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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
04/02/2010

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
RRCC11R Poyner

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
16 Years

Sex
All

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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