#### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	[D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>⊗ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 othe impact on sleep components of the study.	er than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to in	mpact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Diago sign to confirm all cligibility or	torio have been reviewed
Please sign to confirm all eligibility cri-	teria nave 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 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	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Asian or Asian British	<ul><li>○ Indian</li><li>○ Pakistani</li><li>○ Bangladeshi</li><li>○ Chinese</li><li>⊗ Any other Asian background</li></ul>
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



Mind & Skin ID	728-1 Group	2 (topical therapy)	(Baseline - Visit 1)
rillia dallip, Skill ib	/ LO I CIOUP	L (topical therapy)	(Duscille Visit 1)

Family History	
Family History	



#### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?		
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?	
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?	☐ Partic ☐ Parer ☐ Siblin ☐ Partn ☐ Other	nt ig er	specify)
Past Medical History			
Past Medical History (select all that apply)	Celiac Cerek Cong Cystic Diabe Dowr Epile Heari Inflan colitis Juven Sickle Spina Urtica Visua	ma m spectr c Disease oral palsy enital he c Fibrosis etes n syndror osy ng impa nmatory s) iile arthr e cell ana n Bifida	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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



Confidential

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	17.00



## **Samples**

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 are	ea)
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	k (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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	24
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
Questionnaire fully completed?	
Date	
BTMS	
Questionnaire fully completed?	
Italy accounts assessing access (0.10)	
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**

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 col Was data output collected for night 2 Yes Was data output col Was data output collected for night 3 Yes Was data output col Was data output collected for night 4 Yes Was data output col Was data output collected for night 5 No Was data output col	ollected for night 6 Yes ollected for night 7 No ollected for night 8 No ollected for night 9 No	
EMFIT Mattress		
Did the patient use the EMFIT Mattress?		
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
If No, please detail why?	[*DATA REMOVED*]



## **Neurocognitive Assessments**

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 assessmen	nt
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*]	



#### age 23

## **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

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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

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	[D*]		
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>		
Has the participant also given consent for:			
Future contact regarding related research			
Use of pseudo-anonymised data for future research			
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**

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



	sturbance from co-morbid illness other than atopic sleep components of the study.	eczema, deemed by the investigator to significantly
○ Yes ⊗	⊙ No	
6. Previous	and/or current substance misuse.	
○ Yes ⊗	⊗ No	
7. Concom	itant systemic medications likely to impact on quali	ty of sleep studies.
○ Yes ⊗	§ No	
8. Current	phototherapy treatment.	
○ Yes ⊗	§ No	
9. Body we	eight < 40kg	
○ Yes ⊗	Ò No	
_eligibility		1
Patient is e	eligible	
Dlooso si	ign to confirm all eligibility criteria have b	ann raviowad
Signed	ign to commin an engionity criteria have b	leen reviewed
-		
Has this be	een signed?	○ Yes ○ No
Print name	e:	[*DATA REMOVED*]
Print role		[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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age 31

# 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	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>		
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>		
Asian or Asian British	<ul> <li>⊗ Indian</li> <li>○ Pakistani</li> <li>○ Bangladeshi</li> <li>○ Chinese</li> <li>○ Any other Asian background</li> </ul>		
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>
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?	
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	$\otimes$ No	○ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes	○ No	
How was sleep disturbance noted?	<ul> <li>☑ Participant</li> <li>☑ Parent</li> <li>☐ Sibling</li> <li>☐ Partner</li> <li>☐ Other (please specify)</li> </ul>		
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		

[\*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)	∨os



## **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	7.80



## **Samples**

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 ar	ea)
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**

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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	15
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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?		
If No, please detail why:	[*DATA REMOVED*]	
Sleep diary		
Has the Sleen Diary been completed?	∴ Yes ⊗ No	

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age 46'

# **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**

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	



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*]	



#### age 49

# **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 the BASELINE VISIT 1 DATE	nerapy) INITIALS [*DATA REMOVED*] [*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	728-3
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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	sturbance from co-morbid illness other than atopic sleep components of the study.	eczema, deemed by the investigator to significantly
○ Yes ⊗	Ò No	
6. Previous	and/or current substance misuse.	
○ Yes ⊗	) No	
7. Concomi	itant systemic medications likely to impact on quali	ty of sleep studies.
○ Yes ⊗	Ò No	
8. Current	phototherapy treatment.	
○ Yes ⊗	) No	
9. Body we	eight < 40kg	
○ Yes ⊗	) No	
_eligibility		1
Patient is e	eligible	
Diago si	ign to confirm all eligibility criteria have b	acon reviewed
Signed	gn to commin an engionity criteria have t	been reviewed
-		
Has this be	een signed?	○ Yes ○ No
Print name	:	[*DATA REMOVED*]
Print role		[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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age 56

# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>⊗ White and Black African</li> <li>○ White and Asian</li> <li>○ Any other Mixed or multiple ethnic background</li> </ul>
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ○ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>
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



Mind & D 728-3 Group 2 (topical therapy) (Baseline - Visit 1)

Page 60

Systemic therapy	
Is the patient starting systemic therapy?	
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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina	ma m spectr c Disease pral palse enital he c Fibrosis etes n syndror psy ng impa nmatory s) nile arthr e cell and a Bifida aria ll impairr	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	15.345 (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 (∘C)	
Room humidity (%)	
PH measurements	
PH meter reading (volar forearm)	○ Yes ⊗ No



## **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	3.60



## **Samples**

Serum sample for immunology profile analysis	
Has the patient consented?	$\otimes$ Yes $\bigcirc$ 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 are	a)
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	



# **Patient-Reported Quality Of Life Measures**

DOEM (0.20)	
POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	0
Date	[*DATA REMOVED*]
Body Mindset Inventory	
Questionnaire fully completed?	
Date	
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	2
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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		
Apriloea Hypophloea ilidex (AHII)/III		
Obstructive AHI (OAHI)/hr		
Central AHI (CnAHI)/hr		
Mean oxygen saturation (%)		
mean oxygen sacaration (70)		
20/ 0		
3% Oxygen Desaturation Index (ODI) /hr		
Absolute oxygen nadir (%)		
Mean oxygen nadir (%)		
Troum only gen riddin (70)		
0/ time avugan sats < 020/		_
% time oxygen sats < 92%		
% REM sleep		
% non REM Sleep		
Arousal index/hr		
Alousai iliuex/ili		
DREEM headband		
DILLI'I HEAGDANG		
Did the patient use the DREEM headband?	⊗ Yes ○ No	
Start Date: [*DATA REMOVED*] End Date: [*DATA REMOVED*]	1.16	
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 colle		
Was data output collected for night 4 Yes. Was data output colle		
Was data output collected for night 5 No Was data output colle	ctea for hight 10 fes	

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EMFIT Mattress	
Did the patient use the EMFIT Mattress?	
If No, please detail why:	[*DATA REMOVED*]
Sleep diary	
Has the Sleep Diary been completed?	

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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	+71.5 (-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	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

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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



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### **Visit**

Mind & Skin ID

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 [*I VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	DATA REMOVED*]
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	<ul><li>⊗ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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.



5. Sleep disturbance from co-morbid illness other impact on sleep components of the study.	than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to imp	pact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Diagon sign to confirm all clinibility suite	wie have have reviewed
Please sign to confirm all eligibility crite Signed	eria nave been reviewed
Signed	
Has this been signed?	○ Yes ○ No
Print name:	[*DATA REMOVED*]
Print role	[*DATA REMOVED*]
Date	[*DATA REMOVED*]

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age 83

# 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	



#### age 84

# **Demographics**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DAVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ATA REMOVED*]	
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>	
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>	
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>	
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	



Mind & amp; Skin ID 728-4 Group 1 (immuno-	modulatory therapy) (Baseline - Visit 1
i iii a aaiip, okiii iz i zo 4 oloap z (iiiiii aiio	modulatory therapy, (Buseline Tisht 2)

Family History	
Family History	



### **Current Eczema Treatment**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>
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
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?	

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# **Medical History**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DAT VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	A REMOVED	)*]	
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	REMOVE	ED*]
Any other specified past medical history or further comments			

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[\*DATA REMOVED\*]

age 89

## **Skin Barrier Function Assessments**

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



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Mind & Camp; Skin ID 728-4 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)
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## **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	13.60



## **Samples**

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 are	ea)
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		



## **Patient-Reported Quality Of Life Measures**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	26
Date	[*DATA REMOVED*]
Body Mindset Inventory	
Questionnaire fully completed?	
Date	
BTMS	
Questionnaire fully completed?	
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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	8
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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 VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	REMOVED*]	
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)		
	<del></del>	
CI (0)		_
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		
Alexalists account and the (OC)		
Absolute oxygen nadir (%)		
Maan ayygan nadir (0/)		
Mean oxygen nadir (%)		
% time oxygen sats < 92%		_
70 time oxygen sats < 5270		
% REM sleep		
70 NEM Sieeβ		
% non REM Sleep		
70 HOH KEM SIEEP		
Arousal index/hr		
Alousul illucayili		
DREEM headband		
Did the patient use the DREEM headband?	⊗ Yes ○ No	
Did the patient use the DNLLM Heathand!	₩ 163 € NO	
Chart Data: [*DATA DEMOVED*] Find Data:		
Start Date: [*DATA REMOVED*] End Date: Was data output collected for pight 1 Yes. Was data output collected.	ected for night 6 Ves	
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 coll	ected for night 9 Yes	
Was data output collected for night 5 Yes. Was data output colle	ected for night 10 Yes	

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EMFIT Mattress	
Did the patient use the EMFIT Mattress?	
If No, please detail why:	[*DATA REMOVED*]
Sleep diary	
Has the Sleep Diary been completed?	



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



# **Neurocognitive Assessments**

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*]



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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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Mind & Camp; Skin ID 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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## **Visit**

Mind & Skin ID

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**

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



Mind & D 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

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### **Current Eczema Treatment 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)	



### **Skin Barrier Function Assessments**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*E 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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Mind & Skin ID 728-4 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

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## **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	12.80



## **Samples**

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 are	ea)
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*]
<b>Body Mindset Inventory</b>	
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:	23
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	39
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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
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*]



# **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 REMOVE	D*]	
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?	$\otimes$ Yes $\bigcirc$ 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 10 No



EMFII Mattress		
Did the patient use the EMFIT Mattress?	⊗ Yes	S O No
Start Date: [*DATA REMOVED*] End Date: Was data output collected for night 1 Yes Was data output collected for night 2 Yes Was data output collected for night 3 Yes Was data output collected for night 4 Yes Was data output collected for night 5 Yes	Was data output collected for Was data output collected for Was data output collected for Was data output collected for	or night 7 Yes or night 8 Yes or night 9 Yes
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes	S O No
Has the Sleep Diary been scanned and uploa	aded? ⊗ Yes	S O No

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Mind & Dr. 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?		
If No, please detail why?	[*DATA REMOVED*]	



## **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*]



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# **Completed By**

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

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Indication	
Medication 4	
Dose Units	
Frequency	
Date started	
Ongoing? Date stopped	
Indication	

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Mind & Skin ID 728-4 Group 1 (immuno-modulatory therapy) (Logs)

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## **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	



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Mind & Dr. Skin ID 728-4 Group 1 (immuno-modulatory therapy) (End of Study)

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# **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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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



	sturbance from co-morbid illness other than atopic sleep components of the study.	eczema, deemed by the investigator to significantly
○ Yes ⊗	Ò No	
6. Previous	and/or current substance misuse.	
○ Yes ⊗	) No	
7. Concomi	itant systemic medications likely to impact on quali	ty of sleep studies.
○ Yes ⊗	Ò No	
8. Current	phototherapy treatment.	
○ Yes ⊗	) No	
9. Body we	eight < 40kg	
○ Yes ⊗	) No	
_eligibility		1
Patient is e	eligible	
Diago si	ign to confirm all eligibility criteria have b	acon reviewed
Signed	gn to commin an engionity criteria have t	been reviewed
-		
Has this be	een signed?	○ Yes ○ No
Print name	:	[*DATA REMOVED*]
Print role		[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li></li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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:	<ul><li>○ Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
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?	
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?	⊠ Pareı □ Siblir □ Partr	ng ner	e specify)
Past Medical History			
Past Medical History (select all that apply)	Celia Cerel Cong Cysti Diabo Down Epile Hear Inflar coliti Juver Sicklo	ma m specti c Diseas bral pals penital he c Fibrosi etes n syndro psy ing impa mmatory s) nile arthr e cell and a Bifida aria al impair	y eart disease s me me irment bowel disease (Crohn's/Ulcerative ritis aemia
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?		
Blood sample for RNA/gene expression analysis		
Has the patient consented?		
Skin swabs for microbiome analyses (flexural area	a)	
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



# **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?	
Date	
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
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
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 (%)		
20/ 0		
3% Oxygen Desaturation Index (ODI) /hr		
Alecalista assurance and dis (0/1)		
Absolute oxygen nadir (%)		
Mean avvgen nadir (0/)		
Mean oxygen nadir (%)		
% time oxygen sats < 92%		
70 time oxygen sats < 3270		
% REM sleep		
70 NET 1 5100P		
% non REM Sleep		
•		
Arousal index/hr		
DDFFM baselines d		
DREEM headband		
Did the patient use the DREEM headband?	$\otimes$ Yes $\bigcirc$ 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		

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EMFIT Mattress	
Did the patient use the EMFIT Mattress?	
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**

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 assessme	nt
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*]	



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# **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) INIT BASELINE VISIT 1 DATE [*DATA REM	TALS [*DATA REMOVED*] 10VED*] 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

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22-01-2025 14:56

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** 

Were there any adverse events?

