ISRCTN17548228 https://doi.org/10.1186/ISRCTN17548228

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 28/10/2016	**Condition category** Skin and Connective Tissue Diseases	

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

Protocol serial number
N0112154888

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Dr C Holden
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration