STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Adjunctive Group Psychotherapy for Moderate-to-Severe Atopic Dermatitis: A Pilot Feasibility Study Comparing Two Interventions

Official Title	Adjunctive Group Psychotherapy for Moderate-to-Severe Atopic Dermatitis: A Pilot Feasibility Study Comparing Two Interventions
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Sponsor / Responsible Party	Semmelweis University, Faculty of Medicine, Clinic of Psychiatry and Psychotherapy
Principal Investigator	Zsolt Szabolcs Unoka, MD, PhD
Ethics Approval	Health Science Council Scientific and Research Ethics Committee (ETT TUKEB), Case No. IV/661-4/2022/EKU; approval date: 15 February 2022
Planned Study Period	15 February 2022 to 30 December 2022
Study Sites	Semmelweis University Clinic of Psychiatry and Psychotherapy; Semmelweis University Department of Dermatology, Venereology and Dermato-oncology; VIKOTE Cognitive and Behavioral Therapy Center

Document note

This final upload document was most recently updated on 11 May 2026 for ClinicalTrials.gov results reporting and document upload. The date 05 February 2022 identifies the original protocol/SAP source date and the 2022 human subjects protection review context; it is not the Document Date of this upload document. The document summarizes the approved study design, interventions, eligibility criteria, assessment schedule, outcome measures, ethical procedures, and statistical analysis plan. Outcome data and interpretive statements are not included.

Version	Date	Description	Status
1.0	11 May 2026	Final protocol document with statistical analysis plan prepared/updated for ClinicalTrials.gov document upload. Document Date corrected to reflect the most recent update date; original 2022 source date identified separately. Outcome data and interpretive statements are not included.	Final for results-reporting document upload

1. Protocol Synopsis

Condition	Moderate-to-severe atopic dermatitis
Study Type	Partially randomized, three-arm, pilot feasibility study
Primary Purpose	Treatment

Intervention Model	Parallel assignment
Allocation	Participants assigned to the two active psychotherapy arms were randomized by computer-generated sequence; assignment to the treatment-as-usual-only arm was non-randomized.
Masking	None
Planned Enrolment	Approximately 32 adult participants
Study Arms	Treatment as usual; treatment as usual plus atopic dermatitis-specific cognitive behavioural and schema mode group therapy; treatment as usual plus stress management and resilience group therapy
Intervention Duration	14 weekly group psychotherapy sessions for active intervention arms
Participant Follow-up	Baseline, post-intervention assessment at week 14, and six-month follow-up
Primary Study Objective	To evaluate the feasibility of delivering adjunctive group psychotherapy interventions in adults with moderate-to-severe atopic dermatitis receiving standard dermatological care
Primary Clinical Outcome Measures	Change from baseline in Eczema Area and Severity Index score at week 14; change from baseline in SCORing Atopic Dermatitis score at week 14
Secondary Clinical Outcome Measures	Change from baseline in Eczema Area and Severity Index and SCORing Atopic Dermatitis scores at six-month follow-up; responder status based on prespecified clinically meaningful change thresholds

2. Background and Rationale

Atopic dermatitis is a chronic inflammatory skin disease characterized by eczematous skin lesions and pruritus. It can be associated with scratching, sleep disturbance, disease-related distress, and reduced quality of life. Psychological stress and behavioural factors may contribute to symptom burden in some patients.

Standard dermatological care remains the main component of treatment. Adjunctive psychotherapeutic interventions may address disease-related behavioural and psychological processes, including itch-related coping, scratching behaviour, emotion regulation, stress coping, and stigma-related experiences. This pilot feasibility study was designed to evaluate structured group psychotherapy delivered alongside standard dermatological care in adults with moderate-to-severe atopic dermatitis.

3. Objectives

3.1 Primary Study Objective

The primary study objective was to evaluate the feasibility of delivering two adjunctive group psychotherapy interventions for adults with moderate-to-severe atopic dermatitis receiving standard dermatological care.

