

# Allergy management support service

<b>Submission date</b> 16/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/06/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Management of allergic patients in the population is becoming more difficult because of increases both in complexity and prevalence. Although general practitioners (GPs) are expected to play an important role in the care of allergic patients, they often feel ill equipped for this task. Therefore, we aim to develop an Allergy Management Support System (AMSS) for primary care and to test the feasibility of this AMSS for primary care. Through literature review, interviewing and testing in secondary and primary care patients, an allergy history questionnaire will be constructed by allergists, dermatologists, GPs, and researchers based on primary care and specialists' allergy guidelines and their clinical knowledge. Patterns of AMSS questionnaire responses and sIgE-test outcomes will be used to identify diagnostic categories and to develop corresponding management recommendations. Validity of the AMSS will be investigated by comparing specialist (gold standard) and AMSS diagnostic categories. The aim of this feasibility study is to evaluate if the AMSS is feasible when >70% of the AMSS recommendations are sent to the GP within ten working days of sIgE-testing.

### Who can participate?

General practitioners and allergy patients/parents of an allergic child.

### What does the study involve?

Participants complete the AMSS questionnaire which consists of 12 (mainly) multiple-choice questions on symptoms, triggers, severity, medication and symptom control of their allergic conditions. Participating GPs are allocated to one of two groups. Those in the first group receive the AMSS questionnaire in addition to sIgE-test results. Those in the second group receive only the sIgE-test results. GPs in both groups completed a short questionnaire with multiple-choice questions on diagnosis and management (medication, referral and/or non-pharmacotherapeutic recommendations) on two occasions: at the time of inclusion of the patient and at the time the sIgE test outcomes were known.

### What are the possible benefits and risks of participating?

Direct benefits for GPs taking part in the study is receiving recommendations in addition to sIgE test outcomes. There are no direct risks for those taking part in the study.

### Where is the study run from?

University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?  
September 2009 to September 2016

Who is funding the study?

1. Phadia BV (Netherlands)
2. ALK Abelló BV (Netherlands)
3. University Medical Center Groningen (Netherlands)

Who is the main contact?

Dr Bertine Flokstra - de Blok  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Bertine Flokstra - de Blok

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

## Study information

### Scientific Title

Development and feasibility of an Allergy Management Support System (AMSS) for primary care

### Acronym

AMSS

### Study objectives

The aim of this study is to develop a Allergy Management Support Service for primary care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics committee of University Medical Center Groningen, 23/05/2013, refs: METc 2011/273, METc 2013/129

### **Study design**

Interventional

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Diagnostic

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Allergy: rhinitis, asthma, atopic dermatitis and food allergy

### **Interventions**

This study uses a cluster randomised controlled design. Participants are randomly allocated to one of two groups: the intervention or the control group. GPs in the intervention group receive Allergy Management Support System (AMSS) recommendations in addition to sIgE test results, while GPs in the control group perform usual care based on sIgE test results only. At inclusion, patients completed the AMSS questionnaire which consists of 12 (mainly) multiple-choice questions on symptoms, triggers, severity, medication and symptom control of their allergic conditions. GPs in both groups completed a short questionnaire with multiple-choice questions on diagnosis and management (medication, referral and/or non-pharmacotherapeutic recommendations) on two occasions: at the time of inclusion of the patient and at the time the sIgE test outcomes were known.

### **Intervention Type**

Other

### **Primary outcome measure**

Feasibility of the AMSS is assessed using the percentage of AMSS recommendations sent to the GP within 10 working days of the sIgE testing.

### **Secondary outcome measures**

There are no secondary outcome measures.

**Overall study start date**

01/09/2009

**Completion date**

01/09/2016

## **Eligibility**

**Key inclusion criteria**

1. General practitioners (GP)
2. Allergic patient or parent of allergic child with sIgE test

**Participant type(s)**

Mixed

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

20 GPs and 100 patients

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/02/2010

**Date of final enrolment**

01/09/2015

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Groningen

Netherlands

9700 AD

## **Sponsor information**

**Organisation**

University Medical Center Groningen

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/03cv38k47>

**Funder(s)****Funder type**

Industry

**Funder Name**

Phadia BV

**Funder Name**

ALK Abelló BV

**Funder Name**

Universitair Medisch Centrum Groningen

**Alternative Name(s)**

University Medical Center Groningen, UMCG

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Netherlands

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

### Intention to publish date

01/01/2018

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. B.M.J. Flokstra – de Blok, b.m.j.flokstra@umcg.nl.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	29/05/2018		Yes	No