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BRIEF REPORT

Clinical Efficacy of a Digital Intervention for Patients with Atopic Dermatitis: a Prospective Single-Center Study

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ABSTRACT

Introduction: Improving disease awareness and treatment adherence is key for the long-term management of atopic dermatitis (AD). Digital interventions can support patients in disease self-management and adopting a healthier lifestyle through behavioral modifications. We aimed to test the clinical efficacy of a digital program in patients with AD.

Methods: Adults with mild-to-severe AD were recruited for a 6-week feasibility study. The intervention was delivered through a mobile app and consisted of symptom and trigger education, treatment reminders, lifestyle coaching, and healthy lifestyle support. Here we report the secondary outcomes of intervention efficacy on clinical symptoms, as assessed by Scoring Atopic Dermatitis (SCORAD) and Patient-Oriented Eczema Measure (POEM), on health-related quality of life (HR QoL) as assessed by Dermatology Life Quality Index (DLQI), and changes in behaviors related to disease management as assessed by a six-item questionnaire.

Results: Twenty of 21 patients (95.2%) completed the program (81% female, mean age 31.4 years, mean time from diagnosis 26.8 years). Clinical symptoms and patient-reported global severity improved by 44% and 46%, respectively, while HR QoL improved by 41% ($p < 0.001$ for all measures). Adherence to treatments and preventive measures improved from pre- to post-intervention, including skincare, avoidance of triggers, and disease-related knowledge. A significant interaction was observed between increased treatment adherence and clinical improvement, such that larger clinical improvements were observed in patients with higher treatment adherence.

Conclusion: Patients with AD are open to and can benefit from a digitally delivered targeted intervention, as demonstrated by significant

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improvements in treatment adherence and related clinical outcomes.

Keywords: Atopic dermatitis; Digital intervention; Eczema; eHealth; Health-related quality of life

Key Summary Points

Atopic dermatitis (AD) is a chronic inflammatory condition that can be managed with medications, topical creams, and disease-conscious behaviors (e.g., trigger avoidance).

Digital interventions are electronically delivered programs that can support patients living with chronic diseases to adopt behaviors that lead to better disease management.

Reduced AD severity and improved health-related quality of life, treatment adherence, trigger avoidance, and behaviors related to disease self-management were associated with using the 6-week digital program.

Digital interventions can be effective supplements to increase the efficacy of existing treatments of AD.

INTRODUCTION

Atopic dermatitis (AD) is a common, chronic skin disease that usually starts in childhood and is estimated to affect up to about 20% of children and 10% of adults worldwide [1]. There is less information on the prevalence of AD in Scandinavian countries, but a few studies reported a prevalence between 20% and 30% in children and 10% and 20% in adults [2–5]. Currently, management of AD is focused on avoiding triggers, improving skin hydration, and reducing skin inflammation, and it is largely dependent on the disease severity and the patients' adherence [6, 7]. Poor treatment adherence is, however, a significant issue. Reasons for poor adherence include inconvenience of treatments, forgetfulness, fear of adverse effects (e.g., with topical corticosteroids), and poor understanding of treatments and disease chronicity [7]. Exploring new ways to improve patients' self-efficacy and treatment adherence is important, as it may improve the patient's overall treatment outcome and quality of life and reduce the economic burden of AD [11, 12].

Digital therapeutics can address several gaps in the management of chronic diseases such as AD. These are evidence-based, software-driven therapeutic interventions that are delivered to patients online and can be used as a supplement to—or replacement for—existing treatments [8]. They were initially developed for diabetes care and are now increasingly being used for various chronic conditions [9–12]. Few studies have explored the benefits of digital interventions in the context of AD, and these focused on a single aspect of disease management such as psychological support, remote patient monitoring, or medication reminders [13–16]. However, management of AD requires an integrative approach, and no holistic digital program targeted at AD was previously tested that incorporates all the above components.

We recently developed a digital program to provide patient education, medication reminders, symptom tracking, stress reduction, and sleep improvement, and to overall facilitate behavior change toward self-efficacy [13–15, 17]. In this study, we tested the preliminary efficacy of a novel AD program delivered via a mobile app platform.

