PARTICIPANT INFORMATION SHEET

PROTECT sub-study:

Smell and Taste function in older Adults in covid-19 Pandemic (STAP)

Thank you for taking part in the PROTECT Study. We would now like to invite you to take part in the above sub-study which will be sponsored and led by King's College London. Before you decide whether to participate 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 friends and relatives if you wish. Please ask a member of the research team if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. If you decide to take part, you may keep this information sheet.

What is the purpose of the study?

In the UK, people with respiratory symptoms or fever are currently being tested for covid-19. However, there is new evidence for the loss of smell and taste as a symptom of covid-19 infection, sometimes in the absence of any other symptoms. Patients with isolated symptoms of loss of smell and taste do not currently meet the criteria for testing and could therefore be missed. Identification of people with these symptoms is important as impairment in smell has been linked to poor quality of life, depression and increased risk for dementia.

This study aims to evaluate smell and taste function in older adults during the covid-19 pandemic period and understand its impact on quality of life, mental health and cognition. Additionally, we aim to identify, in as close to real time as possible, individuals who have loss of smell using a home smell test kit.

Why have I been invited to take part?

You have been invited to take part because you are existing participant of the PROTECT study and have agreed to be contacted for future studies. We are giving you the opportunity to take part in this sub-study because it may help us to understand more about the symptoms of covid-19 and their impact on health and wellbeing.
All participants are invited from PROTECT study who are above 50 years of age without dementia, whether affected with or without covid-19 illness and who are able to complete the questionnaire. However, it may not be appropriate for people if they have suffered with smell impairment even before the covid-19 pandemic due to other causes (e.g., nasal surgery, nasal polyps, head injury).

Do I have to take part?

It is up to you to decide whether or not to take part in this sub-study. If you decide to take part, you will be emailed a copy of this information sheet and will be asked to sign an online consent form. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the PROTECT Study, who are essentially acting as gatekeepers for us to conduct this sub study.

What will happen to me if I take part?

If you would like to take part in this study, you will be asked to fill in a consent form on the PROTECT Study website.

Survey: We would like to collect information on your smell function, taste function, as well as information relating to other covid-19 symptoms, testing, diagnosis and management with additional questions on vaccination and re-infections. If you have experienced loss of smell as a symptom, we would also like you to answer some questions that will assess the impact of changes in your smell function on your quality of life. The survey will be completed through your account on the PROTECT Study website.

The survey will take approximately 5-10 minutes to complete but may be longer for people who have been more affected. We will contact you every 3 months for 1 year to repeat the survey.

Home smell test kit (optional): At the final survey, whether you have experienced smell loss as a symptom or not during the covid-19 pandemic period, you will be able to consent to receive a home smell test kit. The smell test kit will be sent to your preferred address with clear instructions on how to fill it in, which takes about 10-15 minutes. A pre-addressed envelope will be provided for you to post your smell test kit back to us. The test is not diagnostic and should in no way affect the way that you manage your healthcare and you should continue to follow normal national and NHS guidelines.

PROTECT Study data: Information, such as demographic, medical history, lifestyle, mental health and cognitive data already collected as part of the main PROTECT Study will help us to analyse the impact of smell and taste function.

What are the possible benefits and risks of taking part?

This is an 'observational' study, meaning we only wish to observe how you progress over time. There is a small risk that some people may find certain questions difficult to answer. You should only answer those questions that you are comfortable with. You do not need to answer any questions that you are not sure about or you do not wish to.

The main advantage of this research is that participants will be taking part in an important study that could provide valuable new knowledge about some of the symptoms of covid-19 and their impact on health and wellbeing.

What will happen to the data I provide?

King's College London is the sponsor for this study. In working with the PROTECT Study team we will be using information from you in order to undertake this study and will act as data controller. This means that we are responsible for looking after your information and using it properly. The PROTECT Study team will keep identifiable information about you and we researchers will have only the anonymised data. Anonymised information collected as part of this study will be kept indefinitely in accordance with the PROTECT Study privacy policy. For more information about how the PROTECT Study uses your personal data, please see the PROTECT Study privacy policy.

To safeguard your rights, we will use the minimum personally-identifiable information possible. 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 withdraw from the study, we will keep all anonymised information about you that we have already obtained.

Individuals from King's College London may look at your research records to check the accuracy of the research study. The only people in King's College London who will have access to information that identifies you will be people who need to contact you to discuss issues directly relating to the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Will participation be kept confidential?

Your data will be processed in accordance with the General Data Protection Regulation (GDPR). All of the data collected as part of this project will be regarded as strictly confidential and will be held securely until the research is finished. No study data will be available in any identifiable format to anyone outside of the immediate research team. We may share anonymised data from this study with other researchers, within the remit of PROTECT study policy and following necessary approvals.

All data for analysis will be anonymised. In reporting on the research findings, we will not reveal the names of any participants. All research staff are provided with training regarding GDPR and KCL standards for handling data. Any data provided electronically will be stored on a database on a restricted server only accessible by specified members of the research team who have been given authorisation to access the database.

Questions, comments and requests about your personal data can be sent to

The Administrator
PROTECT Study
College House G.03
St Luke's Campus
The University of Exeter
Exeter, EX1 2LU
United Kingdom
Or
The Co-ordinator
PROTECT Study
Institute of Psychiatry, Psychology and Neuroscience
King's College London
16 De Crespigny Park
London SE5 8AF

Alternatively, you may also contact the University of Exeter's Data Protection Officer who is responsible for monitoring compliance with relevant legislation in relation to personal data, by emailing dataprotection@exeter.ac.uk or the King's College London Data Protection Officer at info-compliance@kcl.ac.uk.You have the right to lodge a complaint with the Information Commissioner's Office at www.ico.org.uk/concerns.

What if I change my mind about taking part?
Your decision to participate in this study is voluntary. You can withdraw from the study at any time without giving a reason by logging into your PROTECT Study account and clicking on the Withdraw from Study option in the Manage Account section of the website. Alternatively, you can contact the PROTECT Study helpdesk by emailing support.protect@exeter.ac.uk or by telephoning 01392 725010. If you withdraw from the study, we will retain all anonymised data that we have collected up to the time you withdraw. This includes all anonymised data from questionnaires.

Who is organising this study?
This sub-study is being led by King's College London, nested within the main PROTECT Study, which is led collaboratively by the University of Exeter, King's College London and South London and Maudsley NHS Trust.

Contact for further information
If you have any questions or require more information about this study, please contact the principle investigator, Dr Latha Velayudhan and team on 02078486997.

What if there is a problem?
If you wish to complain or have concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact King's College London using the details below for further advice and information: The Chair, PNM Research Ethics Subcommittee.

Additional information and Frequently Asked Questions are available on the PROTECT Study website. If this does not answer your query you can contact the PROTECT Study team by calling 01392 725010.

Thank you for reading this information sheet and for considering taking part in this research.

Consent to Take Part

- I confirm that I have read and understand the Participant Information Sheet version 3 dated 23.02.2022 for the above sub-study, sponsored and led by King's College London. I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I consent to the processing of my personal information for the purposes explained to me via the Participant Information Sheet. I understand that such information will be handled and stored in accordance with the General Data Protection Regulation (GDPR) and other Data Protection Laws.
- I give my consent for the researchers to access relevant information already being collected about me from the PROTECT Study.
- I understand that my information may be subject to review by responsible individuals from King's College London for monitoring and audit purposes.
- If I chose to withdraw, I understand that all anonymised data will be retained in the study.
- I agree to take part in the PROTECT sub-study: Smell and Taste function in older Adults in covid-19 Pandemic (STAP).