Visit

Mind & Skin ID	728-1

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	98.55 (10kg - 100kg)
Height (cm)	171.30

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ⊗ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
Asian or Asian British	◯ Indian ◯ Pakistani ◯ Bangladeshi ◯ Chinese ⊗ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No
Number of criteria	4

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:
- ◯ Mild
- ◯ Moderate
- ◯ Potent
- ⊗ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No

Potency
- ◯ Mild
- ◯ Moderate
- ⊗ Potent
- ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	◯ Yes ⊗ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?
- ☐ Participant
- ☒ Parent
- ☐ Sibling
- ☐ Partner
- ☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	21.134 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	24.561 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	23.505 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ○ No

Total score   17.00

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	6.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	24
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.9 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	13
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.58 (0 - 99)
2. Sleepiness subscale	0.75 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.33 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	21 (0 - 99)
T-Score:	86 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	7 (0 - 99)
T-Score:	72 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	11 (0 - 99)

T-Score:	64 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	9 (0 - 99)
T-Score:	86 (0 - 99)
Total score	62 (0 - 99)
Total T-Score:	85
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ◯ Yes   ⊗ No

If no, please give reason why   [*DATA REMOVED*]

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID
_____

Bedtime
_____

Waketime
_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)
_____

Sleep efficiency SE (%)
_____

Apnoea Hypopnoea Index (AHI)/hr
_____

Obstructive AHI (OAHI)/hr
_____

Central AHI (CnAHI)/hr
_____

Mean oxygen saturation (%)
_____

3% Oxygen Desaturation Index (ODI) /hr
_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?　　⊗ Yes　○ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 No
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 No Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　○ Yes　⊗ No

If No, please detail why:　　　　　　　　[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?　　○ Yes　⊗ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	◯ Yes ⊗ No
If No, please detail why?	[*DATA REMOVED*]

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Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	79 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	10
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

_____

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

_____

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 3

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 4

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-2

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	18.3
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	◯ Yes ⊗ No
Use of pseudo-anonymised data for future research	◯ Yes ⊗ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	88.45 (10kg - 100kg)
Height (cm)	175.10

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ⊗ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
Asian or Asian British	⊗ Indian ◯ Pakistani ◯ Bangladeshi ◯ Chinese ◯ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No
Number of criteria	4

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	◯ Yes ⊗ No

2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	◯ Yes ⊗ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown

Does the patient have a history of sleep disturbance?   ⊗ Yes   ◯ No

How was sleep disturbance noted?
☒ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	14.682 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	15.744 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	17.757 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	7.80

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	4.5 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	18
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ◯ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ◯ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	6
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 18.3 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	15
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.85 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	1 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	30 (0 - 99)
T-Score:	100 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	7 (0 - 99)
T-Score:	72 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	17 (0 - 99)

T-Score:	88 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	65 (0 - 99)
Total T-Score:	89
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ◯ Yes   ⊗ No

If no, please give reason why   [*DATA REMOVED*]

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used
_____

Device ID
_____

Bedtime
_____

Waketime
_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)
_____

Sleep efficiency SE (%)
_____

Apnoea Hypopnoea Index (AHI)/hr
_____

Obstructive AHI (OAHI)/hr
_____

Central AHI (CnAHI)/hr
_____

Mean oxygen saturation (%)
_____

3% Oxygen Desaturation Index (ODI) /hr
_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 No Was data output collected for night 7 No
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 No Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ⊗ No

If No, please detail why: [*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?   ◯ Yes   ⊗ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+75 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	93 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	10
Number of incorrect skips	20
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date   [*DATA REMOVED*]

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

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Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-3

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date   [*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.3
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	59.40 (10kg - 100kg)
Height (cm)	166.60

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group

Mixed or multiple ethnic groups	◯ White and Black Caribbean ⊗ White and Black African ◯ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	◯ Yes ◯ No

2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No

Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%

Add another calcineurin inhibitor?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

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Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ○ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.345 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	16.196 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	16.16 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature ($\circ$C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

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EASI (score 0-72)	
Test performed?	⊗ Yes ◯ No

Total score	3.60

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	4.5 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	0
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	0
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.3 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	2
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	10 (0 - 99)
T-Score:	50 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	5 (0 - 99)

T-Score:	42 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	30 (0 - 99)
Total T-Score:	43
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? ⊗ Yes ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch? ⊗ Yes ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD? ⊗ Yes ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 _____
  Was data output collected for night 4 Yes Was data output collected for night 9 _____
  Was data output collected for night 5 No Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?	◯ Yes ⊗ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+71.5 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	126 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	13
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	2
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	11
Number of incorrect skips	6
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 [*DATA REMOVED*]   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

Indication

_____

Medication 4

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-4

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.2
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	⊗ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	50.22 (10kg - 100kg)
Height (cm)	160.60

Demographics

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated
Ethnicity	⊗ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group
White	○ English, Welsh, Scottish, Northern Irish or British ○ Irish ○ Gypsy or Irish Traveller ○ Roma ⊗ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No
3. History of flexural involvement	⊗ Yes ○ No
4. History of generally dry skin	⊗ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No
Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	⊗ Yes ◯ No
1. Systemic therapy	
1. Name of systemic therapy	⊗ Oral Methotrexate ◯ Subcutaneous Methotrexate ◯ Other (please specify)
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	◯ mg/kg ⊗ mg
1. Frequency of systemic therapy	⊗ Weekly ◯ Other (please specify)
2. Add another systemic therapy?	◯ Yes ⊗ No

Medical History

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?
☐ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☒ Other medical history

If Other, please specify: [*DATA REMOVED*]

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	12.28 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	13.00 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   13.60

Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	9.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ⊗ No

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Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	26
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.2 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	8
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.38 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.5 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	20 (0 - 99)
T-Score:	82 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	5 (0 - 99)
T-Score:	58 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	15 (0 - 99)
T-Score:	79 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	7 (0 - 99)

T-Score:	50 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	53 (0 - 99)
Total T-Score:	73
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: _____
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?	◯ Yes ⊗ No

Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	◯ Yes ⊗ No
If No, please detail why?	[*DATA REMOVED*]
Resting state:	◯ Yes ⊗ No
If No, please detail why?	[*DATA REMOVED*]

Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score

Left-handedness - Less than -40
Ambidexterity=Between -40 and +40
Right-handness=More than +40

+100
(-100 to 100)

Date — [*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed? — ⊗ Yes ◯ No

Total FSIQ-4 score — 102
(0 - 160)

Date — [*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed? — ⊗ Yes ◯ No

Reaction time (milliseconds) — [*DATA REMOVED*]

RT Standard Deviation (milliseconds) — [*DATA REMOVED*]

Probability inhibition (%) — [*DATA REMOVED*]

Premature responses — 0

Date — [*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed? — ⊗ Yes ◯ No

Reaction time (milliseconds) — [*DATA REMOVED*]

RT Standard Deviation (milliseconds) — [*DATA REMOVED*]

Premature responses — 0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	10
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

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Visit

Mind & Skin ID	728-4

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Visit date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Weight (kg)	51.86 (10kg - 100kg)
Height (cm)	162.50

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Current Eczema Treatment Visit 3

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	◯ Yes ◯ No

2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ◯ No

Assign to Group 2 (topical therapy)

_____

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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	14.95 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	15.79 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.2
PH measurment 2	6.1
PH measurment 3	6.1

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Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	12.80

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Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	○ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer?	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	○ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ○ No
Has the non-lesional sample been taken?	⊗ Yes ○ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ○ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	8.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ○ No
Total score	15
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ○ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	5
Body is an Capable score: (mean of items : 5, 6)	5
Body is a Responsive score: (mean of items :7, 8)	4
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ○ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	23
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	39
Total score	62
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	5
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.2 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	7
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.67 (0 - 99)
2. Sleepiness subscale	0.25 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.83 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	24 (0 - 99)
T-Score:	95 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	5 (0 - 99)
T-Score:	70 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	24 (0 - 99)
T-Score:	100 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	12 (0 - 99)

T-Score:	69 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	72 (0 - 99)
Total T-Score:	99
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID   [*DATA REMOVED*]

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime   22:00

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 No
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
   Was data output collected for night 1 Yes Was data output collected for night 6 Yes
   Was data output collected for night 2 Yes Was data output collected for night 7 Yes
   Was data output collected for night 3 Yes Was data output collected for night 8 Yes
   Was data output collected for night 4 Yes Was data output collected for night 9 Yes
   Was data output collected for night 5 Yes Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Confidential

Mind & Skin ver 4.0
Mind & Skin ID 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Was the MRI peformed? ◯ Yes ⊗ No

If No, please detail why? [*DATA REMOVED*]

Confidential

Mind & Skin ver 4.0
Mind & Skin ID 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	◯ Yes ⊗ No

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	2
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	21
Number of incorrect skips	17
Date	[*DATA REMOVED*]

Confidential

Mind & Skin ver 4.0
Mind & Skin ID 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

_____   Frequency

 _____

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

_____   Frequency

 _____

 Date started

_____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 [*DATA REMOVED*]   Frequency

 _____

 Date started

 [*DATA REMOVED*] Ongoing? _____   Date stopped

 _____

Indication

_____

Medication 4

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

End of Study

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] End of Study

Did participant complete the trial?　　　　　　　◯ Yes　　◯ No

Visit

Mind & Skin ID	728-5

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	12.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility   1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?   ◯ Yes   ◯ No

Print name: [*DATA REMOVED*]

Print role   [*DATA REMOVED*]

Date   [*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	36.35 (10kg - 100kg)
Height (cm)	147.20

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	5

Family History

Family History

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	$\otimes$ Yes $\quad \bigcirc$ No

Potency:	$\bigcirc$ Mild $\otimes$ Moderate $\bigcirc$ Potent $\bigcirc$ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	$\bigcirc$ Yes $\quad \otimes$ No

2. Calcineurin inhibitor/s ?	$\bigcirc$ Yes $\quad \otimes$ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	$\bigcirc$ Yes $\quad \bigcirc$ No

2. Other?	$\bigcirc$ Yes $\quad \bigcirc$ No

3. Other?	$\bigcirc$ Yes $\quad \bigcirc$ No

Systemic therapy

Is the patient starting systemic therapy?	$\bigcirc$ Yes $\quad \otimes$ No

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ○ No ⊗ Unknown
Contact allergies	○ Yes ○ No ⊗ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ○ No

How was sleep disturbance noted?
- ☐ Participant
- ☒ Parent
- ☐ Sibling
- ☐ Partner
- ☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	37.10 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	36.55 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   17.25

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	9.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	19
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	8
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 12.1 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	11
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.4 (0 - 99)
2. Sleepiness subscale	0.33 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.38 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	22 (0 - 99)
T-Score:	89 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	16 (0 - 99)
T-Score:	84 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	10 (0 - 99)

T-Score:	62 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	5 (0 - 99)
T-Score:	64 (0 - 99)
Total score	60 (0 - 99)
Total T-Score:	82
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ○ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
   Was data output collected for night 1 Yes Was data output collected for night 6 Yes
   Was data output collected for night 2 Yes Was data output collected for night 7 Yes
   Was data output collected for night 3 Yes Was data output collected for night 8 Yes
   Was data output collected for night 4 Yes Was data output collected for night 9 Yes
   Was data output collected for night 5 Yes Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?	⊗ Yes ◯ No

Has the Sleep Diary been scanned and uploaded?	⊗ Yes ◯ No

Did the patient use the EMFIT Mattress?   ◯ Yes   ⊗ No

If No, please detail why: [*DATA REMOVED*]

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes　◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes　◯ No
T2FLAIR:	⊗ Yes　◯ No
N-back:	⊗ Yes　◯ No
Delayed RT:	⊗ Yes　◯ No
Resting state:	⊗ Yes　◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	96 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	3

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	20
Number of incorrect skips	11
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

Indication

_____

Medication 4

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 5

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Confidential

Visit

Mind & Skin ID	728-6

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	17.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	61.75 (10kg - 100kg)
Height (cm)	170.00

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ⊗ White and Black African ◯ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ⊗ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	4

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	⊗ Yes ◯ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?
☐ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.30 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	16.84 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   0.80

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	2.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ○ No
Total score	22
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	○ Yes ○ No
Date	_____

BTMS

Questionnaire fully completed?	○ Yes ○ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ○ No
Total score	8
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ○ No
Patient is 17.5 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ○ CDLQI (< =16 years old, range 0-30)
Total score	6
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	11 (0 - 99)
T-Score:	54 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	9 (0 - 99)
T-Score:	54 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	6 (0 - 99)

T-Score:	46 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	4 (0 - 99)
T-Score:	58 (0 - 99)
Total score	37 (0 - 99)
Total T-Score:	53
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 No Was data output collected for night 7 No
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?	◯ Yes ⊗ No

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Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	91 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	2

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	17
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

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Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 3

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-7

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	13.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:	
Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	◯ Yes ⊗ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	63.00 (10kg - 100kg)
Height (cm)	165.50

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated
Ethnicity	○ White ⊗ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group
Black, Black British, Caribbean or African	⊗ Caribbean ○ African ○ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No
3. History of flexural involvement	⊗ Yes ○ No
4. History of generally dry skin	⊗ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No
Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No
Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%
Add another calcineurin inhibitor?	◯ Yes ◯ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	○ No	○ Unknown
Food allergies	⊗ Yes	○ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	29.95 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	29.36 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

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EASI (score 0-72)	
Test performed?	⊗ Yes ◯ No

Total score	16.60

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	3.6 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No

Was the sample taken from left volar forearm	⊗ Yes ◯ No

Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No

Date of sample	[*DATA REMOVED*]

Was sample received by site?	⊗ Yes ◯ No

Was sample stored in -80°C freezer?	⊗ Yes ◯ No

Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	10
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 13.5 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	9
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.14 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	16 (0 - 99)
T-Score:	70 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	8 (0 - 99)

T-Score:	53 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	38 (0 - 99)
Total T-Score:	54
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?	⊗ Yes ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?	◯ Yes ⊗ No
If no, please give reason why	[*DATA REMOVED*]