METHODS

Study Design and Participants

We conducted a 6-week, single-arm feasibility trial at the Hudlaeknastodin Dermatology Clinic in Iceland between November 2021 and January 2022. The study included pre- and post-clinical assessment and subjective reporting of AD symptoms and their influence on health-related quality of life (HR QoL). Twenty-one patients were recruited through advertisements

on flyers and social media and invitation from a patient registry. Interested patients were given further details in handouts. Potential participants were screened by the study nurse and were required to sign an informed consent prior to completing the pre-program clinical assessment and questionnaires, downloading the app, and enrolling in the AD digital intervention. The study was approved by the Icelandic National Bioethics Committee (institutional review board registration number VSNb2021090028/03.01).

Patients were eligible if they were 18 years or older with mild-to-severe AD, understood verbal and written Icelandic, and owned and knew how to operate a smartphone. Patients who were receiving phototherapy or oral treatment within 4 weeks of study start, or biological treatment for AD, had other inflammatory skin conditions, or were pregnant were excluded from the study.

The Digital Intervention

The digital intervention was delivered through a smartphone app developed by Sidekick Health [18, 19]. It uses gamification with principles of behavioral psychology to motivate users and achieve behavioral modifications in patients with chronic illnesses. The app prompts users to complete daily missions themed around nutrition, exercise, mindfulness, disease-specific educational content, and general health. The AD program particularly focused on medication reminders, disease education, patient-reported outcomes (PROs) on AD symptoms and quality of sleep, energy and stress levels, and healthy lifestyle coaching, including trigger education (Fig. 1).

Measurements

This paper reports changes in disease severity and HR QoL, and adherence to treatments and preventive measures. The clinical assessment and validated patient-reported outcomes (PRO) questionnaires were administered before participants started the program and within 1 week after program finalization. Outcomes of program retention and engagement are reported separately [20].

A designated dermatologist assessed AD severity using Scoring Atopic Dermatitis (SCORAD), including lesional extent and severity of six signs (redness, swelling, lichenification, excoriation, oozing, dryness). Sleep-related problems and itching were patient-reported on a visual analog scale [21, 22].

PROs on AD severity were measured by Patient-Oriented Eczema Measure (POEM), a seven-item questionnaire assessing the frequency of AD symptoms in the past week. PROs on HR QoL were measured by the Dermatology Life Quality Index (DLQI), a ten-item questionnaire assessing impact of skin disease on quality of life [23, 24].

Adherence to treatments and preventive measures recommended to patients with AD was evaluated using a six-question survey, focusing on regular skincare, avoiding triggers such as drying and irritating substances, avoiding smoking at home, learning relaxation techniques, seeking advice on self-help, and using AD-related educational materials [25]. Patients could answer each question indicating the adoption of recommended behaviors as "never," "partly," or "regularly."

Data Analysis

Results are presented as mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables and as count and percentages for categorical data. The changes in clinical symptoms from baseline to post-intervention were tested with paired *t*-tests. Additionally, we applied established cut-offs to the clinical assessment scores (SCORAD [26], POEM [23], DLQI [27, 28]) to define the severity of the clinical picture for each patient at baseline and at follow-up. Counts and percentages for the treatment adherence questions were computed for both baseline and follow-up. To explore the relationship between treatment adherence and the clinical changes, we stratified the sample into two groups according to the answers to question one in the treatment adherence questionnaire ("Do you use regular

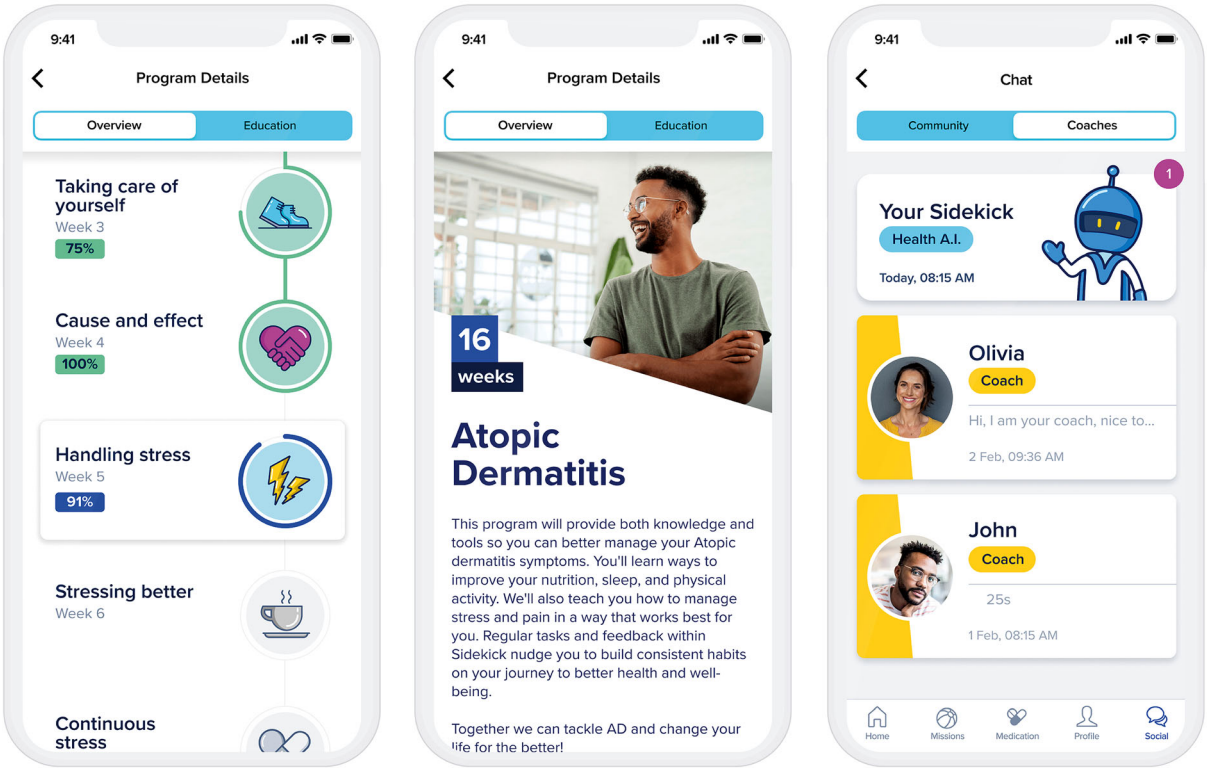

Fig. 1 App user interface showing missions and features. The educational content in the program focused on different topics each week, such as mindfulness and stress, and users also received an overview of the whole program. In addition to education and missions, coaches were also sending regular, personalized motivational messages to participants

skincare?"). The "high adherence" group was defined as people who maintained (answered "regularly" both pre- and post-program) or reached high treatment adherence (answered "never" or "partly" pre-program and "regularly" post-program); the "low adherence" group was defined as those who maintained lower adherence (answered either "never" or "partly" both pre- and post-program) or worsened their adherence (answered "regularly" pre-program and "partly" or "never" post-program, or "partly" pre- and "never" post-program). All statistical analyses were run in R version 4.1.2.

RESULTS

Study Population and Program Engagement

Twenty-one patients with AD were enrolled in the study, 20 of whom finished the program (95% completion); one discontinued after week 1. The mean (SD) time since AD diagnosis was 26.8 (11) years and body mass index (BMI) was 25.7 kg/m^2 (5.2); 95% were nonsmokers, and in total 71% had attended university (Table 1). All participants reported using topical treatments, the most common of which were corticosteroids [n = 19 (90.5%)]. Ten (47.6%) reported applying moisturizers during the study period. Four (19%) individuals reported using oral antihistamines. Most participants (n = 20) engaged with the medication reminder and disease education features of the app.

AD Severity

In general, symptom severity decreased over time (Fig. 2a). While about half the patients at baseline had severe AD symptoms as measured by SCORAD, at post-program most of these patients had only moderate or mild symptoms

Table 1 Baseline characteristics and engagement with in-app medication reminders and disease education

Baseline characteristics	Value (N = 21)
Age (years), mean (SD)	31.4 (8.7)
Female, *n* (%)	17 (81)
Years since diagnosis, mean (SD)	26.8 (11.3)
BMI (kg/m^2) mean (SD)	25.7 (5.2)
Obese ($\geq$ 30), *n* (%)	5 (23.8)
Overweight (25.0–29.9), *n* (%)	6 (28.6)
Normal weight (18.5–24.9), *n* (%)	10 (47.6)
Education, *n* (%)	
High school	1 (4.8)
College	5 (23.8)
University	15 (71.4)
Smoker status, *n* (%)	
Current	1 (4.8)
Former	4 (19.0)
Nonsmoker	16 (76.2)
Used medication reminders, *n* (%)	20 (95)
Used disease education, *n* (%)	20 (95)

BMI body mass index, *IQR* interquartile range, *SD* standard deviation

and a few participants were completely cleared of symptoms. Strikingly, all patients who reported severe or very severe symptoms on the POEM questionnaire pre-program reported only moderate or mild symptoms, or being clear from symptoms, by program end. Similarly, most people whose lives were severely or moderately affected by their skin disease pre-intervention (as assessed with DLQI) reported only moderate or (mostly) mild effects, respectively, post-intervention.

All clinical outcome measures improved significantly from pre- to post-intervention (Fig. 2b, Supplementary Table 1). The mean (SD) SCORAD significantly decreased from 56.1 (16.7) to 31.2 (18.4) (44% change, $p < 0.001$), and subjective symptoms assessed by POEM decreased from 15.7 (6.7) to 8.5 (4.9) (46% change, $p < 0.001$). DLQI assessment showed that the participants' HR QoL was affected significantly less by their skin disease after the program [mean (SD) pre: 7.9 (4.5), post: 4.6 (4.0), 41% change, $p < 0.001$]. Importantly, the observed improvements met the minimal clinically important difference threshold in 80%, 75%, and 66% of patients respectively for SCORAD, POEM, and DLQI [16, 18].

Treatment Adherence

We found a trend toward overall increase in participants' reported adherence to treatments and preventive measures from pre- to post-intervention (Fig. 3), including applying regular skincare [pre: n = 9 (43%), post: n = 14 (70%)]. Similarly, five (24%) reported that they never avoided triggers (e.g., excessive hand washing, using strong soaps and detergents) pre-program, while all participants paid attention to this at least partly post-program. Similar behavioral improvements were seen for all other questions regarding smoking, self-help, relaxation, and disease-related education.

We additionally explored how medical treatment adherence impacted the efficacy of the intervention. Individuals who maintained or increased their usage of regular skincare ("high treatment adherence") showed significantly larger improvements in their total SCORAD scores ($p < 0.005$) and a trend toward higher POEM and DLQI scores post-program (Fig. 4). These individuals were also significantly more active in the app: they used it a median of 40 out of 42 days (IQR 35.3, 41.8), compared with the "low adherence" group, who used it on 32 days (IQR 24.6, 38.5), $p < 0.05$.

DISCUSSION

This study demonstrated the preliminary efficacy of a digital intervention developed for patients with AD. We found high retention as all but one participant completed the full program, and significant improvements in AD signs and symptoms and patients' HR QoL, which met the minimal clinically important difference

