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

Submission date
12/01/2022

Recruitment status
No longer recruiting

Registration date
06/04/2022

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact information

Type(s)
Principal investigator

Contact name
Dr Philip Braude

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310265

Protocol serial number
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

Study type(s)
Other

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 partcipants 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(s)
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. Electricardiogram (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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Bristol Health Research Charity

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 0.21	12/01/2022	18/01/2022	No	Yes
Protocol (preprint)		01/09/2022	05/09/2022	No	No
Protocol file	version 1.1		18/01/2022	No	No