ISRCTN95538067 https://doi.org/10.1186/ISRCTN95538067

Adolescent hayfever and quality of life

Submission date 24/06/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 19/08/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] 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

Contact name
Prof Aziz Sheikh

Contact details
Division of Community Health Sciences: GP Section
The University of Edinburgh
20 West Richmond Street
Edinburgh
United Kingdom
EH8 9DX
+44 (0)131 6514151
aziz.sheikh@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/08/2008

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

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
264

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
Scotland

United Kingdom

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)

Sponsor details
St Andrews House
Edinburgh
United Kingdom
ED1 3DG
-
elaine.moir@scotland.gsi.gov.uk

Sponsor type
Government

Website
http://www.sehd.scot.nhs.uk/cso

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	05/08/2010		Yes	No
Results article	results	05/06/2014		Yes	No