

Allergy management support service

Submission date 16/11/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/11/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/06/2018	Condition category Respiratory	☐ 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

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Contact details

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Interventional

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

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

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?
Results article	results	29/05/2018		Yes	No