**Design of Study and Protocol**

Assessing the Feasibility of Virtual Reality Technology as an Intervention for Women in Labour and an Exploration of the Experiences of Women using Virtual Reality in Labour.

**Study Summary**

This project is a mixed methods study to explore the experiences of women in a tertiary maternity unit using Virtual Reality (VR) as a non-pharmacological method of pain relief in labour and to discover whether VR has an effect on the experience of labour pain for women. The design brief is to assess the acceptability and feasibility of the VR intervention pre-birth; to determine its effectiveness in reducing subjective and objective measures of labour pain intensity and post-birth to explore women’s experiences of using VR in their labour and birth. The first outcome for this research is to conduct usability assessments for the VR device and for the range of VR environments that will be trialed by the participants. The second outcome is to collect quantitative data on subjective and objective labour pain intensity. The third outcome is to collect qualitative data on the experience of using VR in labour and birth. The research will be carried out by a PhD student towards her Doctorate Degree with academic support from her Supervisors. The researcher has clinical expertise in the area of Midwifery as a practicing Midwife. The research participants are pregnant women who will provide feedback on their experience (i.e. the usability) of the Virtual Reality device pre-birth, during labour and post-birth.

**Study Question**

There is worldwide concern over rising epidural analgesia rates for women in childbirth and the use of pharmacological methods of pain relief in normal labour. Epidural analgesia is directly linked to the rise in morbidity associated with obstetric interventions (Leap & Anderson, 2008) and renders birth non-physiological (Walsh, 2009). There are a range of side-effects of epidural and opiate analgesia for mother and baby, from minor inconvenience to life threatening. Birth is a normal physiological process and many women want a natural non-pharmacological birth. There are a range of non-pharmacological methods that can help women manage labour pain. Many of these methods use distraction and visualisation techniques, such as mindfulness, guided imagery, hypnosis, touch and controlled breathing. VR utilises many of these elements, distraction and visualisation with meditative and hypnotic features. VR provides the user with a sense of ‘presence’, the illusion that users are in a computer-generated environment or ‘virtual world’ (Gold et al, 2007). This unusually strong illusion of being in a virtual world is theorized to contribute to the effectiveness of VR in reducing pain (Hoffman et al, 2008, 2011).

The overall study question is: “What are women’s experiences of using Virtual Reality during labour?”. The researcher will be conducting research that will contribute to answering this question.

**Study Design**

The study is to assess the feasibility of using VR as an intervention for women in labour, to determine whether there is an effect on the experience of labour pain and to explore the experience of using VR in labour and birth. The study design is mixed methods with three phases. Phase I is a qualitative phase. A feasibility study is planned which will trial four – six VR environments with the participants in the antenatal period. Semi-structured interviews will be conducted to determine acceptability and feasibility of using VR in labour. These interviews will be audio recorded and transcribed. Attributes of the VR environments will be assessed by the participants to help determine the optimum VR experience for use in labour. Phase II is a quantitative phase and is a quasi-experiment within-subjects method. The participants will have baseline data recorded pre-intervention (before using the VR device). This consists of pain scores using a Verbal Rating Scale (VRS) and maternal heart rate and blood pressure. During the intervention these same measures will be taken every 5 mins for 15 mins while wearing the VR device and every 10 mins after that. Once the VR device is stopped the same measures will be taken 10 mins and 15 mins post-intervention. Phase III is the final qualitative phase. This phase will explore the experiences of the women who used VR in their labour and birth. In this post-natal period data will be collected using audio recorded semi-structured interviews.

Participant data collection will also include non-identifying demographic information and relevant medical information to determine eligibility criteria and relevant clinical information relating to their pregnancy.

The setting for this research is firstly in the community – participants will be interviewed in their home or at a place of their choosing. In the second phase the setting will be where they choose to give birth, either their home, a midwifery-led unit or a tertiary maternity unit. In the final phase the setting will again be in the community – in their home or at a place of their choosing. Inclusion criteria for participants is: 35 weeks pregnant, primiparous or multiparous, 18 years and older. Exclusion criteria is: no seizure history, vision or hearing deficits, history of psychiatric disturbances, history of severe nausea or predisposition to motion sickness, English as a second language needing the use of an interpreter.

Invitations for participant involvement will be made through their Lead Maternity Carers – either midwives or obstetricians or directly to the participants via antenatal classes, hypnobirthing groups and the VR community. The participants will self-select based on a discussion with the researcher and the information they receive in the information sheet. The engagement of Māori participants in this research will be undertaken by the recruitment invitation process. The researcher will be orientated to the appropriate behaviours with Māori participants by attending a Research Advisory Group Māori (RAG-M) Tikanga Māori training session.

Dissemination of the study findings and a summary report will be sent to Research Advisory Group Māori (RAG-M) and a locality report to the Māori DHB reviewing team. All participants in the research will be offered a copy of the final report.

