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Asthma GOAL elicitation feasibility study

Submission date
24/04/2012

Recruitment status
No longer recruiting

Registration date
18/06/2012

Overall study status
Completed

Last Edited
02/10/2018

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Backgroundand study aims
Working in partnership with people with asthma by considering and utilising their treatment goals within a tailored self-management plan is a potentially important step in asthma management, which, if effective, is likely to result in clinically relevant improvements in asthma outcomes.
Self-management education which includes a personalised asthma action plan is recommended by national and international guidelines for everyone with asthma. An essential step in developing and agreeing a tailored self-management plan depends not only on the provision of appropriate medication, but on people with asthma being able to identify and prioritise their own goals for their disease. This acknowledges their expertise on the way in which asthma impacts on their life and their preferences for managing their condition. Health professionals need to support and guide patients in this process, providing appropriate education and support linked to behaviour change. However, uncertainty exists on the best way to assist with this activity within a brief asthma review consultation.
A simple clinical questionnaire has been designed that may have a positive impact on this process. The tool aims to help patients identify and set their own asthma goals and to encourage health professionals to initiate a focused conversation that will facilitate change in patient attitudes and management strategy. Based on preliminary work which indicated that use of an asthma goal-eliciting questionnaire, completed by the patient at home prior to the consultation and utilised as a focus for discussion during the review, is likely to be associated with:
1. More patient goals being discussed in the asthma consultation
2. More change talk in the asthma consultation
3. Greater acceptability of the consultation to patient and nurse
We have concluded that a brief, intensive patient-orientated intervention may be successful in improving involvement of the patient in the management process, which in turn has the potential to improve disease control and patients quality of life. However, before starting a study to evaluate its acceptability, effectiveness and cost-effectiveness, we need to establish whether such a project is feasible within the primary care setting. To inform this process we will undertake a initial small study to assess the ability to recruit patients and primary care staff and furthermore to establish the best way of delivering this intervention (treatment) within a general practice setting.

Who can participate?
Eight practices from two health regions in Scotland. Patients need to be 18years or over, have

been diagnosed with asthma for more than a year, have active asthma, and be capable of taking part in the study.

What does the study involve?
Eight practices with an asthma clinic run by a nurse in possession of an accredited asthma diploma will be recruited. The practices will be randomly allocated to control or intervention and each practice will recruit a minimum of 10 patients to the study. All eligible patients will be approached.
An asthma review consultation will be arranged for the patient with the practice nurse. Nurses in both study groups will conduct a standard review consultation in line with guideline driven protocol (control assessment; peak expiratory flow (PEF); check of inhaler technique; review of medication etc.)
In addition, patients in the intervention arm will be asked to complete the goal-elicitation tool prior to the asthma review. As part of the review procedure discussion will include the elicited goals. Follow-up outcome questionnaires will be sent by the researcher to patients for completion at 3 months and again at 6 months.

What are the benefits and risks of participating?
Patients and health professionals may benefit from the introduction of a goal-elicitation tool to help them think about, facilitate and focus the self-management discussion. There are no direct risks in taking part in the project although some participants may not find it easy to think and talk about their asthma specific goals.

Where is the study run from?
This study has been set up by the University of Stirling in collaboration with academics and clinicians from the Universities of Dundee, Aberdeen and Edinburgh.

When is the study starting and how long is it expected to run?
The study will begin on 1st September 2012 and run for 15 months

Who is funding the study?
Funding has been provided by the Chief Scintist Office, Scotland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CZH/4/697

Study information

Scientific Title
Can eliciting and addressing health-related goals improve asthma control and asthma related quality of life? Feasibility phase ll pilot randomised controlled trial of a brief intervention

Acronym
GOAL

Study objectives
It is hypothesised that a brief, intensive, patient-orientated intervention in the form of a simple goal elicitation questionnaire will improve a patients ability to identify, prioritise and act on their own goals for asthma self management.

The null hypothesis is that there will be no improvement. This may arise due to the inneffectiveness of the tool or to the difficulties in conducting a clustered randomised controlled trial of the tool in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic researcher-blinded two armed multi-centre clustered randomised controlled feasibility study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Ability to identify patient goals for asthma

Interventions
Control Group: An asthma review consultation will be arranged for the patient with the practice nurse. The nurse will conduct a standard review consultation in line with guideline driven protocol [control assessment; peak expiratory flow (PEF); check of inhaler technique; review of

medication etc]. Follow-up outcome questionnaires will be sent by the researcher to patients for completion and return by mail, or over the telephone depending on patient choice, at 3 months and again at 6 months.

