

Effect of a low-cost Virtual Reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

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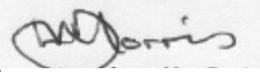
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Tygerberg Hospital's adult burn unit

DECLARATION

“I, the undersigned, hereby declare that the work contained in this thesis is my original work and that I have not previously in its entirety or in part submitted it at any university for a degree.”

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Date: _____31 August 2009_____

ABSTRACT

Background Albeit Virtual Reality (VR) has been shown to be a useful adjunct in the reduction of pain during burn care and therapy, the current VR systems are expensive and may not be economically feasible for developing countries such as South Africa, where health budgets are stringent. **Objective** The purpose of this study was to ascertain the effect of a low-cost VR system (eMagin Z800 3DVisor), used in conjunction with pharmacologic analgesics, on reducing pain and anxiety in adult burn injury patients undergoing physiotherapy treatment, compared to pharmacologic analgesics alone at a South African hospital. **Study design** Single-blinded, within-subject study design. **Methods** Pain and anxiety outcome measures were measured by a blinded assessor using the Numeric Pain Rating Scale and Burn Specific Pain and Anxiety Scale. Descriptive statistics, Chi-square tests as well as the Student's paired *t*-test were used to analyze data. **Main findings** Eleven eligible adult burn injury patients consented to participate in this study (3 female, 8 male; median age 33 years: range 23-54 years). A marginal ($p=0.06$) to insignificant ($p=0.13$) difference between the two conditions (analgesics with VR and analgesics alone) in reducing pain was found. No significant difference ($p=0.58$) was found between the two conditions (analgesics with VR and analgesics alone) for anxiety. **Interpretation** There is a trend that a low-cost VR system, when added to routine pharmacologic analgesics, is an economically feasible and safe adjunct therapy and could be of considerable benefit if implemented into the current pain management regimen of burn injury patients at a South African Hospital.

Key words *virtual reality, burn injury, adults, physiotherapy, pain and anxiety*

ABSTRAK

Agtergrond Ofskoon dit al bewys is dat Virtuele Realiteit (VR) 'n nuttige hulpmiddel is om pyn tydens die versorging en behandeling van brandslagoffers te verlig, is die huidige VR-stelsels duur en dalk nie uitvoerbaar in ontwikkelende lande soos Suid-Afrika waar die gesondheidsbegrotings beperk is nie. **Doel** Om die uitwerking te bepaal van 'n laekoste VR-stelsel (eMagin Z800 3DVisor) op die vermindering van pyn en angs by volwasse pasiënte met brandwonde wat fisioterapeutiese behandeling in 'n Suid-Afrikaanse hospitaal ondergaan. **Studieplan** 'n Enkel-blinde, binnesubjek-ontwerp. **Metodes** Volwasse proefpersone is opeenvolgend gewerf by die brandeenheid van die Tygerberg-hospitaal. Die laekoste VR-stelsel, tesame met pynstillers, is ewekansig aan een helfte van die pasiënte in 'n fisioterapeutiese behandelingsessie toegewys en die proefpersone is slegs een keer getoets. Die pyn en angs se resultaatmetings is deur 'n blinde meting gedoen deur die numeriese pynskattingskaal en die brandspesifieke pyn- en angsskaal te gebruik. Beskrywende statistieke, Chi-kwadraat-toetse en studente se gepaarde t-toets is gebruik om die data te analiseer. **Bevindings** Elf geskikte volwasse pasiënte met brandwonde het ingestem om aan die studie deel te neem, drie was vroulik en agt was manlik (mediaan-ouderdom 33; reeks 23-54). 'n Marginale ($p=0.06$) tot onbeduidende verskil ($p=0.13$) is gevind tussen die twee kondisies om pyn te verlig (met of sonder die toediening van VR). Wat angs betref, is geen beduidende verskille ($p=0.58$) tussen die twee kondisies (met of sonder die toediening van VR) gevind nie. **Interpretasie** Daar is 'n neiging dat 'n laekoste VR-stelsel, wanneer dit saam met die gewone farmakologiese pynstillers gebruik word, 'n veilige en ekonomiese praktiese adjunk terapie is en beduidend voordelig kan wees wanneer dit geïmplementeer word as deel van die huidige pynbeheerregimen van brandslagofferpasiënte by 'n Suid-Afrikaanse hospitaal.

Sluitel woorde *virtuele realiteit, brandwond, volwasse, fisioterapie, pyn en angs*

DEDICATION

This thesis is dedicated to my amazing husband, Grant, and my beautiful daughter, Georgia, who has been my inspiration and has supported me throughout with love and patience. Thank you for being my rock!

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ACRONYMS

- **VR** – Virtual Reality
- **NPRS** – Numeric pain rating scale
- **BSPAS** – Burn-specific pain anxiety scale
- **TBH** – Tygerberg Hospital

DEFINITION OF TERMS

- **Adult**

A person grown to full size and strength; one who has reached maturity, an individual aged 18 years and older (<http://dict.die.net/adult/>)

- **Burn injury**

Burns are injuries to tissues caused by heat, friction, electricity, radiation, or chemicals. Scalds are a type of burn caused by a hot liquid or steam (<http://www.merck.com/mmhe/print/sec24/ch289/ch289a.html>).

- **First degree burn or superficial burn injury**

A burn injury that causes little concern, represents injury to the most superficial layers of the skin, and clinically presents as erythema and pain (<http://www.merck.com/mmhe/print/sec24/ch289/ch289a.html>; DiGregorio 1984).

- **Procedural pain**

Pain felt by burn injury patients during daily procedures, e.g. wound dressing changes and joint range of motion exercises (usually by a physiotherapist). Pain is shorter in duration, but much greater in intensity than resting pain (Pal et al 1997).

- **Resting (background) pain**

Pain felt by burn injury patient when motionless or lying in bed between procedures. Constant and dull pain in nature (Pal et al 1997)

- **Second degree or partial thickness burn injury**

A burn injury that extends into the dermis and is clinically characterized by pain and blistering. Most second degree burns should re-epithelialize from the surviving skin appendages (hair follicles, sweat and sebaceous glands), however, some, although they do epithelialize, can produce significant morbidity. Therefore, second degree burns or partial thickness burns are further categorized into superficial partial thickness burns, which heal spontaneously with little morbidity, and deep partial thickness burns which produce delayed epithelialization and significant morbidity

(<http://www.merck.com/mmhe/print/sec24/ch289/ch289a.html>; DiGregorio 1984).

- **Third degree or full thickness burn injury**

Represents a burn injury to all layers of the skin. The damaged skin must be replaced, usually by split-skin grafts from other unburned portions, healed partial thickness skin, skin from another human, possibly a cadaver, or skin from another species, such as a pig

(<http://www.merck.com/mmhe/print/sec24/ch289/ch289a.html>; DiGregorio 1984).

- **Virtual reality**

A technology which allows a user to interact with a computer-stimulated environment be it real or imagined. Virtual reality environments are primarily visual experiences, displayed either on a computer screen or through special stereoscopic displays, but some simulations include additional sensory information, such as sound through speakers or headphones. Users can interact with the environment via an input device such as a mouse, joystick or keyboard (http://en.wikipedia.org/w/index.php?title=Virtual_reality&printable=yes).

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OUTLINE OF THESIS

The following thesis will be presented in a ‘**masters by publication**’ format.

Chapter 1 introduces the concept of Virtual Reality (VR) and provides rationale for conducting the study, as well as the ethical considerations for the study.

Chapter 2 presents a systematic overview of the current literature concerning the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients, during wound dressing changes and/or physiotherapy management, compared to pharmacologic analgesics alone or other distraction techniques.

Chapter 3 presents a short report on the pain and anxiety experiences of South African adult burn injury patients during physiotherapy management when they are only given pharmacologic analgesics to manage their procedural pain.

Chapter 4 concerns the randomized (condition only), single-blinded, within-subject trial which aimed to preliminarily investigate the effect of a low-cost VR system, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in adult burn injury patients during physiotherapy management, compared to pharmacologic analgesics alone.

In **Chapter 5**, the findings of this thesis are critically reviewed and discussed, with mention of clinical and cost implications, limitations and future recommendations.

PLEASE NOTE:

As the chapters in this thesis were written with the intention to be submitted for publication (in a ‘masters by publication’ format), the full methodology of chapters 3 and 4 were added as appendices in **Chapter 6** (appendix D2-3) for further information. In addition, although not specifically referenced to in the text of this thesis, the data collection form used to collect data from subjects for the studies in chapters 3 and 4 (appendix A), the construction process of the data collection form (appendix D1), outcome measurement tools – NPRS and BSPAS (appendix B and C) and informed consent forms (appendix E, F and G) used in these studies are all also listed as appendices.

INTRODUCTION

The following thesis reports on an analysis of the effect of a low-cost Virtual Reality (VR) system, in conjunction with traditional pharmacologic analgesics, on reducing pain and anxiety experienced by adult burn injury patients during physiotherapy management at the Tygerberg Hospital's adult burn unit in South Africa, compared to traditional pharmacologic analgesics alone.

BACKGROUND

Burn injuries are a common form of trauma and among the most devastating and painful of all injuries (James et al 2003; Forjough 2006). Clinical outcomes for a burn injury range from physical impairments and disability, to psychological disorders such as depression and anxiety (Forjough et al 2006; Wiechman et al 2004). The healing process following a severe burn is extensive and often entails long, grueling hours of physiotherapy rehabilitation, which may produce tremendous amounts of pain and subsequent anxiety on its own (Haik et al 2006). Unfortunately, pain caused during the physiotherapy procedure and subsequent anxiety, in anticipation of the painful procedure, hinders rehabilitation and often discourages patients from being compliant during their physiotherapy treatment sessions (Hoffman et al 2000; van Twillert et al 2007). Ultimately, patients' non-adherence during burn injury rehabilitation can lead to permanent reduction in limb mobility, with detrimental effects on functional daily activities (Hoffman et al 2001, Haik et al 2006). Adequate management of procedural pain and subsequent anxiety thus plays an important role in building a trusting relationship between the burn victim and the physiotherapist, and in promoting patient compliance with rehabilitation (de Jong et al 2007). Whilst traditional pharmacologic analgesics form part of any burn pain management regimen, alone they are often inadequate to effectively alleviate procedural pain experienced during physiotherapy management and are associated with side-effects. It is for this reason that supplemental use of non-pharmacologic adjunct therapies which are non-invasive and associated with less side-effects, are warranted in the rehabilitation process of burn injuries (Hoffman et al 2001). An example of such an adjunct therapy is a distraction analgesic technique called Virtual Reality (VR).

The application of VR is based on the assumption that pain perception has a large psychological component (Wismeijer et al 2005). It is assumed that pain attracts a strong attentive response because of the potential threat on the damaged tissue associated with the sensation of pain (Dunckley et al 2007). The redirection of this attention manipulates the pain perception, thereby reducing the intensity of pain (van Griensven et al 2005; Dunckley et al 2007). VR is a technology which allows a user to immerse and interact with a computer-generated environment (Das et al 2005). It redirects the patient's attention, distracts the patient and in essence, reduces the pain experienced during painful daily procedures. Since VR has minimal side-effects associated with it, it could possibly be a safe adjunct to traditional pharmacologic analgesics in the management of procedural pain experienced by burn injury patients during physiotherapy treatment (Hoffman et al 2006).

A systematic review of the literature found that to date nine studies have been conducted investigating the effect of VR, in conjunction with pharmacologic analgesics, on pain and/or anxiety in burn injury patients during wound dressing changes or physiotherapy management, compared to pharmacologic analgesics alone (Morris et al 2009). The majority of the studies had small sample sizes and only two of the included studies trialed VR during the physiotherapy treatment session of burn injury patients. The rest trialed VR during the wound care sessions, warranting more research investigating the effect of VR during physiotherapy management of burn injury patients. None of the studies included in the review were conducted in a developing country setting, where burn injuries are usually more prevalent and more severe than in developed countries (Ahuja et al 2004; Mock et al 2008). The review concluded that VR, in conjunction with pharmacologic analgesics, was effective in reducing pain in burn injury patients, but that equivocal evidence remained for the effect of VR in reducing anxiety, during wound dressing changes and physiotherapy, compared to pharmacologic analgesics alone.

SIGNIFICANCE OF STUDY

Despite the fact that VR has been found to be effective in the reduction of pain in burn injury patients from developed worlds (Morris et al 2009); the current VR systems used in international studies are expensive. For developing countries such as South Africa, where burn injuries are prevalent, but health budgets are stringent (Louw et al 2007), these current

VR systems may not be economically feasible as adjunct therapies. Cost concerns as well as constraints of time, resources and access to treatment prohibits developing countries from implementing expensive interventions (Rand et al 2008). Not only are effective interventions required in developing countries where the burden of disease tends to be higher (Lopez et al 2001), but less expensive interventions are imperative (Rand et al 2008). It is for this reason that the idea of investigating the use of a low-cost VR system, in the management of pain and anxiety in burn injury patients in a developing world clinical burn setting, was posited.

The following study thus aimed to analyze the effect of a low-cost VR system (the eMagin Z800 3DVisor), in conjunction with pharmacologic analgesics, on reducing pain and anxiety experienced by adult burn injury patients during physiotherapy in a South African hospital, compared to pharmacologic analgesics alone. The lower-cost VR system used in this study is different to the current VR systems in many ways, but most importantly it costs a fraction of the price. Table 1 illustrates the main differences between the low-cost VR system used in this study (http://www.3dvisor.com/pdf/Z800_datasheet.pdf) and the VR system usually used in previous VR studies (the ProView SR80A) (http://www.rockwellcollins.com/ecat/gs/ProView_SR80A.html).

Table 1: Differences between VR systems

	ProView SR80A (usual VR system)	eMagin Z800 3DVisor (low-cost VR system)
Cost	± R230 000 (excluding shipping costs)	± R13 000 (no shipping costs involved)
Weight	1.75 pounds (± 794g)	<8 oz (<227g)
Resolution	1280 x 1024 full color	800 x 600 triad pixels per display, 24 bit color for more than 16.7 million
Control unit dimensions	2.5" x 8" x 10"	6.1" x 3.45" x 1.15"
Viewing angle	80 degrees diagonal	40 degrees diagonal
Head tracker	Head tracker has to be bought separately at approx. R16 800 (The Intersense IC3)	System has a built-in head tracker (360-degrees horizontal, >60-degrees vertical, 6-degrees of freedom motion tracking)

Since the low-cost VR system possesses similar technical properties as the usual VR system, it is hypothesized that the less-expensive VR system used in a developing world setting, will illustrate similar clinical results to its more expensive counterpart used in developed worlds. To our knowledge, this was the first study which investigated the effect of a low-cost VR system on pain and anxiety experienced by adult burn injury patient's during physiotherapy management at a developing world clinical burn setting.

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ETHICAL AND LEGAL CONSIDERATIONS FOR THIS PROJECT

Ethical approval for this study was obtained from the Committee for Human Research at the Stellenbosch University during January 2008 (N08/01/019).

Consent

All subjects were required to give written informed consent prior to participating in the study. Each eligible subject was individually informed of the purpose and procedures of the study, and this informed session was in the language most well understood by the subject (either English, Afrikaans or Xhosa). An informed consent form was read and signed by each subject on agreement of participation. Consent forms were in triplicate, one for the subject's folder that the subject completed, one completed by the study personnel and one that the subject kept. In addition, there were standard protocols for introductions, explanations, VR administrations and data collection, which would allow for inter- and intra-rater reliability. Informed and written consent was obtained for VR administration, collection of data, storage of data and data analyzing procedures.

Confidentiality

The subjects' identity and study results were kept confidential at all times, and the subject was informed of his/her anonymity throughout the study procedure. The data recorded did not have any subject identification attached to it. Instead, a study record/reference number was allocated to each subject (e.g. VR1-01, VR2-01, etc). The study record/reference number and respective subject's name correlation were stored in completely separate file. All subjects were treated the same irrespective of entry into the study or not. All decisions were made in the subjects' best interest.

PERMISSION TO CONDUCT STUDY

Permission to conduct the main study in the Tygerberg Hospital's (TBH) adult burn unit was requested and obtained from the Head of the TBH adult burn unit, Dr van der Merwe. Further liaisons with the head matron, Mrs. Stigling and administration head, Mrs. Basson and Mrs. Smith were conducted to inform the ward staff of the study procedures.

THE EFFECTIVENESS OF VIRTUAL REALITY ON REDUCING PAIN AND ANXIETY IN BURN INJURY PATIENTS A SYSTEMATIC REVIEW

The following chapter provides a systematic overview of the current literature available concerning the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients, during wound dressing changes or physiotherapy management, compared to pharmacologic analgesics alone or other distraction techniques.

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**THE EFFECTIVENESS OF VIRTUAL REALITY ON REDUCING PAIN AND
ANXIETY IN BURN INJURY PATIENTS
A SYSTEMATIC REVIEW**

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ABSTRACT

Objective: To systematically review the current evidence for the effectiveness of Virtual Reality (VR), in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients, undergoing wound dressing changes, and physiotherapy management, compared with pharmacologic analgesics alone or other forms of distraction.

Methods: A comprehensive search was conducted between December 2007 and January 2008, and updated in January 2009, before publication. Computerized bibliographic databases were individually searched using specifically developed search strategies to identify eligible studies.

Results: Nine studies were deemed eligible for inclusion in this review. Wound dressing changes was the most common procedure during which VR was trialed. Pain was the main outcome measure in all of the studies included. Anxiety was a secondary outcome measure in 3 of the 9 included studies. VR, in conjunction with pharmacologic analgesics, significantly reduced pain experienced by burn injury patients during wound dressing changes and physiotherapy. There is equivocal evidence for the effect of VR, in conjunction with pharmacologic analgesics, on reducing anxiety in burn injury patients during wound dressing changes and physiotherapy.

Discussion: This is the first known systematic review to report on the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients undergoing wound dressing changes and physiotherapy management, compared with pharmacologic analgesics alone or other forms of distraction. Used as an adjunct to the current burn pain management regimens, VR could possibly assist health professionals in making the rehabilitation process for burn patients less excruciating, thereby improving functional outcomes. Further research investigating the effect of VR on anxiety in burn injury patients is warranted.

Key Words: *virtual reality, burns, burn injury, burn, pain and anxiety*

INTRODUCTION

Patients, who have sustained burn injuries, not only suffer physical and psychological distress resulting from the initial trauma, but also have to deal with painful experiences from daily procedures such as wound dressing changes and physiotherapy management (Abdi et al 2002). The procedural pain experienced during wound dressing changes and physiotherapy management, is often excruciating, and is frequently underestimated and ignored by the health professionals and the family of the burn victim. Furthermore, the anticipation of undergoing these painful procedures may elevate the patients' anxieties, which in turn exacerbate their perception of pain (Abdi et al 2002; Chapman et al 1986; Ashburn et al 1995), exemplifying a possible strong correlation between pain and anxiety. Adequate management of procedural pain and anxiety plays an important role in building a trusting relationship between the burn victim and the multi-disciplinary team, and in promoting patient compliance with rehabilitation (Latarjet et al 2002; De Jong et al 2007).

Although pharmacologic analgesics form part of the cornerstone of any burn pain management regime, their efficacy for extreme procedural pain is limited, and alone are often inadequate to alleviate the pain and anxiety experienced (Ashburn et al 2002; Hoffman et al 2001a). In addition, pharmacologic analgesics may have side-effects such as nausea, excessive sedation, cognitive dysfunction and constipation, as well as place the patient at risk for drug addiction, which limit their use (Hoffman et al 2001a). In contrast, non-pharmacologic distractive analgesic techniques, such as Virtual Reality (VR), typically produce minimal and short-lived side-effects, and are less invasive (Hoffman et al 2006a; Hoffman et al 2004a). The implementation of such non-invasive and non-addictive analgesic techniques is therefore warranted as they may serve as valuable additions to traditional pharmacologic analgesics (Hoffman et al 2006a; Hoffman et al 2004a).

The application of VR distraction (a technology which allows the user to be immersed and interact with a computer-generated environment), is based on the assumption that pain perception has a large psychological component and that pain attracts a strong attentive response because of the potential threat of damaged tissue associated with the sensation (Wismeijer et al 2005). The redirection (distraction) of this attention manipulates the pain perception, thereby reducing the intensity of pain (Dunckley et al 2007; van Griensven 2005).

It appears that VR provides significant cognitive distraction to users, and the head-mount display blocks the patient's external view of the immediate medical environment such as the equipment, health care personnel and their wounds, thereby increasing the level of immersion and contributing to distracting the patient from the pain perception (Hoffman et al 2004a; Wismeijer et al 2005; Dahlquist et al 2008). The more immersive the VR system, the more the patient's attention will be drawn into the virtual world, leaving less attention available to process nociceptive signals, or pain, during painful procedures (Hoffman et al 2006a; Wismeijer et al 2005). Recently it has also been found that VR changes the way people interpret incoming pain signals, and actually reduces the amount of pain-related brain activity (Hoffman et al 2004b; Hoffman et al 2007). Used as an adjunct to the current burn pain management regimes, VR could possibly assist health professionals, such as physiotherapists, in making the rehabilitation process for burn patients less excruciating, improve patient compliance and decrease anxiety levels, thereby improving functional outcomes.

To our knowledge, no systematic review has to date collated the available evidence for the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients undergoing wound dressing changes and physiotherapy management. The main objectives of this review were thus to systematically identify, collate and analyze the current evidence for the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients undergoing wound dressing changes and/or physiotherapy management, compared to pharmacologic analgesics alone or other forms of distraction. Secondary objectives of this review were to provide descriptive data of the included studies and to critically appraise the methodological quality of the included studies with a view to identify opportunities to improve future research quality.

METHODS

Criteria for considering studies

Randomized controlled trials (RCTs), controlled trials, case series or case studies reporting on the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and/or anxiety in burn injury patients undergoing wound dressing changes and/or physiotherapy management, compared to pharmacologic analgesics alone (which included,

but were not confined to: opioids, anesthetics, and nonsteroidal anti-inflammatory drugs) or other forms of distraction (which included, but were not confined to: normal video games, television, etc.) were sought and considered for this review. Participants were not limited to any gender, age, race, nationality or culture. The burn injury could have been sustained through any of the following, but were not confined to: fire, chemicals, coal, hot liquids or substances, or electricity. The burn injury could have occurred on any part of the body, and be of any degree or depth. Participants with a burn injury of any percentage of total body surface area were eligible. All participants may or may not have been given pharmacologic analgesics prior to or during the administration of VR intervention. The subjects may have acted as their own controls (within-subject study designs), or may have been compared to a control group. Primary outcomes of interest included, but were not confined to: a) Subjective evaluation of pain in burn injury patients, using the visual analogue scale (VAS), numeric rating pain scale (NRPS), graphic rating scale (GRS), FACES pain scale or any similar scale or measuring tool; and/or b) Subjective evaluation of the level of anxiety in burn injury patients, using the burn specific pain anxiety scale (BSPAS), Spielberger State-Trait anxiety inventory scale (STAI), or any similar scale or measuring tool.

Search strategy for identification of studies

A comprehensive search was conducted between December 2007 and January 2008 in all accessible bibliographic databases of published research reports available at the Stellenbosch University Medical Library and on the Internet. An update of the search was conducted in January 2009, before publication. No date limit was applied to any of the databases searched, and thus each database was searched since its inception date. Only published English language studies were sought. The electronic bibliographic databases included: PubMed (1950 to present), CiNAHL (1982 to present), Cochrane Library (inception to present), BIOMED central (inception to present), PEDro (1929 to present), Science Direct (1823 to present), PsycInfo (1806 to present), Proquest Medical Library, IngentaConnect (1998 to present), and Sport Discus (1800 to present). Clinicaltrials.gov (2000 to present) was searched for any ongoing trials. Each database has its own indexing terms and functions, and therefore different search strategies were developed for each database. In PubMed, medical subject headings (MeSH) terms were used where possible, with Boolean operators. The search strategies for the remaining databases were adapted and applied accordingly, and are illustrated in figure 1. The

main search terms used for the search strategies were: *virtual reality*, *burn*, *burns*, *burn injury*, *pain* and *anxiety*. Manual searching of journals not indexed in electronic databases was considered but this method was discarded as it would be difficult to replicate. Secondary searching (or PEARLing) was however undertaken, whereby the reference lists of the included and excluded articles were reviewed for additional references not identified in the primary search. Studies identified during the database searches were assessed for relevance from a review of the title, abstract and descriptors of the study. The full text of all potentially relevant articles were retrieved and screened by the two reviewers independently, using the same criteria in order to determine the eligibility of the study for inclusion in this review.

PUBMED

1. virtual reality
2. "Burn"[MeSH Major Topic]
3. #1 AND #2
4. #3 AND pain
5. #3 AND anxiety
6. #3 AND pain AND anxiety
7. #1 AND burn
8. #7 AND pain
9. #7 AND anxiety
10. #7 AND pain AND anxiety
11. #1 AND burns
12. #11 AND pain
13. #11 AND anxiety
14. #11 AND pain AND anxiety
15. #1 AND burn injury
16. #15 AND pain
17. #15 AND anxiety
18. #15 AND pain AND anxiety

Science Direct

1. S1: (virtual reality) or (MM "Virtual Reality")
2. S2: (burn) or (MM "burns") or (MH "Burn Patients") or (MH "Burn Units") or (MH "Burns") or (MH "Burns, Electric") or (MH "Burns, Chemical")
3. S1 and S2
4. S3 and pain
5. S3 and anxiety
6. S3 and anxiety and pain

PsycInfo

1. virtual reality
2. ("Burns" in Mj, MN) or ("Electical-Injuries" in MJ, MN) or (Injuries-" in MJ, MN) or ("Wounds" in MJ, MN)
3. ("Burns" in Mj, MN) or ("Electical-Injuries" in MJ, MN) or (Injuries-" in MJ, MN) or ("Wounds" in MJ, MN) and (virtual reality)
4. ("Burns" in Mj, MN) or ("Electical-Injuries" in MJ, MN) or (Injuries-" in MJ, MN) or ("Wounds" in MJ, MN) and (virtual reality) and (pain)
5. ("Burns" in Mj, MN) or ("Electical-Injuries" in MJ, MN) or (Injuries-" in MJ, MN) or ("Wounds" in MJ, MN) and (virtual reality) and (anxiety)
6. ("Burns" in Mj, MN) or ("Electical-Injuries" in MJ, MN) or (Injuries-" in MJ, MN) or ("Wounds" in MJ, MN) and (virtual reality) and (pain) and (anxiety)

Proquest Medical Library

1. virtual reality
2. LSU{VIRTUAL REALITY}
3. LSU{VIRTUAL REALITY} AND burn
4. LSU{VIRTUAL REALITY} AND burn AND pain
5. LSU{VIRTUAL REALITY} AND burn AND anxiety
6. LSU{VIRTUAL REALITY} AND burn AND pain AND anxiety
7. LSU{VIRTUAL REALITY} AND burns
8. LSU{VIRTUAL REALITY} AND burns AND pain
9. LSU{VIRTUAL REALITY} AND burns AND anxiety
10. LSU{VIRTUAL REALITY} AND burns AND pain AND anxiety
11. LSU{VIRTUAL REALITY} AND burn injury
12. LSU{VIRTUAL REALITY} AND burn injury AND pain
13. LSU{VIRTUAL REALITY} AND burn injury AND anxiety
14. LSU{VIRTUAL REALITY} AND burn injury AND pain AND anxiety

Cochrane library

1. MeSH descriptor Burns explode all trees
2. (virtual reality AND burn):ti,ab,kw
3. (virtual reality AND burn AND pain):ti,ab,kw
4. (virtual reality AND burn AND anxiety):ti,ab,kw
5. (virtual reality AND burn AND pain AND anxiety):ti,ab,kw
6. (virtual reality AND burn):ti,ab,kw
7. (virtual reality AND burns AND pain):ti,ab,kw
8. (virtual reality AND burns AND anxiety):ti,ab,kw
9. (virtual reality AND burns AND pain AND anxiety):ti,ab,kw

10. (virtual reality AND burn injury):ti,ab,kw
11. (virtual reality AND burn injury AND pain):ti,ab,kw
12. (virtual reality AND burn injury AND anxiety):ti,ab,kw
13. (virtual reality AND burn injury AND pain AND anxiety):ti,ab,kw

Sport discuss

1. TX virtual reality

Cinahl

1. S1: (virtual reality) or (MM "Virtual Reality")
2. S2: (burn) or (MM "burns") or (MH "Burn Patients") or (MH "Burn Units") or (MH "Burns") or (MH "Burns, Electric") or (MH "Burns, Chemical")
3. S1 and S2
4. S3 and pain
5. S3 and anxiety
6. S3 and pain and anxiety

PEDro

1. virtual reality
2. virtual reality AND burn
3. virtual reality AND burns
4. virtual reality AND burn injury

Biomed Central

1. virtual reality (all words) in all fields
2. virtual reality (all words) in all fields and burn (all words) in all fields
3. virtual reality (all words) in all fields and burn (all words) in all fields and pain (all words) in all fields
4. virtual reality (all words) in all fields and burn (all words) in all fields and anxiety (all words) in all fields
5. virtual reality (all words) in all fields and burn (all words) in all fields and pain (all words) in all fields and anxiety (all words) in all fields
6. virtual reality (all words) in all fields and burns (all words) in all fields
7. virtual reality (all words) in all fields and burns (all words) in all fields and pain (all words) in all fields
8. virtual reality (all words) in all fields and burns (all words) in all fields and anxiety (all words) in all fields
9. virtual reality (all words) in all fields and burns (all words) in all fields and pain (all words) in all fields and anxiety (all words) in all fields
10. virtual reality (all words) in all fields and burn injury (all words) in all fields
11. virtual reality (all words) in all fields and burn injury (all words) in all fields and pain (all words) in all fields
12. virtual reality (all words) in all fields and burn injury (all words) in all fields and pain (all words) in all fields and anxiety (all words) in all fields

Ingenta connect

1. Ti: virtual reality (tka)
2. Ti: virtual reality and burn (tka)
3. Ti: virtual reality and burn and pain (tka)
4. Ti: virtual reality and burn and anxiety (tka)
5. Ti: virtual reality and burn and pain and anxiety (tka)
6. Ti: virtual reality and burns (tka)
7. Ti: virtual reality and burns and pain (tka)
8. Ti: virtual reality and burns and anxiety (tka)
9. Ti: virtual reality and burn injury (tka)
10. Ti: virtual reality and burn injury and pain (tka)
11. Ti: virtual reality and burn injury and anxiety (tka)
12. Ti: virtual reality and burn injury and pain and anxiety (tka)

clinicaltrials.gov

1. virtual reality
2. virtual reality AND burn
3. virtual reality AND burns
4. virtual reality AND burn injury

Figure 1: Search strategies

Study quality assessment

❖ *Level of evidence*

The hierarchy of evidence used in this review was adapted from the Scottish Intercollegiate Guideline Network (SIGN) system (Table 1) (Scottish Intercollegiate Guidelines Network 2004; Chisolm et al 2007). The original SIGN rating system is more detailed than the adapted version as it also assigns pluses and minuses to designate further subcategories within the first two levels, a stratification that was deemed unnecessary for this review (Chisolm et al 2007).

Table 1: Levels of evidence used for rating studies in this review as adapted from the Scottish Intercollegiate Guideline Network (SIGN) System

1	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with very low risk of bias
1	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with low risk of bias
1	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with very low risk of confounding, bias, or chance, and high probability that the relationship is causal
2	Well-conducted case-control or cohort studies with low risk of confounding, bias, or chance, and a moderate probability that the relationship is causal
2	Case-control or cohort studies with a high risk of confounding, bias, or chance, and a significant risk that the relationship is not causal
3	Non-analytical studies (e.g., case reports, case series)
4	Expert opinion

❖ *Assessment of methodological quality*

The ‘PEDro scale’ was adapted and used to critically appraise the methodological quality of eligible studies (Addendum 1). The PEDro scale normally consists of a checklist of eleven criteria, each requiring a yes/no response, with a ‘yes’ response being allocated one point, and a ‘no/unclear’ response being allocated zero points. The PEDro scale measures the validity of research articles and also identifies whether articles contain sufficient statistical data to make their results interpretable.

Criterion 1 assesses the external validity of the trials. Criteria 2 to 9 assess the internal validity and reliability, while criteria 10 and 11 determine whether the statistical analyses were appropriate. However, as the eligible studies in this review mostly consisted of within-subject study designs and were psychological intervention trials, criteria 2, 3, 5 and 6 were omitted as they were not applicable. Justification for excluding criteria 5 and 6 lies within a systematic

review on chronic pain published in 2003 by Eccleston (Eccleston et al 2003). The review states that blinding should not be criteria for judging the quality of psychological interventions, as it is rarely possible to blind participants or therapists to psychological interventions and therefore these trials should not be given criteria to meet. In addition, the remaining criteria were amended to be applicable to the eligible studies. In criterion 4, 'groups' was changed to 'subjects' and in criterion 8, 'groups' was changed to 'conditions (intervention or control condition)'. In criterion 10, 'between-group' was changed to 'within-subjects or between subjects'. Consequently, the studies included in this review could potentially score a maximum of 7 points on the adapted PEDro scale. Two independent reviewers critically appraised each selected study. A third reviewer was consulted if there was any disagreement between the two reviewers.

Data analysis

Data were collated, extracted and entered into a purpose-built Microsoft Excel worksheet by the principle reviewer. Two independent reviewers were involved in the extraction and capturing of data into the Microsoft Excel sheet. Data were entered into the following categories in the worksheet: record number for article (which coincides with number on article), author reference, publication year, country of publication, title of study, journal in which study was published, study setting, age range, gender, population, population description, study design, sample size, wound dressing change/physiotherapy procedure, intervention, comparison/control, procedure, statistical analysis, statistical tests, results, outcome measures, outcome measurement tools, conclusions, recommendations, limitations, and methodological quality score.

The statistical pooling of results was inappropriate due to heterogeneity of studies; therefore a meta-analysis was not possible and the findings were summarized in a narrative form. Where necessary, attempts to contact the researchers of a study to obtain missing information were made. For data analyses purposes, the studies were divided into different groups; those for which the effect size and 95% CI could be calculated and those for which only the percentage reduction could be established.

The following formula was used to calculate the effect sizes were possible (Krombey et al 1996):

$$\text{Effect size} = \frac{\text{mean (intervention condition)} - \text{mean (control condition)}}{\text{Standard deviation (control condition)}}$$

[The effect size represents the clinical magnitude of difference between groups; a greater observed effect represents a larger significant difference.¹⁶ The interpretations of the effect sizes were as follows: negligible effect ($\geq -.15$ and $< .15$); small effect ($\geq .15$ and $< .40$); medium effect ($\geq .40$ and $< .75$); large effect ($\geq .75$ and < 1.10); very large effect (≥ 1.10 and < 1.45) and huge effect (> 1.45) (Thalheimer et al 2002)]

The following formula was used to calculate the 95% CI, if the SD was provided (Herbert et al 2005):

$$95\% \text{ CI} \approx \text{difference between means} \pm (3 \times \text{SD}/_{\text{av}}) \sqrt{n}_{\text{av}}$$

If the standard error (SE) instead of the SD was provided, the following formula was used to calculate the 95% CI (Herbert et al 2005):

$$95\% \text{ CI} \approx \text{difference between means} \pm (3 \times \text{SE})$$

Where the effect size and 95% CI could not be calculated, the amount of the reduction in pain and anxiety was reported in millimeters (mm) instead.

RESULTS

The comprehensive search for published research into the effectiveness of VR on reducing pain and anxiety in burn injury patients yielded 415 hits. A total of 408 articles were excluded as the title, abstract or full text clearly did not conform to the objectives of the review or duplications were present. Two articles were included via the PEARLing method.

Consequently, **nine** eligible articles were included in this review (Hoffman et al 2000a; Hoffman et al 2000b; Hoffman et al 2004c; Das et al 2005; van Twillert et al 2007; Chan et al 2007; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008).

The database search process and results are depicted in figure 2.

