Participant Information Sheet

You are invited to take part in a research study. Before you decide to take part here is some information about why the research is being done and what it will involve. Taking part is voluntary and choosing not to take part will not affect your care. You are welcome to ask questions anytime about the study.

What is the purpose of the VIGIL study?

We run a geriatric medicine clinic to discuss the risks, benefits and options before an operation. We also assess and improve people's health while waiting for the operation date. The VIGIL study is trying to find out if we can deliver this type of clinic over a video call.

During the first wave of the COVID-19 pandemic we converted all of our clinics from face-to-face to video appointments. This worked well and received positive feedback from staff and patients. We would now like to collect evidence to work out if video calls are a safe and effective way of doing things when compared to a face-to-face appointment. This requires a large trial of many people having either types of appointment.

The point of this study is to find out if a large study could work. We want to get the process of running a trial right, and check whether patients are able and wish to take part. This smaller study will not show if video or face-to-face appointments are better than one another, but will help us to sort out the complicated process of running a large trial in the future.

Why have I been invited?

You are in the process of being assessed for an operation by the vascular surgical team. You may not have much information about this yet. This geriatric medicine appointment, and others appointments you will have with the vascular and anaesthetic departments, will provide you with the details you need to make a decision about an operation. We are asking everyone having particular operations if they wish to take part in this study.

Do I have to take part?

Taking part is voluntary. If you choose to take part in the study then this will not affect your care. You can leave the study at any time without giving a reason. Contact

details are provided at the bottom of this leaflet. None of the rest of your treatment will change whether you take part or not.

What will happen if I choose to take part?

You will be asked to complete a consent form over the telephone confirming your agreement to take part in the study. We have sent you a blank copy of the consent form for you to read over, but do not need to fill it in

We usually offer people the option for their geriatric medicine appointment either via video call or face-to-face at Southmead hospital. If you agree to take part in the study, then a computer system will decide which option you get. The computer will select at random - this means there is an equal chance of getting either a face-to-face or video appointment.

Both types of appointment will take the same time to complete – about 45 minutes, cover the same topics, and be with the same healthcare staff. You can choose to have a carer, friend or relative present in either type of appointment.

After your consultation, a member of the study team (who is different to the doctor you just spoke to) will ask you to fill out a short questionnaire about your experience. If either you or your doctor is unhappy with the quality of the video consultation, we will offer you an extra face-to-face appointment on a day you are already attending Southmead Hospital.

What happens after this assessment?

We will collect most of the information about your from your medical notes. We would like to collect data at four time points in the study:

When booking the clinic: we will telephone you to ask about the computer equipment you have at home to make sure you can take part

At the face-to-face or video clinic: you will have a detailed assessment of your health which is part of the usual care we deliver in the geriatric medicine clinic. We will also ask you to complete a form about your quality of life.

If you have an operation…while you are in hospital we would like to assess you for any health problems that occur during your stay. We would like to telephone you again three months after your operation to hear about your health and quality of life.

If you do not have an operation…we would still like to collect information from you by telephone three months later about your health and quality of life.

What are the possible disadvantages of taking part?

There are no disadvantages to taking part in the study. There is a chance we can't get all the information we need by the video call, or the video call may fail. In that case we will arrange an extra face-to-face appointment on a day you are already attending Southmead Hospital

What are the benefits of taking part?

Some patients may find a video call more convenient as there is no travelling and you can be in your own home. You will also be contributing to research which although will not benefit you, may benefit others in the future. We are unable to offer any payment or expenses for taking part.

What happens if I lose capacity (the ability to make decisions)?

Some people will become delirious (acutely confused) after their operation. This may cause some people to lose capacity and be unable to decide on continuing to take part in the study. If this happens we will contact a person nominated by you when you signed up at the beginning of the study. We will provide this person with a similar information sheet to this one and check they are happy for you to carry on in the study. If they are not happy they can withdraw you from the study.

Data collection, processing and storage

Your data will be stored and used in compliance with the relevant current data protection laws: Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR). Any information collected will be deleted three years after the study has finished.

Is the study confidential?

All the data we collect from you and your medical notes is confidential. We will only use information that we need for this research study. We will not use your name or other information that could identify you when the results are published.

We will inform your GP you are taking part and send them a copy of the signed consent from so they know you have been involved in this trial.

What will happen to the results of the study?

The results of this study will be presented to other healthcare professionals at conferences and published in a medical journal. If you are interested in receiving the results of the study we can send a copy to you when published.

Who has funded this study?

The Bristol Health Research Charity has funded this project. They are not involved in the design or running of the study.

If you have any questions, or wish to withdraw from the study, please contact:

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