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] BASELINE VISIT 1 DATE [*DATA REMOVED*] Logs	
DASELINE VISIT I DATE [ DATA NEMOVED ] E093	

○ Yes ○ No



### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	:D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	o disturbance from co-morbid illness other than a on sleep components of the study.	topic eczema, deemed by the investigator to significantly
○ Yes	⊗ No	
6. Previ	ous and/or current substance misuse.	
○ Yes	⊗ No	
7. Conc	omitant systemic medications likely to impact on	quality of sleep studies.
○ Yes	⊗ No	
8. Curre	ent phototherapy treatment.	
○ Yes	⊗ No	
9. Body	weight < 40kg	
○ Yes	⊗ No	
_eligibil	ity	1
Patient	is eligible	
Please	sign to confirm all eligibility criteria ha	ave been reviewed
Signed		
Has this	s been signed?	○ Yes ○ No
Print na	me:	[*DATA REMOVED*]
Print rol	e	[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li>⊗ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>	
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>	
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>⊗ White and Black African</li> <li>○ White and Asian</li> <li>○ Any other Mixed or multiple ethnic background</li> </ul>	
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		
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	



<b>Family History</b>		
Family History		



#### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	○ Yes ○ No	
2. Calcineurin inhibitor/s ?		
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?	⊠ Parer □ Siblin □ Partn	ig er	e specify)
Past Medical History			
Past Medical History (select all that apply)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina Visua	ma m specti c Diseas oral pals enital he c Fibrosi etes n syndror psy ng impa nmatory s) nile arthr e cell and aria il impairi	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	
P	
Room humidity (%)	
PH measurements	
PH meter reading (volar forearm)	



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## **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	0.80



## **Samples**

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 are	ea)
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	k (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?	
Was sample collection logged on freezer sample log?	



# **Patient-Reported Quality Of Life Measures**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	22
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	6
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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		
	⊗ Yes ○ No	
Did the patient use the DNLLM Headballa!	⊗ 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

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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**

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)	
Night-handness—More than +40		
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*]



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# **Completed By**

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



## **Concomitant Medications**

BASELINE VISIT 1 DAT	il therapy) INITIALS [*DATA REMOVED*] TE [*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
<del></del>	

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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



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## **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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	rbance from co-morbid illness other than atopic ec ep components of the study.	zema, deemed by the investigator to significantly
○ Yes ⊗ N	0	
6. Previous ar	nd/or current substance misuse.	
○ Yes ⊗ N	0	
7. Concomitar	nt systemic medications likely to impact on quality	of sleep studies.
○ Yes ⊗ N	0	
8. Current pho	ototherapy treatment.	
○ Yes ⊗ N	0	
9. Body weigh	nt < 40kg	
○ Yes ⊗ N	0	
_eligibility		1
Patient is eligi	ible	
Please sign	to confirm all aligibility critoria have be	an raviowad
Please sign to confirm all eligibility criteria have been reviewed  Signed		
J		
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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
Black, Black British, Caribbean or African	<ul><li>⊗ Caribbean</li><li>○ African</li><li>○ Any other Black, Black British or Caribbean Background</li></ul>
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**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?	○ Yes ○ No	
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>	
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	



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Systemic therapy		
Is the patient starting systemic therapy?		
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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina Visua	ma m spectr c Disease oral palse enital he c Fibrosise etes n syndror osy ng impa nmatory s) iile arthr e cell and a Bifida aria I impairr	eart disease eart disease me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	



Mind & Skin ID 728-7 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	16.60



## **Samples**

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?	$\otimes$ Yes $\bigcirc$ 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 are	a)
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*]



⊗ Yes ○ No
⊗ Yes ○ No
[*DATA REMOVED*]
⊗ Yes ○ No
[*DATA REMOVED*]
⊗ Yes ○ No
⊗ Yes ○ No
⊗ Yes ○ No

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# **Patient-Reported Quality Of Life Measures**

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?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	9
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



## **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 coll Was data output collected for night 2 Yes Was data output col Was data output collected for night 3 Yes Was data output col Was data output collected for night 4 Yes Was data output col Was data output collected for night 5 Yes Was data output col	ected for night 6 No lected for night 7 Yes lected for night 8 No lected for night 9 No
EMFIT Mattress	
Did the patient use the EMFIT Mattress?	
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

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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**

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 assessme	nt
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?	



[\*DATA REMOVED\*]

### **Visit**

Visit date

Mind & Skin ID	728-8
GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	



# Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	o disturbance from co-morbid illness other than a on sleep components of the study.	topic eczema, deemed by the investigator to significantly
○ Yes	⊗ No	
6. Previ	ous and/or current substance misuse.	
○ Yes	⊗ No	
7. Conc	omitant systemic medications likely to impact on	quality of sleep studies.
○ Yes	⊗ No	
8. Curre	ent phototherapy treatment.	
○ Yes	⊗ No	
9. Body	weight < 40kg	
○ Yes	⊗ No	
_eligibil	ity	1
Patient	is eligible	
Please	sign to confirm all eligibility criteria ha	ave been reviewed
Signed		
Has this	s been signed?	○ Yes ○ No
Print na	me:	[*DATA REMOVED*]
Print rol	e	[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>⊗ White and Black Caribbean</li> <li>○ White and Black African</li> <li>○ White and Asian</li> <li>○ Any other Mixed or multiple ethnic background</li> </ul>
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	



### **Current Eczema Treatment**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li>○ Mild</li><li>○ Moderate</li><li>⊗ Potent</li><li>○ Ultra-potent</li></ul>
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?	☐ Partic ☐ Parer ☐ Siblin ☐ Partn ☐ Other	nt g er	specify)
Past Medical History			
Past Medical History (select all that apply)	Celiac Cerek Cong Cystic Diabe Down Epilep Heari Inflan colitis Juven Sickle Spina Urtica	ma m spectrom spectro	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
Any other specified past medical history or further comments			

[\*DATA REMOVED\*]



### **Skin Barrier Function Assessments**

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



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Mind & Skin ID 728-8 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	2.20



## **Samples**

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 are	a)
Has the control sample been taken?	$\otimes$ Yes $\bigcirc$ 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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	4
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
Questionnaire fully completed?	○ Yes ○ No
Date	
	<del></del>
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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	6
Date	[*DATA REMOVED*]



### **Questionnaire-Based Sleep Assessments**

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	
Apriloea Trypoprioea Index (Arii)/III	
Obstructive AHI (OAHI)/hr	
Central AHI (CnAHI)/hr	
Mean oxygen saturation (%)	
3% Oxygen Desaturation Index (ODI) /hr	
-	<del></del>
Absolute oxygen nadir (%)	
, absolute oxygen naam (70)	
Moan ovugen nadir (0/)	
Mean oxygen nadir (%)	
% time oxygen sats < 92%	
% REM sleep	
% non REM Sleep	
	<del></del>
Arousal index/hr	
DREEM headband	
Did the patient use the DREEM headband?	⊗ Yes ○ No
Start Date: [*DATA REMOVED*] End Date: [*DATA REM	MOVED*1
Was data output collected for night 1 Yes Was data ou	Itput collected for night 6 No

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

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EMFIT Mattress	
Did the patient use the EMFIT Mattress?	⊗ Yes ○ No
Start Date: [*DATA REMOVED*] End Date: [*D Was data output collected for night 1 No Was Was data output collected for night 2 No Was Was data output collected for night 3 No Was Was data output collected for night 4 No Was Was data output collected for night 5 No Was	data output collected for night 6 No data output collected for night 7 Yes data output collected for night 8 No data output collected for night 9 No
Sleep diary	
Has the Sleep Diary been completed?	

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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**

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*]	



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# **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 th BASELINE VISIT 1 DATE [	erapy) INITIALS [*DATA REMOVED*] *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

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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



[\*DATA REMOVED\*]

### **Visit**

Visit date



# Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	o disturbance from co-morbid illness other tha on sleep components of the study.	an atopic eczema, deemed by the investigator to significantly	/
○ Yes	⊗ No		
6. Previ	ous and/or current substance misuse.		
○ Yes	⊗ No		
7. Conc	omitant systemic medications likely to impact	t on quality of sleep studies.	
○ Yes	⊗ No		
8. Curre	ent phototherapy treatment.		
○ Yes	⊗ No		
9. Body	weight < 40kg		
○ Yes	⊗ No		
_eligibil	ity	1	
Patient	is eligible		
Please	sign to confirm all eligibility criteria	have been reviewed	
Signed			
Has this	been signed?	○ Yes ○ No	
Print na	me:	[*DATA REMOVED*]	
Print rol	е	[*DATA REMOVED*]	
Date		[*DATA REMOVED*]	

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# 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	<ul><li></li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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)	
6. Onset before the age of 2 years (not used if child aged < 4 years)	○ Yes ⊗ No
Number of criteria	3



Family History		
Family History		



### **Current Eczema Treatment**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li></li></ul>
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?	
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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Colitis Juver Sickle Visua	ma m spectr c Disease oral palse enital he c Fibrosis etes n syndror psy ing impa mmatory s) nile arthr e cell and a Bifida aria al impairr	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
Any other specified past medical history or further comments			

[\*DATA REMOVED\*]



### **Skin Barrier Function Assessments**

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)	
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	



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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	2.40



### **Samples**

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 are	a)
Has the control sample been taken?	$\otimes$ Yes $\bigcirc$ 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?		
Was sample collection logged on freezer sample log?		