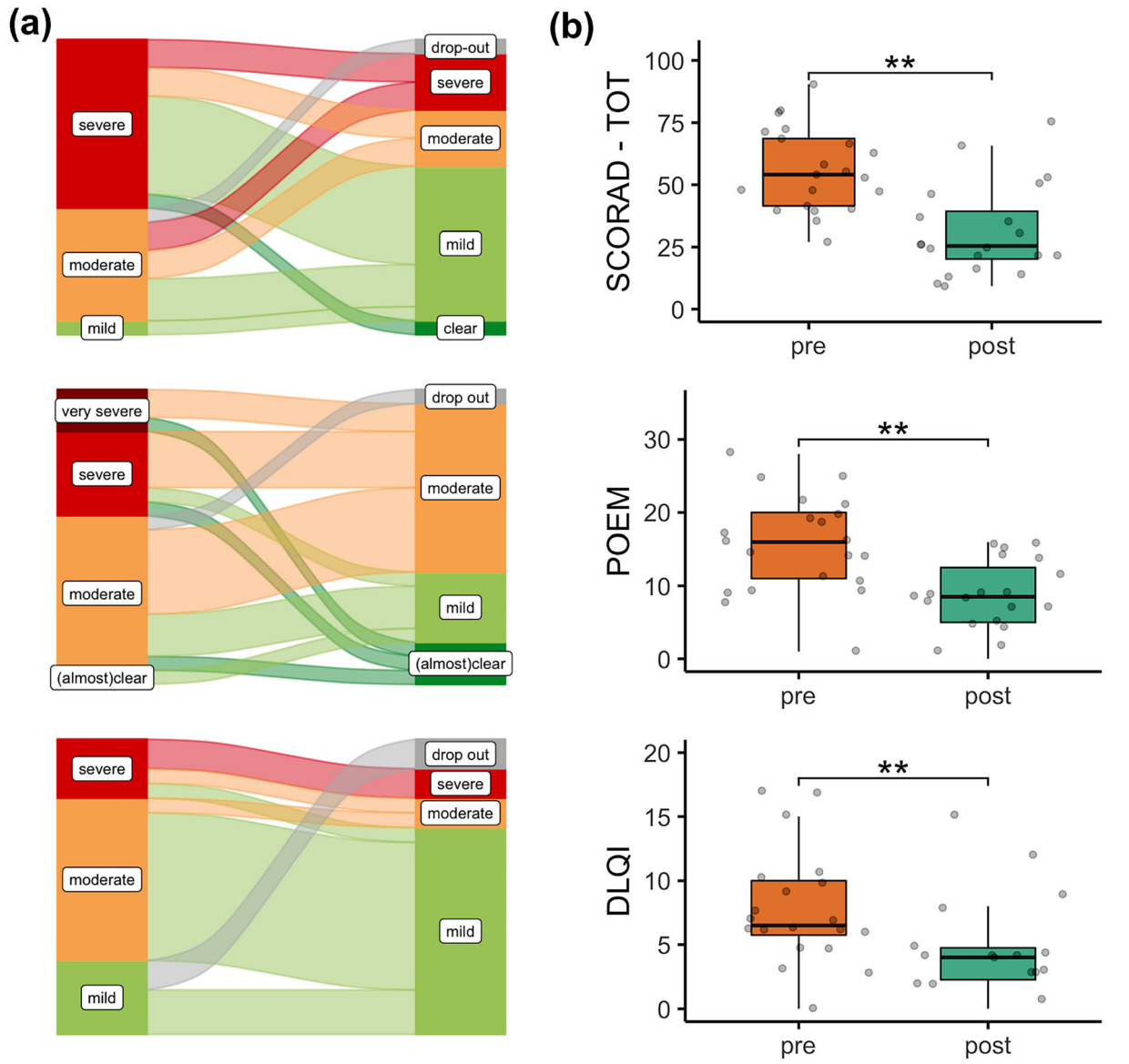

Fig. 2 Changes in **a** AD symptom severity according to defined severity strata and **b** in SCORAD, POEM, and DLQI scores from pre- to post-program. $n = 21$ before and $n = 20$ after intervention for SCORAD-TOT and POEM, and $n = 20$ before and $n = 18$ after intervention for DLQI. *DLQI* Dermatology Life Quality Index, *POEM* Patient-Oriented Eczema Measure, *SCORAD-TOT* Scoring Atopic Dermatitis Total score. $^{**}p < 0.001$

criteria for all outcomes [21, 23]. These results support the use of digital interventions to achieve behavioral modifications in patients with AD and improve their treatment adherence, leading to significant clinical improvements.

