A Novel Digital Therapeutic Intervention to Improve Symptoms of Atopic Dermatitis: A Feasibility Study

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Background:
Atopic Dermatitis (AD) is a chronic disease requiring long-term treatments, such as corticosteroids, antihistamines, emollients, and other topical and oral medications. However, poor medication adherence (due to e.g., safety concerns, inconvenience or less usage as symptoms improve) is a major hurdle in long-term AD management. We developed a digital therapeutic solution aimed to improve lifestyle, treatment adherence and clinical outcomes for patients with AD. The objective of this study was to investigate the feasibility of this program and gather preliminary results about its efficacy.

Methods:
Adults with mild to severe AD were recruited in a single-arm feasibility study. The participants joined a six-week digital therapeutic program, including symptom and trigger education, treatment reminders, lifestyle coaching and healthy lifestyle support. Feasibility was assessed by retention and engagement throughout the program and clinical outcome measures were assessed at baseline and follow-up. Dermatologist-assessed objective eczema severity and subjective itching and sleep-related problems were measured by the SCORing Atopic Dermatitis (SCORAD) scale. Self-reported eczema severity and quality of life were measured by Patient-Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI). Adherence to treatment and preventive measures was evaluated using self-

reported questions at baseline and follow-up. In-app Patient-Reported Outcomes (PROs) included quality of sleep, stress, and energy levels on a sliding visual analogue scale (0-10).

Results:
Twenty-one patients with AD were enrolled in the study, 20 of whom finished the program; one discontinued after week one. Eighty-one percent were female, with a median age of 31 (range 20-55) and median age at diagnosis of one year (range 1-30). Mean BMI was 25.7 kg/m^2 (range 18.9-35.9), 95% were non-smokers and 71% had a university education. All users reported using topical (most commonly corticosteroid-containing) medications and four used additional oral antihistamines.

Participants engaged with the app a median of 6.5 days per week and logged a mission 8.9 times a day on average. A total of 60% of users were dedicated, defined as visiting the app at least 5 days per week. Clinical symptom severity according to SCORAD significantly decreased from 56.1 (SD=16.7) to 31.2 (SD=18.4) (44% improvement, $p<0.001$), and subjective symptoms assessed by POEM significantly decreased from 15.6 (SD=6.7) to 8.5 (SD=4.9) (46% improvement, $p<0.001$) from baseline to follow-up. The DLQI assessment showed that the eczema affected participants' quality of life significantly less after the program (7.8 (SD=4.5) to 4.6 (SD=4.0), 41% improvement, $p<0.001$). Effect sizes calculated according to Hedge's g were large, and the improvements seen met the minimal clinically important difference threshold in 80%, 75% and 66% of patients respectively for SCORAD, POEM and DLQI. These findings were corroborated by significantly improved energy levels by 15% ($p<0.01$), and trends toward improved quality of sleep by 8% ($p=0.317$) and stress levels by 12% ($p=0.211$) as measured in-app.

Regarding adherence to treatment and preventive measures, we observed an overall increase from pre- to post-intervention. At baseline, 43% of participants reported using regular skincare and this increased to 70% at follow-up. Similarly, at baseline, 24% reported never avoiding irritating substances, while all participants did so at least partly by program end. Similar behavioral improvements were seen for all other questions regarding smoking, self-help, relaxation, and disease-related education.
We additionally explored how regular skincare moderates the effect of the intervention on clinical changes. Individuals who maintained or increased their usage of regular skincare had significantly larger improvements in the total and objective SCORAD scores ($p<0.005$). The same trend was observed for all other clinical outcomes. These individuals also tended to have higher program engagement.

Conclusion:
A digital therapeutic intervention is feasible for patients with AD as demonstrated by excellent engagement and retention rates. It can also improve clinically assessed eczema severity and QoL. A digital therapeutic intervention can achieve behavioral modifications in patients with AD and improve their treatment adherence, leading to clinical improvements within six weeks.

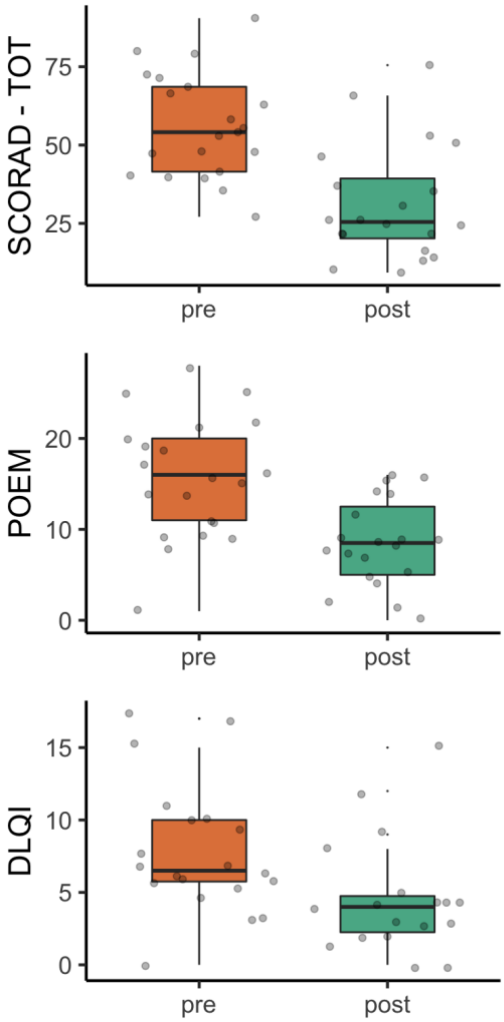

Figure 1. Box plots showing the changes in SCORAD, POEM and DLQI scores before and after the digital intervention.