# **Patient-Reported Quality Of Life Measures**

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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	1
Date	[*DATA REMOVED*]



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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 (%)		
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

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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**

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*]



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# **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

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22-01-2025 14:56

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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]		
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>		
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	ty 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 b	een 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)	64.40 (10kg - 100kg)
Height (cm)	174.00



## **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>○ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>⊗ Any other White background</li> </ul>
UK Diagnostic Criteria	
Patients must have:	
1. An itchy skin condition in the last year*	
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	



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Mind & Skin ID 728-10 Group 3 (healthy controls) (Baseline - Visit 1)

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#### **Current Eczema Treatment**

GROUP Group 3 (healthy controls) INITIALS [*DATA R VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	REMOVED*]
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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Sickle Spina Urtica	ma m spectrom spectro	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia

[\*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	



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Mind & D 728-10 Group 3 (healthy controls) (Baseline - Visit 1)

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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	[*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 are	ea)
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	

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Mind & D 728-10 Group 3 (healthy controls) (Baseline - Visit 1)

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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
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

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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



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## **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*]



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## **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 constant of BASELINE VISIT 1 DATE [	ontrols) INITIALS [*DATA REMOVED*] *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	



Mind & Skin ID 728-10 Group 3 (healthy controls) (Logs)

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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	728-11	
GROUPINITIALS 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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
Has the participant also given consent for:	
Future contact regarding related research	
Use of pseudo-anonymised data for future research	
Focus group participation	
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	
	<del></del>
Please sign to confirm all eligibility criteria have be	en reviewed
Signed	
Has this been signed?	○ Yes ○ No
Print name:	
Print role	
Print role  Date	

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#### Mind & Skin ID 728-11 (Baseline - Visit 1)

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# 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	<ul><li>○ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
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	



### **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?	
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**

GROUPINITIALS 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   □ 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 [*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	



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Mind & D 728-11 (Baseline - Visit 1)

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### **Skin Examination**

GROUP INITIALS VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
EASI (score 0-72)	
Test performed?	○ Yes ○ No
Total score	



Mind & Skin ID 728-11 (Baseline - Visit 1)

#### Page

## **Samples**

GROUPINITIALS 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	a)	
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 nor	n-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	
<b>Body Mindset Inventory</b>			
Questionnaire fully completed?	○ Yes	○No	
BTMS			
Questionnaire fully completed?	○ Yes	○ No	
Hab acceptance with a constitution of the cons			
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 ○ I	No
Sleep Disturbances Scale For Children (SDSC)		
Questionnaire completed?	○ Yes ○ I	No



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Mind & D 728-11 (Baseline - Visit 1)

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## **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	



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Mind & amp; Skin ID 728-11 (Baseline - Visit 1)

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## **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 (WA	SI-II)	
Assessment completed?	○ Yes	○ No
Motor response inhibition assessment		
Go/No-go task completed?	○ Yes	○ No
Interference inhibition/selective attention asses	sment	
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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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 impa	ct 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 criter	ia have been reviewed	
Signed		
Use this been signed?	O Vos. O No	
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)	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	<ul><li></li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>○ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>⊗ Any other White background</li> </ul>
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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Mind & Skin ID 728-12 Group 3 (healthy controls) (Baseline - Visit 1)

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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 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	5		

[\*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	[*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:	$\otimes$ LVF $\bigcirc$ RVF $\bigcirc$ Other
PH reading date:	[*DATA REMOVED*]
PH measurment 1	5.5
PH measurment 2	5.4
PH measurment 3	

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Mind & D 728-12 Group 3 (healthy controls) (Baseline - Visit 1)

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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	[*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 are	ea)
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?	
Date sample taken	[*DATA REMOVED*]



Tape stripping (arm) for cutaneous cytokine work (	rom 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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Mind & Camp; Skin ID 728-12 Group 3 (healthy controls) (Baseline - Visit 1)

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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
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*]



## **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	[*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

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**EMFIT Mattress** 

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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	

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## **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	100 (-100 to 100)	
Right-handness=More than +40		
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*]	



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## **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 of BASELINE VISIT 1 DATE [	ontrols) INITIALS [*DATA REMOVED*] *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	



Mind & D 728-12 Group 3 (healthy controls) (Logs)

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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

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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
Has the participant also given consent for:	
Future contact regarding related research	
Use of pseudo-anonymised data for future research	
Focus group participation	
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
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 be	en reviewed
Signed	
Has this been signed?	
	○ Yes ○ No
Print name:	○ Yes ○ No
Print name:	
Print name:	

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Mind & D 728-13 (Baseline - Visit 1)

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# 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	<ul><li>○ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>	
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>	
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		



### **Current Eczema Treatment**

GROUP INITIALS VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Current topical therapy	
Current topical therapy	
1. Corticosteroid/s ?	○ Yes ○ No
2. Calcineurin inhibitor/s ?	○ Yes ○ No
3. Soap substitutes /moisturisers?	
4. Other topical therapy	
	<del></del>
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



### **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	



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### **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	



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Mind & D 728-13 (Baseline - Visit 1)

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# **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	
	<b>O</b> 1 <b>33</b>	<b>O</b> 110	
Wechsler Abbreviated Scale of Intelligence	(WASI-II)		
Assessment completed?		○ No	
·	· ·		
Motor response inhibition assessment			
Piotor response minibition assessment			
Go/No-go task completed?	○ Yes	○ No	
Interference inhibition/selective attention a	ssessment		
Simon task completed?	○ Yes	○ No	
Simon task completed:	<b>○ 163</b>	ONO	
Sustained/selective attention assessment			
Continuous performance task completed?	○ Yes	○ No	
·	<u> </u>		
Time perception assessment			
Time discrimination task completed?		○ No	
·	<b>G</b>		
Vinilana anamani			
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

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	:D*]	
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>	
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



	o disturbance from co-morbid illness other than a on sleep components of the study.	topic eczema, deemed by the investigator to significantly
○ Yes	⊗ No	
6. Previ	ous and/or current substance misuse.	
○ Yes	⊗ No	
7. Conc	omitant systemic medications likely to impact on	quality of sleep studies.
○ Yes	⊗ No	
8. Curre	ent phototherapy treatment.	
○ Yes	⊗ No	
9. Body	weight < 40kg	
○ Yes	⊗ No	
_eligibil	ity	1
Patient	is eligible	
Please	sign to confirm all eligibility criteria ha	ave been reviewed
Signed		
Has this	s been signed?	○ Yes ○ No
Print na	me:	[*DATA REMOVED*]
Print rol	e	[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Asian or Asian British	<ul><li>○ Indian</li><li>○ Pakistani</li><li>⊗ Bangladeshi</li><li>○ Chinese</li><li>○ Any other Asian background</li></ul>
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:	<ul><li> Mild</li><li> ⊗ Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>
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



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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			

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[\*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)	21.533 (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



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Mind & Skin ID 728-14 Group 2 (topical therapy) (Baseline - Visit 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	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*]



rape stripping (arm) for cutaneous cytokine work (ii	om non-lesional left voiar 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)	
	0.11
Questionnaire fully completed?	⊗ Yes ○ No
Total score	6
	<u> </u>
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
Questionnaire fully completed?	○ Yes ○ No
Date	
	<del></del>
BTMS	
Questionnaire fully completed?	○ Yes ○ No
Itch severity numerical rating score (0-10)	
VAS completed	⊗ Yes ○ No
Total score	4
Data	[*DATA DEMO\/ED*]
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)
4.55.50	$\otimes$ 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
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
Sleep Hyperhydrosis (sum the score of the items 9,10)	(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 REMOVE	D*]
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

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**EMFIT Mattress** 

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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 colle Was data output collected for night 2 Yes Was data output col Was data output collected for night 3 Yes Was data output col Was data output collected for night 4 Yes Was data output col Was data output collected for night 5 Yes Was data output col	ected for night 6 Yes lected for night 7 Yes lected for night 8 Yes lected for night 9 Yes
Sleep diary	
Has the Sleep Diary been completed?	⊗ Yes ○ No
Has the Sleep Diary been scanned and uploaded?	⊗ 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**

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 assessme	nt
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	2	
Date	[*DATA REMOVED*]	



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## **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

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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?	



#### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	:D*]		
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>		
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**

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 impact on sleep components of the study.	than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to imp	pact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Bloom of the land	-Za bassa bassa saa Zassa d
Please sign to confirm all eligibility crite	ria 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 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Weight (kg)	68.30 (10kg - 100kg)
Height (cm)	166.50



# **Demographics**

4		
○ Yes ⊗ No		
⊗ Yes ○ No		
0		
⊗ Yes ○ No		
<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>② Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> <li>○ Indian</li> <li>○ Pakistani</li> <li>○ Bangladeshi</li> <li>○ Chinese</li> <li>⊗ Any other Asian background</li> </ul>		
<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>		



<b>Family History</b>		
Family History		



#### **Current Eczema Treatment**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ⊗ No
2. Calcineurin inhibitor/s ?	
3. Soap substitutes /moisturisers?	
4. Other topical therapy	
1. Other?	
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No



Systemic therapy	
Is the patient starting systemic therapy?	
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?	⊠ Parer □ Siblin □ Partn	ig er	e specify)
Past Medical History			
Past Medical History (select all that apply)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina Urtica Visua	ma m specti c Diseas oral pals enital he c Fibrosi etes n syndror psy ng impa nmatory s) nile arthr e cell and aria il impairi	y eart disease s me irment bowel disease (Crohn's/Ulcerative ritis aemia
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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Mind & Skin ID 728-15 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	8.40



## **Samples**

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 (	rom 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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	6
Date	[*DATA REMOVED*]
Body Mindset Inventory	
Questionnaire fully completed?	○ Yes ○ No
Date	
	<del></del>
BTMS	
Questionnaire fully completed?	
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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	1
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

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



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Mind & D 728-15 Group 2 (topical therapy) (Baseline - Visit 1)

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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



#### **Neurocognitive Assessments**

GROUP Group 2 (topical therapy) INITIALS [\*DATA REMOVED\*] VISIT DATE [\*DATA REMOVED\*] Baseline - Visit 1 **Edinburgh Handedness Inventory** Assessment completed? Wechsler Abbreviated Scale of Intelligence (WASI-II) Assessment completed?  $\otimes$  Yes  $\bigcirc$  No Total FSIQ-4 score 103 (0 - 160)Date [\*DATA REMOVED\*] Motor response inhibition assessment Go/No-go task completed? Interference inhibition/selective attention assessment Simon task completed? 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? 



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## **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
Madian 2
Medication 3
Dose Units
Frequency
Date started
Ongoing? Date stopped

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Indication

Adverse	<b>Events</b>
---------	---------------

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

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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



	rbance from co-morbid illness other than atopic ec ep components of the study.	zema, deemed by the investigator to significantly
○ Yes ⊗ N	0	
6. Previous ar	nd/or current substance misuse.	
○ Yes ⊗ N	0	
7. Concomitar	nt systemic medications likely to impact on quality	of sleep studies.
○ Yes ⊗ N	0	
8. Current pho	ototherapy treatment.	
○ Yes ⊗ N	0	
9. Body weigh	nt < 40kg	
○ Yes ⊗ N	0	
_eligibility		1
Patient is eligi	ible	
Please sign	to confirm all eligibility criteria have be	an raviowad
Signed	to commin an engionity criteria have be	en revieweu
J		
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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
Black, Black British, Caribbean or African	<ul><li>Caribbean</li><li>African</li><li>Any other Black, Black British or Caribbean Background</li></ul>
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li>⊗ Mild</li><li>○ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	○ Yes ○ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>
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



Mind & D 728-16 Group 2 (topical therapy) (Baseline - Visit 1)

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Systemic therapy	
Is the patient starting systemic therapy?	
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)	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



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Mind & Skin ID 728-16 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	2.30



## **Samples**

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	a)
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		
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**

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?	
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*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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 REMOVE	D*]	
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 Was data output collected for night 5 Yes Was data output collected for night 10 Yes

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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 was data output collected for night 2 No Was data output was data output collected for night 3 Yes Was data output was data output collected for night 4 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data	out collected for night 6 Yes ut collected for night 7 Yes out collected for night 8 Yes out collected for night 9 No	
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes ○ No	
Has the Sleep Diary been scanned and uploaded?	⊗ 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**

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*]	



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# **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? 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?	



### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 impact on sleep components of the study.	than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to imp	pact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Bloom of the land	-Za bassa bassa saa Zassa d
Please sign to confirm all eligibility crite	ria 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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>	
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>	
Asian or Asian British	<ul> <li>⊗ Indian</li> <li>○ Pakistani</li> <li>○ Bangladeshi</li> <li>○ Chinese</li> <li>○ Any other Asian background</li> </ul>	
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	



<b>Family History</b>		
Family History		



### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li>○ Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li>○ Mild</li><li>○ Moderate</li><li>⊗ Potent</li><li>○ Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?	○ Yes ⊗ No	
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>	
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?	
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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Juven Sickle Spina Visua	ma m spectr c Disease oral palse enital he c Fibrosise etes n syndror osy ng impa nmatory s) iile arthr e cell and a Bifida aria I impairr	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	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 (%)	
	<del></del>
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



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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	4.80



## **Samples**

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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	8
Date	[*DATA REMOVED*]
Body Mindset Inventory	
Questionnaire fully completed?	
Date	
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
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 Sieep 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*]



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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
DREEM headband		
Did the patient use the DREEM headband?	○ Yes	○ No
EMFIT Mattress		
Did the patient use the EMFIT Mattress?	○ Yes	○No



Mind & D 728-17 Group 2 (topical therapy) (Baseline - Visit 1)

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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



## **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	( = 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
Date	[*DATA REMOVED*]	
Wechsler Abbreviated Scale of Intelligence (W	ASI-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 asso	essment	
Simon task completed?	○ Yes ○ No	
Sustained/selective attention assessment		
Continuous performance task completed?	○ Yes ○ No	
Time perception assessment		
Time discrimination task completed?	○ Yes ○ No	



Mind & D 728-17 Group 2 (topical therapy) (Baseline - Visit 1)

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Vigilance assessment	
Mackworth Clock task completed?	○ Yes ○ No



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## **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 t BASELINE VISIT 1 DATE	herapy) INITIALS [*DATA REMOVED*] [*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	<b>Events</b>
---------	---------------

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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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**

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 imp	pact 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 crite	ria 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)	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	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>
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**

○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	
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		
	Yes Yes Yes Yes Yes Yes ADHD Asthm Autisr Celiac Cereb Conge Cystic Diabe Down Epilep Hearii Inflam colitis Juven Sickle Spina Urtica Visua	<ul> <li>Yes ⊗ No</li> <li>Geliac Disease</li> <li>Cerebral palsy</li> <li>Congenital he</li> <li>Cystic Fibrosis</li> <li>Diabetes</li> <li>Down syndror</li> <li>Epilepsy</li> <li>Hearing impai</li> <li>Inflammatory colitis</li> <li>Juvenile arthri</li> <li>Sickle cell and</li> <li>Spina Bifida</li> <li>Urticaria</li> <li>Visual impair</li> </ul>

, ,

[\*DATA REMOVED\*]



22-01-2025 14:56

#### **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



Mind & Skin ID 728-18 Group 3 (healthy controls) (Baseline - Visit 1)

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#### **Skin Examination**



### **Samples**

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 are	ea)
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	



Mind & D 728-18 Group 3 (healthy controls) (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



### **Questionnaire-Based Sleep Assessments**

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)



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:		
		<del></del>
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 REMOVE	D*]
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		
		<del></del>
Central AHI (CnAHI)/hr		
Mean oxygen saturation (%)		
ricum oxygen sacaration (70)		
3% Oxygen Desaturation Index (ODI) /hr		
	-	
Absolute oxygen nadir (%)		
		<del></del>
Mean oxygen nadir (%)		
Medit oxygen riadii (70)		
% time oxygen sats < 92%		
% REM sleep		
0/ non DEM Cloop		
% non REM Sleep		
Arousal index/hr		
DREEM headband		
Did the patient use the DREEM headband?	⊗ Yes ○ No	
Start Date: [*DATA REMOVED*] End Date: [*DATA RE Was data output collected for night 1 No Was data ou Was data output collected for night 2 No Was data output c	utput collected for night 6 No	

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 3 No Was data output collected for night 3 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

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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 No Was data output Was data output collected for night 2 Yes Was data output Was data output collected for night 3 Yes Was data output Was data output collected for night 4 No Was data output Was data output collected for night 5 Yes Was data output	ut collected for night 6 Yes ut collected for night 7 Yes ut collected for night 8 No ut collected for night 9 Yes	
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes ○ No	
Has the Sleep Diary been scanned and uploaded?	⊗ Yes ○ No	

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## **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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score	-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	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	



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*]



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## **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



Mind & Controls | Cont

**Adverse Events** 



[\*DATA REMOVED\*]

#### **Visit**

Visit date

Mind & Skin ID	728-19
GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	

### Registration

GROUP Group 2 (topical therapy) INITIALS [\*DATA REMOVED\*] VISIT DATE [\*DATA REMOVED\*] Baseline - Visit 1 **Initials** [\*DATA REMOVED\*] Date of birth [\*DATA REMOVED\*] [\*DATA REMOVED\*] Date of patient consent/assent 15.1 \_age 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  $\bigcirc$  No Use of pseudo-anonymised data for future research Yes  $\otimes$  No Focus group participation  $\otimes$  No ○ Yes GP contact  $\otimes$  Yes  $\bigcirc$  No Contact Notes: (please do not enter any indentifying [\*DATA REMOVED\*] (do not add any identifying information)



### **Inclusion/Exclusion Criteria**

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



	o disturbance from co-morbid illness other than a on sleep components of the study.	topic eczema, deemed by the investigator to significantly	
○ Yes	⊗ No		
6. Previ	ous and/or current substance misuse.		
○ Yes	⊗ No		
7. Conc	omitant systemic medications likely to impact or	quality of sleep studies.	
○ Yes	⊗ No		
8. Curre	ent phototherapy treatment.		
○ Yes	⊗ No		
9. Body	weight < 40kg		
○ Yes	⊗ No		
_eligibil	ity	1	
Patient	is eligible		
Please sign to confirm all eligibility criteria have been reviewed			
Signed			
Has this	been signed?	⊗ Yes ○ No	
Print na	me:	[*DATA REMOVED*]	
Print rol	e	[*DATA REMOVED*]	
Date		[*DATA REMOVED*]	

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# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>White and Black Caribbean</li> <li>White and Black African</li> <li>White and Asian</li> <li>Any other Mixed or multiple ethnic background</li> </ul>
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>
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?		
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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Sickle Spina Visua	ma manama spectra palse enital he called from the called from	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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



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Total score

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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



### **Samples**

Serum sample for immunology profile analysis	
Has the patient consented?	
Blood sample for RNA/gene expression analysis	
Has the patient consented?	
Skin swabs for microbiome analyses (flexural ar	rea)
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 wo	rk (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*1



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?	
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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	24
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
Questionnaire fully completed?	
Date	
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	6
Date	[*DATA REMOVED*]



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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?	⊗ Yes ○ No
Actigraphy wristwatch	
Did the patient use the Actigraphy wristwatch?	⊗ Yes ○ No
Time period used From [*DATA REMOVED*] To [*DATA REMOVE	D*]
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 (%)	
Annoog Hyponnoog Indox (AUI)/hr	
Apnoea Hypopnoea Index (AHI)/hr	
Obstructive AHI (OAHI)/hr	
Central AHI (CnAHI)/hr	
Mean oxygen saturation (%)	
3% Oxygen Desaturation Index (ODI) /hr	
570 Oxygen Desaturation index (ODI) /iii	
Absolute oxygen nadir (%)	
Mean oxygen nadir (%)	
% time oxygen sats < 92%	
% REM sleep	
·	
% non REM Sleep	
70 HOH KEM SIEED	
Arousal index/hr	
DREEM headband	
Did the patient use the DREEM headband?	⊗ Yes ○ No
2.2 patient and the Dividing Headband	
Start Date: [*DATA REMOVED*] End Date: [*DATA REMOV	
Was data output collected for night 1 Yes Was data output	at collected for night 6 Yes

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 10 No

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EMFII Mattress		
Did the patient use the EMFIT Mattress?	⊗ Yes ○ No	
Start Date: [*DATA REMOVED*] End Date: [*DATA REMO Was data output collected for night 1 Yes Was data output was data output collected for night 2 No Was data output was data output collected for night 3 No Was data output was data output collected for night 4 No Was data output was data output collected for night 5 No Was data output was data output collected for night 5 No Was data output was data output collected for night 5 No Was data output was data output collected for night 5 No Was data output was data output collected for night 5 No Was data output was data output was data output collected for night 5 No Was data output was data o	out collected for night 6 Yes ut collected for night 7 Yes ut collected for night 8 Yes ut collected for night 9 Yes	
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes ○ No	
Has the Sleep Diary been scanned and uploaded?	⊗ 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**

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 assessme	nt
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	3	
Date	[*DATA REMOVED*]	



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# **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

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22-01-2025 14:56

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*]



## Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 othe impact on sleep components of the study.	er than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to im	npact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Discourse to the configuration of the configuration	
Please sign to confirm all eligibility crit	eria 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 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Weight (kg)	61.10 (10kg - 100kg)
Height (cm)	180.00



# **Demographics**

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Sex at birth	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	⊗ Yes ○ No
Potency	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>
Name of steriod 2	[*DATA REMOVED*]
Add another steroid?	⊗ Yes ○ No
Potency	<ul><li></li></ul>
Name of steroid 3	[*DATA REMOVED*]
Add another steroid?	○ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>○ Tacrolimus 0.1%</li></ul>
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?	<ul> <li>□ Participant</li> <li>☑ Parent</li> <li>□ Sibling</li> <li>□ Partner</li> <li>□ Other (please specify)</li> </ul>		
Past Medical History			
Past Medical History (select all that apply)	Celia Cere Cong Cysti Diabo Down Epile Hear Inflar coliti Juver Sicklor Urtic Visua	ma m specti c Diseas bral pals lenital he c Fibrosi etes n syndrol psy ing impa mmatory s) nile arthr e cell and a Bifida aria al impairi	y eart disease s me me irment bowel disease (Crohn's/Ulcerative ritis aemia
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)	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



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Mind & D 728-20 Group 2 (topical therapy) (Baseline - Visit 1)

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#### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	5.20



### **Samples**

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 are	a)
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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	22
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
Questionnaire fully completed?	○ Yes ⊗ No
Date	
	<del></del>
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	10
Date	[*DATA REMOVED*]



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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?	$\otimes$ Yes	○ No	
Time period used From [*DATA REMOVED*] To [*DATA REMOVED	D*]		
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		<u> </u>
% non REM Sleep		<del>_</del>
Arousal index/hr		<del>_</del>
DREEM headband		_
Did the patient use the DREEM headband?		
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 Was data output collected for night 2 No Was data output Was data output collected for night 3 No Was data output Was data output collected for night 4 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was data output collected for night 5 Yes Was data output was	ut collected for night 6 Yes ut collected for night 7 Yes ut collected for night 8 Yes out collected for night 9 Yes	
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes ○ No	
Has the Sleep Diary been scanned and uploaded?	⊗ 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**

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 assessme	nt
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*]	



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# **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) INIT BASELINE VISIT 1 DATE [*DATA REM	TALS [*DATA REMOVED*] #INVED*] 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

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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

#### **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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Mind & Skin ver 4.0

Mind & D 728-21 Group 2 (topical therapy) (Baseline - Visit 1)

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#### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 impact on sleep components of the study.	than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to imp	pact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Bloom of the land	-Za bassa bassa saa Zassa d
Please sign to confirm all eligibility crite	ria 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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>		
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>		
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>⊗ White and Black African</li> <li>○ White and Asian</li> <li>○ Any other Mixed or multiple ethnic background</li> </ul>		
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)			
Number of criteria	4		



Family History	
Family History	



#### **Current Eczema Treatment**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	⊗ Yes ○ No
Potency:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
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?	
Assign to Group 2 (tonical 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		

[\*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)	14.107 (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



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Mind & Skin ID 728-21 Group 2 (topical therapy) (Baseline - Visit 1)

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#### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	1.60



### **Samples**

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?	
Skin swabs for microbiome analyses (flexural area	a)
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	

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# **Patient-Reported Quality Of Life Measures**

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:	62	
(sum items: 1, 5, 7, 12, 14, 17)		
Bodily threat appraisals score:	18	
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)		
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	4
Date	[*DATA REMOVED*]

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### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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?	$\otimes$ 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	

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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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score  Left-handedness - Less than -40 Ambidexterity=Between -40 and +40 Right-handness=More than +40	14.25 (-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	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*]



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# **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 the BASELINE VISIT 1 DATE [*I	rapy) INITIALS [*DATA REMOVED*] DATA REMOVED*] Logs
Medication 1	
[*DATA REMOVED*] Dose Units	
Frequency	
Date started	
Ongoing? E	Pate stopped
Indication	
Medication 2	
Dose Units	
Frequency	
Date started	
Ongoing? E	Pate 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

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 impact on sleep components of the study.	than atopic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
○ Yes ⊗ No	
7. Concomitant systemic medications likely to imp	pact on quality of sleep studies.
○ Yes ⊗ No	
8. Current phototherapy treatment.	
○ Yes ⊗ No	
9. Body weight < 40kg	
○ Yes ⊗ No	
_eligibility	1
Patient is eligible	
Bloom of the land	-Za bassa bassa saa Zassa d
Please sign to confirm all eligibility crite	ria 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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>⊗ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Black, Black British, Caribbean or African	<ul><li>⊗ Caribbean</li><li>○ African</li><li>○ Any other Black, Black British or Caribbean Background</li></ul>
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



<b>Family History</b>		
Family History		



### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
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?	
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?	□ Partion     □ Paren     □ Siblin     □ Partn     □ Other	nt g er	specify)
Past Medical History			
Past Medical History (select all that apply)	Celiac Cerek Cong Cystic Diabe Dowr Epile Heari Inflan colitis Sickle Spina Urtica Visua	ma m spectr c Disease oral palse enital he c Fibrosise es n syndror osy ng impa nmatory s) ille arthr e cell and aria I impairr	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	(Dance F., 40)
ADM 2 Floor (as a factor of the singlet)	(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

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Mind & Skin ID 728-22 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	2.00



## **Samples**

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	a)
Has the control sample been taken?	$\otimes$ Yes $\bigcirc$ 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*]



rape stripping (arm) for cutaneous cytokine work (ii	oni non-lesional left voial forearmi
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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	15
Date	[*DATA REMOVED*]
Body Mindset Inventory	
Questionnaire fully completed?	○ Yes ⊗ No
Date	
	<del></del>
BTMS	
Questionnaire fully completed?	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	7
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



## **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?	$\otimes$ Yes	○ No	
Time period used From [*DATA REMOVED*] To [*DATA REMOVED	D*]		
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		
	⊗ 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

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EMFIT Mattress	
Did the patient use the EMFIT Mattress?	⊗ Yes ○ No
Start Date: [*DATA REMOVED*] End Date: [ Was data output collected for night 1 Yes V Was data output collected for night 2 Yes V Was data output collected for night 3 Yes V Was data output collected for night 4 Yes V Was data output collected for night 5 Yes V	las data output collected for night 6 Yes las data output collected for night 7 No las data output collected for night 8 No las data output collected for night 9 No
Sleep diary	
Has the Sleep Diary been completed?	

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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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score  Left-handedness - Less than -40  Ambidexterity=Between -40 and +40	100 (-100 to 100)	
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*]



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# **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) BASELINE VISIT 1 DATE [*DATA	INITIALS [*DATA REMOVED*] REMOVED*] Logs	
Medication 1		
[*DATA REMOVED*] Dose Units		
Frequency		
Date started		
Ongoing? Date s	topped	
Indication		
Medication 2		
[*DATA REMOVED*] Dose Units		
Frequency		
Date started		
Ongoing? Date s	copped	
Indication		
Medication 3		
Dose Units		
Frequency		
Date started		
Ongoing? Date s	topped	

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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



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### **Visit**

Mind & Skin ID

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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 o	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	ve 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)	58.70 (10kg - 100kg)
Height (cm)	164.00



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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)	
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	D*]
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?	
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 comment	S

[\*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



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Mind & D 728-23 Group 3 (healthy controls) (Baseline - Visit 1)

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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	[*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 are	ea)
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?	
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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Mind & Camp; Skin ID 728-23 Group 3 (healthy controls) (Baseline - Visit 1)

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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
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 REMOVE	ED*]	
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 10 Yes Was data output collected for night 5 Yes Was data output collected for night 10 Yes

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EMFII Mattress		
Did the patient use the EMFIT Mattress?	⊗ Yes ○ No	
Start Date: [*DATA REMOVED*] End Date: [*DATA RE Was data output collected for night 1 No Was data ou Was data output collected for night 2 Yes Was data ou Was data output collected for night 3 No Was data ou Was data output collected for night 4 No Was data ou Was data output collected for night 5 No Was data output collected for night 6 No Was data output colle	utput collected for night 6 No output collected for night 7 No utput collected for night 8 No utput collected for night 9 No	
Sleep diary		
Has the Sleep Diary been completed?	⊗ Yes ○ No	
Has the Sleep Diary been scanned and uploaded?	⊗ Yes ○ No	

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## **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	100 (-100 to 100)		
Right-handness=More than +40			
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*]



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# **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



### **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*]



## Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>◇ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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



	o disturbance from co-morbid illness other than on sleep components of the study.	n atopic eczema, deemed by the investigator to significantly
○ Yes	⊗ No	
6. Previ	ous and/or current substance misuse.	
○ Yes	⊗ No	
7. Conc	omitant systemic medications likely to impact	on quality of sleep studies.
○ Yes	⊗ No	
8. Curre	ent phototherapy treatment.	
○ Yes	⊗ No	
9. Body	weight < 40kg	
○ Yes	○ No	
_eligibil	ity	1
Patient	is eligible	
Please	sign to confirm all eligibility criteria	have been reviewed
Signed		
Has this	been signed?	⊗ Yes ○ No
Print na	me:	[*DATA REMOVED*]
Print rol	е	[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>	
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>	
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or Britis</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>	
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	



<b>Family History</b>		
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:	<ul><li>○ Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
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	$\otimes$ No	○ Unknown
Does the patient have a history of sleep disturbance?	⊗ Yes	○ No	
How was sleep disturbance noted?	☐ Partic ☐ Paren ☐ Siblin ☐ Partn ☐ Other	it g er	specify)
Past Medical History			
Past Medical History (select all that apply)	☐ Celiad ☐ Cerek ☐ Congding ☐ Cystid ☐ Diabe	na m spectr c Disease oral palsy enital he c Fibrosis	/ art disease s
	☐ Epilep☐ Heari☐ Inflancolitis☐ Juven☐ Sickle☐ Spina☐ Urtica☐ Visua☐	osy ng impa nmatory i) ile arthri e cell and Bifida	irment bowel disease (Crohn's/Ulcerative itis aemia ment

[\*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)	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**

Has the non-lesional sample been taken?

Date sample collected

Was the sample taken from left volar forearm

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? 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  $\bigcirc$  No Has the non-lesional sample been taken? Yes  $\bigcirc$  No Has the lesional sample been taken? ○ Yes ○ No Tape stripping (arm) for cutaneous cytokine work (from non-lesional left volar forearm)

Stool sample for gut microbiome analysis		
Has the sample container been provided to the patient?	○ Yes ○ No	

○ 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
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:	39
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	19
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
Total score	20
Date	[*DATA RFMOVFD*]



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	<ul><li>             ⊗ DLQI (&gt;16 years old, range 0-30)</li></ul>
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
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)



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*]



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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
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 ID 728-24 Group 2 (topical therapy) (Baseline - Visit 1)

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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



## **Neurocognitive Assessments**

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
Motor response inhibition assessment	
Go/No-go task completed?	○ Yes ○ No
Interference inhibition/selective attention assessmen	ent
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



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# **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?	



### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 ato impact on sleep components of the study.	opic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
Yes ⊗ No	
7. Concomitant systemic medications likely to impact on o	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	ve heen verieured
Signed	ve 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 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	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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



<b>Family History</b>		
Family History		



### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?	○ Yes ○ No	
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>○ Tacrolimus 0.1%</li></ul>	
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?	



# **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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina	ma m specti c Diseas oral pals enital he c Fibrosi etes n syndroi psy ing impa mmatory s) nile arthr e cell and a Bifida aria il impairi	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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	D*]
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



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Mind & Skin ID 728-25 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	11.75



## **Samples**

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 are	a)
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 (f	rom 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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	19
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	38
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	19
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	11
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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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
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**

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	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 assessme	nt
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	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	

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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



[\*DATA REMOVED\*]

### **Visit**

Visit date

Mind & Skin ID

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

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# Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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.
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 ha	ve heen reviewed	
Signed	ve 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)	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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>		
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>		
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>		
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	n		



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			

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[\*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



Mind & D 728-26 Group 3 (healthy controls) (Baseline - Visit 1)

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#### **Skin Examination**



### **Samples**

Serum sample for immunology profile analysis	
Has the patient consented?	⊗ Yes ○ No
Date sample taken	
	<del></del>
Was sample received by site?	
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	1)
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 (f	rom 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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Mind & Camp; Skin ID 728-26 Group 3 (healthy controls) (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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)



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*]



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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
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**

Edinburgh Handedness Inventory	
Assessment completed?	⊗ Yes ○ No
Total score  Left-handedness - Less than -40  Ambidexterity=Between -40 and +40	+66.75 (-100 to 100)
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	0
Date	[*DATA REMOVED*]
Interference inhibition/selective attention assessme	nt
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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]			
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>			
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**

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 of	n 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	nave 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)	68.00 (10kg - 100kg)
Height (cm)	185.42



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]				
Sex at birth	<ul><li></li></ul>				
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>				
White	<ul> <li>English, Welsh, Scottish, Northern Irish or Briti</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>				
UK Diagnostic Criteria					
Patients must have:					
1. An itchy skin condition in the last year*					
Assign to Group 3 (healthy controls)	0				
*If yes, patient must have three or more of the following:					
2. Visual flexural dermatitis					
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)					
6. Onset before the age of 2 years (not used if child aged < 4 years)					
Number of criteria	0				



Family History	



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#### **Current Eczema Treatment**

GROUP Group 3 (healthy controls) INITIALS [*DATA VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	REMOVED*]
<b>Current topical therapy</b>	
2. Other?	○ Yes ○ No
3. Other?	○ Yes ○ No
Control the control	
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/Ulcerativ 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

Mind & Camp; Skin ID 728-27 Group 3 (healthy controls) (Baseline - Visit 1)

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#### **Skin Examination**



### **Samples**

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 are	ea)
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?	
Date sample taken	[*DATA REMOVED*]



rape stripping (arm) for cutaneous cytokine work (ii	om non-lesional left voiar 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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Mind & D 728-27 Group 3 (healthy controls) (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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 REMOVE	D*]
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 (%)	
20/ Overgon Deseturation Index (ODI) /hr	
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*] End Date: [*DATA REMOVED*]	MOVED*] output collected for night 6 Yes

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

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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 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	

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## **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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score  Left-handedness - Less than -40  Ambidexterity=Between -40 and +40	71.5 (-100 to 100)	
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	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 of BASELINE VISIT 1 DATE	controls) INITIALS [*DATA REMOVED*] [*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	



Mind & Controls | Controls | Mind & Controls | Controls

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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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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**

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	D*]
Sex at birth	<ul><li>⊗ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>○ White and Black African</li> <li>○ White and Asian</li> <li>⊗ Any other Mixed or multiple ethnic background</li> </ul>
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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	/ED*]
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)	Celia Cerek Cong Cystic Diabe Dowr Epile Heari Inflan colitis Juven Sickle Spina Urtica	ma manama spectra palse enital he called from the called from	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
Any other specified past medical history or further comments	5		

[\*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



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Mind & D 728-28 Group 3 (healthy controls) (Baseline - Visit 1)

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### **Skin Examination**



## **Samples**

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 are	ea)
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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Mind & Controls | Controls | Mind & Controls | (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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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
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**

Edinburgh Handedness Inventory			
Assessment completed?	⊗ Yes ○ No		
Total score Left-handedness - Less than -40	-42.75 (-100 to 100)		
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	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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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		



Mind & Controls) (Logs)

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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



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### **Visit**

Mind & Skin ID

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	'ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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**

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 ha	ve heen reviewed	
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)	70.10 (10kg - 100kg)
Height (cm)	180.00



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	)*]
Sex at birth	<ul><li>             ⊗ Male             ○ Female             ○ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>○ White and Black African</li> <li>○ White and Asian</li> <li>⊗ Any other Mixed or multiple ethnic background</li> </ul>
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)	
Number of criteria	0



Family History	
Family History	



Mind & Skin ID 728-29 Group 3 (healthy controls) (Baseline - Visit 1)

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#### **Current Eczema Treatment**

GROUP Group 3 (healthy controls) INITIALS [*DATA VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
<b>Current topical therapy</b>	
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)	Celiac Cerek Conge Cystic Diabe Down Epilep Heari Inflan colitis Sickle Spina Urtica Visua	na m spectr c Disease oral palsy enital he c Fibrosis etes n syndror osy ng impal nmatory s) ile arthri e cell and Bifida	eart disease services me irment bowel disease (Crohn's/Ulcerative itis aemia
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

Mind & D 728-29 Group 3 (healthy controls) (Baseline - Visit 1)

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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	[*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 are	ea)
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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Mind & Controls | Gaseline - Visit 1 | Mind & Controls | Gaseline - Visit 1 |

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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



Mind & D 728-29 Group 3 (healthy controls) (Baseline - Visit 1)

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# **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



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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



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## **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	-50 (-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	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		



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*]	



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# **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



Mind & Controls) (Logs)

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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



Mind & Skin ver 4.0

Mind & D 728-30 Group 2 (topical therapy) (Baseline - Visit 1)

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#### **Visit**

Mind & Skin ID

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 fr impact on sleep compo		eczema, deemed by the investigator to significantly
○ Yes ⊗ No		
6. Previous and/or curr	rent substance misuse.	
7. Concomitant system	nic medications likely to impact on qua	lity of sleep studies.
8. Current phototherap	by treatment.	
9. Body weight < 40kg	I	
○ Yes ○ No		
_eligibility		1
Patient is eligible		
Please sign to con	firm all eligibility criteria have	heen reviewed
Signed	inin an engionity criteria nave	been reviewed
Han thin book sixuada		O Vac. O Na
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 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Asian or Asian British	<ul><li>○ Indian</li><li>○ Pakistani</li><li>⊗ Bangladeshi</li><li>○ Chinese</li><li>○ Any other Asian background</li></ul>
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**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li>⊗ Mild</li><li>○ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>	
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 (tonical 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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Juven Sickle Spina Urtica	ma manama spectra palse enital he called from the called from	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	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



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#### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	3.40



### **Samples**

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	

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# **Patient-Reported Quality Of Life Measures**

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:	9
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	8
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
Total score	17
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 13.7 years old at registration	
Questionnaire used	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	2
Date	[*DATA REMOVED*]

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#### **Questionnaire-Based Sleep Assessments**

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)
	(0 33)
T-Score:	(0 - 99)
Class Wake Transition Disorders assure /sure that assure	
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)		
of the items 22,23,24,23,20)	(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		
		-



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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
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**

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	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*]	



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## **Completed By**

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



[\*DATA REMOVED\*]

### **Visit**

Visit date

Mind & Skin ID	728-31
GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	

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## Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]		
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>		
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**

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.



5. Sleep disturbance from co-morbid illness other than ato impact on sleep components of the study.	opic eczema, deemed by the investigator to significantly
○ Yes ⊗ No	
6. Previous and/or current substance misuse.	
Yes ⊗ No	
7. Concomitant systemic medications likely to impact on o	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	ve heen verieured
Signed	ve 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 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	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>		
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>		
Asian or Asian British	<ul><li>○ Indian</li><li>○ Pakistani</li><li>⊗ Bangladeshi</li><li>○ Chinese</li><li>○ Any other Asian background</li></ul>		
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		



<b>Family History</b>		
Family History		



### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li>⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>	
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?	
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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina Visua	ma m spectr c Disease oral palsy enital he c Fibrosis etes n syndror psy ng impa nmatory s) nile arthr e cell and	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	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



Mind & Skin ID 728-31 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	25.70



## **Samples**

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*]

rape stripping (arm) for cutaneous cytokine work (f	rom 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**

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:	11	
(sum items: 1, 5, 7, 12, 14, 17)		
Bodily threat appraisals score:	20	
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)		
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	1
Date	[*DATA REMOVED*]

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### **Questionnaire-Based Sleep Assessments**

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*]



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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
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**

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 assessme	nt
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*]	



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## **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



### **Visit**

Mind & Skin ID

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 [*I VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	DATA REMOVED*]
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	<ul><li>⊗ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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 oth impact on sleep components of the study.	ner than atopic eczema, deemed by the investigator to significantly
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	
Diago sign to confirm all aligibility or	iitaria haya haan rayiawad
Please sign to confirm all eligibility cr Signed	iteria nave 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 VISIT DATE [*DATA REMOVED*] Bas	y therapy) INITIALS [*DATA REMOVED*] eline - Visit 1	
Weight (kg)	65.80 (10kg - 100kg)	
Height (cm)	163.50	



## **Demographics**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DA' VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	TA REMOVED*]
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>⊗ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Black, Black British, Caribbean or African	<ul><li>○ Caribbean</li><li>⊗ African</li><li>○ Any other Black, Black British or Caribbean</li><li>Background</li></ul>
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



	Mind & amp; Skin ID 728-	32 Group 1 (	immuno-modulatory	therapy) (Bas	seline - Visit 1
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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:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>
Name of steroid 1:	[*DATA REMOVED*]
Add another corticosteriod?	
2. Calcineurin inhibitor/s ?	
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	<ul><li>○ Oral Methotrexate ⊗ Subcutaneous Methotrexate ○ Other (please specify)</li></ul>
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	⊝ mg/kg ⊗ mg



Mind & Damp; Skin ID 728-32 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)

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1. Frequency of systemic therapy	
2. Add another systemic therapy?	○ Yes ⊗ No

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# **Medical History**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DA' VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	TA REMOVED*]
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?	
Past Medical History	
Past Medical History (select all that apply)	□ ADHD   □ Asthma   □ Autism spectrum disorder   □ Celiac Disease   □ Corgenital 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 [*DAVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ATA REMOVED*]
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



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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	30.90



## **Samples**

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?	$\otimes$ Yes $\bigcirc$ 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 (f	rom 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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	12
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	14
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	32
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	9
Date	[*DATA REMOVED*]

**REDCap**°

## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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# **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**

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*]



Mind & Drawn; 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**

Weight (kg)	66.50 (10kg - 100kg)
Height (cm)	164.50



Mind & Company Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

### **Current Eczema Treatment 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)		



### **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



Mind & D 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

**Skin Examination** 

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	20.60



### **Samples**

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 are	ea)
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**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	20
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	14
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	24
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	5
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



Mind & Damp; Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

# Homebased Sleep Assessments



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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**

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?	
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 assessme	nt
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*]



Mind & Dr. Skin ID 728-32 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

# Completed By

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



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### **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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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 ha	ve heen reviewed	
Signed	ve 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)	53.14 (10kg - 100kg)
Height (cm)	177.60



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
Sex at birth	<ul><li></li></ul>
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> </ul>
White	<ul> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>
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



<b>Family History</b>		
Family History		



Mind & D 728-33 Group 3 (healthy controls) (Baseline - Visit 1)

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### **Current Eczema Treatment**

GROUP Group 3 (healthy controls) INITIALS [*DATA VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
<b>Current topical therapy</b>	
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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Sickle Spina Urtica Visua	na m spectr c Disease oral palsy enital he c Fibrosis etes n syndror osy ng impal nmatory s) ile arthri e cell and Bifida	y art disease sees sees sees sees sees sees see
Any other specified past medical history or further comments	Sickle Spina Urtica	e cell and Bifida aria I impairr	nemia ment

[\*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)	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



Mind & Skin ID 728-33 Group 3 (healthy controls) (Baseline - Visit 1)

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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	[*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 are	ea)
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 (f	rom 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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Mind & Camp; Skin ID 728-33 Group 3 (healthy controls) (Baseline - Visit 1)

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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
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



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# **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	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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
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



Mind & Camp; Skin ID 728-33 Group 3 (healthy controls) (Logs)

**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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Mind & D 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)
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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 [*E VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	DATA REMOVED*]
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	<ul> <li>⊗ Group 1 (immuno-modulatory therapy)</li> <li>○ Group 2 (topical therapy)</li> <li>○ Group 3 (healthy controls)</li> </ul>
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**

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 fr impact on sleep compo		eczema, deemed by the investigator to significantly
○ Yes ⊗ No		
6. Previous and/or curr	rent substance misuse.	
7. Concomitant system	nic medications likely to impact on qua	lity of sleep studies.
8. Current phototherap	by treatment.	
9. Body weight < 40kg	I	
○ Yes ○ No		
_eligibility		1
Patient is eligible		
Please sign to con	firm all eligibility criteria have	heen reviewed
Signed	inin an engionity criteria nave	been reviewed
Han thin book sixuada		O Vac. O Na
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-modulator VISIT DATE [*DATA REMOVED*] Bas	y therapy) INITIALS [*DATA REMOVED*] seline - Visit 1	
Weight (kg)	41.80 (10kg - 100kg)	
Height (cm)	151.50	



# **Demographics**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DAVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	TA REMOVED*]
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>
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**

Current topical therapy	
1. Current topical therapy	
1. Corticosteroid/s ?	○ Yes ⊗ No
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No
Calicineurin drug 1	<ul><li>⊗ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>○ Tacrolimus 0.1%</li></ul>
Add another calcineurin inhibitor?	⊗ Yes ○ No
Calicineurin drug 2	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>
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
1. Dose of systemic therapy	[*DATA REMOVED*]



Mind & D 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)

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1. Units of systematic therapy	⊝ mg/kg ⊗ mg	
Frequency of systemic therapy	<ul><li>⊗ Weekly</li><li>○ Other (please specify)</li></ul>	
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)	Celia Cerel Cong Cysti Diabo Down Epile Hear Inflar coliti Juver Sicklo	ma m spectr c Disease bral palse enital he c Fibrosis etes n syndror psy ing impa mmatory s) nile arthr e cell and a Bifida	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
Any other specified past medical history or further comments	☐ Othe	r medica	l history

[\*DATA REMOVED\*]



22-01-2025 14:56

## **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



Mind & Damp; Skin ID 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)

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PH measurment 3	



Mind & Dr. Skin ID 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1) Page 860

**Skin Examination** 

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	18.60



### **Samples**

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 are	ea)	
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 wor	k (from nor	n-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**

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:	19
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	34
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	20
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



Mind & D 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)

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## **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	



Mind & D 728-34 Group 1 (immuno-modulatory therapy) (Baseline - Visit 1)

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



# **Neurocognitive Assessments**

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	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		



Mind & Drawn; Skin ID 728-34 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)
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[\*DATA REMOVED\*]

### **Visit**

Visit date



# 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	



Mind & Skin ID 728-34 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

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### **Current Eczema Treatment 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)		



### **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	



Mind & Skin ID 728-34 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

**Skin Examination** 

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	2.40



### **Samples**

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	a)
Has the control sample been taken?	$\otimes$ Yes $\bigcirc$ 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	



## **Patient-Reported Quality Of Life Measures**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	4
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	18
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	25
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>⊗ DLQI (&gt;16 years old, range 0-30)</li><li>○ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	4
Date	[*DATA REMOVED*]



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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?		