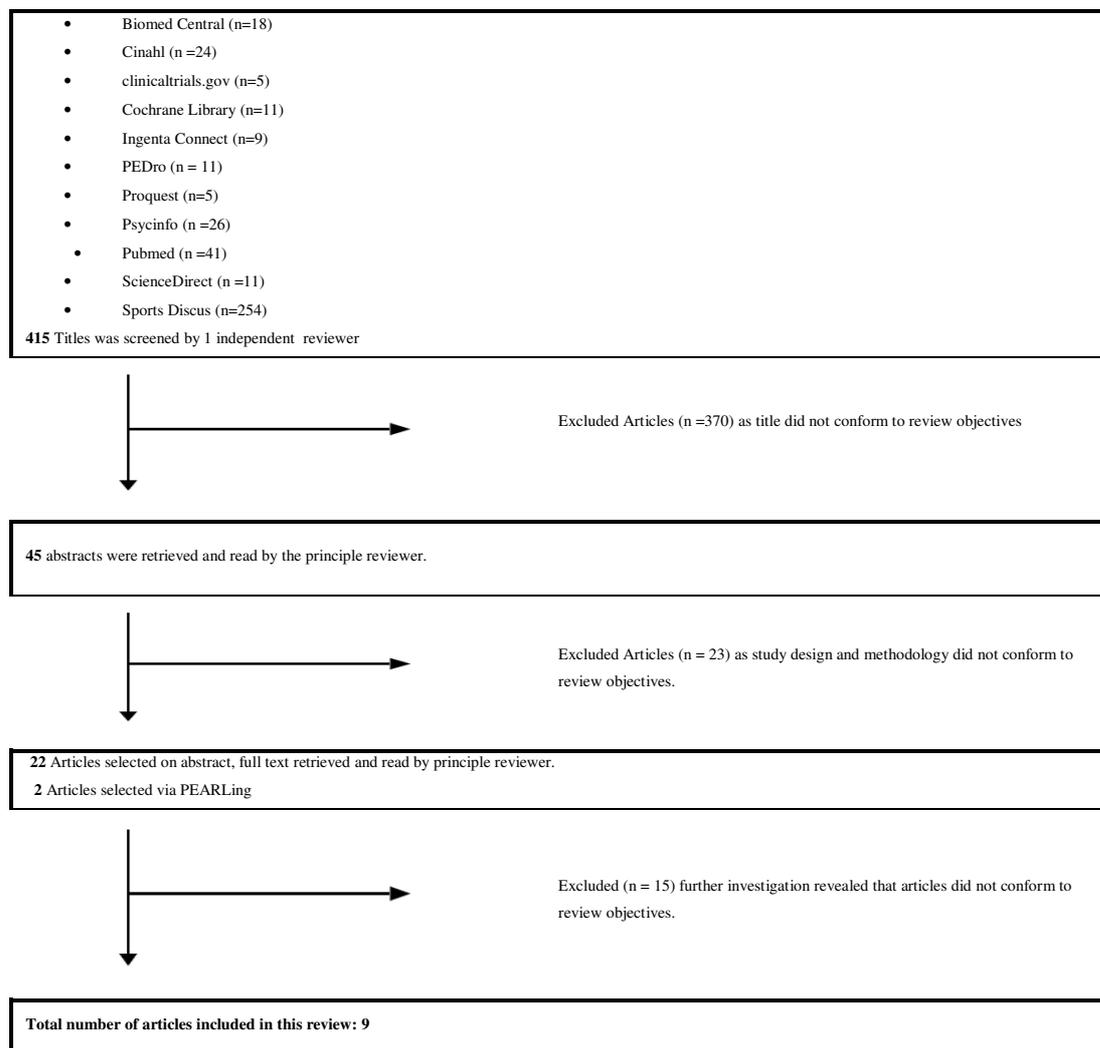


Figure 2: CONSORT diagram - Database search results

General description of studies

Descriptive data extracted from the nine included studies are reported as an overview summary in table 2. All nine eligible studies were conducted recently and published between the years 2000 and 2008. The majority of the studies (n=6) were conducted in the United States of America (Hoffman et al 2000a; Hoffman et al 2000b; Hoffman et al 2004c; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008), and the rest were conducted in Australia (Das et al 2005), Hong Kong (Chan et al 2007) and the Netherlands (van Twillert et al 2007). The total number of subjects for the eligible studies was n = 152. The number of subjects in the study by Sharar et al (2007) was the highest (n=88) as a result of the combination of the

preliminary results from three studies (Sharar et al 2007). Five of the included studies were conducted on males and females, and the rest had been conducted on males only (Hoffman et al 2000a; Hoffman et al 2004c; Hoffman et al 2008; Maani et al 2008). The age range for eight of the nine studies collectively ranged from 65 to 5 years old. One study did not specify an age range, but reported a mean age of 6.5 years old (Chan et al 2007).

❖ *Burn area, mechanism, depth and surface area*

The area of the burn was provided in five of the included studies (Hoffman et al 2000a; Hoffman et al 2000b; Hoffman et al 2004c; Chan et al 2007; Maani et al 2008). The total body surface area (TBSA) ranged from 60% to 1.5%. The most common mechanism of the burn injury reported was fire or flames. One study detailed the mechanism of the burn injury clearly, including the number of subjects per mechanism (Das et al 2005). The depth of the burn was only provided by four studies, and burn injuries ranged from first degree to third degree burns (Hoffman et al 2000a; Das et al 2005; Chan et al 2007; Maani et al 2008).

❖ *Treatment procedures*

Wound dressing changes or wound care was the most common procedure during which the VR was trialed. Only two studies reported on trialing VR during physiotherapy management (Hoffman et al 2000a; Sharar et al 2007). The seven studies which trialed VR during wound dressing changes or wound care provided a definition for the wound dressing procedure (Hoffman et al 2000a; Hoffman et al 2004c; Das et al 2005; van Twillert et al 2007; Hoffman et al 2008; Maani et al 2008). The wound dressing changes or wound care was most commonly described as the 'removal of the bandages, the debridement of the wound and the reapplication of fresh dressings'. Slight variations of this definition was evident, but were basically the same. Only one of the two studies which trialed VR during physiotherapy, provided a definition of physiotherapy which was stated as 'slow stretching of selected extremity to the end of range of affected joint in all possible planes' (Sharar et al 2007).

Table 2: General description of included studies

Author	Country	Population	Setting	Gender	Age range	Type of study	Procedure	Burn area/s	TBSA %	Degree of burn	No of subj.
Hoffman et al 2000a ²¹	USA	Adolescents	Hospital	M	16-17	Case report	WDC	Face, chest, back, stomach, upper legs, R arm, lower R leg	5 and 33	Third	2
Hoffman et al 2000b ²²	USA	Adults	Hospital	M/F	19-47	Controlled study, W-S study design	PT	Upper and lower extremities	21(m)	NM	12
Hoffman et al 2004 ²³	USA	Adults	Hospital	M	40	Case study	WDC	Neck, legs, back and buttocks	19	Third	1
Das et al 2005 ²⁴	Australia	Children and adolescents	Hospital	M/F	5-16	RCT, W-S study design	WDC	NM	5.3 (m)	NM	9
Van Twillert et al 2007 ²⁵	Netherlands	Children to adults	Hospital	M/F	8-65	W-S study design	WDC	NM	7.1(m)	NM	19
Chan et al 2007 ²⁶	Hong Kong	Children	Hospital	M/F	Mean 6.54	W-S study design	WDC	Lower parts of body, neck and face	NM	First and third	8
Sharar et al 2007 ²⁷	USA	Children to adults	Hospital	M/F	6-65	RCT, W-S study design	PT	NM	1.5-60	NM	88
Hoffman et al 2008 ²⁸	USA	Children to adults	Hospital	M	9-40	W-S study design	Wound debridement	Upper and lower extremities	NM	NM	11
Maani et al 2008 ²⁹	USA	Adults	Hospital	M	21-22	W-S study design	Wound care	Upper and lower extremities, hands, back, trunk, buttocks	15 and 32	Second and third	2

Key: WDC = Wound dressing changes, PT = Physiotherapy, m=mean, w-s = within-subject study design, M=Male, F=Female, NM = not mentioned

❖ *Interventions and comparisons*

The intervention for all the eligible studies included the administration of VR in addition to standard pharmacologic analgesics. Seven of the nine eligible studies compared VR plus pharmacologic analgesics (intervention) to pharmacologic analgesics alone (control condition) (Hoffman et al 2000b; Hoffman et al 2004c; Das et al 2005; Chan et al 2007; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008). One study compared VR plus pharmacologic analgesics (intervention condition) to a normal video game plus pharmacologic analgesics (control condition) (Hoffman et al 2000a), and the remaining study compared VR plus pharmacologic analgesics (intervention condition) to alternative distraction namely: television, music, video game, etc., and pharmacologic analgesic alone (control conditions) (van Twillert et al 2007). The interventions and comparisons are depicted in Table 3 below.

Table 3: Interventions and comparisons, and outcome measures of included studies

Study	Intervention	VR game	Comparison/Control	Main Outcome measures	OM tools
Hoffman et al 2000a	VR with analgesic	SpiderWorld	Video game with analgesic (Nintendo game)	Pain and anxiety	VAS and BSPAS
Hoffman et al 2000b	VR with analgesic	SpiderWorld	Analgesics alone	Pain and anxiety	VAS
Hoffman et al 2004c	VR with analgesic	SnowWorld	Analgesics alone	Pain	10 point GRS
Das et al 2005	VR with analgesic	Quake	Analgesics alone	Pain	FACES Pain scale and VAS
Van Twillert et al 2007	VR with analgesic	SnowWorld	Standard care and other distraction methods i.e. TV, music, video game	Pain and anxiety	VAT and STAI
Chan et al 2007	VR with analgesic	Ice-cream factory game	Analgesics alone	Pain	FACES pain scale, usability and modified presence questionnaire (PQ)
Sharar et al 2007	VR with analgesic	SnowWorld	Analgesics alone	Pain	10 point GRS
Hoffman et al 2008	VR with analgesic	SnowWorld	Analgesics alone	Pain	10 point GRS
Maani et al 2008	VR with analgesic	SnowWorld	Analgesics alone	Pain	10 point GRS

Key: VR=virtual reality, OM=outcome measure, VAS=visual analogue scale, GRS=graphic rating scale, VAT=visual analogue thermometer, STAI= Spielberger State-Trait anxiety inventory scale

The VR game ‘SnowWorld’ was used in five of the nine included studies (Hoffman et al 2004c; van Twillert et al 2007; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008).

'SnowWorld' depicts an icy three-dimensional virtual canyon with a river and waterfalls. The patient shoots snowballs at virtual snowmen, igloos, robots and penguins by aiming his gaze and pressing the trigger button on the joystick. The snowballs explode with animations and three-dimensional sound effects upon impact. The original game was developed by Dr Hunter Hoffman with programming help and software tools from www.MultiGen.com; www.SimWright.com and www.howard-3d.com. The University of Washington's latest version of SnowWorld (2006) (www.vrpain.com), was created by world-builders at www.Imprintit.com using www.Virtools.com Virtual World Development Software (Hoffman et al 2008; Maani et al 2008).

The VR game 'SpiderWorld' was used in two of the nine included studies (Hoffman et al 2000a; Hoffman et al 2000b) and a VR game based on the game 'Quake' developed by ID Software, was used in one study (Das et al 2005). 'SpiderWorld', developed at the University of Washington, Seattle, is a modified version of Division LTD's DVS-3.1.2 'KitchenWorld' (Division Incorporated, San Mateo, CA [www.division.com]) complete with countertops, a window, and three-dimensional cabinets. Patients can 'pick-up' virtual objects with their cyberhand. Using tactile augmentation, if willing, patients could 'physically' touch the furry body of a virtual Guyana tarantula with wiggling legs and could physically eat a virtual candy bar linked via a position sensor attached to its real-world twin. 'Quake' was developed by ID Software, and modified by the Department of Computer and Information Sciences, UNISA. The game involved a visual simulation giving the children a feel of being on a track, using a pointer to aim and shoot monsters. Only one study developed their own VR prototype which entailed a patrol person patrolling an ice-cream factory (Chan et al 2007). (See Table 3)

❖ *Outcome measures*

All the studies had pain as one of their main outcome measures, and the VAS, VAT, GRS and FACES pain scale were used as the outcome measurement tools (see Table 3). Anxiety was a secondary outcome measure in three of the nine studies (Hoffman et al 2000a; Hoffman et al 2000b; van Twillert et al 2007). To measure anxiety, the VAS, BSPAS and STAI were utilized (see Table 3). Other outcome measures included in the studies were 'time spent thinking about pain' (Hoffman et al 2000a; Hoffman et al 2000b; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008), 'sense of presence' (Hoffman et al 2000a, Hoffman et al 2000b; Hoffman et al 2004c), and 'bothersomeness' (Hoffman et al 2000a; Hoffman et al 2000b). For the purposes of measuring these outcomes, the VAS (Hoffman et al 2000a; Hoffman et al

2000b), a 10 point graphic scale (Hoffman et al 2000a; Hoffman et al 2008; Maani et al 2008) and a modified presence questionnaire (PQ) (Chan et al 2007) were utilized. These outcome measures will not be dealt with for the purposes of this review.

❖ *Reliability and validity of outcome measurement tools*

Das et al (2005) was the only study that did not report on the reliability and validity of the outcome measurement tools used (Das et al 2005). The rest of the eligible studies either mentioned or cited an article which described the reliability and validity of the outcome measurement tools used. Hoffman et al (2000a and 2000b) both cited an article by Gift (1989) which described the validity, reliability and sensitivity of the VAS (Hoffman et al 2000a; Hoffman et al 2000b; Gift et al 1989). van Twillert et al (2007) reported that the STAI demonstrated excellent reliability and validity, and that it was the most widely used measure for anxiety in psychological and behavioural medicine research (van Twillert et al 2007). Chan et al (2007) reported that the FACES scale is easily used with school-aged children and has good psychometric properties (Chan et al 2007). The GRS was reported by Sharar et al (2007) to be valid through the strong associations with other measures of pain intensity, as well as their ability to detect treatment effect (Sharar et al 2007).

❖ *Type of pharmacologic analgesics used*

The following types of pharmacologic analgesics were used in the included studies; Hydromorphone, Hydrocodone, Acetaminophen, Oxycodone, Fentanyl, Oxycodone, Morphine sulphate, Demerol, Tylenol, Systemic opioids, Fentanyl lollipops, Percocet tablets and Benzodiazepine. Two studies did not provide the name of the pharmacologic analgesics administered to the subjects (Das et al 2005; van Twillert et al 2007).

Study quality assessment

❖ *Level of evidence*

The studies identified for inclusion in this review denoted level 2 and 3 on the SIGN hierarchy of evidence outlined in Table 1.

❖ *Methodological quality of studies*

The methodological scores of the identified studies are reported in Table 4. For the methodological appraisal of the eligible studies, an adapted 7-point PEDro scale scoring system was used, which required a 'yes' or 'no' answer. A 'yes' answer was given where the criteria were met and was indicated with a plus sign (+). A 'no' answer was given where the

criteria were not met and was indicated with a zero (0). An average was calculated for all the studies, to compare methodological scores. *(It has to be noted, however, that as the PEDro scale was adapted, the scores and interpretations of the methodological quality appraisal of the included studies have to be viewed with caution.)*

Table 4: Methodological appraisal of included studies (PEDro scale)

Criteria	1	2	3	4	5	6	7	8	9	10	11	Total score / 7	%
Hoffman et al 2000a	0	NA	NA	+	NA	NA	0	+	+	+	+	5	71.4
Hoffman et al 2000b	+	NA	NA	+	NA	NA	0	+	+	+	+	6	85.7
Hoffman et al 2004	0	NA	NA	+	NA	NA	0	+	+	+	+	5	71.4
Das et al 2005	+	NA	NA	+	NA	NA	+	+	+	+	+	7	100
Van Twillert et al 2007	+	NA	NA	+	NA	NA	0	+	+	+	+	6	85.7
Chan et al 2007	0	NA	NA	+	NA	NA	0	+	+	+	+	5	71.4
Sharar et al 2007	+	NA	NA	+	NA	NA	0	+	+	+	+	6	85.7
Hoffman et al 2008	+	NA	NA	+	NA	NA	0	+	+	+	+	6	85.7
Maani et al 2008	0	NA	NA	+	NA	NA	0	+	+	+	+	5	71.4

Key: Criteria= criterion number corresponding with PEDro scale (Appendix A), NA=not applicable, + = meets criteria, 0 = does not meet criteria

The main shortcoming in the methodological quality of the included studies was evident in the ‘no’ response to criterion 7 (blinding of all therapists). Only one study had a ‘yes’ response to criterion 7 (Das et al 2005). Four of the nine included studies had a ‘no’ response for criterion 1 (eligibility criteria was specified) (Hoffman et al 2000a; Hoffman et al 2004c; Chan et al 2007; Maani et al 2008). All the studies had a ‘yes’ response to criterion 8 (measures of at least one key outcome were obtained from more than 85% of the subjects), criterion 9 (all subjects received treatment), 10 (statistical comparisons reported), and 11 (point measures and measures of variability provided). Only one study scored 100% on the adapted version of the PEDro scale (Das et al 2005). Overall, the studies scored an average score of 5.6 out of 7 (80%).

Patient outcomes: PAIN

❖ Studies reporting the amount of the reduction in pain

The effect sizes or 95% CIs could not be calculated for all included studies. However, the amount of the reduction in pain was provided. On a pain scale from 0mm to 100mm, Hoffman et al (2000a) reported clinically meaningful 80mm and 47mm reductions in worst pain levels for subjects one and two with the use of VR (with pharmacologic analgesics) during the first wound care session, respectively, compared to the control condition (normal video game and pharmacologic analgesics). Subject one reported a further 30mm reduction in pain levels with the use of VR (with pharmacologic analgesics) during the second wound care session (there was no second wound care session for subject two) (Hoffman et al 2000a). In a case study by Hoffman et al (2004c), the subject reported a clinically meaningful reduction in worst pain levels from 70mm with no VR to 20mm with the use of VR (with pharmacologic analgesics) during wound care (Hoffman et al 2004c). Maani et al (2008) reported no reduction in worst pain for patient 1, and a 60mm reduction in 'worst pain' for patient 2, with the use of VR (with pharmacologic analgesics) during wound care compared to the control condition (pharmacologic analgesics alone) (Maani et al 2008).

❖ Studies for which effect sizes and/or 95% CIs could be calculated, or were provided

Hoffman et al (2000b) found a significant difference between the intervention (VR with pharmacologic analgesics) condition and the control (pharmacologic analgesics alone) condition ($p=0.002$; 95% CI 11.32 to 32.84), with a 47 mm reduction in pain levels due to the intervention condition during physiotherapy (Hoffman et al 2000b). In the study by van Twillert et al (2007), patients were offered VR (with pharmacologic analgesics) during one of the daily wound dressing changes in the first week of admission. On the other days, standard care or an alternative distraction technique was offered. van Twillert et al (2007) found that there was a significant difference in pain scores during the wound dressing changes on the day that VR (with pharmacologic analgesics) was offered compared with the day before, when only standard care (pharmacologic analgesics alone, no distraction) was offered ($p=0.000$; 95% CI 1.328 to 3.903). A significant difference was also found between the pain scores taken on the day that VR (with pharmacologic analgesics) was offered compared to the day after, when only standard care were offered ($p=0.035$; 95% CI -2.905 to -0.084). Although several alternative distraction techniques, such as television, were offered, only a few patients chose to try the alternative distraction and this was only after they had experienced the VR.

Compared with standard care, VR distraction ($p < 0.001$) and watching television ($p = 0.033$) were the only distraction techniques that showed significant pain reductions. VR distraction ($n = 19$) was more effective at reducing pain compared to television distraction ($n = 16$). Nevertheless, the difference between the VR and television analgesia was not statistically significant (probably due to the fact that paired comparisons could only be conducted on the six patients that participated in both VR and television conditions) (van Twillert et al 2007). The effect size and 95% CI between the intervention and control condition could be calculated for Das et al (2005) and Hoffman et al (2008) as sufficient data were provided. The results from Das et al (2005) illustrated that the intervention condition (VR with pharmacologic analgesics) was significantly better at reducing pain during the wound dressing changes ($p < 0.01$; 95% CI -5.33 to -0.27) than the control condition (pharmacologic analgesics alone). There was a large effect (0.97) due to the intervention (Das et al 2005). The results from Hoffman et al (2008) illustrate that there was a significant difference between the intervention condition (VR with pharmacologic analgesics) and the control (pharmacologic analgesics alone) condition ($p = 0.015$) in reducing pain during wound care. There was a very large effect (1.11) due to the intervention (Hoffman et al 2008). Only the 95% CI's could be calculated for Chan et al (2007) and Sharar et al (2007) as they provided the SE and not the SDs (Chan et al 2007; Sharar et al 2007). Sharar et al (2007) found significant differences between the intervention (VR with pharmacologic analgesics) and control conditions (pharmacologic analgesics alone) ($p = 0.003$; 95% CI 9.5 to 11.9) in reducing pain during physiotherapy (Sharar et al 2007). Chan et al (2007) did not find a significant difference between the intervention (VR with pharmacologic analgesics) and control condition (pharmacologic analgesics alone) ($p = > 0.05$, 95% CI -28.7204 to 8.7204) in reducing pain during wound dressing changes (Chan et al 2007).

Patient outcomes: ANXIETY

Only three of the nine included studies reported on anxiety as an outcome measure. Hoffman et al (2000a) reported a significant reduction of 58mm and 27mm in anxiety with the first use of VR (with pharmacologic analgesics) during wound care compared to a normal video game with pharmacologic analgesics and pharmacologic analgesics alone for patient one and two respectively (Hoffman et al 2000a). Hoffman et al (2000b) found that all twelve subjects reported significantly less anxiety during physiotherapy when distracted with VR

(Hoffman et al 2000b). van Twillert et al (2007), however, found that there was neither a significant difference between the intervention (VR with pharmacologic analgesics) condition and the control (standard care, pharmacologic analgesics alone) condition ($p=0.927$) in reducing anxiety, nor between the standard care condition and watching television ($p=0.351$) during wound care (van Twillert et al 2007).

DISCUSSION

This is the first known systematic review to report on the effectiveness of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients, of all ages, undergoing wound dressing changes or physiotherapy management, when compared to pharmacologic analgesics alone or other forms of distraction. (Although Sharar et al (2008) recently published a literature review reporting on the application of VR for pain management in burn-injured patients, the review did not follow a systematic review methodology format.)

The results of this review illustrate that VR may show promise to be used as an adjunct therapy to traditional pharmacologic analgesics in reducing pain during the grueling daily procedures burn injury patients have to endure. Eight of the nine included studies reported that VR, coupled with pharmacologic analgesics, significantly (or showed clinically meaningful results) reduced pain scores in burn injury patients undergoing wound dressing changes or physiotherapy management, when compared to pharmacologic analgesics alone (Hoffman et al 2000b; Hoffman et al 2004c; Das et al 2005; van Twillert et al 2007; Sharar et al 2007; Hoffman et al 2008; Maani et al 2008) or to a normal video game (with pharmacologic analgesics) (Hoffman et al 2000a). VR most likely manifests its analgesic effects by altering the perception of pain, distracting the user's focus away from the painful procedure, whereas pharmacologic analgesics act directly on the receptors of the nervous system (Sharar et al 2008). In addition, while immersed in the VR with the head-mount display in place, the patient's inability to see the burn wound, medical staff or medical equipment, may further enhance the level of immersion, contributing to the reduction of the pain experience (Dalquist et al 2008; Hoffman et al 2007; Hoffman et al 2000a). Traditional pharmacologic analgesics are not always adequate in treating the pain, burn injury patients experience (Ashburn et al 1995; Hoffman et al 2001a) and are associated with many side-effects (Hoffman et al 2001a), thus often necessitating the implementation of additional therapies or treatments, which may

not pose further health threats. Larger RCTs are however needed to confirm the effect of VR analgesia on reducing pain in burn injury patients during painful medical procedures such as wound dressing changes and physiotherapy management.

Recent laboratory analog pain research into the physiological effects of VR on brain activity using functional magnetic resonance imaging (fMRI), enrich our understanding of VR analgesia (Hoffman et al 2004b; Hoffman et al 2007). These studies found that VR changes the way the burn injury patient interprets incoming pain signals and thereby the amount of pain-related brain activity is reduced (Hoffman et al 2004b). However, the body of knowledge into the physiological responses of the brain in response to VR is limited to the above referenced studies which incorporated small samples of up to 14 individuals and further investigations into the physiological mechanisms of VR are thus necessary.

The painful daily procedures which burn injury patients have to endure often provoke high anxiety levels which in turn exacerbate pain levels (Sharar et al 2008; Summer et al 2007). While it seems logical to assume that the anxiety levels of patients decrease over time as they familiarize themselves with the painful procedure, the contrary seems to be true (Summer et al 2007). A recent study found that once burn injury patients experience a procedure to be painful, their anxiety levels in fact increase in anticipation of a similar painful procedure, even though they know what to expect (Summer et al 2007). Three of the nine studies reviewed reported on anxiety as an outcome measure. The findings of this review illustrate equivocal evidence with respect to the effect of VR on anxiety in burn injury patients. Although VR has been found to possibly be valuable in the treatment of various clinical anxiety disorders (Garcia-Palacios et al 2007), further innovative research addressing whether VR has a positive effect on anxiety levels, and not only on pain experiences, in burn injury patients are warranted.

On average the studies reviewed were methodologically well conducted. The only major methodological shortcoming was that eight of the nine studies did not report on blinding the assessor. Although the criteria for blinding the therapist and subjects were omitted as it is rarely possible to achieve in psychological intervention trials (Eccleston et al 2003), a satisfactory assessor or investigator blinding can be attained in most instances and should be

applied if possible (Ernst et al 1995). Without blinding of at least the assessors/investigators, a potential for observational bias is easily introduced into a study (Eccleston et al 2003; Portney et al 2000). The performance or the recording and reporting of outcomes are thus influenced, substantially decreasing the validity of conclusions (Portney et al 2000). It is recommended that the assessor, at least, should be more carefully blinded in future clinical studies.

The generalizability of the review findings is however questionable as the majority of the studies had small sample sizes. None of the studies reported on sample size calculation, therefore the power of the studies were unknown. Several controlled laboratory studies have nonetheless shown strong evidence of VR analgesia with multiple treatments over longer periods of time, and contribute to understanding the exact mechanism by which VR works (Hoffman et al 2001a; Hoffman et al 2003; Wright et al 2005; Patterson et al 2006). These laboratory studies provide ethical justification for conducting RCTs incorporating larger sample sizes, longer treatment duration (such as longer time spent in VR during wound dressing changes or physiotherapy), and larger numbers of treatments per patient. It would also then be feasible to investigate whether patients become uninterested or stop paying attention to VR after a while.

Physiotherapy management is a grueling part of burn rehabilitation, which incites tremendous amounts of pain, possibly even more pain than experienced by the patient at the time of the burn injury (Patterson et al 2004). Rehabilitation is unfortunately hindered by pain caused by the physiotherapy procedure and patients are discouraged from being compliant during their treatment sessions (Hoffman et al 2000a; van Twillert et al 2007). Although pharmacologic analgesics form part of the cornerstone of the burn pain management plan, their efficacy for physiotherapy sessions are limited, and alone are often inadequate to alleviate the pain experienced (van Twillert et al 2007; Haik et al 20006). Nevertheless, successful participation in physiotherapy after a severe burn is crucial for minimizing long-term disability (Hoffman et al 2001b). Adequate management of procedural pain plays an important role in building a trusting relationship with the burn victim and the multi-disciplinary team, and in promoting patient compliance with rehabilitation (De Jong et al 2007). Even though, VR was found to significantly reduce pain and anxiety in burn injury patients undergoing physiotherapy, only two of the nine studies trialed VR during physiotherapy. RCTs investigating the effect of VR,

in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients during physiotherapy management are therefore required.

The growing evidence that the use of VR, in conjunction with analgesics, can lead to large reductions in subjective pain experiences, as well as actually reduce the pain-related brain activity in the brain of humans, shows promise that VR may be a valuable addition in the burn injury rehabilitation regime (Hoffman et al 2004c; Hoffman et al 2006). However, the evidence currently available seems to be generated in developed countries where burn injury populations and the etiology of the burn injuries differ from developing countries (Ahuja et al 2004). Developed countries are often equipped with more extensive technology compared to developing countries, where there is a lack of resources due to stringent health care budgets (Ahuja et al 2004; Louw et al 2007). It may therefore not be easy to extrapolate the evidence from populations in developed countries to burn injury populations in developing countries, as the burn injuries in developing countries tend to be more severe and more prevalent (Ahuja et al 2004). Studies investigating the effect of VR, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in burn injury patients in developing countries are therefore warranted.

CONCLUSION

From the results of this review, it can be deduced that VR may be an effective non-pharmacologic, non-invasive adjunct analgesic technique to current pain management regimens utilized in the modulation of pain in burn injury patients undergoing wound dressing changes and physiotherapy treatment. VR could possibly assist health professionals, such as physiotherapists, in making the rehabilitation process for burn patients less excruciating and to improve patient compliance, thereby improving functional outcomes. Equivocal evidence remains for the effect of VR, in conjunction with pharmacologic analgesics, on reducing anxiety in burn injury patients during wound dressing changes and physiotherapy.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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ADDENDUM 1: PEDRO SCALE: ADAPTED VERSION

Note: Shaded section were omitted, 'groups' were changed to 'subjects' or 'conditions' and 'between-groups' was changed to 'within-subjects/between subjects'. Total possible PEDro score = 7

1. eligibility criteria were specified	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
3. allocation was concealed	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
4. the 'subjects' were similar at baseline regarding the most important prognostic indicators	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
5. there was blinding of all subjects	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
6. there was blinding of all therapists who administered the therapy	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
7. there was blinding of all assessors who measured at least one key outcome	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to 'conditions (intervention or control)'	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
10. the results of 'within-subject/between subject' statistical comparisons are reported for at least one key outcome	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:
11. the study provides both point measures and measures of variability for at least one key outcome	no <input type="checkbox"/>	yes <input type="checkbox"/>	where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Notes on administration of the PEDro scale:

- All criteria **Points are only awarded when a criterion is clearly satisfied.** If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
- Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	<i>Concealed allocation</i> means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the <u>subjects</u> ’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	<i>Key outcomes</i> are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-6	<i>Blinding</i> means the person in question (subject or therapist) did not know which <u>condition</u> the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different <u>conditions</u> .
Criterion 7	<i>Blinding</i> means the person in question (assessor) did not know which <u>condition</u> the subject had been allocated to. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states <i>both</i> the number of subjects initially allocated to groups <i>and</i> the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An <i>intention to treat</i> analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A <i>within-subject/between subjects</i> statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one <u>condition</u> with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a “p” value, describing the probability that the <u>conditions</u> differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A <i>point measure</i> is a measure of the size of the treatment effect. The treatment effect may be described as a difference in <u>subject’s</u> outcomes, or as the outcome in (each of) all <u>conditions</u> . <i>Measures of variability</i> include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each <u>condition</u> .

PAIN AND ANXIETY EXPERIENCES OF SOUTH AFRICAN ADULT BURN INJURY PATIENTS DURING PHYSIOTHERAPY MANAGEMENT SHORT REPORT

The following chapter presents a short report on the pain and anxiety experiences of South African adult burn injury patients before, during, immediately after and 30 minutes after physiotherapy management when given pharmacologic analgesics only. The study served as justification for the main part of this thesis, underpinning whether South African burn injury victims cope well on the pain management regimens currently in place at the burn units and if adjunct therapies to this pain management regimen are needed.

**Please note that the full methodology of this chapter is listed as Appendix D2.

**PAIN AND ANXIETY EXPERIENCES OF SOUTH AFRICAN ADULT BURN
INJURY PATIENTS DURING PHYSIOTHERAPY MANAGEMENT
SHORT REPORT**

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ABSTRACT

Adequate management of procedural pain during physiotherapy plays an important role in building a trusting relationship between the burn victim and the physiotherapist, and in ensuring desirable functional outcomes. However, the burn pain management regimens currently utilized in burn units globally, primarily consist of traditional pharmacologic analgesics. These analgesics are associated with numerous side-effects and alone are often reported as inadequate to alleviate procedural pain, warranting safer and effective adjunct therapies. Prior to the introduction and implementation of adjunct therapies into a developing world, it is imperative that the current situation in a burn unit, in terms of whether or not the pain management regimens in place are adequate, is first assessed, due to cost concerns. The following short report exemplifies the pain and anxiety experiences of a small number of burn injury patients during physiotherapy at the Tygerberg Hospital adult burn unit, South Africa. It was hypothesized that the results of this study would underpin whether adult burn injury patients in a developing country require adjunct therapies during physiotherapy management to supplement traditional pharmacologic analgesics in managing their procedural pain and subsequent anxiety.

Key words: *burn injury, adults, pain, anxiety and physiotherapy*

INTRODUCTION

Successful participation in physiotherapy after a severe burn is crucial for minimizing long-term disability. It prevents the healing skin from contracting and losing its elasticity, which could potentially lead to a reduced range of limb motion and a decrease in function (Hoffman et al 2000). Unfortunately, rehabilitation is hindered by pain and subsequent anxiety caused by the physiotherapy procedure itself and the anticipation of the procedure. As a result, this often discourages patients from being compliant during their treatment sessions (Hoffman et al 2000; van Twillert et al 2007). Adequate management of procedural pain thus plays an important role in building a trusting relationship between the burn victim and the physiotherapist, in reducing subsequent anxiety and in promoting patient compliance with rehabilitation, thereby improving functional outcomes (de Jong et al 2007).

The current burn pain management regimens for procedural pain used in most burn units globally, primarily consist of the administration of traditional pharmacologic analgesics which are associated with numerous side-effects. Alone these analgesics are often reported as inadequate to successfully alleviate procedural pain, warranting the use of adjunct therapies (Haik et al 2006; van Twillert et al 2007). Although resources in developed countries allow for the possibility of implementing expensive adjunct therapies; in developing countries, such as South Africa, this is not always possible as healthcare budgets are stringent (Louw et al 2007). It may therefore not be economically feasible to implement expensive interventions from first world countries into a third world clinical setting.

For this reason it is imperative that the current burn pain management regimens in place in developing countries are first assessed to ascertain the need for adjunct therapies, before implementation takes place. The following short report thus exemplifies the pain and anxiety experiences of a small number of burn injury patients during physiotherapy at the Tygerberg Hospital adult burn unit, South Africa. It was hypothesized that the results of this study would underpin whether adult burn patients in a developing country require adjunct therapies during physiotherapy management to assist in managing their procedural pain and subsequent anxiety.

METHODS

Ethical approval for this study was granted by the Committee for Human Research at the Stellenbosch University. A month-long prospective audit was conducted at the Tygerberg Hospital's adult burn unit in South Africa during October 2008. Subjects were recruited consecutively if they were male or female, between the ages of 18 years and older, had sustained a burn injury of any degree and to any part of their body, and underwent physiotherapy burn management at the time of data collection. Subjects, whose medical condition was deemed unstable, were unconscious and unaware of their surroundings, and who had any cognitive deficits were excluded from the study. Informed consent was obtained from all subjects prior to participation in the study. Demographical, personal, burn injury, analgesic and physiotherapy treatment information, as well as baseline pain and anxiety data using the Numeric Pain Rating scale (NPRS) and the Burn Specific Pain and Anxiety scale (BSPAS), was extracted/collected for each subject and recorded by the principle researcher or the research assistant. The reliability and validity of the NPRS and BSPAS have been previously established (Mawdsley et al 2002 and Taal et al 1997).

The maximum duration of the physiotherapy treatment session for each subject, which consisted of passive range of motion exercises in the same planes of movement, was 20 minutes and was divided into two equal components. Midway through and immediately after the physiotherapy session, a blinded assessor administered the second and third sets of the NPRS and BSPAS forms. Thirty minutes after the physiotherapy session, the blinded assessor administered the fourth and final set of the NPRS and BSPAS forms to the subject. In essence, four pain and anxiety scores were recorded for each subject: before the physiotherapy session, midway through the physiotherapy session, immediately after the physiotherapy session and 30 minutes after the physiotherapy session.

Data analysis

Student's paired *t*-tests (PHStat2 program) were used to analyze differences between mean pain and anxiety scores before and during-; before and after-; and before and 30 minutes after the physiotherapy session (significant level $\alpha = 0.05$). 95% confidence intervals (CIs) around the mean differences (MD) were calculated. In addition, descriptive statistics incorporating

the median and range were also done, to illustrate changes in severity of pain and anxiety during physiotherapy.

RESULTS

Participants

A total of 17 (13 males and 4 females) adult burn injury patients, with a median age of 33 years (range 20 to 56 years) admitted to the TBH adult burn unit, consented to participating in this study. Eight of the 17 subjects were coloured of race, eight were black of race and one subject was Zimbabwean. Ten subjects were burnt by fire, six by hot water and one by hot porridge. The body areas burnt included the face, upper limbs, lower limbs, abdomen, buttocks, back, chest, back of head and trunk. Fourteen of the 17 subjects had second degree burns, while two had a combination of first and second degree burns and one had a combination of second and third degree burns. The median Total Body Surface Area (TBSA) was 22% (range TBSA of 4% to 55%). The following pharmacologic analgesics were administered to the subjects up to 2½ hours before commencement of the physiotherapy treatment session: Morphine, Dolorol Forte and Brufen, with dosages varying from 5mg to 25mg. The body areas treated during the physiotherapy treatment session consisted of: bilateral upper limbs (n=5), bilateral lower limbs (n=4), bilateral hands (n=1), right upper limb (=5), left hand (n=1), and left upper limb (n=1) and the mean duration of the physiotherapy treatment sessions was 17 minutes (range 12 -20 minutes).

Reported pain experience during physiotherapy treatment session

Table 1 report the mean (SD) and median (range) scores for pain before, during, immediately after and 30 minutes after physiotherapy when using pharmacologic analgesics only. Pain was measured using an 11-point NPRS. The minimum score on the NPRS was 0 and the maximum score was 10.

Table 1: Pain scores before, during, immediately after and 30 minutes after physiotherapy session

	Pain scores (n=17)	
	Mean (SD)	Median (range)
Before physiotherapy	4.4 (2.9)	5 (0- 8)
During physiotherapy	7.9 (2.4)	9 (3-10)
After physiotherapy	6.4 (2.5)	6 (2-10)
30 minutes after physiotherapy	4.1 (3.1)	4 (0- 8)

During the physiotherapy session, a median pain score of 9 (range 3-10) was reported, compared to a median score of 5 (range 0 -8) before the physiotherapy session, indicating that the majority of the included subjects reported severe pain during the physiotherapy session than before the physiotherapy session. The mean pain scores reported during the physiotherapy treatment were significantly higher *t-test* ($p=0.006$; MD -3.5; 95% CI -5.87 to -1.13) than the pain scores reported before the commencement of the physiotherapy session. Significantly higher scores *t-test* ($p=0.04$; MD -2; 95% CI -3.89 to -0.11) were also reported immediately after the physiotherapy session compared to before the physiotherapy session. No significant differences *t-test* ($p=0.77$; MD 0.3; 95% CI -1.80 to 2.40) were found between before and 30 minutes after the physiotherapy session.

Reported anxiety experience during physiotherapy treatment session

Table 2 illustrates the mean (SD) and median (range) scores for anxiety before, during, immediately after and 30 minutes after physiotherapy when using pharmacologic analgesics alone. Anxiety was measured using a BSPAS. The BSPAS had a maximum score of 90 and a minimum score of 0.

Table 2: Anxiety scores before, during, immediately after and 30 minutes after physiotherapy session

	Anxiety scores (n=17)	
	Mean (SD)	Median (range)
Before physiotherapy	44.8 (23.2)	47 (2 -78)
During physiotherapy	60.4 (19.5)	58 (27 – 90)
After physiotherapy	52.4 (22.0)	52 (8 – 88)
30 minutes after physiotherapy	42.5 (25.0)	40 (0 – 83)

During the physiotherapy session, a median anxiety score of 58 (range 27-90) was reported, compared to a median anxiety score of 47 (range 2-78) before the physiotherapy session, indicating that the majority of the included subjects reported higher anxiety levels during than before the physiotherapy session. The mean anxiety scores were significantly higher *t-test* ($p=0.04$; MD -15.6; 95% CI -30.57 to -0.63) during the physiotherapy treatment session compared to the mean anxiety scores reported before the commencement of the physiotherapy session. No significant differences were found between before and immediately after the physiotherapy sessions *t-test* ($p=0.31$; MD -7.6; 95% CI -22.73 to 7.53), and between before and 30 minutes after the physiotherapy sessions *t-test* ($p=0.77$; MD 2.3; 95% CI -13.91 to 18.51).

