchers. Participants were not compensated in any way.

Intervention

The intervention consisted of an online group psychoeducation program that uniquely integrated elements of the scientifically proven MBSR and MSC programs. This involved weekly 90-minute live interactive online sessions of 8-weeks in duration, an optional silent 5-hour meditation retreat, and a 180-minute booster session via a cloud-based videoconferencing platform (Zoom Video Communications Inc., 2016). During the 3-hour orientation, the participants introduced themselves, received guidelines for the sessions, and previewed the meditations. All eight sessions were conducted online only on the same day and time of the week, each week. Participants chose between the offline and online formats for the orientation, the optional silent meditation retreat, and the booster session at their convenience, as a hybrid format was allowed. The first four sessions incorporated key elements of the MBSR. Sessions five to eight contained key elements of MSC (Table 1). Participants were given audio meditation guides and home practice regimens. The instructions were available for participants on the education technology platform PowerSchool Learning (PowerSchool Group LLC., 1997).
Table 1
Outline of sessions

<table>
<thead>
<tr>
<th>Session</th>
<th>Theme</th>
<th>Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1</td>
<td>Introduction to mindfulness, awareness of body</td>
<td>90</td>
</tr>
<tr>
<td>Session 2</td>
<td>Awareness of body and breath</td>
<td>90</td>
</tr>
<tr>
<td>Session 3</td>
<td>Reactivity to stress</td>
<td>90</td>
</tr>
<tr>
<td>Session 4</td>
<td>Responding to stress</td>
<td>90</td>
</tr>
<tr>
<td>Session 5</td>
<td>Introduction to Self-compassion</td>
<td>90</td>
</tr>
<tr>
<td>Session 6</td>
<td>Loving-kindness for oneself, inner compassionate voice for self-motivation</td>
<td>90</td>
</tr>
<tr>
<td>Retreat</td>
<td>Integration of practice</td>
<td>300</td>
</tr>
<tr>
<td>Session 7</td>
<td>Exploring difficult emotions and shame</td>
<td>90</td>
</tr>
<tr>
<td>Session 8</td>
<td>Self-appreciation, integrating mindfulness and self-compassion into daily life</td>
<td>90</td>
</tr>
<tr>
<td>Booster session</td>
<td>Experiencing key practices and reflection</td>
<td>180</td>
</tr>
</tbody>
</table>

Interventions were led by a masters-level Japanese licensed clinical psychologist with certification in mindfulness and psychotherapy from the Institute for Meditation and Psychotherapy in Massachusetts, formal MBSR and MSC training from the University of California, San Diego and the Center for Mindful Self-Compassion, and teaching experience in MBSR and MSC programs in Japan. The teaching manual for this intervention was developed by the instructor and a clinical psychologist, a co-developer of the MSC program, who integrated the program for adults with AD. A psychiatrist with clinical research experience in cognitive behavioral therapy approved the quality of the manual. Video recordings of all online sessions monitored the teaching quality and adherence to the protocol. Participants were able to watch and review the videos after each session to deepen their understanding.

**Outcomes**

Assessments were conducted at baseline, mid-intervention (week 4), post-intervention (week 8), at week 12 prior to the booster session, and at week 20 from baseline (See Additional file 1). The primary outcome was skin disease specific QOL at week 20. We used two questionnaires for skin disease specific QOL (both English and Japanese versions are validated): the Dermatology Life Quality Index (DLQI) [24, 25] and the Skindex-16 [26, 27]. The DLQI ranges from 0 to 30 with $0–1 = $no effects on QOL, $2–5 = $small effects, $6–10 = $moderate effects, $11–20 = $very large effects, and $21–30 = $extremely large effects. The Skindex-16 comprises three scales: symptoms, emotions, and functioning. The total score ranged from 0–100. For both DLQI and Skindex-16, high scores signify reduced QOL.
Secondary outcomes included the Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) [28], itchiness numeric rating scale, Mindful Attention Awareness Scale (MAAS) [29], Self-Compassion Scale (SCS) [30], Hospital Anxiety and Depression Scale (HADS) [31], and adherence to self-care, which indicated the patient's willingness to follow their physician's instructions. Participants rated their satisfaction level and provided descriptive feedback regarding their experience using qualitative data.

