ISRCTN08506572 https://doi.org/10.1186/ISRCTN08506572

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

Registration date
19/05/2014

Overall study status
Completed

Last Edited
19/07/2019

Condition category
Skin and Connective Tissue Diseases

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

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
Schipholweg 73/75
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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?
Results article	results	01/08/2019	19/07/2019	Yes	No