The clinical improvements seen corroborate the results of PROs collected within the app about AD symptoms and QoL, which showed a reduction in the reported number and severity of symptoms, as well as an improvement in quality of sleep, energy, and stress levels [20]. This suggests that in-app PROs provide a reasonable approximation of these QoL-related measures for patients and can be used as a tool

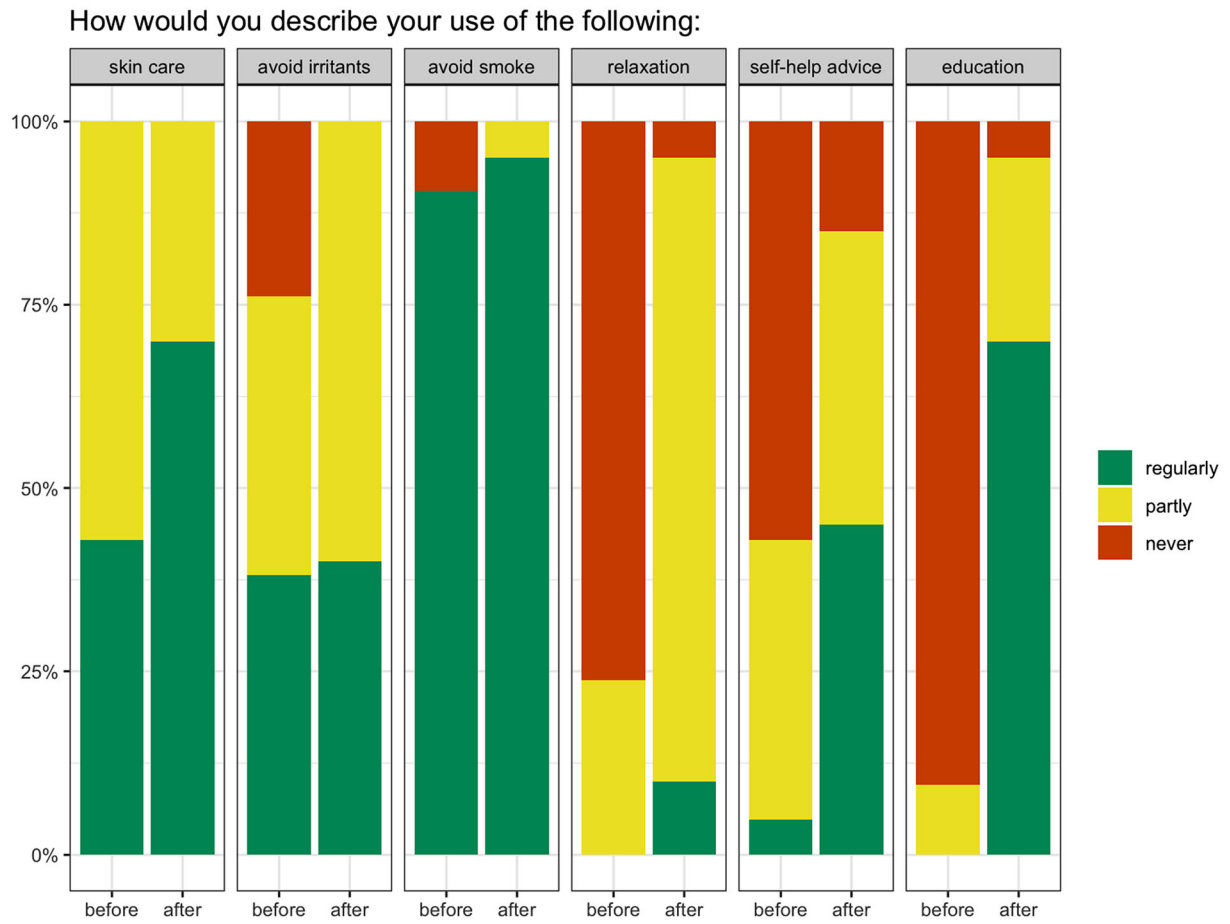

Fig. 3 Adherence to treatment and preventive measures as assessed by a six-item questionnaire before and after the study. Participants were rated according to whether they answered with "regularly," "partly," or "never." $n = 21$ before and $n = 20$ after intervention

to collect reliable information on symptom changes over time.

Poor treatment adherence is a major problem in management of chronic disease in general and AD in particular [7, 17]. Many reasons, such as poor understanding of disease chronicity and treatments, or fear of adverse effects, stem from lack of disease-specific education. Promoting patients' understanding of their disease increases the likelihood of continued treatment adherence even when symptoms improve, and ultimately can lead to self-efficacy, improved HR QoL, and reduced need for doctors' visits [17]. This study showed that a digital intervention can help address these issues through targeted educational content. In addition to education, medication reminders are an important feature of this program. A previous study found that reminders using "memory buttons" coupled with a mobile app achieved 43% improvement in SCORAD, 31% in POEM, and 36% in DLQI scores [15]. Thus, combining education with medication reminders within a digital platform provides a powerful tool for these patients.

