STATISTICAL ANALYSIS PLAN

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
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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-date and transparency statement

This document was most recently updated on 11 May 2026 for ClinicalTrials.gov results reporting. The date 05 February 2022 refers to the original protocol/SAP source date and the 2022 human subjects protection review context; it is not the Document Date of this upload document. This SAP contains no outcome data or interpretive results. Analyses documented in the original protocol/SAP may be described as protocol-specified only to the extent supported by contemporaneous documentation. Analytic details added during 2026 results-reporting preparation should be labelled results-reporting, exploratory, or post hoc as applicable.

Version	Date	Description	Status
1.0	11 May 2026	Final upload document prepared for ClinicalTrials.gov results reporting. Document Date corrected to reflect the most recent update date; original 2022 source date identified separately.	Final for results-reporting document upload

1. Purpose and scope

This Statistical Analysis Plan documents the analysis approach for ClinicalTrials.gov results reporting for a pilot feasibility study of adjunctive group psychotherapy for adults with moderate-to-severe atopic dermatitis. It summarizes analysis populations, outcome definitions, time points, descriptive summaries, exploratory comparative analyses, responder definitions, missing data handling, feasibility metrics, safety summaries, software, and planned outputs.

The SAP should be read together with the final study protocol, the ClinicalTrials.gov registration record, case report forms, scoring manuals for EASI and SCORAD, and any available data dictionary or analysis log. This document does not change the registered outcomes and does not include study results.

2. Study overview

Condition	Moderate-to-severe atopic dermatitis
Study Type	Partially randomized, three-arm, parallel-group, pilot feasibility study
Primary Purpose	Treatment
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 (EASI) score at week 14; change from baseline in SCORing Atopic Dermatitis (SCORAD) score at week 14
Secondary Clinical Outcome Measures	Change from baseline in EASI and SCORAD scores at six-month follow-up; responder status based on prespecified clinically meaningful change thresholds

3. Analysis populations

Population	Definition	Primary use	Notes
Enrolled population	All participants who provided written informed consent and were enrolled in the study.	Disposition, feasibility summaries, and baseline summaries where applicable.	Denominators will be stated for each feasibility metric.
Allocated/randomized population	Participants assigned to one of the three study arms; active-arm participants were randomized between the two psychotherapy interventions, whereas treatment-as-usual-only assignment was non-randomized.	Participant flow and descriptive denominators.	Group-assignment method will be made explicit in reporting.
Clinical outcome analysis population	Participants with available data for the relevant clinical outcome at the relevant assessment time point.	Primary and secondary clinical outcome analyses.	Available-case/completer-only approach due to pilot sample size.
Responder analysis population	Participants with valid baseline and relevant endpoint scores for EASI or SCORAD.	Responder classification and logistic regression where model stability allows.	No imputation of missing responder status is planned.
Feasibility population	Enrolled participants with available data for recruitment, retention, attendance, adherence, withdrawal, or related feasibility variables.	Feasibility outcomes and pilot interpretation.	Metric-specific denominators will be stated.

Safety population	Participants exposed to a study procedure or intervention with safety or clinical deterioration monitoring available.	Adverse event and safety summaries.	Summaries will be descriptive.

4. Outcome and endpoint definitions

EASI and SCORAD are severity measures in which higher scores indicate greater atopic dermatitis severity. Where change scores are reported, the direction of change will be stated explicitly. For interpretability, reductions from baseline may be described as improvement.

Outcome category	Measure	Endpoint definition	Time point(s)	Analysis status
Primary clinical	EASI total score	Change from baseline in total EASI score. EASI total score ranges from 0 to 72, with higher scores indicating greater severity.	Week 14 post-intervention assessment	Exploratory clinical analysis in a pilot feasibility study
Primary clinical	SCORAD total score	Change from baseline in total SCORAD score. SCORAD total score ranges from 0 to 103, with higher scores indicating greater severity.	Week 14 post-intervention assessment	Exploratory clinical analysis in a pilot feasibility study
Secondary clinical	EASI total score	Change from baseline in total EASI score.	Six-month follow-up	Exploratory
Secondary clinical	SCORAD total score	Change from baseline in total SCORAD score.	Six-month follow-up	Exploratory
Secondary clinical / responder	EASI clinically meaningful improvement	Responder if EASI total score decreases by at least 6.6 points from baseline.	Week 14 and/or six-month follow-up where data are available	Exploratory
Secondary clinical / responder	SCORAD clinically meaningful improvement	Responder if SCORAD total score decreases by at least 8.7 points from baseline.	Week 14 and/or six-month follow-up where data are available	Exploratory
Feasibility	Recruitment, retention, attendance/adherence, withdrawal/discontinuation	Number screened/enrolled where available; assessment completion; group-session attendance; adequate attendance defined as 10 or more of 14 sessions; withdrawal or discontinuation before scheduled assessments.	Throughout study period, week 14, and six-month follow-up	Descriptive
Safety	Adverse events or clinical deterioration	Events or deterioration reported or observed during study participation and follow-up.	Throughout study period and follow-up	Descriptive

5. Assessment time points and visit windows

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		
EASI		X	X	X

SCORAD		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.

