HEaD Patient Information Sheet v1.7

[insert hospital here]



# Study title

Headache in Emergency Departments - HEAD

# Invitation and brief summary

The HEAD study aims to understand the difference between how various types of headaches are dealt with by the Emergency Department. This study doesn’t involve any additional treatments or tests, and no extra questions other than those that your Doctor will ask you routinely.

We aren’t seeking written consent for this study because it involves no change to your clinical assessment or care. However, if you don’t want to take part it is easy to opt-out as described below.

## Why is the study happening?

Headache is a common reason for presentation to emergency departments (ED). The vast majority of headaches are benign and do not require any invasive testing, but a minority of headaches can have a serious underlying cause.

This study is trying to discover what features indicate a more serious type of headache, how Doctors currently investigate headache across the world and how the management of headache varies between hospitals. With this information we hope to give Doctors and Patients a clearer understanding of when to be worried about a headache, what is the best way to investigate a headache and importantly what treatments may help improve headache symptoms.

## What does the study involve?

The data we will be collecting will be about your symptoms, contributing factors like your other medical problems and what treatment you have taken at home. We will then compare this to the investigations and final diagnosis you had whilst in hospital and what treatment your hospital gave you. To take part in the study you don’t have to do anything. The information we need is the information you will be speaking to your Doctor about today during your routine care. We won’t need to ask you any further questions, either today or at a later date.

North Bristol NHS Trust (NBT) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NBT will keep identifiable information about you for 1 year after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you opt-out of the study, any information collected about you will be deleted. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information:

https://www.nbt.nhs.uk/about-us/information-governance/privacy-policy-data-protection

[HOSPITAL] will collect information from you and your medical records for this research study in accordance with our instructions. [HOSPITAL] will keep your name, hospital number and contact details confidential and will not pass this information to NBT. [HOSPITAL] will only use this information to pass your details to the clinical care team if we find something on the scan that we need to discuss with you . Certain individuals from NBT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NBT will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, hospital number or contact details. [Hospital] will keep identifiable information about you from this study for 1 year.

## What are the possible benefits of taking part?

There will be no direct benefit to you by taking part. However, this research may change the way that headaches are managed in the future and therefore impact on your future treatment. It could also positively impact someone who comes to the hospital with the same problem as you.

## What are the possible disadvantages and risks of taking part?

The only risk within the study is one of data storage. However, we have minimised this through use of a specialist medical database service which conforms to all current international standards. We are also treating this project like any serious research study, with strict oversight and regular review.

## Who has organised the Research?

This study is an International project, examining headaches around the world. The co-ordinating centre is based in Australia. In the UK, this study is supported and led by NBT research and development team. The study has been reviewed and approved by [ETHICS COMMITTEE].

## What if I don’t want to take part?

If you decide you don’t want to be involved in this study, this will not affect your medical care in any way. You can simply tell the Doctor or Nurse seeing you during this attendance or you can contact the research team by email or telephone. The contact details are at the bottom of the sheet. You do not need to give a reason and even if you don’t initially opt out, you are free to change your mind and withdraw at any stage. You can choose to opt-out for 4 weeks after your attendance today.

## When will I hear about the results?

Once we have collected all the data, the results will be published in a medical journal. This means that Doctors can read the results and have the opportunity to change how they manage headaches.

## More information and helpful resources

Further detail on this study can be found on the educational website for the Royal College of Emergency medicine, at the following web address. Or you can scan in the QR reader provided on the reference card to your mobile phone:https://www.rcemlearning.co.uk/foamed/current-projects-hed/

There are also many national organisations that provide advice and guidance for patients with headache symptoms. Try any of the following of you want to learn more about common headache conditions:

<http://www.bash.org.uk>

<https://www.nice.org.uk/guidance/cg150/ifp/chapter/About-this-information>

## What if my symptoms get worse?

This study is not trialling new medicines or testing strategies. The research team will also not be able to offer any clinical advice on your condition. If your symptoms change or you are worried, please get in touch with your GP or reattend the ED.

## Contact Information

Version: 1.7

Date: 11 June 2019

Site: [HOSPITAL]

Principal Investigator: [NAME]

Research Team contact details: [EMAIL@EMAIL.COM] / [PHONE NUMBER]

Disclaimer:
‘In the unlikely 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 North Bristol NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.’