**Scientific Justification**

Epidural rates among childbearing women are rising and the use is widespread. In New Zealand 26% of women in 2015 were reported to have received epidural analgesia (New Zealand Ministry of Health Report on Maternity, 2015). The largest maternity hospital in New Zealand, National Women’s in Auckland, reported an epidural rate among all birthing women of 67.5% in 2017 compared with 52% in 2010, 72% of women who were induced had an epidural compared with 43% of women in spontaneous labour (Auckland District Health Board Maternity Annual Clinical Report, 2010 & 2017). The drugs used in labour epidurals are powerful to numb and usually paralyse the mother’s lower body, it is not surprising that there can be significant side effects for mother and baby. These range from minor effects to life threatening. Maternal effects include: increases the length of first and second stage of labour; increases use of synthetic oxytocin use; higher rates of instrumental delivery; higher rates of caesarean section for foetal distress; increase in third and fourth degree perineal tears; leads to hypotension; causes motor blockage; causes urine retention and maternal fever. Neonatal side effects include: tachycardia due to maternal fever; higher rates of hypoglycaemia; reduced rates of breastfeeding (Howell, 2011).

Several systematic literature reviews have analysed the scientific evidence for the effectiveness of VR for acute pain and have concluded that VR can be recommended as a standard or adjunct clinical intervention for pain management in acute pain (Shahrbanian et al, 2009; Sharar et al, 2007; Morris et al, 2009).

A recent pilot study investigated the use of VR in twenty-seven laboring women in the USA. Women were observed during un-medicated contractions in the first stage of labour with and without VR. Statistically significant decreases in sensory pain, affective pain, cognitive pain and a moderate effect on anxiety were observed during VR.

**Skills and Resources**

Dr Brian Robinson, Senior Lecturer, Graduate School of Nursing, Midwifery & Health, Victoria University of Wellington

Dr Edgar Rodriguez, Associate Professor, School of Design, Victoria University of Wellington

Dr Robyn Maude, Senior Lecturer, Graduate School of Nursing, Midwifery & Health

Dr Craig Anslow, Assistant Professor in Software Engineering, School of Engineering, Victoria University of Wellington

The supervising investigators experience, and expertise is a mix of health physiology, midwifery, industrial design and software engineering. Dr Robinson has clinical research experience, including physiology of pain, and in addition has experience in the usability and design of medical devices. Associate Professor Rodriguez has expertise in the design and usability of interactive devices and qualitative research methods. Dr Maude has clinical research experience in the areas of midwifery and mixed methods research. Dr Anslow has expertise in software development and programming.

**Protocol**

**Study Aim:**

The aim of this iterative sequential mixed methods study is in the first qualitative phase to determine whether women will use Virtual Reality in labour. The second quantitative phase will measure subjective and objective variables of labour pain intensity. The third qualitative phase aims to explore women’s experience of using Virtual Reality in the postnatal period.

**Data Required:**

**Demographic data**

**Rationale:** The data will be collected to describe the research participant group. Data will be collected by completion of an information sheet at interview. Clinical notes will not be accessed.

**Data Collected:** Age, ethnicity, educational qualification, parity.

**Experience of user data**

**Rationale:** User experience informs the usefulness of the device and software from a user-behaviour perspective. This informs future research studies and allows changes to be made to software.

**Data collected**: Participants will be invited to describe their experience using the device and software and will be asked questions regarding ease or difficulty of use, comfort or discomfort relating to use. Participants will be asked questions relating to the VR environments, if they appealed, or not, or were neutral and what features of the VR environments they enjoyed, did not enjoy, or were neutral. They will be invited to make suggestions for improvement. Participants will be asked whether they would use the VR device in their labour and if not, why not. Participants would also be asked questions relating to a sense of ‘presence’, whether they experienced ‘presence’, in one scene more than another.

**Effectiveness of intervention data**

**Rationale:** The data collected will determine the effectiveness of VR as an intervention to reduce labour pain intensity.

**Data collected:** Participants will self-report their pain intensity by scoring using the Verbal Rating Scale – a validated instrument and having their heart rate and blood pressure recorded pre-intervention, during intervention – every 5 minutes for 15 minutes and then every 10 minutes and post intervention.

**Experience of user data**

**Rationale:** User experience in labour informs the usefulness of the device and software from a user-behaviour perspective.

**Data collected:** Participants will be invited to describe their labour and birth experience using the device and software. Qualitative data will be collected via semi-structured interviews regarding their labour experience in terms of pain, fear, anxiety and locus of control. They will be asked questions asking them about ‘presence’ in the virtual environments.

**Data Storage and Confidentiality**

All data will be securely stored as digital files within the Victoria University data system for 5 years after collection. All data stored will have any identifiable information removed.

**Participant Numbers**

Qualitative research and analysis require smaller numbers of participants compared to quantitative research. As this project is using a mixed methods approach with the qualitative method being dominant a smaller number of participants will be recruited, noting how this will affect the statistical power required for the quantitative component. The study aims to collect and analyse data for 10 participants. There will not be a limit to recruitment numbers due to potential drop out.

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