



## **PARTICIPANT INFORMATION SHEET – PATIENTS AND CARERS**

Study Title: Evaluating video and hybrid group consultations

*We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, please ask us. You can also find further information about how researchers use information from patients at: [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)*

### **What is the purpose of the study?**

Some GP practices in the UK invite patients to take part in clinical consultations as a group. These group sessions usually involve 6-8 patients with the same condition or similar health needs. Patients discuss test results, any medication changes and/or other health concerns with a clinician, and also provide support to each other in a group setting. In response to the Covid-19 pandemic, some of these group sessions are now delivered online on video, or involve some people joining online and others in-person in the same 'hybrid' session.

In this research we are working with GP practices where video and in-person group consultations are implemented to better understand what drives successful delivery of this new model of care. The study also examines if there are different experiences between patients attending group consultations and those attending individual appointments, in terms of how they feel about their health, how much they need to use health services and how satisfied they are with the service. We would like to invite you to participate in this survey as someone who participates in one-to-one consultations only at your practice, so we can learn more about the differences between care models.

### **Why have I been invited to take part?**

You have been invited to take part in this research study because in the last 12-24 months you have attended a one-to-one menopause appointment at one of the participating GP practices in our study. All participants should be over 18 years old. We plan to recruit 500 patients and carers to this study in total. We are also involving 20-30 staff, and 10-17 commissioning and policy stakeholders.

### **Do I have to take part?**

No, taking part in this study is voluntary and you can withdraw at any time without giving a reason if you later change your mind.

### **What will happen to me if I decide to take part?**

If you are happy to participate in this study, you will be asked to provide consent. A copy of the record of consent will be given to you or sent by email for you to keep.

The research team will obtain anonymised data from your health records so that we can understand more about your health and usage of health services (over a period of 12 months following a one-to-one menopause appointment in the last 12-24 months).

### **What if I need help from a health or support worker?**

You can ask your support worker, a family member or someone you trust to help you. You can let them know about this information sheet and confirm with them if you want to take part.

### **What should I consider?**

The main thing to consider is whether you are comfortable with responding to survey questions on your experiences and views on primary care services. This could raise some potentially sensitive subjects around your health or care experiences.

### **Are there any possible disadvantages or risks from taking part?**

There are minimal risks in this study other than time commitment.

### **What are the possible benefits of taking part?**

Whilst we cannot guarantee any direct benefit to you, our aim is to use the research results to help improve the NHS. Learning from this study could potentially lead to improved organisation of remote group-based service delivery in general practice, better patient care and self-management.

### **Will I be reimbursed for taking part?**

There will be no reimbursement.

### **Will my taking part in the study be kept confidential?**

Yes. 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 a separate paper record in a locked cabinet of your real name and corresponding code number.

If anything is said that raises a concern of harm to self or others, or suggests poor practice, we have safeguarding obligations to follow this up, which may mean discussing with others.

We will write our reports in a way that no-one can work out that you took part in the study.

Responsible members of the University of Oxford and the relevant GP practice may be given access to data for monitoring and/or audit of the study to ensure that the research being done properly.

### **What will happen to my data?**

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records to do this research and will use the minimum personally-identifiable information possible. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure on a non-networked computer at the Universities of Oxford, York and Exeter.

Research documents with personal information, such as consent forms, will be held securely at the University of Oxford for 15 years after the end of the study. We will keep some of the data so we can check the results.

Some of your information will be sent to our research partners at the University of Exeter.

Data will be handled in line with UK General Data Protection Regulation (GDPR) and the Data Protection Act (2018).

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

<https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how your information is used by asking one of the research team or by emailing the Chief Investigator ([chrysanthi.papoutsi@phc.ox.ac.uk](mailto:chrysanthi.papoutsi@phc.ox.ac.uk))

You can find general information about how patient information is used in research at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

### **What will happen to my data at the end of the study?**

The members of our research team will analyse the data and write some papers and reports, including a summary for the general public. Our findings will be published and available through journal publications. You will not be identified from any report or publication placed in the public domain.

### **Can I change my mind about participating?**

You can stop at any time, without giving a reason and without penalty, by telling the researchers of your decision (using the contact details at the end of this information sheet). Your participation is voluntary and even if you originally said yes, you may change your mind at a later stage (any time before the project end date in May 2025). The researchers will ask for your permission to keep data already collected but you are free to refuse this. Please note information from your consultations is also recorded by the GP surgery as part of standard clinical care and the study team has no control over how this information is processed.

A member of our study team may wish to record a reason about why you have withdrawn for our record keeping, but you do not have to provide one.

### **What if there is a problem?**

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Chief Investigator Dr. Chrysanthi Papoutsi [chrysanthi.papoutsi@phc.ox.ac.uk](mailto:chrysanthi.papoutsi@phc.ox.ac.uk) or you may

contact the University of Oxford Research Governance Ethics and Assurance (RGEA) office on 01865 616480, or the director of RGEA, email [ctrgea@admin.ox.ac.uk](mailto:ctrgea@admin.ox.ac.uk).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

You can contact the local NHS Patient Advice and Liaison Service (PALS), at 01865 221473 or here: < [https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-\(PALS\)/LocationSearch/363](https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363) >

### **How have patients and the public been involved in this study?**

Patient and public contributors helped design the research study and data collection tools.

### **Who is organising and funding the study?**

The project is led by Drs Chrysanthi Papoutsis and Sara Shaw at the Department of Primary Care Health Sciences and funded by the National Institute for Health Research through the Health Services and Delivery Research (HS&DR) Programme.

### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the London - Hampstead Research Ethics Committee.

### **Further information and contact details:**

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please email the Chief Investigator:

Chrysanthi Papoutsis, Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Primary Care Building, Woodstock Rd, Oxford OX2 6GG

E: [chrysanthi.papoutsis@phc.ox.ac.uk](mailto:chrysanthi.papoutsis@phc.ox.ac.uk)

*Thank you for considering taking part.*