



UNIVERSITY OF
CAMBRIDGE



Healthy Volunteer Information Sheet

TASCC

*UNDERSTANDING THE PERCEPTION OF **TASTE**
AND **SMELL** IN **CANCER CACHEXIA***

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UNDERSTANDING THE PERCEPTION OF TASTE AND SMELL IN CANCER CACHEXIA (TASCC)

You are invited to participate in a research study. Before deciding whether to take part, it is important that you understand the purpose of the study and what your participation will entail.

Please take sufficient time to read the information carefully and discuss it with others if you wish. The research team are happy to discuss all aspects of the study.

What is the purpose of the study?

We want to find out more about how living with cancer can disturb taste and smell perception. We think this is an important question because the ability to taste and smell is really important in determining how and what we eat. If your appetite and desire for food is poor this can cause unintended weight loss. This is a real problem in people living with cancer because it is poorly understood, difficult to reverse and get in the way of effective anti-cancer treatment.

Although some of the drugs and treatments for cancer are well recognised to upset people's sense of taste and smell, we think that the cancer itself may be driving these changes in perception and we want to know more about how this happens. If we can do this, ultimately, we hope to be able to better predict who might be at biggest risk of unintended weight loss and look to be able to focus our efforts to try and stop it happening in the first place.

The first step in that process is to be get an accurate measure of what is really happening to people's appetite and their ability to taste and smell.

Why have I been invited?

This study will look at both patients living with cancer and people without cancer as (healthy volunteers). You have been approached because you are a healthy volunteer.

It is important for the research team to collect data from healthy volunteers; we can compare the responses from participant living with cancer and healthy volunteers. If we can successfully identify the difference, it is possible that this could be possible early screening tools for risk stratification of cancer cachexia and potential to improve the lives of people living with cancer.

Do I have to take part in this research?

No. Taking part in this study is completely voluntary. Your decision will not affect your clinical care and treatment in any way. If you decide to participate, you will be provided with more detailed information and will be asked to sign a consent form. You are still free to change your mind and withdraw the study at any time without giving a reason.

What does the study involve?

This study involves a series of self-reported questionnaires, some simple office based interactive assessments of taste and smell perception, a dual-energy X-ray absorptiometry (DXA) body scan to get a measure of body fat and lean body mass and a blood sample being collected. These are explained in more detail below, but these are all carried out in a single morning visit.

What will happen to me if I take part?

If you are interested in taking part, the study team will arrange a telephone screening call at a convenient time to check if you have any health conditions which may prevent you from participating in the study. All information from the telephone screening will be kept confidential.

i) Eligibility

To be eligible for this study as a healthy volunteer, you must meet the following criteria:

- Aged 18 years or above
- Willing and able to comply with study procedures and visits
- Not have or be recovering from any form of cancer
- No unintentional weight loss or unexplained loss of appetite
- No pre-existing taste or smell disorder and no history of neurological disorder affecting sensory function
- No active inflammation (e.g. mucositis, oral thrush) and/or active infection having symptoms and/or requiring antibiotics
- Non-smoker or Stopped smoking at least 3 months ago
- Not pregnant or breast feeding (for women participants)

ii) Study visit

If you are eligible to take part and wish to participate you will be invited to attend the TRF (Translational Research Facility) for a morning session lasting no more than 3 hours.

The TRF is a clinical facility staffed by nurses and a dedicated study doctor. When you arrive, a member of the research team will meet with you to go through this information sheet and answer any questions you may have. You will then be asked to provide written, informed consent to proceed with the study.

You will be asked to complete a nutrition intake record for at least 5 consecutive days by using “Intake 24”- a simple to use, computerised dietary recall system. The study team will send you a link and will guide you how to use it.

We will ask you to take your usual breakfast in the morning of the study visit, however, please do not eat or chew bubble gum or drink coffee/tea for **1 hour before the taste and smell assessment.**

Medical History and Physical Examination

The study team will ask you questions about your demographics, medical and surgical history and medications and if required, may carry out a clinical examination. Vital signs, weight and height will be recorded. Women of childbearing age will be asked to provide a urine sample for a pregnancy test. The urine sample will be tested by a research nurse and discarded. This will be completed prior to the DXA scan for safety reasons. The study team may review and document routine blood test results conducted between 24 months prior to consent and up to 2 months after completion of the study. If these results are recorded by a local hospital and/or GP surgery, the study team may request them.

