VOLATILE VS TOTAL INTRAVENOUS ANAESTHESIA
FOR MAJOR NON-CARDIAC SURGERY

Health Research Authority

FULL/LONG TITLE OF THE STUDY
Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: Study within a trial (SWAT): Rapid qualitative study of patient consent in co-recruiting studies

SHORT STUDY TITLE / ACRONYM
VITAL SWAT

PROTOCOL VERSION NUMBER AND DATE
V2.0 10Aug2023

RESEARCH REFERENCE NUMBERS

IRAS Number:	297034
FUNDERS Number:	NIHR 130573
SWAT registration Number	165

LIST of CONTENTS

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation/Term	Explanation
CI	Chief Investigator
COREQ	COnsolidated criteria for REporting Qualitative research
CTU	Clinical Trials Unit
DAH	Days Alive and at Home
DMC	Data Monitoring Committee
eTMF	Electronic Trial Master File
GCP	Good Clinical Practice
IRAS	Integrated Research Application System
NHS	National Health Service
NIHR	National Institute for Health Research
NVivo	A qualitative data analysis computer software package
PIS	Patient Information Sheet
PQIP	Perioperative Quality Improvement Programme
RAP	Rapid Assessment Procedures
REC	Research Ethics Committee
R&D	Research & Development
SOP	Standard Operating Procedure
SWAT	Study Within A Trial
TIVA	Total IntraVenous Anaesthesia
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
UoW	University of Warwick
VITAL	Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: A pragmatic randomised triaL
WCTU	Warwick Clinical Trials Unit

KEY STUDY CONTACTS

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Committees	Details of all trial committees can be found in the relevant charter.

STUDY SUMMARY

Study Title	Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: Study within a trial (SWAT)
Internal ref. no. (or short title)	VITAL SWAT
Study Design	A formative qualitative study within the VITAL trial to examine ways of consenting patients to two complementary studies
Study Participants	Patients, carers and staff who have either been involved in taking part/delivering VITAL, or who declined to take part in VITAL
Planned Size of Sample (if applicable)	60
Research Question/Aim(s)	1. Explore patient, carer and staff views and experiences with different recruitment approaches 2. Examine patient and carer experiences of participating in VITAL and PQIP (Perioperative Quality Improvement Programme) 3. Identify barriers and enablers to trial set-up, recruitment and trial delivery

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Health Technology Assessment	Grant awarded for the duration of VITAL, VITAL will be applying for portfolio adoption in order to assist with and monitor the set up and ongoing recruitment to the trial, and subsequently to the SWAT. The trial will be eligible for NHS Service Support costs

ROLE OF STUDY SPONSOR AND FUNDER

The University of Warwick will sponsor the study. Sub-contracts delegating responsibilities to research sites will be established using our standard contracting processes with NHS organisations. Coordination of VITAL and SWAT has been delegated to Warwick Clinical Trials Unit. A Trial Master File will be set up according to Warwick SOPs and held securely at the coordinating centre. Sites will be provided with Investigator Site Files, containing all documentation required for both VITAL and the SWAT.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Management Group (TMG)

The Trial Management Group, consisting of the project staff and co-investigators involved in the day-to-day running of the VITAL trial and this SWAT, will meet regularly throughout the project. Significant issues arising from management meetings will be referred to the Trial Steering Committee or Investigators, as appropriate.

Trial Steering Committee (TSC)

The trial and SWAT will be guided by a group of respected and experienced personnel and trialists as well as at least one 'lay' representative. The TSC will have an independent Chairperson. Ongoing meetings will be held at regular intervals determined by need but not less than once a year. Routine business is conducted by email or teleconferencing.

The Steering Committee, in the development of this protocol and throughout the study will take responsibility for:

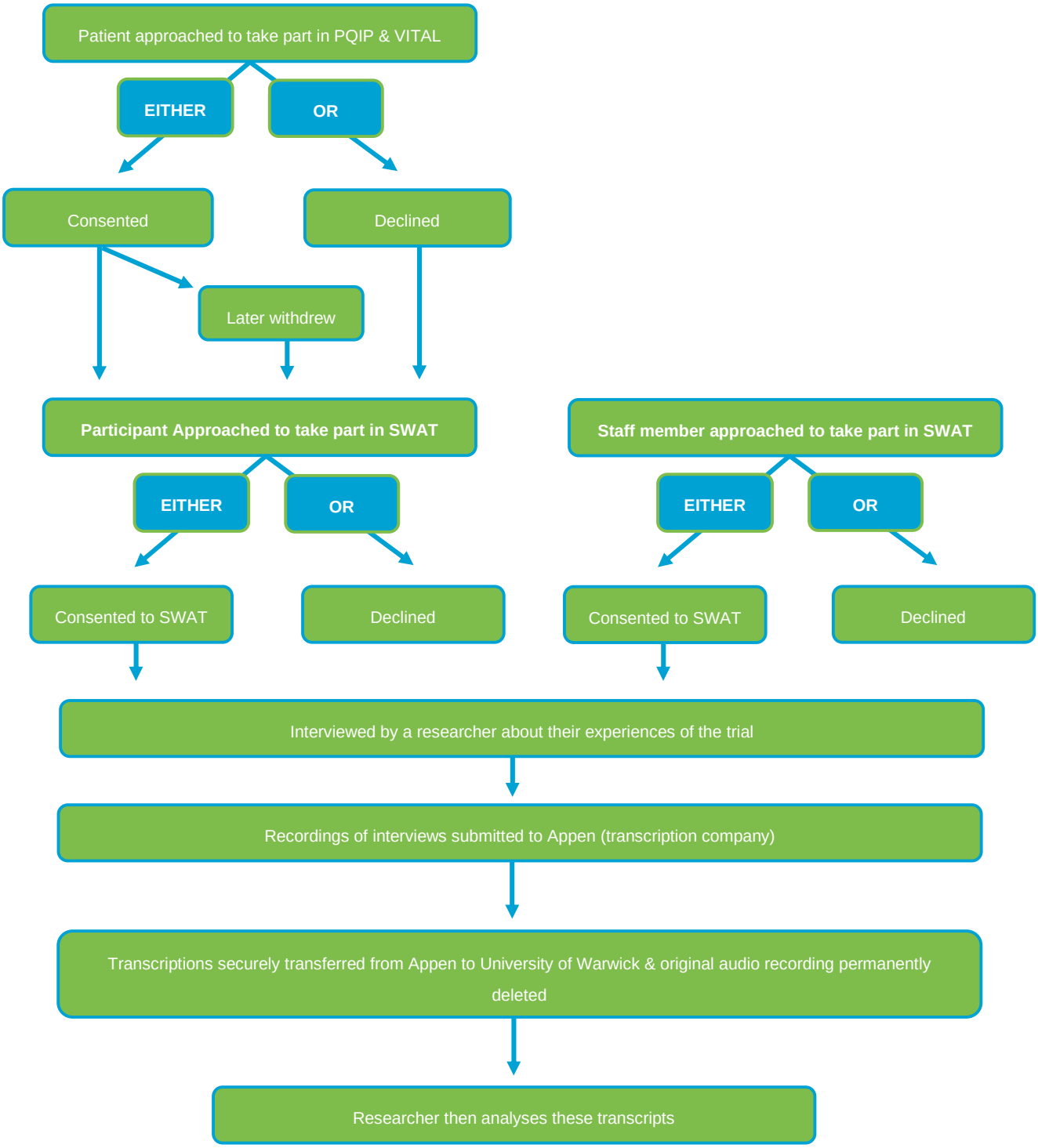
- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the study
- Reviewing relevant information from other sources
- Considering recommendations from the DMC
- Informing and advising on all aspects of the study

The full remit and responsibilities of the TSC will be documented in the Committee Charter which will be signed by all members.

Data Monitoring Committee (DMC)

The DMC will consist of independent experts with relevant clinical research, and statistical experience. DMC meetings will also be attended by the Chief Investigator and Trial Manager (for non-confidential parts of the meeting) and the trial statistician. The full remit and responsibilities of the DMC will be documented in the Committee Charter which will be signed by all members

STUDY FLOW CHART



VOLATILE VS TOTAL INTRAVENOUS ANAESTHESIA FOR MAJOR NON-CARDIAC SURGERY

NHS Health Research Authority

STUDY PROTOCOL

Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: Study within a trial (SWAT).

1 BACKGROUND

Improving outcomes after surgery is a major public health research priority for patients, clinicians and the NHS.[62,63] The greatest burden of perioperative complications, mortality and healthcare costs lie amongst the population of patients aged over 50 years who undergo major non-cardiac surgery. Apart from the recent study in specialist cardiac surgery, there is no major trial to define the optimal anaesthetic technique. Cardiac surgery represents only a small proportion of surgical activity in the NHS; 35,000 patients per year compared to more than 1.5 million patients undergoing non-cardiac surgery each year.[1] The lack of robust evidence means that neither TIVA nor inhalational anaesthesia can be recommended as standard for vast majority of patients. Patients may therefore be exposed to avoidable harm. The choice of anaesthesia not only affects the care of patients during surgery but may also impact on their quality of recovery, survival and other patient safety outcomes, including awareness under anaesthesia. Prompt recovery and discharge from hospital will enhance physical recovery, limiting immobility and physical deconditioning.[64,65] These aspects are of growing importance as frail older patients now undergo major surgery more often than ever before.[66,67] Improving recovery and reducing complications post-surgery are ranked as one of the top James Lind Alliance research priorities for both patients and clinicians.[63]

The VITAL trial will specifically address the effect of anaesthetic technique on key patient outcomes: speed and quality of recovery after surgery (quality of recovery after anaesthesia, patient satisfaction and major perioperative complications), survival and patient safety. VITAL proposes an efficient trial design partnering with an existing national cohort study hosted by the Royal College of Anaesthetists: the Perioperative Quality Improvement Programme, PQIP. Using PQIP's prospective clinical dataset and existing NHS data sources, VITAL will limit the burden of research for participants and data collection requirements. As a result, participants in VITAL will also be participating in PQIP.

With our patient representatives, we have chosen Days alive and at home up to 30 days after surgery (DAH30) as a patient-centred, well-validated and measurable outcome.[68,69] If improved anaesthesia care could reduce hospital stay by just one day, the NHS would save £343 million each year whilst releasing in-patient beds for other patients to undergo surgery sooner.[70]

2 RATIONALE

As opportunities to participate in clinical trials become more widespread, patients are often invited to participate in more than one study at the same time. There is limited research addressing the conflicts, ethical issues and consent preferences to concurrent clinical trials.[78,79] We will conduct a formative qualitative study within VITAL trial to examine ways of consenting patients to two complementary studies. The study findings will be shared regularly with the trial team and inform approaches for patient recruitment.

3 THEORETICAL FRAMEWORK

The qualitative SWAT will follow conceptual frameworks for qualitative research in clinical trials proposed by O'Cathain et al. (2015), which rely on the adaptation of programme theories and logic models frequently used in evaluations and the documentation of implementation (trial delivery) processes (considering concepts such as fidelity, acceptability, adaptability and perceived impact). We have also adapted these frameworks to a rapid feedback approach proposed by McNall et al. (2004), where trial findings are shared on a continuous and emerging basis so they can be used by trial implementers to make changes in the trial design and delivery.

4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

We will conduct a formative qualitative study within the VITAL trial to examine ways of consenting patients to two complementary studies with the following aims:

1. Explore patient, carer and staff views and experiences with different recruitment approaches
2. Examine patient and carer experiences of participating in VITAL and PQIP
3. Identify barriers and enablers to trial set-up, recruitment and trial delivery

4.2 Outcome

The results of the SWAT will be used to inform the best methods of consenting participants into VITAL for the main trial, and help to develop any site training materials, Site Initiation Visits and highlight any changes required to the consenting materials (i.e. Patient Information Sheet and Consent Form).

