Virtual Reality as a Distraction technique for management of acute pain at Outpatient Hysteroscopy.

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Protocol authorised by:

Name & Role	**Date**	**Signature**
Mr Raj Rai	26/3/18	

Study Management Group

Chief Investigator: Mr Raj Rai

Co-investigators: Nandita Deo (PI)
Jonathan Benn,
Gianopaulo Fusari
Philip Pratt

Statistician: Research team

Study Management: Nandita Deo, PI

Study Coordination Centre *Imperial College London*

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator: Ms Nandita Deo
Address: Department of Obstetrics and Gynaecology, Whipps Cross University Hospital, London, E11 1NR
nandita.deo@gmail.com
Tel: 07939360357

Clinical Queries

Clinical queries should be directed to Ms Nandita Deo, Consultant Obstetrician and Gynaecologist, Whipps Cross Hospital, London, who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Joint Research Compliance Office
Imperial College London & Imperial College Healthcare NHS Trust
2nd Floor Medical School Building
St Mary's Hospital
Praed Street
London
W2 1NY
Tel: 020759 41862

Funder

There is no funder for the study as it is an MSc project

This protocol describes 'Virtual Reality as a Distraction technique for management of acute pain at outpatient hysteroscopy' and provides information about the procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

OPH	Outpatient Hysteroscopy
VR	Virtual Reality

KEYWORDS

Distraction techniques

Acute pain

Outpatient Hysteroscopy

STUDY SUMMARY

TITLE	Virtual Reality as a Distraction technique for management of acute pain at Outpatient Hysteroscopy
DESIGN	Randomised Control Trial with Mixed methods – Qualitative and quantitative
AIMS	To study the role of distraction techniques for management of acute pain in Outpatient Hysteroscopy and to assess feasibility of using Virtual Reality for managing pain.
OUTCOME MEASURES:	Primary objective: • Feasibility of using virtual reality as a distraction technique in management of acute pain in patients undergoing Outpatient Hysteroscopy. Secondary objectives: • Understanding the acceptability and effectiveness of VR interventions within the procedural groups and how these might vary as a function of different patient demographics. • Understanding the factors that might influence the willingness of patients to participate in a future formal trial of the technology. • Understanding how best to implement the technology and designing of the contents of the VR intervention. • Understanding the effective mechanisms for the analgesic effect of VR and explore how this could be tailored to individual patients.
POPULATION	Patients attending the Outpatient Hysteroscopy clinics
ELIGIBILITY	Patients undergoing Outpatient Hysteroscopy

DURATION 6 months

1. INTRODUCTION

1.1 BACKGROUND

Performing procedures for investigation and treatment of gynaecological conditions in the office setting is becoming commonplace. Outpatient gynaecological procedures can reduce risks of general anaesthetic, decrease health care costs and make the procedure more convenient for the patient and provider. However, ensuring adequate pain relief and allaying anxiety during the procedure can prove to be challenging. Appropriate patient selection, counselling and adequate pain management during the procedure can improve patient experience and reduce the number of failed procedures.

Common office gynaecological procedures include outpatient hysteroscopy, colposcopy and large loop excision of transformation zone, manual vacuum aspiration for treatment of miscarriages, intrauterine contraceptive device insertion, hysteroscopic sterilisation and endometrial biopsy.

Pain in gynaecological procedures can originate from the cervix and uterus. The uterine fundus is innervated by sympathetic fibres from T10 to L2, which enter through the uterosacral ligaments via the inferior hypogastric plexus, and by nerves from the ovarian plexuses at the cornua. Parasympathetic fibres from S2 to S4 travel through the broad ligament to enter the cervix at the 3 0 clock and 9 o clock positions to provide innervation to the upper vagina, cervix and the lower uterine segment. The pudendal nerve (S 2,3, 4) supplies the lower vagina and vulva.

Physical, psychological and social factors influence the intensity of pain experienced. Counselling the patients pre procedurally helps to better manage expectations and pain.

Outpatient hysteroscopy is usually performed for patients having abnormal uterine bleeding and subfertility. Pain levels during this procedure can be influenced by the

diameter of the hysteroscope. Mini hysteroscopes with an outer diameter of 3.5 mm have been associated with lower pain scores. (Paulo et al., 2015) Additional procedures performed (like polypectomy or Coil insertions) could increase the duration of the procedure and the pain experienced during the procedure. Pain scores in the vaginoscopic approach have been noted to be 3.8 when compared to 5.3 in the traditional group, which uses a speculum and tenaculum. (Sagiv et al., 2006)

Pain in hysteroscopy is significantly related to the presence of cervical synechiae, to the duration of the procedure, and to the use of normal saline; conversely, parity seems to have a protective role.(Mazzon et al., 2014)

