

Education, self-management & empowerment in exacerbation-prone asthma

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| Submission date 10/02/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 07/04/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 15/12/2021 | Condition category Respiratory | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

There is a significant unmet need in severe asthma, from effective treatments to strategies at improving outcomes through empowerment and education. ESMENA (Education, Self-Management and Empowerment in exacerbation prone Asthma) is a multi-disciplinary team (MDT) participatory action research intervention providing education for patients with exacerbation-prone asthma. Through education, the aim is for patients to have a better of their asthma, which will empower them to better self-manage their condition. It will target at-risk groups of patients who have attended the Emergency Department for treatment or who heavily rely on unscheduled care at their GP, who are not already known to secondary or tertiary asthma services. The aim of the programme is to provide these individuals with the education and tools that they need to improve disease control and overall quality of life. Education is a central component for improving an individual's self-management of their asthma. There is good evidence that self-management education, particularly targeted at those individuals who have had ED attendances or hospital admissions, can reduce subsequent use of healthcare resources.

Who can participate?

Patients aged 18 and over who frequently exacerbate and either rely on unscheduled GP appointments or attend the emergency department at Queen Alexandra Hospital in Portsmouth

What does the study involve?

Patients will be identified through audit and a review of asthma clinic referral letters and will be invited to attend the education programme. The programme will be delivered in the community in non-clinical environments by different members of the asthma multi-disciplinary team. Groups of patients will take part in a variety of interactive sessions and following each session, anonymous feedback will be used to improve future sessions. Markers of asthma control and quality of life will be recorded at the start of the study, after the education programme and 6 months after the education, to assess both the effectiveness of the programme and its delivery.

What are the possible benefits and risks of participating?

It is hoped is that the education programme will make participants feel more confident in managing their asthma and what to do if their symptoms get worse. However, as this is a pilot study, the researchers cannot guarantee that the education programme will fulfil their

educational needs. As mentioned above, the researchers would welcome feedback on how to improve future sessions to make them more relevant and useful. The more that they can understand about patients' experiences and understanding of their asthma the more they can tailor their services to patients' needs to give them the best service possible. The researchers do not anticipate any risks as the programme involves a teaching session.

Where is the study run from?

Portsmouth Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

April 2018 to April 2023

Who is funding the study?

NHS Portsmouth CCG (UK)

Who is the main contact?

Prof. Anoop Chauhan

anoop.chauhan@porthosp.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Prof Anoop Chauhan

ORCID ID

<https://orcid.org/0000-0003-4044-6114>

Contact details

Portsmouth Hospitals NHS Trust

Southwick Hill Road

Portsmouth

United Kingdom

PO6 3LY

+44 (0)2392286300

anoop.chauhan@porthosp.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

256682

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 40713, IRAS 256682

Study information

Scientific Title

ESMENA: education, self-management and empowerment in exacerbation-prone asthma; a multi-disciplinary team (MDT) participatory action research intervention, providing education for patients with exacerbation-prone asthma

Acronym

ESMENA

Study objectives

There is a significant unmet need in severe asthma, from effective treatments to strategies at improving outcomes through empowerment and education. ESMENA (Education, Self-Management and Empowerment in exacerbation prone Asthma) is a multi-disciplinary team (MDT) participatory action research intervention providing education for patients with exacerbation-prone asthma. Through education, the aim is for patients to have a better of their asthma, which will empower them to better self-manage their condition. It will target at-risk groups of patients who have attended the Emergency Department for treatment or who heavily rely on unscheduled care at their GP, who are not already known to secondary or tertiary asthma services. The aim of the programme is to provide these individuals with the education and tools that they need to improve disease control and overall quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 31/01/2019, South Central – Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol BS1 2NT, UK; Tel: +44 (0)2071048057; Email: nrescommittee.southcentral-berkshire@nhs.net), REC ref: 19/SC/0005

Study design

Non-randomised; Both; Design type: Treatment, Education or Self-Management, Qualitative

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma

Interventions

Patients identified as suitable for the Initial clinic, with a presumed diagnosis of asthma which has not been previously characterized, will be selected from the daily review of ED attendances

carried out routinely by the Asthma Nurse Specialist at Queen Alexandra Hospital, Portsmouth, and from new asthma referrals from primary care. These patients will be contacted by phone by a member of the clinical research team and offered an appointment in an initial ESMENA clinic.

Those patients with characterised asthma will be offered a review at an initial screening visit. During this phone call, they will be informed that they will be offered the opportunity to also participate and help develop an optional follow-on education programme that forms part of a research programme. They will be reassured that their clinic attendance is not dependent on their participation in the research element. This phone call will be followed by an invitation letter detailing their appointment time and containing the Participant Information Sheet (PIS). The letter will again reinforce that their initial clinic will not be influenced by their decision regarding participation in research.

During the clinical review, they will undergo lung function testing and see a doctor who will ensure they are receiving the correct treatment. Following the clinic review, all patients with a confirmed diagnosis of asthma will be invited to attend the ESMENA education programme and consent will be obtained to allow involvement in the research project. Patients who are not found to have a diagnosis of asthma (but possibly different conditions) will be guided to alternative appropriate clinics and will not be involved in the education programme. If the patient requires a follow-up appointment, this will be made within the normal asthma service.