Somnotouch HD

Did the patient use the Somnotouch HD?	⊗ Yes ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

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Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No   Was data output collected for night 6 No
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ⊗ No

If No, please detail why: [*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	100 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ○ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ○ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ○ No
Number of missed skips	28
Number of incorrect skips	25
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 3

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

_____   Ongoing? _____   Date stopped

_____

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Indication

_____

Medication 4

_____

Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-8

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
   VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	55.08 (10kg - 100kg)
Height (cm)	152.10

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated
Ethnicity	○ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ⊗ Mixed or multiple ethnic groups ○ Other ethnic group
Mixed or multiple ethnic groups	⊗ White and Black Caribbean ○ White and Black African ○ White and Asian ○ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	○ Yes ⊗ No
3. History of flexural involvement	⊗ Yes ○ No
4. History of generally dry skin	⊗ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No
Number of criteria	4

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

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Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?
- ☐ Participant
- ☒ Parent
- ☐ Sibling
- ☐ Partner
- ☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
- ☐ ADHD
- ☒ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	_____
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	16.07 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	19.27 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	19.22 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

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Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   2.20

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	2.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ◯ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ◯ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.5 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	6
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.33 (0 - 99)
2. Sleepiness subscale	0.75 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.88 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	21 (0 - 99)
T-Score:	86 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	5 (0 - 99)
T-Score:	70 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	13 (0 - 99)

T-Score:	73 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	56 (0 - 99)
Total T-Score:	77
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
 Was data output collected for night 1 Yes Was data output collected for night 6 No
 Was data output collected for night 2 No Was data output collected for night 7 No
 Was data output collected for night 3 Yes Was data output collected for night 8 No
 Was data output collected for night 4 Yes Was data output collected for night 9 No
 Was data output collected for night 5 Yes Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 No Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 No
  Was data output collected for night 5 No Was data output collected for night 10 No

Sleep diary

Has the Sleep Diary been completed?   ◯ Yes   ⊗ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	105 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	2

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	13
Number of incorrect skips	5
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

[*DATA REMOVED*]

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 3

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 4

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Medication 5

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-9

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	49.40 (10kg - 100kg)
Height (cm)	173.00

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	◯ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ⊗ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ⊗ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No
Number of criteria	3

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	○ Mild ○ Moderate ⊗ Potent ○ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	⊗ Mild ○ Moderate ○ Potent ○ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ⊗ No
2. Calcineurin inhibitor/s ?	○ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	○ Yes ○ No
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ○ No ○ Unknown
Food allergies	⊗ Yes ○ No ○ Unknown
Contact allergies	⊗ Yes ○ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	◯ Yes ⊗ No

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	16.713 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	15.256 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.4
PH measurment 2	5.7
PH measurment 3	_____

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

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EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   2.40

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	2.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ◯ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ◯ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.1 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	1
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.38 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.5 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	21 (0 - 99)
T-Score:	86 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	13 (0 - 99)
T-Score:	70 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	14 (0 - 99)

T-Score:	77 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	57 (0 - 99)
Total T-Score:	79
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ⊗ No

If No, please detail why: [*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score

Left-handedness - Less than -40
Ambidexterity=Between -40 and +40
Right-handness=More than +40

+100
(-100 to 100)

Date
[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score
113
(0 - 160)

Date
[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	13
Number of incorrect skips	15
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 3

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-10

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Confidential

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	○ Group 1 (immuno-modulatory therapy) ○ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes　○ No
Use of pseudo-anonymised data for future research	⊗ Yes　○ No
Focus group participation	⊗ Yes　○ No
GP contact	⊗ Yes　○ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ⊗ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	64.40 (10kg - 100kg)
Height (cm)	174.00

Confidential

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	◯ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ⊗ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No
Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	○ No	○ Unknown
Food allergies	○ Yes	⊗ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	9.097 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	9.798 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.7
PH measurment 2	5.7
PH measurment 3	_____

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	_____

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.31 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.5 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	23 (0 - 99)
T-Score:	93 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	7 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	6 (0 - 99)

T-Score:	46 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	43 (0 - 99)
Total T-Score:	60
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? ⊗ Yes ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch? ⊗ Yes ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD? ⊗ Yes ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No   Was data output collected for night 6 Yes
  Was data output collected for night 2 No   Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes   Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes   Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes   Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?	○ Yes ⊗ No

If No, please detail why:	[*DATA REMOVED*]

Sleep diary

Has the Sleep Diary been completed?	⊗ Yes ○ No

Has the Sleep Diary been scanned and uploaded?	⊗ Yes ○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	119 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	14
Number of incorrect skips	10
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

[*DATA REMOVED*]

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ○ Yes   ○ No

Visit

Mind & Skin ID	728-11

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials

_____

Date of birth

_____

Date of patient consent/assent

_____

_age

_____

Date of parent/guardian consent

_____

Subject group

◯ Group 1 (immuno-modulatory therapy)
◯ Group 2 (topical therapy)
◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research ◯ Yes ◯ No

Use of pseudo-anonymised data for future research ◯ Yes ◯ No

Focus group participation ◯ Yes ◯ No

GP contact ◯ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP _____ INITIALS _____
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

◯ Yes   ◯ No

4. Willingness to comply with all study requirements.

◯ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

◯ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ◯ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ◯ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ◯ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ◯ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ◯ No

6. Previous and/or current substance misuse.

◯ Yes   ◯ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ◯ No

8. Current phototherapy treatment.

◯ Yes   ◯ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility

_____

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No

Print name:

_____

Print role

_____

Date

_____

Height&Weight

GROUP _____ INITIALS _____
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ◯ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ◯ No

Assign to Group 3 (healthy controls)	_____

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	_____

Family History

Family History	_____

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Current Eczema Treatment

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

REDCap

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	◯ Yes ◯ No

2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ◯ No

Assign to Group 2 (topical therapy)

_____

Medical History

GROUP _____ INITIALS _____
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma ○ Yes ○ No ○ Unknown

Allergic rhino-conjunctivitis (hayfever) ○ Yes ○ No ○ Unknown

---

Food allergies ○ Yes ○ No ○ Unknown

Contact allergies ○ Yes ○ No ○ Unknown

Does the patient have a history of sleep disturbance? ○ Yes ○ No

---

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

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Skin Barrier Function Assessments

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement
(uninvolved skin left volar forearm)   ◯ Yes   ◯ No

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 2 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 3 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

Decent measurement curves?   ◯ Yes   ◯ No

Temperature (◦C)

_____

Room humidity (%)

_____

PH measurements

PH meter reading (volar forearm)   ◯ Yes   ◯ No

Skin Examination

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ◯ Yes   ◯ No

Total score

_____

Samples

GROUP _____   INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	○ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	○ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	○ Yes ○ No
Has the non-lesional sample been taken?	○ Yes ○ No
Has the lesional sample been taken?	○ Yes ○ No

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	○ Yes ○ No
Was the sample taken from left volar forearm	○ Yes ○ No
Date sample collected	_____

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	○ Yes ○ No

Patient-Reported Quality Of Life Measures

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed? ◯ Yes ◯ No

Body Mindset Inventory

Questionnaire fully completed? ◯ Yes ◯ No

BTMS

Questionnaire fully completed? ◯ Yes ◯ No

Itch severity numerical rating score (0-10)

VAS completed ◯ Yes ◯ No

Skin-specific quality of life questionnaire

Questionnaire fully completed? ◯ Yes ◯ No

Questionnaire-Based Sleep Assessments

GROUP _____ INITIALS _____
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?   ◯ Yes   ◯ No

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?   ◯ Yes   ◯ No

Homebased Sleep Assessments

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ◯ No

Neurocognitive Assessments

GROUP _____   INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?   ○ Yes   ○ No

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?   ○ Yes   ○ No

Motor response inhibition assessment

Go/No-go task completed?   ○ Yes   ○ No

Interference inhibition/selective attention assessment

Simon task completed?   ○ Yes   ○ No

Sustained/selective attention assessment

Continuous performance task completed?   ○ Yes   ○ No

Time perception assessment

Time discrimination task completed?   ○ Yes   ○ No

Vigilance assessment

Mackworth Clock task completed?   ○ Yes   ○ No

Completed By

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-12

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ⊗ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

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7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility   0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?   ◯ Yes   ◯ No

Print name: [*DATA REMOVED*]

Print role   [*DATA REMOVED*]

Date   [*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	56.20 (10kg - 100kg)
Height (cm)	165.60

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	◯ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ⊗ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No
Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.91 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	16.25 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.5
PH measurment 2	5.4
PH measurment 3	_____

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	9 (0 - 99)
T-Score:	47 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	5 (0 - 99)
T-Score:	58 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	8 (0 - 99)
T-Score:	50 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	8 (0 - 99)

T-Score:	53 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	35 (0 - 99)
Total T-Score:	50
Date	[*DATA REMOVED*]

Confidential

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? $\otimes$ Yes $\bigcirc$ No

---

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch? $\otimes$ Yes $\bigcirc$ No

---

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD? $\otimes$ Yes $\bigcirc$ No

---

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
 Was data output collected for night 1 No Was data output collected for night 6 Yes
 Was data output collected for night 2 Yes Was data output collected for night 7 Yes
 Was data output collected for night 3 Yes Was data output collected for night 8 Yes
 Was data output collected for night 4 Yes Was data output collected for night 9 Yes
 Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No   Was data output collected for night 6 No
  Was data output collected for night 2 No   Was data output collected for night 7 No
  Was data output collected for night 3 No   Was data output collected for night 8 No
  Was data output collected for night 4 No   Was data output collected for night 9 Yes
  Was data output collected for night 5 No   Was data output collected for night 10 No

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	113 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	1

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	3
Number of incorrect skips	8
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ○ Yes   ○ No

REDCap

Visit

Mind & Skin ID	728-13

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	_____
Date of birth	_____
Date of patient consent/assent	_____
_age	_____
Date of parent/guardian consent	_____
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	◯ Yes ◯ No
Use of pseudo-anonymised data for future research	◯ Yes ◯ No
Focus group participation	◯ Yes ◯ No
GP contact	◯ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

◯ Yes   ◯ No

4. Willingness to comply with all study requirements.

◯ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

◯ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ◯ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ◯ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ◯ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ◯ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ◯ No

6. Previous and/or current substance misuse.

◯ Yes   ◯ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ◯ No

8. Current phototherapy treatment.

◯ Yes   ◯ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility

_____

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No

Print name:

_____

Print role

_____

Date

_____

Height&Weight

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ◯ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ◯ No

Assign to Group 3 (healthy controls)

_____

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria

_____

Family History

Family History

_____

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Current Eczema Treatment

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	○ Yes ○ No
2. Calcineurin inhibitor/s ?	○ Yes ○ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	○ Yes ○ No
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

Systemic therapy

Is the patient starting systemic therapy?	○ Yes ○ No

Assign to Group 2 (topical therapy)

_____

Medical History

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes ◯ No ◯ Unknown
Food allergies	◯ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ◯ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ◯ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

Confidential

Skin Barrier Function Assessments

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement
(uninvolved skin left volar forearm)   ◯ Yes   ◯ No

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 2 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 3 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

Decent measurement curves?   ◯ Yes   ◯ No

Temperature (◦C)

_____

Room humidity (%)

_____

PH measurements

PH meter reading (volar forearm)   ◯ Yes   ◯ No

Skin Examination

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ◯ Yes   ◯ No

Total score

_____

Samples

GROUP _____ INITIALS _____
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	◯ Yes ◯ No
Has the non-lesional sample been taken?	◯ Yes ◯ No
Has the lesional sample been taken?	◯ Yes ◯ No

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	◯ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ◯ No
Date sample collected	_____

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ◯ No

Confidential

Patient-Reported Quality Of Life Measures

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed? ○ Yes ○ No

Body Mindset Inventory

Questionnaire fully completed? ○ Yes ○ No

BTMS

Questionnaire fully completed? ○ Yes ○ No

Itch severity numerical rating score (0-10)

VAS completed ○ Yes ○ No

Skin-specific quality of life questionnaire

Questionnaire fully completed? ○ Yes ○ No

Questionnaire-Based Sleep Assessments

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed? ◯ Yes ◯ No

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed? ◯ Yes ◯ No

Homebased Sleep Assessments

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP _____   INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ◯ No

Neurocognitive Assessments

GROUP _____ INITIALS _____
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

REDCap

Edinburgh Handedness Inventory

Assessment completed?   ○ Yes   ○ No

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?   ○ Yes   ○ No

Motor response inhibition assessment

Go/No-go task completed?   ○ Yes   ○ No

Interference inhibition/selective attention assessment

Simon task completed?   ○ Yes   ○ No

Sustained/selective attention assessment

Continuous performance task completed?   ○ Yes   ○ No

Time perception assessment

Time discrimination task completed?   ○ Yes   ○ No

Vigilance assessment

Mackworth Clock task completed?   ○ Yes   ○ No

Completed By

GROUP _____ INITIALS _____
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-14

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	47.80 (10kg - 100kg)
Height (cm)	150.50

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	○ White ○ Black, Black British, Caribbean or African ⊗ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

Asian or Asian British	○ Indian ○ Pakistani ⊗ Bangladeshi ○ Chinese ○ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No

3. History of flexural involvement	⊗ Yes ○ No

4. History of generally dry skin	⊗ Yes ○ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steroid 3	[*DATA REMOVED*]
Add another steroid?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No
3. Soap substitutes /moisturisers?	_____
4. Other topical therapy	_____
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ⊗ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

REDCap

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	21.533 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	28.332 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	24.822 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	23.5
Room humidity (%)	53.9

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.4
PH measurment 2	5.3
PH measurment 3	5.4

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

REDCap

EASI (score 0-72)	
Test performed?	⊗ Yes ◯ No
Total score	3.00

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	5.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?   ⊗ Yes   ◯ No

Was the sample taken from left volar forearm   ⊗ Yes   ◯ No

Date sample collected   [*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?   ⊗ Yes   ◯ No

Date of sample

_____

Was sample received by site?   ◯ Yes   ⊗ No

Was sample stored in -80°C freezer?   ◯ Yes   ◯ No

Was sample collection logged on freezer sample log?   ◯ Yes   ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	6
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ◯ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ◯ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 14.9 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	1
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	7 (0 - 99)
T-Score:	41 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	5 (0 - 99)

T-Score:	42 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	26 (0 - 99)
Total T-Score:	38
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress? ⊗ Yes ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed? ⊗ Yes ◯ No

Has the Sleep Diary been scanned and uploaded? ⊗ Yes ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	-25 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	114 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	4
Number of incorrect skips	2
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 _____   Frequency

 [*DATA REMOVED*]

 Date started

 _____   Ongoing? _____   Date stopped

 _____

Indication

_____

Medication 4

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-15

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	○ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ○ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ○ No
Use of pseudo-anonymised data for future research	⊗ Yes ○ No
Focus group participation	⊗ Yes ○ No
GP contact	⊗ Yes ○ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	68.30 (10kg - 100kg)
Height (cm)	166.50

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated
Ethnicity	○ White ○ Black, Black British, Caribbean or African ⊗ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group
Asian or Asian British	○ Indian ○ Pakistani ○ Bangladeshi ○ Chinese ⊗ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No
3. History of flexural involvement	⊗ Yes ○ No
4. History of generally dry skin	⊗ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	○ Yes ⊗ No
Number of criteria	4

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	◯ Yes ⊗ No

2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?