**Data collection**

Study data were collected and managed using a secure web-based electronic data capture system, Research Electronic Data Capture (REDCap), hosted by the Department of Clinical Biostatics, Graduate School of Medicine and Faculty of Medicine, Kyoto University. Participant identifiers were masked and assigned unique study codes. Participants were informed that their data would be concealed from the instructor and researchers.

**Statistical analyses**

We examined the feasibility and acceptability of our intervention by evaluating participant adherence, program satisfaction, and any technical issues they faced. Primary and secondary outcomes were evaluated and estimated the program's effectiveness in preparation for a randomized controlled trial (RCT). To calculate differences, and compare pre- and post- intervention values, a paired sample t-test was performed using IBM SPSS Statistics software. P-values < 0.05 were considered statistically significant. Qualitative data regarding descriptive feedback from participants were reviewed.

**Results**

**Participants**

Twenty-eight participants were enrolled between December 2017 and January 2018; 13 of whom were ineligible to participate as they lacked sufficient time for the program (n = 7), were undergoing psychiatric treatment (n = 2), did not provide consent (n = 2), had prior knowledge of mindfulness (n = 1), and were unable to use a computer due to a physical illness (n = 1). The intervention and assessment for the remaining 15 participants (10 women; 5 men) was conducted between January and June 2018. Of the 15 participants, six were recruited from the Shimizu Dermatology Clinic, four via social media posts, three via word-of-mouth, and two from Kyoto University. The average age of the participants was 38.3 ± 8.98 years (Table 2). Two groups were established based on the availability schedules of the participants.
Table 2
Baseline characteristics of participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Sample (N = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>38.3 (8.98)</td>
</tr>
<tr>
<td>Sex (female), n (%)</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td><strong>Education (years), mean (SD)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; High school</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Some college or vocational school</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>College graduate</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td><strong>Marital status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td>Single, divorced, separated or widowed</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Married</td>
<td>4 (26.7)</td>
</tr>
<tr>
<td><strong>Living situation, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>By oneself</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td>With someone</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td><strong>Clinical characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Age of onset (years), mean (SD)</td>
<td>5.2 (7.2)</td>
</tr>
<tr>
<td>Outpatient clinic visit (yes), n %</td>
<td>9 (60.0)</td>
</tr>
<tr>
<td><strong>Frequency of out-patient visit, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Monthly or more</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>Up to once three months</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Up to once six months</td>
<td>2 (60.0)</td>
</tr>
<tr>
<td>N/A</td>
<td>7 (60.6)</td>
</tr>
<tr>
<td><strong>Use of steroid ointment, n (%)</strong></td>
<td>6 (40.0)</td>
</tr>
<tr>
<td><strong>Frequency of use of steroid ointment</strong></td>
<td></td>
</tr>
<tr>
<td>Only use when getting worse</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Proactively use on a regular basis even when getting better</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>N/A</td>
<td>9 (60.0)</td>
</tr>
</tbody>
</table>
Feasibility and acceptability

Thirteen (86.7%) participants attended all eight planned weekly sessions. We included live make-up sessions for missed lessons and video recordings of all the sessions. Two participants contacted us in advance to inform that they would miss two scheduled live sessions. They attended one live make-up session and watched one video-recorded session each. Therefore, all participants completed all eight sessions. There were no major technical problems with the Zoom online platform and no adverse events were reported. Assessment response rates at all time points were all 100%.

Fifteen (100%) participants reported satisfaction with this program (very satisfied: 10 [66.7%] participants, somewhat satisfied: 5 [33.3%] participants) and positively rated the quality of the program (10 [66.7%] participants: “very good”, 5 [33.3%] participants: “somewhat good”). Thirteen (86.7%) participants stated that they would recommend this program to other patients with skin diseases. Regarding the format of the intervention, 11 (73.3%) participants reported that the duration of each session (90-min) was appropriate. Twelve (80%) participants found the numbers of sessions suitable. Fourteen (93.3%) participants preferred the web-based format (see Additional file 2). Fifteen (100%) participants thought home practices were helpful (7 [46.7%] participants: “very helpful”, 8 [53.3%] participants: “somewhat helpful”). The top five home practices that participants considered helpful are shown in Additional file 3.

Primary and secondary outcomes

The primary outcomes showed improved QOL (DLQI score: 8.3 vs. 6.1; Skindex-16 score: 43.5 vs. 36.4 at baseline and at week 20, respectively), but the differences in the primary and secondary outcomes were not significant (Table 3). In the post-hoc analysis, we analyzed the binary data based on their impact on the baseline QOL. The DLQI improved significantly (t = 3.32, P = 0.045) at week 20 among all four participants with DLQI scores above 11 (Table 3), showed minimal clinically important difference (MCID) or greater change, which indicated that their AD-related QOL had improved. The percentage of clinically meaningful improvement in DLQI differed significantly (P = 0.001) between the groups with DLQI scores ≥ 11 and DLQI scores < 11 (the DLQI ≥ 11 group was 100% and 33%, respectively). Additional files show the mean change from baseline of the DLQI scores for individual participants (See Additional file 4), and qualitative data regarding participant perspectives (See Additional file 5). Participants reported that their relationships with AD and themselves were transformed because they responded mindfully and compassionately.
Table 3
Primary and secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>Baseline (week 4)</th>
<th>Mid-intervention (week 4)</th>
<th>Post-intervention (week 8)</th>
<th>Follow-up (week 12)</th>
<th>Follow-up (week 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DLQI, mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All participants (N = 15)</td>
<td>8.3 (7.1)</td>
<td>7.7 (7.8)</td>
<td>6.4 (4.7)</td>
<td>6.9 (6.8)</td>
<td>6.1 (4.6)</td>
</tr>
<tr>
<td>Participants with DLQI ≥11 (N = 4)</td>
<td>17.5 (5.4)</td>
<td>15.8 (9.6)</td>
<td>9.0 (3.4)</td>
<td>9.0 (7.0)</td>
<td>10.0 (4.9)</td>
</tr>
<tr>
<td>Skindex-16, mean (SD)</td>
<td>43.5 (27.8)</td>
<td>45.4 (31.7)</td>
<td>42.7 (29.1)</td>
<td>43.3 (29.4)</td>
<td>36.4 (25.3)</td>
</tr>
<tr>
<td>PO-SCORAD, mean (SD)</td>
<td>36.1 (21.3)</td>
<td>32.4 (22.7)</td>
<td>31.9 (21.4)</td>
<td>34.6 (25.7)</td>
<td>29.3 (19.4)</td>
</tr>
<tr>
<td>Bothersome itchiness, mean (SD)</td>
<td>3.1 (1.5)</td>
<td>3.1 (1.5)</td>
<td>3.1 (1.4)</td>
<td>3.3 (1.6)</td>
<td>2.8 (1.5)</td>
</tr>
<tr>
<td>Itchy scale, mean (SD)</td>
<td>3.7 (2.4)</td>
<td>4.3 (3.4)</td>
<td>4.5 (3.1)</td>
<td>4.1 (2.9)</td>
<td>3.6 (2.4)</td>
</tr>
<tr>
<td>MAAS, mean (SD)</td>
<td>4.3 (0.9)</td>
<td>3.8 (0.9)</td>
<td>3.98 (0.96)</td>
<td>4.1 (0.95)</td>
<td>4.0 (1.0)</td>
</tr>
<tr>
<td>SCS, mean (SD)</td>
<td>3.1 (0.6)</td>
<td>2.97 (0.6)</td>
<td>3.2 (0.7)</td>
<td>3.2 (0.8)</td>
<td>3.3 (0.95)</td>
</tr>
<tr>
<td>HADS Anxiety, mean (SD)</td>
<td>4.9 (4.1)</td>
<td>5.3 (4.1)</td>
<td>5.9 (4.7)</td>
<td>6.9 (5.9)</td>
<td>6.9 (5.7)</td>
</tr>
<tr>
<td>HADS Depression, mean (SD)</td>
<td>5.3 (2.3)</td>
<td>7.2 (3.6)</td>
<td>6.9 (3.5)</td>
<td>6.5 (4.7)</td>
<td>6.3 (4.0)</td>
</tr>
<tr>
<td>Adherence to self-care, Always n/N</td>
<td>66.7%</td>
<td>50.0%</td>
<td>83.3%</td>
<td>66.7%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Topical Steroid (N = 6) †</td>
<td>40.0%</td>
<td>80.0%</td>
<td>66.7%</td>
<td>60.0%‡</td>
<td>66.7%</td>
</tr>
</tbody>
</table>

† For those who applied topical steroid at baseline only
‡ One participant answered not applicable

