Title: Virtual Reality in Elective Caesarean sections - VREC

A prospective randomised exploratory study to determine the impact of a pre-operative virtual reality film on anxiety-related outcomes in women undergoing elective caesarean section.

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Protocol authorised by:

Dr Kelly Spencer Head of Research Operations ……. Date

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Abbreviations

NHS FT	National Health Service Foundation Trust
BBC	Bath Birthing Centre
CS	Caesarean section
LSCS	Lower segment caesarean section
T1, T2 etc	Time points 1, 2 etc
RUH	Royal United Hospitals Bath
VR	Virtual reality
VREC	Virtual Reality in elective caesarean section
VREF	Virtual reality educational film
APGAR	Score that measures 5 variables each scored on a scale of 0 to 2 with 2 being the best score. Total score out of 10. Appearance (skin colour) Pulse (heart rate) Grimace (reflexes Activity (muscle tone) Respiration (breathing rate and effort)
STAI-5	State Trait Anxiety Inventory Scale 5
VAS-A	Visual analogue scale for anxiety
VAS-P	Visual analogue scale for pain
NICE	National Institute for Health and Care Excellence
NICU	Neonatal intensive care unit
HDU	High dependency unit
QDS	Four times a day
TDS	Three times a day
mg	milligrams
IM	Intramuscular

1. Study Summary

Study Title	Virtual Reality in Elective Caesarean Sections
Short title	VREC
Study Design	Prospective randomised feasibility study
Study Participants	Pregnant women
Planned Sample Size	40 (20 intervention group and 20 control group)
Treatment Duration	No longer than four weeks
Follow up duration	From decision for elective CS by 38 weeks gestation to 24 hours post-LSCS. Planned duration no longer than four weeks
Planned study period	Five months (November 2023 – March 2024)
Primary	From pre-assessment at approximately 38-39 weeks gestation to two hours post-LSCS
Secondary	From 2 hours post-LSCS to 24 hours post-LSCS
Intervention	Access to a virtual reality video demonstrating the patient pathway for elective section to be watched prior to surgery.
Intervention Protocol	Participants randomised to the intervention group will be given unlimited access to a VR educational film demonstrating the patient pathway for elective caesarean section at 38 weeks. Anxiety will then be assessed using state trait anxiety inventory scale 5, visual anxiety scale and cortisol levels and compared between the intervention and control group at four time points.
Funder	Research Capability Funding

2 Study Rationale

At the Royal United Hospitals Bath (RUH), approximately 4500 deliveries occur every year of which approximately 10% (450) of these deliveries are performed as elective caesarean sections (CS).

Anxiety is considered to be an emotional response to a perceived threat or danger [1]. More specifically peri-operative anxiety is the subjective feeling of apprehension and fear associated with impending procedures, such as anaesthesia or surgery. Whilst a CS is seen as a routine procedure, Wyatt et al. reported high pre-operative anxiety in women prior to their CS [2]. Studies have demonstrated that in mothers-to-be undergoing CS their subjective anxiety is highest before CS and significantly declines at skin closure after the baby was born [3,4].

Although anxiety is defined as a psychological insult which may result in avoidance of healthcare services and a lack of trust or confidence in healthcare professionals, the physiological sequelae also confer significant morbidity in the peri-operative period.

These include increased pain perception and thus analgesic requirements, delayed wound healing due to raised cortisol and blood glucose, prolonged recovery and length of hospital stay, and increased risk of infection. [5-10]. In addition, in obstetric patients specifically high anxiety levels before a CS are linked to slower recovery from the surgery, higher postoperative pain levels and reduced patient satisfaction [11,12].

The importance of providing high-quality pre-operative information to help patients reduce their anxiety is well reported [13-16]. More recently novel ways of delivering pre-operative information has been investigated. A recent study found that showing paediatric patients a virtual reality tour of the operating theatre before anaesthesia reduced pre-operative anxiety by 30% and increased compliance during induction of anaesthesia in children [17]. Another study again, demonstrated lower anxiety levels in children who had been shown a preoperative virtual reality exposure tour compared to the control group [18].

