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The Help for Hay Fever Study

Submission date 18/04/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 18/06/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/02/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hay fever is a common long term condition in Scotland. People with poorly controlled hay fever can experience poor quality of life, reduced productivity at work and/or poor exam performance. When hay fever occurs in combination with asthma, it often leads to poor asthma outcomes. Effective treatments are available but are not always used correctly. Clinical guidelines have been produced for primary care health professionals (GPs and pharmacists) and, when implemented effectively, can improve management of hay fever. However, research suggests that in practice, hay fever continues to be poorly managed in the UK.
In Australia, researchers have developed an intervention for delivery in community pharmacies. In two studies, people with hay fever received an intervention that involved setting goals that aimed to eliminate or minimise their hay fever symptoms, and to avoid or minimise triggers of their hay fever symptoms. Their results showed improvements in quality of life, symptom severity, adherence to medication and self management of symptoms.
We want to find out if this intervention could improve management of hay fever in the UK. We plan to repeat the Australian research to test whether the intervention would work in a Scottish setting.

Who can participate?
Community pharmacies: a random selection of twelve community pharmacies recruited from two regions in Scotland. Pharmacy staff in the Intervention Group must be available to attend expert led training sessions. Community pharmacy customers: customers from the community pharmacies taking part in the study who are:
18 years old and over
Hay fever sufferers (during the hay fever months but not all year round).
Not pregnant
Not terminally ill
Not already involved in a hay fever study (current or recent)

What does the study involve?
All community pharmacy staff will receive training in participant recruitment and data collection before recruiting customers to the Intervention and Control groups. Pharmacy staff in the Intervention Group will receive additional expert led training in intervention delivery.
Recruited customers in the Intervention Group will receive a one-off intervention comprising: a hay fever pack (including printed information about hay fever symptoms, triggers and general

information); advice from pharmacy staff about treatment and management of hay fever; and a goal card with two goals:
1. To eliminate or minimise hay fever symptoms
2. To avoid or minimise hay fever triggers
Pharmacy staff will support customer participants in formulating action plans for achieving the two goals.
Recruited customers in the Control Group will receive usual care.
Using data collection cards both groups will be asked to record, in the week after recruitment, a daily symptom severity score and adherence to hay fever medication. They will also be asked to complete a questionnaire on the day they are recruited, and at one week and six weeks after recruitment.

What are the possible benefits and risks of participating?
We hope that, as was found in previous Australian research, hay fever symptoms will improve for pharmacy customers in the Intervention Group leading to improved quality of life as well as other outcomes. Pharmacy staff in the Intervention Group may benefit from the training provided.
We do not believe that the proposed intervention poses any particular risk to community pharmacy staff or to customer participants in either the Intervention or Control Groups.

Where is the study run from?
The University of Aberdeen

When is the study starting and how long is it expected to run for?
The study started in May 2012 and it is expected to run for four months, or until the required number of 144 participants have been recruited.

Who is funding the study?
Chief Scientist Office, Scotland

Who is the main contact?
Dr Terry Porteous
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Can a goal-focussed intervention delivered in Scottish community pharmacies improve outcomes for people with intermittent allergic rhinitis? A pilot randomised controlled trial

Study objectives
That a goal focussed intervention delivered in Scottish community pharmacies can improve outcomes for people with intermittent allergic rhinitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, 05/04/2012, Ethics reference: 12/NS/0040

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Intermittent Allergic Rhinitis (Hay Fever)

Interventions

A random sample of twelve community pharmacies will be selected from those responding positively to an invitation to participate. Selected pharmacies will be randomly allocated to intervention or control group. Intervention pharmacy staff will attend a three hour training workshop about the pathophysiology and treatment of allergic rhinitis, and delivery of the intervention.

Intervention pharmacy customers will receive a one-off intervention comprising: an Allergic Rhinitis Pack (including printed information about Allergic Rhinitis symptoms, triggers and general information); advice from pharmacy staff about treatment and management of AR; a goal card with two pre-determined goals (Eliminate/minimise hay fever symptoms and avoid /minimise hay fever triggers); and a card to record their personal symptoms and triggers.

Pharmacy staff will support participants in formulating action plans for achieving the two goals.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outcome measures have been selected to represent a range of clinical indicators and social functioning that are relevant to allergic rhinitis.
Quality of Life (QOL), measured using a validated and widely used disease specific health status instrument (mini Rhinoconjunctivitis Quality of Life Questionnaire- miniRQLQ, (Juniper, 2000)), whose psychometric properties and minimally clinically important difference are well described. QOL will be measured by questionnaire on the day of recruitment, and one week and six weeks after recruitment.

Secondary outcome measures
Pharmacy staff:
1. A multiple choice questionnaire will measure knowledge of Allergic Rhinitis management and treatment before and after the intervention. For the intervention group, training will be evaluated using a questionnaire based on the one used previously in Australia.
2. Semi-structured telephone interviews with a sub-sample of pharmacy staff (one from each intervention pharmacy) will collect qualitative data about their experiences of implementing the intervention, perceived benefits of and barriers to introducing it into usual practice, and general issues around acceptability of and satisfaction with the intervention
3. The interview schedule will be informed by the findings of the Australian study. Questions assessing the estimated time input of pharmacists per client will also be included to inform the economic analysis.

Pharmacy customers: We will measure the following patient-reported outcomes:
1. Quality Of Life using the miniRQLQ
2. Generic health status using the EQ-5D
3. Symptom severity using the adapted 12-item Spector scale used in the Australian studies
4. Productivity using the 6-item Work Productivity and Activity Impairment Questionnaire: Allergy Specific
5. Medication adherence using the 5-item Medication Adherence Reporting Scale
6. Self-efficacy using a 6-item generic instrument adapted for Allergic Rhinitis by the Australian team

7. Allergic Rhinitis related contacts with health services since recruitment, measured by patient self-report
8. Medication use during the 6-week follow-up period by patient self-report

Overall study start date
31/05/2012

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Community pharmacies, from the two nominated study areas in Scotland, with staff available to attend training if randomised to the intervention group.

Community pharmacy customers who:
1. Present opportunistically in participating community pharmacies
2. Have a history of intermittent allergic rhinitis i.e. experience symptoms on ≤4 days per week OR <4 weeks
3. Are currently experiencing symptoms of allergic rhinitis, defined as 2 or more of the following symptoms for ≥1 hour on most days: runny nose with both sides affected, blocked nose on both sides, itchy nose, sudden bouts of sneezing,sore, red, itchy eyes, itchy throat.
4. Are 18 years of age or over
5. Are able to speak, write and understand English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
Community pharmacies, from the two nominated study areas in Scotland, whose staff are not available to attend training if randomised to the intervention group.

Community pharmacy customers who:
1. Present with any of the following symptoms: blocked nose with no other symptoms suggestive of hay fever, thick yellow or green nose discharge, thick mucus at the back of the throat, sinus pain, recurrent nose bleeds, loss of smell.
2. Are under 18 years of age

3. Are unable to speak, write or understand English
4. Are pregnant
5. Are terminally ill
6. Have participated in another hay fever study within the last two years

Date of first enrolment
31/05/2012

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Room 1.006 Polwarth Building
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research and Innovation
University Office
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Sponsor type
University/education

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (CSO) (UK)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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	15/07/2013		Yes	No