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Data Collection

The study will run in parallel to the main VITAL trial and will combine semi-structured interviews with patients, carers and staff and documentary analysis (reports, meeting minutes, etc.) in 4 NHS Trusts across the UK. The sample will include interviews with 10 patients and carers and five interviews with staff at each site for a total of 60 interviews (see sampling). The interviews with staff will focus mainly on documenting their experience of setting-up or implementing the trials, the main barriers encountered during these stages and strategies used to overcome them. These experiences will be understood by taking into consideration the context of the each of the sites where the trial is delivered.

The interviews with patients/carers who have decided to take part in the study will focus on their experiences with the main VITAL trial, their understanding of trial information, reasons why they decided to or declined to take part in a trial, reasons for withdrawal and experiences with treatment options. The interviews with all patients/carers will take place at least 1 week after surgery.

The interviews will be audio recorded and the researcher will also take notes during the interviews. The interviews will be carried out online or telephone... Following, rapid evaluation approaches, the interview notes will then be summarised and added to a Rapid Assessment Procedures (RAP) sheet to enable the sharing of emerging findings with the trial team on a regular basis. One RAP sheet per site will be developed to facilitate cross-site comparisons.

Key documents from each site, including trial documentation, meeting minutes and other local reports will be collected throughout the study. These documents will be used to understand the strategies developed for trial set-up and implementation, changes in these plans over time, barriers to implementation and strategies used to overcome these.

5.2 Data Management

Personal data collected during the trial will be handled and stored in accordance with UK GPDR. At the point of consent/decline of the main VITAL trial, patients will give their consent to their name and contact details being shared with a researcher from UCL. These details will be used to invite the individual to take part in the SWAT. The information passed to the researcher will include name, email address/telephone number, age, gender, surgery date and, if applicable, which anaesthetic technique they received as part of the main VITAL trial. Personal identifiable information (name, email address/telephone number) will be deleted as soon as the interview is carried out or upon the participants decision of declining the SWAT. No identifiable information will be collected in the interviews.

Data will be collected in the form of notes during the interviews and interviews will be audio recorded.

5.3 Data Storage

All essential documentation and study records will be stored by either WCTU, UCL or NHS sites in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel.

Interview notes (not containing any identifiable information) will be transcribed and saved in a secure UoW-approved file storage system with rigorous back-up facilities. The audio recordings will also be saved electronically by UoW and stored until a full transcript is received from the transcription company. The UoW-approved transcription company Appen will transcribe the audio recordings. A contract with Appen will be in place to ensure that all data is handled in accordance with legislation. After the transcript is received, the recording will be deleted. The transcript will be anonymised and stored for 10 years on the secure UoW-approved file storage system, accessible only to designated personnel.

5.4 Data access and quality assurance

All data access will be controlled by unique usernames and passwords, and any changes to data will require the user to enter their username and password as an electronic signature in accordance with regulatory requirements. The Trial Manager will control and monitor staff access to the functionality and data as appropriate for their role in the study.

5.5 Data shared with third parties

Audio recordings from the interviews will be sent for transcription to Appen. Appen utilise a secure portal for uploading and returning transcripts, with restricted access by username and password protection for staff members required to use the service. A data processing agreement has been signed with the company

5.6 Archiving

Study documentation and data will be archived for at least ten years after completion of the study.

5.7 Data analysis

Transcripts and key documents will be imported into appropriate software, such as NVivo, and analysed using framework analysis[81]. The framework will be shaped by the research questions, published literature on qualitative research during trial implementation and additional topics emerging from the data. Data collection and analysis will be carried out in parallel as emerging findings will be shared with the trial team at TMG meetings on a monthly basis to inform trial design and delivery.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

Participants are eligible to be included in the study if they meet the following criteria:

6.1.1 Inclusion criteria

1. Provision of written informed consent
2. Approached to take part in VITAL trial and PQIP or delivering the trial (in case of staff interviews)
3. Good level of spoken and written English

6.1.2 Exclusion criteria

1. Not willing to sign a consent form
2. Does not meet language requirement

6.2 Sampling

6.2.1 Size of sample

A purposive sample of 20 staff members and 40 patients and carers will be included in the study. Potential staff participants will include: staff from the research office in charge of setting up the trial, research nurses, staff delivering treatment, central research team, research team at individual sites, surgeons and anaesthetists involved in delivering the trial.

6.2.2 Sampling technique

Patients will also be sampled purposively to reflect a balance in relation to gender, age, treatment arm (if participating in main VITAL trial). In cases where patients do not agree to take part in an interview, carers might be approached.

6.3 Recruitment

6.3.1 Sample identification

For the ***staff interviews***, potential participants will be contacted by the qualitative researcher via email and provided with a copy of the PIS and SWAT Consent form.

For the ***interviews with patients who have decided to take part in PQIP and VITAL and/or their carers***, the clinical team will ask at the point of consent to the main VITAL trial if they are willing for their contact details to be passed on to a qualitative researcher to discuss their experiences of the trial. If they agree, this will be recorded on the main VITAL trial consent form and the clinical team will pass their details to the qualitative researcher via secure electronic data transfer. The qualitative researcher will then approach the patient post-surgery either by email or telephone and provide them with a copy of the SWAT PIS and SWAT Consent form. If no email is available, the forms may be sent out via post.

For the ***interviews with patients who have declined participation in VITAL and/or their carers***, the member of the clinical team approaching them to obtain consent for the main VITAL trial will ask them if they would be happy for their contact details to be passed on to a qualitative researcher to discuss their experiences of the trial. If they agree, this will be recorded on the main VITAL trial consent form (relevant section only, all other sections to be marked as not applicable) and the clinical team will pass their details to the qualitative researcher via secure electronic data transfer. The qualitative researcher will then approach the patient post-surgery either by email or telephone and provide them with a copy of the SWAT PIS and SWAT Consent form. If no email is available, the forms may be sent out via post.

6.3.2 Consent

Staff members: They will have at least 48 hours to read and consider the PIS. Following this, the researcher will make contact to provide an opportunity to discuss the SWAT and ask questions. This consultation may be online or by telephone.. If members of staff decide to take part in the study, they will be asked to sign the consent form which was sent with the PIS. This will be returned to the researcher via email or post. Staff will be able to withdraw consent at any time before or during interviews. Interview recordings will be kept for seven days in order to allow staff to withdraw consent. Following this the recordings will be sent for transcription, and withdrawal will not be possible.

Interviews with patients and/or their carers who have decided to take part in the trial: They will have at least 48 hours to read and consider the PIS, followed by an opportunity to discuss with the researcher and ask questions. If they decide to take part in the study, they will be asked to sign the consent form which was sent with the PIS. This will be returned to the researcher via email or post. They will be informed that they will be able to withdraw consent at any time before or during interviews. Interview recordings will be kept for seven days in order to allow participants to withdraw consent. Following this the recordings will be sent for transcription, and withdrawal will not be possible. They will also be informed that their decision to participate or not in the qualitative study will not have any impact on the care they or the patient they care for will receive.

Interviews with patients who have declined participation in the trial and/or their carers: They will have at least 48 hours to read and consider the PIS, followed by an opportunity to discuss with the researcher and ask questions. If they decide to take part in the study, they will be asked to sign the consent form which was sent with the PIS. This will be returned to the researcher email or post. They will be informed that they will be able to withdraw consent at any time before or during interviews. Interview recordings will be kept for seven days in order to allow staff to withdraw consent. Following this the recordings will be sent for transcription, and withdrawal will not be possible. They will also be informed that their decision to participate or not in the qualitative study will not have any impact on the care they or the patient they care for will receive.

Consent forms for all SWAT participants will be stored securely by the qualitative researcher at UCL.

7 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in full conformance with the principles of the Declaration of Helsinki and to Good Clinical Practice (GCP) guidelines. It will also comply with all applicable UK legislation and Warwick Standard Operating Procedures (SOPs). All data will be stored securely and held in accordance with UK GPDR.

The following ethical issues will be taken into consideration:

1. Ensuring voluntary participation

Potential participants are informed in participant information sheets that they do not have to take part in this research and that participation is voluntary. There are no obvious power relationships which suggest participants may feel coerced into participating.

2. Informed Consent

Potential participants are informed of the risks and direct benefits prior to participating. The only potential risk we have identified is the fact that some participants will feel uncomfortable discussing their experiences of participating or declining to participate in VITAL. We will make sure the questions in the interviews minimise the use of any questions that might make participants feel uncomfortable.

3. Confidentiality

Participants are informed that the researchers will maintain confidentiality unless there is evidence of wrongdoing or potential harm is uncovered.

4. Anonymity

The interviews will not collect any personal information. The researcher will identify interview notes and recordings by participant code only, which for participants taking part in VITAL, will relate to their trial-specific ID. These will be stored securely on UoW-approved file storage systems. In order to carry out the interview, the qualitative researcher might need to collect email addresses and/or telephone numbers. This information will be stored in a separate password protected file in UoW-approved file storage systems. After the interview is complete, this information will be deleted. If any personal information is mentioned in the interview, this should be removed from the audio recording by the researcher prior to transfer to UoW who will then transfer the recording to Appen for transcription.

7.1 Assessment and management of risk

A full risk assessment of this SWAT will be conducted alongside the VITAL trial, and a monitoring plan will be developed in line with the level of resulting risk.

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

The SWAT will be registered on the Northern Ireland MRC Trials Hub for Methodology Research SWAT Registry.

Before the start of the VITAL trial and SWAT, a favourable opinion will be sought from an NHS REC for the trial and study protocol, informed consent forms and other relevant documents. All required ethical approval(s) for the study will be sought using the Integrated Research Application System. The study will be conducted in accordance with all relevant regulations.

Before data collection begins, each study site must ensure that the local conduct of the study has the agreement of the relevant NHS Trust Research & Development (R&D) department.

Substantial amendments will not be implemented until REC review is in place and other mechanisms are in place to implement at site. Approvals and amendments will be coordinated by the VITAL trial team and Chief Investigator.

7.3 Peer review

High quality peer review of this protocol will be provided by the Department of Health and Social Care and the NIHR Health Technology Assessment Board and University of Warwick Sponsorship committee.

7.4 Patient & Public Involvement

Our patient partners, Monica Jefford and John Braun are co-investigators on the VITAL TMG, and will be asked to review and approve all patient-facing documents and patient-involved processes of data collection.

7.5 Protocol compliance

Protocol non-compliance will be documented using a specified non-compliance form and returned to WCTU for analysis. These will be stored centrally in the VITAL eTMF.

7.6 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Identifiable and special category data will be electronically stored in a secure and restricted University of Warwick-approved file storage location. Identifiable data will only be maintained in order to contact participants and carry out the interviews. Upon receipt of the interview transcriptions, all identifiable data will be permanently deleted. The remaining data will be pseudonymised by linkage to a trial-specific identifier. Only the SWAT researcher and trial staff required to process the data will be provided with access to the data storage systems, and this will be controlled and monitored by the Trial Manager. Any presented results or outcomes will be presented as fully anonymised.

7.7 Indemnity

NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS bodies carry this risk themselves or spread it through the Clinical Negligence Scheme for Trusts, which provides unlimited cover for this risk. The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol.

7.8 Access to the final study dataset

Only members of the research team will have access to the study dataset.

8 DISSEMINIATION POLICY

8.1 Dissemination policy

The results of the study will be reported first to trial collaborators. The main report will be drafted by the trial coordinating team, and the final version will be agreed by the Trial Steering Committee before submission for publication, on behalf of the research team.

The success of the SWAT depends on the collaboration of doctors, nurses and researchers from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the study.

The study will be reported in accordance with COREQ.

The summary results of the study will be published on the VITAL website (www.warwick.ac.uk/VITAL), and participants are able to request a copy of the results by contacting the local study team.

8.2 Authorship eligibility guidelines and any intended use of professional writers

For details relating to publication and dissemination, please see the VITAL Publication Policy.

9 REFERENCES

McNall MA, Welch VE, Ruh KL, Mildner CA, Soto T. The use of rapid-feedback evaluation methods to improve the retention rates of an HIV/AIDS healthcare intervention. Evaluation and Program Planning. 2004 Aug 1;27(3):287-94.

O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, Adamson J, Jansen YJ, Mills N, Moore G, Donovan JL. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. Pilot and feasibility studies. 2015 Dec;1(1):1-3.

10. APPENDICIES

10.1 Appendix 1- Required documentation

Interview topic guides

Interview topic guide for patients

Introduction

- Introduce self, study, and interview
- Go over key points from information sheet
- Assure confidentiality
- Check permission to use audio recorder
- Thank interviewee for agreeing to contribute (no right or wrong answers; views and experiences are what matter)

Aims of in-depth interviews with patients:

1. *Explore patients' understanding of the trial and their experiences of receiving information relating to the trial*
2. *Explore reasons that eligible patients have for taking part or refusing the trial*
3. *Explore the reasons of withdrawal from the trial (if applicable).*

Questions

1. Where did you first hear about the trial from? Who approached you?
2. What did you think about the written information (Patient Information Sheet) you got about the trial? Which sections of the PIS were helpful or unhelpful?
3. What did you think about the verbal information you got about the trial?
4. Did you ask any questions when the trial was explained to you? If so, what did you ask? What reply did you receive? Were you satisfied with these responses?
5. Can you think of any other ways in which the information could have been delivered?

For those accepting participation in the trial:

6. What encouraged you to take part in the trial? What were your reasons?
7. Do you feel that you know what participating in the trial will entail?

8. Do you have any questions or concerns about participating in the trial?
9. Would anything make you consider withdrawing from the trial?

For those declining participation:

10. What were your reasons for declining the invitation to take part in the trial?
11. Would anything have convinced you to take part in the trial?
12. Would you consider taking part in any future trials?

For those withdrawing from the trial:

13. What were the reasons you decided to withdraw from the trial?

All

14. Can you think of anything to improve the ways in which the information is delivered when patients are asked if they would like to take part in the trial?
15. Is there anything else you think I should know that I have not asked you today?

Close and thank them for their time.

Interview topic guide for staff

Introduction

- Introduce self, study, and interview
- Go over key points from information sheet
- Assure confidentiality
- Check permission to use audio recorder
- Thank interviewee for agreeing to contribute (no right or wrong answers; views and experiences are what matter)

Aim: To explore staff experiences delivering the trial. .

1. Can you describe how you would normally approach a potential participant for the trial?
2. Can you describe the informed consent process?
3. Does the informed consent process vary in any way? If so, how does it vary? Why do you think this is?
4. What would you say are patients' general perceptions of the trial?
5. What would you say are their perceptions of the study information (i.e. PIS and consent form)?

6. What are their perceptions of the informed consent process?
7. Did you encounter any problems during patient recruitment? If so, did you use any strategies to address them?
8. Did you encounter any problems during the informed consent process? If so, did you use any strategies to address them?
9. Are trials running in parallel prioritised in any way? If so, how are these decisions made?
10. Why do you think some patients decline participation in the trial?
11. Why do you think some patients withdraw from the trial?
12. What are your views in relation to recruitment of patients for VITAL and PQIP at the same time vs. recruiting them independently?
13. Is there anything that could be done to improve recruitment processes?
14. Is there anything that could be done to improve informed consent processes?
15. If other sites were setting up a similar trial, is there any advice you would be able to share with them?
16. Is there anything else that you think I should know that I have not asked you today?

Close and thank them for their time.

10.2 Appendix 2 – Schedule of Procedures

Procedures	**Visits (insert visit numbers as appropriate)**	
	Screening	**Week 1**
Informed consent to main VITAL trial	x	
Declined main VITAL trial	x	
Informed consent to SWAT	x	x
Interview		x