

MIND & SKIN ID		Initials	
VISIT DATE		SCREENING & BASELINE	

Mind & Skin Source Document: SCREENING + BASELINE (V1)

REGISTRATION

Please complete this registration section and upload as soon as possible. This can be done prior to the completion of the other screening data collection and irrespective of successful continuation through the screening visit.

Participant Initials	<div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block; vertical-align: middle;"></div> <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block; vertical-align: middle;"></div> <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block; vertical-align: middle;"></div>
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Date of birth (dd/mmm/yyyy)	__ / __ / __
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Date of patient consent/assent (dd/mmm/yyyy)	__ / __ / __
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Date of parent/guardian consent (dd/mmm/yyyy)	__ / __ / __
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Subject ID	
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Subject Group (please tick):	Group 1	
	Group 2	
	Group 3	

Has the participant also given consent for:

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

Contact notes

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INCLUSION/EXCLUSION CRITERIA

Inclusion criteria		YES	NO
1.	Patients aged 5 years or above with atopic eczema (groups 1 and 2), which has been diagnosed by a Consultant Dermatologist.		
2.	Patients with atopic eczema warranting systemic immuno-modulatory therapy or patients with atopic eczema on topical therapy or healthy controls.		
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.		
4.	Willingness to comply with all study requirements.		
5.	Competent use of English language, in accordance with patient's age.		
Exclusion criteria		YES	NO
1.	Insufficient understanding of the study by the patient and/or parent/guardian.		
2.	Any contra-indication to MRI scanning.		
3.	Any condition deemed by the Investigator to limit a patient's ability to undertake MRI components or neuro-cognitive assessments in the study.		
4.	Formal diagnosis of sleep disorder, requiring systemic medication.		
5.	Sleep disturbance from co-morbid illness other than atopic eczema, deemed by the Investigator to significantly impact on sleep components of the study.		
6.	Previous and/or current substance misuse.		
7.	Concomitant systemic medications likely to impact on quality of sleep studies.		
8.	Current phototherapy treatment.		

Please sign to confirm all eligibility criteria have been reviewed	
Print name	
Role	
Signature	
Date (dd/mmm/yyyy)	__ / __ / __

HEIGHT & WEIGHT

Weight (kg) (10kg-100kg)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Height (cm) (120cm-200cm)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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DEMOGRAPHICS

Sex at birth	Male		Female		Undifferentiated	
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Ethnicity	White	
	English, Welsh, Scottish, Northern Irish or British	
	Irish	
	Gypsy or Irish Traveller	
	Roma	
	Any other White Background	
	Black, Black British, Caribbean or African	
	Caribbean	
	African	
	Any other Black, Black British or Caribbean Background	
	Asian or Asian British	
	Indian	
	Pakistani	
	Bangladeshi	
	Chinese	
	Any other Asian background	
	Mixed or multiple ethnic groups	
	White and Black Caribbean	
	White and Black African	
	White and Asian	
	Any other Mixed or multiple ethnic background	
	Other ethnic group	
	Arab	
	Any other ethnic group	

UK DIAGNOSTIC CRITERIA				
Patients must have:				
1. An itchy skin condition in the last year	*Yes		No	
*If yes, patient must have three of 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	

CURRENT ECZEMA TREATMENT

Is participant in Group 3?	Yes		No	
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1) Current topical therapy (add more if necessary, following the template below):				
Corticosteroid?	Yes		No	
Potency:				
Mild				
Moderate				
Potent				
Ultra-potent				
2) Calcineurin inhibitor?	Yes		No	
Pimecrolimus 1% Tacrolimus 0.03% Tacrolimus 0.1%				
3) Soap substitutes/moisturisers	Add free text			
Other	(if required)			

Is the patient starting systemic therapy?	*Yes		No+	
*If YES, which treatment and at what dose?				
Name of therapy:	Oral methotrexate Subcutaneous methotrexate			
Dose:				
Units:	Mg Mg/kg			
Frequency:	Weekly *Other			
If other, please specify:				
+If NO, is the patient in Group 2?				

MEDICAL HISTORY

Does the patient have any allergic co-morbidities?			
	Yes	No	Unknown
Asthma			
Allergic rhino-conjunctivitis (hayfever)			
Food allergies			
Contact allergies			

Does the patient have a history of (diagnosed) sleep disturbance?		Yes		No	
How was sleep disturbance noted?					
Participant		Parent			
Sibling		Partner			
Other (please specify): _____					

CONCOMITANT MEDICATIONS

Please list any OTHER concomitant medication and any new medication prescribed throughout the study on this form. Complete relevant co-morbidity and AE records if necessary.

Medication prescribed	Dose	Units	Frequency	Date Medication Started	Ongoing ?	Date Medication Stopped

SKIN BARRIER FUNCTION ASSESSMENTS

Transepidermal (TEWL) water loss measurement (uninvolved skin left volar forearm)				
	*Yes		No	
<u>Select from: LVF, RVF, other (detail):</u> <u>Time :</u> <u>Date:</u>				
Measurement (ARM)	1	2	3	
Flux (mg/meter sq * height) (Range 5-40)				
Decent measurement curves?	Yes		No	

PH meter reading (volar forearm)				
	*Yes		No	
<u>Select from: LVF, RVF, other (detail):</u> <u>Time :</u> <u>Date:</u>				
Measurement	1	2	3	

SKIN EXAMINATION

ECZEMA DISEASE SEVERITY SCORING

EASI (score 0-72)									
Test performed?	Yes		No						
Total score	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">.</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>						.		
		.							

SAMPLES

Serum sample for immunology profile analysis				
Has the patient consented?	*Yes		No	
Date sample taken:	<div> <div> <div></div> <div></div> <div></div> </div> <div>/</div> <div> <div></div> <div></div> <div></div> </div> <div>/</div> <div> <div></div> <div></div> <div></div> </div> </div>			
Was sample received by site?	Yes		No	
Was sample stored in -80C 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:	<div> <div> <div></div> <div></div> <div></div> </div> <div>/</div> <div> <div></div> <div></div> <div></div> </div> <div>/</div> <div> <div></div> <div></div> <div></div> </div> </div>			
Was sample received by site?	Yes		No	
Was sample stored in -80C 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 sample taken (please specify):								
Local EASI at non-lesional site:	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table>						.	
		.						
Has the lesional sample been taken?	Yes		No					

Location of sample taken (please specify):						
Local EASI at lesional site:	<table border="1"> <tr> <td></td> <td></td> <td></td> <td>.</td> <td></td> </tr> </table>				.	
			.			
Date sample taken:	<div> <div></div> <div>/</div> <div></div> <div>/</div> <div></div> <div></div> </div>					

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	
*If no, please specify where non-lesional sample was taken from:				
Date sample collected	<div> <div></div> <div>/</div> <div></div> <div>/</div> <div></div> <div></div> </div>			

Stool sample for gut microbiome analysis				
Has the sample container been provided to the patient?	Yes		No	
Date of sample	<div> <div></div> <div>/</div> <div></div> <div>/</div> <div></div> <div></div> </div>			
Was sample received by site?	Yes		No	
Was sample stored in -80C 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	<div style="border: 1px solid black; display: inline-block; width: 30px; height: 30px; margin: 0 auto;"></div>			
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> __/____/______ </div>			

Body Mindset Inventory				
Questionnaire fully completed?	Yes		No	
Body is an Adversary score: (Mean of items : 1, 2, 3, 4)				
Body is Capable score: (Mean of items: 5, 6)				
Body is Responsive score (Mean of items: 7, 8)				
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> __/____/______ </div>			

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	<div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>	
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>__ /</div> <div>__ /</div> <div>__</div> </div>	

Itch severity numerical rating score (0-10)				
VAS completed?	Yes		No	
Total score	<div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>			
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>__ /</div> <div>__ /</div> <div>__</div> </div>			

Skin-specific quality of life questionnaire <i>(please select as indicated by patient's age):</i>						
Questionnaire fully completed?			Yes	No		
DLQI (>16 years old, range 0-30)		CDLQI (<16 years old, range 0-30)				
Total score			<table border="1"> <tr> <td></td> <td></td> </tr> </table>			
Date:			<div> <div></div> <div>/</div> <div></div> <div>/</div> <div></div> <div></div> </div>			

QUESTIONNAIRE-BASED SLEEP ASSESSMENTS

Paediatric Sleep Questionnaire				
Questionnaire completed?	Yes		No	
1. SRBD scale (including snoring and sleepiness subscales)	<input type="text"/>	<input type="text"/>		
2. Sleepiness subscale	<input type="text"/>	<input type="text"/>		
3. Periodic Leg Movement/Restless Legs Syndrome scale	<input type="text"/>	<input type="text"/>		

Sleep Disturbances Scale For Children (SDSC)					
Questionnaire completed?	Yes		No		T-scores
Disorders of initiating and maintaining sleep score (sum the score of the items 1,2,3,4,5,10,11)	<input type="text"/>	<input type="text"/>			
Sleep Related Breathing Disorders score (sum the score of the items 13,14,15)	<input type="text"/>	<input type="text"/>			
Disorders of arousal score (sum the score of the items 17,20,21)	<input type="text"/>	<input type="text"/>			
Sleep-Wake Transition Disorders score (sum the score of the items 6,7,8,12,18,19)	<input type="text"/>	<input type="text"/>			
Disorders of excessive somnolence score (sum the score of the items 22,23,24,25,26)	<input type="text"/>	<input type="text"/>			
Sleep Hyperhydrosis (sum the score of the items 9,16)	<input type="text"/>	<input type="text"/>			
Total score	<input type="text"/>	<input type="text"/>			<input type="text"/>
Date:	___/___/___				