☐ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	18.504 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	21.371 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	21.802 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.5
PH measurment 2	5.5
PH measurment 3	5.6

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Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   8.40

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	6.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ○ No
Total score	6
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	○ Yes ○ No
Date	_____

BTMS

Questionnaire fully completed?	○ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ○ No
Total score	2
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ○ No
Patient is 16.9 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ○ CDLQI (< =16 years old, range 0-30)
Total score	1
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No

1. SRBD scale (including snoring and sleepiness subscales)	0.24 (0 - 99)

2. Sleepiness subscale	0 (0 - 99)

3. Periodic Leg Movement/Restless Legs Syndrome scale	0.13 (0 - 99)

Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No

Disorders of initiating and maintaining sleep score
(sum the score of the items 1,2,3,4,5,10,11)
_____
(0 - 99)

T-Score:
_____
(0 - 99)

Sleep Related Breathing Disorders score (sum the score
of the items 13,14,15)
_____
(0 - 99)

T-Score:
_____
(0 - 99)

Disorders of arousal score (sum the score of the items
17,20,21)
_____
(0 - 99)

T-Score:
_____
(0 - 99)

Sleep-Wake Transition Disorders score (sum the score
of the items 6,7,8,12,18,19)
_____
(0 - 99)

T-Score:

_____
(0 - 99)

Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Sleep Hyperhydrosis (sum the score of the items 9,16)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Total score

_____
(0 - 99)

Total T-Score:

_____

Date

_____

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?	○ Yes ⊗ No

Please specify why home-based sleep assessments were not performed	[*DATA REMOVED*]

DREEM headband

Did the patient use the DREEM headband?	○ Yes ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	○ Yes ○ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?　　　　　　　　　　　◯ Yes　◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	◯ Yes ◯ No

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No
Total FSIQ-4 score	103 (0 - 160)
Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	◯ Yes ◯ No

Interference inhibition/selective attention assessment

Simon task completed?	◯ Yes ◯ No

Sustained/selective attention assessment

Continuous performance task completed?	◯ Yes ◯ No

Time perception assessment

Time discrimination task completed?	◯ Yes ◯ No

Vigilance assessment

Mackworth Clock task completed?	◯ Yes ◯ No

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 3

 _____
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-16

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ⊗ No

_eligibility   1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	78.05 (10kg - 100kg)
Height (cm)	165.10

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ⊗ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

Black, Black British, Caribbean or African	◯ Caribbean ⊗ African ◯ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ○ No

Potency:	○ Mild ⊗ Moderate ○ Potent ○ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ○ No

Potency	⊗ Mild ○ Moderate ○ Potent ○ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	○ Yes ○ No

2. Calcineurin inhibitor/s ?	⊗ Yes ○ No

Calicineurin drug 1	○ Pimecrolimus 1% ○ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%

Add another calcineurin inhibitor?	○ Yes ○ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	○ Yes ○ No

2. Other?	○ Yes ○ No

3. Other?	○ Yes ○ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes	⊗ No	◯ Unknown

Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown

Food allergies	⊗ Yes	◯ No	◯ Unknown

Contact allergies	◯ Yes	⊗ No	◯ Unknown

Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

REDCap

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	14.96 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	13.1 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	14.92 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.0
PH measurment 2	6.4
PH measurment 3	6.5

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   2.30

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	3.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	6
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 16.1 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	5
Date	[*DATA REMOVED*]

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Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ○ No
1. SRBD scale (including snoring and sleepiness subscales)	0.09 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ○ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	13 (0 - 99)
T-Score:	60 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	9 (0 - 99)
T-Score:	54 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	14 (0 - 99)

T-Score:	77 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	45 (0 - 99)
Total T-Score:	63
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　⊗ Yes　◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?　　⊗ Yes　◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?　　⊗ Yes　◯ No

Date used　　[*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 No Was data output collected for night 7 No
  Was data output collected for night 3 No Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 No Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	103 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	2
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No

% Omission error	[*DATA REMOVED*]

Premature errors	0

% Commission error	[*DATA REMOVED*]

Mean reaction time (milliseconds)	[*DATA REMOVED*]

MRT Standard Deviation	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No

%Total error	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No

Number of missed skips	10

Number of incorrect skips	6

Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____ Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____ Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? Yes   Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose _____ Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? _____   Date stopped

 _____

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Indication

_____

Medication 4

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Confidential

Visit

Mind & Skin ID	728-17

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Confidential

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.4
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ⊗ Female ◯ Undifferentiated

Correction:

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ⊗ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

Asian or Asian British	⊗ Indian ◯ Pakistani ◯ Bangladeshi ◯ Chinese ◯ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	◯ Yes ⊗ No

2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No

Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%

Add another calcineurin inhibitor?	◯ Yes ⊗ No

3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

| Asthma | ◯ Yes | ⊗ No | ◯ Unknown |

| Allergic rhino-conjunctivitis (hayfever) | ⊗ Yes | ◯ No | ◯ Unknown |

| Food allergies | ◯ Yes | ⊗ No | ◯ Unknown |

| Contact allergies | ⊗ Yes | ◯ No | ◯ Unknown |

| Does the patient have a history of sleep disturbance? | ◯ Yes | ⊗ No |

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	28.87 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	27.63 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.6
PH measurment 2	5.6
PH measurment 3	5.6

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   4.80

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	3.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	8
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	5
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.4 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	6
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.14 (0 - 99)
2. Sleepiness subscale	0.33 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	9 (0 - 99)
T-Score:	47 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	9 (0 - 99)

T-Score:	58 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	32 (0 - 99)
Total T-Score:	46
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	116 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	◯ Yes ◯ No

Interference inhibition/selective attention assessment

Simon task completed?	◯ Yes ◯ No

Sustained/selective attention assessment

Continuous performance task completed?	◯ Yes ◯ No

Time perception assessment

Time discrimination task completed?	◯ Yes ◯ No

Vigilance assessment

Mackworth Clock task completed?   ◯ Yes   ◯ No

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

[*DATA REMOVED*]

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-18

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

○ Yes   ⊗ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ○ No

4. Willingness to comply with all study requirements.

⊗ Yes   ○ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ○ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

○ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

○ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

○ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

○ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

○ Yes   ⊗ No

6. Previous and/or current substance misuse.

○ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	66.10 (10kg - 100kg)
Height (cm)	177.80

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated

Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No

3. History of flexural involvement	◯ Yes ◯ No

4. History of generally dry skin	◯ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	0

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ⊗ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes ⊗ No ◯ Unknown
Food allergies	◯ Yes ⊗ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	13.03 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	14.78 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	16.53 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.9
PH measurment 2	5.9
PH measurment 3	5.9

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ○ No
Was the sample taken from left volar forearm	⊗ Yes ○ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ○ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer?	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.29 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.13 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	_____ (0 - 99)

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T-Score:

_____
(0 - 99)

Disorders of excessive somnolence score (sum the score
of the items 22,23,24,25,26)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Sleep Hyperhydrosis (sum the score of the items 9,16)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Total score

_____
(0 - 99)

Total T-Score:

_____

Date
[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 No Was data output collected for night 7 No
  Was data output collected for night 3 No Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 Yes
  Was data output collected for night 5 No Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　　　⊗ Yes　○ No

Start Date:　[*DATA REMOVED*]　End Date:　[*DATA REMOVED*]
　Was data output collected for night 1 No　Was data output collected for night 6 Yes
　Was data output collected for night 2 Yes　Was data output collected for night 7 Yes
　Was data output collected for night 3 Yes　Was data output collected for night 8 No
　Was data output collected for night 4 No　Was data output collected for night 9 Yes
　Was data output collected for night 5 Yes　Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed?　　　　　⊗ Yes　○ No

Has the Sleep Diary been scanned and uploaded?　　⊗ Yes　○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	-25 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	118 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	2
Number of incorrect skips	3
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 2

 _____
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-19

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	◯ Yes ⊗ No
Focus group participation	◯ Yes ⊗ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	55.86 (10kg - 100kg)
Height (cm)	150.90

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ⊗ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	◯ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	⊗ Yes	◯ No	◯ Unknown
Contact allergies	◯ Yes	⊗ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	21.26 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	21.23 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	25.7
Room humidity (%)	56.8

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.9
PH measurment 2	5.3
PH measurment 3	5.7

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ○ Yes   ⊗ No

Total score

_____

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	3.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	
	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Stool sample for gut microbiome analysis

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	24
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.1 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	6
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.25 (0 - 99)
2. Sleepiness subscale	0.75 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.83 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	22 (0 - 99)
T-Score:	89 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	12 (0 - 99)
T-Score:	66 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	9 (0 - 99)

T-Score:	58 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	51 (0 - 99)
Total T-Score:	70
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? $\otimes$ Yes $\bigcirc$ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch? $\otimes$ Yes $\bigcirc$ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD? $\otimes$ Yes $\bigcirc$ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 No

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EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　　⊗ Yes　　◯ No

Start Date: [*DATA REMOVED*]　End Date: [*DATA REMOVED*]
　Was data output collected for night 1 Yes　Was data output collected for night 6 Yes
　Was data output collected for night 2 No　Was data output collected for night 7 Yes
　Was data output collected for night 3 No　Was data output collected for night 8 Yes
　Was data output collected for night 4 No　Was data output collected for night 9 Yes
　Was data output collected for night 5 No　Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed?　　　　⊗ Yes　　◯ No

Has the Sleep Diary been scanned and uploaded?　　　⊗ Yes　　◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	90 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	10
Number of incorrect skips	3
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____ Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 _____ Ongoing? _____ Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____ Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 _____ Ongoing? _____ Date stopped

 _____

 Indication

 _____

Medication 3

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 _____ Frequency

 [*DATA REMOVED*]

 Date started

 [*DATA REMOVED*] Ongoing? _____   Date stopped

 _____

Indication

_____

Medication 4

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? _____   Date stopped

_____

Indication

_____

Medication 5

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-20

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

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Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.8
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	61.10 (10kg - 100kg)
Height (cm)	180.00

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Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	5

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	⊗ Yes ◯ No

Potency	⊗ Mild ◯ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 3	[*DATA REMOVED*]

Add another steroid?	◯ Yes ⊗ No

2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No

Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ◯ Tacrolimus 0.1%

3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy	[*DATA REMOVED*]

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ◯ No

How was sleep disturbance noted?
☐ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	8.4 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	14.5 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	13.9 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	26.5
Room humidity (%)	58.2

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.9
PH measurment 2	6.5
PH measurment 3	6.2

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   5.20

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer?	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ○ No
Has the non-lesional sample been taken?	⊗ Yes ○ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ○ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	6.5 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	22
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	6
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 14.8 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	10
Date	[*DATA REMOVED*]

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Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.55 (0 - 99)
2. Sleepiness subscale	0.75 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.63 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	25 (0 - 99)
T-Score:	99 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	13 (0 - 99)

T-Score:	73 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	4 (0 - 99)
T-Score:	58 (0 - 99)
Total score	60 (0 - 99)
Total T-Score:	82
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?	◯ Yes ⊗ No
If No, please detail why:	[*DATA REMOVED*]

EMFIT Mattress

Did the patient use the EMFIT Mattress? ⊗ Yes ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 No Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed? ⊗ Yes ◯ No

Has the Sleep Diary been scanned and uploaded? ⊗ Yes ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ○ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ○ No
T2FLAIR:	⊗ Yes ○ No
N-back:	⊗ Yes ○ No
Delayed RT:	⊗ Yes ○ No
Resting state:	⊗ Yes ○ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	42.75 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	132 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	2
Number of incorrect skips	0
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 3

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 4

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 5

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

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Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-21

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.2
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ⊗ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	54.10 (10kg - 100kg)
Height (cm)	162.90

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ⊗ White and Black African ◯ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No
Number of criteria	4

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	◯ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	⊗ Yes	◯ No	◯ Unknown
Contact allergies	◯ Yes	⊗ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	[*DATA REMOVED*]

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	14.107 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	13.26 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	22.9
Room humidity (%)	65.4

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.6
PH measurment 2	6.8
PH measurment 3	7.1

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	1.60

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	0.4 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?   ⊗ Yes   ◯ No

Was the sample taken from left volar forearm   ⊗ Yes   ◯ No

Date sample collected   [*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?   ⊗ Yes   ◯ No

Date of sample

_____

Was sample received by site?   ◯ Yes   ◯ No

Was sample stored in -80°C freezer?   ◯ Yes   ◯ No

Was sample collection logged on freezer sample log?   ◯ Yes   ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	1
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	2.75
Body is an Capable score: (mean of items : 5, 6)	3
Body is a Responsive score: (mean of items :7, 8)	2.5
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	62
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	18
Total score	44
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	2
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.2 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	4
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.09 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	12 (0 - 99)
T-Score:	58 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	7 (0 - 99)

T-Score:	50 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	39 (0 - 99)
Total T-Score:	55
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ○ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ○ Yes   ⊗ No

If no, please give reason why   [*DATA REMOVED*]

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ○ No

Date used   [*DATA REMOVED*]

Device ID   _____

Bedtime   _____

Waketime   _____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)   _____

Sleep efficiency SE (%)   _____

Apnoea Hypopnoea Index (AHI)/hr   _____

Obstructive AHI (OAHI)/hr   _____

Central AHI (CnAHI)/hr   _____

Mean oxygen saturation (%)   _____

3% Oxygen Desaturation Index (ODI) /hr   _____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 No

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score	14.25
	(-100 to 100)
Left-handedness - Less than -40	
Ambidexterity=Between -40 and +40	
Right-handness=More than +40	

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	94
	(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	29
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	_____
Number of incorrect skips	_____
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____ Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-22

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	13.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

REDCap

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ⊗ No

_eligibility   1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	◯ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ⊗ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

Black, Black British, Caribbean or African	⊗ Caribbean ◯ African ◯ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	◯ Yes ◯ No

2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No

2. Other?	◯ Yes ◯ No

3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No

Assign to Group 2 (topical therapy)   0

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Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	◯ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	⊗ Yes	◯ No	◯ Unknown
Contact allergies	◯ Yes	⊗ No	◯ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes	◯ No	

How was sleep disturbance noted?

☒ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	◯ Yes ◯ No
Temperature (◦C)	27.1
Room humidity (%)	55.4

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.3
PH measurment 2	5.2
PH measurment 3	5.0

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score   2.00

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	0.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	15
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	◯ Yes ⊗ No
Date	_____

BTMS

Questionnaire fully completed?	◯ Yes ⊗ No

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	5
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 13.7 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	7
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.6 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.5 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	25 (0 - 99)
T-Score:	99 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	7 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	16 (0 - 99)

T-Score:	85 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	56 (0 - 99)
Total T-Score:	77
Date	[*DATA REMOVED*]

Confidential

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? $\otimes$ Yes $\bigcirc$ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch? $\otimes$ Yes $\bigcirc$ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD? $\otimes$ Yes $\bigcirc$ No

Date used

_____

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 Yes
  Was data output collected for night 5 No Was data output collected for night 10 No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 Yes Was data output collected for night 7 No
  Was data output collected for night 3 Yes Was data output collected for night 8 No
  Was data output collected for night 4 Yes Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 No

Sleep diary

Has the Sleep Diary been completed?   ◯ Yes   ⊗ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score	100
	(-100 to 100)
Left-handedness - Less than -40	
Ambidexterity=Between -40 and +40	
Right-handness=More than +40	

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	101
	(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	23

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ○ No
% Omission error	[*DATA REMOVED*]
Premature errors	15
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ○ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ○ No
Number of missed skips	17
Number of incorrect skips	26
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 2

 [*DATA REMOVED*]
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

 Indication

 _____

Medication 3

 _____
 Dose _____   Units

 _____   Frequency

 _____

 Date started

 _____   Ongoing? _____   Date stopped

 _____

Indication

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-23

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	17.2
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ⊗ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

⊗ Yes   ◯ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	58.70 (10kg - 100kg)
Height (cm)	164.00

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ⊗ No

3. History of flexural involvement	◯ Yes ⊗ No

4. History of generally dry skin	◯ Yes ⊗ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ⊗ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No

Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

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Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	○ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes	⊗ No	○ Unknown
Food allergies	○ Yes	⊗ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	10.67 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	10.2 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	22.9
Room humidity (%)	39.9

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.1
PH measurment 2	6.2
PH measurment 3	6.3

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	_____ (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	10 (0 - 99)
T-Score:	50 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	7 (0 - 99)

T-Score:	50 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	31 (0 - 99)
Total T-Score:	45
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 Yes Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 No Was data output collected for night 9 No
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 No
  Was data output collected for night 2 Yes Was data output collected for night 7 No
  Was data output collected for night 3 No Was data output collected for night 8 No
  Was data output collected for night 4 No Was data output collected for night 9 No
  Was data output collected for night 5 No Was data output collected for night 10 No

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ○ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ○ No
T2FLAIR:	⊗ Yes ○ No
N-back:	⊗ Yes ○ No
Delayed RT:	⊗ Yes ○ No
Resting state:	⊗ Yes ○ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	124 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	3
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

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Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ⊗ No

Visit

Mind & Skin ID	728-24

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
   VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

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Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	17.2
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	○ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ○ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ○ No
Use of pseudo-anonymised data for future research	⊗ Yes ○ No
Focus group participation	⊗ Yes ○ No
GP contact	⊗ Yes ○ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	⊗ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ○ Irish ○ Gypsy or Irish Traveller ○ Roma ○ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No

3. History of flexural involvement	⊗ Yes ○ No

4. History of generally dry skin	⊗ Yes ○ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No

Number of criteria	5

Family History

Family History

_____

Confidential

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes ○ No

How was sleep disturbance noted?
☐ Participant
☒ Parent
☐ Sibling
☐ Partner
☐ Other (please specify)

Past Medical History

Past Medical History (select all that apply)
☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	18.03 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	17.25 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (∘C)	24.3
Room humidity (%)	58.7

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.2
PH measurment 2	5.1
PH measurment 3	5.1

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Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	1.30

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	○ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	○ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	○ Yes ○ No
Has the non-lesional sample been taken?	○ Yes ○ No
Has the lesional sample been taken?	○ Yes ○ No

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	○ Yes ○ No
Was the sample taken from left volar forearm	○ Yes ○ No
Date sample collected	_____

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	○ Yes ○ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	6
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	1.5
Body is an Capable score: (mean of items : 5, 6)	3
Body is a Responsive score: (mean of items :7, 8)	1
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	39
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	19
Total score	20
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 17.2 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	4
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.25 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	1 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	14 (0 - 99)
T-Score:	64 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	6 (0 - 99)
T-Score:	82 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	11 (0 - 99)

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T-Score:	64 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	6 (0 - 99)
T-Score:	69 (0 - 99)
Total score	52 (0 - 99)
Total T-Score:	72
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	○ Yes ○ No

Motor response inhibition assessment

Go/No-go task completed?	○ Yes ○ No

Interference inhibition/selective attention assessment

Simon task completed?	○ Yes ○ No

Sustained/selective attention assessment

Continuous performance task completed?	○ Yes ○ No

Time perception assessment

Time discrimination task completed?	○ Yes ○ No

Vigilance assessment

Mackworth Clock task completed?	○ Yes ○ No

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-25

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.3
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	58.90 (10kg - 100kg)
Height (cm)	171.50

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	○ Mild ⊗ Moderate ○ Potent ○ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	○ Mild ○ Moderate ⊗ Potent ○ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ○ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	○ Pimecrolimus 1% ○ Tacrolimus 0.03% ○ Tacrolimus 0.1%
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	○ Yes ○ No
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	◯ Yes ⊗ No

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	○ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	○ No	○ Unknown
Food allergies	⊗ Yes	○ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☒ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	27 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	27.5 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	27.4 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	24.4
Room humidity (%)	46.1

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.1
PH measurment 2	5.95
PH measurment 3	5.83

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	11.75

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	7.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	19
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	1.5
Body is an Capable score: (mean of items : 5, 6)	4
Body is a Responsive score: (mean of items :7, 8)	5
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	38
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	19
Total score	20
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.3 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	11
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.31 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.8 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	14 (0 - 99)
T-Score:	64 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	13 (0 - 99)
T-Score:	70 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	8 (0 - 99)

T-Score:	53 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	45 (0 - 99)
Total T-Score:	63
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score	100
	(-100 to 100)
Left-handedness - Less than -40	
Ambidexterity=Between -40 and +40	
Right-handness=More than +40	

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	114
	(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	3
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	14
Number of incorrect skips	15
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 3

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-26

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Confidential

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.4
Date of parent/guardian consent	_____
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	55.20 (10kg - 100kg)
Height (cm)	157.50

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated
Ethnicity	⊗ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group
White	⊗ English, Welsh, Scottish, Northern Irish or British ○ Irish ○ Gypsy or Irish Traveller ○ Roma ○ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	○ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	○ Yes ○ No
3. History of flexural involvement	○ Yes ○ No
4. History of generally dry skin	○ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	○ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	○ Yes ○ No
Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?			
Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes	⊗ No	○ Unknown
Food allergies	○ Yes	⊗ No	○ Unknown
Contact allergies	⊗ Yes	○ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	16.8 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	18.2 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	18.1 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	25.3
Room humidity (%)	36.0

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.7
PH measurment 2	6.0
PH measurment 3	5.9

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	_____
Was sample received by site?	○ Yes ⊗ No
Was sample stored in -80°C freezer	○ Yes ⊗ No
Was sample collection logged on freezer sample log?	○ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer?	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ○ No
Has the non-lesional sample been taken?	⊗ Yes ○ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	○ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.09 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.38 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	13 (0 - 99)
T-Score:	60 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	7 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	8 (0 - 99)

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T-Score:	53 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	37 (0 - 99)
Total T-Score:	53
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ○ Yes   ○ No

DREEM headband

Did the patient use the DREEM headband?   ○ Yes   ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+66.75 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	94 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	13
Number of incorrect skips	16
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

Visit

Mind & Skin ID	728-27

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	16.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ⊗ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	68.00 (10kg - 100kg)
Height (cm)	185.42

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated

Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ⊗ No

3. History of flexural involvement	◯ Yes ⊗ No

4. History of generally dry skin	◯ Yes ⊗ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ⊗ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No

Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

| Asthma | ○ Yes | ⊗ No | ○ Unknown |

| Allergic rhino-conjunctivitis (hayfever) | ⊗ Yes | ○ No | ○ Unknown |

| Food allergies | ○ Yes | ⊗ No | ○ Unknown |

| Contact allergies | ○ Yes | ⊗ No | ○ Unknown |

| Does the patient have a history of sleep disturbance? | ○ Yes | ⊗ No |

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	12.29 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	13.0 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ⊗ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.4
PH measurment 2	5.4
PH measurment 3	5.4

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.05 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	10 (0 - 99)
T-Score:	50 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	9 (0 - 99)

T-Score:	58 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	33 (0 - 99)
Total T-Score:	47
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

---

Time period used From [*DATA REMOVED*] To [*DATA REMOVED*]

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ⊗ Yes   ◯ No

Date used   [*DATA REMOVED*]

Device ID

_____

Bedtime

_____

Waketime

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

Apnoea Hypopnoea Index (AHI)/hr

_____

Obstructive AHI (OAHI)/hr

_____

Central AHI (CnAHI)/hr

_____

Mean oxygen saturation (%)

_____

3% Oxygen Desaturation Index (ODI) /hr

_____

Absolute oxygen nadir (%)

_____

Mean oxygen nadir (%)

_____

% time oxygen sats < 92%

_____

% REM sleep

_____

% non REM Sleep

_____

Arousal index/hr

_____

DREEM headband

Did the patient use the DREEM headband?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 Yes Was data output collected for night 6 Yes
  Was data output collected for night 2 No Was data output collected for night 7 Yes
  Was data output collected for night 3 Yes Was data output collected for night 8 Yes
  Was data output collected for night 4 Yes Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ⊗ Yes   ◯ No

Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]
  Was data output collected for night 1 No Was data output collected for night 6 Yes
  Was data output collected for night 2 No Was data output collected for night 7 Yes
  Was data output collected for night 3 No Was data output collected for night 8 Yes
  Was data output collected for night 4 No Was data output collected for night 9 Yes
  Was data output collected for night 5 Yes Was data output collected for night 10 Yes

Sleep diary

Has the Sleep Diary been completed?   ⊗ Yes   ◯ No

Has the Sleep Diary been scanned and uploaded?   ⊗ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	71.5 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	106 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	13
Number of incorrect skips	1
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-28

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ◯ White and Asian ⊗ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No
Number of criteria	0

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Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes	⊗ No	○ Unknown
Food allergies	○ Yes	⊗ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	18.02 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	17.46 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	17.11 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.6
PH measurment 2	5.7
PH measurment 3	5.67

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.29 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.5 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	17 (0 - 99)
T-Score:	73 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	5 (0 - 99)
T-Score:	70 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	10 (0 - 99)
T-Score:	58 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	14 (0 - 99)

T-Score:	77 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	52 (0 - 99)
Total T-Score:	72
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　◯ Yes　◯ No

DREEM headband

Did the patient use the DREEM headband?　　　◯ Yes　◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　◯ Yes　◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	$\otimes$ Yes $\bigcirc$ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	$\otimes$ Yes $\bigcirc$ No
T2FLAIR:	$\otimes$ Yes $\bigcirc$ No
N-back:	$\otimes$ Yes $\bigcirc$ No
Delayed RT:	$\otimes$ Yes $\bigcirc$ No
Resting state:	$\otimes$ Yes $\bigcirc$ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	-42.75 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	98 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	4

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	9
Number of incorrect skips	15
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-29

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	70.10 (10kg - 100kg)
Height (cm)	180.00

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Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ◯ White and Asian ⊗ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No
Number of criteria	0

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

REDCap

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.1 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	15.5 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.1
PH measurment 2	5.9
PH measurment 3	5.8

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

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Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?   ⊗ Yes   ◯ No

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?   ◯ Yes   ⊗ No

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	◯ Yes ⊗ No

If No, please detail why?	[*DATA REMOVED*]

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	-50 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	115 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	4
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Were there any adverse events?	◯ Yes ◯ No

Visit

Mind & Skin ID	728-30

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	13.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	63.40 (10kg - 100kg)
Height (cm)	153.50

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ⊗ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

Asian or Asian British	◯ Indian ◯ Pakistani ⊗ Bangladeshi ◯ Chinese ◯ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	⊗ Mild ◯ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