DLQI, Dermatology Life Quality Index
Discussion

To the best of our knowledge, this is the first study to examine the feasibility and acceptability of an online live group format mindfulness and self-compassion integrated intervention for adults diagnosed with AD. Our online program contributes to the literature [21–23] by demonstrating strong feasibility and acceptability for adults with AD. This program may enhance AD-specific QOL outcomes, especially for individuals reporting a low QOL. Standard MBSR and MSC protocols require participants attend at least six of the eight sessions and all participants in this study met this requirement. All participants completed the assessments at all time points and indicated that they were satisfied with the program. We confirmed that the online group format was also preferred by adults with AD. Our findings of the 12-week follow-up assessment revealed that there was an improvement trend in the QOL. Therefore, our results suggested that daily home practice was beneficial to AD patients over time.

People with severe AD symptoms, especially facial AD, can be hesitant when going out. Therefore, it was valuable for participants to access this group program. Furthermore, due to the limited access and resources for mindfulness therapists in Japan, the online format made it possible for participants to receive such therapeutic education. Our qualitative data (See Additional file 5) revealed that both mindfulness and self-compassion were essential for participants to strengthen their practice. Symptoms of AD have an impact on QOL, and patients are often in pain, with difficult symptoms and experience unnecessary distress if self-blame and judgment are directed at them. By nurturing self-compassion based on mindfulness, they can intentionally choose to direct kindness, understanding, and self-care to their skin and to themselves.

Conclusions

Our study revealed that the online mindfulness and self-compassion integrated program developed in this study was feasible and acceptable among adults with AD. There were no significant changes in QOL for the participants. However, findings from this first feasibility study suggested that this program may enhance AD-specific QOL outcomes for those with a lower QOL. Additional RCTs are needed to examine the clinical efficacy of our program.

Limitations

This study was a single-arm, open-label pre-post study with a small sample size. Thus, it will be necessary to conduct RCTs to evaluate its effectiveness. However, we investigated its clinical feasibility and acceptability of the interventions. One important limitation was that we included participants with relatively good QOL, provided they met the inclusion criteria. Therefore, we did not anticipate much
enhancement of QOL after the intervention in these participants. Because the main purpose of our study was to investigate its feasibility, we did not exclude participants based on their QOL.

**Abbreviations**

AD  
Atopic Dermatitis  
DLQI  
Dermatology Life Quality Index  
HADS  
Hospital Anxiety and Depression Scale  
MAAS  
Mindful Attention Awareness Scale  
MBSR  
Mindfulness-Based Stress Reduction  
MCID  
Minimal Clinically Important Difference  
MSC  
Mindful Self-Compassion  
PO-SCORAD  
Patient-Oriented SCORing Atopic Dermatitis  
QOL  
Quality Of Life  
REDCap  
Research Electronic Data Capture  
RCT  
Randomized Controlled Trial  
SCS  
Self-Compassion Scale

**Declarations**

**Ethics approval and consent to participate**

The study was conducted in accordance with the Declaration of Helsinki on the ethical principles established for research involving human subjects and the ethical guidelines for clinical studies published by the Japanese Ministry of Health, Labor, and Welfare. The study was approved by the Ethics Committee of Kyoto University Graduate School of Medicine (protocol code C1291 and December 2017). All participants provided written informed consent for participation after receiving an explanation of the purpose and procedures of the study. This study has been registered at the UMIN Clinical Trials Registry (registration number: UMIN000030484).
Availability of data and materials

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to IRB protocol and procedures.

Funding

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Consent for publication

Written informed consent was obtained from the patients to publish the findings in this paper.

Competing Interests

TAF reports personal fees from Mitsubishi-Tanabe, MSD and Shionogi, and a grant from Mitsubishi-Tanabe, outside the submitted work. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results. TAF has a patent 2018-177688 pending. All the other authors report no financial or other conflicts of interest.

Author's Contributions

SK, RS, NW, YY, CG, MT, and TAF developed the study protocol. SK developed and conducted the program. NW, YY, CG, ES and TAF supervised the study implementation. SK and RS recruited participants. SK intervened with the participants. SK, NW, YY, CG, MT, ES and TAF contributed to the interpretation of the results. SK developed the grant proposal and was responsible for the study implementation and management. SK drafted the manuscript. All authors critically reviewed the results and the manuscript, and approved the final version of the manuscript.

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**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- [SupplementarydataSanaeKishimoto20220505.docx](#)