

# A controlled trial of group behavioural therapy in the management of atopic dermatitis in adults

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2016	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

A controlled trial of group behavioural therapy in the management of atopic dermatitis in adults

### Study objectives

The principal question the study addresses is whether or not a form of behavioural therapy known as habit reversal is effective in improving atopic dermatitis by means of reducing the scratching that is often associated with the condition. A secondary objective is to see if a dermatological education session alone gives an improvement in the condition.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Atopic dermatitis

### Interventions

Participants will be allocated randomly to one of two groups.

The first group will receive an hour-long educational session run by a consultant dermatologist. This will reinforce the optimal use of standard treatments for atopic dermatitis and incorporate standard advice on managing the condition.

The second group will receive the educational session as well as 3 further hour-long sessions to learn and practise the habit reversal technique. These 3 sessions will be run by a Specialist Registrar in psychiatry. Homework will be set between the sessions to reinforce the technique. The severity of the atopic dermatitis will be assessed at baseline, 1 month, 3 month and six

months. The two groups will be compared. The assessors will be blind to the group allocation of participants. A pilot study with 6 participants has already been carried out. Feedback from participants was requested and this has been taken into account for the purpose of the current full scale trial.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. The SCORAD - an index developed by the European Task Force on Atopic Dermatitis to rate the severity of atopic dermatitis .
2. The DLQI - The Dermatology Life Quality Index. A questionnaire that assesses the impact of a number of skin conditions on daily life in preceding week.
3. The HADS - the Hospital Anxiety and Depression Scale. A self- rating scale to detract evidence of the two conditions.

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

24/12/2004

**Completion date**

01/06/2006

**Eligibility****Key inclusion criteria**

1. A diagnosis of atopic dermatitis by the Hanifen & Najka criteria
2. Chronicity of at least one year
3. Aged 18 years and above

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Number of patients: 20 in each group

**Key exclusion criteria**

1. Systemic therapy for atopic dermatitis in the last 6 months
2. Participants will be excluded if not English speaking

**Date of first enrolment**

24/12/2004

**Date of final enrolment**

01/06/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Dr C Holden**

Carshalton

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**Sponsor information****Organisation**

Department of Health

**Sponsor details**

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dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

# **Funder(s)**

## **Funder type**

Government

## **Funder Name**

Epsom and St Helier University Hospitals NHS Trust (UK)

## **Funder Name**

NHS R&D Support Funding (UK)

# **Results and Publications**

## **Publication and dissemination plan**

Not provided at time of registration

## **Intention to publish date**

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Not provided at time of registration