

The child with atopic dermatitis/food allergy and his parents: from victum to expert in the multidisciplinary team

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The research question of the underlying study is: What are the effects of GMA*s on children with atopic dermatitis/ food allergy and their parents as compared with individual visits on:- physical complaints- self management- quality of life

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37146

Source

ToetsingOnline

Brief title

study to Group Medical Appointments

Condition

- Other condition
- Epidermal and dermal conditions

Synonym

atopic dermatitis, food allergy

Health condition

voedselallergie

Research involving

Human

Sponsors and support

Primary sponsor: dermatologie

Source(s) of monetary or material Support: Stichting Kinderpostzegels Nederland

Intervention

Keyword: atopic dermatitis, food allergy, group medical appointments, quality of life, self management

Outcome measures

Primary outcome

Emotional coping of parents, measured with the in Dutch translated questionnaire: *Quality of life in parents of children with atopic dermatitis* . This questionnaire consists of 26 items, divided into 5 subscales: psychosomatic wellbeing, effects on social life, confidence in medical treatment, emotional coping (primary outcome) and acceptance.

Secondary outcome

Secondary Outcome parameters are:

- Physical complaints (severity and complaints of Atopic dermatitis) measured by the Self-Administered Eczema Area and Severity Index (SA-EASI) and TARC: thymus and activation-regulated chemokine
- Self management by JUCKKI-COPECI for children of 8-12 years (36 items) and the JUCKJU-COPEJU for adolescents of 13-18 years (40 items), with subscales:
 - o Depressive mood/ social anxiety
 - o Itch scratch cycle
 - o Stress
 - o Catastrophizing cognitions

o Coping cognitions

- anxiety by the State Trait Anxiety Inventory; two subscales: state anxiety

and trait anxiety measured with an adult version for parents and a child

version for children of 8 years up.

Study description

Background summary

Atopic Dermatitis is a chronic skin disease, with relapses and remissions. The prevalence of atopic dermatitis worldwide is estimated at 3-10% (guideline Atopic Dermatitis 2007). Besides, 30 - 60% of children with Atopic Dermatitis suffer from food allergy. Because of the food allergy, patients have to follow diets to prevent (them from) severe and dangerous allergic reactions. Atopic Dermatitis as well as food allergy have a great impact on quality of life of the children and their families.

In the last two years, we have developed Group Medical Appointments (GMA*s) for children and their parents. During a GMA, the child and his parents have a regular individual appointment in a group, consisting of about 8 patients and their parents, a dermatologist and a dermatology nurse.

The patients and the members of the multidisciplinary team may give their reactions on the problem of one of the patients. Thereby, patients and professionals can learn from each other and help each other. Patients will become expert patients. The presence of different professionals during the GMA will be beneficial to patients* knowledge and self management and will stimulate the compliance to the therapy and the life style adjustments for the atopic dermatitis/foodallergy.

Themes during the GMA and individual visits are the same, namely: monitoring of the severity of the eczema, medical treatment, carrying out the medical treatment, coping with consequences of eczema in daily life of the children and their families.

GMA*s were developed in the United States. The Dutch CBO introduced the GMA concept in the Netherlands. At this moment GMA*s have been implemented in care for adults and children with different kinds of diseases and experiences are satisfactory both for caretakers as for caregivers. However, the effects of GMA*s on patient outcomes are unknown.

We hypothesize that patients and their parents will become better expert patients by attending GMA*s as compared to individual visits. The child and his parent will sooner achieve adequate self management, a better quality of life

and a reduction of physical complaints.

Study objective

The research question of the underlying study is: What are the effects of GMA*s on children with atopic dermatitis/ food allergy and their parents as compared with individual visits on:

- physical complaints
- self management
- quality of life

Study design

Prospective randomized controlled study

Intervention

In the underlying study Group Medical Appointments (GMA) will be compared with individual visits. About 6-8 patients and their parents, a dermatology nurse and a dermatologist will attend the GMA. The programme of a GMA is comparable to that in the individual visit. Themes during the GMA and individual visits are: monitoring of the severity of the eczema, medical treatment, carrying out the medical treatment, coping with consequences of eczema in daily life of the children and their families.

Study burden and risks

The burden of the study consists of filling out the questionnaires, four times during one year, about 30 minutes per time. Besides, a Group Medical Appointment (GMA) takes 45 minutes more than an individual visit. We expect a beneficial effect of attending the GMA*s: adequate self management, a better quality of life and a reduction of physical complaints. There will be no extra invasive interventions. There are no risks in participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

- Diagnose Atopic dermatitis/ food allergy
- able to attend the Group Medical Appointments with children and their parents as experts
- ready for randomization
- able to fill in Dutch questionnaires
- age of child: 0-18

Exclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2009
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO	
Date:	19-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	22-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL24802.041.08