

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2016	Condition category 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

Dr Colin Holden

Contact details

Department of Dermatology
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA
+44 (0)20 8296 2285
colin.holden@esth.nhs.uk

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

United Kingdom

SM5 1AA

Sponsor information**Organisation**

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

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