Intervention Group:
1. An asthma review consultation is arranged.
2. Goal-eliciting tool sent to patients prior to arranged review consultation
3. Patient completes goal-eliciting tool independently at their own convenience
4. Patient attends the practice for review bringing completed goal-eliciting tool
5. Patients not bringing it will complete it in the waiting area prior to the review
6. Nurse conducts a review consultation in line with guidelines [control assessment; PEFR; check of inhaler technique; review of medication etc]
7. In addition the nurse will review the patients own goals as identified using the goal-eliciting tool
8. Nurse and patient will discuss the individual goals and, if necessary, the appropriateness of, and the priority given, to each goal.
9. An individualised implementation strategy will be discussed and agreed, tailored to the number and complexity of the elicited goals.
10. A plan of agreed goal implementation intention will be given to the patient.
11. All patients will be contacted after 6 weeks by telephone, email, or text message to reinforce the plan and discuss any barriers to goal achievement. Follow-up will be at the discretion of the nurse based on clinical need.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Change in quality of life as measured by the mini Asthma-related Quality of Life Questionnaire (mAQLQ) at 6 months post randomisation
2. Compare mAQLQ scores at 3-months post-randomisation to establish the most appropriate time-point for assessment of clinical endpoints
3. Recruitment rate and retention - dates for each step recorded
4. Contamination review consultations will be audio-recorded (with the patients consent), and listened to for consultation variation

Measured at baseline; 3 months post intervention; 6 months post intervention

Key secondary outcome(s))
Secondary outcome measures have been selected to reflect the wider dimensions of the impact of asthma.

From patients via telephone interview and mailed questionnaire:
1. Asthma control using the Asthma Control Questionnaire (ACQ)[29]
2. Patient Enablement using Patient Enablement Instrument[30]
3. Quality of life using e.g. the SEIQoL-DW[31]
4. Number of patient goals identified/achieved

Manually from practice records of individual patients:
1. Number of patient goals identified/achieved
2. Time to follow up telephone or face-to-face
3. Consultation length recorded by the nurse
4. Primary and secondary asthma-related health care resource use 6 months pre and post intervention
5. Exacerbations / use of emergency asthma medication 6 months pre/post intervention
6. Number of short-acting bronchodilator inhalers prescribed to each patient in 1 year
7. List size, response rate and retention rate
8. Signs of control group contamination elicited from analysis of a random sample of consultation recordings

Measured at baseline; 3 months post intervention; 6 months post intervention

Completion date
30/11/2013

Eligibility

Key inclusion criteria
Patients must be:
1. Registered with a general practice
2. Be 18 years of age or over and on the practice asthma register
3. Have had a diagnosis of asthma for more than 1 year
4. Have active asthma i.e. currently on prescribed preventative asthma medication or are on bronchodilator medication only but have used more than six bronchodilator inhalers in the previous 12 month period.
5. Be able to understand English enough to participate in the consultation process, read /understand the project documentation e.g. the information sheet and the consent form, and converse within an interview.
6. Have the mental capacity to take part.

Practices need to:
1. Be in one of the two health board areas chosen for the study
2. Have an experienced asthma trained nurse willing to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. They are not registered with a practice in one of the two health board areas chosen for the study
2. Are under 18 years of age
3. Do not have active asthma
4. They have Chronic obstructive pulmonary disease (COPD) or other significant lung disease
5. Are adults with incapacity including major psychological problems
6. Be able to understand English enough to participate in the consultation process, read /understand the project documentation e.g. the information sheet and the consent form, and converse within an interview
6. Have the mental capacity to take part
7. The GP considers they should not be invited to participate because of major medical, social, or communication reasons

Practices:
1. Not in one of the two health board areas chosen for the study
2. Do not have an experienced asthma trained nurse
3. Do not provide asthma services to patients or do not have a register of asthma patients
4. The practice nurse is unwilling to participate despite the practice agreeing to take part

Date of first enrolment
01/09/2012

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Nursing, Midwifery and Allied Health Professions (NMAHP) Research Unit
Stirling
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Sponsor information

Organisation
University of Stirling (UK)

ROR

https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (CSO) (UK) ref: CZH/4/697

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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	08/12/2016		Yes	No
Protocol article	protocol	11/09/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes