

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

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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

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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?
Results article	results	01/03/2002		Yes	No