Mind & Dr. 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**

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?	
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 assessme	nt
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*]



Date

Mind & D 728-34 Group 1 (immuno-modulatory therapy) (6 Month Followup - Visit 3)

**Completed By** 

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA R VISIT DATE [*DATA REMOVED*] 6 Month Followup - Visit 3	EMOVED*]
Signed	
	<del></del>
Name	



### **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\*] [\*DATA REMOVED\*] Date of patient consent/assent 12.4 \_age 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  $\otimes$  Yes  $\bigcirc$  No Use of pseudo-anonymised data for future research  $\otimes$  Yes  $\bigcirc$  No Focus group participation  $\otimes$  Yes  $\bigcirc$  No GP contact  $\otimes$  Yes  $\bigcirc$  No Contact Notes: (please do not enter any indentifying [\*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 fr impact on sleep compo		eczema, deemed by the investigator to significantly
○ Yes ⊗ No		
6. Previous and/or curr	rent substance misuse.	
7. Concomitant system	nic medications likely to impact on qua	lity of sleep studies.
8. Current phototherap	by treatment.	
9. Body weight < 40kg	I	
○ Yes ○ No		
_eligibility		1
Patient is eligible		
Please sign to con	firm all eligibility criteria have	heen reviewed
Signed	inin an engionity criteria nave	been reviewed
Han thin book sixuada		O Vac. O Na
Has this been signed?		⊗ Yes ○ No
Print name:		[*DATA REMOVED*]
Print role		[*DATA REMOVED*]
Date		[*DATA REMOVED*]

**₹EDCap**°

# 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	<ul><li>⊗ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>○ White and Black African</li> <li>⊗ White and Asian</li> <li>○ Any other Mixed or multiple ethnic background</li> </ul>
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:	<ul><li> Mild</li><li>⊗ Moderate</li><li>○ Potent</li><li>○ Ultra-potent</li></ul>
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?	
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)	Celia Cerel Cong Cysti Diabe Dowr Epile Heari Inflar colitis Sickle Spina	ma m spectr c Disease pral palse enital he c Fibrosis etes n syndror psy ng impa nmatory s) nile arthr e cell and a Bifida aria ll impairr	eart disease eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia
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)	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



Mind & Skin ID 728-35 Group 2 (topical therapy) (Baseline - Visit 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	3.70



## **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	[*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?	
Skin swabs for microbiome analyses (flexural are	ea)
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 (f	rom 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:	7
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	11
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	4
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
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)



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?		$\bigcirc$ No	



Mind & D 728-35 Group 2 (topical therapy) (Baseline - Visit 1)

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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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## **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	+100 (-100 to 100)
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	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 assessme	nt
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*]	



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## **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
[*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**

Visit date

Mind & Skin ID

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

[\*DATA REMOVED\*]



## Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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 qualit	y 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 be	een 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)	69.55 (10kg - 100kg)
Height (cm)	178.00



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
Sex at birth	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>White and Black Caribbean</li> <li>White and Black African</li> <li>White and Asian</li> <li>Any other Mixed or multiple ethnic background</li> </ul>
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	



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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**

○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	○ Unknown
○ Yes	⊗ No	
Asthm Autisr Celiac Cereb Conge Cystic Diabe Down Epilep Heari Inflam colitis Juven Sickle Spina Urtica Visua	na m spectr c Disease ral palsy enital he c Fibrosis tes syndror osy ng impain matory ) ile arthri c cell and Bifida uria	e // art disease s me frment bowel disease (Crohn's/Ulcerative tis nemia
	Yes Yes Yes Yes Yes Yes ADHD Asthm Autisr Celiac Cereb Conge Cystic Diabe Down Epilep Hearii Inflam colitis Juven Sickle Spina Urtica Visua	<ul> <li>Yes ⊗ No</li> <li>ADHD</li> <li>Asthma</li> <li>Autism spectr</li> <li>Celiac Disease</li> <li>Cerebral palsy</li> <li>Congenital he</li> <li>Cystic Fibrosis</li> <li>Diabetes</li> <li>Down syndror</li> <li>Epilepsy</li> <li>Hearing impai</li> </ul>

[\*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



Mind & D 728-36 Group 3 (healthy controls) (Baseline - Visit 1)

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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	
	<del></del>
Was sample received by site?	
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	1)
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 (f	rom 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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Mind & Camp; Skin ID 728-36 Group 3 (healthy controls) (Baseline - Visit 1)

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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
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*]



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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
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	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 assessme	nt
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	15
Number of incorrect skips	4
Date	[*DATA REMOVED*]



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## **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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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 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	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 bee	n reviewed
Please sign to confirm all eligibility criteria have bee	n reviewed
	n reviewed
	Yes No
Signed	
Signed  Has this been signed?  Print name:	
Signed  Has this been signed?	

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# Height&Weight

GROUP INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1		
Weight (kg)		_
	(10kg - 100kg)	
Height (cm)		



## **Demographics**

GROUP INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Sex at birth	<ul><li>○ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
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	



## **Medical History**

GROUP INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	
Does the patient have any allergic co-morbidities?	
Asthma	
Allergic rhino-conjunctivitis (hayfever)	○ Yes ○ No ○ Unknown
Food allergies	
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	



Mind & Skin ID 728-37 (Baseline - Visit 1)
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#### **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		
Corum comple for immunology profile analysis		
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	1)	
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 nor	n-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?		
BTMS		
Questionnaire fully completed?		
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	



Mind & Skin ID 728-37 (Baseline - Visit 1)

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## **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 as	sessment	
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)



Mind & To Take 10 728-38 (Baseline - Visit 1)

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### **Inclusion/Exclusion Criteria**

GROUP INITIALS VISIT DATE Baseline - Visit 1	
Exclusion criteria	
_eligibility	0



Mind & Skin ver 4.0

Mind & amp; Skin ID 728-38 (Baseline - Visit 1)

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# Height&Weight

GROUP INITIALS VISIT DATE Baseline - Visit 1	
Weight (kg)	(10kg - 100kg)
Height (cm)	



Mind & amp; Skin ID 728-38 (Baseline - Visit 1)

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## **Demographics**

GROUP INITIALS VISIT DATE Baseline - Visit 1		
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	
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



Mind & Skin ID 728-38 (Baseline - Visit 1)

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#### **Skin Barrier Function Assessments**



Mind & Skin ID 728-38 (Baseline - Visit 1)

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#### **Skin Examination**



Mind & D 728-38 (Baseline - Visit 1)

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## **Samples**



## **Patient-Reported Quality Of Life Measures**



## **Questionnaire-Based Sleep Assessments**



Mind & Skin ID 728-38 (Baseline - Visit 1)

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## **Homebased Sleep Assessments**



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Mind & amp; Skin ID 728-38 (Baseline - Visit 1)

**Magnetic Resonance Imaging** 

GROUP INITIALS VISIT DATE Baseline - Visit 1	
Was the MRI peformed?	○ Yes ○ No



Mind & Skin ID 728-38 (Baseline - Visit 1)

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## **Neurocognitive Assessments**



Mind & D 728-38 (Baseline - Visit 1)

## **Completed By**

GROUP \_\_\_\_\_ INITIALS \_\_\_\_ VISIT DATE \_\_\_\_\_ Baseline - Visit 1

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[\*DATA REMOVED\*]

#### **Visit**

Visit date

Mind & Skin ID	728-39
GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	

# Registration

GROUP Group 2 (topical therapy) INITIALS [*DATA REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	[D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>⊗ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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	
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



	o disturbance from co-morbid illness other than ato on sleep components of the study.	opic eczema, deemed by the investigator to significantly
○ Yes	⊗ No	
6. Previ	ous and/or current substance misuse.	
○ Yes	⊗ No	
7. Conc	omitant systemic medications likely to impact on	quality of sleep studies.
○ Yes	⊗ No	
8. Curre	ent phototherapy treatment.	
○ Yes	⊗ No	
9. Body	weight < 40kg	
○ Yes	○ No	
_eligibil	ity	1
Patient	is eligible	
Please	sign to confirm all eligibility criteria ha	ve been reviewed
Signed		
Has this	s been signed?	⊗ Yes ○ No
Print na	me:	[*DATA REMOVED*]
Print rol	e	[*DATA REMOVED*]
Date		[*DATA REMOVED*]

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# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>		
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>⊗ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>		
Asian or Asian British	<ul><li>○ Indian</li><li>○ Pakistani</li><li>○ Bangladeshi</li><li>○ Chinese</li><li>⊗ Any other Asian background</li></ul>		
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**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?	○ Yes ⊗ No	
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>	
Add another calcineurin inhibitor?		
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?	
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)	Celiac Cerek Congo Cystic Diabe Down Epilep Heari Inflan colitis Sickle Spina Urtica	ma manama spectra palse enital he called from the called from	y Part disease S me irment bowel disease (Crohn's/Ulcerative itis gemia
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)	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



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Mind & Skin ID 728-39 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	9.50



## **Samples**

Serum sample for immunology profile analysis	
Has the patient consented?	⊗ Yes ○ No
Date sample taken	
Was sample received by site?	
Was sample stored in -80°C freezer	
Was sample collection logged on freezer sample log?	
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?	
Was sample collection logged on freezer sample log?	
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?	

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# **Patient-Reported Quality Of Life Measures**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	21
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	7
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	12
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	8
Date	[*DATA REMOVED*]

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## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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## **Homebased Sleep Assessments**

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



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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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score Left-handedness - Less than -40	-71.5 (-100 to 100)	
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	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*]	



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# **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 the BASELINE VISIT 1 DATE	nerapy) INITIALS [*DATA REMOVED*] [*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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22-01-2025 14:56

Indication

Adverse	<b>Events</b>
---------	---------------

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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	:D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>⊗ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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.



5. Sleep disturbance fr impact on sleep compo		eczema, deemed by the investigator to significantly
○ Yes ⊗ No		
6. Previous and/or curr	rent substance misuse.	
7. Concomitant system	nic medications likely to impact on qua	lity of sleep studies.
8. Current phototherap	by treatment.	
9. Body weight < 40kg	I	
○ Yes ○ No		
_eligibility		1
Patient is eligible		
Please sign to con	firm all eligibility criteria have	heen reviewed
Signed	inin an engionity criteria nave	been reviewed
Han thin book sixuada		O Vac. O Na
Has this been signed?		⊗ Yes ○ No
Print name:		[*DATA REMOVED*]
Print role		[*DATA REMOVED*]
Date		[*DATA REMOVED*]

**₹EDCap**°

# 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	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>
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**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
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?		