Taste and Smell test

Taste strips test evaluates a person's ability to perceive and identify basic tastes of impregnated paper strips with sweet (sucrose), sour (citric acid), salty (sodium chloride), bitter (Quinine hydrochloride dihydrate) and additional umami (sodium L-glutamate monohydrate) and some strips with no taste. Tweezer will be used to pull out taste strips. You will be asked to place the taste strip in the middle of the tongue, close your mouth and move tongue and the strip slowly back and forth to dissolve the substances in the saliva. The strip can be flipped and placed on the tongue again. The mouth must be rinsed with water after testing each taste strip.

Smell test will be evaluated by Sniffin' Sticks test to identify 12 different smells from daily experience. Disposable paper strips will be used for each participant, and it will be disposed with sealed bag after the test.

Dual-energy X-ray absorptiometry (DXA) scan

As part of this study, you will be asked to have a DXA scan whilst you are in hospital. DXA scans are being performed as part of this study to assess your body composition (the amount of fat, bone, and muscle in your body).

This type of scan uses low dose X-rays (ionising radiation) called dual energy X-ray absorptiometry (shortened to DXA). The scan involves lying on your back on a table bed whilst a large scanning arm passes slowly over your body. As the scanning arm passes slowly over your body, a narrow beam of X-rays will be passed through the parts of your body being examined. Some of the X-rays that are passed through your body will be absorbed by tissue, such as fat and bone. An X-ray detector inside the scanning arm measures the amount of X-rays that have passed through your body and uses the information to produce an image of the scanned area.

The scan is a quick and painless procedure, but you will be asked to keep very still during the scan, so the images are not blurred. The scan usually takes about 10 to 20 minutes.

Questionnaires

You will be asked to complete a number of questionnaires relating to taste and smell perception changes and food intake. The questionnaires can be completed either on a computer or in paper form, and if you are unable to complete these on the day of the study visit, these can be completed at home within 5 days of the study visit.

Blood tests

You will be asked to provide a 20ml (approximately 4 teaspoons) blood sample which will be confidentially stored and may be used in the future for ethically approved research. Blood taken from you will be immediately processed to remove human cells. The samples will be labelled with anonymous ID. Analysis of the samples may include measurement of circulatory factors relevant to body weight, body composition and metabolism and may involve collaboration with research organisations and academic institutions outside the UK.

Are there any drugs involved?

No. There are no drugs involved in this study. You will continue on your usual medication.

What are the possible risks of taking part?

The procedures and investigations are all very safe, but may involve discomfort from blood draws, or claustrophobia. The DXA scans will involve a very low dose of X-rays (ionising radiation). These are additional to that you would have if you did not take part. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small (0.00001 - 0.0001%) chance of this happening to you.

You may get some slight bruising where the blood sample is taken from your arm, but this will subside quickly. If at any point in the study you feel uncomfortable and unable to continue, you can ask to stop the session. You will have the option of either withdrawing completely from the study at that point or only continuing with part of it. For example, if you feel claustrophobic in the scanner, you can press the alarm bell, and we will stop the scan and get you out.

The strong taste or smell stimuli may rarely trigger some mild discomfort or malaise. There is possibility of unpleasant tastes or smells, even at low concentrations.

What are the possible benefits of taking part?

We acknowledge that it is unlikely that the study will immediately benefit the participants. However, any insight we can gain into the relationship between alteration in taste and smell perception and food intake in people with cancer will greatly improve our understanding of what drives weight loss in cancer and better inform future care to improve the lives of people with cancer.

Will I be reimbursed?

Participants will be reimbursed £20 for their time and effort involved with taking part in this study. Additional reasonable travel expense and parking will also be reimbursed.

What will happen at the end of the study?

At the end of the study session, you will be seen by the study team to make sure you are well. Participants will receive a lay summary of the study results either by post or email. After the study is completed and the data are analysed, we will publish the results of this research at scientific conferences and journals to share the results with other

researchers. However, no-one will be able to identify you as one of the participants in the study.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your full medical and surgical history and demographics [gender/ethnicity and age]. Once data collection is complete, data will be stored in an pseudonymised manner.

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.

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the Sponsor of this research and are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- our partners who analyse your samples
- other public sector research organisations, academic institutions, charities and both commercial and non-commercial organisations

We will keep all information about you safe and secure by:

- Limiting who can access your data so only personnel who have been given permission / authorisation may access it
- Keeping paper copies of your data in locked filing cabinets in restricted access areas
- Keeping your electronic data on secure computers that are password protected
- If consent has been given for samples to be used in future research, all samples will be sorted with a unique ID and only anonymised information will be disclosed for future ethically approved research.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- help maximise the benefit of conducting trials and allow other researchers to verify results and avoid duplicating research.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data (as **anonymised** information) that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- our partners who analyse your samples

- other public sector research organisations, academic institutions, charities and both commercial and non-commercial organisations

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- some of the countries your data may be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK, which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner's Office \(ICO\) website](#)
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the Information Commissioner's Office \(ICO\) website](#)

How will we use information about you after the study ends?

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.

We will keep your study data for a maximum of 5 years. The trial data will then be fully anonymised and securely archived or destroyed.

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.

If you choose to stop taking part in the study, we would like to continue collecting information about your medical history. If you do not want this to open, tell us and we will stop. We may not always be able to do this if it means we cannot use your data to do the research, if so, we will tell you why we cannot do this.

If you take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information at:
<https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/lookingafter-your-information> or

email the Data Protection Officer at: cuh.gdpr@nhs.net

Who is organising and funding the research?

This study team is part of a wider consortium called “Cancer Cachexia Action Network (CANCAN)” and we are funded by the Cancer Grand Challenges initiative (Cancer Research UK and the National Cancer Institute). The researchers for this study are based at the Institute of Metabolic Science, University of Cambridge. This study is jointly sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge.

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the clinical trial caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the trial, but no-one has acted negligently. The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the clinical trial.

Who has reviewed the study?

The study has been reviewed by the Cambridge South Research Ethics Committee and was peer-reviewed by the Research Advisory Committee (RAC) at Cambridge University Hospitals NHS Foundation Trust. This committee comprises of twenty leading academics employed by both Cambridge University Hospitals NHS Foundation Trust and University of Cambridge, including experts in this study’s field. The committee meet quarterly to review studies and provide independent peer review for proposed studies that will be sponsored solely by Cambridge University Hospitals NHS Foundation Trust or jointly with the University of Cambridge. To maintain the independence of the committee all reviews are undertaken in a confidential manner.

What if there is a problem?

If you have a concern about any aspect of this study, please ask to speak to the researchers who will do their best to answer your questions. If you are unhappy about the conduct of the study and wish to complain, you can do this through the Addenbrooke’s Patient Advice and Liaison Service (PALS). You can contact PALS by calling 01223 216765 or by email: cuh.pals@nhs.net.

Will my taking part in this study be kept confidential?

All information collected about you during the study will be kept strictly confidential. The normal principles of confidentiality apply just as when you visit your doctor. There are rare occasions when doctors and researchers are obliged to break confidentiality, and this is when they are concerned for your safety or for the safety of others. In such situations, the doctors and researchers have a duty to inform the relevant authorities and take the necessary steps to ensure your and/or other people’s safety. If any lab tests, questionnaires or any other measurements made during the screening or procedures of this protocol show clinically significant abnormalities that may impact your health or

well-being, you will be notified by a member of the research team and appropriate follow-up with your GP will be arranged with your consent.

What will happen to my samples?

We will collect a 20ml (approximately 4 teaspoons) blood sample from you. These samples will be labelled with anonymous ID and stored in case we decide to measure any relevant components within the blood in the future ethically approved research. Analysis of the samples may include measurement of circulatory factors relevant to body weight, body composition and metabolism (**not include genetic analysis of a participants' DNA**) and may involve collaboration with research organisations and academic institutions outside the UK. If you withdraw from the study, your samples will be destroyed, however, any data gained from them may still be included in the study. All samples will be stored securely in the Institute of Metabolic Science, University of Cambridge. Only members of the research team will have access to your samples. All samples will be stored with a unique ID and only the research team will be able to link this ID back to you. These samples will be stored for a minimum of 15 years.

If you would like more information:

We encourage you to think about the points made on this information sheet. You can contact one of the research team members (see below) if you have further questions, and we would be very happy to discuss these with you.

If you have any questions about the study, please contact the study team via email:

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