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Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	◯ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes	⊗ No	◯ Unknown
Food allergies	◯ Yes	⊗ No	◯ Unknown
Contact allergies	⊗ Yes	◯ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	18.16 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	19.07 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	19.2 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.2
PH measurment 2	6.0
PH measurment 3	5.9

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	3.40

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	_____ (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?   ⊗ Yes   ◯ No

Was the sample taken from left volar forearm   ⊗ Yes   ◯ No

Date sample collected   [*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?   ◯ Yes   ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	15
Body is an Capable score: (mean of items : 5, 6)	8
Body is a Responsive score: (mean of items :7, 8)	6
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	9
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	8
Total score	17
Date	[*DATA REMOVED*]

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Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No

Patient is 13.7 years old at registration

Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	2
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.17 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	_____ (0 - 99)
T-Score:	_____ (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	_____ (0 - 99)

T-Score:

_____
(0 - 99)

Disorders of excessive somnolence score (sum the score
of the items 22,23,24,25,26)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Sleep Hyperhydrosis (sum the score of the items 9,16)

_____
(0 - 99)

T-Score:

_____
(0 - 99)

Total score

_____
(0 - 99)

Total T-Score:

_____

Date

_____

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ○ Yes   ○ No

DREEM headband

Did the patient use the DREEM headband?   ○ Yes   ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	95 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	1
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	11
Number of incorrect skips	32
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-31

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	13.4
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3. Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ⊗ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
Asian or Asian British	◯ Indian ◯ Pakistani ⊗ Bangladeshi ◯ Chinese ◯ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ⊗ No
Number of criteria	4

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ○ No

Potency:	○ Mild ○ Moderate ⊗ Potent ○ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ○ No

Potency	○ Mild ⊗ Moderate ○ Potent ○ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]

Add another steroid?	○ Yes ⊗ No

2. Calcineurin inhibitor/s ?	○ Yes ⊗ No

3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	○ Yes ○ No

2. Other?	○ Yes ○ No

3. Other?	○ Yes ○ No

Systemic therapy

Is the patient starting systemic therapy? ◯ Yes ⊗ No

Assign to Group 2 (topical therapy) 0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ○ No ○ Unknown
Food allergies	⊗ Yes ○ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	17.7 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	19.6 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	25.1
Room humidity (%)	38.5

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.1
PH measurment 2	6.2
PH measurment 3	6.3

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No

Total score	25.70

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ○ No

Date sample taken

_____

Was sample received by site?	○ Yes ○ No
Was sample stored in -80°C freezer	○ Yes ○ No
Was sample collection logged on freezer sample log?	○ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ○ No

Date sample taken

_____

Was sample received by site?	○ Yes ○ No
Was sample stored in -80°C freezer?	○ Yes ○ No
Was sample collection logged on freezer sample log?	○ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ○ No
Has the non-lesional sample been taken?	⊗ Yes ○ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ○ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	5.5 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	2.25
Body is an Capable score: (mean of items : 5, 6)	2
Body is a Responsive score: (mean of items :7, 8)	3.5
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	11
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	20
Total score	31
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	2
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 13.4 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	1
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.14 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.63 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	13 (0 - 99)
T-Score:	60 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	5 (0 - 99)
T-Score:	58 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	9 (0 - 99)
T-Score:	54 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	7 (0 - 99)

T-Score:	50 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	39 (0 - 99)
Total T-Score:	55
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	20 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	105 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	5

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	9
Number of incorrect skips	32
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

_____   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

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Visit

Mind & Skin ID	728-32

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

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Registration

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.4
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	⊗ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	65.80 (10kg - 100kg)
Height (cm)	163.50

Demographics

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	○ White ⊗ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

Black, Black British, Caribbean or African	○ Caribbean ⊗ African ○ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes　○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes　○ No

3. History of flexural involvement	⊗ Yes　○ No

4. History of generally dry skin	⊗ Yes　○ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes　○ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes　○ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	⊗ Yes ◯ No
1. Systemic therapy	
1. Name of systemic therapy	◯ Oral Methotrexate ⊗ Subcutaneous Methotrexate ◯ Other (please specify)
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	◯ mg/kg ⊗ mg

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1. Frequency of systemic therapy

⊗ Weekly
◯ Other (please specify)

2. Add another systemic therapy?

◯ Yes   ⊗ No

Medical History

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes	⊗ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	⊗ Yes	◯ No	◯ Unknown
Contact allergies	◯ Yes	⊗ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	20.56 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	21.41 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	22
Room humidity (%)	38.4

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.5
PH measurment 2	6.7
PH measurment 3	6.7

Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   30.90

Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	_____ (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	_____ (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ○ No
Was the sample taken from left volar forearm	⊗ Yes ○ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ○ No
Date of sample	_____
Was sample received by site?	○ Yes ⊗ No
Was sample stored in -80°C freezer?	○ Yes ⊗ No
Was sample collection logged on freezer sample log?	○ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	12
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	3.25
Body is an Capable score: (mean of items : 5, 6)	5
Body is a Responsive score: (mean of items :7, 8)	4
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	14
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	32
Total score	46
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.4 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	9
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.31 (0 - 99)
2. Sleepiness subscale	0.25 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	23 (0 - 99)
T-Score:	93 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	6 (0 - 99)
T-Score:	64 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	13 (0 - 99)
T-Score:	70 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	10 (0 - 99)

T-Score:	62 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	_____ (0 - 99)
Total T-Score:	_____
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

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Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	118 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	1
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No

% Omission error	[*DATA REMOVED*]

Premature errors	0

% Commission error	[*DATA REMOVED*]

Mean reaction time (milliseconds)	[*DATA REMOVED*]

MRT Standard Deviation	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No

%Total error	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No

Number of missed skips	9

Number of incorrect skips	5

Date	[*DATA REMOVED*]

Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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Mind & Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Visit

Mind & Skin ID	728-32

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Visit date	[*DATA REMOVED*]

Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Weight (kg)	66.50 (10kg - 100kg)
Height (cm)	164.50

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Current Eczema Treatment Visit 3

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?   ◯ Yes   ◯ No

2. Calcineurin inhibitor/s ?   ◯ Yes   ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ◯ No

Assign to Group 2 (topical therapy)

_____

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Mind & Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	16.328 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	24.018 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	17.885 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	23.8
Room humidity (%)	58.5

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.6
PH measurment 2	6.5
PH measurment 3	6.4

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Mind & Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No
Total score	20.60

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Mind & Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	6.6 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken? ⊗ Yes ◯ No

Was the sample taken from left volar forearm ⊗ Yes ◯ No

Date sample collected [*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient? ◯ Yes ⊗ No

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Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	20
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	11
Body is an Capable score: (mean of items : 5, 6)	10
Body is a Responsive score: (mean of items :7, 8)	12
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	14
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	24
Total score	38
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.4 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	5
Date	[*DATA REMOVED*]

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Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.05 (0 - 99)
2. Sleepiness subscale	0.25 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	21 (0 - 99)
T-Score:	86 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	12 (0 - 99)
T-Score:	66 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	9 (0 - 99)

T-Score:	58 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	51 (0 - 99)
Total T-Score:	70
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Were home-based sleep assessments performed?   ○ Yes   ○ No

DREEM headband

Did the patient use the DREEM headband?   ○ Yes   ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Sleep diary

Has the Sleep Diary been completed?   ○ Yes   ○ No

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Mind & Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

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Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100.0 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	◯ Yes ⊗ No

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No

% Omission error	[*DATA REMOVED*]

Premature errors	0

% Commission error	[*DATA REMOVED*]

Mean reaction time (milliseconds)	[*DATA REMOVED*]

MRT Standard Deviation	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No

%Total error	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No

Number of missed skips	5

Number of incorrect skips	6

Date	[*DATA REMOVED*]

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Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

[*DATA REMOVED*]   Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?	○ Yes ○ No

Visit

Mind & Skin ID	728-33

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

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Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes　○ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes　○ No

4. Willingness to comply with all study requirements.

⊗ Yes　○ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes　○ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

○ Yes　⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

○ Yes　⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

○ Yes　⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

○ Yes　⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

○ Yes　⊗ No

6. Previous and/or current substance misuse.

○ Yes　⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility   1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?   ⊗ Yes   ◯ No

Print name: [*DATA REMOVED*]

Print role   [*DATA REMOVED*]

Date   [*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	53.14 (10kg - 100kg)
Height (cm)	177.60

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Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male
	◯ Female
	◯ Undifferentiated

Ethnicity	⊗ White
	◯ Black, Black British, Caribbean or African
	◯ Asian or Asian British
	◯ Mixed or multiple ethnic groups
	◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British
	◯ Irish
	◯ Gypsy or Irish Traveller
	◯ Roma
	◯ Any other White background

UK Diagnostic Criteria

Patients must have:

| 1. An itchy skin condition in the last year* | ◯ Yes   ⊗ No |

| Assign to Group 3 (healthy controls) | 0 |

*If yes, patient must have three or more of the following:

| 2. Visual flexural dermatitis | ◯ Yes   ◯ No |

| 3. History of flexural involvement | ◯ Yes   ◯ No |

| 4. History of generally dry skin | ◯ Yes   ◯ No |

| 5. Personal history of atopic disease (children under 4 years: family history of atopic disease) | ◯ Yes   ◯ No |

| 6. Onset before the age of 2 years (not used if child aged < 4 years) | ◯ Yes   ◯ No |

| Number of criteria | 0 |

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ⊗ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	11.01 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	12.43 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	24.6
Room humidity (%)	42.2

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.0
PH measurment 2	4.9
PH measurment 3	4.8

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Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.36 (0 - 99)
2. Sleepiness subscale	0.75 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.13 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	26 (0 - 99)
T-Score:	100 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	15 (0 - 99)
T-Score:	79 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	13 (0 - 99)

T-Score:	73 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	6 (0 - 99)
T-Score:	69 (0 - 99)
Total score	67 (0 - 99)
Total T-Score:	93
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　　○ Yes　　○ No

DREEM headband

Did the patient use the DREEM headband?　　　　○ Yes　　○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　　○ Yes　　○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

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Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score	100
	(-100 to 100)
Left-handedness - Less than -40	
Ambidexterity=Between -40 and +40	
Right-handness=More than +40	

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	106
	(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	2

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	4
Number of incorrect skips	1
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

[*DATA REMOVED*]

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

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Visit

Mind & Skin ID	728-34

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.7
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	⊗ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	41.80 (10kg - 100kg)
Height (cm)	151.50

Demographics

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	⊗ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ○ Irish ○ Gypsy or Irish Traveller ○ Roma ○ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No
3. History of flexural involvement	⊗ Yes ○ No
4. History of generally dry skin	⊗ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No
Calicineurin drug 1	⊗ Pimecrolimus 1% ◯ Tacrolimus 0.03% ◯ Tacrolimus 0.1%
Add another calcineurin inhibitor?	⊗ Yes ◯ No
Calicineurin drug 2	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%
Add another calcineurin inhibitor?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	⊗ Yes ◯ No

1. Systemic therapy

1. Name of systemic therapy	⊗ Oral Methotrexate ◯ Subcutaneous Methotrexate ◯ Other (please specify)
1. Dose of systemic therapy	[*DATA REMOVED*]

1. Units of systematic therapy	◯ mg/kg ⊗ mg
1. Frequency of systemic therapy	⊗ Weekly ◯ Other (please specify)
2. Add another systemic therapy?	◯ Yes ⊗ No

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Medical History

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	⊗ Yes ○ No ○ Unknown
Contact allergies	⊗ Yes ○ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ◯ RVF ⊗ Other
If Other, please specify:	[*DATA REMOVED*]
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	47.23 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	49.76 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	21.8
Room humidity (%)	35.4

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ◯ RVF ⊗ Other
If Other, please specify:	[*DATA REMOVED*]
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.8
PH measurment 2	5.7

PH measurment 3

_____

Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score   18.60

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Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented? ◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented? ◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken? ◯ Yes ◯ No

Has the non-lesional sample been taken? ◯ Yes ◯ No

Has the lesional sample been taken? ◯ Yes ◯ No

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken? ◯ Yes ◯ No

Was the sample taken from left volar forearm ◯ Yes ◯ No

Date sample collected

_____

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient? ◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	25
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	_____
Body is an Capable score: (mean of items : 5, 6)	_____
Body is a Responsive score: (mean of items :7, 8)	_____
Date	_____

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	19
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	34
Total score	53
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.7 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	20
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.18 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	23 (0 - 99)
T-Score:	93 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	18 (0 - 99)
T-Score:	93 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	19 (0 - 99)

T-Score:	95 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	5 (0 - 99)
T-Score:	64 (0 - 99)
Total score	71 (0 - 99)
Total T-Score:	98
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　○ Yes　○ No

DREEM headband

Did the patient use the DREEM headband?　　　○ Yes　○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　○ Yes　○ No

Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ⊗ No

If No, please detail why?   [*DATA REMOVED*]

Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score

Left-handedness - Less than -40
Ambidexterity=Between -40 and +40
Right-handness=More than +40

100
(-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No
Total FSIQ-4 score	112 (0 - 160)
Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	12
Number of incorrect skips	5
Date	[*DATA REMOVED*]

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Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

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Visit

Mind & Skin ID	728-34

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Visit date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Weight (kg)	42.18 (10kg - 100kg)
Height (cm)	152.30

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Current Eczema Treatment Visit 3

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ◯ No

Assign to Group 2 (topical therapy)

_____

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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.172 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	22.97 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	24.517 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	26
Room humidity (%)	49.8

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.4
PH measurment 2	6.3
PH measurment 3	6.4

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Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	2.40

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Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	_____ (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken? ⊗ Yes ◯ No

Was the sample taken from left volar forearm ⊗ Yes ◯ No

Date sample collected [*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient? ⊗ Yes ◯ No

Date of sample [*DATA REMOVED*]

Was sample received by site? ⊗ Yes ◯ No

Was sample stored in -80°C freezer? ⊗ Yes ◯ No

Was sample collection logged on freezer sample log? ⊗ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ○ No
Total score	4
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ○ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	10
Body is an Capable score: (mean of items : 5, 6)	5
Body is a Responsive score: (mean of items :7, 8)	2
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ○ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	18
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	25
Total score	43
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	3
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.7 years old at registration	
Questionnaire used	⊗ DLQI (>16 years old, range 0-30) ◯ CDLQI (< =16 years old, range 0-30)
Total score	4
Date	[*DATA REMOVED*]

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Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.27 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	17 (0 - 99)
T-Score:	73 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	15 (0 - 99)
T-Score:	79 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	14 (0 - 99)

T-Score:	77 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	10 (0 - 99)
T-Score:	93 (0 - 99)
Total score	62 (0 - 99)
Total T-Score:	85
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Sleep diary

Has the Sleep Diary been completed?   ◯ Yes   ◯ No

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Mind & Skin ID 728-34 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100.0 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	◯ Yes ⊗ No

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ○ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ○ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ○ No
Number of missed skips	5
Number of incorrect skips	1
Date	[*DATA REMOVED*]

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Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-35

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	12.4
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	44.80 (10kg - 100kg)
Height (cm)	159.30

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ⊗ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ⊗ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	4

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No
Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ○ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	15.88 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	17.56 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	16.61 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	24.1
Room humidity (%)	53.5

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.8
PH measurment 2	5.8
PH measurment 3	5.6

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	3.70

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Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	1.5 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	2.5
Body is an Capable score: (mean of items : 5, 6)	5
Body is a Responsive score: (mean of items :7, 8)	4.5
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	7
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	11
Total score	18
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No

Patient is 12.4 years old at registration

Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	4
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.09 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	12 (0 - 99)
T-Score:	58 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	16 (0 - 99)
T-Score:	84 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	6 (0 - 99)

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T-Score:	46 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	42 (0 - 99)
Total T-Score:	59
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ⊗ Yes   ◯ No

Actigraphy wristwatch

Did the patient use the Actigraphy wristwatch?   ⊗ Yes   ◯ No

Time period used From _____ To _____

Device ID

_____

Mean Bedtime BT (time 24 hr clock)

_____

Mean Wake time WT (time 24 hr clock)

_____

Total Sleep Time TST _____ Hours _____ Minutes

Sleep latency SL (minutes)

_____

Sleep efficiency SE (%)

_____

WASO (minutes)

_____

Somnotouch HD

Did the patient use the Somnotouch HD?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Sleep diary

Has the Sleep Diary been completed?   ○ Yes   ○ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	105 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	6
Number of incorrect skips	2
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

[*DATA REMOVED*]   Frequency

_____

Date started

[*DATA REMOVED*] Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-36

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	69.55 (10kg - 100kg)
Height (cm)	178.00

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group

Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ⊗ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No

3. History of flexural involvement	◯ Yes ◯ No

4. History of generally dry skin	◯ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	0

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?   ○ Yes   ○ No

3. Other?   ○ Yes   ○ No

Systemic therapy

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

| Asthma | ◯ Yes | ⊗ No | ◯ Unknown |

| Allergic rhino-conjunctivitis (hayfever) | ◯ Yes | ⊗ No | ◯ Unknown |

| Food allergies | ◯ Yes | ⊗ No | ◯ Unknown |

| Contact allergies | ◯ Yes | ⊗ No | ◯ Unknown |

| Does the patient have a history of sleep disturbance? | ◯ Yes | ⊗ No |

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	28.2 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	29.5 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	29.5 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (∘C)	24.6
Room humidity (%)	51.8

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.2
PH measurment 2	5.0
PH measurment 3	4.9

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.09 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	13 (0 - 99)
T-Score:	60 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	9 (0 - 99)
T-Score:	54 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	6 (0 - 99)

T-Score:	46 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	36 (0 - 99)
Total T-Score:	51
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ○ Yes   ○ No

DREEM headband

Did the patient use the DREEM headband?   ○ Yes   ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	128 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	2

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	1

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Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	15
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-37

GROUP _____ INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	_____
Date of patient consent/assent	_____
_age	_____
Date of parent/guardian consent	_____
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	◯ Yes ◯ No
Use of pseudo-anonymised data for future research	◯ Yes ◯ No
Focus group participation	◯ Yes ◯ No
GP contact	◯ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

◯ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

◯ Yes   ◯ No

4. Willingness to comply with all study requirements.

◯ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

◯ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ◯ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ◯ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ◯ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ◯ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ◯ No

6. Previous and/or current substance misuse.

◯ Yes   ◯ No

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7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ◯ No

8. Current phototherapy treatment.

◯ Yes   ◯ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility   0

Patient is not eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?   ◯ Yes   ◯ No

Print name:

_____

Print role

_____

Date

_____

Height&Weight

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

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Demographics

GROUP _____ INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ○ Female ○ Undifferentiated

Ethnicity	○ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	○ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	○ Yes ○ No
3. History of flexural involvement	○ Yes ○ No
4. History of generally dry skin	○ Yes ○ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	○ Yes ○ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	○ Yes ○ No

Number of criteria

_____

Family History

Family History

_____

Current Eczema Treatment

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	◯ Yes ◯ No
2. Calcineurin inhibitor/s ?	◯ Yes ◯ No

3. Soap substitutes /moisturisers?

_____

4. Other topical therapy

_____

1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ◯ No
Assign to Group 2 (topical therapy)	0

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Medical History

GROUP _____ INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes ◯ No ◯ Unknown
Food allergies	◯ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ◯ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ◯ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement
(uninvolved skin left volar forearm)   ◯ Yes   ◯ No

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 2 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

ARM 3 Flux (mg/meter sq * height)

_____
(Range 5 - 40)

Decent measurement curves?   ◯ Yes   ◯ No

Temperature (◦C)

_____

Room humidity (%)

_____

PH measurements

PH meter reading (volar forearm)   ◯ Yes   ◯ No

Skin Examination

GROUP _____ INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ○ Yes   ○ No

Total score

_____

Samples

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

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Serum sample for immunology profile analysis

Has the patient consented?	○ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	○ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	○ Yes ○ No
Has the non-lesional sample been taken?	○ Yes ○ No
Has the lesional sample been taken?	○ Yes ○ No

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	○ Yes ○ No
Was the sample taken from left volar forearm	○ Yes ○ No
Date sample collected	_____

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	○ Yes ○ No

Patient-Reported Quality Of Life Measures

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	○ Yes ○ No

Body Mindset Inventory

Questionnaire fully completed?	○ Yes ○ No

BTMS

Questionnaire fully completed?	○ Yes ○ No

Itch severity numerical rating score (0-10)

VAS completed	○ Yes ○ No

Skin-specific quality of life questionnaire

Questionnaire fully completed?	○ Yes ○ No

Questionnaire-Based Sleep Assessments

GROUP _____ INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?   ◯ Yes   ◯ No

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?   ◯ Yes   ◯ No

Homebased Sleep Assessments

GROUP _____ INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP _____ INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?   ◯ Yes   ◯ No

Neurocognitive Assessments

GROUP _____ INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	◯ Yes ◯ No

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	◯ Yes ◯ No

Motor response inhibition assessment

Go/No-go task completed?	◯ Yes ◯ No

Interference inhibition/selective attention assessment

Simon task completed?	◯ Yes ◯ No

Sustained/selective attention assessment

Continuous performance task completed?	◯ Yes ◯ No

Time perception assessment

Time discrimination task completed?	◯ Yes ◯ No

Vigilance assessment

Mackworth Clock task completed?	◯ Yes ◯ No

Completed By

GROUP _____ INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-38

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Visit date

_____

Registration

GROUP _____ INITIALS _____
VISIT DATE _____ Baseline - Visit 1

_age

_____

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Exclusion criteria

_eligibility   0

Height&Weight

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

Demographics

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

REDCap

UK Diagnostic Criteria

Assign to Group 3 (healthy controls)   0

Number of criteria

_____

Family History

Family History

_____

Current Eczema Treatment

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy) 0

Medical History

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

REDCap

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Skin Examination

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

REDCap

Samples

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

REDCap

Patient-Reported Quality Of Life Measures

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Homebased Sleep Assessments

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Magnetic Resonance Imaging

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Was the MRI peformed?　　　　　　　　　　　◯ Yes　◯ No

Neurocognitive Assessments

GROUP _____ INITIALS _____
  VISIT DATE _____ Baseline - Visit 1

Completed By

GROUP _____ INITIALS _____
 VISIT DATE _____ Baseline - Visit 1

Visit

Mind & Skin ID	728-39

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	◯ Yes ⊗ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)

_____
(10kg - 100kg)

Height (cm)

_____

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Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	○ White ○ Black, Black British, Caribbean or African ⊗ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

Asian or Asian British	○ Indian ○ Pakistani ○ Bangladeshi ○ Chinese ⊗ Any other Asian background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No

3. History of flexural involvement	⊗ Yes ○ No

4. History of generally dry skin	⊗ Yes ○ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No

Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No
Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%
Add another calcineurin inhibitor?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes ⊗ No

Assign to Group 2 (topical therapy)　　　　　　　0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ⊗ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes ⊗ No ◯ Unknown
Food allergies	◯ Yes ⊗ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	29.026 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	20.683 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	23.544 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	24.4
Room humidity (%)	42.7

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.8
PH measurment 2	5.8
PH measurment 3	5.9

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ○ No

Total score   9.50

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	5.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	21
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	14
Body is an Capable score: (mean of items : 5, 6)	7
Body is a Responsive score: (mean of items :7, 8)	7
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	7
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	12
Total score	19
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	7
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No

Patient is 14.9 years old at registration

Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	8
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.19 (0 - 99)
2. Sleepiness subscale	0.25 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.25 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	14 (0 - 99)
T-Score:	64 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	10 (0 - 99)
T-Score:	58 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	9 (0 - 99)

T-Score:	58 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	41 (0 - 99)
Total T-Score:	58
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?	◯ Yes ◯ No

DREEM headband

Did the patient use the DREEM headband?	◯ Yes ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	◯ Yes ◯ No

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	-71.5 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	101 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	10
Number of incorrect skips	7
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

[*DATA REMOVED*]

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 2

[*DATA REMOVED*]
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

Indication

_____

Medication 3

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____   Ongoing? _____   Date stopped

_____

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Indication

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-40

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.1
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying
data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility   1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	62.35 (10kg - 100kg)
Height (cm)	166.90

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	○ Male ⊗ Female ○ Undifferentiated

Ethnicity	⊗ White ○ Black, Black British, Caribbean or African ○ Asian or Asian British ○ Mixed or multiple ethnic groups ○ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ○ Irish ○ Gypsy or Irish Traveller ○ Roma ○ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ○ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ○ No

3. History of flexural involvement	⊗ Yes ○ No

4. History of generally dry skin	⊗ Yes ○ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ○ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ○ No

Number of criteria	5

Family History

Family History

_____

REDCap

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No

Potency:	
	◯ Mild
	◯ Moderate
	⊗ Potent
	◯ Ultra-potent

Name of steroid 1:	[*DATA REMOVED*]

Add another corticosteriod?	⊗ Yes ◯ No

Potency	
	◯ Mild
	◯ Moderate
	⊗ Potent
	◯ Ultra-potent

Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Is the patient starting systemic therapy?   ◯ Yes   ⊗ No

Assign to Group 2 (topical therapy)   0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ○ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	16.274 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	17.689 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	18.283 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	25.5
Room humidity (%)	47.6

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	7.1
PH measurment 2	6.8
PH measurment 3	6.5

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	20.50

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No

Date sample taken

_____

Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No

Date sample taken

_____

Was sample received by site?	◯ Yes ⊗ No
Was sample stored in -80°C freezer?	◯ Yes ⊗ No
Was sample collection logged on freezer sample log?	◯ Yes ⊗ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	7.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?　　　　⊗ Yes　◯ No

Was the sample taken from left volar forearm　　　⊗ Yes　◯ No

Date sample collected　　　　　　　　　　　　[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?　　◯ Yes　⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	28
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	18
Body is an Capable score: (mean of items : 5, 6)	6
Body is a Responsive score: (mean of items :7, 8)	6
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	1
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	3
Total score	4
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	10
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 15.1 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	21
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.5 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	1 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	31 (0 - 99)
T-Score:	100 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	4 (0 - 99)
T-Score:	58 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	19 (0 - 99)
T-Score:	95 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	20 (0 - 99)

T-Score:	100 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	7 (0 - 99)
T-Score:	75 (0 - 99)
Total score	85 (0 - 99)
Total T-Score:	100
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?	○ Yes ○ No

DREEM headband

Did the patient use the DREEM headband?	○ Yes ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?	○ Yes ○ No

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Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100.0 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	72 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ○ No
% Omission error	[*DATA REMOVED*]
Premature errors	2
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ○ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ○ No
Number of missed skips	22
Number of incorrect skips	13
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Confidential

Mind & Skin ver 4.0
Mind & Skin ID 728-41 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)
Page 1015

Visit

Mind & Skin ID	728-41

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	12
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	⊗ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes ⊗ No

8. Current phototherapy treatment.

◯ Yes ⊗ No

9. Body weight < 40kg

◯ Yes ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	59.70 (10kg - 100kg)
Height (cm)	141.50

Demographics

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male
	◯ Female
	◯ Undifferentiated

Ethnicity	◯ White
	⊗ Black, Black British, Caribbean or African
	◯ Asian or Asian British
	◯ Mixed or multiple ethnic groups
	◯ Other ethnic group

