A Study of Medical, Psychological and Socio-economic Factors Influencing the Severity of Chronic Rhinosinusitis

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You are being invited to take part in a research study. Before you decide to agree it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

We are looking to see if factors such as where people live and other medical conditions they have affect the severity of their nasal and sinus symptoms (chronic rhinosinusitis).

2. Why have I been chosen?

You have been chosen because you have been diagnosed with chronic rhinosinusitis (inflammation of the nose and sinuses for more than 12 weeks). If you do not have chronic rhinosinusitis you have been chosen as a control against which we can compare those people who do have chronic rhinosinusitis.
3. **Do I have to take part?**

No.

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to complete the questionnaires. A decision to not to take part, will not affect the standard of care you receive. By agreeing to take part you will be helping us achieve valuable information into patients suffering with your type of symptoms.

4. **What will happen to me if I take part?**

You will be given a questionnaire in 3 parts which will take 10-20 minutes to complete in total. You can either opt to complete this after your appointment and hand it to the doctor before leaving or take an addressed return envelope so that you can complete the questionnaire at your own convenience. You can also complete an electronic version on a laptop computer, when available. Participation in this study will not interfere in any way with your treatment at the ENT department.

5. **Will my taking part in this study be kept confidential?**

The questionnaire is totally anonymous and you will not be identifiable from it. The information from the questionnaire you complete will be compiled and will be held securely on a password encrypted database. Your case notes will not be used for the purposes of this study.

6. **What will happen to the information from the questionnaires I complete?**

The information will be analysed by the researchers to look for any common patterns in patients who suffer with chronic rhinosinusitis. It will be discussed amongst specialists in the field of Ear, Nose and Throat surgery in order to determine whether certain patients are likely to have worse symptoms from their nose and sinuses due to other factors in their history. This information will be published in medical journals and the database will be kept for 10 years and then disposed of securely in compliance with the Data Protection Act. Any interview recordings will also be stored securely at the University of East Anglia in the same fashion.

7. **Who is organising the research?**

The research is organised by Mr Carl Philpott. The researchers are not paid for this study other than their normal salary.
8. Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS research ethics committee before it goes ahead. This study has been reviewed by the Oxford Research Ethics Committee C. Approval does not guarantee that you will not come to any harm if you take part. However approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

9. What happens if I wish to withdraw from the study?

Once your questionnaire has been returned to the researchers, it will not be possible to retrieve it due to the anonymous nature of the study.

10. What if I am harmed by the study?

Nothing in this study is expected to cause you any harm. In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds for a legal action for compensation against the University of East Anglia but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

11. Contact for further information.

If you have any queries or concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. In this situation please don’t hesitate to contact:

Mr Carl Philpott
ENT Consultant
James Paget University Hospital
Via the secretary on 01493 452832 or via switchboard (contact available 24/7)

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital through the Patient Advice & Liaison Service on 01493 453240.

Thank you for reading this.