A Digital Therapeutic Solution for Atopic Dermatitis; Protocol for a Nonrandomized, Single-Arm, Interventional Trial

Authors: Gudmundsdottir SL[1], Eysteinsdottir J[2], Þorleifsdottir RH[2], Ulfsdottir H[1], Reykdal E[3], Hrafnkelsdottir SK[1], Bragadottir HB[1], Oddsson S[1], Silverberg J[4]
Affiliations: [1] Sidekick Health, Kópavogur, Iceland, [2] Húðlæknastöðin Dermatology Clinic, Kópavogur, Iceland, [3] Landspitali University Hospital, Reykjavik, Iceland,
[4] George Washington University, School of Medicine and Health Sciences, Washington DC, USA [5] University of Iceland, Department of Health Promotion, Sport and Leisure Studies, Reykjavik, Iceland

Background: Atopic dermatitis (AD) is a complex, chronic, systemic disease where management is largely dependent on adherence to over-the-counter and prescription treatments and avoiding triggering factors. Long-term treatment is required and poor treatment adherence often hampers improvement. Research has suggested that lifestyle affects the AD progression, where stress and sleep seem to play a key role. Exploring new ways to improve treatment adherence and lifestyle is important, as it might improve the overall outcome and quality of life. Limited data are available regarding the feasibility and effectiveness of digitally delivered lifestyle intervention for AD patients.

Objective: To ascertain the feasibility and efficacy of a AD digital therapeutic and lifestyle program delivered via a mobile app. We will assess changes in treatment adherence, AD severity and quality of life. User satisfaction will be assessed post-intervention.

Methods: Twenty adult (≥18 years) patients with mild to severe AD will be recruited from a dermatology clinic in this six week, single-arm, interventional study. A therapeutic program delivered via a smartphone app will provide education and medication reminders, communication with a lifestyle coach and dermatology nurse, track symptoms and support healthy lifestyle behavioral change. Participants' demographics will be collected at baseline. Clinical outcome measures will be collected at baseline and follow up; Scoring Atopic Dermatitis (SCORAD), Patient Oriented Eczema Measure (POEM), Dermatology Life Quality Index (DLQI), Patient Global Index - Symptoms (PGI-S) and questions regarding treatment adherence. At follow up, Patient Global Index - Change (PGI-C) will be included, as well as the mHealth app usability questionnaire (MAUQ). In-app patient reported outcomes will be gathered throughout the 6-week period;
data on sleep, stress and energy levels three times per week and data on AD symptoms
once per week. Descriptive statistics will be summarised. Changes from pre- to post intervention will be assessed.

Results: Changes in treatment adherence, AD signs and symptoms, quality of life and user satisfaction will be assessed at 6-weeks.

Conclusions: This pilot study will provide proof of concept for the utility of this digital therapeutic program, inform revisions of the therapeutic program, and identify challenges and opportunities for future randomized controlled studies.

Conflict of interest: SO is a cofounder of Sidekick Health, HBB, HU, SLG and SKH are current employees of Sidekick Health. JHE, RHÞ, ER and JS were consultants during the program and protocol creation and received reimbursement for their work.

Keywords: atopic dermatitis, lifestyle, stress, sleep, treatment adherence.