HOME-BASED SLEEP ASSESSMENTS

Were home-based sleep assessments performed?				Yes				*No			
*If no, please detail why:											
Please indicate which sleep devices were used by patient:											
Actigraphy wristwatch		Yes				No					
Somnotouch HD		Yes				No					
Time period used:		____ / ____ / ____ to ____ / ____ / ____				Date used:		____ / ____ / ____			
Device ID						Device ID					
Mean Bedtime BT(time 24 hr clock)						Bedtime					
Mean Wake time WT (time 24 hr clock)						Wake time					
Total Sleep Time TST (hrs mins)						Total Sleep Time (hrs mins)					
Sleep latency SL (mins)						Sleep latency SL (mins)					
Sleep efficiency SE (%)						Sleep efficiency SE (%)					
WASO (Mins)						Apnoea Hypopnoea Index (AHI) /hr					

					Obstructive AHI (OAHl) /hr				
					Central AHI (CnAHI) /hr				
					Mean oxygen saturation (%)				
					3% Oxygen Desaturation Index (ODI) /hr				
					Absolute oxygen nadir (%)				
					Mean oxygen nadir (%)				
					% time oxygen sats < 90%				
					% REM sleep				
					% Stage N1				
					% Stage N2				
					% Stage N3				
					Wake after sleep onset (mins)				
					Arousal index /hr				
					PLMs index				
					DREEM headband	Yes		No	
Was data output collected?	Yes		No		Was data output collected?	Yes		No	
Date used:	__ / __ / __				Time period used:	__ / __ / __			

			to ____/____/____
Was the sleep diary completed?	Yes		*No
If no, please enter Day number missed: (e.g Day 1, Day 3 etc.)			
If yes, please enter Day number: (e.g Day 1, Day 3 etc.)			
Descriptive data			
Short sleep duration (check National Sleep Foundation)			
Day time naps			
Sleep fragmentation (> 1 night waking)			
Prolonged sleep onset (>1 hr)			
Caffeinated drinks			
Other: (please specify)			

MAGNETIC RESONANCE IMAGING

Was a functional MRI performed?	Yes		*No	
*If no, please detail why:				
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>__ / __ / __</div> </div>			

Was a structural MRI performed?	Yes		*No	
*If no, please detail why::				
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>__ / __ / __</div> </div>			

Was participant trained on fMRI tasks?	Yes		*No	
*If no, please detail why:				
Date:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>__ / __ / __</div> </div>			

Was the Working Memory task completed during the fMRI?	Yes		*No	
*If no, please detail why::				
Total score	<div style="border: 1px solid black; width: 40px; height: 30px; margin: 0 auto;"></div>			
Date:	<div style="display: flex; justify-content: center; align-items: center;"> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px;"></div> </div>			

Was the Sustained Attention task completed during the fMRI?	Yes		*No	
*If no, please detail why:				
Total score	<div style="border: 1px solid black; width: 40px; height: 30px; margin: 0 auto;"></div>			
Date:	<div style="display: flex; justify-content: center; align-items: center;"> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px;"></div> </div>			

NEUROCOGNITIVE ASSESSMENTS

Edinburgh Handedness Inventory:				
Assessment completed?	Yes		No	
Total score <i>Left-handedness = Less than -40</i> <i>Ambidexterity = Between -40 and +40</i> <i>Right-handedness = More than +40</i>	<div style="border: 1px solid black; width: 40px; height: 30px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <div style="border-right: 1px solid black; width: 20px; height: 20px;"></div> <div style="width: 20px; height: 20px;"></div> </div>			
Date:	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px;"></div> </div>			

Wechsler Abbreviated Scale of Intelligence (WASI-II):				
Assessment completed?	Yes		No	
Total FSIQ-4 score:	<div style="border: 1px solid black; width: 40px; height: 30px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <div style="border-right: 1px solid black; width: 20px; height: 20px;"></div> <div style="width: 20px; height: 20px;"></div> </div>			
Date:	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px;"></div> </div>			

Motor response inhibition assessment:				
Go/No-go task completed?	Yes		No	
Reaction Time				
RT Standard Deviation				
Probability Inhibition				
Premature Responses				
Date:	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border-bottom: 1px solid black; width: 20px;"></div> </div>			

Interference inhibition/selective attention assessment:				
Simon task completed?	Yes		No	
Reaction Time				
RT Standard Deviation				
Premature Responses				
RT Effect				
Date:	__ / __ / __			

Sustained/selective attention assessment:				
Continuous performance task completed?	Yes		No	
% Omission Error				
Premature Errors				
% Commission Error				
Mean Reaction Time				
MRT Standard Deviation				
Date:	__ / __ / __			

Time perception assessment:				
Time discrimination task completed?	Yes		No	
% Total Error				
Date:	__ / __ / __			

Vigilance assessment:			
Mackworth Clock task completed?	Yes		No
Number of missed skips:			
Number of incorrect skips:			
Date:	_ _ / _ _ / _ _		

COMPLETED BY

Print name:	
Signature:	
Date:	_ _ / _ _ / _ _

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