3.2 Clinical Objectives

- To assess atopic dermatitis severity using the Eczema Area and Severity Index at baseline, post-intervention assessment at week 14, and six-month follow-up.
- To assess atopic dermatitis severity using SCORing Atopic Dermatitis at baseline, post-intervention assessment at week 14, and six-month follow-up.
- To classify clinically meaningful improvement using prespecified responder thresholds for Eczema Area and Severity Index and SCORing Atopic Dermatitis.

3.3 Feasibility Objectives

- To describe recruitment and enrolment feasibility in a university clinical setting.
- To describe attendance and adherence to the group psychotherapy interventions.
- To describe retention through post-intervention and six-month follow-up assessments.

- To document participant withdrawal or discontinuation during the study period.

4. Study Design

This was a partially randomized, three-arm, parallel-group pilot feasibility study. All participants received standard dermatological care. Participants were assigned to treatment as usual alone, treatment as usual plus atopic dermatitis-specific cognitive behavioural and schema mode group therapy, or treatment as usual plus stress management and resilience group therapy.

Participants allocated to the two active psychotherapy arms were randomized between the active interventions using a computer-generated sequence. Assignment to the treatment-as-usual-only arm was based on non-random procedures. No blinding was applied.

The study was conducted in a university clinical setting involving dermatology and psychotherapy services. The planned study period was 15 February 2022 to 30 December 2022. The study was designed as a pilot feasibility study; the planned sample size was based on feasibility considerations rather than a formal power calculation.

5. Study Setting

Participants were recruited from the outpatient dermatology service at Semmelweis University, Budapest, Hungary. Psychotherapy interventions were delivered in a university hospital or affiliated psychotherapy setting by trained psychotherapists. The participating sites were Semmelweis University Clinic of Psychiatry and Psychotherapy, Semmelweis University Department of Dermatology, Venereology and Dermato-oncology, and VIKOTE Cognitive and Behavioral Therapy Center.

6. Participants and Eligibility Criteria

Eligible participants were adults with moderate-to-severe atopic dermatitis. Screening was performed by consultant dermatologists. Suitability for group psychotherapy was assessed through a secondary clinical interview with two psychotherapists.

6.1 Inclusion Criteria

- Adults aged 18 years or older
- Clinical diagnosis of atopic dermatitis
- Moderate-to-severe atopic dermatitis, defined as SCORing Atopic Dermatitis score of 25 or higher
- Suitability for group therapy confirmed through a secondary clinical interview with two psychotherapists
- Written informed consent provided before participation

6.2 Exclusion Criteria

- Mild atopic dermatitis, defined as SCORing Atopic Dermatitis score below 25
- Other chronic inflammatory or infectious skin diseases
- Ongoing systemic immunosuppressive or biological treatment
- Psychotic disorder
- Drug dependence
- Pregnancy
- Refusal to participate
- Suitability for group therapy not confirmed through a secondary clinical interview with two psychotherapists

7. Recruitment, Screening, and Consent

Potential participants were identified through the outpatient dermatology service. Consultant dermatologists conducted eligibility screening, including confirmation of atopic dermatitis severity. Potentially eligible participants then completed a secondary clinical interview with two psychotherapists to assess suitability for participation in group psychotherapy.

Written informed consent was obtained before participation. Participation was voluntary. Participants could withdraw from the study without affecting access to standard dermatological care.

8. Study Arms and Interventions

Study Arm	Description
Treatment as Usual	Standard dermatological care according to clinical indication. Treatment as usual could include topical corticosteroids, emollients, and antihistamines for pruritus.

Treatment as Usual plus ADCBST	Standard dermatological care plus atopic dermatitis-specific cognitive behavioural and schema mode group therapy. The intervention consisted of 14 weekly group sessions of approximately 2.5 hours.
Treatment as Usual plus SRCST	Standard dermatological care plus stress management and resilience group therapy. The intervention consisted of 14 weekly group sessions of approximately 2.5 hours.

8.1 Treatment as Usual

Treatment as usual consisted of standard dermatological care according to clinical indication. Care could include topical corticosteroids, emollients, and antihistamines for pruritus. Dermatological care was provided independently of assignment to psychotherapy intervention arms.

8.2 Atopic Dermatitis-Specific Cognitive Behavioural and Schema Mode Group Therapy

The atopic dermatitis-specific cognitive behavioural and schema mode group therapy intervention was delivered as 14 weekly group sessions of approximately 2.5 hours. The intervention combined schema mode therapy with atopic dermatitis-specific cognitive behavioural strategies.

The intervention addressed disease-related psychological and behavioural processes, including itch-related coping, scratching behaviour, emotion regulation, coping with visible skin symptoms and stigma-related experiences, and schema mode work relevant to chronic skin disease.

8.3 Stress Management and Resilience Group Therapy

The stress management and resilience group therapy intervention was delivered as 14 weekly group sessions of approximately 2.5 hours. The intervention followed a structured stress management and resilience-oriented protocol.

The intervention addressed stress management, emotion regulation, interpersonal functioning, coping skills, and resilience.

8.4 Intervention Delivery and Adherence

Both group psychotherapy interventions were delivered by trained psychotherapists in a university hospital or affiliated psychotherapy setting. Session attendance was recorded for participants assigned to active psychotherapy arms. Adequate attendance was defined as attendance at 10 or more of the 14 scheduled group sessions.

9. Schedule of Assessments

Procedure / Measure	Screening	Baseline (T1)	Week 14 (T2)	Six-month follow-up (T3)
Eligibility screening	X			
Secondary psychotherapy suitability interview	X			
Written informed consent	X			
Demographic and baseline clinical information		X		
Eczema Area and Severity Index		X	X	X
SCORing Atopic Dermatitis		X	X	X
Group psychotherapy attendance		Throughout 14-week intervention period	X	
Retention and withdrawal status		Throughout study period	X	X
Adverse event or clinical deterioration monitoring		Throughout study period	X	X

The post-intervention assessment was scheduled after completion of the 14-week intervention period. The follow-up assessment was scheduled six months after the post-intervention period.

10. Outcome Measures

10.1 Primary Clinical Outcome Measures

Outcome Measure	Definition
Change from baseline in Eczema Area and Severity Index score at week 14	The Eczema Area and Severity Index is a clinician-rated measure of objective atopic dermatitis severity. It assesses erythema, excoriation, edema or papulation, and lichenification across anatomical regions. Total scores range from 0 to 72, with higher scores indicating greater severity. The endpoint is change in total score from baseline to week 14.
Change from baseline in SCORing Atopic Dermatitis score at week 14	SCORing Atopic Dermatitis is a clinician-rated and patient-informed measure of atopic dermatitis severity. It includes disease extent, intensity of clinical signs, and subjective symptoms including pruritus and sleep disturbance. Total scores range from 0 to 103, with higher scores indicating greater severity. The endpoint is change in total score from baseline to week 14.

10.2 Secondary Clinical Outcome Measures

Outcome Measure	Definition
Change from baseline in Eczema Area and Severity Index score at six-month follow-up	Change in total score from baseline to six-month follow-up.
Change from baseline in SCORing Atopic Dermatitis score at six-month follow-up	Change in total score from baseline to six-month follow-up.
Clinically meaningful improvement in Eczema Area and Severity Index	Clinically meaningful improvement was defined as a reduction of at least 6.6 points in total Eczema Area and Severity Index score from baseline.
Clinically meaningful improvement in SCORing Atopic Dermatitis	Clinically meaningful improvement was defined as a reduction of at least 8.7 points in total SCORing Atopic Dermatitis score from baseline.

