ACTIOHN
ACTIVITY AS MEDICINE – HEAD AND NECK

Local headed paper

PATIENT INTERVIEW INFORMATION SHEET

Activity as medicine in oncology for head and neck

The ACTIOHN Study

You are invited to take part in an interview as part of the ACTIOHN study

- We understand that a team member discussed the ACTIOHN study with you recently. We're now inviting you to talk with a researcher about your experience of that discussion and your views of the ACTIOHN study. We'd like to talk people who didn't take part in ACTIOHN as well as those who did. This is so we can improve studies like ACTIOHN for future patients.
- Before you decide whether or not to speak to the researcher it is important for you to understand why the ACTIOHN Interview Study is being done and what it will involve. Please take time to read this sheet carefully and discuss it with others if you wish.
- Talking to the researcher is voluntary. If you don't want to, that's ok. Your care will not be affected and you don't need to give a reason.
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Important things you need to know about the ACTIOHN Interview Study

- Our aim in doing the interview study is to improve how we do research studies like ACTIOHN. We are very interested in hearing about your views of ACTIOHN and exercise so that we understand what really matters to patients. Your views are very important to us.
- If you agree to take part, a researcher will contact you to arrange a convenient time to talk with you. With your permission the conversation will be audio-recorded.
- The conversation(s) will usually take place in by telephone or Skype/Zoom as you prefer, and last for about 40-60 minutes. If there are any questions that you don't want to answer, just tell the researcher and s/he will move to the next question. You can also stop the interview at any point.
- All information collected during this study will be kept confidential. This means that apart from the ACTIOHN Interview Study research team, no one, including your doctors and nurses, will know what you have said.
- A typing agency will type out the recordings, but all names will be removed before analysing the transcripts. The recording will be marked with a number only and destroyed as soon as possible.
- We may include brief quotations from some patients in our reports, but we will always change details such as names and places so nobody can be identified.
- We cannot say that you will benefit from talking with the researcher, but many people find it useful to have a chance to air their views.

Please continue to read the supporting information below if you are interested in taking part.

What will happen if I don't want to carry on in the study?

You can withdraw your consent at any time and for any reason, without having to give an explanation. Your care will not be affected in any way. We will ask if you are happy for us to:

- use any information already collected about you
- continue using information collected as part of your usual care until the end of the study.

What if there is a problem?

If you are not happy with any part of ACTIOHN, you should ask to speak to the study team first who will do their best to help you. Their contact details included at the end of this information sheet. If you are still unhappy you may wish to raise your concerns with someone who is not directly involved in your care. You can contact the Patient Advice Liaison Service (PALS) who provide a confidential service on 0800 0320202, www.PALS.nhs.uk.

In the unlikely event that you are harmed during the research and this is due to someone's negligence, you may have grounds for legal action for compensation, but you may need to meet your own legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

Will my GP be told about my involvement in ACTIOHN?

Yes, we will inform your GP that you are taking part. It will also be noted in your hospital medical records so that staff in the hospital are aware.

Will the information about me be kept confidential?

Yes. All of the information collected will be entered on computers that are kept secure and password protected.

- We will use a number to identify you instead of using your name.
- Your contact details will only be shared with the Cancer Exercise Specialist - nobody else will be able to access these.

The study information and your medical notes will be looked at by people directly involved in the study. Research regulatory authorities may access the information, to check the study is running as it should. Your personal data will be kept according to the General Data Protection Regulation and Data Protection Act 2018. More information on research data can be found at www.hra.nhs.uk/information-about-patients

What will happen to my data?

The University of Liverpool is the sponsor for this study based in the United Kingdom. We will be using information from you and your hospital patient medical notes 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.

Research is a task that we perform in the public interest. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 6-12 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at The University of Liverpool for 10 years after the study has finished after which time any link between you and your information will be removed.

The [insert local NHS Trust] will use your name and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They will keep identifiable information about you from this study for 6-12 months after the study has finished.

Data Protection Privacy Notice

The University of Liverpool conducts research to the highest standards of research integrity. As a publicly funded organisation, the University has to ensure that it is in the public interest when we use personally identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website:

(https://www.liverpool.ac.uk/legal/data_protection/policy/)

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Liverpool is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

How will we use information about you?

We will need to use information from your hospital medical records for this research project.

This information will include

- Your name
- Your NHS number
- Your 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 or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you 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/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to joanne.patterson@liverpool.ac.uk or legal@liverpool.ac.uk or daniel.howarth@liverpool.ac.uk

Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team (debra.fisher@liverpool.ac.uk or joanne.patterson@liverpool.ac.uk). If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What will happen to the results of the study?

Results will be published in medical journals, presented in meetings to other HaNC teams and researchers and a report will be written by the study funder. Findings will be available at the end of the study on our website (www.Liverpoolheadandneckcancer.co.uk). You will not be named in any of these reports, and they won't include any information that could identify you. We will send you a summary of the results at the end of the study if you would like one.

Who is organising and funding ACTIOHN?

The main person for the study is Professor Jo Patterson, University of Liverpool. The study team includes senior doctors and physiotherapists, exercise specialists, research experts, and members of the public. It is funded by the National Institute for Health Research, Research for Patient Benefit scheme. The project is sponsored by the University of Liverpool.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. ACTIOHN has been reviewed and given a favourable opinion by the XXX Research Ethics Committee. Patients have been involved in deciding how to do the ACTIOHN study from the start and have helped devise the patient materials.

What if I have any questions?

Please ask the doctor or nurse who is looking after you. They can put you in touch with the research team for ACTIOHN at your hospital.

What happens next?

You can take time to think about the study and whether you want to take part. A member of the research team will contact you, if you have any more questions. They can go through this information sheet with you before you make your final decision.

ACTIOHN team contact details for your hospital:

Principal Investigator:

Research Nurse:

Thank you for taking the time to read this information sheet.

How to contact us

Please contact us if there's anything that's not clear, or you would like more information: (Researcher name, email, postal address and telephone number).
Alternatively, please contact your local researcher on the main ACTIOHN study (Local PI name and contact details).