Previous vaginal deliveries, experience of the operator and quicker operative time are known to be associated with successful outcomes of the outpatient procedures. However, nulliparity, postmenopausal status, anxiety and anticipated pain and a history of dsymenorrhoea are known to be associated with higher perception of pain and reduced success rates. (Ireland and Allen, 2016, de Carvalho Schettini et al., 2007)

The type of pain relief offered can include various levels of sedation, local anaesthetic, analgesics and verbal support techniques through distraction by conversation, gentle language, music, guided imagery and positive suggestion. A Cochrane Review showed no consistent good quality evidence of a significant difference in safety or effectiveness between different types of pain relief compared with each other or with placebo/ no treatment. (Ahmad et al., 2010) There is no consensus on the choice of analgesia for outpatient hysteroscopy and rescue analgesia in the form of intracervical blocks is often used. (O'Flynn et al., 2011)

In the UK, most units offer analgesics either as NSAIDs, acetaminophen or oral opiods. NSAIDS such as ibuprofen decrease uterine activity and pain by inhibiting cyclooxygenase and thereby reduce circulating prostaglandins. They reduce pain levels especially postoperatively. Acetaminophen also inhibits the enzyme cyclooxygenase, but its action is in the central nervous system rather in the periphery. Hence is inferior to NSAIDS but is offered to women who cannot tolerate NSAIDS. Oral opiods act by interacting with endogenous opioid mu receptors. (Ireland and Allen, 2016)

The only pharmacological method that has demonstrated its effectiveness in reducing pain during and 30 minutes after hysteroscopy in several meta-analysis and reviews is paracervical block. (del Valle et al., 2016) However, it fails to anaesthetise the uterus for intrauterine procedures and a previous Cochrane review was unable to confirm this. (Tangsiriwatthana et al., 2009) The administration of the local anaesthetic itself may be uncomfortable, have side effects due to toxicity, may cancel the beneficial effect of performing a vaginoscopic hysteroscopy and does not anaesthetise the uterus. Addition of soda bicarbonate as a buffering agent to the local anaesthetic and using dental syringes with a 27-gauge needle has been seen to decrease the pain during the injection. Topical local anaesthetics on the cervix in the form of gel or sprays have not been shown to be effective.

Women undergoing outpatient hysteroscopy experience significant levels of preoperative anxiety which is higher than patients attending the gynaecology clinic and comparable to those experienced before major surgery under general anaesthesia. (Gambadauro et al., 2015, Gupta et al., 2004)
Anxiolytics help reduce anxiety, however they do not have a direct analgesic effect.
Units often employ a trained person to engage with the patient to provide emotional support during the procedure.

Distraction Techniques

Type of distraction techniques range from active distraction techniques to passive techniques. Active distraction included interactive toys, virtual reality, guided imagery and relaxation and controlled breathing. Passive distraction techniques included auditory distraction in the form of music and audio-visual distraction through watching television. Intraoperative pain and anxiety rating have been noted to be lower by use of simple intraoperative distraction techniques e.g. interacting with nurses, watching DVDs or using stress balls. (Hudson et al., 2015)

There has been limited research done on the role of distraction techniques in pain management in outpatient gynaecological procedures. Music has been used as a complementary method to control anxiety and reduce perception of pain by relaxing the patient and causing less discomfort during outpatient hysteroscopy. (Angioli et

al., 2014). However, a RCT showed no positive effect of music on patients' level of pain, anxiety or satisfaction of patient or doctor for office hysteroscopy and colposcopy.(Mak et al., 2017). Watching the procedure on the screen at office hysteroscopy has not been shown to reduce pain scores.(Ogden et al., 2009)
Women with high level of preprocedural state- trait anxiety are more likely to perceive higher levels of pain and discomfort during colposcopy. (Baser et al., 2013) Simple passive visual distraction during colposcopic examination was associated with a reduction in pain scores, however anxiety levels were unchanged. (Carwile et al., 2014) A Cochrane review in 2007 concluded that anxiety appears to be reduced by playing music during colposcopy. Although information leaflets did not reduce anxiety levels, they did increase knowledge levels and helped with consenting for the procedure. (Galaal et al., 2007)

Virtual reality is a relatively new intervention, which has been studied as a non-pharmacological method for pain relief. (Loreto-Quijada et al., 2013, Loreto-Quijada et al., 2014). VR as a form of managing pain has been studied in paediatrics, dentistry, burns treatment, treatment of chronic pain. (Hoffman et al., 2000) It has not been studied in the management of pain of gynaecological procedures, which are increasingly being performed as office procedures.
It acts as a method of distraction for pain relief by changing the activity of the body's pain modulation system. This multisensory technology gives an immersive and engaging experience and serves as a distraction technique. Head tracking systems, visually stimulating scenery and audio and tactile feedback enable integration of many sensory experiences. Different psychological factors influence the effectiveness of the analgesic effect of VR. While sense of presence influence the effectiveness of VR as a distraction tool, anxiety as well as positive emotions directly affects the experience of pain. (Triberti et al., 2014)
VR distraction has been associated with significant increases in pain threshold and pain tolerance and significant decreases in pain intensity, time spent thinking about pain, and self-reported anxiety, relative to baseline. Repeated exposure did not appear to affect the benefits of VR. (Rutter et al., 2009). Simultaneous exposure to VR and supplementary sound increases pain tolerance. (Johnson and Coxon, 2016)

Pain management in ambulatory procedures should be multimodal and should include both pharmacological and non-pharmacological interventions. Giving the patient a range of options will increase the number of successful procedures in the outpatient setting and improve patient experience.

1.2 RATIONALE FOR CURRENT STUDY

To study the role of distraction techniques for management of acute pain in ambulatory gynaecology procedures and to assess feasibility of using Virtual Reality for managing pain.

2. STUDY OBJECTIVES

Primary objective:

- Feasibility of using virtual reality as a distraction technique in management of acute pain in patients undergoing Outpatient Hysteroscopy.

Secondary objectives:

- Understanding the acceptability and effectiveness of VR interventions within the procedural groups and how these might vary as a function of different patient demographics.
- Understanding the factors that might influence the willingness of patients to participate in a future formal trial of the technology.
- Understanding how best to implement the technology and designing of the contents of the VR intervention.
- Understanding the effective mechanisms for the analgesic effect of VR and explore how this could be tailored to individual patients.

3. STUDY DESIGN

The study is a randomised control trial involving mixed methods of qualitative and quantitative analysis. Participants will be recruited for the study at the Gynaecology Department at Whipps Cross University Hospital, Barts Health NHS Trust from June

2018 to October 2018. The patients will be identified from the gynaecology clinic by the clinicians who schedule them for Outpatient Hysteroscopy procedure. The study will include 40 patients attending the outpatient hysteroscopy clinic and randomised to either a VR intervention group or standard procedure by computer-generated randomisation.

They will be given a study information sheet, an invitation to participate with a reply slip to indicate whether they would like to participate in the study. Patients will be given standard pre procedural information about the procedure as per standard practice. Written informed consent will be obtained from participants and the interview outputs will be anonymisied.

All patients will fill in a questionnaire before and after the procedure. Patients who have been randomised to the VR arm will have a semi-structured interview regarding their experience with VR.

The staff in the clinic will include a clinician performing the procedure and a staff nurse supporting the clinic. They will be given a study information sheet regarding the study and a written informed consent for a questionnaire will be obtained from them if they agree to participate. The clinician performing the procedure will fill in a questionnaire per patient regarding the ease of the procedure and perceived pain levels of the patient. The Clinician performing the procedure and nursing staff's perception regarding feasibility of using the VR equipment for each patient who had the intervention was also assessed through the questionnaire. The staff questionnaire responses will be anonymised by assigning a unique staff number for each of the staff. The list of the names of the staff and the study number allocated will be saved by the PI on a separate file.

Patient follow up will not be routinely arranged for the purpose of the study. Routine follow up as per clinical requirements will be arranged as routine for the procedure performed.

3.1 STUDY OUTCOME MEASURES

Efficacy of VR in acute pain management

Feasibility of VR implementation during office gynaecology procedures

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

Clinical indications for undergoing an office hysteroscopy will be confirmed.

Staff in the outpatient hysteroscopy clinic.

4.2 INCLUSION CRITERIA

Patients: Inclusion criteria will include all women of at least 18 – 70 years of age, planned for an office hysteroscopy.

Staff: Inclusion criteria will include the clinician performing the outpatient hysteroscopy and the nurse supporting the clinic.

4.3 EXCLUSION CRITERIA

Patients:

- Hearing impairments and blindness
- Any known anatomical characteristics that may make performing the office procedure more difficult (e.g., cervical conization, Manchester Fothergill).
- The denial or withdrawal of oral informed consent

Staff: The denial or withdrawal of informed consent

4.4 WITHDRAWAL CRITERIA

Patients and staff can withdraw from the study if they so desire at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care / treatment that they receive.

5. ADVERSE EVENTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement will be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, will also be considered serious.

5.3 REPORTING PROCEDURES

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, will be recorded.

5.3.2 Serious AEs

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to <condition>, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to **Newcastle and North Tyneside 1 National Research Ethics Committee** where in the opinion of the Chief Investigator, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
Fax: xxx, attention xxx
Please send SAE forms to: xxx
Tel: xxx (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

The study will aim to recruit 40 patients and randomise them via computer generated random number allocation to either the VR intervention group or those having treatment as per routine protocol.

Both groups of patients will fill a pre and post procedural questionnaire. Pain and anxiety scores prior to the procedure and after the procedure will be compared against a control group of 20 patients for pain management by standard protocol. Scores will be measured by a Numeric Rating Scale (NRS) which is a validated measure of pain which is easy to use, has high compliance rates and is detects

meaningful changes in pain. The NRS is an 11-point scale consisting of integers from 0 through 10; 0 representing ‘‘No pain’’ and 10 representing ‘‘worst imaginable pain.’’ Respondents select the single number that best represents their pain intensity. Ratings of pre-operative anxiety were measured by an 11-point numeric rating scale. (NRS; Kindler et al., 2000): ‘How would you rate any anxiety you may currently be feeling’ 0 (no anxiety) and 10 (worst anxiety imaginable).
The VR intervention will involve watching a standard content of the video on a mobile device using a VR headset to distract them during the procedure. The duration of the video will be 15 minutes; but the video will only be played for the duration of the outpatient hysteroscopy. Patients are allowed to stop viewing the video if they so desire and this will be recorded.

A semi-structured interview will be conducted with the patients who have received the VR intervention, each lasting approximately 20 minutes. The semi structured interviews will allow for all participants to be asked similar question within a flexible framework.(Dearnley, 2005, Tindall, 2009) The interviews will be conducted within 30 minutes of the procedure, in a suitable location and will be recorded on a digital voice recorder. The questions will be focused on the women’s experiences of the procedure, in specific pain perception and questions around the VR intervention as well as any other aspect of their hospital care they felt to be relevant. If further clarification or exploration of any particular aspect of their care was required, the interview will readdress these topics before the end of the interview. Interviews will continue until no new information was being obtained, indicating that the theoretical saturation point had been reached. (Pope et al., 2000)

Clinician and nursing staff’s perception regarding feasibility of using the VR equipment was also assessed through a questionnaire. The clinician questionnaire will also assess the ease of the procedure and perceived pain scores for the patient.

Patient follow up will not be routinely arranged for the purpose of the study. Routine follow up as per clinical requirements will be arranged as routine for the procedure performed.

The study will end once the proposed numbers of patients have been recruited and data analysis completed. Participants will be debriefed after their participation in the study and will be directed to suitable support agencies if necessary.

7. STATISTICS AND DATA ANALYSIS

The recruitment of women and interviewing proceeded alongside data coding and preliminary analysis.

Interviews will be transcribed verbatim and initially coded by reading and re reading the transcript and making notes, drawing on the observations made during the interviews and transcription. Transcripts will be coded line-by-line, describing, summarising and attending to linguistic elements such as pronoun and metaphor use. (Tindall, 2009) The transcripts will be entered into a qualitative software package (N6) and a thematic analysis undertaken from the emergent themes developed from these codes and cluster with related themes. Initial coding is Initial phase will involve open coding. Axial coding and selective coding with use of constant comparison will enable a cyclical and iterative process on the principles of grounded theory. Analytic frame for the analysis will be linked to the primary and secondary aims.

The statistically analysis with include statistical comparison of pre and post anxiety and pain scores as a function of membership of VR or control groups. Analysis of covariance (ANCOVA) will be used to determine whether the VR intervention led to a significantly difference between baseline and follow up pain and anxiety scores between VR and control arm.

Staff questionnaires will be analysed to correlate pain scores of actual vs. perceived and feasibility of carrying out the intervention will be assessed.

Demographic data would include age, parity, menopausal status and ethnicity.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the Newcastle and North Tyneside 1 National Research Ethics Committee..The study must be submitted for Site Specific Assessment (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the Trust R&D approval letter before accepting participants into the study. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so will be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

In the event of the patient and the staff nurse consenting for the study but the gynaecologist not consenting for the procedure, the patient will be recruited and randomised as per protocol. In the event of the patient and the gynaecologist consenting for the study, but the staff nurse not consenting for the procedure, the patient will be recruited and randomised as per protocol. In these instances, the staff nurse and / or the gynaecologist will not fill the questionnaire and a note will be made.

8.3 CONFIDENTIALITY

Confidentiality

Information related to participants will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldecott Principles, The

Research Governance Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval.

- Record Retention and Archiving

When the research trial is complete, the records are kept for a further 10 years. The approved repository for long-term storage of local records is the Trust Modern Records Centre

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies that apply to this study.

8.5 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6 FUNDING

The study is a part of an MSc thesis and there is no funding this study.

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Nandita Deo, Consultant Obstetrician and Gynaecologist and PI for the study.

10. PUBLICATION POLICY

On completion of the study, the MSc thesis dissertation will be published as per Imperial College policy and publication of the findings will be done via peer-reviewed journals.

10. REFERENCES

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APPENDICES

1. Patient Questionnaire
2. Semi structured interview questions for patients who have had the distraction technique (VR)
3. Staff Questionnaire
4. Patient information Leaflet

5. Staff Information Leaflet
6. Patient Consent form with reply slip.
7. Staff Consent form