10.3 Feasibility Variables

- Recruitment and enrolment: number of participants screened and enrolled during the recruitment period, where available.
- Retention: number of participants completing post-intervention and six-month follow-up assessments.
- Attendance and adherence: number of group psychotherapy sessions attended; adequate attendance defined as attendance at 10 or more of 14 sessions.
- Withdrawal or discontinuation: number of participants discontinuing participation before post-intervention or follow-up assessment, where available.

11. Statistical Analysis Plan

11.1 General Principles

Analyses were specified as exploratory because the study was designed as a pilot feasibility study and was not powered for confirmatory efficacy testing. Statistical tests were used to describe and explore group differences in clinical outcome measures. Statistical significance was defined as $p < 0.05$. No adjustment for multiple comparisons was planned because of the exploratory design.

IBM SPSS Statistics version 29 was used for statistical analyses.

11.2 Analysis Populations

The primary analysis population for clinical outcome analyses consisted of participants with available outcome data at the relevant assessment time point. Completer-only analyses were planned because of the pilot sample size. Feasibility variables were summarized for enrolled participants where data were available.

11.3 Descriptive Analyses

Baseline demographic and clinical variables were summarized descriptively. Continuous variables were summarized using means and standard deviations or medians and ranges, as appropriate. Categorical variables were summarized using frequencies and percentages.

11.4 Primary Clinical Analyses

Primary clinical analyses examined post-intervention Eczema Area and Severity Index and SCORing Atopic Dermatitis scores at week 14. Analysis of covariance was used with study group as the between-subject factor. Baseline value of the relevant outcome, age, and gender were included as covariates.

11.5 Follow-up Analyses

Follow-up analyses examined Eczema Area and Severity Index and SCORing Atopic Dermatitis scores at six-month follow-up using the same general analysis of covariance framework, including baseline value of the relevant outcome, age, and gender as covariates.

11.6 Responder Analyses

Responder status was defined using prespecified clinically meaningful improvement thresholds. Participants were classified as responders for Eczema Area and Severity Index if the total score decreased by at least 6.6 points from baseline. Participants were classified as responders for SCORing Atopic Dermatitis if the total score decreased by at least 8.7 points from baseline. Logistic regression was planned to estimate responder status by study group. Baseline severity, age, and gender were considered covariates when model stability allowed.

11.7 Missing Data

No imputation of missing clinical outcome data was planned. Analyses were conducted using available data for participants with complete data at the relevant assessment point. Reasons for withdrawal or discontinuation were summarized descriptively where available.

11.8 Sample Size Considerations

The planned sample size was based on feasibility considerations rather than formal statistical power. The study was intended to inform the conduct of future adequately powered randomized trials.

12. Data Management and Confidentiality

Participant information was handled confidentially. Study data were coded or de-identified for analysis. Access to identifiable information was restricted to authorized study personnel. Data storage and handling followed applicable institutional and ethical requirements.

13. Safety and Risk Management

The psychotherapy interventions involved structured group sessions and were considered low risk. Potential risks included temporary emotional discomfort during discussion of disease-related experiences, stress, interpersonal difficulties, or stigma. Participants could pause participation or withdraw from the group intervention. Psychotherapists monitored participant distress during sessions and referred participants for additional clinical care if needed.

Participants continued to receive dermatological care according to clinical indication. Relevant clinical deterioration or adverse events reported during the study period were to be documented and managed according to institutional procedures.

14. Ethics and Regulatory Considerations

The study was approved by the Health Science Council Scientific and Research Ethics Committee (ETT TUKEB), Case No. IV/661-4/2022/EKU, with approval dated 15 February 2022. The study was conducted in accordance with the Declaration of Helsinki and applicable institutional requirements. Written informed consent was obtained from participants before participation.

The study was conducted without external funding or commercial sponsorship.

15. Version History

Version 1.0, 11 May 2026: Final protocol document with SAP prepared/updated for ClinicalTrials.gov upload; original source date: 05 February 2022; no outcome data included.