Systemic therapy		
Is the patient starting systemic therapy?		
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)	□ Abhd □ 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



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Mind & Skin ID 728-40 Group 2 (topical therapy) (Baseline - Visit 1)

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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	20.50



# Samples

Serum sample for immunology profile analysis	
Has the patient consented?	⊗ Yes ○ No
Date sample taken	
Was sample received by site?	
Was sample stored in -80°C freezer	
Was sample collection logged on freezer sample log?	
Blood sample for RNA/gene expression analysis	
Has the patient consented?	⊗ Yes ○ No
Date sample taken	
Was sample received by site?	
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	

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# **Patient-Reported Quality Of Life Measures**

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:	1
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	3
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	21
Date	[*DATA REMOVED*]

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## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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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
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	+100.0 (-100 to 100)	
Right-handness=More than +40		
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*]	



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# **Completed By**

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



**Visit** 

Mind & Skin ID 728-41

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 [*I VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	DATA REMOVED*]	
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	<ul><li>⊗ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>	
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**

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 or impact on sleep components of the study.	ther than atopic eczema, deemed by the investigator to significantly
○ 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 of	riteria 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-modulator VISIT DATE [*DATA REMOVED*] Bas	y therapy) INITIALS [*DATA REMOVED*] seline - Visit 1	
Weight (kg)	59.70 (10kg - 100kg)	
Height (cm)	141.50	



# **Demographics**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DAVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	TA REMOVED*]	
Sex at birth	<ul> <li>         ⊗ Male         ○ Female         ○ Undifferentiated     </li> <li>         ○ White         ⊗ Black, Black British, Caribbean or African         ○ Asian or Asian British         ○ Mixed or multiple ethnic groups         ○ Other ethnic group     </li> </ul>	
⊗ Black, Black British, Carib ○ Asian or Asian British ○ Mixed or multiple ethnic o		
Black, Black British, Caribbean or African	<ul><li>Caribbean</li><li>African</li><li>Any other Black, Black British or Caribbean Background</li></ul>	
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	



<b>Family History</b>		
Family History		



#### **Current Eczema Treatment**

Current topical therapy		
1. Current topical therapy		
1. Corticosteroid/s ?	⊗ Yes ○ No	
Potency:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?		
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>⊗ Tacrolimus 0.1%</li></ul>	
Add another calcineurin inhibitor?		
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	$\bigcirc$ Oral Methotrexate $\bigcirc$ Subcutaneous Methotrexate $\otimes$ 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	<ul><li>○ Weekly</li><li>⊗ Other (please specify)</li></ul>
1. Please specify other frequency for systemic therapy	[*DATA REMOVED*]
2. Add another systemic therapy?	



# **Medical History**

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



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### **Skin Examination**

EASI (score 0-72)	
Test performed?	⊗ Yes ○ No
Total score	28.40



### **Samples**

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 are	ea)
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	



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### **Patient-Reported Quality Of Life Measures**

POEM (0-28)	
Questionnaire fully completed?	⊗ Yes ○ No
Total score	28
Date	[*DATA REMOVED*]
<b>Body Mindset Inventory</b>	
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:	14
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	21
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	16
Date	[*DATA REMOVED*]

**₹EDCap**°

### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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## **Homebased Sleep Assessments**

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

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 assessme	nt
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*]



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# **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

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 [*IVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	DATA REMOVED*]
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	<ul><li>⊗ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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**

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 impact on sleep components of the st	illness other than atopic eczema, deemed by the investigator to significantly tudy.
○ Yes ⊗ No	
6. Previous and/or current substance	misuse.
○ Yes ⊗ No	
7. Concomitant systemic medications	s 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 eligi	bility 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)	36.54 (10kg - 100kg)	
Height (cm)	147.40	



# **Demographics**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DAVISIT DATE [*DATA REMOVED*] Baseline - Visit 1	TA REMOVED*]
Sex at birth	<ul><li>             ⊗ Male             ⊝ Female             ⊙ Undifferentiated         </li></ul>
Ethnicity	<ul> <li>⊗ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
White	<ul> <li>⊗ English, Welsh, Scottish, Northern Irish or British</li> <li>○ Irish</li> <li>○ Gypsy or Irish Traveller</li> <li>○ Roma</li> <li>○ Any other White background</li> </ul>
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





#### **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:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>	
Name of steroid 1:	[*DATA REMOVED*]	
Add another corticosteriod?	⊗ Yes ○ No	
Potency	<ul><li> Mild</li><li> Moderate</li><li> ⊗ Potent</li><li> Ultra-potent</li></ul>	
Name of steriod 2	[*DATA REMOVED*]	
Add another steroid?		
2. Calcineurin inhibitor/s ?	⊗ Yes ○ No	
Calicineurin drug 1	<ul><li>○ Pimecrolimus 1%</li><li>○ Tacrolimus 0.03%</li><li>○ Tacrolimus 0.1%</li></ul>	
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
1. Add systemic therapy?	⊗ Yes ○ No
1. Systemic therapy	
1. Name of systemic therapy	⊗ Oral Methotrexate
1. Dose of systemic therapy	[*DATA REMOVED*]
1. Units of systematic therapy	⊝ mg/kg ⊗ mg
1. Frequency of systemic therapy	<ul><li>⊗ Weekly</li><li>Other (please specify)</li></ul>
2. Add another systemic therapy?	

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# **Medical History**

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



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### **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	a)
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 (f	rom 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\*] 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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	17
Date	[*DATA REMOVED*]

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## **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
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*]



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## **Homebased Sleep Assessments**

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



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# **Completed By**

GROUP Group 1 (immuno-modulatory therapy) INITIALS [*DATA R VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	EMOVED*]	
Signed		
•		
		<del> </del>
Name		
Date		



### **Concomitant Medications**

GROUP Group 1 (immui BASELINE VISIT 1 DAT	no-modulatory therapy) INITIALS [*DATA REMOVED*] FE [*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	



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#### **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 REMOVE VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	:D*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>⊗ Group 2 (topical therapy)</li><li>○ Group 3 (healthy controls)</li></ul>
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 or impact on sleep components of the study.	ther than atopic eczema, deemed by the investigator to significantly
○ 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 of	riteria 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 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	<ul><li>⊗ Male</li><li>○ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>⊗ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>○ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
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:	<ul><li> Mild</li><li> Moderate</li><li> Potent</li><li> ⊗ Ultra-potent</li></ul>
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?	
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)	Celiac Cerek Cong Cystic Diabe Down Epile Heari Inflan colitis Sickle Spina Visua	ma m spectrom spectro	eart disease seart disease me irment bowel disease (Crohn's/Ulcerative itis aemia

Any other specified past medical history or further comments



22-01-2025 14:56

### **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



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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	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*]



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*]
<b>Body Mindset Inventory</b>	
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:	2
(sum items: 1, 5, 7, 12, 14, 17)	
Bodily threat appraisals score:	6
(sum items : 2, 3, 4, 6, 8, 9, 10, 11, 13, 15, 16, 18, 19)	
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	<ul><li>○ DLQI (&gt;16 years old, range 0-30)</li><li>⊗ CDLQI (&lt; =16 years old, range 0-30)</li></ul>
Total score	1
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
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*]



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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
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	+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	



#### **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

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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**

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.	
9. Body weight < 40kg	
○ Yes ○ No	
_eligibility	1
Patient is eligible	
Please sign to confirm all eligibility criteria have be	en reviewed
Signed	
	<del></del>
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)	40.55 (10kg - 100kg)
Height (cm)	150.70



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]		
Sex at birth	<ul><li>             ⊗ Male             ⊝ Female             ⊝ Undifferentiated         </li></ul>		
Ethnicity	<ul> <li>White</li> <li>Black, Black British, Caribbean or African</li> <li>Asian or Asian British</li> <li>Mixed or multiple ethnic groups</li> <li>Other ethnic group</li> <li>English, Welsh, Scottish, Northern Irish or British</li> <li>Irish</li> <li>Gypsy or Irish Traveller</li> <li>Roma</li> <li>Any other White background</li> </ul>		
White			
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 I VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	REMOVED*]
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



22-01-2025 14:56

#### **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	



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#### **Skin Examination**



#### **Samples**

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 are	ea)
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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Mind & D 728-44 Group 3 (healthy controls) (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



#### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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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
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**

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	



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*]	



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## **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*]

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## Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	ED*]		
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>		
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**

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.



7. Concomitant systemic medications likely to impact o	n 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 h	ave 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)	59.50 (10kg - 100kg)
Height (cm)	175.10



## **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]			
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>			
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>			
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>○ White and Black African</li> <li>○ White and Asian</li> <li>⊗ Any other Mixed or multiple ethnic background</li> </ul>			
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	Λ			



Family History	
Family History	



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#### **Current Eczema Treatment**

GROUP Group 3 (healthy controls) INITIALS [*DATA VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	REMOVED*]
<b>Current topical therapy</b>	
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



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### **Skin Examination**



## **Samples**

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	
	<del></del>
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 (f	rom 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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Mind & Camp; Skin ID 728-45 Group 3 (healthy controls) (Baseline - Visit 1)

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# **Patient-Reported Quality Of Life Measures**



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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



Mind & Camp; Skin ID 728-45 Group 3 (healthy controls) (Baseline - Visit 1)

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# **Magnetic Resonance Imaging**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]	
Was the MRI peformed?	○ Yes ○ No	



# **Neurocognitive Assessments**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score  Left-handedness - Less than -40	100.0 (-100 to 100)	
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	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*]	



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# **Completed By**

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



[\*DATA REMOVED\*]

#### **Visit**

Visit date

Mind & Skin ID	728-46
GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED*] VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	



# Registration

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	'ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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	
GP contact	⊗ Yes ○ No
Contact Notes: (please do not enter any indentifying data)	
	(do not add any identifying information)



## **Inclusion/Exclusion Criteria**

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.	
9. Body weight < 40kg	
○ Yes ○ No	
_eligibility	1
Patient is eligible	
Please sign to confirm all eligibility criteria have be	en reviewed
Signed	
	<del></del>
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)	55.90 (10kg - 100kg)
Height (cm)	182.90



# **Demographics**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	D*]
Sex at birth	<ul><li>○ Male</li><li>⊗ Female</li><li>○ Undifferentiated</li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>○ White and Black Caribbean</li> <li>○ White and Black African</li> <li>○ White and Asian</li> <li>⊗ Any other Mixed or multiple ethnic background</li> </ul>
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



<b>Family History</b>		
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



### **Skin Barrier Function Assessments**

GROUP Group 3 (healthy controls) INITIALS [*DATA REMOVED VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	<b>)*</b> ]
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)	$\otimes$ Yes $\bigcirc$ 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**



## **Samples**

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 ar	rea)	
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?		
Date sample taken	[*DATA REMOVED*]	



Tape stripping (arm) for cutaneous cytokine work (f	rom 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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Mind & D 728-46 Group 3 (healthy controls) (Baseline - Visit 1)

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# **Patient-Reported Quality Of Life Measures**



## **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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*]



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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



Mind & Skin ID 728-46 Group 3 (healthy controls) (Baseline - Visit 1)

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# **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**

Edinburgh Handedness Inventory		
Assessment completed?	⊗ Yes ○ No	
Total score Left-handedness - Less than -40	100.0 (-100 to 100)	
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*]	



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# **Completed By**

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



#### **Visit**

Mind & Skin ID

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 REMOV VISIT DATE [*DATA REMOVED*] Baseline - Visit 1	'ED*]
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	<ul><li>○ Group 1 (immuno-modulatory therapy)</li><li>○ Group 2 (topical therapy)</li><li>⊗ Group 3 (healthy controls)</li></ul>
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**

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 impac	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*]	

**₹EDCap**°

# 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	D*]
Sex at birth	<ul><li></li></ul>
Ethnicity	<ul> <li>○ White</li> <li>○ Black, Black British, Caribbean or African</li> <li>○ Asian or Asian British</li> <li>⊗ Mixed or multiple ethnic groups</li> <li>○ Other ethnic group</li> </ul>
Mixed or multiple ethnic groups	<ul> <li>White and Black Caribbean</li> <li>White and Black African</li> <li>White and Asian</li> <li>Any other Mixed or multiple ethnic background</li> </ul>
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\*]



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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)	Celiac Cerek Conge Cystic Diabe Down Epilep Heari Inflan colitis Juven Sickle Spina Urtica	ma m spectr c Disease oral palsy enital he c Fibrosis etes n syndror osy ng impal nmatory s) ile arthri e cell and	eart disease s me irment bowel disease (Crohn's/Ulcerative itis aemia

Any other specified past medical history or further comments



22-01-2025 14:56

#### **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**



### **Samples**

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 (f	rom 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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Mind & Camp; Skin ID 728-47 Group 3 (healthy controls) (Baseline - Visit 1)

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## **Patient-Reported Quality Of Life Measures**



### **Questionnaire-Based Sleep Assessments**

Paediatric Sleep Questionnaire	
Questionnaire completed?	⊗ Yes ○ No
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)



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



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## **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**

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		
	(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*]	

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## **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		



Mind & Skin ID 728-47 Group 3 (healthy controls) (Logs)

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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

