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Exploring the feasibility of using virtual reality as a non-pharmacological intervention to alleviate patient fear of needles during medical treatment: A study protocol

Abstract

Background: An extreme fear of needles results in patients avoiding procedures that involve needle exposure, potentially compromising their health outcomes. Virtual reality is a simulated three-dimensional environment created using an audio-visual headset that may reduce patients' level of anxiety during needle exposure.

Aims: The primary aim of the study is to determine the feasibility of using virtual reality to manage anxiety and reduce fear during intravenous cannulation. The safety and experiences of patients and health care professionals using virtual reality will be explored.

Methods: This feasibility study will use mixed methods. Participants will undergo needle exposure with standard care and the virtual reality intervention. Quantitative data of physiological vital signs and qualitative data, gathered using semi-structured interviews, will be used to describe participants' physiological and anxiety responses. Both patient and clinician experiences of, barriers to and enablers of the virtual reality intervention will be explored.

Discussion: Distraction therapy using a virtual reality simulated environment has the potential to reduce negative patient reactions associated with needle phobia. If virtual reality is found to be a feasible distraction therapy for adult patients with needle fear, then larger trials can be undertaken to determine the effectiveness of the intervention as part of usual practice.

Background

Needle fear and needle phobia

Needle phobia, also known as blood-injection-injury phobia, is a severe form of needle fear and is described in medical literature using multiple terms including trypanophobia, belonephobia and aichmophobia.[1] The World Health Organisation has classified it with an International Classification of Disease – Tenth Revision (ICD-10) code as the fear of injections and transfusions, with the condition being defined as being such a severe fear of needles that the patient actively avoids undergoing any procedure that involves exposure to needles or injections.[2]

The fear response from a patient can be so intense that even seeing a needle can trigger a physiological response such as increased blood pressure and heart rate.[3] Needle phobia has also been associated

with avoidance of preventative treatments like vaccinations, needle-based procedures such as diagnostic tests and treatment of both acute and chronic conditions.[4]

Approximately 75 per cent of patients with needle phobia will have an extreme physiological response when faced with venepuncture, experiencing symptoms such as a physiologically significant increase in heart rate and blood pressure followed by a reversal of these increases, leading to a vasovagal or fainting episode.[5] Hamilton[6] analysed patient case studies and reported 23 deaths attributed to vasovagal episodes related to needle phobia. Although these deaths were attributed to the patients having a previously compromised cardiovascular system, such as atherosclerosis or impairment in the sinoatrial or atrioventricular node in the heart resulting in ventricular fibrillation or asystole, they were catalysed by needle phobia–related vasovagal episodes,[6] which may be triggered or heightened by needle exposure.

The level of needle phobia in the general population is dependent on age and ranges from 20 to 50 per cent in adolescents and 20 to 30 per cent in young adults. The percentage of patients with needle phobia decreases by 8.7 per cent per decade and is less than 5 per cent in the aging population.[4] However, older patients are at a significantly greater risk of vasovagal episodes and complications arising from such episodes.[7]

The current management methods for needle phobia include sedation, topical anaesthetic agents, benzodiazepines and hypnosis.[8] The use of medications increases costs and has a risk of unwanted side effects, and hypnosis can also be costly and time-consuming. Increased accessibility to virtual reality technology creates an opportunity for using this technology to distract and calm patients as an alternative to current management methods.

During needle-based procedures, such as intravenous cannulation, a patient needs to remain still while the needle is being inserted to provide the best possible chance of correct insertion on the first attempt and to reduce the risk of a needle stick injury. Virtual reality interventions, which involve the person wearing a headset while seated or lying down, provide an ideal method for keeping a patient distracted yet still. By reducing fear and anxiety, the patients' satisfaction with their procedural experience is likely to be increased and the likelihood of vasovagal responses and possible medical emergencies induced by fear of needles is likely to be reduced.

Virtual reality

Virtual reality is a computer-generated, three-dimensional, interactive environment that creates a sense of immersion for the user.[9] The user's virtual presence in the simulated environment is generated through visual stimuli via a head-mounted display that tracks head motion and displays images or video footage that adapts the virtual environment in response to the wearer's movement.[9] This visual input combined with sound, either provided through inbuilt speakers or headphones, gives the wearer a sense of presence in the simulated environment. Phobia management techniques focus on reducing attention bias to reduce the level of fear associated with specific phobias and anxiety disorders.[10] Similarly, virtual reality works by reducing attention bias, thereby reducing the level of fear and severity of symptoms that result from the patient's needle phobic response.[11]

Virtual reality has been successfully used as an intervention for paediatric patients undergoing intravenous cannulation and has resulted in a reduction of the patients' procedural pain and anxiety.[12,13] Virtual reality has also been successfully studied for the treatment and management of other phobias including social anxiety disorders, agoraphobia, acrophobia and aerophobia.[3] However, there are very few studies into and evidence is lacking about the use of virtual reality for needle fear or needle phobia in an adult population.

Research question and study aims

This proposed study seeks to answer the research question, 'Is virtual reality a feasible distraction therapy for adult patients with needle phobia, undergoing intravenous cannulation?' The study aims are to explore:

- the feasibility of using virtual reality as a distraction intervention in patients with needle phobia
- clinicians' experience of providing care to patients receiving virtual reality distraction intervention
- the barriers to and enablers of using virtual reality as a distraction intervention in the hospital setting.

Methods

Study design

The study is a feasibility investigation using mixed methods underpinned by a framework of pragmatism. As shown in Table 1, Bowen et al.[14] assert that feasibility studies have eight general areas of focus. These are acceptability, demand, implementation,practicality, adaptation, integration, expansion and efficacy.

This study will investigate four of these areas:

- how both those delivering and those receiving the virtual reality intervention are affected by its implementation (acceptability)
- how successfully the virtual reality intervention is delivered to participants (implementation)
- the extent to which the virtual reality intervention can be delivered, and the resources, time and commitment required (practicality)
- how easily the virtual reality intervention can be implemented within the existing systems (integration)

The study is guided by pragmatic reasoning, combining both inductive and deductive reasoning resulting in a greater understanding of the experience under investigation.[15] Quantitative data can be improved with descriptive language and qualitative data backed up with numerical data.[15] Using mixed methods provides triangulation between the different data sets being examined[16] and provides a voice to the study participants so that the findings reflect the participants' experiences.[17]

Participants and setting

Inclusion criteria

Two types of participants will be recruited for the study:

1. patients aged 18 years or older with self-reported fear of needles, previous episode/s of vasovagal response induced by needle exposure, and/or diagnosis of needle phobia, and who are scheduled to attend Albury Wodonga Health, a regional health service in Australia.
2. health care workers who are present when a participant is using the virtual reality distraction intervention.

Exclusion criteria

Potential participants will be excluded if they:

- require guardian consent. This exclusion criterion is due to difficulty in obtaining informed consent.
- have insufficient English to understand the study information and consent form. The study is unfunded and therefore there is no capacity to employ an interpreter service.
- require, or are awaiting the outcome of, a COVID-19 test. This exclusion criterion is to reduce any chance of transmission of the COVID-19 virus.

Recruitment

Recruitment will be conducted using a multi-tiered approach described below. The recruitment process will be enacted until a convenience sample of five (n=5) patients and three (n=3) health care workers have been recruited. The potential participant pool is patients who present for needle exposure at either Albury Wodonga Health or affiliated organisations.

During recruitment and other stages of the study, the term 'needle fear' will be used with patient participants as it is a lay-friendly description. The term 'needle phobia' will be used with staff participants as needle phobia is a known diagnosis and commonly used medical term.

Table 1: Key areas of focus for feasibility studies (adapted from Bowen et al.[14])

Area of focus	
Acceptability	Is the idea or measure being studied considered appropriate or desirable by deliverers and recipients?
Demand	Is the idea or measure being studied needed and likely to be used?
Implementation	Can the idea or measure being studied be successfully delivered to intended recipients?
Practicality	Can the idea or measure being studied be delivered to intended recipients using existing resources, without outside intervention?
Adaptation	Can the idea or measure being studied be changed to suit different circumstances?
Integration	Can the idea or measure being studied be included within the existing system?
Expansion	Can the idea or measure being studied be expanded to provide a new program or service?
Limited efficacy	Does the idea or measure being studied show promise of being successful with the intended population, even in a highly controlled setting?

Patient recruitment

Recruitment of patient participants to the study will be targeted or by referral.

Targeted approach

The nursing staff at Albury Wodonga Health maintain a registry of patient requirements, including those patients with severe needle fear or needle phobia. Nursing staff and the principal researcher, who is a nurse employed by Albury Wodonga Health, will identify any scheduled patients who meet the inclusion criteria for the study. The nursing staff and the principal researcher will meet weekly to identify potential participants.

At the time a potential participant books a procedure, the nursing staff will inform them about the study and ask if they are willing to learn more about the study. If they agree, the nursing staff will provide their name and contact details to the principal researcher. The potential participant will be sent an information sheet about the study. The principal researcher will follow up with the potential participant one to two weeks before their scheduled procedure to invite them to participate, if they request additional information the participant information and consent form will be sent to them in the mail. The consent will be required to be signed on the day of their procedure. All participants will be provided with a fresh copy of the document.

If the potential participant provides verbal consent to participate, a laminated tag identifying them as a potential participant will be added to their admission file. After they have been admitted, the principal researcher will meet with them to answer questions and obtain their signed consent to participate.

Referral approach

If a patient meets the inclusion criteria and has a needle fear–related event during a medical procedure, nursing staff will provide the patient with information about the study. The nurse will ask if the patient agrees to their name and contact details being forwarded to the principal researcher for telephone follow-up, and then possible recruitment as detailed in the targeted approach above.

Staff recruitment

Nursing staff will be given details of the study by the appropriate nurse unit manager (NUM) and the principal researcher at either a team meeting or via email. With the team meeting approach, the NUM will introduce the principal researcher and topic to the team. The principal researcher will present the study to the nursing staff to reduce any perceived pressure to participate and the NUM will emphasise that participation by staff is completely voluntary. The participant information and consent form will be available at the team meeting, and nursing staff will have the opportunity to ask questions. The email approach will involve the principal researcher emailing the NUM with information about the study, and the NUM forwarding this email to the staff. Signed consent will be obtained from participating staff on the day prior to the procedure.

Intervention

The intervention will be introducing the participant to the Samsung Oculus Go virtual reality environment for a virtual reality experience in the *exVRience relaxation*[18] application. Participants will be offered a choice of three virtual environments – beach, lagoon or waterfall. The visual presentation the patient is experiencing will also be displayed on a mobile tablet for the principal researcher to view, to ensure that the system is working correctly. Participants will undergo intravenous cannulation, and therefore needle exposure, while in the virtual environment.

Data collection

Patient participants

A combination of measurement of multiple physiological parameters and completion of a self-reported scale has been found to be the most reliable indicators of patient anxiety.[19] Patient participants will therefore have physiological parameters measured and complete a self-reported visual analogue scale (VAS) for procedural anxiety twice, once before and again after the intravenous cannulation procedure.

Baseline physiological measurements will be recorded from standard portable patient observation machines (PPOM) and will include:

- non-invasive blood pressure (NIBP)
- heart rate (HR)
- pulse oximetry (SpO2)
- respiration rate (RR).

PPOMs are located in each department in the health care setting. Peripheral patient monitoring attachment accessories will be worn as per clinical protocols. The standard patient observations will be collected by the nurse and recorded on the patient observation and response form (MR59). The principal researcher will take a copy of the MR59 to include as data in the study.

The self-reported VAS for procedural anxiety that will be used has been developed by Cao et al.[20] This method of assessing anxiety has been evaluated as an effective measurement scale.[20–22]

Once the first set of physiological measurements and VAS are completed, the participant will be introduced to the virtual reality, and undergo needle exposure while in the virtual environment.

Following intravenous cannulation, the second set of physiological measurements and VAS will be completed, and the patient participants will be interviewed by the principal researcher. The focus of this semi-structured interview will be to explore the patient participant's past and present experience of needle fear and of the virtual reality intervention.

Staff participants

After completion of the medical procedure, the health care worker performing the intravenous cannulation will be interviewed. The focus of the staff participant interviews will be the acceptability of the virtual reality intervention, how the intervention compares with standard care, and the usability of and barriers to using the virtual reality intervention.

Analysis

Quantitative data will be presented as raw case data for all physiological measurements and summary pre- and post-descriptive statistics (mean and standard deviations) only. Any physiological changes will be examined against the participants' self-reported levels of anxiety recorded on the VAS. As this study is a feasibility study, inferential statistics and statistical significance will not be conducted; however, the data will be used to inform sample size estimation for a potential, larger future study.

The qualitative data will be analysed using thematic analysis. Thematic analysis is used to identify, analyse, interpret and then report on themes that occur within data. Thematic analysis requires care, attention and transparency to ensure the trustworthiness of the findings made by the researcher.[23] The thematic analysis will follow the six phases as outlined by Braun and Clarke.[24] Firstly, the transcriptions will be read while listening to the audio recordings to reinforce the initial understanding of the data. Following this process, preliminary codes will be generated and collated into emerging themes. The themes will be reviewed and defined before coding the entire dataset. The themes will be described and defined to the main purpose and breadth of each theme to produce the report and provide analytical insights. The principal researcher will carefully select de-identified examples of data to illustrate the themes.

Materials required

The materials required for the study include the use of the Albury Wodonga Health portable patient observation equipment and a digital data recorder available for use from the John Richards Centre for Rural Ageing Research. Access to a multi-function printer to scan and store copies of the patient's MR59 charts will also be required. All the required equipment is available for the study.

Discussion

This proposed study is to determine the feasibility of virtual reality to alleviate patient fear of needles during medical treatment. Although the fear of needles or needle phobia affects a small proportion of the older adult population, the consequences are profound and magnified due to age-related risk factors. Despite this, there is a lack of research into needle phobia in comparison to other phobias.[11] A literature review we have conducted found that virtual reality as a distraction therapy has not been used in the adult population. This is important for patients with needle phobia as the proposed study has the potential to add a new method for coping with their level of fear and anxiety.

The benefits of the study have implications for the care received by needle phobic patients and include a reduction in the level of fear and anxiety experienced by the patient. This reduction in fear and anxiety has the potential to lead to increased health compliance in patients with needle phobia by increasing their uptake of health interventions that involve needles, including vaccinations and blood tests.

Trustworthiness

To assist with trustworthiness in qualitative research, four elements should be established – credibility, transferability, dependability and confirmability.[25] Vasileiou et al.[26] recommended that there be transparency about how evaluations of sample size sufficiency are calculated in qualitative health research. The projected sample size for the current study is small due to the restraints of being a feasibility study; a small sample size is acceptable for a feasibility study.[27,28] In addition, the principal researcher will be supervised and assisted with the data analysis by the second author, who is an experienced qualitative researcher.

To assist with the transferability of the results to a reader's local context, a clear narrative and outline of the context of the study will be written with the research results enabling readers to decide if their circumstances are comparable.[29] With regard to dependability, the triangulation between the results will assist in ensuring that the

findings are consistent between the participants. An audit trail will be created for any methodological decisions that are made during the study. Confirmability will be established by the interviews being recorded and conducted soon after the time of needle exposure, to aid participant recall of the experience.

Study strengths and limitations

The strength of the proposed study is that it was conceived in response to a problem observed in clinical practice by a nurse practising in a major regional hospital. Hence the findings are likely to have implications in the real world.

A limitation is the small sample size so effectiveness, if any, cannot be inferred. In addition, the sample pool is from a single regional health service in Victoria, Australia and the results may not be generalisable to the wider populations. To reduce these limitations, additional studies are proposed once the feasibility of the intervention has been established.

Timeline

The proposed study will be conducted in four stages.

Stage 1: Approval process

Ethical approval was granted by the Albury Wodonga Health Human Research Ethics Review Committee and the La Trobe University Science Health and Engineering Human Ethics Committee in December 2021 with reference number HREC/77359/AWHEC-2021-291166(v1).

Stage 2: Recruitment and trial of virtual reality equipment

Six months have been allocated for this stage of the study.

Stage 3: Data collection and analysis

Data collection and analysis will commence once the first participant has been recruited and will run concurrently with recruitment. The analysis is scheduled to be completed within three months after data has been collected from the final participant.

Stage 4: Writing and reporting

A report of the study will be submitted for publication to an appropriate journal. An additional four months after completion of data analysis has been allocated for writing the report. Results of the study will also be submitted to the Victorian Perioperative Nurses Group (VPNG) and/or the Australian College of Perioperative Nurses (ACORN) for presentation at their conferences.

Declaration of conflicting interests

The authors have declared no competing interests with respect to the research, authorship and publication of this article.

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Authors' contributions

The primary author conceived the idea for this study and led the writing of the protocol. The second and third authors are research supervisors for the proposed study. All authors contributed to the drafting and development of the protocol. All authors read and approved the final manuscript.

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