ISRCTN36780877 https://doi.org/10.1186/ISRCTN36780877

Allergy management support service

Submission date	Recruitment status	[ ] Prospectively registered
16/11/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2018	Respiratory	

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 in addition to sIgE-test results. Those in the second group receive only the to 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
b.m.j.flokstra@umcg.nl

Contact information

Type(s)
Scientific

Contact name
Dr Bertine Flokstra - de Blok

Contact details
University Medical Center Groningen
PO Box 196
Groningen
Netherlands
9700 AD
+31 (0)50 3616687
b.m.j.flokstra@umcg.nl

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 slgE 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
PO Box 196
Groningen
Netherlands
9700 AD
+31 (0)50 3616687
b.m.j.flokstra@umcg.nl

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?
Results article	results	29/05/2018		Yes	No