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

Demographics

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*]
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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	[*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*]
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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*]

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