ACTIOHN
ACTIVITY AS MEDICINE – HEAD AND NECK

Local headed paper

MAIN STUDY PATIENT INFORMATION SHEET

Activity as medicine in oncology for head and neck

The ACTIOHN Study

We wish to invite you to take part in a research study. Please read the following information to help you decide if you want to participate. We want you to understand why we are doing this research and what it might mean for you. You do not need to decide straight away. Please feel free to talk to others about it if you wish. Please ask us if there is anything that is unclear or you want to know more.

Study Summary

- There are many proven benefits of keeping active or exercising before, during, and following cancer treatment. These include reducing side-effects, and improving health and well-being. We want to find out ways to help head and neck cancer (HaNC) patients maintain or increase their activity levels and participation in exercise.
- Many HaNC patients find it difficult to keep active and/or exercise, for several reasons such as treatment side-effects, other health problems, or just finding things that they can do and having the confidence to do them.
- The ACTIOHN study aims to develop an activity programme tailored to patients' needs, ability and preferences.
- Patients can decide whether they want to join before or up to 8 weeks after treatment finishes. They will be helped by a Physiotherapist and trained Cancer Exercise Specialist.
- The activity programme will last for 8 weeks in total
- The results will tell us how best to provide this programme and whether we can plan a bigger study to fully understand the effect of this intervention

Please read the following information if you may be interested in taking part

Why is the ACTIOHN study needed?

An activity programme for people with cancer can help reduce treatment side effects, speed up recovery and improve quality of life. Our survey found that many HaNC patients want to participate in an activity / exercise programme. While patients with other types of cancer may have this opportunity, this is not yet part of HaNC care. We don't know the best ways to

provide this due to HaNC symptoms and side-effects, which activities to advise and when to introduce the programme. ACTIOHN is a small study to help answer some of these questions.

Why have I been invited to take part in the ACTIOHN study?
You have been invited because you have been diagnosed with HaNC and are due to have, or have completed treatment. The study is available only to people at two centres: Liverpool University Hospitals Foundation Trust and South Tyneside and Sunderland NHS Foundation Trust.

Do I have to take part?
No, it is up to you to decide if you want to take part in ACTIOHN. If you do not want to take part, your decision will not affect the standard of care or treatment that you will receive. If you agree to take part, you can change your mind and withdraw from the study at any time without having to give a reason.

What does taking part involve?
ACTIOHN is an 8-week activity / exercise programme tailored to your ability, level of fitness and preferred activities. You will be guided and supported by a qualified Cancer Exercise Specialist. We will collect information on your health and well-being at the start and end of the programme. You will be invited to take part *before* you start HaNC treatment. If you decline, we will ask your permission to offer the opportunity again at the *start* or within two months following the *end* of your HaNC treatment.

What will happen first?
Your HaNC team will first check that you are suitable for the programme. A member of the team will check that you've understood the study information and will answer any questions. If you are happy to take part, they will ask you to sign a consent form. Then, you will be assessed by a Physiotherapist for your level of fitness and any physical difficulties relating to your HaNC. They will send your preferred contact details and assessment results to our Cancer Exercise Specialist.

The Specialist will contact you within one week, to develop your programme. They will ask you whether you have exercised in the past, which activities or exercises you enjoy, what might get in the way of doing them and what you want to achieve. Taking all of this into account, they will create a programme specially for you.

What will I have to do?
You will be asked to follow the programme, as best as you can manage. You will have a diary to complete every day, to monitor your progress with the activities / exercises. We also want you to record any problems you've had doing the programme. The Physiotherapist will repeat the same fitness assessments at the end of the programme

How will I be supported?
The Specialist will contact you every week during the programme, either by phone or video-call. They will check whether the programme needs to be changed if it is too easy or too difficult for you. They will help solve any problems you are having, and advise you on things that can help. They will text you two times a week, to help you keep up with the programme.

You will be given 1) a 'top-tips and exercise stories' leaflet, written by HaNC patients and 2) a cancer exercise website link 3) either a booklet or app to show you exactly how to do the exercises.

Collecting Data
We will use some information that is already collected about you, as part of your clinical care e.g. age, type of treatment. For our study evaluation, we will collect the Physiotherapy assessment information and your daily programme diary.

Patient Interviews
We would also like to talk to people to see what they think of the study, to help improve the intervention. It's important for us to talk to as many people as possible, including those who decide not to take part in ACTIOHN as well as those who take part. We might not need to contact everyone. If we do contact you, a member of the research team will call you to answer any questions and arrange an interview.
A member of the ACTIOHN team will give you more information to take away and read. We will need your written consent for a member of the study team to call you and talk to you about it further.

What happens when the research study stops?
At the end of the study you will receive a plan from the Cancer Exercise Specialist, to encourage you to maintain your activity / exercise. You will continue to receive usual clinical care.

What are the benefits of taking part?
We hope that by participating in ACTIOHN we can improve HaNC patients' health and quality of life. At present, we cannot say for sure whether or not it will help you.

Are there any possible side effects?
The Cancer Exercise Specialist is fully trained to develop a programme that is safe and should not result in any side-effects. You will be given a safety advice sheet, to help prevent any activity-related problems, with guidance on when to seek further help.

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.Liverpoolheadand neckcancer.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.