Chronic stress is an important factor in AD pathogenesis, resulting in prolonged activation of neurons and immune cells that exacerbate skin inflammation [29]. Thus, in addition to medication adherence, practicing psychological stress management such as meditation and cognitive behavioral therapy can directly help with the most burdensome symptoms by easing effects of stress. We found that, at baseline,

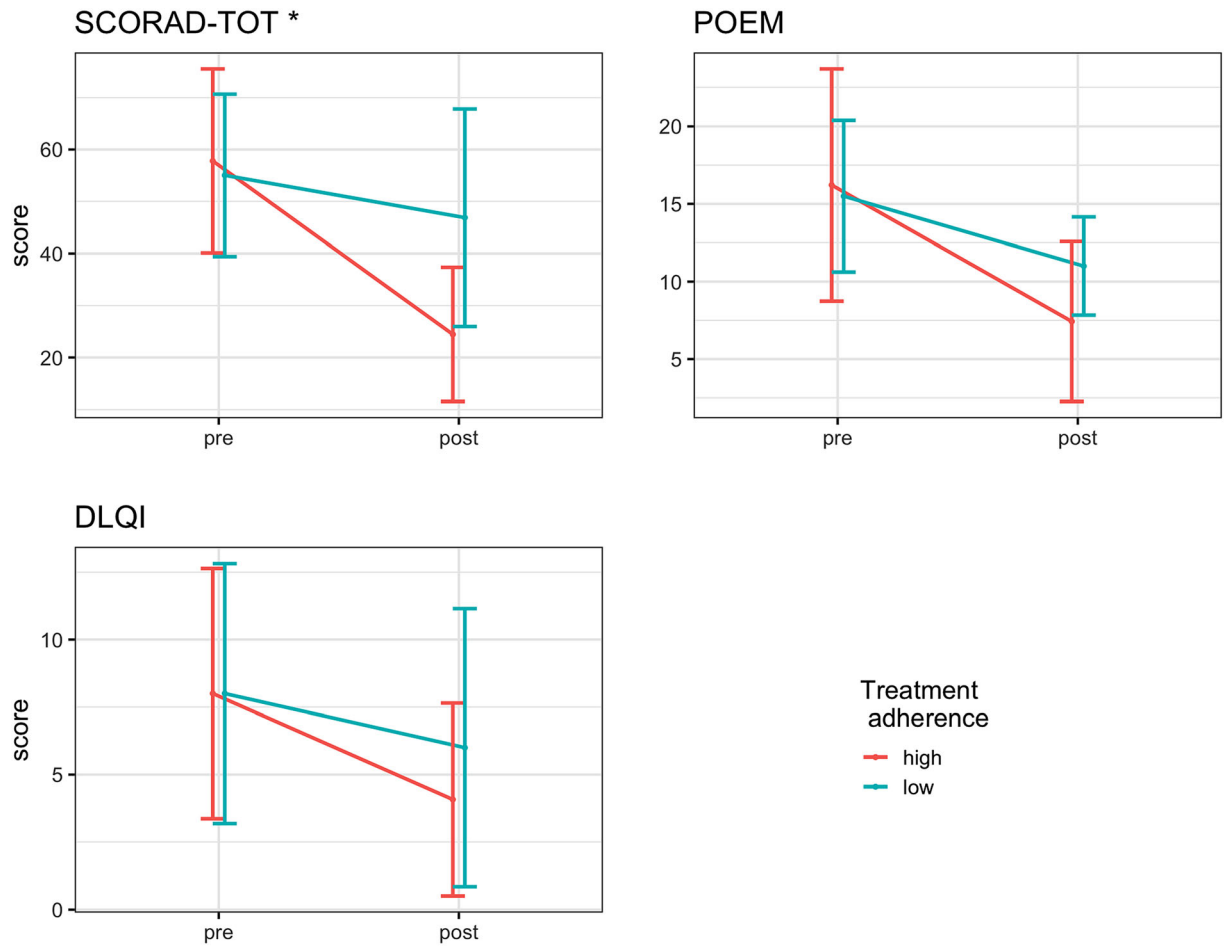

Fig. 4 Interaction between treatment adherence and clinical changes pre- and post-program. *DLQI* Dermatology Life Quality Index, *POEM* Patient-Oriented Eczema Measure, *SCORAD-TOT* Scoring Atopic Dermatitis Total score. $^{*}p < 0.05$