If patients already have a confirmed diagnosis of asthma which has been previously characterized, they will instead be invited to an initial screening visit. During this visit they will complete questionnaires to ensure comorbidities are identified and will have any outstanding investigations (for example inflammometry) performed. Following this screening visit, they will be invited to attend the education programme.

If patients opt out of the education programme or decline consent, their reasons will be recorded and their care transferred back to their usual GP. The acceptability of the programme will be reviewed throughout the process and any reasons not to attend will be included in this analysis.

Patients who consent to research and the education programme will be invited to attend 3 sessions, facilitated by members of the specialist asthma MDT. The sessions, which will last approximately 90 minutes, will be held in the community, in locations with good transport links, mainly on weekday evenings or weekend days to allow as many people to attend as possible. Patients will be encouraged to attend all three sessions. During the sessions they will receive information and advice from the members of the asthma MDT which will include a physiotherapist, dietician, psychologist and asthma nurse. The sessions will be held in an informal group environment promoting engagement and peer support. Following each session, participants will be encouraged to leave feedback both about the individual sessions and the general running of the programme. This feedback will directly influence the following sessions and ensure the content remains patient-centred and appropriate.

At the end of the education programme, participants will be invited to attend a final clinic review, in order that we summarise the education and managements plans that they have received.

Intervention Type

Behavioural

Primary outcome(s)

The main outcome measure is whether or not the ESMENA education programme can improve adherence, asthma control and quality of life for patients with poorly controlled asthma:

1. Adherence measured using MARS questionnaire at baseline, following completion of the programme and at 6 months post programme
2. Asthma control measured using Asthma Control Questionnaire (ACQ) at baseline, following completion of the programme and at 6 months post programme
3. Quality of life measured using Asthma Quality of Life questionnaire at baseline, following completion of the programme and at 6 months post programme

Key secondary outcome(s))

Feasibility outcomes:

1. Characteristics of patients identified as suitable for the ESMENA programme, measured using demographics, smoking status, disease phenotype, baseline medication, at baseline, following completion of the programme and at 6 months
2. Consent rate to research and education programme, measured using number of consents at the end of the study
3. Attendance rates at education sessions, and reasons for decline, measured using number of attendances at baseline, following completion of the programme and at 6 months
4. Topics identified by patients for discussion in the programme (at the asthma clinic and during the education sessions), measured using topics that patient wish to discuss at baseline, following completion of the programme and at 6 months
5. Adherence to programme completion, measured using attendance rates at baseline, following completion of the programme and at 6 months
6. Number of patients requiring further secondary care appointments following ESMENA review, measured using number of patients at baseline, following completion of the programme and at 6 months
7. Extent to which programme targets appropriate patients, measured by identifying reasons which drive repeat unscheduled care attendances with participants, at baseline, following completion of the programme and at 6 months
8. Extent to which programme meets educational needs of participants, measured using 'Completion of ESMENA Questionnaire' at baseline, following completion of the programme and at 6 months
9. Patient and staff experience of delivery, acceptability of current programme design and identified areas for improvement, measured using 'Completion of ESMENA Questionnaire' at baseline, following completion of the programme and at 6 months

Clinical effectiveness:

1. Number of patients requiring changes in disease management, including inhaler technique education, and types of changes required, measured using number of patients requiring change at baseline, following completion of the programme and at 6 months
2. Frequency of unscheduled care usage, rescue medication usage and exacerbations requiring steroid/antibiotic courses amongst participants, measured using number of unscheduled care visits in the 6 months prior to attending the programme with 6 months after
3. Disease control, measured with the Asthma control questionnaire (ACQ) and mini Asthma Quality of Life Questionnaire (mini-AQLQ) at baseline, following completion of the programme and at 6 months
4. Participant knowledge of asthma, measured using 'Completion of Esmena Questionnaire at the end of the ESMENA education programme, 6 months and 12 months post completion
5. Participant ability and confidence to self-manage, measured using a Likert scale questionnaire at baseline, following completion of the programme and at 6 months
6. Medication adherence measured using MARS questionnaire at baseline, post-programme, and

at 6 months

7. Baseline medication beliefs measured using BMQ at baseline, post-programme, and at 6 months

Completion date

30/04/2023

Eligibility

Key inclusion criteria

1. Aged 18 years and above
2. Two or more attendances in ED or frequent unscheduled care visits to the GP within the last 12 months
3. Willing and able to give consent
4. Confirmed diagnosis of asthma

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Declined or unable to give consent
2. Aged under 18

Date of first enrolment

06/02/2019

Date of final enrolment

30/04/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

ROR
<https://ror.org/009fk3b63>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Portsmouth CCG

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The de-identified 'raw data' will be held on Portsmouth Hospitals NHS Trust servers. The type of data that will be available after de-identification will be text, tables, figures. The data will be available at the beginning and ending 12 months after the article publication. Data will be available to researchers who provide a sound proposal – these should be directed to Anoop.chauhan@porthosp.nhs.uk for access and requestors will be to sign a data-sharing agreement.

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |

