

Adolescent hayfever and quality of life

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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. These 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

30/11/2009

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
Protocol article	protocol	05/08/2010		Yes	No