Identification of meaningful aspects of health connected to the symptom of nocturnal scratching in patients with atopic dermatitis

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Introduction:
The clinical features of atopic dermatitis (AD) include skin redness, thickness and lichenification, as well as a common symptom with the greatest reported disease burden in AD patients - itch. The primary physical characteristic often accompanying itch is the action of scratching, further aggravating dermatitis by damaging the epidermal skin barrier and leading to itch-scratch cycle. Only a small number of studies offer a deeper dive into the specific impacts of scratching and its effect on patients' everyday lives. There is a gap in measuring nocturnal scratching through traditional approaches, largely due to the habitual itch-scratch cycles and barriers to cognizance during sleep. As digital measurement of nocturnal scratch has been of interest to both industry and academia research groups, the objective of this work is to assess the impact of scratching, particularly, nocturnal scratching, within the context of existing AD conceptual disease models and assess the meaningfulness of nocturnal scratch as a concept of interest from the patient perspective. This work shall support a patient-centered approach to develop a novel digital measure for nocturnal scratch.

Materials & Methods:
Utilizing a mixed-methods qualitative and quantitative approach, we explored the patient experience with AD, the impact of AD, and impacts of scratching, particularly, nocturnal scratching. We performed qualitative semi-structured patient interviews (n=49) to identify meaningful concepts related to scratching. The interviewed cohorts were: adult patients with AD (n=15); adult caregivers or spouses of adult patients with AD (n=6); adult caregivers for children with AD aged 7-<18 years (n=14); and child patients with AD aged 7-<18 years old (n=14). Transcripts of interviews were analyzed according to FDA guidance "Patient-Focused Drug Development: Methods to Identify What is Important to Patients" and the coding approach was used for interpretation of collected data. The quantitative survey will be informed by qualitative results, and will be distributed to 600 representative patients in two cohorts of adult patients with AD (n=300) and adult caregivers for pediatric patients with AD aged 7-<18 years (n=300).

Results & Discussion:
The qualitative part of the study provided direct patient input on meaningful aspects of everyday life impacted by AD. The most common themes were skin appearance, feeling of itch, urge to scratch and awareness of scratching, poor quality of sleep or stress and anxiety. Scratching during sleep was reported by all interviewed participants. They consistently reported worsening of the itch sensation and urge to scratch in the evening and at night, and observation of signs of nocturnal scratching in the morning (skin flakes, blood, new scratch marks, etc.). Nocturnal scratching affecting sleep was a consistent finding across all cohorts. The reported impacts of nocturnal scratching included worsened skin condition, worsening of daily mood, feeling mentally and physically exhausted, lack of energy and increased stress levels. A portion of the patients
stated observing signs of nocturnal scratching in the morning without remembering the actual behavior, which supports the need of a passive measurement supplementing the patient report. Importance of a treatment to reduce nocturnal scratching together with other AD symptoms was
consistently noted across all cohorts. A major portion of participants reported willingness to use or wear a tool or a sensor for their own education as well as to support research of new treatments. The patients also reported reservations regarding privacy, comfort or wear location. Preliminary qualitative data indicate a strong link between the nocturnal scratching and meaningful aspects of everyday life for patients with AD. In particular, the impact of nocturnal scratching on the appearance of skin, quality of sleep, daily mood and functioning, and mental health aspects. The value of a novel measure quantifying nocturnal scratching is indicated in these preliminary findings, as cognizance at night and recall are often challenging. The potential challenges to overcome in development of digitally measured nocturnal scratch appear to be the value perceived by the patients, concerns about privacy or willingness to wear a digital tool or sensor. Following quantitative survey will provide additional quantitative insights into the burden of nocturnal scratch on patients with AD and will inform the development of specific quantitative digital measures of nocturnal scratch.