most participants reported never learning techniques for relaxation or seeking advice for self-help, despite previous studies showing their efficacy in AD [13, 16, 30]. After the intervention however, most patients showed improvement in this regard. This suggests not only that the app can help teach relaxation techniques, but also that people became more involved in their own treatment and seeking more advice. This is an important finding because it shows that the digital intervention successfully nudges users toward self-efficacy. The most drastic difference was seen in education, as most people who never used educational materials on AD prior to participation in the study reported regular self-education after the program.

One limitation of this study is the single-armed study design, as the primary goal here was to assess the initial feasibility in a small sample of patients with AD. Nonetheless, even with power limitations, we found significant improvements in objective and subjective AD severity and patient HR QoL. The results of this study suggest that digital support programs can improve the efficiency of existing treatments through improved adherence and education. An additional potential is to facilitate remote symptom monitoring and possibly even access to healthcare providers. One of the reasons for poor treatment adherence in patients with AD is not establishing accountability between patients and doctors early on after the initial

consultation, but having regular online check-ins with doctors can promote this accountability for using prescribed treatments and avoiding triggers [7, 31].

An additional limitation is that our sample was composed of patients who were on average young and highly educated and who had been living with AD for most of their lives. Studies found that patients with higher education, longer disease duration, and worse QoL tend to adhere more to preventive guidelines (while this association was not found regarding clinical severity) [25]. Thus, our results were likely skewed toward higher engagement and adherence, and it will be important to test the generalizability of our results in a larger and more representative sample.

CONCLUSION

This study showed that an AD-focused digital intervention can significantly improve clinical outcomes for patients. Our findings support the use of digital intervention to promote behavioral modifications toward higher disease awareness, treatment adherence, and self-efficacy and, in turn, help improve disease symptoms.

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Disclosures. Sigrídur Lára Gudmundsdóttir, Tommaso Ballarini, María L Ámundadóttir, Judit Mészáros, Sigrídur K Hrafnkelsdóttir and Heida B Bragadóttir are employees of Sidekick Health and Saemundur Oddsson is employee and co-founder of Sidekick Health. Jonathan I Silverberg has received honoraria as a consultant and/or advisory board member for Sidekick Health, Abbvie, Afyx, Aobiome, Arena, Asana, Aslan, BioMX, Biosion, Bluefin, Bodewell, Boehringer-Ingelheim, Cara, Castle Biosciences, Celgene, Connect Biopharma, Dermavant, Dermira, Dermtech, Eli Lilly, Galderma, GlaxoSmithKline, Incyte, Kiniksa, Leo Pharma, Luna, Menlo, Novartis, Optum, Pfizer, RAPT, Regeneron, Sanofi-Genzyme, Shaperon, Union; speaker for Abbvie, Eli Lilly, Leo Pharma, Pfizer, Regeneron, Sanofi-Genzyme; institution received grants from Galderma, Pfizer. Jenna H Eysteinsdóttir and Ragna H Thorleifsdóttir have no competing interests to declare.

Compliance with Ethics Guidelines. The study was approved by the Icelandic National Bioethics Committee (Institutional Review Board registration number: VSNb2021090028/03.01), and was conducted in accordance with the ethical principles outlined by the Declaration of Helsinki 2008 and the International Conference on Harmonisation guidelines. Potential participants were screened by the study nurse and were required to sign an informed consent prior to completing the pre-program clinical assessment and questionnaires, downloading the app and enrolling in the AD digital intervention.

Data Availability. The anonymized datasets generated and/or analyzed during the current study are available from the corresponding author upon request.

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