Project Title

A Single Centre, Randomized, Parallel-group, Pilot Study to Compare Traditional Training for Chest Drain Insertion to a Novel Immersive Virtual Reality Training Software Program.

Short Title

Virtual Reality Insertion of Chest-drain Outcomes Research

Acronym

VICTOR

Research protocol: Version 1.3

06/01/2021

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1 Project Details

Protocol/Research Project Title:	A Single Centre, Randomized, Parallel-group, Pilot Study to Compare Traditional Training for Chest Drain Insertion to a Novel Immersive Virtual Reality Training Software Program. Short title: Virtual Reality Insertion of Chest-drain Outcomes Research Acronym: VICTOR		
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Sponsor Name (if applicable):	Vantari VR and Fiona Stanley Innovation Leadership Group		
Laboratory Name (if applicable):			

Project Summary

The Virtual Reality Insertion of Chest-drain Outcomes Research (VICTOR) study will compare the traditional teaching of chest drain insertion against an immersive Virtual Reality (VR) training system. Junior and senior anaesthetic registrars will be the targeted study population and will be randomly assigned to one of the two study groups. The traditional education group will receive instruction on chest drain insertion via written text and an instructional video. The VR education group will receive instruction via the VR software training programme. After instruction, both groups will be assessed by two blinded researchers using a validated chest drain insertion assessment tool.

Assessment of chest drain insertion will be done by utilizing a simulation mannikin fitted with a chest drain insertion module. Any differences between the traditional training group and the VR group will be assessed by measuring the following outcomes; Scores recorded on a validated checklist for chest drain insertion proficiently, time to completion of the task and the number of deviations from the checklist. Self-reported participant confidence will also be recorded.

2 Rationale / Background

Virtual reality is a computer-generated 3D virtual environment. This virtual environment can be defined as one that “capitalizes upon natural aspects of human perception by extending visual information in three spatial dimensions”, “may supplement this information with other stimuli and temporal changes” and “enables the user to interact with the displayed data (1).” The ability to create virtual worlds that the user can then interact with makes VR a potentially useful simulation-based education tool.

Due to the multitude of terms used to describe virtual reality education (VRE) the following table has been included. The included table (2) provides specific definitions for terms related to VRE.

Table 1: Standard definition of terms

Virtual Simulation	A screen-based simulation where the graphics, sound, and navigation

	emphasize the 3D nature of the environment.
Virtual Reality	Use of immersive, highly visual, 3D characteristics to replicate real-life situations; typically incorporates physical or other interfaces such as a head-mounted display, motion sensors, or haptic devices in addition to computer keyboard, mouse, speech, and voice recognition. The user interacts as if it takes place in the real world and the focus of the interaction remains in the digital environment.
Augmented Reality	A type of VR in which synthetic stimuli are superimposed on real-world objects (overlays digital computer-generated information on objects or places in the real world) for the purpose of enhancing the user experience; may include head-mounted display, overlays of computer screens, wearable computers, or displays projected onto humans and mannequins. The focus of the interaction of the performed task lies within the real world instead of the digital environment.
Virtual Standardised Patient	Avatar-based representations of human standardized patients that can converse with learners using natural language
Serious Games	Interactive computer applications simulating real-world events designed for a primary educational purpose rather than pure entertainment. Present challenging goals; are engaging to the user; incorporate some scoring mechanism; and supply the user with skills, knowledge, or attitudes useful in reality

The VRE in this study will fall under the definition for virtual reality, as it incorporates a head mounted display (oculus rift headset) to create an immersive virtual world.

Simulation based education (SBE), with deliberate practice as a teaching tool, has been shown to be superior to traditional clinical education for acquisition of a wide range of medical skills.(3) With the recent technological advances in virtual reality hardware in terms of graphic ability, portability and cost, there is increasing interest in the use of VR in SBE. The traditional Halsted's educational model of *"see one, do one, teach one*" has held a prominent place in the teaching of all surgical specialities (4). The same educational model has been applied by other medical disciplines, but it is insufficient in terms of patient safety with trainees learning by practising on real patients (5). SBE does not expose patients to avoidable and preventable errors (6) and thus may improve patient safety and comfort.

Virtual reality technology has previously been used by various medical disciplines, as an educational tool. The majority of VR use has been in the areas of surgical, gynaecological and gastrointestinal procedural training (4, 7). There are currently very few studies looking at task based virtual reality training in anaesthesia.

There are a number of advantages in the use of VRE and these include; repeatability, portability, self-directed learning, data collection, and cost (8). Taekman et al attribute further human elements such as, instant feedback, rewards, competition, scalability, standardisation and convenience (9).

Virtual Reality Education provides an opportunity to deliberately practise rare, potentially lifesaving procedures and scenarios in a risk-free environment. These advantages make VRE an attractive educational tool, provided that the virtual reality education program is at least as effective or superior to the traditional education method. This remains the motivation behind this pilot study.

3 Project Aims / Objectives / Hypotheses

Primary objectives: Compare the effectiveness of VRE training with traditional education methods for the placement of a chest drain by anaesthesia registrars. Effectiveness of education will be assessed by proficiency of chest drain insertion, non-deviation from standardised chest drain checklist and the time taken to complete the task of chest drain insertion.

Secondary Objectives: Assessment of registrar levels of confidence regarding chest drain insertion pre- and post-educational sessions.

Hypothesis: VRE training is as effective if not superior to a traditional teaching approach for the insertion of chest drains.

Null Hypothesis: There is no difference in chest drain insertions outcomes when instructed by either a traditional or VR training approach.

4 Project Design

Project Design

Pilot study

Pre-test survey assessing prior chest drain insertion training; number of chest drain insertions performed in patients; current confidence level related to chest drain insertion ability.

Subjects randomly assigned to one of two groups

Traditional teaching method.

Text and instructional video

Virtual reality training method

All study participants will be assessed by two anaesthetic consultants blinded to group allocation using a validated checklist for chest drain competency. Chest drain insertion success with be assessed using scores from assessment tool, number of deviations from the checklist, time to task completion and self-reported chest drain insertion confidence levels.

Source and Selection of Participants

The study participants will be the junior and senior anaesthetic registrars from the Fiona Stanley & Fremantle Hospital Group Department of Anaesthesia & Pain Medicine. An email will be sent by Dr Robert Swart containing information regarding the study and a request for participation.

Participant inclusion criteria.

All the registrars in the Fiona Stanley & Fremantle Hospital Group Department of Anaesthesia & Pain Medicine as of 3rd August 2020.

Participant exclusion criteria.

Unwilling to participate or sign consent.

Not completing the chest drain training.

Adverse reaction to virtual reality hardware.

Previous use of the VR chest drain scenario if allocated to the control group.

Participant withdrawal criteria

If unable to use the virtual reality training program due to motion sickness, nausea or headache. The facilitators will attempt to improve the comfort of the headset. If the participant still cannot use the headset due to discomfort they will be removed from the study.

Bias

The participants will be allocated to groups by computer-generated randomisation. The assessors of the two groups will be blinded to the training method that all the participants received.

Blinding and Randomisation

Due to the varying skills/capabilities of the junior and senior registrars, the two groups will be randomised separately to ensure an equal balance between the control and experiment groups.

The researchers will have a separate list of participants that will contain the information regarding which training method each participant received. This will be correlated against the score sheets from the blinded assessors.

Method

The traditional education group will use the teaching material from the Emergency Trauma Management (ETM) course manual. This course is accredited as part of the professional development program by the Australian College of Rural and Remote Medicine. The VR education group will use the novel VR training software. Assessment of the two groups will be performed on a SimMan 3g mannikin with a chest drain module inserted. The assessment tool used is a validated checklist for chest drain insertion proficiency.

Project Duration/Schedule

The expected duration of data collection is six months. Data analysis is expected to take a further 6 months to complete. This includes the writing of a research manuscript for publication.

Project Termination

Once all participants have completed their allocated training program and have been subsequently assessed by a blinded assessor the data collection process will end.

5 Treatment of Participants

Description and justification for treatments, interventions or methods to be utilised

The hypothesis that the VRE may prove to be a more effective training method is of potential benefit to all the study participants and patients, especially as this technology becomes more widely incorporated into medical training. The "*Traditionally trained*" group will not be disadvantaged as this is currently the accepted standard of training. Furthermore, access to the VR training software will be made freely available to all participants once their blinded assessment has been completed.

Permitted medications/treatments

There is no medication or treatment in this study.

Monitoring of participant compliance

Onsite facilitators will be present to conduct the virtual reality training session. Facilitators will further ensure that the traditional group reads the notes provided and watches the instructional video.

6 Assessment of Efficacy

Outcomes

Raw scores on the validated chest drain insertion competency checklist

Any deviation from the validated checklist

Time taken for task completion

Matched confidence scores using Likert data from a pre- and post-intervention survey.

Efficacy assessment

The TACTIC validated checklist for chest drain insertion competency will be used (10). The assessors will determine the number of deviations from the checklist and record the time taken to complete the procedure. Confidence levels will be assessed via matched Likert data.

7 Assessment of Safety

Risks and Benefits

Potential risks to the participants include motion sickness, nausea and headaches from the virtual reality training programme. Facilitators will attempt to improve comfort and ensure correct use of the virtual reality headsets in order to limit these effects. Infection risk and cross contamination will be managed by the use of a UVC irradiation device.

Emergent chest drain insertion is a potentially life-saving procedure and the benefits for potentially improving knowledge and skill of chest drain insertion is enormous.

Safety

Facilitators will be present and monitor for any ill effects developing as a result of the training intervention. Infection control will be provided via UVC irradiation device, used on the virtual reality headset. The controllers will be wiped down with disinfectant wipes between uses.

Adverse events reporting

Any adverse events will be reported via the research team.

- Minor event: follow up with candidate
- More serious event: Regular follow up until resolved/ referral to care provider as determined by independent assessment.

Follow-up of Adverse Events

Any adverse events will be followed up until resolution of any symptoms.

8 Data Management, Statistical Analysis and Record Keeping

Statistics and Interim Analysis

Wilcoxon signed-rank test will be employed to assess any differences that may exist between the two groups. Likert-type questions will be used to obtain self-reported confidence data pre- and post-educational sessions. The median results of the Likert-type questions will be shown to describe central tendency.

Sample Size

The pilot project will use a convenience sample of Anaesthesia registrars at FSFHG. Currently there are 51 registrars. All registrars will be approached to participate. The study is a proof of concept study. Due to the fact that virtual reality software has only recently been developed, there is to the best of our knowledge no other published data to refer to. If a difference is noted between the study groups, a power analysis will be conducted to calculate the sample size necessary in a follow up study, to confirm differences that may exist.

Study Power and Significance

A validated checklist will be used to assess each candidate's placement of a chest drain. This checklist has 20 steps, graded out of 40 points, that must be completed in order for the chest drain placement to be deemed safe & successful. The mean score of the two study groups will be compared. A difference in the mean score p value of 0,05 will be deemed significant.

A power analysis will be conducted for a subsequent study, based on the results of this pilot trial.

As there is no data for VR teaching in terms of medical procedures in anaesthesia this study will provide a baseline comparison to traditional teaching. Certainly, an increase of 20% in the mean score would be seen as significant.

Statistical plan deviations

There is no anticipated deviation from the scoring system used to assess the placement of the chest drain. Incomplete scoring systems will not be included in the final analysis but may be used to make trends in comparisons between the two groups. Should any unanticipated protocol deviation occur this will be reported to the hospital ethics committee and a decision to proceed further will be made by the investigators.

Selection of participants for analyses

Participant selection will be via a convenience sampling of Anaesthesia Registrars from the Department of Anaesthesia and Pain Medicine at FSFHG. All consenting and participating registrars will be included in the final analysis of the two teaching methods employed in the study.

Data Management

All of the participate data will be anonymised and deidentified. The data will be stored on the chief investigator's password protected work computer. The data will only be accessible by the research team. The computer is locked in a cupboard in the anaesthetic department, which is only accessible by staff access security badges. Access to this data will be further blocked by passwords to specific folders minimizing access. No personal data will be shared with any 3rd party sponsors or external teams. Data including electronic, hardcopy and consents will be stored for a period of 7 years from the period of publication and will be made available should a written request be made by the ethics committee or hospital board. The data, hardcopies and consents will be destroyed after 7 years.

Procedure for accounting for missing, unused, and spurious (*false*) data.

All collected data will be analysed by each member of the investigating team. Incomplete data will not be included in the final analysis. Incomplete data may be used to analyse trends in the data from which no final conclusions will be drawn. Incorrectly completed checklists will not be utilised for final analysis.

9 Monitoring / Audit

Monitoring, Audit and Regulatory Inspections Statement

The project investigators/institutions will permit project-related monitoring, audits, and regulatory inspections, providing direct access to source data/documents. This may include, but not limited to, review by external sponsors, Human Research Ethics Committees and institutional governance review bodies.

Procedures for Monitoring and auditing

The project investigators will allow for any monitoring of processes to occur during the investigation. Further nomination by FSFHG Innovation Group or Vantari in terms of requests for monitoring will be considered by the investigating group.

10 Quality Control and Quality Assurance

Compliance statement

The project will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements.

Quality control

Quality control & quality assurance measures to ensure quality of data.

11 Ethics

In terms of the ethical considerations related to “Research merit and integrity” the research is believed to be justifiable through the potential benefit of improved training and patient safety. The study has been designed using appropriate methods to achieve the aims outlined in the proposal. This is novel research, medical VR software has only recently been created and our research team is the first to study its application. The study has been designed to ensure that respect for the participants is not compromised by the aims of the research, its methodology, or results. The study will be conducted and supervised by appropriately trained and qualified persons or teams. The study will be conducted using appropriate facilities and resources. Participant integrity will be ensured by conducting the research under the over-riding principles of Good Clinical Practice, a commitment to searching for knowledge and understanding; following recognised principles of research conduct; conducting research honestly; and disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

In terms of “Justice” the researchers will take into account the scope and objectives of the proposed research. The selection, exclusion and inclusion of categories of research participants will be fair and accurately described in the results of the research. The process of participant recruitment will be fair; there is no unfair burden of participation in research for any particular group. There is a fair distribution of the benefits of participation in research and there is no exploitation of participants in the conduct of research. We will ensure that there is fair access to the benefits demonstrated through the results of the of research. Research outcomes will be made accessible to all research participants in timely and clear manner.

In terms of “Beneficence”, the possible benefits of the study outweigh any potential risks to the participants. The study has been designed to minimise any risks of harm or discomfort that may be experience by any participant. The potential benefits and risks will be clearly explained to all participants in the consent document.

In terms of “Respect”, the participants will be recognised for their intrinsic value. This recognition will be demonstrated through the values of research merit and integrity, justice and beneficence. The study will respect and acknowledge the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research. The research group will respect the privacy, confidentiality and cultural sensitivities of all the participants. Respect for the participants will be maintained by supporting autonomy throughout the research procedures.

The consent form was created using guidance from the National Health and Medical Research Council.

12 Budget, Financing, Indemnity and Insurance

The innovation group of the Fiona Stanley & Fremantle Hospital Group has provided $7919 for a virtual reality ready laptop computer and UVC irradiation hardware for infection control. Vantari VR is providing the VR software free of charge. The traditional group’s learning materials have been provided free of charge from the Emergency Trauma Management course.

13 Publication

Publication in a high impact international anaesthetic journal.

14 References

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15 Appendices

1. Virtual Reality Insertion of Chest-drain Outcomes Research- VICTOR pre and post survey
2. Email permission for use of traditional teaching methods
3. Chest drain insertion checklist (10)