6. General statistical principles

- Analyses are exploratory because the study was designed as a pilot feasibility study and was not powered for confirmatory efficacy testing.
- Statistical significance was defined as $p < 0.05$ for exploratory analyses. No adjustment for multiple comparisons was planned because of the exploratory design.
- Estimates, standard errors or standard deviations, confidence intervals, and denominators will be reported where informative.
- Baseline variables will be summarized descriptively. Formal baseline significance tests will not be used to determine group comparability.
- For all percentages, the denominator will be stated. Missing and not-applicable categories will be displayed separately where relevant.
- Clinical outcome results will not be interpreted as definitive evidence of efficacy.

7. Descriptive analyses

Baseline demographic and clinical variables will be summarized by study arm and overall. Continuous variables will be summarized using means and standard deviations or medians and ranges, as appropriate. Categorical variables will be summarized using frequencies and percentages. Intervention exposure and adherence will summarize group-session attendance for active intervention arms and the proportion meeting adequate attendance, defined as 10 or more of 14 scheduled sessions.

8. Primary clinical analyses

Primary clinical analyses will examine post-intervention EASI and SCORAD scores at week 14. Analysis of covariance will be used with study group as the between-subject factor. Baseline value of the relevant outcome, age, and gender will be included as covariates. Results will be reported as exploratory adjusted group comparisons with appropriate descriptive statistics and confidence intervals where feasible.

9. Follow-up analyses

Follow-up analyses will examine EASI and SCORAD 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. These analyses are exploratory and intended to describe persistence or change in clinical outcomes after the post-intervention assessment.

10. Responder analyses

Responder status will be defined using prespecified clinically meaningful improvement thresholds: at least a 6.6-point decrease from baseline in total EASI score and at least an 8.7-point decrease from baseline in total SCORAD score. Logistic regression will be used to estimate responder status by study group when model stability allows. Baseline severity, age, and gender may be considered as covariates when sample size and event counts are sufficient. If model stability is inadequate, responder outcomes will be summarized descriptively by group.

11. Missing data handling

No imputation of missing clinical outcome data is planned. Analyses will use available data for participants with complete data at the relevant assessment point. Reasons for withdrawal or discontinuation will be summarized descriptively where available. The amount and pattern of missing data will be described by group, outcome, and time point where feasible. Missingness itself will be treated as relevant feasibility information.

12. Feasibility and pilot-study interpretation

Feasibility results will be summarized descriptively and interpreted using observed rates, practical implementation considerations, and uncertainty rather than confirmatory hypothesis testing. The study was designed to inform the conduct of future adequately powered randomized trials, including recruitment feasibility, retention, adherence, acceptability of intervention delivery, and completeness of clinical outcome measurement.

13. Safety and adverse event analyses

Adverse events or clinical deterioration reported or observed during the study period will be summarized descriptively. The number and percentage of participants with relevant events will be displayed by group where applicable. Formal comparative testing of safety outcomes is not planned.

14. Sample size considerations

The planned sample size of approximately 32 adult participants was based on feasibility considerations rather than formal statistical power. The study was not designed to provide definitive tests of clinical efficacy.

15. Statistical software and reproducibility

IBM SPSS Statistics version 29 was used for statistical analyses. Derived variables, scoring rules, exclusions, analysis-population flags, and model specifications should be documented in the analysis file, data-processing log, or statistical report to support reproducibility.

16. Planned tables, figures, and listings

Output	Content	Population / denominator
Table 1	Participant flow: screened, eligible, enrolled, allocated/randomized, received intervention, completed assessments, withdrawals, and analysis populations.	Screened, enrolled, and allocated/randomized participants as applicable
Table 2	Baseline demographic and clinical characteristics by group and overall.	Allocated/randomized or enrolled population
Table 3	Primary clinical outcomes: EASI and SCORAD at baseline and week 14, with exploratory ANCOVA results.	Clinical outcome analysis population
Table 4	Follow-up clinical outcomes: EASI and SCORAD at six-month follow-up, with exploratory ANCOVA results.	Clinical outcome analysis population
Table 5	Responder outcomes for EASI and SCORAD using clinically meaningful improvement thresholds.	Responder analysis population
Table 6	Feasibility outcomes: recruitment, retention, attendance/adherence, withdrawal/discontinuation, and data completeness.	Feasibility population with metric-specific denominators
Table 7	Adverse events or clinical deterioration summaries.	Safety population
Figure 1	Participant flow diagram.	All screened/enrolled/allocated participants

17. Source documents

This SAP was prepared from the study protocol/SAP source material for the official title listed on the cover page. The original protocol/SAP source date is 05 February 2022; the documented ethics approval is 15 February 2022. The document was most recently updated on 11 May 2026 for ClinicalTrials.gov results reporting and document upload.