# Adolescent hayfever and quality of life

[ ] Prospectively registered Submission date Recruitment status 24/06/2008 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 19/08/2008 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 20/02/2015 Respiratory

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

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## Additional identifiers

Protocol serial number CZF/1/40

## Study information

#### Scientific Title

Cluster randomised controlled trial of an educational intervention for healthcare professionals into the management of school-age children with hayfever

### Study objectives

The primary aim of this study is to examine the effectiveness of standardised allergy training in promoting disease-specific quality of life of adolescents with hayfever. A one-day short course which focuses specifically on allergic rhinitis and asthma will be delivered to practice nurses in Lothian.

### The objectives are:

- 1. To evaluate the effectiveness of standardised allergy training for health care professionals on adolescent (12 18 years) rhinitis-specific quality of life
- 2. To examine the impact of improving symptoms of hayfever on examination performance of adolescents
- 3. To assess the change in allergy practice and improvement in confidence, understanding and managing allergy symptoms of trained nurses or doctors

#### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Lothian Research Ethics Committee, September 2008, ref: 08/S1102/37

### Study design

Pragmatic cluster randomised controlled trial

#### Primary study design

Interventional

### Study type(s)

Treatment

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

Seasonal allergic rhinitis (hayfever)

#### Interventions

The randomisation is at the level of the general practice, i.e. the practices are the clusters.

The health care professional intervention is a one-day short course entitled 'Essential Asthma and Allergic Rhinitis' and is run by the charity Education for Health.

The patient intervention is one consultation with a nurse or doctor (both intervention and control groups). In the intervention arm, the nurse or doctor will have attended the training day. In the control arm the nurse or doctor will not have attended the training day.

The control group will also receive usual care and a leaflet on hayfever management (Allergy UK factsheet). Once the trial is complete, control practice staff will be invited to attend the course.

### Intervention Type

Other

#### Phase

Not Applicable

### Primary outcome(s)

Difference in the validated Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) score between the intervention and control groups at baseline and 3 and 6 weeks post-intervention.

### Key secondary outcome(s))

- 1. Symptom scores, assessed using a visual analogue scale at 3 and 6 weeks post intervention
- 2. Overall assessment of seasonal allergic rhinitis symptoms compared with the previous season, assessed 6 weeks post intervention
- 3. Number of general practitioner and practice nurse consultations for hayfever; prescribed (from clinical records) and over-the-counter (from patients) medication data will be collected for cost-effectiveness comparison. Theses will be assessed at end of hayfever period (September 2009)
- 4. Examination performance, assessed at end of hayfever period (September 2009)
- 5. Assessment of change in clinical practice on completion of trial

### Completion date

30/11/2009

## **Eligibility**

### Key inclusion criteria

- 1. Young people (both males and females) aged 12 18 years
- 2. Hayfever, defined by the presence of a documented clinician diagnosis in the patient's health record and any evidence of treatment used for allergic rhinitis

### Participant type(s)

Patient

### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

12 years

#### Upper age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Unable to give consent
- 2. Taking part in any other clinical trials involving treatment for allergic rhinitis

#### Date of first enrolment

01/08/2008

#### Date of final enrolment

### Locations

#### Countries of recruitment

United Kingdom

Scotland

Study participating centre

Division of Community Health Sciences: GP Section

The University of Edinburgh Edinburgh United Kingdom EH8 9DX

## Sponsor information

### Organisation

Chief Scientist Office of the Scottish Executive Health Department (UK)

#### **ROR**

https://ror.org/01bw7zm61

## Funder(s)

### Funder type

Charity

#### **Funder Name**

Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZF/1/40)

## **Results and Publications**

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	05/06/2014	Yes	No
<u>Protocol article</u>	protocol	05/08/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes