

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

Submission date 16/03/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/05/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/07/2019	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

About 20% of children in West-European countries suffer from atopic dermatitis (AD). It is commonly known as eczema, can be due to an allergic reaction and requires intensive treatment. Shared Medical Appointments (SMAs) are doctors appointments where a group of patients with the same condition are seen together. This can save a lot of time, as the doctor does not have to repeat information relevant to all patients on a one-to-one basis. Our study compares SMAs to one-to-one appointments when treating children with AD. Our goal is to find out whether SMAs help young patients and their parents to cope better with the disease and have a better quality of life.

Who can participate?

Children with mild to moderate AD, between the ages of 0-18 and a patient at the University Medical Center, Pediatric Dermatology Department, Utrecht, and their parents.

What does the study involve?

Each child and their parents are randomly allocated to one of two groups, SMA or one-to-one consultations. After the consultations, the patients and their parents are asked to complete two questionnaires, one 6 weeks after the consultation and the other after 6 months.

What are the possible benefits and risks of participating?

Possible benefits include a positive effect on coping with the disease and a better quality of life. There are no direct health risks to participating.

Where is the study run from?

The University Medical Center, Utrecht (Netherlands)

When is the study starting and how long is it expected to run for?

From November 2009 to May 2013

Who is funding the study?
The Foundation for Childrens Welfare Stamps (Netherlands)

Who is the main contact?
Professor Suzanne Pasmans
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Contact information

Type(s)
Scientific

Contact name
Prof Suzanne Pasmans

Contact details
Contact information on Monday, Wednesday, Thursday and Friday (see also Interventions field):
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Additional identifiers

Protocol serial number
SMA

Study information

Scientific Title
A randomised controlled study: effects of shared medical appointments (SMAs) on parental quality of life and disease severity of children with atopic dermatitis

Acronym
SMA

Study objectives
Shared Medical Appointments result in greater improvements in disease coping, quality of life and disease severity than individual face-to-face consults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Ethical Committee of University Medical Center Utrecht, 25/05/2009, 08-368/K
2. Central Committee on Research Involving Human Subjects, 25/05/2009, NL24802.041.08

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atopic dermatitis (and food allergy within the atopic syndrome)

Interventions

1. Intervention group: three shared medical appointments in the outpatient clinic of Pediatric Dermatology UMC Utrecht
2. Control group: three face-to-face consults in the outpatient clinic of Pediatric Dermatology UMC Utrecht

Contact information for Prof Suzanne Pasmans on Tuesday:

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Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Coping of parents, measured with a subscale of the QoLPAD

All outcomes were measured at baseline, within 2 weeks after the third appointment, at 2 months and at 6 months.

Key secondary outcome(s)

1. Quality of life of parents, measured with the QoLPAD
2. Severity of eczema, measured with SA-EASI
3. Anxiety to corticosteroids, measured with the State Anxiety scale of the STAI
4. Trait Anxiety, measured with the Trait Anxiety scale of the STAI

Only children 8 or over:

1. Coping with itch, measured with the JUCKKI-JUCKJU
2. Coping with disease, measured with the COPEKI-COPEJU

All outcomes were measured at baseline, within 2 weeks after the third appointment, at 2 months and at 6 months.

Completion date

06/05/2013

Eligibility

Key inclusion criteria

1. Moderate or severe atopic dermatitis
2. New patient of Pediatric Dermatology Allergology Department of UMC Utrecht
3. Children up to the age of 18
4. Parents are able to speak and write in Dutch
5. Internet access and able to use the Digital Eczema Center Utrecht

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

All

Total final enrolment

140

Key exclusion criteria

Current participation in another study

Date of first enrolment

06/11/2009

Date of final enrolment

06/05/2013

Locations

Countries of recruitment

Netherlands

Study participating centre

Contact information on Monday, Wednesday, Thursday and Friday (see also Interventions field):
Rotterdam

Netherlands
3000 CA

Sponsor information

Organisation

Foundation for Children's Welfare Stamps Netherlands (Stichting Kinderpostzegels Nederland)
(Netherlands)

ROR

<https://ror.org/01dq08926>

Funder(s)

Funder type

Charity

Funder Name

Foundation for Children's Welfare Stamps Netherlands (Stichting Kinderpostzegels Nederland)
(Netherlands)

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	01/08/2019	19/07/2019	Yes	No