Black, Black British, Caribbean or African	◯ Caribbean
	⊗ African
	◯ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

| 1. An itchy skin condition in the last year* | ⊗ Yes ◯ No |

| Assign to Group 3 (healthy controls) | 0 |

*If yes, patient must have three or more of the following:

| 2. Visual flexural dermatitis | ⊗ Yes ◯ No |

| 3. History of flexural involvement | ⊗ Yes ◯ No |

| 4. History of generally dry skin | ⊗ Yes ◯ No |

| 5. Personal history of atopic disease (children under 4 years: family history of atopic disease) | ⊗ Yes ◯ No |

| 6. Onset before the age of 2 years (not used if child aged < 4 years) | ⊗ Yes ◯ No |

| Number of criteria | 5 |

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ◯ No
Potency:	◯ Mild ⊗ Moderate ◯ Potent ◯ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ◯ No
Potency	◯ Mild ◯ Moderate ⊗ Potent ◯ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	◯ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ◯ No
Calicineurin drug 1	◯ Pimecrolimus 1% ◯ Tacrolimus 0.03% ⊗ Tacrolimus 0.1%
Add another calcineurin inhibitor?	◯ Yes ⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes ◯ No
2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

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Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	⊗ Yes ◯ No
1. Systemic therapy	
1. Name of systemic therapy	◯ Oral Methotrexate ◯ Subcutaneous Methotrexate ⊗ Other (please specify)
1. Please specify other systemic therapy	[*DATA REMOVED*]
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	◯ mg/kg ⊗ mg
1. Frequency of systemic therapy	◯ Weekly ⊗ Other (please specify)
1. Please specify other frequency for systemic therapy	[*DATA REMOVED*]
2. Add another systemic therapy?	◯ Yes ⊗ No

Medical History

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes	⊗ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	⊗ Yes	◯ No	◯ Unknown
Contact allergies	⊗ Yes	◯ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

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Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	20.6 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	19.1 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	18.7 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	23.50
Room humidity (%)	49

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	8.5
PH measurment 2	8.45
PH measurment 3	8.47

Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score   28.40

Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	7.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ⊗ No

Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ○ No
Total score	28
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ○ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	18
Body is an Capable score: (mean of items : 5, 6)	9
Body is a Responsive score: (mean of items :7, 8)	6
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ○ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	14
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	21
Total score	35
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	9
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 12 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	16
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.27 (0 - 99)
2. Sleepiness subscale	0.5 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0.43 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	21 (0 - 99)
T-Score:	86 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	6 (0 - 99)
T-Score:	82 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	11 (0 - 99)
T-Score:	62 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	12 (0 - 99)

T-Score:	69 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	55 (0 - 99)
Total T-Score:	76
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　○ Yes　○ No

DREEM headband

Did the patient use the DREEM headband?　　　○ Yes　○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　○ Yes　○ No

Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

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Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100.0 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	93 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	2

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	9
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

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Visit

Mind & Skin ID	728-42

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	12.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	⊗ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	36.54 (10kg - 100kg)
Height (cm)	147.40

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Demographics

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated

Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No

3. History of flexural involvement	⊗ Yes ◯ No

4. History of generally dry skin	⊗ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No

Number of criteria	5

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	○ Mild ○ Moderate ○ Potent ⊗ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	○ Mild ○ Moderate ⊗ Potent ○ Ultra-potent
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	○ Pimecrolimus 1% ○ Tacrolimus 0.03% ○ Tacrolimus 0.1%
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]

4. Other topical therapy

_____

1. Other?	○ Yes ○ No
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

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Systemic therapy

Is the patient starting systemic therapy?	⊗ Yes ◯ No
Assign to Group 2 (topical therapy)	0
1. Add systemic therapy?	⊗ Yes ◯ No
1. Systemic therapy	
1. Name of systemic therapy	⊗ Oral Methotrexate ◯ Subcutaneous Methotrexate ◯ Other (please specify)
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	◯ mg/kg ⊗ mg
1. Frequency of systemic therapy	⊗ Weekly ◯ Other (please specify)
2. Add another systemic therapy?	◯ Yes ⊗ No

Medical History

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes	◯ No	◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes	◯ No	◯ Unknown
Food allergies	◯ Yes	⊗ No	◯ Unknown
Contact allergies	⊗ Yes	◯ No	◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	36.802 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	35.743 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	37.240 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	27.1
Room humidity (%)	42.8

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5
PH measurment 2	5.25
PH measurment 3	5.3

Skin Examination

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?   ⊗ Yes   ◯ No

Total score   10.20

Samples

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ○ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ○ No
Was sample stored in -80°C freezer?	⊗ Yes ○ No
Was sample collection logged on freezer sample log?	⊗ Yes ○ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ○ No
Has the non-lesional sample been taken?	⊗ Yes ○ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ○ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	4.2 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	20
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	5
Body is an Capable score: (mean of items : 5, 6)	10
Body is a Responsive score: (mean of items :7, 8)	8
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	_____
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	_____
Total score	_____
Date	_____

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ○ No
Total score	6
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ○ No
Patient is 12.5 years old at registration	
Questionnaire used	○ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	17
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.55 (0 - 99)
2. Sleepiness subscale	1 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	1 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	31 (0 - 99)
T-Score:	100 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	24 (0 - 99)
T-Score:	100 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	19 (0 - 99)

T-Score:	95 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	8 (0 - 99)
T-Score:	80 (0 - 99)
Total score	88 (0 - 99)
Total T-Score:	100
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed? ○ Yes ○ No

DREEM headband

Did the patient use the DREEM headband? ○ Yes ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress? ○ Yes ○ No

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Mind & Skin ver 4.0
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Magnetic Resonance Imaging

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100.0 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	92 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	12
Number of incorrect skips	7
Date	[*DATA REMOVED*]

Completed By

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose _____ Units

_____ Frequency

[*DATA REMOVED*]

Date started

_____ Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____ Units

_____ Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-43

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.3
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ⊗ Group 2 (topical therapy) ◯ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

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Inclusion/Exclusion Criteria

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

1. Patients aged 5 years or above with atopic eczema (groups 1 and 2) which has been diagnosed by a Consultant Dermatologist.

⊗ Yes   ◯ No

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	58.20 (10kg - 100kg)
Height (cm)	173.00

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated
Ethnicity	◯ White ⊗ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group
Black, Black British, Caribbean or African	⊗ Caribbean ◯ African ◯ Any other Black, Black British or Caribbean Background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	⊗ Yes ◯ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	⊗ Yes ◯ No
3. History of flexural involvement	⊗ Yes ◯ No
4. History of generally dry skin	⊗ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	⊗ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	⊗ Yes ◯ No
Number of criteria	5

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

1. Current topical therapy

1. Corticosteroid/s ?	⊗ Yes　◯ No
Potency:	◯ Mild ◯ Moderate ◯ Potent ⊗ Ultra-potent
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	◯ Yes　⊗ No
2. Calcineurin inhibitor/s ?	◯ Yes　⊗ No
3. Soap substitutes /moisturisers?	[*DATA REMOVED*]
4. Other topical therapy	[*DATA REMOVED*]
1. Other?	◯ Yes　◯ No
2. Other?	◯ Yes　◯ No
3. Other?	◯ Yes　◯ No

Systemic therapy

Is the patient starting systemic therapy?	◯ Yes　⊗ No
Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?			
Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes	⊗ No	○ Unknown
Food allergies	⊗ Yes	○ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ◯ RVF ⊗ Other
If Other, please specify:	[*DATA REMOVED*]
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	18.934 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	19.714 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	23.1
Room humidity (%)	51.3

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	◯ LVF ◯ RVF ⊗ Other
If Other, please specify:	[*DATA REMOVED*]
PH reading date:	[*DATA REMOVED*]
PH measurment 1	4.8
PH measurment 2	4.75
PH measurment 3	4.7

Skin Examination

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

EASI (score 0-72)

Test performed?	⊗ Yes ◯ No

Total score	13.00

Samples

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	⊗ Yes ◯ No
Location of lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at lesional site	7.0 (0.0 - 99.9)
Date sample taken	[*DATA REMOVED*]

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Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	◯ Yes ⊗ No
Please specify where non-lesional sample was taken from	[*DATA REMOVED*]
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	◯ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

POEM (0-28)

Questionnaire fully completed?	⊗ Yes ◯ No
Total score	4
Date	[*DATA REMOVED*]

Body Mindset Inventory

Questionnaire fully completed?	⊗ Yes ◯ No
Body is an Adversary score: (mean of items : 1, 2, 3, 4)	8
Body is an Capable score: (mean of items : 5, 6)	10
Body is a Responsive score: (mean of items :7, 8)	8
Date	[*DATA REMOVED*]

BTMS

Questionnaire fully completed?	⊗ Yes ◯ No
Bodily monitoring score: (sum items: 1, 5, 7, 12, 14, 17)	2
Bodily threat appraisals score: (sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	6
Total score	8
Date	[*DATA REMOVED*]

Itch severity numerical rating score (0-10)

VAS completed	⊗ Yes ◯ No
Total score	2
Date	[*DATA REMOVED*]

Skin-specific quality of life questionnaire

Questionnaire fully completed?	⊗ Yes ◯ No
Patient is 14.3 years old at registration	
Questionnaire used	◯ DLQI (>16 years old, range 0-30) ⊗ CDLQI (< =16 years old, range 0-30)
Total score	1
Date	[*DATA REMOVED*]

Questionnaire-Based Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.05 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	11 (0 - 99)
T-Score:	54 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	5 (0 - 99)

T-Score:	42 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	30 (0 - 99)
Total T-Score:	43
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　○ Yes　○ No

DREEM headband

Did the patient use the DREEM headband?　　　○ Yes　○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　○ Yes　○ No

Magnetic Resonance Imaging

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

Neurocognitive Assessments

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+75 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	106 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	8
Number of incorrect skips	3
Date	[*DATA REMOVED*]

Completed By

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name   [*DATA REMOVED*]

Date

_____

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Concomitant Medications

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

[*DATA REMOVED*]
Dose [*DATA REMOVED*]   Units

[*DATA REMOVED*]   Frequency

[*DATA REMOVED*]

Date started

_____ Ongoing? Yes   Date stopped

_____

Indication

_____

Medication 2

_____
Dose _____   Units

_____   Frequency

_____

Date started

_____ Ongoing? _____   Date stopped

_____

Indication

_____

Adverse Events

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No

Visit

Mind & Skin ID	728-44

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	12.5
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	◯ Yes ◯ No
GP contact	⊗ Yes ◯ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	40.55 (10kg - 100kg)
Height (cm)	150.70

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	⊗ Male ◯ Female ◯ Undifferentiated

Ethnicity	⊗ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ◯ Mixed or multiple ethnic groups ◯ Other ethnic group

White	⊗ English, Welsh, Scottish, Northern Irish or British ◯ Irish ◯ Gypsy or Irish Traveller ◯ Roma ◯ Any other White background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No

3. History of flexural involvement	◯ Yes ◯ No

4. History of generally dry skin	◯ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	0

Family History

Family History

_____

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes	⊗ No	○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes	⊗ No	○ Unknown
Food allergies	○ Yes	⊗ No	○ Unknown
Contact allergies	○ Yes	⊗ No	○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes	⊗ No	

Past Medical History

Past Medical History (select all that apply)

☐ ADHD
☐ Asthma
☐ Autism spectrum disorder
☐ Celiac Disease
☐ Cerebral palsy
☐ Congenital heart disease
☐ Cystic Fibrosis
☐ Diabetes
☐ Down syndrome
☐ Epilepsy
☐ Hearing impairment
☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
☐ Juvenile arthritis
☐ Sickle cell anaemia
☐ Spina Bifida
☐ Urticaria
☐ Visual impairment
☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	12.117 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	11.809 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	22.10
Room humidity (%)	48.80

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	4.6
PH measurment 2	4.7
PH measurment 3	_____

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Confidential

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0.19 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	12 (0 - 99)
T-Score:	58 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	8 (0 - 99)

T-Score:	53 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	34 (0 - 99)
Total T-Score:	49
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ○ Yes   ○ No

DREEM headband

Did the patient use the DREEM headband?   ○ Yes   ○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ○ Yes   ○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?	⊗ Yes ◯ No
Date MRI performed:	[*DATA REMOVED*]
MP RAGE:	⊗ Yes ◯ No
T2FLAIR:	⊗ Yes ◯ No
N-back:	⊗ Yes ◯ No
Delayed RT:	⊗ Yes ◯ No
Resting state:	⊗ Yes ◯ No

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Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ○ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	+100.00 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ○ No

Total FSIQ-4 score	135 (0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	3

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ○ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Premature responses	1

REDCap

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	0
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	12
Number of incorrect skips	9
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-45

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	13.9
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	⊗ Yes ◯ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No

Print name:	[*DATA REMOVED*]

Print role	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	59.50 (10kg - 100kg)
Height (cm)	175.10

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group

Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ◯ White and Asian ⊗ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No

3. History of flexural involvement	◯ Yes ◯ No

4. History of generally dry skin	◯ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	0

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	○ Yes ⊗ No ○ Unknown
Allergic rhino-conjunctivitis (hayfever)	○ Yes ⊗ No ○ Unknown
Food allergies	○ Yes ⊗ No ○ Unknown
Contact allergies	○ Yes ⊗ No ○ Unknown
Does the patient have a history of sleep disturbance?	○ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

[*DATA REMOVED*]

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	9.34 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	9.87 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	23.3
Room humidity (%)	32.6

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.6
PH measurment 2	5.0
PH measurment 3	4.9

Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?   ⊗ Yes   ◯ No

Date sample taken

_____

Was sample received by site?   ◯ Yes   ◯ No

Was sample stored in -80°C freezer   ◯ Yes   ◯ No

Was sample collection logged on freezer sample log?   ◯ Yes   ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?   ⊗ Yes   ◯ No

Date sample taken

_____

Was sample received by site?   ◯ Yes   ◯ No

Was sample stored in -80°C freezer?   ◯ Yes   ◯ No

Was sample collection logged on freezer sample log?   ◯ Yes   ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?   ⊗ Yes   ◯ No

Has the non-lesional sample been taken?   ⊗ Yes   ◯ No

Location of non-lesional sample taken (please specify)   [*DATA REMOVED*]

Local EASI at non-lesional site   0.0
                                                             (0.0 - 99.9)

Has the lesional sample been taken?   ◯ Yes   ⊗ No

Date sample taken   [*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	[*DATA REMOVED*]
Was sample received by site?	⊗ Yes ◯ No
Was sample stored in -80°C freezer?	⊗ Yes ◯ No
Was sample collection logged on freezer sample log?	⊗ Yes ◯ No

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Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	9 (0 - 99)
T-Score:	47 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	5 (0 - 99)

T-Score:	42 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	3 (0 - 99)
T-Score:	51 (0 - 99)
Total score	29 (0 - 99)
Total T-Score:	42
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?　　　　　　　　　　　○ Yes　○ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score

Left-handedness - Less than -40
Ambidexterity=Between -40 and +40
Right-handness=More than +40

100.0
(-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score

111
(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	3
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No

% Omission error	[*DATA REMOVED*]

Premature errors	0

% Commission error	[*DATA REMOVED*]

Mean reaction time (milliseconds)	[*DATA REMOVED*]

MRT Standard Deviation	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No

%Total error	[*DATA REMOVED*]

Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No

Number of missed skips	8

Number of incorrect skips	12

Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit

Mind & Skin ID	728-46

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	15.4
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	○ Group 1 (immuno-modulatory therapy) ○ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ○ No
Use of pseudo-anonymised data for future research	⊗ Yes ○ No
Focus group participation	○ Yes ⊗ No
GP contact	⊗ Yes ○ No

Contact Notes: (please do not enter any indentifying data)

_____
(do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes   ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes   ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes   ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes   ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes   ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes   ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes   ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes   ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes   ⊗ No

6. Previous and/or current substance misuse.

◯ Yes   ⊗ No

7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	55.90 (10kg - 100kg)
Height (cm)	182.90

Confidential

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated

Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group

Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ◯ White and Asian ⊗ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No

Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No

3. History of flexural involvement	◯ Yes ◯ No

4. History of generally dry skin	◯ Yes ◯ No

5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No

6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No

Number of criteria	0

Family History

Family History

_____

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Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

REDCap

Current topical therapy

2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	◯ Yes ⊗ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	◯ Yes ⊗ No ◯ Unknown
Food allergies	◯ Yes ⊗ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	13.614 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	15.738 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	14.283 (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	_____
Room humidity (%)	_____

PH measurements

PH meter reading (volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	6.1
PH measurment 2	6.2
PH measurment 3	6.4

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Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ◯ No
1. SRBD scale (including snoring and sleepiness subscales)	0 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ◯ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	12 (0 - 99)
T-Score:	58 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	3 (0 - 99)
T-Score:	45 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	6 (0 - 99)
T-Score:	41 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	5 (0 - 99)

T-Score:	42 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	31 (0 - 99)
Total T-Score:	45
Date	[*DATA REMOVED*]

Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?   ◯ Yes   ◯ No

DREEM headband

Did the patient use the DREEM headband?   ◯ Yes   ◯ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?   ◯ Yes   ◯ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?　　　　　　　　　　　◯ Yes　◯ No

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score	100.0
	(-100 to 100)
Left-handedness - Less than -40	
Ambidexterity=Between -40 and +40	
Right-handness=More than +40	

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	92
	(0 - 160)

Date	[*DATA REMOVED*]

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Probability inhibition (%)	[*DATA REMOVED*]
Premature responses	1
Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0

Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ○ No
% Omission error	[*DATA REMOVED*]
Premature errors	3
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ○ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ○ No
Number of missed skips	20
Number of incorrect skips	4
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Visit

Mind & Skin ID	728-47

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Visit date	[*DATA REMOVED*]

Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Initials	[*DATA REMOVED*]
Date of birth	[*DATA REMOVED*]
Date of patient consent/assent	[*DATA REMOVED*]
_age	14.2
Date of parent/guardian consent	[*DATA REMOVED*]
Subject group	◯ Group 1 (immuno-modulatory therapy) ◯ Group 2 (topical therapy) ⊗ Group 3 (healthy controls)

Has the participant also given consent for:

Future contact regarding related research	⊗ Yes ◯ No
Use of pseudo-anonymised data for future research	⊗ Yes ◯ No
Focus group participation	◯ Yes ⊗ No
GP contact	⊗ Yes ◯ No
Contact Notes: (please do not enter any indentifying data)	[*DATA REMOVED*] (do not add any identifying information)

Inclusion/Exclusion Criteria

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Inclusion criteria

2. Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy control.

⊗ Yes ◯ No

3.Written informed consent for study participation obtained from patient or parent/guardian, with assent as appropriate by the patient, depending on the level of understanding.

⊗ Yes ◯ No

4. Willingness to comply with all study requirements.

⊗ Yes ◯ No

5. Competent use of English language, in accordance with patient's age.

⊗ Yes ◯ No

Exclusion criteria

1. Insufficient understanding of the study by the patient and/or parent/guardian.

◯ Yes ⊗ No

2. Any clear contra-indication to MRI scanning. (including braces)

◯ Yes ⊗ No

3. Any condition deemed by the investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.

◯ Yes ⊗ No

4. Formal diagnosis of sleep disorder, requiring systemic medication.

◯ Yes ⊗ No

5. Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the investigator to significantly impact on sleep components of the study.

◯ Yes ⊗ No

6. Previous and/or current substance misuse.

◯ Yes ⊗ No

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7. Concomitant systemic medications likely to impact on quality of sleep studies.

◯ Yes   ⊗ No

8. Current phototherapy treatment.

◯ Yes   ⊗ No

9. Body weight < 40kg

◯ Yes   ◯ No

_eligibility	1

Patient is eligible

Please sign to confirm all eligibility criteria have been reviewed

Signed

_____

Has this been signed?	⊗ Yes ◯ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Height&Weight

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Weight (kg)	49.10 (10kg - 100kg)
Height (cm)	165.00

Demographics

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Sex at birth	◯ Male ⊗ Female ◯ Undifferentiated
Ethnicity	◯ White ◯ Black, Black British, Caribbean or African ◯ Asian or Asian British ⊗ Mixed or multiple ethnic groups ◯ Other ethnic group
Mixed or multiple ethnic groups	◯ White and Black Caribbean ◯ White and Black African ⊗ White and Asian ◯ Any other Mixed or multiple ethnic background

UK Diagnostic Criteria

Patients must have:

1. An itchy skin condition in the last year*	◯ Yes ⊗ No
Assign to Group 3 (healthy controls)	0

*If yes, patient must have three or more of the following:

2. Visual flexural dermatitis	◯ Yes ◯ No
3. History of flexural involvement	◯ Yes ◯ No
4. History of generally dry skin	◯ Yes ◯ No
5. Personal history of atopic disease (children under 4 years: family history of atopic disease)	◯ Yes ◯ No
6. Onset before the age of 2 years (not used if child aged < 4 years)	◯ Yes ◯ No
Number of criteria	0

Family History

Family History   [*DATA REMOVED*]

Current Eczema Treatment

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Current topical therapy

2. Other?	◯ Yes ◯ No
3. Other?	◯ Yes ◯ No

Systemic therapy

Assign to Group 2 (topical therapy)	0

Medical History

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Does the patient have any allergic co-morbidities?

Asthma	⊗ Yes ◯ No ◯ Unknown
Allergic rhino-conjunctivitis (hayfever)	⊗ Yes ◯ No ◯ Unknown
Food allergies	⊗ Yes ◯ No ◯ Unknown
Contact allergies	◯ Yes ⊗ No ◯ Unknown
Does the patient have a history of sleep disturbance?	◯ Yes ⊗ No

Past Medical History

Past Medical History (select all that apply)

- ☐ ADHD
- ☐ Asthma
- ☐ Autism spectrum disorder
- ☐ Celiac Disease
- ☐ Cerebral palsy
- ☐ Congenital heart disease
- ☐ Cystic Fibrosis
- ☐ Diabetes
- ☐ Down syndrome
- ☐ Epilepsy
- ☐ Hearing impairment
- ☐ Inflammatory bowel disease (Crohn's/Ulcerative colitis)
- ☐ Juvenile arthritis
- ☐ Sickle cell anaemia
- ☐ Spina Bifida
- ☐ Urticaria
- ☐ Visual impairment
- ☐ Other medical history

Any other specified past medical history or further comments

Skin Barrier Function Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	⊗ Yes ◯ No
If yes, please select:	⊗ LVF ◯ RVF ◯ Other
TEWL Date:	[*DATA REMOVED*]
Give details (what, where and when?) of TEWL water loss measurement	_____

Measurement (ARM)

ARM 1 Flux (mg/meter sq * height)	23.45 (Range 5 - 40)
ARM 2 Flux (mg/meter sq * height)	25.57 (Range 5 - 40)
ARM 3 Flux (mg/meter sq * height)	_____ (Range 5 - 40)
Decent measurement curves?	⊗ Yes ◯ No
Temperature (◦C)	25.5
Room humidity (%)	28.6

PH measurements

PH meter reading (volar forearm)	◯ Yes ⊗ No

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Skin Examination

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Samples

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Serum sample for immunology profile analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Blood sample for RNA/gene expression analysis

Has the patient consented?	⊗ Yes ◯ No
Date sample taken	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Skin swabs for microbiome analyses (flexural area)

Has the control sample been taken?	⊗ Yes ◯ No
Has the non-lesional sample been taken?	⊗ Yes ◯ No
Location of non-lesional sample taken (please specify)	[*DATA REMOVED*]
Local EASI at non-lesional site	0.0 (0.0 - 99.9)
Has the lesional sample been taken?	◯ Yes ⊗ No
Date sample taken	[*DATA REMOVED*]

Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Has the non-lesional sample been taken?	⊗ Yes ◯ No
Was the sample taken from left volar forearm	⊗ Yes ◯ No
Date sample collected	[*DATA REMOVED*]

Stool sample for gut microbiome analysis

Has the sample container been provided to the patient?	⊗ Yes ◯ No
Date of sample	_____
Was sample received by site?	◯ Yes ◯ No
Was sample stored in -80°C freezer?	◯ Yes ◯ No
Was sample collection logged on freezer sample log?	◯ Yes ◯ No

Patient-Reported Quality Of Life Measures

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Questionnaire-Based Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Paediatric Sleep Questionnaire

Questionnaire completed?	⊗ Yes ○ No
1. SRBD scale (including snoring and sleepiness subscales)	0.136 (0 - 99)
2. Sleepiness subscale	0 (0 - 99)
3. Periodic Leg Movement/Restless Legs Syndrome scale	0 (0 - 99)
Date:	[*DATA REMOVED*]

Sleep Disturbances Scale For Children (SDSC)

Questionnaire completed?	⊗ Yes ○ No
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	12 (0 - 99)
T-Score:	58 (0 - 99)
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	4 (0 - 99)
T-Score:	51 (0 - 99)
Disorders of arousal score (sum the score of the items 17,20,21)	3 (0 - 99)
T-Score:	47 (0 - 99)
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	8 (0 - 99)
T-Score:	50 (0 - 99)
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	7 (0 - 99)

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T-Score:	50 (0 - 99)
Sleep Hyperhydrosis (sum the score of the items 9,16)	2 (0 - 99)
T-Score:	45 (0 - 99)
Total score	36 (0 - 99)
Total T-Score:	51
Date	[*DATA REMOVED*]

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Homebased Sleep Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Were home-based sleep assessments performed?　　　○ Yes　　○ No

DREEM headband

Did the patient use the DREEM headband?　　　○ Yes　　○ No

EMFIT Mattress

Did the patient use the EMFIT Mattress?　　　○ Yes　　○ No

Magnetic Resonance Imaging

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Was the MRI peformed?　　　　　　　　　　○ Yes　○ No

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Neurocognitive Assessments

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Edinburgh Handedness Inventory

Assessment completed?	⊗ Yes ◯ No

Total score Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	100 (-100 to 100)

Date	[*DATA REMOVED*]

Wechsler Abbreviated Scale of Intelligence (WASI-II)

Assessment completed?	⊗ Yes ◯ No

Total FSIQ-4 score	_____ (0 - 160)

Date	_____

Motor response inhibition assessment

Go/No-go task completed?	⊗ Yes ◯ No

Reaction time (milliseconds)	[*DATA REMOVED*]

RT Standard Deviation (milliseconds)	[*DATA REMOVED*]

Probability inhibition (%)	[*DATA REMOVED*]

Premature responses	1

Date	[*DATA REMOVED*]

Interference inhibition/selective attention assessment

Simon task completed?	⊗ Yes ◯ No
Reaction time (milliseconds)	[*DATA REMOVED*]
RT Standard Deviation (milliseconds)	[*DATA REMOVED*]
Premature responses	0
Date	[*DATA REMOVED*]

Sustained/selective attention assessment

Continuous performance task completed?	⊗ Yes ◯ No
% Omission error	[*DATA REMOVED*]
Premature errors	1
% Commission error	[*DATA REMOVED*]
Mean reaction time (milliseconds)	[*DATA REMOVED*]
MRT Standard Deviation	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Time perception assessment

Time discrimination task completed?	⊗ Yes ◯ No
%Total error	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

Vigilance assessment

Mackworth Clock task completed?	⊗ Yes ◯ No
Number of missed skips	11
Number of incorrect skips	7
Date	[*DATA REMOVED*]

Completed By

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1

Signed

_____

Name

_____

Date

_____

Concomitant Medications

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
 BASELINE VISIT 1   DATE [*DATA REMOVED*] Logs

Medication 1

 [*DATA REMOVED*]
 Dose [*DATA REMOVED*]   Units

 [*DATA REMOVED*]   Frequency

 [*DATA REMOVED*]

 Date started

_____   Ongoing? _____   Date stopped

_____

 Indication

_____

Medication 2

 _____
 Dose _____   Units

_____   Frequency

_____

 Date started

_____   Ongoing? _____   Date stopped

_____

 Indication

_____

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Adverse Events

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*]
  BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs

Were there any adverse events?   ◯ Yes   ◯ No