

# A randomised controlled feasibility trial protocol comparing face-to-face and video delivery of a specialist preoperative clinic for older people

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<b>Registration date</b> 06/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

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.

### Who can participate?

Adults over 18 years old, in the process of being assessed for a planned aortic aneurysm operation by the vascular surgical team.

### What does the study involve?

Patients referred from the vascular surgeons will receive a geriatrician face-to-face or video appointment as usual.

We will approach people to consent to the study who need planned aortic aneurysm surgery. This will not include people due an urgent operation. It will also exclude those unable to join a video clinic due to lack of equipment, eyesight or hearing being too poor, or severe communication difficulties.

The admin team will email or post-study leaflets to patients interested. A doctor will call to

answer questions and take consent. If a person lacks capacity (unable to make a decision) to consent to join the trial, an appropriate carer or relative can provide advice to the study team if they would have wanted to join. Consent will be checked at the appointment. Information for the study will be collected before and after the person's operation, while in hospital including any complications, and then after the operation to look at changes in quality of life and abilities at home, as well as readmission to hospital or death.

What are the possible benefits and risks of participating?

Some patients may find a video call more convenient as there is no traveling and they can be in their own home. Patients will also be contributing to research that will although not benefit them, may benefit others in the future. We are unable to offer any payment or expenses for 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 the patient is already attending Southmead Hospital

Where is the study run from?

North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for

March 2021 to April 2023

Who is funding the study?

The Bristol Health Research Charity (UK)

Who is the main contact?

Dr Philip Braude, [philip.braude@nbt.nhs.uk](mailto:philip.braude@nbt.nhs.uk)

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Philip Braude

### ORCID ID

<http://orcid.org/0000-0003-2936-8805>

### Contact details

CLARITY (Collaborative Ageing Research) group

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

310265

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IRAS 310265

# Study information

## Scientific Title

VIGIL - Video In Geriatric Intervention cLinic

## Acronym

VIGIL

## Study objectives

This study aims to provide proof of concept examining the outcomes of a standard-of-care preoperative virtual geriatric clinic, compared to a face-to-face clinic, using standardised perioperative outcomes. It will test feasibility of the intervention with a view to developing a fully powered randomised controlled trial

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 28/02/2022, Leeds and Bradford REC (Meeting held by video-conference via Zoom; +44 (0)207 104 8083, (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 22/YH/0035

## Study design

Single-centre randomized controlled feasibility trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Other

## **Participant information sheet**

See additional files

## **Health condition(s) or problem(s) studied**

Aneurysm surgery

## **Interventions**

Geriatric perioperative care outpatients clinic delivered by video or face-to-face. Patients will be referred by the vascular team where they will be screened for inclusion. Eligible patients will be contacted to explain the study and study information sheets will be emailed or posted. Potential participants will be telephoned two days later to take consent. Participants will be randomised to each arm of the study. The intervention will be delivered by video or in a face-to-face clinic. Follow-up data will be collected during and directly after the consultation, then while and inpatient for the surgery, three months later. If surgery no surgery occurs only three month follow-up will occur.

## **Intervention Type**

Other

## **Primary outcome measure**

To assess the feasibility of delivering a video geriatric preoperative clinic, compared to a face-to-face clinic:

1. Number of patients randomised: The number of patients willing to be randomised to different modalities of delivering the clinic. Success is defined as 50 patients, partial success if 80% are randomised (40 or more patients).
2. Proportion of patients adhering to the intervention allocated
3. Proportion of patients followed up
4. Proportion of completed preoperative assessments:
  - 4.1. Cardiac assessments including:
    - 4.1.1. Blood pressure (in last 12 months)
    - 4.1.2. Electriccardiogram (in last 12 months)
    - 4.1.3. Exercise capacity (completion of Duke Activity Status Index)
    - 4.1.4. Examination for heart failure (fluid balance assessment)
  - 4.2. Cognitive assessments including: T-MoCA (Telephone Montreal Cognitive Assessment)
  - 4.3. Respiratory assessments including: saturations (in last 12 months)
  - 4.4. Diabetes assessments including: HbA1c (within the last 3 months if patient has diabetes)

## **Secondary outcome measures**

1. To assess the feasibility of measuring shared decision making
  - 1.1. Proportion of completed shared decision making tool immediately after the clinic (collaboRATE)
  - 1.2. Proportion of patients that convert to surgery
2. To test feasibility through process mapping of the preoperative pathway:
  - 2.1. Process map of the perioperative pathway to determine optimal time for recruitment
  - 2.2. Suggested time points for delivery of a video clinic
3. To test the feasibility of collecting clinical outcomes of:
  - 3.1. For all patients surgery or not surgery:
    - 3.1.1. Quality of life (EQ-5D at baseline and 3 months post-surgery, or matched time point if not had surgery)

3.1.2. Mortality (at discharge and 3 months post-surgery, or matched time point if not had surgery)

3.2. For those that have surgery only:

3.2.1 Length of hospital stay

3.2.2. Complications (postoperative morbidity score at inpatient days 1, 3, 5, 8)

**Overall study start date**

01/03/2021

**Completion date**

01/01/2023

## **Eligibility**

**Key inclusion criteria**

1. Proposed aortic aneurysm surgery
2. Be able to read and communicate in English
3. Over 18 years old

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**Key exclusion criteria**

1. Emergency surgery prior to clinic attendance (within 1 week of referral)
2. Inability to participate in video consultation due to:
3. Lack of access to appropriate technology
4. Significant sensory impairment: registered blind or functional severe sight impairment e.g. unable to read study materials, or auditory e.g. unable to communicate using the telephone on screening
5. Inability to communicate on the telephone at screening e.g. advanced dementia

**Date of first enrolment**

01/02/2022

**Date of final enrolment**

01/08/2022

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Southmead Hospital**

North Bristol NHS Trust

Southmead Road

Westbury-on-trym

Bristol

United Kingdom

BS10 5NB

**Sponsor information****Organisation**

North Bristol NHS Trust

**Sponsor details**

Research & Innovation Department

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researchsponsor@nbt.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nbt.nhs.uk/>

**ROR**

<https://ror.org/036x6gt55>

**Funder(s)****Funder type**

Charity

**Funder Name**

Bristol Health Research Charity

## Results and Publications

**Publication and dissemination plan**

The completed study will be submitted for peer review journal publication. It will be presented at national conferences. A study report will be written for the Bristol Health Research Charity funders.

**Intention to publish date**

01/01/2023

**Individual participant data (IPD) sharing plan**

Requests for data sharing will be considered at reasonable request in discussion with the funder and sponsor.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 0.21	12/01/2022	18/01/2022	No	Yes
<a href="#">Protocol file</a>	version 1.1		18/01/2022	No	No
<a href="#">Protocol (preprint)</a>		01/09/2022	05/09/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No