

# The effects of a nurse run clinic on the quality of life of children with atopic eczema and the impact of the disease on their families

**Submission date**

23/01/2004

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

23/01/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

04/02/2010

**Condition category**

Skin and Connective Tissue Diseases

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr David Chinn

**Contact details**

Centre for Primary and Community Care

University of Sunderland

Benedict Building

St George's Way

Sunderland

United Kingdom

SR2 7BW

+44 (0)191 515 3840

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Study objectives

To evaluate the effect of a primary care nurse-led clinic (the intervention) on the quality of life (QoL) of children aged up to 16 years with atopic eczema. Secondary objective: to assess the impact of the intervention on the QoL of the family of these children.

Null hypotheses to be tested:

1. There is no effect on change in quality of life at 4 weeks (or 12 weeks) from a short intervention by a trained nurse in children aged 6 months to 16 years who present with atopic eczema
2. There is no effect on change in the family impact at 4 weeks (or 12 weeks) from a short intervention by a trained nurse in children aged 6 months-16 years who present with atopic eczema

### 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)

GP practice

### Study type(s)

Quality of life

### Participant information sheet

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

Skin and connective tissue diseases

### Interventions

1. Primary care nurse-led clinic
2. Standard care

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Quality of life will be assessed using validated instruments:

1. Family Impact Questionnaire (FIQ).
2. Infant Eczema Life Quality Index questionnaire (IELQI) for children aged 6 months to 4 years.
3. Children's Dermatology Life Quality Index Questionnaire (CDLQI) for children aged 4-16.
4. Change in the Family Dermatitis Index (FDI), Infants Eczema Life Quality Index (IELQI) and Children's Dermatology Life Quality Index (CDLQI) recorded at baseline and at 4 weeks and 12 weeks post-intervention.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

04/01/1999

**Completion date**

08/01/2000

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

1. Age 6 months up to 16th birthday
2. Diagnosis of atopic eczema made using British Association of Dermatology guidelines
3. New cases and patients requesting repeat prescription for medication issued for a diagnosis of atopic eczema.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

235 (added 21/01/10; see publication)

**Key exclusion criteria**

1. Poorly controlled asthma defined as patient receiving oral steroids or having a change in dose of medication in the 4 weeks prior to recruitment (children with stable asthma will be included).
2. Children from the same family of a child who has already participated in the trial (to eliminate the risk of contamination of intervention and control groups).

**Date of first enrolment**

04/01/1999

**Date of final enrolment**

08/01/2000

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

England

United Kingdom

**Study participating centre**

Centre for Primary and Community Care

Sunderland

United Kingdom

SR2 7BW

**Sponsor information****Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

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.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive Northern and Yorkshire (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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2002		Yes	No