

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

<b>Submission date</b> 16/03/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2019	<b>Condition category</b> Skin and Connective Tissue Diseases	<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 parent 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  
s.pasmans@umcutrecht.nl

## 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet.

**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

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**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

06/11/2009

### **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

### **Age group**

Child

### **Upper age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

140

### **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)

**Sponsor details**

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**Sponsor type**

Charity

**Website**

<http://www.kinderpostzegels.nl/>

**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

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