

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

Registration date
30/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
28/10/2016

Condition category
Skin and Connective Tissue Diseases

☐ Individual participant data

☐ 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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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