Historically VR has been used clinically most frequently for the treatment of phobias, as it allows patients exposure to fearful situations in a safer, less embarrassing and cost-effective way. It has also been found that patients acceptance of the use of VR is high [19].

A study performed by Schaal et al compared anxiety levels on the day of CS in women receiving their first CS compared to those who had already had one. They found that women receiving their first CS were more anxious than women who had already experienced one [4]. This is thought to because the mother-to-be is aware of what will happen during the procedure. This is in line with other research, which shows that having experienced a specific operation or anaesthesia before has a very positive effect on the psychological state of the patient when they undergo the same procedure again [20-22]. This evidence lends weight to the idea that an intervention such as a virtual reality film allowing mothers-to-be to ‘virtually’ experience having a CS should have a soothing effect on pre-operative anxiety and thereby improve postoperative pain and maternal satisfaction [12].

Whilst new research is emerging for the use of VR for pre-operative education in paediatric patients there is currently no evidence to show if it is of benefit for obstetric patients. For a mother, the day of their babies birth is one of the most important and memorable days of their lives and everything should be done to minimise anxiety and stress for these women. Therefore, in this study we will consider the effect of a VR educational film on peri-operative anxiety in patients undergoing an elective CS.

3 Study Aims and Objectives

3.1 Primary Research Aim

The overarching aim of this prospective study is to establish if we can produce a virtual reality education film which is acceptable for women undergoing elective caesarean section.

3.2 Primary Hypothesis

Can we produce an informative virtual reality film which is acceptable to women undergoing elective caesarean section.

3.3 Null Hypothesis

The null hypothesis is that we produce a virtual reality education film which is acceptable to our obstetric patients.

3.4 Secondary aims

Our secondary aim is to investigate if pre-operative preparation with a virtual reality film can alter the course of anxiety in women undergoing elective caesarean section.

In addition, research suggests that perioperative anxiety has a negative affect on patient's pain post operatively. Therefore, we intend to look at patient's pain scores and analgesic requirements.

We will also collect data on patient satisfaction scores.

Furthermore, we intend to collect data on how quickly patients fed their baby post-delivery, how quickly they mobilise and what the babies APGAR score is at the time of delivery.

3.5 Study Outcome Measures

Primary outcome measures:

- Patient feedback questionnaire after watching virtual reality education film.

Secondary outcome measures:

- State Trait Anxiety Inventory Scale 5 at 5 time points (T1 at pre-clerking (approximately 38-39 weeks gestation), T2 on admission for LSCS, T3 at skin closure, T4 2 hour's post-LSCS, T5 at 24 hours post-LSCS patient will be phoned if they have left the hospital) (Score 20-80).

- Visual Analogue Scale for Anxiety (VAS-A) at 5 time points (T1 at pre-clerking approximately 38-39 weeks gestation, T2 on admission for LSCS, T3 at skin closure, T4 2 hours post-LSCS, T5 at 24 hours post-LSCS patient will be phoned if they have left the hospital) (Score 0-10).
- Serum Cortisol at 4 time points (T1 at pre-clerking at approximately 38-39 weeks gestation, T2 on admission for LSCS, T3 at skin closure, T4 at 2 hours post-LSCS) (Units).

- Patient satisfaction scores at two time points (T4 at 2 hours post-LSCS and T5 at 24 hours post-LSCS, patient will be phoned if they have left the hospital)(Score 0-10)

- Visual Analogue Scores (VAS) for pain at two time points (T4 at 2 hours post-LSCS, T5 at 24 hours post-LSCS patient will be phoned if they have left the hospital) (Score 0 to 10)

- Analgesia consumption in first 24 hours post-LSCS (amount of morphine in mg)

- Time to feed baby post-LSCS (breast or bottle) (minutes)

- Time to mobilise post-LSCS (minutes)

- Fetal 5-minute APGAR

3.6 Study Population and Eligibility

The study population are patients over the age of 18 who are undergoing their first elective lower segment caesarean section (LSCS) at the Royal United Hospitals, Bath.

Inclusion criteria:

To be eligible to participate in the study participants must:

- Have had the decision for elective LSCS by 38 weeks gestation.
- Has never had an emergency or elective section previously

- Have a procedure planned and performed as a category 4 LSCS (an elective LSCS booked at a time that suits both the woman and obstetric team)
- Have use of an android or iOS operating system smartphone or tablet device.
- Have access to the internet.
- Have an active email address.
- Have capacity to consent to participate in the study.

Exclusion criteria:

- Patient <18 years of age
- Patient refusal
- Patients who have had an emergency or elective LSCS previously.
- Patients with a history of anxiety disorders
- Patients with medical or obstetric co-morbidities requiring pre-determined admission to maternity HDU care
- Congenital structural abnormalities requiring pre-determined admission to NICU
- Patients where spinal anaesthesia is contra-indicated
- Women who have English of an insufficient standard to comprehend the consent and assessment process
- Prisoners

Withdrawal criteria:

- Emergency LSCS - those in the following standardised categories of urgency as set out by NICE[23].
    - Category 1 – immediate threat to life of woman or fetus
    - Category 2 – maternal or fetal compromise which is not immediately life-threatening
    - Category 3 – no maternal or fetal compromise but needs early birth
- Women who receive a general anaesthetic.

3.7 Project Duration

The overall study period will be approximately 6 weeks. The patient will only be in the study at the point of recruitment and then for a maximum of 24 hours after the participant has delivered her baby by elective lower segment caesarean section.

4 Study Design

4.1 Study Outline

This is a prospective, randomised, single-centred exploratory study with two groups, the intervention group and the control group. Women will be recruited from the Royal United Hospital NHS Foundation Trust.

The Intervention

A virtual reality educational film (VREF) will be produced. The film will be scripted, and the following specialists will have input on the content and structure of the film:

1. Patients who have either recently had an elective CS or who are waiting to have an elective CS.
2. Midwives
3. Anaesthetists
4. Obstetricians

The film will be 15 minutes long and will be shot by an external professional film company on site at the RUH birthing centre using real locations (including the pre-operative assessment clinic, the birthing centre, the operating theatre, recovery and the post-natal ward).

Prior to use in this study the film will be reviewed by:

1. Patients who have either recently had an elective CS or who are waiting to have an elective CS.
2. Midwives including the research midwifery team and the Director of Midwifery
3. Anaesthetists
4. Obstetricians
5. Maternity Voices Partnership Lead
6. RUH Head of Communications

Intervention Group

Women recruited to the intervention group of the study will be emailed or texted a link to be able to watch the VREF. The VREF will provide a 360 degree, 3-dimensional virtual tour. It will show what will happen on the day of delivery; from entering the Bath Birthing Centre (BBC) through to being on the postnatal ward with their new baby. They will be able to watch this as many times as they would like prior to having their CS. They will be given the contact details of the research midwife to contact if they have any questions after watching the film. If there is a clinical question, this is

the escalation process which will be followed; research midwives to take details and forward on to Dr Rebecca Leslie (by email) who will reply to patient directly over phone. Dr Leslie will liaises with obstetric clinical team prior to speaking to patient if felt necessary.

Control Group

The control group will be given the routine pre-operative information by the midwives and standard written information leaflets, along with the contact details of the research midwife if they require any further information.

Day of Delivery

On the day patients are admitted to the BBC for their elective LSCS all patients in the VREC trial will receive the same care and will have the same data collected as per the data schedule.

Anaesthesia

All patients in this study will receive a spinal anaesthetic for their elective LSCS. The amount of intrathecal local anaesthetic and opiate used will be at the discretion of the anaesthetist.

Post-operative medication

All patients will be prescribed regular paracetamol 1g qds and ibuprofen 400mg tds for post-operative pain management. Dihydrocodeine 30mg qds and Oramorph 10mg every 2 hours will be prescribed as required. Ondansetron 4mg and prochlorperazine 12.5mg IM will be prescribed for nausea. Naloxone 50mcg subcutaneously and chlorpheniramine 4mg orally will be prescribed for post-operative itching.

5 Recruitment and Consent

5.1 Recruitment

Potential participants will be identified and given information (patient information leaflet) about the study on an ad-hoc basis when booked for their elective LSCS at any point during their pregnancy (as long as it's prior to 38 weeks gestation); this can be done by either their obstetrician or the research midwives.

Approved posters will be on the walls of the antenatal clinic with information about the study and contact details. Research midwives will then contact all eligible patients by phone to invite them for a formal appointment to consent at 38 weeks. Many

patients will be attending hospital at around 38-39 weeks for obstetric follow up, so if feasible, research appointments will be aligned with this. If patients are not attending routinely, we will invite them for an appointment with the research midwives at an alternative time.

5.2 Consent

Women will have received information about the study from either the obstetrician or the research midwives on an ad hoc basis when booked for an elective LSCS at any point of their pregnancy up to 38 weeks gestation. (Women will be invited to join the study, if the decision is made for a caesarean section, prior to 38 weeks). They will be given at least 24 hours between approach and consent being sort in which to consider whether or not they would like to take part. A member of the research team will phone all patients who received the information to see if they are happy to participate. They will then be invited to attend an appointment with the research midwives, this will be combined with their obstetric follow up appointment if able. At this appointment, formal consent will be sought in person. All members of the research team are experienced at recruiting participants and are Informed Consent or Good Clinical Practice trained.

Patients will be given contact details of the study team (research midwives) should they have any questions between consent and their LSCS. They will be able to withdraw consent at any time, before or after their LSCS.

6 Risks

There are very few risks to patients involved in this study. If the participants have any concerns after watching the VREF, they will be given a number to call to discuss with a member of the research midwifery team.

High anxiety levels are associated with significant morbidity including increased pain perception (with higher analgesic requirement), increased length of hospital stay and a higher risk of post-operative wound infection (5-10). If patients are found to have a high STAI-5 or VAS, this will trigger a brief psychological assessment by the research team which will exclude acute suicidal ideation or psychosis and a referral to the perinatal mental health team will be completed if required (with patient consent, unless there are concerns regarding capacity). There is an existing mental health screening tool with a scoring system on the hospital computer system which will be used and patients referred on as required.

No risks to researchers have been identified.

7 Data

7.1 Patient Randomisation

Patients will be block randomised 1:1 in blocks of 10 between standard pre-operative education and the use of a virtual reality film. Randomisation will occur by random number generation by the research midwife with a coded master list after consent has been obtained.

7.2 Data Collection and Storage

All data will be entered into a secure Trust-based computer that is password protected. Subject names will be kept on a database and will be linked only with a study identification number for this research. There will be no direct patient identifiers kept on the main database. Only the direct research team will have access to this computer. Data will be stored in a locked office and maintained for a minimum of five years after the completion of the study.

8 Patient Follow Up

8.1 Data Collection Required

The following data will be recorded for all patients enrolled in the study.

Pre-operative Demographic data

- Date decision for a category 4 LSCS was made.
- Gestation at the above 'decision' date.
- Gravity
- Parity
- Were any unexpected changes made to the date of the LSCS?

8.2 Data Collection timings

T1: Consent appointment with research midwives (approx. 38-39 weeks gestation)

- State Trait Anxiety Inventory Scale 5
- Visual Analogue Scale for Anxiety
- Serum Cortisol

Day of LSCS:

T2: On admission (all performed by research midwives unless out of hours and on call anaesthetist will do)

- State Trait Anxiety Inventory Scale 5
- Visual Analogue Scale for Anxiety
- Serum Cortisol

T3: At skin closure (all performed by research midwives unless out of hours and on call anaesthetist will do)

- State Trait Anxiety Inventory Scale 5
- Visual Analogue Scale for Anxiety
- Serum Cortisol

Post-operatively:

T4: 2 hours post-LSCS (all performed by research midwives unless out of hours and on call anaesthetist will do)

- State Trait Anxiety Inventory Scale 5
- Visual Analogue Scale for Anxiety
- Serum Cortisol
- Patient satisfaction score
- Visual Analogue Scores for pain

T5: 24 hours post-LSCS (all performed by research midwives unless out of hours and on call anaesthetist will do)

- Patient satisfaction score
- State Trait Anxiety Inventory Scale 5
- Visual Analogue Scale for Anxiety
- Visual Analogue Scores for pain
- Analgesia consumption in first 24 hours post-LSCS
- Time to breastfeed post-LSCS
- Time to mobilise post-LSCS

The following information will be collected from the patient's notes/anaesthetic chart (a sticker will be attached to the anaesthetic chart for the anaesthetist to complete):

- Time of anaesthesia
- Time of adequate block
- Time of birth
- Time of closing of the skin

- Did the mother have skin-to-skin with baby? What time?
- Fetal 5-minute APGAR
- Any unexpected events

Data Collection Details

State Trait Anxiety Inventory Scale 5 – this is a scoring system for anxiety consisting of a 5-item self-completed questionnaire (24). There are a choice of four answers ranging from 'not at all' to 'very much so'. We expect this to take 2 minutes to complete.

Visual Analogue Scale for Anxiety (VAS–A) – this is also a scoring system for anxiety. It is one question with a Likert scale of 0-10. We expect this to take 1 minute to complete.

Serum Cortisol- this is a hormone and requires a blood test to be measured. There are four points at which this will occur. The first three will coincide with routine blood tests that are required during routine antenatal care. The fourth is 2 hours after delivery and this can be done in recovery, when the spinal anaesthetic is still working.

Patient satisfaction score – It is one question with a likert scale of 0-10. We expect this to take 1 minute to complete.

Visual Analogue Scores for pain (VAS-P) - this is a scoring system for pain. It is one question with a likert scale of 0-10. We expect this to take 1 minute to complete.

9 Study Analysis

9.1 Sample size

We have included a target sample size of 40 patients. This is an exploratory study and as such, precise effect-sizes are not known.

9.2 Statistical analysis

Demographic data will be tabulated to demonstrate any differences between the two groups, which have occurred by chance. This will include the date the LSCS was made, age of mother, gestation, gravity, pariety and if there were any unexpected changes made to the date of the LSCS. This is to ensure there are no large discrepancies between the groups which may influence their anxiety scores. The items in this table will not be tested statistically.

Ordinal data will be collected from the Likert scales used in the STAI-5, VAS-A, VAP-P and satisfactory score. The main outcome of area under curve for these, as well as the cortisol levels will be calculated using the trapezium rule and examined for normality using histograms.

Normally distributed differences between the two groups will be tested using an independent sample 2 tailed t-test and illustrated using mean difference and confidence interval. If not normally distributed the difference between the groups will be tested using a Mann-Whitney U test and differences demonstrated using medians, interquartile ranges and box plots.

Fisher's exact test and chi-squared tests will be used for analysis of categorical data.

10 Data Storage

Data will be collected and retained in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR).

Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of five years following the data collection. Where trial related information is documented in the medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where date is five years after the last patient last visit.

11 Study Sponsorship and Management

The sponsor for this study is the Royal United Hospitals Bath NHS Foundation Trust. The trial will comply with the Data Protection Legislation including GDPR and will comply with all relevant local policies and procedures.

Participants have been and will continue to be involved at each stage of this trial including design, trial documents (e.g. consent forms, information sheets), conduct, analysis and reporting.

The Research & Development office at the RUH is highly familiar with research studies like this and will ensure appropriate governance procedures are met and audit a percentage of Trust sponsored projects per year as part of their Research Governance responsibilities.

12 Publication Policy and Dissemination to Participants

The results of the study will be disseminated to participants if they have chosen to receive them when they are asked during the consent procedure.

The study results will be submitted to national and international journals and conferences for presentation and publication.

13 Disclosures

No conflicts of interest have been identified.

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