PROTOCOL FOR PIVOT PILOT STUDY: PATIENT INFORMATION VIDEOS ON OPERATIONS TRIAL

SUMMARY

Patient education is an important part of preparing patients for surgical procedures. This pilot project aims to determine the use of two educational videos created by specialists for patients due to have either an elective caesarean section or a trans-vaginal tape / trans-obturator tape. This pilot study aims to gather the information required to undertake a larger scale study which will assess whether there is a relationship between preoperative anxiety levels and education on the procedure when the educational video is used as an information giving tool alongside existing resources. A total of 120 patients will be enrolled (60 per group) and randomised to either watch the video or not watch the video. Assessment will be done by means of a questionnaire, and results will be collected over the course of eight months. It is expected that the video may reduce anxiety in preoperative patients and that they may feel better informed about the reason for the operation, the procedure and the post-operative period.

RESEARCH QUESTION

Does the additional use of multimedia provide a more effective means of educating the patient on risks and benefits of a common elective surgical procedure as well as reduce overall pre-operative anxiety?

RATIONALE & BACKGROUND INCLUDING LITERATURE REVIEW

While patients are always explained the key risks and complications of any elective surgical intervention, they often feel unprepared for both the hospital stay and the postoperative period.[1,2] Multimedia has already been used in randomised trials as a means of delivering information to patients preoperatively to reduce overall anxiety regarding the procedure.[2,3,4]

Currently in the NHS patient information regarding surgical procedures is delivered through tools such as leaflets in combination with consultations where the patient is able to ask questions. A video is a concise learning tool which the patient would be able to access 24/7 and also show their relatives. This would not only allow them enough time to think through the possible complications but also to inform them of accurate and up to date information which is included in the consent forms they are presented pre-operatively.

A learning needs assessment where patients were approached post-operatively in Royal Devon and Exeter Trust, Wonford Hospital and asked to complete a questionnaire regarding pre-operative knowledge and anxiety highlighted certain points which patients felt they would have liked to have been informed of sooner. For example patients who had undergone a C-section commented that side effects of the anaesthetic were not fully explained and therefore not expected, and this was subsequently included in the video for this patient group. Other comments from the TVT/TOT post-operative patients involved a request for a detailed explanation of urinary incontinence and treatment options, including recovery time. Every effort was made to include the feedback from patients as points to cover in the educational videos created.

This study aims to highlight the benefit of provision of a cheap and accurate information tool in the form of a video designed to complement existing methods of preparing patients for elective surgical admissions. The ultimate goal is to prepare a database of a selection of videos accessible to patients in their own home at any time. The videos will be

monitored and updated, and any videos submitted to the website will be assessed by two specialist consultants for accuracy prior to being added to the database.

AIMS AND OBJECTIVES

Aim: Determine whether educational videos are of use as an additional learning resource for pre-operative patients.

Objectives:
1- Quantify the change between baseline patient anxiety and operative knowledge at preoperative assessment, compared to immediately pre-operatively in intervention and control group.
2- Record the relative change in anxiety level of pre-operative consented patients who have seen the video to those who have not using a ten point visual analogue scale and the State Trait Anxiety Inventory.
3- Record the relative change in knowledge base of pre-operative consented patients who have seen the video to those who have not. Specifically these headings will be assessed:

- The condition
- The operation
- The risks and complications
- The post-operative period

Secondary Objectives:
1- Receive verbal and written feedback on the videos in order to improve them
2- Test data collection methods, especially questionnaires.
3- Assess recruitment rate
4- Test the delivery of the video
5- Get an estimate of standard deviation of the outcome measures.
6- Get an estimate of required resources for a full randomised control study.

PLAN OF INVESTIGATION

General research design: A pilot randomised controlled study

Randomisation will be secured through the use of opaque envelopes for allocation to study arm. Block randomisation of 10 participants will be used in order to keep the sizes of treatment groups similar. The co-investigator will organise the blocks of envelopes and distribute these to the sub-investigators.
The questionnaires for knowledge will contain a linear scale representing two extremes with patients deciding where they lie on the scale by choosing a numerical value, and the answers will be allocated to a point scoring system for quantitative analysis.
The assessor will be blinded to the allocation during data input.
The study analysis will be performed by a member of the team who will be blinded to patient allocation.

Study Population

Target population: Stage 1 (baseline anxiety and knowledge): Preoperative assessment patients who have been consented for the study. Stage 2: Pre-operative patients who have been consented for their operation and for the study, in the Royal Devon and Exeter Trust, Wonford Hospital
Operations: Elective Caesarean Section, Trans-Vaginal/Trans-Obturator Tape

Age range: Minimum 18 years of age. No maximum age
Ethnicity: Any
Inclusion criteria:

- Patients due to have one of the following operations: Elective Caesarean Section, Trans-Vaginal / Trans-Obturator Tape
- Patients must be consented for the operation before participating in stage 2 of the study.
- English speaking

Exclusion criteria:

- Any conditions which may affect capacity: eg dementia, previous CVE or reduced cognitive ability

Mechanism of Selection and Recruitment:
Eligible patients will be approached by their clinician or nurse within the direct care team during consultation and the project will be explained to them. Verbal consent will be obtained to provide the patient with a Patient Information Sheet (see appendices)

Three weeks before the operation, either a research nurse or research midwife will telephone the patient and obtain verbal consent for participation in the study, explaining the project and answering any questions. This will be recorded in the notes. If consent is not obtained, it will be recorded in the notes that the project was explained and the patient is not willing to take part. If consent is gained, the patient will be seen during preoperative assessment by the research nurse or midwife to obtain written consent. Two copies of the completed consent form will be made (1 (original copy): to be filed for study data, 2: to be given to the patient, 3: to be inserted into medical notes). The patient will then be asked to complete Questionnaire 1.

On the day the patient is admitted to hospital for their operation, the patient will be approached by the research nurse or research midwife, who will confirm the patient is still happy to take part in the study. If the patient gives continued consent, the patient will then be allocated the intervention or control group as per opaque envelope allocation. This will then be marked on the consent form appropriately. The research nurse or research midwife will then double check the allocation number matches on each of the following forms: Consent form, Questionnaire 1, Questionnaire 2.

If the patient is allocated the intervention group, the video will be shown through use of a laptop or ipad, with earphones or in a private room. The patient will then be asked to complete Questionnaire 2. If control group is allocated, then no video will be shown, and the patient will be asked to complete Questionnaire 2.

No questions regarding the video or operation will be answered by the research nurse or research midwife until after completion of Questionnaire 2 during phase 2 of the study.

Potentially eligible patients within 8 months:

- Elective Caesarean section: 120 (4 patients per week with no recruitment during holiday periods). 60 patients per arm could potentially be approached.
- TVT/TOT: 150 (5 patients per week with no recruitment during holiday periods). 75 patients per arm could potentially be approached.

Of these, an estimated 3/10 will not accept to take part, or will be lost to follow up (drop out at stage 2 of the project). Sub-investigators may not be available for each of the operating

lists.
Target number of total patients to enrol in pilot study:

- Elective Caesarean section: 60 in total. 30 patients per arm
- TVT/TOT: 60 in total. 30 patients per arm.

Interventions

- Elective Caesarean section:
  Intervention: 'C-Section Video' shown on a laptop. It will run through once only.
  Control: No video

- TVT/TOT:
  Intervention: 'TVT/TOT Video' shown on a laptop. It will run through once only.
  Control: No video

Adverse events/patient safety

No issues of patient safety should arise. An adverse event would be if the video caused undue additional anxiety due to a question the patient may have after watching it.

- The videos will be presented to the communications manager of the RD&E trust for approval prior to showing them to the patients.
- Should the patient have any further questions due to watching the video, having completed the questionnaires, it will be ensured that either a nurse or a doctor can answer these before the operation.

Any adverse event will be appropriately logged and submitted to the Research and Development department quarterly, if required.

Data collection and outcome measures:

Data will be collected by two delegates (sub-investigators: research nurse or research midwife).
The data will be collected in the form of written questionnaires – see appendices for drafts.

<u>Stage 1: Gaining consent and Baseline assessment:</u>

1) Consent forms and questionnaires will be grouped according to operative procedure, and numbered consecutively: 001-120.
   (001-060: TVT/TOT, 061-120: ELECTIVE CAESAREAN SECTION)
2) Potential patients will be given the Patient Information sheet by a member of their direct care team during clinic.
3) Three weeks before their operation, the patient will be telephoned by the research nurse or midwife, the project explained to them, and verbal consent will be gained for study participation.
4) Patients who have given verbal consent for participation will be seen during preassessment and the patient will be asked to complete the written consent form and questionnaire 1.
5) On arrival at the hospital for their operation, the patients will be approached by the research nurse or research midwife to confirm consent and continue with phase 2 of the study:

<u>Stage 2: Allocation and re-assessment</u>

6) When the patient arrives for her operation, the research nurse or midwife will

approach the patient, and verbally confirm that she is still happy to continue with the project.

7) The research nurse will ensure allocation number matches on all documents, including questionnaire 2.
8) The patient will be asked to complete the second consent form that will then be inserted into the medical notes.
9) The research nurse will open an opaque envelope to view allocation of patient
10) If intervention:

a) The research nurse will give the laptop to the patient with the video to play. No comments are made regarding the operative procedure etc.

b) The research nurse marks the intervention box on the consent form.

c) The research nurse ensures the patient name matches the consent form, and the number on the consent form matches the number on 'Questionnaire 2'.

d) Following the viewing of the video, the research nurse presents 'Questionnaire 2' to the patient.

e) The questionnaire will be collected and filed into the wallet with other questionnaires for that operative procedure group.

10) If control:

a) The research nurse marks the control box on the consent form.
b) The research nurse ensures the patient name matches the consent form, and the number on the consent form matches the number on 'Questionnaire 2'.
c) The research nurse presents the 'Questionnaire 2' to the patient.
d) The questionnaires will be collected and filed into the wallet with other questionnaires for that operative procedure group.

<u>Stage 3: Data Analysis</u>

1. Data analysis: The co-investigator will be given the wallets with the questionnaires and assimilate the data in an excel sheet, recording the participant number alongside the results.
2. Once all the data has been entered, the co-investigator will send the Excel sheet to the chief investigator as the initial stage of analysis, and date and sign it.
3. Then the co-investigator will open the wallet containing the consent forms and record the allocation next to the participant number, and regroup the data.
4. The data will then be sent to the statistician in order to proceed to statistical analysis.

<u>Note on Blinding:</u>

As the participant number and the subsequent allocation will be completely random as per point 8), the initial stage of the data assimilation onto the Excel sheet will be performed blindly as the co-investigator will not know which participant number corresponds to which study arm. As this document will then be sent to the chief investigator this prevents the data from being altered once the allocation is viewed in the second stage (Stage 3, point 1,2).

Data management and statistical analysis

Patient consent forms and questionnaires will be filed securely in a padlock protected

locker at the Research and Development Building, Wonford.
No patient identifiers will be recorded on home laptops or home computers.
The data will be assimilated in an Excel Sheet and stored on a password protected computer/laptop.
Consent forms will be held for 3-6 months and then destroyed.
Additional data will be held for 5 years.
All Data Protection guidelines and the Data Protection act will be adhered to for confidentiality purposes.

The trust statistician will be approached for advice on randomisation of the opaque envelopes.
The person who undertakes the role of randomisation will be recorded in the research study log.
Descriptive statistics of baseline characteristics will be compared between study groups to demonstrate the effectiveness of randomisation. Categorical data will be summarised as proportions and percentages as appropriate with associated confidence intervals. No attempt will be made at this stage to make formal comparisons of outcome measures – this will be done in the eventual definitive study. Summaries of secondary outcome measures will also be produced in a similar manner to the above.

PROJECT MANAGEMENT

Personnel

Producing the video:

Animator: Consultant Anaesthetist
Producer and Voiceover: Consultant Obstetrician & Gynaecologist
Camerawoman and Editor: Communications and Corporate Affairs Officer
Writer, Director and Researcher, Creation of Storyboards: Year 5 Intercalating Medical Student (2011/12)
Quality Control: Trust Communications Manager

The Study

There will be four delegates:

Chief Investigator: Consultant Obstetrician & Gynaecologist.
Co-Investigator: Foundation Year 1 Doctor, RD&E (2013-14)
2x Sub-Investigators: Until December 2012: Clinical Medical Student and Foundation doctor
From July 2013: Research nurse and research midwife
Statistician: Hospital Trust Statistician

Project Responsibilities:

Data storage/monitoring: Sub-Investigators
Consenting: Sub-Investigators
Recruitment: Sub-Investigators
Statistical advice: Hospital Trust Statistician
Data analysis: Co-investigator
Write-up: Co-investigator and Chief Investigator

Additional Training Required: For the Sub-Investigators, if not already obtained, GCP Training will be required.

First Main Contact for the Study: Eleanor Zimmermann, Foundation Year 1 Doctor, RD&E. efzimmermann@doctors.org.uk, 07845508419

Time-schedule
Start date: 31st August 2011

Month	1 (Sep)	2	3	4	5 (Jan) 2012	6	7	April 2012 – June 2013 *Recruitment delay and re-evaluation*			11 (Jul) 2013	12	13	14	15	16	17 (Jan 2014)	18	19	20	21	22	23	24 (Aug 2014)
Create Videos	X	X																							
Protocol Submission		X			X																				
Ethics Submission					X																				
Delegate recruitment						X																			
Patient Enrolment*							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Research staff recruitmend											X														
Data Entry												X		X		X		X		X	X	X			
Data Analysis and write-up																						X	X	X	

*Should the necessary minimum number of patients required be recruited before month 13 then patient enrolment will cease accordingly.

Day-to-day study management
Day to day management will be ensured by the Co-investigator, Foundation Year 1 Doctor. Additional delegates recruited, if not GCP trained, will be notified to the Research department and be registered for a training day.

ETHICAL CONSIDERATIONS
An Integrated Research Application System Form is being completed for ethics approval.
Written consent will be gained from patients for participation. See appendices
Confidentiality:

- Questionnaires will not contain any patient details other than demographic information.
- Questionnaires will record participant number, which will be recorded with the consent form.
- One original consent form will be collected and two copies of the complete form will be made. One will be filed securely with co-investigator, one will be given to the patient, and the other inserted into medical notes.
- Documents containing patient identifiers will be held for 3-6 months from study end and then shredded.
- All other documentation will be held for 5 years.

Any queries patients may have regarding the study will be answered by the research team (Delegate A or B) prior to obtaining consent during Stage 1 of the study.
Participants willing to receive a copy of the study findings will indicate this in the consent form. These patients will be sent the information within 6 months of study end.

BUDGET SUMMARY AND COSTINGS

Please see separate budget listing.

Funding of £250 has been obtained through the May Sullivan Research Prize towards costs of the project.

A small grants application (R&D) will be made once protocol has been accepted.

POSSIBLE IMPLICATIONS OF STUDY

The results from the study will be entered into the following:

1)Conferences for presentation:

- International Forum on Quality and Safety in Healthcare
- Annual Academic Meeting and William Blair Memorial Lecture
- RCSEd Student Research Symposium
- Association of Surgeons in Training

2) Prizes

- The Blair Bell Research Prize

3) Publications

- The aim will be to publish the results in an educational peer reviewed journal

The videos created will be copyright protected by the Royal Devon and Exeter NHS Foundation Trust.

REFERENCES

1. Rankinen S. Salantera S, Heikkinen K, Johansson K et al. Expectations and received knowledge by surgical patients. *Int J Qual Health Care*. 2007;19(2):113-119
2. Jlala HA, French JL, Foxall GL, Hardman JG, Bedforth NM. Effect of preoperative multimedia information on perioperative anxiety in patients undergoing procedures under regional anaesthesia. *Br J Anaesth*. 2010;104(3):369-374
3. Doering S, Kaltzberger F, Rumpold G et al. Videotape preparation of patients before hip replacement surgery reduces stress. *Psychosom Med*. 2000;62:365-73
4. Shaw M, Beebe T, Tomshine P, Adlis S, Cass O. A randomized, controlled trial of interactive, multimedia software for patient colonoscopy education. *J Clin Gastronter.* 2001;32(2):142-147

APPENDICES/ANNEXES Study questionnaires and consent forms

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Patient Information Sheet

Patient Education on Common Surgical Procedures:
Using Rapid Sequence Animation Videos

Dear Patient,

Before you have your operation at the Royal Devon and Exeter NHS Trust, Wonford Hospital, we would like to ask you if you would consider taking part in a small research project for an educational resource. Please read the following information in order to gain a better understanding of what the project involves, and what the study aims to achieve.

We have created two short animation videos which aim to help patients prepare for their stay in hospital for common surgical procedures. In particular the videos cover the elective caesarian section and trans-vaginal/trans-obturator tape procedure, and this is why you are eligible to participate in the study.

Our goal is to determine their benefit in helping patients prepare for their operation, as well as seeing whether they reduce anxiety before the procedure. We are looking to recruit a total of 120 patients. The study has been approved by the Southwest Ethics Committee by proportionate review and is sponsored by the Royal Devon and Exeter NHS Foundation Trust.

Three weeks before your operation, you will be called by our research nurse or midwife who will ask you if you would like to participate in the study. If you decide to take part in the project, when you come into hospital for your preoperative assessment, you will be asked to fill in a written consent form and questionnaire about how you feel and how well prepared you feel for your operation. This should take about 20 minutes. Then, you will be seen by the research nurse or midwife when you come into hospital for your operation, and will either be shown the video about your operation, or not shown it. (This is to help the results be more accurate when analysing them) We will then ask you to complete the same questionnaire.

This project will help us assess the overall benefit of these videos as an education tool which would be accessible to patients at home, and would complement their hospital stay. If they are found to be of use to patients, they would be used together with current means of giving information, such as leaflets, and this could also offer the opportunity to produce more videos to cover other common surgical procedures as well.

The questionnaires will be collected anonymously, and no patient identifiers will be used. You will be allocated a unique identification number ensuring privacy and respecting your right to confidentiality. At all times your data will remain anonymous and your name will not appear on any of the results. As this study is entirely voluntary, you will be free to withdraw at any time, without providing a reason. If you do decide to withdraw it will not affect the standard of your routine clinical care and we will safely destroy any questionnaires or

consent forms you may have completed.

If you decide to take part, you will be able to choose whether you would like to be informed of the study results, in which case we will keep your consent form for a maximum of six months before safely destroying it so we can post the summary of our findings to you. Otherwise, your consent form will be destroyed three months after study completion, which is estimated to be in November 2014.

If you have any questions you would like to ask before you come into hospital, or before our research staff call you, please don't hesitate to ask. You can contact me by email or by phone, as below.

Please take your time to consider participation in this study and feel free to discuss it with others.

Many thanks for taking the time to read this letter,

Dr Eleanor Zimmermann BSc BMBS
Co-Investigator for PIVOT Study
efzimmermann@doctors.org.uk
07845508419

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Operation: TRANS-VAGINAL TAPE / TRANS-OBTURATOR TAPE

Affix Patient Sticker here:	
Participant Number:	
Allocation*: (delete as appropriate) *To be completed at Stage 2 of study	**INTERVENTION / CONTROL***

CONSENT FORM
To be completed before allocation.

I hereby give my consent to participate in the pilot project entitled "PIVOT: Patient Information Videos on Operations Trial".

INITIALS

- I have read the information sheet dated ……..…..... and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
- I understand that may be presented with an educational video about my surgical procedure, or may not, depending on my allocation. ☐
- I understand that should I have any questions about my operation after watching the video, every effort will be made to ensure they get answered. ☐
- I understand that the questionnaire is anonymous, and that every effort will be made to keep my details confidential. ☐
- I understand that the information I give in the questionnaires will be entered onto a study database. This database will hold anonymised data and may be accessed by members of the Research team regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
- I understand that copies of this consent form will be made where necessary, and a copy will be retained in my medical notes, and the original will be filed securely until up to six months after study end, when it will be shredded to ensure data protection. ☐

I would like to / would not like to receive a summary of the study findings in the post after study end (please delete as appropriate)

PRINTED NAME (PATIENT) PRINTED NAME (RESEARCHER)

…..... …..
SIGNATURE and DATE SIGNATURE and DATE

…..... …..

When completed: 1 for participant; 1 for researcher site file (original); 1 to be kept in medical notes.

Royal Devon and Exeter NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Operation: ELECTIVE CAESAREAN SECTION

Affix Patient Sticker here:	
Participant Number:	
Allocation*: (delete as appropriate) *To be completed at Stage 2 of study	**INTERVENTION / CONTROL***

CONSENT FORM
To be completed before allocation.

I hereby give my consent to participate in the pilot project entitled "PIVOT: Patient Information Videos on Operations Trial".

INITIALS

- I have read the information sheet dated ……..…..... and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
- I understand that I may be presented with an educational video about my surgical procedure, or may not, depending on my allocation. ☐
- I understand that should I have any questions about my operation after watching the video, every effort will be made to ensure they get answered. ☐
- The questionnaire is anonymous, and that every effort will be made to keep my details confidential. ☐
- I understand that the information I give in the questionnaires will be entered onto a study database. This database will hold anonymised data and may be accessed by members of the Research team regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
- I understand that copies of this consent form will be made where necessary, and a copy will be retained in my medical notes, and the original will be filed securely until up to six months after study end, when it will be shredded to ensure data protection. ☐

I would like to / would not like to receive a summary of the study findings in the post after study end (please delete as appropriate)

PRINTED NAME (PATIENT) PRINTED NAME (RESEARCHER)

…..... …..
SIGNATURE and DATE SIGNATURE and DATE

…..... …..

When completed: 1 for participant; 1 for researcher site file (original); 1 to be kept in medical notes.

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Patient Education on Common Surgical Procedures:
Using Rapid Sequence Animation Videos

QUESTIONNAIRE 1 : to be completed by the patient after verbal consent gained by research nurse, approximately three weeks before the operation (stage 1)

Operation: TRANS-VAGINAL / TRANS-OBTURATOR TAPE

Participant Number:	001

ABOUT YOU
1- Please select the appropriate box for each category:

Age

<24	25-29	30-39	40-49	50-59	60-69	70-79	>80

Education Level

Secondary school	GCSEs	College / A - levels	Diploma	Undergraduate degree	Postgraduate degree

Employment status

Unemployed	Employed	Student	Retired	Other

Do you / did you work in healthcare?

Yes		No	

Have you had this operation before?

Yes		No	

QUESTIONNAIRE

A- PREOPERATIVE ANXIETY

1- Please rate your anxiety regarding your procedure below, with 0 being not anxious, and 10 being extremely anxious, **by putting an X on the line below**:

0 1 2 3 4 5 6 7 8 9 10
Not anxious Moderately anxious Extremely anxious

State Trait Anxiety Inventory

2- Please read each statement and select the appropriate response to indicate how you feel right now, that is, at this very moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		1 Not at all	**2 A little**	**3 Somewhat**	**4 Very Much So**
1.	I feel calm	1	2	3	4
2.	I feel secure	1	2	3	4
3.	I feel tense	1	2	3	4
4.	I feel strained	1	2	3	4
5.	I feel at ease	1	2	3	4
6.	I feel upset	1	2	3	4
7.	I am presently worrying over possible misfortunes	1	2	3	4
8.	I feel satisfied	1	2	3	4
9.	I feel frightened	1	2	3	4
10.	I feel uncomfortable	1	2	3	4
11.	I feel self confident	1	2	3	4
12.	I feel nervous	1	2	3	4
13.	I feel jittery	1	2	3	4
14.	I feel indecisive	1	2	3	4
15.	I am relaxed	1	2	3	4
16.	I feel content	1	2	3	4
17.	I am worried	1	2	3	4
18.	I feel confused	1	2	3	4
19.	I feel steady	1	2	3	4
20.	I feel pleasant	1	2	3	4

TOTAL SCORE (to be filled in by research nurse):	/80	Verified by co-investigator? (initials)

B- PREOPERATIVE KNOWLEDGE

How informed do you feel about your condition?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How informed do you feel about the reasons why this operation has been offered to you?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you feel ready for the operation?

1	2	3	4	5	6	7	8	9	10

Not at all ready Moderately ready Extremely ready

Do you feel you know what to expect in the operating theatre?

1	2	3	4	5	6	7	8	9	10

Not at all Moderate Extremely Well

Do you feel you understand what the surgeon will do in the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you know how your anaesthetic will be given to you?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How well do you think you have been informed of the side effects of the anaesthetic?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Are you aware of the possible complications and risks involved in your operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know how long you are likely to stay in hospital?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

How well do you feel you have been explained the benefit and success rate of the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately Extremely well

How well informed do you feel about your recovery period after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel you have questions you would have liked to have asked that have not been answered?

1	2	3	4	5	6	7	8	9	10

Not at all Some questions A lot of questions

Many thanks for your time and honesty. This completes the questionnaire, and we look forward to seeing you again soon, to complete the second stage of the project.

Best wishes,

Dr Eleanor Zimmermann
Co-Investigator for PIVOT Study

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Patient Education on Common Surgical Procedures:
Using Rapid Sequence Animation Videos

QUESTIONNAIRE 1 : to be completed by the patient after verbal consent gained by research midwife, approximately three weeks before the operation (stage 1)

Operation: ELECTIVE CAESAREAN SECTION

Participant Number:	061

ABOUT YOU
1- Please select the appropriate box for each category:

Age

<24	25-29	30-39	40-49	>50

Education Level

Secondary school	GCSEs	College / A - levels	Diploma	Undergraduate degree	Postgraduate degree

Employment status (when not on maternity leave)

Unemployed	Employed	Student	Other

Do you work in healthcare?

Yes		No	

Have you had this operation before?

Yes		No	

QUESTIONNAIRE

A- PREOPERATIVE ANXIETY

1- Please rate your anxiety regarding your procedure below, with 0 being not anxious, and 10 being extremely anxious, **by putting an X on the line below**:

0	1	2	3	4	5	6	7	8	9	10
Not anxious				Moderately anxious						Extremely anxious

State Trait Anxiety Inventory

2- Please read each statement and select the appropriate response to indicate how you feel right now, that is, at this very moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		1 Not at all	**2 A little**	**3 Somewhat**	**4 Very Much So**
21.	I feel calm	1	2	3	4
22.	I feel secure	1	2	3	4
23.	I feel tense	1	2	3	4
24.	I feel strained	1	2	3	4
25.	I feel at ease	1	2	3	4
26.	I feel upset	1	2	3	4
27.	I am presently worrying over possible misfortunes	1	2	3	4
28.	I feel satisfied	1	2	3	4
29.	I feel frightened	1	2	3	4
30.	I feel uncomfortable	1	2	3	4
31.	I feel self confident	1	2	3	4
32.	I feel nervous	1	2	3	4
33.	I feel jittery	1	2	3	4
34.	I feel indecisive	1	2	3	4
35.	I am relaxed	1	2	3	4
36.	I feel content	1	2	3	4
37.	I am worried	1	2	3	4
38.	I feel confused	1	2	3	4
39.	I feel steady	1	2	3	4
40.	I feel pleasant	1	2	3	4

TOTAL SCORE (to be filled in by research nurse):	/80	Verified by co-investigator? (initials)

B- PREOPERATIVE KNOWLEDGE

How informed do you feel about the reasons for your having a caesarean section?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel ready for the operation?

1	2	3	4	5	6	7	8	9	10

Not at all ready Moderately ready Extremely ready

Do you feel you know what to expect in the operating theatre?

1	2	3	4	5	6	7	8	9	10

Not at all Moderate Extremely Well

Do you feel you understand what the surgeon will do in the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you know how your anaesthetic will be given to you?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How well do you think you have been informed of the side effects of the anaesthetic?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Are you aware of the possible complications and risks involved in your operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know where you and your baby will go after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know when you can start breastfeeding your baby?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How aware are you of the long term implications of having a c-section?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

Do you know how long you are likely to stay in hospital?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

How well informed do you feel about your recovery period after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel you have questions you would have liked to have asked that have not been answered?

1	2	3	4	5	6	7	8	9	10

Not at all Some questions A lot of questions

Many thanks for your time and honesty. This completes the questionnaire, and we hope you have a quick recovery from your operation!

Best wishes,

Dr Eleanor Zimmermann
Co-Investigator for PIVOT Study

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Patient Education on Common Surgical Procedures:
Using Rapid Sequence Animation Videos

QUESTIONNAIRE 2 : to be completed on the day of the operation (Stage 2)

Operation: TRANS-VAGINAL / TRANS-OBTURATOR TAPE

Participant Number:	001

The questionnaire is three pages long, and should take approximately 15 minutes to complete.

Please turn over to start the questionnaire.

QUESTIONNAIRE 2

A- PREOPERATIVE ANXIETY

1- Please rate your anxiety regarding your procedure below, with 0 being not anxious, and 10 being extremely anxious, **by putting an X on the line below**:

0 1 2 3 4 5 6 7 8 9 10
Not anxious Moderately anxious Extremely anxious

State Trait Anxiety Inventory

2- Please read each statement and select the appropriate response to indicate how you feel right now, that is, at this very moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	1 Not at all	**2 A little**	**3 Somewhat**	**4 Very Much So**
41.	I feel calm	1	2	3	4
42.	I feel secure	1	2	3	4
43.	I feel tense	1	2	3	4
44.	I feel strained	1	2	3	4
45.	I feel at ease	1	2	3	4
46.	I feel upset	1	2	3	4
47.	I am presently worrying over possible misfortunes	1	2	3	4
48.	I feel satisfied	1	2	3	4
49.	I feel frightened	1	2	3	4
	I feel uncomfortable	1	2	3	4
50.	I feel self confident	1	2	3	4
51.	I feel nervous	1	2	3	4
52.	I feel jittery	1	2	3	4
53.	I feel indecisive	1	2	3	4
54.	I am relaxed	1	2	3	4
55.	I feel content	1	2	3	4
56.	I am worried	1	2	3	4
57.	I feel confused	1	2	3	4
58.	I feel steady	1	2	3	4
59.	I feel pleasant	1	2	3	4

TOTAL SCORE (to be filled in by sub-investigator):	/80	Verified by co-investigator? (initials)

B- PREOPERATIVE KNOWLEDGE

How informed do you feel about your condition?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How informed do you feel about the reasons why this operation has been offered to you?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you feel ready for the operation?

1	2	3	4	5	6	7	8	9	10

Not at all ready Moderately ready Extremely ready

Do you feel you know what to expect in the operating theatre?

1	2	3	4	5	6	7	8	9	10

Not at all Moderate Extremely Well

Do you feel you understand what the surgeon will do in the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you know how your anaesthetic will be given to you?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How well do you think you have been informed of the side effects of the anaesthetic?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Are you aware of the possible complications and risks involved in your operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know how long you are likely to stay in hospital?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

How well do you feel you have been explained the benefit and success rate of the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately Extremely well

How well informed do you feel about your recovery period after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel you have questions you would have liked to have asked that have not been answered?

1	2	3	4	5	6	7	8	9	10

Not at all Some questions A lot of questions

Many thanks for your time and honesty. This completes the questionnaire, and we look forward to seeing you again soon, to complete the second stage of the project.

Best wishes,

Dr Eleanor Zimmermann
Co-Investigator for PIVOT Study

Royal Devon and Exeter NHS
NHS Foundation Trust

PIVOT: Patient Information Videos on Operations Trial

Patient Education on Common Surgical Procedures:
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QUESTIONNAIRE 2 : to be completed on the day of the operation (Stage 2)

Operation: ELECTIVE CAESAREAN SECTION

Participant Number:	061

The questionnaire is three pages long, and should take approximately 15 minutes to complete.

Please turn over to start the questionnaire.

QUESTIONNAIRE 2

A- PREOPERATIVE ANXIETY

1- Please rate your anxiety regarding your procedure below, with 0 being not anxious, and 10 being extremely anxious, **by putting an X on the line below**:

0 1 2 3 4 5 6 7 8 9 10
Not anxious Moderately anxious Extremely anxious

State Trait Anxiety Inventory

2- Please read each statement and select the appropriate response to indicate how you feel right now, that is, at this very moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

		1 Not at all	**2 A little**	**3 Somewhat**	**4 Very Much So**
60.	I feel calm	1	2	3	4
61.	I feel secure	1	2	3	4
62.	I feel tense	1	2	3	4
63.	I feel strained	1	2	3	4
64.	I feel at ease	1	2	3	4
65.	I feel upset	1	2	3	4
66.	I am presently worrying over possible misfortunes	1	2	3	4
67.	I feel satisfied	1	2	3	4
68.	I feel frightened	1	2	3	4
69.	I feel uncomfortable	1	2	3	4
70.	I feel self confident	1	2	3	4
71.	I feel nervous	1	2	3	4
72.	I feel jittery	1	2	3	4
73.	I feel indecisive	1	2	3	4
74.	I am relaxed	1	2	3	4
75.	I feel content	1	2	3	4
76.	I am worried	1	2	3	4
77.	I feel confused	1	2	3	4
78.	I feel steady	1	2	3	4
79.	I feel pleasant	1	2	3	4

TOTAL SCORE (to be filled in by research nurse):	/80	Verified by co-investigator? (initials)

B- PREOPERATIVE KNOWLEDGE

How informed do you feel about the reasons for your having a caesarean section?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel ready for the operation?

1	2	3	4	5	6	7	8	9	10

Not at all ready Moderately ready Extremely ready

Do you feel you know what to expect in the operating theatre?

1	2	3	4	5	6	7	8	9	10

Not at all Moderate Extremely Well

Do you feel you understand what the surgeon will do in the operation?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately informed Extremely Well Informed

Do you know how your anaesthetic will be given to you?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How well do you think you have been informed of the side effects of the anaesthetic?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Are you aware of the possible complications and risks involved in your operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know where you and your baby will go after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you know when you can start breastfeeding your baby?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

How aware are you of the long term implications of having a c-section?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

Do you know how long you are likely to stay in hospital?

1	2	3	4	5	6	7	8	9	10

Not at all Moderately aware Extremely aware

How well informed do you feel about your recovery period after the operation?

1	2	3	4	5	6	7	8	9	10

Not at all informed Moderately informed Extremely Well Informed

Do you feel you have questions you would have liked to have asked that have not been answered?

1	2	3	4	5	6	7	8	9	10

Not at all Some questions A lot of questions

Many thanks for your time and honesty. This completes the questionnaire, and we hope you have a quick recovery from your operation!

Best wishes,

Dr Eleanor Zimmermann
Co-Investigator for PIVOT Study