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ESMENA: Education, Self-Management and Empowerment in exacerbatioN prone Asthma

A new education programme for patients with difficult-to-control asthma

INFORMATION SHEET

We would like to invite you to take part in a research study. Before you decide whether to participate, we would like you to understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you if you wish – please contact us on the above phone number.

What is ESMENA?

ESMENA is an education programme aimed to improve the care for patients with asthma in the local area. Through the research study we will look at the effects of this new service on the lives of the people who participate. The education programme has been designed by both healthcare professionals and patients and we are keen to make it a success; we will use feedback that you provide at the end of the session to improve future sessions.

Why have I been invited?

You have been invited to take part in this study because you have asthma and are under the care of the Portsmouth Asthma Service, or have previously needed to see your GP or attend the emergency department for help, when your asthma has got out of control.

Do I have to take part?

No. Participating in any research project is voluntary. If you decide you do not wish to take part this will not affect your usual NHS treatment in any way.

If you are interested in taking part in the study please read this information sheet. If you agree to take part then we ask you to sign a consent form.

What does it involve?

Information about your asthma: If you would like to take part we would ask your permission to collect information about your asthma from your notes in the hospital and from your GP. This will include the treatments you are taking and the number of times you have required an escalation in your treatment. This information will be collected anonymously and then analysed.

Education session: You will be asked to attend an education session where you will hear talks about how to manage your asthma from a variety of specialists, including a physiotherapist and pharmacist. The session will be informal and interactive with plenty of opportunities for you to ask questions. Due to the COVID-19 pandemic, this may be a virtual educational session. If it is a virtual session, we would like you to have access to a microphone to ensure you can ask us questions, but it is your choice whether to have your camera turned on or off. The session will likely last three - four hours (the time frame will be guided by your needs).

We will also provide access to an online app called healthinote. Healthinote will provide access to summary videos of the main talks in ESMENA, some useful written information and links to other websites.

At the end of the session, we will ask you to give us feedback; for example, how useful you found it and how it could be improved for future patients.

Six months after the education session, we will ask you to complete a further feedback questionnaire to help us design future sessions. This will take approximately five minutes to answer and can be completed electronically or via a written questionnaire. We will also ask you about your asthma control using standard clinical questionnaires; these should take no more than 15 minutes to complete. If you are attending the asthma clinic, these may be completed during your clinic visit. Otherwise, we will send the questionnaires electronically or in the post (with a stamped addressed envelope) and will follow them up with a phone call or email if we have not received them back from you within two weeks. A final questionnaire, similar to the six months one, will be sent around twelve months after the education session. These provide us with information about your asthma control for the whole year. Once you have completed these questionnaires, your involvement in the study will finish.

A flow diagram on the following page explains what to expect if you participate in the study.

You are invited to attend an Asthma Clinic appointment. At this appointment, you will also be asked to complete some or all of the following questionnaires as part of the usual standard assessment in asthma clinic:

1) An assessment of quality of life and disease control: ACQ and mini-AQLQ questionnaires
2) An assessment of additional contributors to asthma control: HADS, Epworth, Nijmegen, TAI, PHQ-9, SNOT-22, EQ-5D-5L and WPAI (A)

These should take no more than 15 minutes to complete. When possible, these will be completed electronically, but paper questionnaires will be supplied if needed. Help completing these questionnaires is available if required.

If you are interested in the ESMENA education programme, we will give you a Participant Information Sheet. If you would like to take part, we will offer you the opportunity to ask questions and then complete the Consent Form. We will then ask you to complete any of the above questionnaires that weren't completed, plus:

1) An Initial participant Questionnaire

Again, ideally this will be completed electronically, but a paper questionnaire is available if needed. This questionnaire should take no longer than 10 minutes to complete, and help is available to complete this if required.

You will then be invited to attend the education programme. Following the session, we will ask you to complete a following questionnaire:

1) A Completion of education Questionnaire

As above, this questionnaire will be completed electronically where possible, but a paper questionnaire is available if needed. This should take no longer than 10 minutes to complete, and help is available to complete this if required.

At three, six and twelve months after attending the education session, you will be sent a selection of questionnaires to complete. If you are seen in asthma clinic around these times, they will be completed at the clinic visit instead. These will include:

1) A Participant Questionnaire
2) An assessment of quality of life and disease control: ACQ and mini-AQLQ questionnaires
3) An assessment of additional contributors to asthma control: HADS, Epworth, Nijmegen, TAI, PHQ-9, SNOT-22, EQ-5D-5L and WPAI (A)

They should take no longer than 15 minutes to complete. As above, they will be sent to you electronically, but paper questionnaires can be supplied if needed and help is available to complete these if required.

What are the benefits to me?

Our hope is that by the time you complete the education programme, you will feel more confident in managing your asthma and will know what to do if your symptoms get worse. However, as this is ongoing research, we cannot guarantee that the education programme will fulfil all your educational needs. As mentioned above, we would welcome feedback on how to improve future sessions to make them more relevant and useful. The more we can understand about patients' experiences and understanding of their asthma the more we can tailor our services to patients' needs to give them the best service possible.

What are the risks?

We do not anticipate any risks as the programme involves a teaching session. If anything happens that you are worried is related to the study please contact us.

What happens to the data and the results of the study?

The results of studies are usually published in medical journals. There will be no way of identifying you or your data from the published results. We can send you a summary of the results if you wish.

How will we use information about you?

We will need to use information from you and your medical records for this research projection. This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name of contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

What are your choices about how your information is used?

You can stop being part of this study at any time, without giving reason but we will keep information about that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to respiratory.research@porthosp.nhs.uk
- by ringing us on 02392 286000 ext 4108

What if I change my mind?

You can stop taking part in this study at any time. You do not have to give a reason to the research team if you change your mind. Your normal NHS treatment will not be affected in any way.

Who is organising and funding this study?

Portsmouth Hospitals University NHS Trust is the sponsor for this study based in the United Kingdom.

Who has reviewed and approved the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. The South Central – Berkshire Research Ethics Committee (REC reference 19/SC/0005) have reviewed the rights, safety and wellbeing of research participants and have approved this study.

Will my GP know that I am taking part?

It is important that your GP knows you are taking part in a study. With your permission we will inform your GP and your asthma nurse that you are taking part and what the study involves. We will also ask your GP for access to their records to collect data for the study.

What if there is a problem?

If you have any complaints about how you are treated during the study you should contact the research staff who will try address any concerns or problems on 02392 286000 ext. 4108. If you remain unhappy and wish to complain formally, you can do this by contacting your hospital's Patient Advice and Liaison Service (PALS). PALS can be contacted by phone on 02392 286757 or email (PALS@porthosp.nhs.uk).

In the event that something goes wrong, and you are harmed during the research study due to someone's negligence, then you may have grounds for legal action for compensation against the study sponsor (Portsmouth Hospitals University NHS Trust) or the NHS Trust where you received your care. However, you may have to pay for your legal fees. The normal NHS complaints mechanisms will still be available to you.

Please take your time to think about this study. Talk to friends and family and let us know what you think.

Who should I contact if I require further information?

Should you require any further information then please do not hesitate to contact us:

CONTACT DETAILS:	
For routine trial-related questions during working hours, please contact:	**Tel:** 02392 286000 Ext: 4108
For further information about research and clinical trials in your local area, please contact:	**Research and Development Office** **Tel:** 02392 286000 Ext: 6236
To speak to your local hospital's Advice and Complaints Team (PALS), please contact:	**Tel:** 02392 286757 **Email:** PALS@porthosp.nhs.uk

For emergency or non-trial-related medical issues please contact medical services as normal.