DISCUSSION

From the results of this study it appears that when South African adult burn injury patients are only given traditional pharmacologic analgesics during physiotherapy management, the majority of the subjects still experienced significantly severe levels of pain and anxiety. This information concurs with international studies conducted in developed countries, that although pharmacologic analgesics currently form part of the cornerstone of any burn pain management plan, the exclusive use of traditional pharmacologic analgesics may be inadequate to alleviate the pain experienced during excruciating procedures such as physiotherapy (Haik et al 2006; van Twillert et al 2007). The results of this study suggest that burn injury patients in a developing world setting may require additional assistance in alleviating the severe procedural pain and anxiety they continue to experience during physiotherapy management.

Although burn injury patients may be aware of the fact that daily physiotherapy sessions are beneficial for their functional recovery, the pain and subsequent anxiety they experience during the physiotherapy rehabilitation may prohibit them from complying with the physiotherapist and achieving their goals (Hoffman et al 2000; van Twillert et al 2007). Therefore, in order for physiotherapists to assist burn injury patients in achieving the most optimal functional outcomes in burn injury rehabilitation, adequate management of procedural pain during physiotherapy treatment is required (de Jong et al 2007). It is also essential that a trusting relationship between the physiotherapist and the burn injury victim is maintained (de

Jong et al 2007). This can only be achieved if the patient's procedural pain during the physiotherapy sessions is successfully recognized, not underestimated, and appropriately addressed. Since it appears that traditional pharmacologic analgesics are inadequate in successfully managing procedural pain in burn injury patients from developing countries, adjunct therapies are thus warranted.

Non-pharmacologic adjunct therapies usually pose less threat to the burn injury patient than traditional pharmacologic analgesics, as they are associated with less side-effects, are less addictive and less invasive (Hoffman et al 2006). Examples of adjunct therapies currently available for burn injury patients are distraction, hypnosis, music therapy and relaxation therapy (Abdi et al 2002; Richardson et al 2009). Previous studies conducted in developed countries amongst burn injury patients have shown that Virtual reality (VR), a distraction technique, is effective in reducing pain and anxiety during physiotherapy treatment sessions and wound dressing changes (Morris et al 2009). One drawback of an adjunct therapy like VR is that it is expensive, costing in the region of R250 000. In a developing world setting like South Africa, where healthcare budgets are stringent and prioritized to conditions such as HIV/AIDS and tuberculosis (Louw et al 2007), the implementation of effective yet expensive adjunct therapies like VR, may not be feasible or affordable (Rand et al 2008). Since the prevalence of burns is higher in developing countries (Ahuja et al 2004), future studies should investigate the possibility of implementing less-costly adjunct therapies into developing world clinical burn settings and not simply discard implementation of certain interventions due to cost concerns.

CONCLUSION

The results of this study suggest that burn injury victims in a developing country could benefit from adjunct therapies to the current pain management regimens in place, it does not signify that the adjunct therapies currently utilized in developed countries will be economically feasible. Pragmatic trials investigating the effect of low-cost adjunct interventions for burn injury pain and anxiety in a developing world clinical burn setting are thus warranted.

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EFFECT OF A LOW-COST VIRTUAL REALITY SYSTEM ON REDUCING PAIN AND ANXIETY IN ADULT BURN INJURY PATIENTS DURING PHYSIOTHERAPY

The following chapter reports on a pilot analysis of the effect of a low-cost Virtual Reality (VR) system, in conjunction with traditional pharmacologic analgesics, on reducing pain and anxiety experienced by adult burn injury patients during physiotherapy management at the Tygerberg Hospital (TBH) adult burn unit in South Africa, compared to traditional pharmacologic analgesics alone.

**Please note that the full methodology of this chapter is listed as Appendix D3

**EFFECT OF A LOW-COST VIRTUAL REALITY SYSTEM ON REDUCING PAIN
AND ANXIETY IN ADULT BURN INJURY PATIENTS DURING PHYSIOTHERAPY**

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ABSTRACT

Background Albeit Virtual Reality (VR) has been shown to be a useful adjunct in the reduction of pain during burn care and therapy, the current VR systems are expensive and may not be economically feasible for developing countries such as South Africa, where health budgets are stringent. **Objective** The purpose of this study was to ascertain the effect of a low-cost VR system (eMagin Z800 3DVisor), used in conjunction with pharmacologic analgesics, on reducing pain and anxiety in adult burn injury patients undergoing physiotherapy treatment, compared to pharmacologic analgesics alone at a South African hospital. **Study design** Single-blinded, within-subject study design. **Methods** Pain and anxiety outcome measures were measured by a blinded assessor using the Numeric Pain Rating Scale and Burn Specific Pain and Anxiety Scale. Descriptive statistics, Chi-square tests as well as the Student's paired *t-test* were used to analyze data. **Main findings** Eleven eligible adult burn injury patients consented to participate in this study (3 female, 8 male; median age 33 years: range 23-54 years). A marginal ($p=0.06$) to insignificant ($p=0.13$) difference between the two conditions (analgesics with VR and analgesics alone) in reducing pain was found. No significant difference ($p=0.58$) was found between the two conditions (analgesics with VR and analgesics alone) for anxiety. **Interpretation** There is a trend that a low-cost VR system, when added to routine pharmacologic analgesics, is an economically feasible and safe adjunct therapy and could be of considerable benefit if implemented into the current pain management regimen of burn injury patients at a South African Hospital.

Key words: *virtual reality, burn injury, adults, physiotherapy, pain and anxiety*

INTRODUCTION

Virtual Reality (VR) is a technology which allows a user to become immersed and interact with an engrossing computer-generated environment (Das et al 2005). The technique can be used to clinically draw the patient's attention into the virtual world, distracting the patient and leaving less attention available to process pain during medical and rehabilitation procedures (Hoffman et al 2006). A non-invasive and supposed non-addictive distractive analgesic technique, VR has minimal side-effects associated with it, making it a safe adjunct to pharmacologic analgesics in the management of procedural pain experienced by burn patients (Hoffman et al 2006). VR systems are different to other gaming systems as they give the user the perception of actually being in a different environment and distracting them from their actual surroundings (Das et al 2005). Visual, auditory and touch sensations can be modified based on the stimuli, and further enhance the virtual experience (Das et al 2005). Recently it has also been found that VR, does not only change the way the patient interprets incoming pain signals, but actually reduces the amount of pain-related brain activity (Hoffman et al 2004).

However, despite the fact that VR has been found to be effective in the reduction of pain in burn injury patients from developed worlds (Morris et al 2009a); the current VR systems used in studies are expensive. The VR systems usually used in previous studies may thus not be economically feasible for developing countries such as South Africa, where the health budgets are limited and prioritized to other diseases such as HIV/AIDS and tuberculosis (Louw et al 2007). We conducted a preliminary study which illustrated that the procedural pain and subsequent anxiety experienced by South African burn victims during physiotherapy rehabilitation is severe and inadequately managed with the administration of traditional pharmacologic analgesics (Morris et al 2009b). The study signified that adjunct therapies in the management of burn pain in developing countries are warranted. However, cost concerns as well as constraints of time and resources, plays a major role in the health service delivery efficiency of a developing country and prohibits purchasing and implementation of expensive first world interventions (Ballard 1998). Effective and less expensive interventions which are affordable and feasible to implement in the average third world clinical facility, yet are able to yield the same clinical outcomes, are thus required in developing countries.

Therefore, in a country like South Africa, where burn injuries are prevalent and severe (van der Merwe 2007, Peck et al 2008), and health budgets are stringent (Louw et al 2007), it is posited that a less-costly VR system may be more economically feasible as an adjunct therapy to the currently inadequate pain management regimens used in the Tygerberg Hospital's (TBH) burn unit, than the expensive VR systems used in international studies. The following study thus provides preliminary evidence of the effect of a low-cost VR system, in conjunction with traditional pharmacologic analgesics on reducing pain and anxiety in adult burn injury patients during physiotherapy management, compared to traditional pharmacologic analgesics alone.

METHODS

Ethical approval for this study was obtained from the Committee for Human Research at the Stellenbosch University during January 2008. All subjects were required to give oral and written informed consent prior to participating in the study. The study was conducted at the adult burn injury unit of the TBH, in the northern suburbs of Cape Town, South Africa. A randomized (condition only), single-blinded (assessor blinded only), single-subject, pre-post experimental case series (within-subject) design was implemented in this study.

Intervention

The administration of the VR coupled with analgesics or analgesics alone were randomly assigned to each half of the physiotherapy treatment session. The subject was given a standard explanation about the VR equipment and the VR game. Each subject was given 5 minutes to familiarize him/herself with the VR equipment and game prior to commencement of the trials. The subject was instructed to use the joystick provided to maneuver the game.

VR equipment

The VR equipment and accessories used in this study consisted of the following:

- An eMagin Z800 3DVISOR (see figures 1 and 2) head-mount display with 2 high-contrast eMagin SVGA 3D OLED microdisplays, 24-bit color for more than 16.7 million colors, 0.59 inch diagonal eMagin OLED displays, 40 degree field view, and 800 x 600 triad pixels per display (http://www.3dvisor.com/pdf/Z800_datasheet.pdf)

- An ASUS F5SL Business series laptop, 2.00GHz, 2GB DDR2 667Mhz (2x1GB), 8 x DVD Super Multi, 1.3 MP Webcam, Radeon Mobility HD3450 256MB, gigabit LAN, Modem, Wireless 802.11a/b/g, Bluetooth
- A LOGIK PC ATTACK 3 joystick
- Walt Disney's Chicken Little PC game (software)



Figure 1: The eMagin Z800 3DVisor Virtual reality system, including the head-mount display and the control unit (source: <http://www.vrlogic.com/html/emagin.html>)



Figure 2: A subject wearing the eMagin Z800 3DVisor head-mount display (source: http://www.3dvisor.com/pdf/Z800_datasheet.pdf)

Outcome measures and tools

Pain outcome: A self-report Numeric Pain Rating Scale (NPRS) was used to subjectively measure the intensity of pain experienced by the subjects undergoing physiotherapy management. Reliability testing: In previous published literature the intraclass correlation coefficient (ICC) was found to be 0.76 and the test-retest reliability of the NPRS measurements was high (0.90) (Mawdsley et al 2002).

Anxiety outcome: A self-report Burn Specific Pain Anxiety Scale (BSPAS) was used to subjectively measure the level of anxiety experienced by the subjects undergoing physiotherapy management. Reliability testing: From previously published literature the Cronbach's coefficient α of the BSPAS was found to be quite high, 0.94, suggesting that the nine BSPAS items as a whole measure the same construct (reliability was considered to be acceptable when α was 0.70). The Pearson correlation coefficient, between the score on each individual item and the sum of the scores on the remaining items was 0.76 ($p < 0.0001$) with a range of 0.71 – 0.82 (all $p < 0.0001$) (Taal et al 1997). Validity testing: In previous published literature the concurrent validity was measured by determining the correlation of the BSPAS with the State-trait anxiety inventory (STAI-S). Correlation between the STAI-S and the BSPAS (0.58, $p < 0.005$) indicated a statistically significant degree of co-variation between the two anxiety scales (Taal et al 1997).

Study procedure

Adults admitted to the adult burn ward at the TBH during November and December 2008 with a burn injury (of any degree, size or on any area), aged 18 years and over, and receiving physiotherapy management, were eligible for inclusion in this study. Adults with burn injuries to the face or bilateral hands, a history of epilepsy, deemed medically unstable and who presented with cognitive deficits, were excluded from this study. The trial was conducted on one subject at a time and each subject was only trialed once. The subjects acted as their own controls. There was no interference with the type or dosage of analgesics which was administered no more than 2 ½ hours prior to the commencement of the VR trials. The physiotherapy treatment session, which was standard physiotherapy for burn injury patients conducted by a qualified physiotherapist, consisted of slow passive range of movement stretches to the end range of the affected joint of the lower or upper extremity only. The maximum duration of the treatment session was 20 minutes and the session was divided into

two components, thus each component was approximately the same duration. The same passive ROM exercises were performed in the same planes, with the same number of repetitions, and same duration of stretch time in each component of physiotherapy treatment. When more than one joint was involved, the proximal joint was ranged first, followed by the distal joint. Descriptive data (using a previously designed data collection form) and baseline outcome measurement data (scores from the NPRS and BSPAS) were collected before the trial commenced. The order of the intervention (VR with analgesics) and control (analgesics alone) conditions was randomized to either the first or second component of the physiotherapy session, so that each treatment condition had an equal chance of occurring first or second for each patient. Randomization of the trial conditions was conducted using a coin toss method - 'heads' was analgesics alone, and 'tails' was VR with analgesics. At the end of first and second component of the physiotherapy treatment session (with or without VR administration), a blinded measurer entered the treatment area and administered the NPRS and BSPAS. Each subject in essence completed three NPRS and three BSPAS forms (one set at baseline, one halfway through the physiotherapy session and one at the end). To determine the presence of adverse effects due to the VR, after each trial the subjects were asked whether or not they felt any nausea during the VR administration and if the VR head-mount display was comfortable to wear on their heads. On completion of the VR trial, the subject had the opportunity to receive additional physiotherapy to the treatment received during the trial, which consisted of the usual active and active-assisted range of movement exercises, functional and flexibility exercises from the physiotherapist.

Statistic analyses

Due to the small sample size and the fact that NPRS and BSPAS scores were skewed, the data extracted in this study were analyzed in a number of ways using the PHStat2 program. For categorical pain data, the NPRS was divided into 3 categories: mild (0-3); moderate (4-6) and severe (7-10). For categorical anxiety data, the BSPAS was divided into 5 categories: very low (0-18); low (19-36); moderate (37-54); high (55-72) and very high (73-90). Statistical analysis of the difference in pain and anxiety categorical scores between the two conditions (analgesics with VR and analgesics alone) was performed using these abovementioned categories in the Chi-square test analysis (significance level $\alpha = 0.05$). Student's paired *t-tests* were used to analyze differences between mean pain and anxiety

scores between the two conditions (analgesics with VR and analgesics alone) (significant level $\alpha = 0.05$). 95% confidence intervals (CIs) were calculated around the mean differences (MD). In addition, descriptive statistics incorporating visual descriptions of the change in pain and anxiety scores were illustrated using the box-and-whisker plot method.

RESULTS

Participants

Eleven eligible adult burn injury patients, with a median age of 33 years (range 23 to 54 years), admitted to the TBH adult burn unit between mid-November and mid-December 2008, consented to participating in the VR trials. The study sample consisted of 3 female and 8 male subjects. Seven subjects were burnt by fire, three with hot water and one with hot oil. The following body areas were burnt: back, trunk (chest area), abdomen, upper limb, unilateral and bilateral lower limb, mouth and chin (not a complete facial burn, such as over the eyes, that may have impeded the use of the VR), neck and hand. Eight of the 11 subjects had second degree burns, while three had a combination of second and third degree burns. The median Total Body Surface Area (TBSA) was 15% (range TBSA of 2%-55%). All the eligible subjects were given Morphine and Dolorol Forte for pain relief throughout the course of each day and the dosages of these analgesics varied from 5 to 25mg. Brufen was only given to two subjects at some point. The above-mentioned analgesics were administered every 4 to 6 hours. All subjects had received some type of pharmacologic analgesic no more than 2½ hours before commencement of the trials. The body areas treated during the physiotherapy treatment session consisted of upper limbs (n=6), and lower limbs (n=5). The median duration of the physiotherapy treatment sessions was 18 minutes (range 15-20 minutes).

Pain outcome

Figure 3 visually represents the pain scores reported by the eleven eligible subjects after each condition (analgesics alone or VR with analgesics).

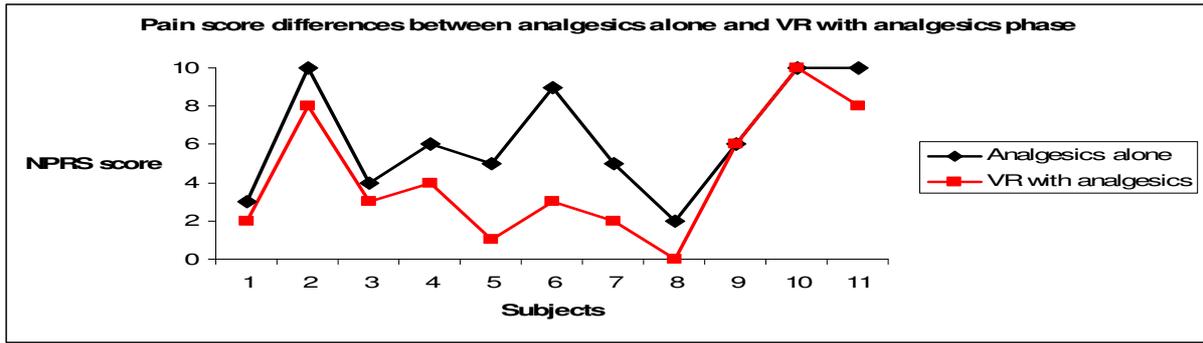


Figure 3: Visual representation of pain score differences (NPRS score 0-10)

The box-and-whisker plot (figure 4) illustrates a lower median of 3 (range 0-10) for the VR with analgesic condition, than for the analgesics alone condition of 6 (range 2-10). 50% of the total sample experienced less severe pain during the VR with analgesics condition than in the analgesics alone condition.

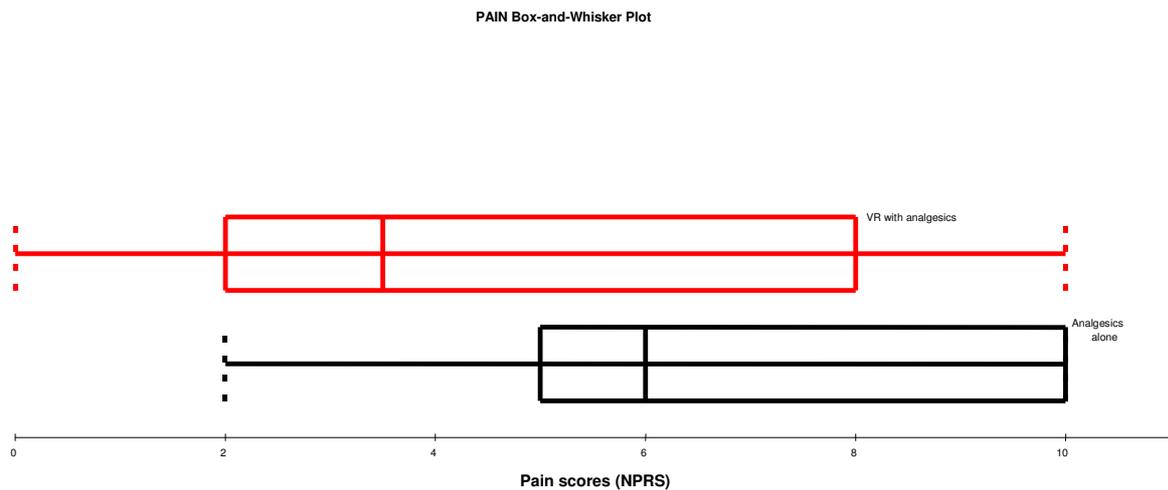


Figure 4: Box-and-whisker plot for pain outcome

In the categorical data, there was a marginally insignificant difference between the two conditions in reducing pain ($p=0.06$). Using the raw data, no significant difference could be detected between the two conditions ($p=0.13$; MD=2.09; 95% CI -0.67 to 4.85).

Anxiety outcome

Figure 5 represents the individual anxiety scores reported by the eleven eligible subjects after each condition (VR with analgesics and analgesics alone).

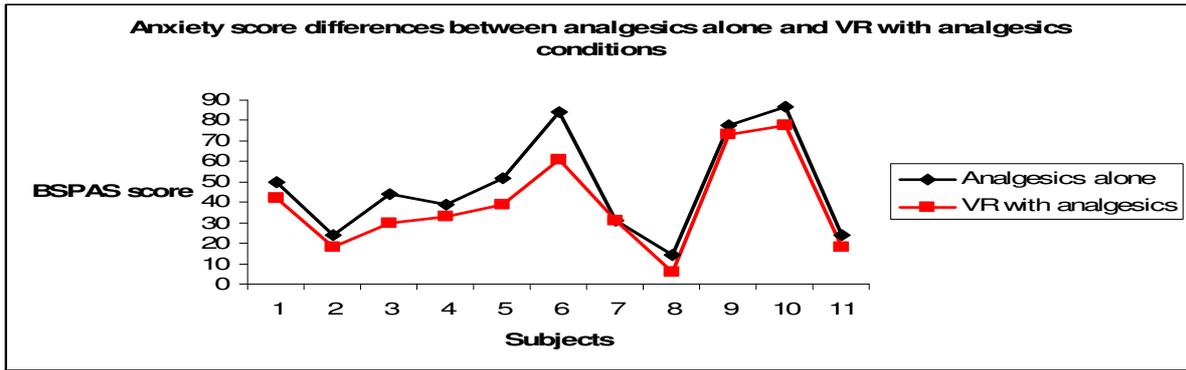


Figure 5: Visual representation of anxiety score differences (BSPAS scores 0-90)

The box-and-whisker plot (figure 6) illustrates a lower median of 33 (range 6-78) for the VR with analgesic condition, compared to the analgesics alone condition of 44 (range 14-87). 50% of the total sample experienced less anxiety in the VR with analgesics condition than in the analgesics alone condition, although not significantly less.

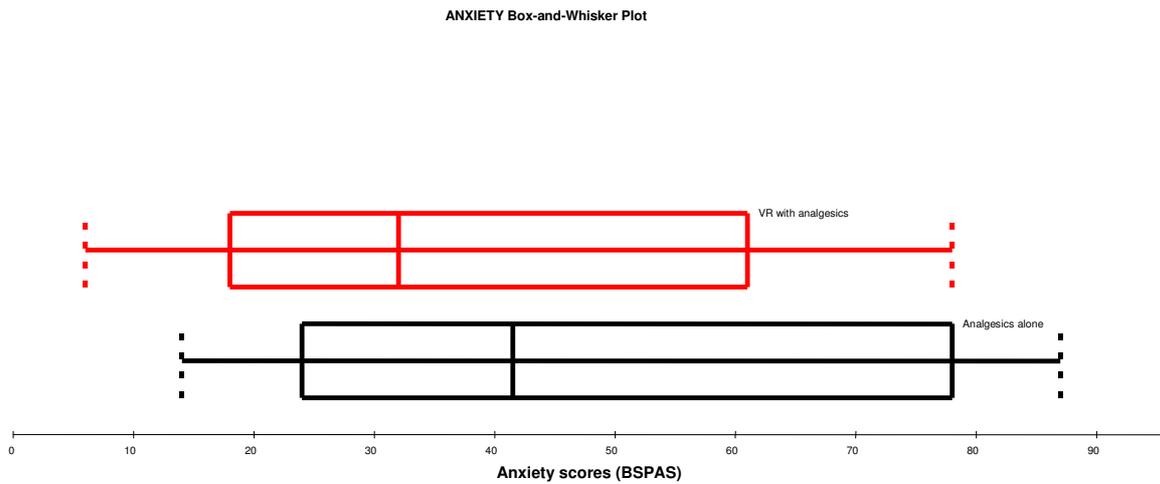


Figure 6: Box-and-whisker plot for anxiety outcome

In the categorical data, no significant difference was found ($p=0.58$) between the two conditions (VR with analgesics and analgesics alone) in reducing anxiety. Using the raw data, no significant difference could be detected between the two conditions ($p=0.39$; MD = 8.91; 95% CI -12.65 to 30.47).

Adverse effects

No adverse effects due to the VR were reported or observed.

DISCUSSION

To our knowledge, this is the first study which aimed to determine the effect of a low-cost VR system, in conjunction with pharmacologic analgesics, on reducing pain and anxiety in adult burn injury patients undergoing physiotherapy, compared to pharmacologic analgesics alone, in a developing country.

The results of this study illustrate that the low-cost VR system shows promise as a clinically useful adjunct therapy to the current burn pain management regimens in South Africa. When added to pharmacologic analgesics, the low-cost VR system successfully decreased pain in nine out of the eleven subjects, by up to 6 points on the NPRS. These results concur with two international studies from developed countries which found that VR was effective in reducing pain in burn injury patients during physiotherapy (Hoffman et al 2000; Sharar et al 2007). Hoffman et al (2000) found that all twelve subjects reported significantly less pain and Sharar et al (2007) reported that the mean subjective pain ratings were reduced by 20-37% when distracted with VR. The results of the study conducted by Sharar et al (2007) were also the first to suggest that VR appeared to be applicable for a diverse population of burn injury patients (Sharar et al 2008). However, the VR systems used in these studies are expensive and for developing countries like South Africa where health budgets are stringent, and it may not have been affordable or appropriate for the burn injury populations in a developing world setting. Therefore, the idea of investigating the effect of a low-cost VR system alternative in a South African adult burn injury population was posited.

Although the results from the previous studies and the current study indicate that the VR systems produce similar clinical outcomes, the VR system used in this study differs from the systems used in the aforementioned international studies. It is considerably less expensive and is directly available in South Africa which eliminates additional shipping and handling costs. Furthermore, the equipment (namely the laptop, joystick and game) utilized in the current study are easily available at local computer stores or online at reasonable prices. This is contrary to the availability and affordability of the customized VR equipment required for the VR systems used in previous studies, which can be costly. Therefore, since the VR system used in this study preliminarily showed favourable effects for pain and no adverse effects were observed, the low-cost VR system could be recommended as a safe, economically

feasible and clinically useful adjunct therapy to current burn pain management regimens in poorer nations. Future feasibility and cost-effectiveness studies are however warranted to further investigate the feasibility and cost-implications of implementing the low-cost VR system into a developing world clinical burn setting.

No significant differences were found for reduction in anxiety levels between the conditions, although reductions in anxiety during the VR with analgesics condition were noted for all but one subject. Since only one other small study to date has been conducted investigating the effect of VR on reducing anxiety in adult burn injury patients during physiotherapy, the evidence remains inconclusive (Hoffman et al 2000). Hoffman et al (2000) found that all twelve subjects reported significantly less anxiety when distracted with VR. For years, the relationship between pain and anxiety has been investigated and the theories derived from these studies seemed to be focused on the fact that pain and anxiety are positively correlated (Ploghaus et al 2001, Abdi et al 2002). It is common clinical experience that anxiety before and during a procedure about pain, will in turn exacerbate the pain levels during the procedure, and that by reducing the pain-related anxiety, one could possibly reduce the pain perceived (Ploghaus et al 2001, Abdi et al 2002). However, in burn injury patients this may not be as simple to achieve. Suffering a severe burn has a significant psychological effect on a person (Taal et al 1998). Burn injury patients not only have to tolerate the pain they experience but also have to cope with anxiety, low self-esteem, body image issues (Taal et al 1998) and humiliation when re-integrated into society (Partridge et al 1995). It is therefore comprehensible that even though a burn injury victim should in fact become less anxious as he becomes familiar with the daily procedure, his anxiety levels may actually increase over time instead (Summer et al 2007). These psychological and social aspects, coupled with the anticipation towards feeling severe pain during rehabilitation procedures, could in turn influence the functional rehabilitation of the patient as he may become non-complaint to treatments (van Baar et al 2006). Since VR is essentially a distraction technique and manifests its analgesic effects by distracting the user's focus away from the painful procedure, it may be valuable to suggest that VR may distract and relax an anxious patient, possibly decrease the pain experienced during physiotherapy (Gorini et al 2008) and encourage compliance to rehabilitation. The reductions in both pain and anxiety levels in this study due to the low-cost VR system, although minimal in anxiety, supports the fact that there is a positive correlation

between pain and anxiety, and that by reducing the one, the other may be reduced as well. Further research is however warranted on the effect of VR on anxiety in burn injury patients.

Physiotherapy after a burn injury is essential to minimize disability and maintain quality of life (Hoffman et al 2001), yet physiotherapy treatment itself incites tremendous amounts of pain and can be excruciating both for the patient and the therapist (Patterson et al 2004). Patients are often discouraged from being compliant during the treatment sessions (Patterson et al 2004) and this non-compliance can lead to complications, such as contractures, compromising function (Hoffman et al 2001; Haik et al 2006). Thus far, physiotherapists in clinical burn settings have relied on the use of pharmacologic analgesics to assist them in making the rehabilitation process for burn victims less painful, encourage patient compliance and maximize functional outcomes (Summer et al 2007). However, since the exclusive use of pharmacologic analgesics has proven to be inadequate (Haik et al 2006, Morris et al 2009b), it is imperative that health professionals seek supplemental therapies to aid them in rehabilitating the burn injury patient to the most desirable functional level (Cahmi et al 2007). The low-cost VR system piloted in this study now offers developing countries an opportunity to improve their health service in burn rehabilitation which may not have been possible before due to minimum resources. Physiotherapists in developing countries can therefore focus less on the pain and anxiety the burn injury patients experience during physiotherapy management and more on the rehabilitation process and reintegration of the patient back into society.

There are several limitations to the current case series and although case studies are a good preliminary exercise for presenting new and innovative interventions or techniques, evidence for effectiveness requires larger, more carefully controlled studies. The main limitation was the small sample size which was due to time and recruitment issues. Nevertheless, the present study provides preliminary evidence for the effect of a low-cost VR system on reducing pain in adult burn injury patients during physiotherapy management. It offers initial support for the use of the low-cost VR system as a safe, economically feasible and clinically useful adjunct therapy to the current burn pain management regimens in developing countries. Future, larger pragmatic trials are however warranted to determine if the low-cost VR system can become part of the burns unit and develop into an everyday practice.

CONCLUSION

From the results of this pilot study, the low-cost VR system can be recommended as a safe, economically feasible and clinically useful adjunct therapy to current developing world burn pain management regimens. The low-cost VR system offers developing countries an opportunity to improve their health service in burn rehabilitation which may not have been possible before due to minimum resources.

CONFLICT OF INTEREST

The authors declare that there are no financial or personal relationships that could have inappropriately influenced this work.

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GENERAL DISCUSSION

The following chapter discusses the findings of the thesis, with mention of cost and clinical implications, study limitations and future recommendations for research.

GENERAL DISCUSSION

The main aim of this thesis was to ascertain the effect of a low-cost Virtual Reality (VR) system, in conjunction with traditional pharmacologic analgesics, on reducing pain and anxiety experienced by adult burn injury patients during physiotherapy management at the Tygerberg Hospital's (TBH) adult burn unit in South Africa, compared to traditional pharmacologic analgesics alone.

Role of VR in the modulation of burn pain during procedures

The origins for the use of VR in the modulation of burn injury pain arose from the recognized need for improvement in current burn pain management regimens (Sharar et al 2008). Since burn pain is unique, complex and varies over time, appropriate adaptation and tailoring of burn pain treatment protocols have been difficult (Konstantatos et al 2008). The management of burn pain has therefore been a major challenge for health professionals working in burn units globally (Abdi et al 2002, Richardson et al 2009, Connor-Ballard et al 2009). Concerns for the risk of drug addiction, drug side-effects, underestimation of the complexity of burn pain and ignorance regarding the proper administration of analgesics during burn rehabilitation often leads to the under treatment of burn pain by health professionals (Ptacek et al 1995; Jonsson et al 1998; Richardson et al 2009). This is of concern as uncontrolled burn pain could result in physical and psychosocial problems and destroy the trust patients may have in their health provider (Connor-Ballard et al 2009). Particularly troubling, is the fact that although procedural pain (pain felt during procedures like physiotherapy and burn wound care) is reported as the most intense pain and may exceed the pain experienced at the initial onset of the burn injury, it is the most likely type of burn injury pain to be under treated (Patterson et al 2004; Summer et al 2007). Adequate pain control during painful procedures like physiotherapy in burn injuries is essential for more than simple humane reasons (Richardson et al 2009). Under treated procedural pain risks poor compliance with treatment from the patient and compromises optimal functional outcomes (Loncăr et al 2006). Thus far, pharmacologic analgesics were an inevitable part of any burn pain management regimen (Richardson et al 2009). However, the results of the audit study (chapter 3) concurred with previous literature that the exclusive use of pharmacological analgesics during painful burn procedures is insufficient (Haik et al 2006; van Twillert et al 2007). Therefore, to assist health professionals in devising satisfactory burn pain management protocols, with less side-effects

and improved pain control, non-pharmacological methods of pain control such as VR could be considered as an adjunct therapy to traditional pharmacologic analgesics.

Whilst distracting a burn injury patient from the pain experienced during a procedure like physiotherapy, it is suggested that VR provides significant cognitive distraction as it is immersive, interactive and blocks visual and aural input from the hospital surroundings (Hoffman et al 2007). Pain perception has a psychological component which attracts a strong attentive response. By re-directing the attention of the patient away from the pain stimulus (in this case the physiotherapy treatment is the pain stimulus), the pain perception is manipulated and the intensity of the pain is reduced. The more immersive the VR system, the more the patient's attention will be drawn into the virtual world, leaving less attention available to process pain experienced during the procedure (Hoffman et al 2006; Wismeijer et al 2005). In addition, it has recently been posited that VR actually reduces the amount of pain-related brain activity and changes the way incoming pain signals are interpreted (Hoffman et al 2004; Hoffman et al 2007). Although the exact neurophysiological mechanism of VR analgesia is not well understood, the distraction theory of VR offers a valuable rationale for the use of VR in burn rehabilitation (Sharar et al 2008).

The current evidence that the use of VR, in conjunction with pharmacologic analgesics, can lead to reductions in subjective pain experiences shows promise that VR may be a valuable addition in burn pain management regimens (chapter 2 and chapter 4). As an adjunct to the current burn pain management regimens, VR could possibly assist health professionals in making the rehabilitation process for burn patients less excruciating and improve patient compliance, thereby improving functional outcomes.

Role of VR in the modulation of procedural burn injury anxiety

In addition to the severe pain, another aspect health professionals have to consider in burn rehabilitation is anxiety (Loncăr et al 2006). It is well known that pain and anxiety are closely inter-related, and if burn pain during procedures is not controlled, anxiety becomes a part of the entire burn injury process (Ploghaus et al 2001; Loncăr et al 2006). The audit study (chapter 3) found that South African adult burn injury patients still experienced significantly severe levels of pain and anxiety during physiotherapy when only given traditional

pharmacologic analgesics. This information concurs with international studies conducted in developed countries, that although pharmacologic analgesics currently form part of the cornerstone of any burn pain management plan, the exclusive use of traditional pharmacologic analgesics may be inadequate to alleviate the pain and associated anxiety experienced during excruciating procedures such as physiotherapy (Haik et al 2006; van Twillert et al 2007). The results of the audit (chapter 3) suggest that adjunct therapies are warranted in the management of burn pain and subsequent anxiety.

Anxiety may be related to the burn injury in different ways, and not just in anticipation of the physiotherapy management (Loncăr et al 2006). Patients may become anxious because of their disfigurement, disability or in anticipation of having to be re-integrated into society when they are discharged from hospital (Taal et al 1997). These psychological and social aspects, coupled with the anticipation towards feeling severe pain during rehabilitation procedures, could in turn influence the functional rehabilitation of the patient as he may become non-compliant to treatments (van Baar et al 2006). Adequate management of burn pain and subsequent anxiety plays an important role in building a trusting relationship between the burn victim and the health professional and assists in promoting patient compliance with rehabilitation (Latarjet 2002; De Jong et al 2007). Given the close relationship between burn pain and anxiety, it is therefore important that both pain and anxiety are managed simultaneously in the rehabilitation of burn injury patients to achieve optimal functional outcomes (Loncăr et al 2006).

VR is essentially a distraction technique and manifests its analgesic effects by distracting the user's focus away from the painful procedure (Sharar et al 2008). It may therefore be valuable to suggest that VR could distract and relax a burn injury patient during physiotherapy, decrease anticipatory anxiety, decrease the pain experienced during physiotherapy, and thereby encourage compliance to rehabilitation (Gorini et al 2008). Consequently, compliance to rehabilitation could assist the patient and physiotherapist in achieving optimal functional outcomes. The simultaneous reductions in both pain and anxiety levels (although insignificant) in the current study (chapter 4) due to the low-cost VR system, supports the fact that there is a positive correlation between pain and anxiety and suggests that VR may have a role to play in the reduction of anxiety of burn injury patients during physiotherapy.

However, to date, only two studies have been conducted investigating the effect of VR on anxiety in burn injury patients during physiotherapy (chapter 2 and 4). The findings of these studies were conflicting, therefore equivocal evidence for the effect of VR on anxiety levels in burn injury patients during physiotherapy remains. Further research is however warranted on the effect of VR on anxiety in burn injury patients during physiotherapy to make any conclusive recommendations.

Role of VR in developing world clinical burn settings

Developing countries have a higher incidence of burn injuries than developed countries (Ahuja et al 2004; Jiburum et al 2005; Forjough et al 2006). Lack of resources, overcrowding, lower education levels, ignorance, and poverty are the main factors associated with the high incidence of burn injuries in poorer nations (Ahuja et al 2004). Burn management in developing countries is faced with many difficulties such as lack of resources, inaccessible burn centres, adequate equipment and inexperienced staff (Ahuja et al 2004). Advances in technology has seen developed worlds improve their burn management regimens, but these advances have not yet had the desired effect on burn populations in developing countries (Jiburam et al 2005).

From the results of the systematic review (chapter 2) it became evident that additional empirical research was needed to determine the precise role for VR analgesia in various clinical burn settings globally. The studies included in the review demonstrated potential efficacy for VR in reducing pain during burn rehabilitation and care, but the small sample sizes and first-world settings, limit the generalizability of the findings to developing worlds where it seems to be needed the most. In an attempt to investigate the need for implementing adjunct therapies like VR into a developing world clinical burn setting, an audit study was conducted at the TBH adult burn unit in South Africa in October 2008 (chapter 3). The study provided confirmation that burn injury patients in a developing world require supplemental therapies to assist in managing procedural pain during physiotherapy treatment (chapter 3) similar to their developed country counterparts (chapter 2). Since the exclusive use of pharmacologic analgesics proved to be inadequate to control pain experienced during physiotherapy treatment, the implementation of non-pharmacological adjunct therapies would have been ideal. However, although the advantages of VR may have become widely

recognized within the clinical setting for its effect on reducing pain during burn rehabilitation procedures (chapter 2), the VR systems used in the developed worlds are expensive. Implementing expensive VR systems into a developing country, like South Africa, where health budgets are stringent and resources are limited (Louw et al 2007), may therefore not have been economically feasible.

To our knowledge, we conducted the first study exploring the effect of a low-cost VR system in a developing world clinical burn setting (chapter 4). The low-cost VR system used in this study was comparable to international VR systems in terms of technical properties, but not in cost. The results of the current study illustrated that the low-cost VR system showed promise as a clinically useful adjunct therapy to the current burn pain management regimens in developing countries (chapter 4), and concurred with international studies from developed countries that VR was effective in reducing pain in burn injury patients during physiotherapy (chapter 2). Therefore, due to cost constraints in developing countries, the low-cost VR system trialed in this study could be a more economically feasible option to consider instead of the more expensive versions, as it is less expensive and easier to acquire.

While the findings of the main study are preliminary, there is considerable scope for further investigation into the effect of this low-cost VR option in developing world clinical settings. The fact that the small sample size limits generalizability warrants further research in other burn populations. Nevertheless, since no side-effects or adverse effects were observed during this trial due to the VR, the low-cost VR system can presently be recommended as an economically feasible, safe and potentially clinically useful adjunct therapy to current South African burn pain management regimens.

Role of VR in physiotherapy practice

Physiotherapists in clinical burn settings often report that the burn rehabilitation process is an excruciating experience to not only the burn victim, but to them as well (Cahmi et al 2007). Since physiotherapy incites tremendous amounts of pain, patients usually become despondent and non-compliant (Patterson et al 2004). This non-adherence to rehabilitation may lead to a significant decrease in functional outcomes and even lead to additional surgery or disability, if limbs do not gain sufficient range of motion (Hoffman et al 2001; Haik et al 2006). Thus far,

physiotherapists have relied on the use of pharmacologic analgesics to assist them in making the rehabilitation process for burn victims less painful and thereby encourage compliance, ignoring the fact that they too need further assistance in coping with the unique challenges of burn pain management (Richardson et al 2009). Given that pharmacological analgesics alone are inadequate to manage procedural pain during physiotherapy treatment (Hoffman et al 2004; Hoffman et al 2006; chapter 3); it would be valuable to consider the use of adjunct therapies like VR during burn rehabilitation to assist not only the burn injury victim but the physiotherapist to cope with the burn rehabilitation process. By intriguing patients using VR, physiotherapists could have an easier task convincing burn injury patients of the importance of rehabilitation and could possibly focus less on the pain and anxiety the burn injury patients display during physiotherapy management, and more on the rehabilitation process itself.

The low-cost VR system trialed in the current study now offers an opportunity for developing countries to improve their health service in burn rehabilitation, which may not have been possible before due to minimal resources (chapter 4). From the results of the systematic review (chapter 2), it was found that only two studies trialing VR during physiotherapy in burn injury patients have been conducted prior to the conduction of this current study (Hoffman et al 2000;Sharar et al 2007). Pain was an outcome in both studies, and anxiety was a secondary outcome in one study (Hoffman et al 2000). Although the evidence remains scant, there seems to be a positive trend that VR is effective on reducing pain in burn injury patients during physiotherapy. It is therefore recommended that since the low-cost VR system is affordable and easily accessible, physiotherapy departments in developing countries may possibly consider acquiring the system as it could compliment physiotherapy treatment for burn injuries considerably.

Future recommendations for the use of VR in physiotherapy burn injury practice include trialing VR during active physiotherapy treatment and not only during passive range of motion exercises. Allowing the burn injury patient to move freely within a virtual world, similar to research done in stroke and VR (Crosbie et al 2007), could assist patients in achieving greater functional outcomes whilst feeling in control of his own rehabilitation. Furthermore, since burn injuries present a paradigm for the management of acute pain in general (Hoffman et al 2000), the use of the low-cost VR system in other acute pain

conditions treated by physiotherapists and other health professionals, is a possibility in the future.

Cost and clinical implications associated with the low-cost VR system

Cost implications

The most significant advantage of the VR system trialed in this study is its cost, which implies that the low-cost VR system may be an economically feasible option for developing countries with stringent health budgets to consider. The low-cost VR system is directly available in South Africa, which eliminates any shipping and handling costs and also provides easily accessible technical support, contrary to the more expensive systems. The game utilized in the trials was an ‘off-the-shelf’ computer game, which is easily accessible. Unlike the more expensive VR systems, which can only operate one type of game which is especially programmed for the specific system, the low-cost VR system can use any compatible game available at the local gaming store or online, which further saves costs.

Clinical implications

Since the low-cost VR system weighs only 227g, less than its more expensive counterpart which weighs more than 794g, it is therefore easier to transport and store. It can simply be stored, with all its accessories, in a small cupboard when not in use and not pose a nuisance to anyone working in the burns unit. Its complete portability allows that the system can be easily moved from one patient to the next within the ward, and merely sterilized with alcohol to reduce cross-infections. Neither extensive technical knowledge nor specialist staff is required to set-up, install or operate the system, which means that significant amounts of additional time will not have to be committed by the ward staff. It is also speculated that with minimal training, the physiotherapist treating the burn injury patient would be able to administer the VR alone. This deems the low-cost VR system highly feasible in a clinical setting as additional staff and resources would probably not be necessary.

Limitations to the current study and previous studies

The current study displayed substantial limitations which are typical of case study designs. The reduced study sample size limits the ability to generalize the results and the consecutive sampling procedure utilized in this study may have further limited the recruitment of subjects

and introduced a level of selection bias. Furthermore, only the assessor could be blinded as blinding of therapists and subjects were impossible due to the nature of the intervention. Care was taken to standardize the treatment, but the physiotherapist performing the treatment was aware of the intervention condition, and may have inadvertently treated the subjects more gently in the VR, which could have resulted in a reduced pain score.

(Recommendations to address these limitations are discussed in the section below.)

Recommendations for future research

Case studies like these are a good preliminary exercise for presenting new and innovative interventions or techniques, but evidence for effectiveness however requires larger, more carefully controlled studies (Hoffman et al 2000; Kinugasa et al 2004). Single-subject designs do however have some advantages, as they are usually easier to incorporate into practical and clinical settings than group research designs and are more appropriate for the study of small populations (Kinugasa et al 2004). Larger sample sizes incorporated into future studies may provide better insight into the usefulness and effect of the low-cost VR system as an adjunct therapy to the current burn pain management regimens. Future studies should also attempt to introduce proper sequence generation during the recruitment of study subjects to eliminate selection bias. It has to however be noted that properly-designed randomized controlled trials (RCTs) may not be possible due to the subjective nature of pain and anxiety. Within-subject designs may be more suitable for the type of intervention. Furthermore, a double-blinded duplication of the present study would be ideal but it may be difficult to perform due to the nature of the intervention, therefore pragmatic trials may be more appropriate for the time being.

Although this study focused on the effect of a low-cost VR system, it is also recommended that cost-effectiveness studies be conducted to ascertain the exact economic value of implementing VR into government and private hospitals, and whether or not VR, as an intervention, would truly decrease the use of pharmacologic analgesics, thereby decrease overhead medical costs by the state and private health budgets. Furthermore, though unethical at this point, removing the analgesic component during the VR administration would indicate

a true effect of VR and in essence eliminate the confounding factor of the analgesics effect of pharmacologic analgesics.

A shortcoming of the VR equipment is that the wires and leads which accompany the VR system can be quite cumbersome, and this is of particular concern in a hospital setting where accidents are prone due to slippery floors, etc. To address this factor, a wireless version of the VR, such as a Bluetooth VR could possibly be designed, which can be used with a small compatible laptop.

Furthermore, since burn injuries present a paradigm for the management of acute pain in general (Hoffman et al 2000), the investigation of the effect of VR in other acute pain populations is a possibility. In addition, wound dressing changes is an equally painful part of burn care, and the effect of the low-cost VR system on pain and anxiety in burn injury patients during burn wound care in a developing clinical setting should be explored.

Lastly, the ‘Walt Disney’s Chicken Little’ game used in this study was originally meant for children and may possibly not have been appropriate for the adult population included in this study. The game may have been too simple and may not have been immersive enough. However, the current game was selected on the basis that it was not a violent game. Due to the already violent environment the participating subjects in South Africa live in and given their recent trauma, a violent game may have been inappropriate. Future studies should however, select age and population appropriate games to captivate the target audience even more.

CONCLUSION

Adequate pain control during physiotherapy in burn rehabilitation can be challenging, but is essential to achieve optimal functional outcomes. The advantages of VR have become widely recognized within the clinical setting for its effect on reducing pain during burn rehabilitation procedures like physiotherapy. Since the exclusive use of pharmacological analgesics has been found to be insufficient to manage procedural pain, non-pharmacological modalities such as VR can be considered as adjunct therapies to assist health professionals and patients in modulating burn pain. However, for developing countries where there is a lack of

resources, the implementation of the VR systems used in the developed worlds may not be economically feasible. This thesis presents the steps taken to investigate the effect of a low-cost VR option on reducing pain and anxiety in adult burn injury patients during physiotherapy in a developing country. The main finding of this thesis suggest that the low-cost VR system can be recommended as a safe, economically feasible and potentially useful adjunct therapy to the current burn pain management regimens in poorer nations. Since burn pain has severe psychosocial implications for burn injury patients and is usually inadequately managed, improvements in current burn pain management regimens are warranted globally. The low-cost VR system now offers an opportunity for developing countries to improve their health services in burn rehabilitation to simulate advances that have taken place in developed countries.

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APPENDICES

Appendix A: Data collection form

Appendix B1-B3: Numeric pain rating scale

Appendix C1-C3: Burn specific pain and anxiety scale

Appendix D1-3: Full methodology procedure for the construction of data collection form, chapter 3 and chapter 4 of study

Appendix E1-3: Patient informed consent form: Phase 1 and pilot study

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Appendix G1-3: Patient informed consent form: Phase 2

Appendix H: Letter to Dr van der Merwe, Head of Department of TBH adult burn unit, requesting permission to conduct study in the TBH adult burn unit

Appendix I: Email from Dr van der Merwe, confirming permission to conduct study in TBH adult burn unit

Appendix J: Letter to interdisciplinary panel of experts regarding construction of data collection form

Appendix K: Short CV of Mrs. LD Morris

APPENDIX A: DATA COLLECTION FORM

Please complete and mark appropriate box.

Record/reference number: _____

Participant's name/Sticker (for record purposes): _____

Date of assessment: ____/____/200__

1. **Gender:** Male Female

2. **Age:** _____

3. **Ethnic group:**

Coloured White Black Other (specify) _____

4. **Marital status:**

Married Single Divorced

5. **Dependants:** _____

6. **Occupation:** _____

Burn injury information

7. **Date of burn injury:** _____ (yyyy/mm/dd)

8. **Area of burn:**

Face back trunk upper limb L or R both upper limb

Lower limb L or R both lower limbs hand L or R

Foot L or R both feet other area (specify) _____

9. **Depth/degree of burn:**

Superficial/1st Partial/2nd Full thickness/3rd

10. **TBSA burnt:** _____%

11. **Cause of burn:**

Hot liquid Fire Coal Abrasion Chemical

Electricity Other cause

12. **Analgesic information:**

Name of analgesic	Dosage/day	Frequency/times administered/day	Last administration time

13. **Physiotherapy treatment information**

a) Time commenced: _____

b) Duration of treatment: _____ minutes

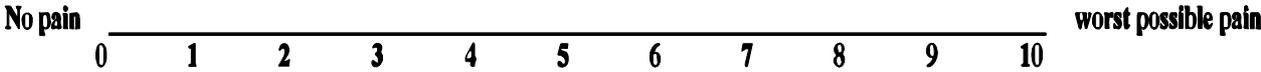
c) Body area treated: _____

14. **Any adverse effects observed/reported:**

APPENDIX B1: NUMERIC PAIN RATING SCALE (NPRS)

Record/reference number: _____
Patient name (for reference purposes only): _____
Date of assessment: _____

Please circle the number that matches what the intensity of the pain is that you feel at this very moment:



Any comments or suggestions:

APPENDIX B2: AMANANI ABONISA IQONDO LEXHALA (NPRS)-XHOSA

Igama lesigulane (kwenzelwa ukungqinisisa kuphela): _____

Umhla wohlobo: _____

Nceda urhangqele inani elingqamene nobungakanani beentlungu obuvayo ngalo mzuzu:

Akukho
zintlungu 0 1 2 3 4 5 6 7 8 9 10 ezona ntlungu zimandla

Naziphi na izimvo:

APPENDIX B3: NUMERIC PAIN RATING SCALE (NPRS) - AFRIKAANS

Rekord/Verwysings nommer: _____

Pasiënt se naam (vir verwysings doel alleenlik): _____

Datum van evaluasie: _____

Sirkel asseblief die nommer wat die intensiteit van jou pyn op hierdie oomblik die beste beskryf:

Geen pyn 0 1 2 3 4 5 6 7 8 9 10 Ergste moontlike pyn

Enige ander kommentaar of voorstelle:

APPENDIX C1: BURN SPECIFIC PAIN ANXIETY SCALE (BSPAS)

Record/reference number: _____

Participant's name (for record purposes only): _____

Date of assessment: _____

Please circle the number which matches how you feel about each question:

BSPAS

1. Do you worry about the burn wound healing?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

2. Do you fear the dressing changes or the physiotherapy treatments?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

3. Do you fear losing control because of pain?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

4. Do you fear pain during the dressing changes and physiotherapy sessions?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

5. Is your pain severe?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

6. Are you stressed out because of having to endure pain?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

7. Are you concerned about the burn wound healing?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

8. Are you always thinking about the pain?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

9. Are you tense during the dressing changes or physiotherapy sessions?

Not at all 0 1 2 3 4 5 6 7 8 9 10 the worst imaginable way

Any comments or suggestions:

APPENDIX C2: ISIKALI SAMAQONDO EXHALA LOKUVISWA IINTLUNGU ZESILONDA SOKUTSHA (BSPAS) - XHOSA

Igama lalowo uthatha inxaxheba (ngenjongo yokuligcina): _____

Umhla wohlo: _____

Nceda urhangqele inani elingqinelana nendlela oziva ngayo ngombuzo ngamnye:

BSPAS

1. Ingaba uyazikhathaza ngokunyangeka kwenxeba lokutsha?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

2. Ingaba woyika ukutshintshwa ibhandeji okanye ukunyangwa umzimba ngokuthanjiswa amalungu?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

3. Ingaba woyikisela ukuba iintlungu zingakwenza ungakwazi ukuzibamba?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

4. Ingaba woyika iintlungu xa utshintshwa amabhandeji naxa unyangwa umzimba ngokuthanjiswa amalungu?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

5. Ingaba iintlungu zakho zimandla?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

6. Ingaba unoxinezelelo ngenxa yokuba kufuneka unyamezele iintlungu?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

7. Ingaba unexhala lokuba izilonda zokutsha aziyi kunyangeka?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

8. Ingaba usoloko ucinga ngeentlungu?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

9. Ingaba uyaxhalaba xa utshintshwa amabhandeji okanye xa unyangwa umzimba ngokuthanjiswa amalungu?

Hayi $\overline{0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10}$ eyona ngcingane imbi

Zikhona ezinye izimvo:

APPENDIX C3: BURN SPECIFIC PAIN ANXIETY SCALE (BSPAS)-Afrikaans

Rekord/Verwysings nommer: _____

Pasiënt se naam (vir verwysings doeleindes alleenlik): _____

Datum van evaluasie: _____

Sirkel asseblief die nommer wat beste beskryf hoe jy vandag voel:

BSPAS

1. Bekommer jou oor hoe die brand wond genees?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

2. Vrees jy die verband veranderinge of die fisioterapie behandelinge?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

3. As gevolg van die pyn, vrees jy dat jy beheer sal verloor?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

4. Vrees jy pyn gedurende die verband verandering of fisioterapie behandelinge?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

5. Is jou pyn erg?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

6. Is jy gestres as gevolg van die pyn wat jy moet verduur?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

7. Is jy bekommerd oor die genesing van die brand wond?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

8. Dink jy gedurig aan die pyn?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

9. Is jy gespanne gedurende die verband verandering of fisioterapie sessies?

Glad nie 0 1 2 3 4 5 6 7 8 9 10 ergste moontlike manier

Enige ander kommentaar of voorstelle:

APPENDIX D1: CONSTRUCTION PROCESS OF DATA COLLECTION FORM

Aim

The aim of this preliminary process was to incorporate the aspects required to establish a profile of the adult burn injury patients undergoing physiotherapy management into a data collection form.

Objectives

The objectives were:

- To construct a data collection form which would collect data relating to the demographical and personal information; burn injury information and analgesic information of adult burn injury patients admitted to the Tygerberg Hospital's (TBH) adult burn unit. In addition, provision for physiotherapy treatment information pertaining to duration of treatment session and area treated would be made on data collection form.
- To determine if the content of the data collection form which was constructed for the administration in adult burn injury patients, was appropriate and specific enough to collect the relevant data.

Construction

The construction of the data collection form took place between January 2008 and February 2008. The data collection form was designed and constructed by the principle researcher.

Questions pertaining to the following were listed on the data collection form:

- Personal and demographic information (e.g. age; gender, ethnic group, occupation, etc)
- Burn injury information (Type of burn i.e. hot water burn, fire burn, etc; Area of burn and Depth of burn i.e. first-, second- or third-degree burn)
- Analgesic information (i.e. type of analgesic, frequency, dosage, etc)
- Physiotherapy information (i.e. time treatment session commenced, duration, area treated)
- Any adverse effects/side-effects observed or reported

Content validity evaluation

To determine if the questions asked in the constructed data collection tool were appropriate and specific enough in collecting the relevant data from the adult burn injury patients, a draft

of the constructed data collection form was sent to a panel of experts. The panel of experts was invited by the principle researcher to assist in validating the content of the data collection form. The panel of experts consisted of three interdisciplinary members namely: Prof K Grimmer-Somers (Director, Centre for Allied Health Evidence, Professor of Physiotherapy, University of South Australia), Dr E van der Merwe (Head of TBH adult burn unit) and Ms A Parbhoo (Head of Physiotherapy Department, Red Cross Children's Hospital).

Procedure of content validation

The main responsibility of the panel members were to determine if the data collection form consisted of the appropriate questions and sections needed to extract the appropriate personal, burn injury, and analgesic information from the subject and the medical records. The members of the panel each received drafts of the data collection form including an information letter outlining the guidelines for the evaluation of the data collection form. It was requested that they objectively assess and scrutinize the data collection form and thereafter suggest possible changes or additional information. The feedback received from the panel members with regards to the changes and appropriateness of the data collection questions, was collated and analyzed.

Final draft construction of data collection form

The changes suggested by the panel of experts were then amended by the principle researcher, and only the sections deemed by the panel as appropriate were included in the final data collection form. Any sections that were not found appropriate by the panel members were eliminated. The revised version of the data collection form was sent back to the panel members and once again subjected to being assessed and scrutinized. On consensus from all the panel members that the data collection form consisted of the appropriate questions and sections needed to extract the appropriate information from the adult burns patients, the final draft of the data collection forms was drawn up (Appendix A). The constructed data collection form was used to collect data from subjects and subject folder pertaining to demographical and personal, burn injury, analgesic and physiotherapy treatment information during audit and main study (chapter 3 and 4).

APPENDIX D2: FULL METHODOLOGY OF CHAPTER 3

Study aim

The aim of the audit study was to identify the level of pain and anxiety experienced by adult burn injury patients before, during, immediately after and 30 minutes after physiotherapy management when given pharmacologic analgesics only.

Research question

The specific research question was:

What was the level of pain and anxiety experienced by adult burn injury patients admitted to Tygerberg Hospital's (TBH) adult burn unit, before, during, immediately after and 30 minutes after physiotherapy management when given pharmacologic analgesics only?

Study objectives

The primary objectives of phase one of the main study were:

- To establish a 'mini' profile (regarding the age, gender, ethnicity, occupation, burn type, burn area, analgesic and physiotherapy treatment information) of the adult burn injury patients admitted to TBH adult burn unit during one month.
- To determine the intensity of pain experienced by adult burn injury patients before, during, immediately after and 30 minutes after physiotherapy management when given pharmacologic analgesics only.
- To determine the level of anxiety experienced by adult burn injury patients before, during, immediately after and 30 minutes after physiotherapy management when given pharmacologic analgesics only.

Research team/support staff and their main roles

- Principle researcher: recruited subjects, obtained informed consent from subjects, explained study procedures, data collection forms, NPRS and BSPAS forms to subjects, collected data from subjects, and conducted data storage, extraction and analysis.
- Research assistant: assisted in recruiting subjects, obtaining consent from subjects, explaining study procedures, data collection forms, NPRS and BSPAS forms to subjects, and assisted in data collection, storage and extraction.

- Translator: assisted in professional translation of instructions regarding procedures, data collection forms, NPRS and BSPAS forms and in obtaining informed consent from subjects, and assisted in translating any feedback and information retrieved from subject
- Qualified Physiotherapist: conducted physiotherapy treatment which consisted of passive exercises.

Methodology

Study Setting

The TBH Adult Burn Unit is a ward located in the TBH, Tygerberg, South Africa, on the 1st floor. The ward currently consists of 22 beds, 5 of which are in the Intensive care unit (ICU). Depending on the demand, the male and female are allocated to designated wards accordingly. An average of 20 to 30 patients is admitted per month, with approximately 50% admitted to ICU on admission. The staff consists of one sister and two nurses in the HCU and 2 sisters and 3 nurses in the ICU. The head of department is Dr E van der Merwe and she is assisted by two to three other doctors. The pain management protocol for patients admitted to the burns unit consists of intermittent administration of pharmacologic analgesics. Patients receive wound dressing changes daily, and physiotherapy is prescribed if necessary.

Study design

A month long 'in-ward audit'/survey (self-report) approach was applied to collect descriptive data for this phase of the study.

Study population

The study population consisted of adult burn injury patients admitted to the TBH Adult Burns Unit undergoing physiotherapy management.

Sample recruitment method

Adult burn injury patients admitted to the TBH adult burn unit during the month of data collection (October 2008) were sampled consecutively and recruited by the principle researcher and research assistant for participation in this study.

Sample size

A total sample size of 17 eligible subjects was attained during the stipulated data collection period.

Sample inclusion criteria

- Adult male and female patients aged 18 years and older, who had sustained a burn injury via any cause or mechanism such as fire, chemicals, hot liquids or substances, abrasions, electricity or coal.
- Patients who had sustained burn injuries to the any part of their body and to any percentage of their total body surface area.
- Patients with bilateral hand burns and burns to their dominant hand were included, but were assisted in any writing tasks.
- Patients who had sustained burn injuries of any degree (first, second or third degree, or a combination of these classifications) or any depth (superficial, partial or full thickness, or a combination of these classifications).
- Patients who were within any phase of healing of the burn wound.
- Patients who either had had or had not had skin grafts, or any other type of burn reconstruction surgery.
- Patients who were undergoing physiotherapy management at time of data collection.
- Patients who spoke, were literate and were proficient in English, Afrikaans or Xhosa.
- Patients who received pharmacologic analgesics up to 2½ hours prior to commencement of physiotherapy session.

Sample exclusion criteria

- Patients whose medical condition was deemed unstable.
- Patient who were unconscious and were unaware of their surroundings.
- Patients who had any cognitive deficits.
- Patients may not have received any other interventions, besides pharmacologic analgesics prior to study.

Duration of phase

This phase of the study was conducted within one month.

Data collection tools

The previously constructed **data collection form** (Appendix A) was used to collect information relating demographical, personal, burn, analgesic and physiotherapy treatment information.

Outcome measurement tools

- A self-report **numeric pain rating scale** (NPRS) was used to subjectively measure intensity of pain experienced by subjects, before, during, after and 30 minutes after physiotherapy management (appendix B). *The NPRS is a self-report or interviewer-administered subjective measurement of pain intensity, whose developers are unknown. It consists of an 11 point scale (0 to 10) with the extreme anchors of “no pain” (0) and “pain as bad as it can be” (10). On the horizontal line are 1 cm intervals, indicating levels of pain. Subjects are presented with a copy of the NPRS and are asked to circle the number corresponding to their perceived level of pain intensity (0 to 10). Scoring is simply the response circled out of 10. For interviewer administration, the interviewer verbally describes the NPRS and then asks the patient for a verbal rating of his/her perceived pain. The patient’s verbal response is then his/her pain intensity out of 10 (Finch et al 2002). **Reliability testing:** In previous published literature the intraclass correlation coefficient (ICC) was 0.76 and the test-retest reliability of the NPRS measurements was high (0.90) (Mawdsley et al 2002).*
- A self-report **Burn Specific Pain Anxiety scale** (BSPAS) was used to subjectively measure the level of anxiety experienced by subjects before, during, after and 30 minutes after physiotherapy management (appendix C). *The BSPAS was developed by L.A. Taal and A.W. Faber, in the Netherlands in 1997. The BSPAS consists of nine items which describe: (1) feelings of worry about wound healing; (2) tension and fear of losing control during dressing changes; (3) anxious anticipation of pain during or after medical procedures; and (4) a generalized feeling of being ‘keyed up’ or ‘on edge’ because of enduring pain. The items are scored on a 10cm visual analogue line, with 1cm intervals between 0 and 10. The reference points are identified by these numbers, and also by the expressions ‘not at all’ (0) and ‘the worst imaginable way’ (10). In the instructions, patients are explicitly requested to scale the strength of their feelings relative to the 11 reference points (Taal et al 1997). The highest total score was, indicating high anxiety*

levels. **Reliability testing:** The Cronbach's coefficient α was quite high, 0.94, suggesting that the nine BSPAS items as a whole measure the same construct (reliability was considered to be acceptable when α was 0.70). The Pearson correlation coefficient, between the score on each individual item and the sum of the scores on the remaining items was 0.76 ($p < 0.0001$) with a range of 0.71 – 0.82 (all $p < 0.0001$) (Taal et al 1997).

Validity testing: Concurrent validity was measured by determining the correlation of the BSPAS with the State-trait anxiety inventory (STAI-S). Correlation between the STAI-S and the BSPAS (0.58, $p < 0.005$) indicated a statistically significant degree of co-variation between the two anxiety scales (Taal et al 1997).

Pilot study

To ensure that the data collection forms and outcome measurement tools (NPRS and BSPAS) were appropriate for the study population, a pilot study was conducted prior to the actual audit study. Five subjects were sampled consecutively and recruited according to the inclusion and exclusion criteria and invited to participate in this pilot study. The study procedures were explained to the subjects and once the subject agreed to participate in the study, he/she was asked to read and sign an informed consent form (Appendix E). The subject was given a variable study record identity code (VR1-01, VR1-02, etc) or number and this number was used to identify the subject throughout the study procedures. The pilot study was conducted during the physiotherapy treatment sessions of the subjects.

When the principle researcher was satisfied that the subject was sufficiently informed, a data collection form was completed for each subject. The previously constructed data collection form was used to extract all data pertaining to the demographical, personal, burn injury, and analgesic information of each subject from the medical folders. In addition, the last administration time of analgesics was recorded. The data collection form was completed in the presence of the subject. Any information unavailable or unclear in the medical folder was directly obtained from the subject. On completion of the data collection form, the principle researcher or research assistant administered one set of the NPRS and BSPAS to the subject to either complete themselves or receive assistance from the principle researcher or research assistant to collect baseline pain and anxiety outcome measurement data. The physiotherapist entered the treatment area and closed the curtain surrounding the subject's bed. For the

purposes of this study, published literature was consulted regarding the physiotherapy treatment procedure (Hoffman et al 2000; Sharar et al 2007). The maximum duration of the treatment session was 20 minutes and was divided into two components (stage one and two) by time, pre-determined by the physiotherapist. Each component of the treatment session was thus approximately the same duration. The physiotherapist then conducted slow passive stretching of the selected affected extremity to the end range of the affected joint, in all possible planes of movement. The same passive ROM exercises were performed in the same planes, same number of repetitions, and same duration of stretch time in each component of physiotherapy treatment. When more than one joint was involved, the proximal joint was ranged first, followed by the distal joint.

Approximately half-way through the treatment session, a blinded assessor entered the treatment area and administered the second set of the NPRS and BSPAS forms. The physiotherapist continued the physiotherapy treatment session, and at the end of the physiotherapy session, a blinded assessor again entered the treatment area. The physiotherapist left the treatment area. The third set of the NPRS and BSPAS forms were administered to the subjects immediately after the physiotherapy treatment session. After a 30-minute time lapse, a blinded assessor administered the fourth and final set of the NPRS and BSPAS forms to the subject. The duration of the physiotherapy treatment session was documented on the data collection form, and any adverse effects reported or observed were recorded.

Outcomes of pilot study

The time taken to complete the procedure was documented. At the end of the procedure, subjects were asked to comment on the ease of using the data collection forms, NPRS and BSPAS. The time and ease at which the subjects in the pilot study completed the data collection tools and outcome measurement tool was determined and documented. The subjects were requested to comment on whether the tools required any further explanation or changes. The pilot study gave a clear indication as to how the subjects had to be instructed on using the data collection forms, NPRS and BSPAS, and also identified any potential problems with the tools. Any potential problems were addressed before the main study commenced.

Data collection procedure (main study)

Each patient admitted to the TBH adult burn unit was screened and either identified as a potential subject or excluded if they did not conform to the inclusion criteria for study. The assistance of the medical staff was requested with regards to identifying patients and locating folders if the folder were not at the subject's bedside. A total of 17 adult burn patients were sampled consecutively and recruited by the principle researcher and the research assistant during one month (October 2008). The qualified physiotherapist was asked to inform the principle researcher or research assistant when the eligible patients received their physiotherapy treatment. The study procedures were explained to the subjects in the language that they preferred (English, Afrikaans or Xhosa) and once the subject understood the study procedure and agreed to participate in the study, he/she was asked to read and sign an informed consent form (Appendix E). The subject was given a study identity code or number, to retain anonymity, and this number was used to identify the subject throughout the study procedures.

When the principle researcher was satisfied that the subject was sufficiently informed, a data collection form was completed for each subject. The previously constructed data collection form was used to extract all data pertaining to the demographical, personal, burn injury and analgesic information of each subject from the medical folders. In addition, the last administration time of analgesics was recorded. The data collection form was completed in the presence of the subject. Any information unavailable or unclear in the medical folder was directly obtained from the subject.

On completion of the data collection form, the principle researcher or research assistant administered one set of the NPRS and BSPAS to the subject to either complete themselves or receive assistance from the principle researcher or research assistant to collect baseline pain and anxiety outcome measurement data. The physiotherapist entered the treatment area and closed the curtain surrounding the subject's bed.

For the purposes of this study, published literature was consulted regarding the physiotherapy procedure (Hoffman et al 2000; Sharar et al 2007). The maximum duration of the treatment session was 20 minutes and was divided into two components (stage one and stage two) by

time (as pre-determined by the physiotherapist), thus each component was approximately the same duration. The physiotherapist then conducted slow passive stretching of the selected extremity to the end range of the affected joint, in all possible planes of movement. The same passive ROM exercises were performed in the same planes, same number of repetitions, and same duration of stretch time in each component of physiotherapy treatment. When more than one joint was involved, the proximal joint was ranged first, followed by the distal joint..

Approximately half-way through the treatment session, a blinded assessor entered the treatment area and administered the second set of the NPRS and BSPAS forms. The physiotherapist continued the physiotherapy treatment session, and at the end of the physiotherapy session, a blinded assessor again entered the treatment area. The physiotherapist left the treatment area. The third set of the NPRS and BSPAS forms were administered to the subjects immediately after the physiotherapy treatment session. After a 30-minute time lapse, a blinded assessor administered the fourth and final set of the NPRS and BSPAS forms to the subject. The duration of the physiotherapy treatment session was documented on the data collection form, and any adverse effects reported or observed were recorded. The subject was thanked for his/her participation in the study.

Blinding of assessor process

Depending on the language of the subject, either the principle researcher or research assistant acted as the blinded assessor. If an English or Afrikaans speaking subject was trialed, the research assistant acted as the blinded assessor and waited outside the treatment area. The research assistant only entered the treatment area once summoned, and quickly administered the outcome measurement tools (the NPRS and BSPAS) to the subject. The research assistant was blinded whatever had been applied prior to his entry. If the subject was Xhosa speaking, the principle researcher acted as the blinded assessor and waited outside the treatment area. The translator was used if required. The principle researcher only entered the treatment area once summoned, and quickly administered the outcome measurement tools (the NPRS and BSPAS) to the subject. The principle researcher was blinded to whatever had been applied prior to her entry. In this way at least the outcome measurement assessor could be blinded.

Sources of data

Data collected from medical folder of subject

The following information was extracted from the medical folders (if possible) by the principle researcher or the research assistant:

- personal and demographic information
- burn injury information
- analgesics information

Data collected from the subject

The following information was collected from the patient (if possible) by the principle researcher, research assistant or translator (if required):

- any information not available in medical folder
- pain intensity measured using the NPRS
- anxiety levels measured using the BSPAS
- adverse effects

Data collected through observation

The following information will be collected through observation by the principle researcher or research assistant:

- physiotherapy information pertaining to duration of treatment, time treatment commenced and area treated.
- adverse effects

Data storage

The signed informed consent forms, data collection forms, NPRS and BSPAS forms were filed in a subject-specific folder by the principle researcher or the research assistant. A variable record/ reference number (VR1-01, VR1-02, etc) was allocated for each subject and only this number was clearly marked on the cover of the folder, so that the subject's identity remained anonymous.

Data analysis

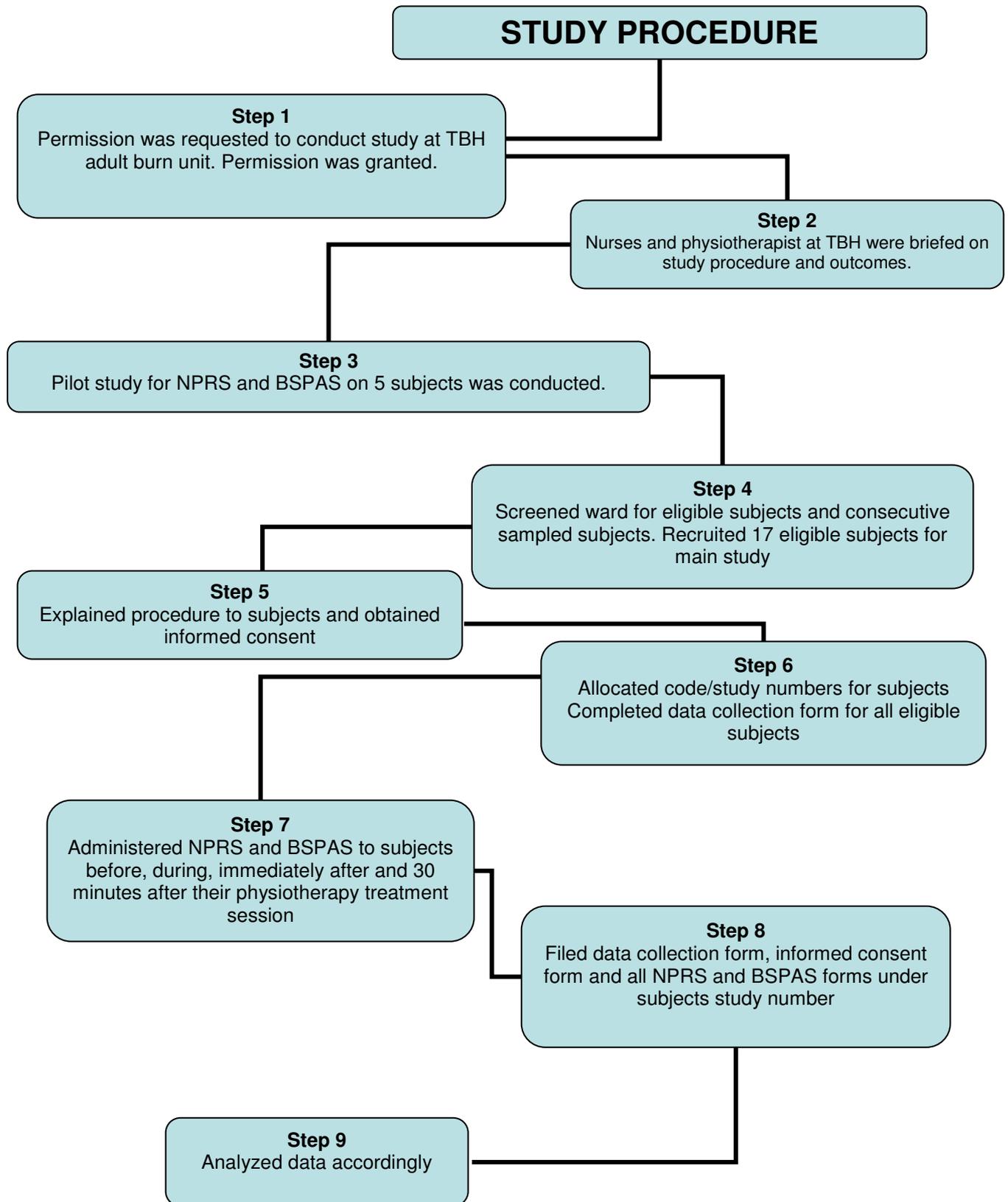
Data was collated, extracted and entered into a purpose-built Microsoft Excel worksheet by the principle researcher. Each record was given a variable name or number. Incorrectly completed forms was discarded and not used for data analysis; however a record was kept of all the eliminated and unusable questionnaires.

Data was entered into the following categories in the worksheet: variable name/number; age; gender; ethnic group; occupation; type of burn; area of burn; depth of burn; type of surgery, area of graft; type of analgesic, dosage of analgesic; frequency of administration of analgesic; last administration time of analgesics; physiotherapy treatment session duration; and body area treated. Pain and anxiety data was entered as before, during and after procedure data and the change in variables was calculated. Responses to close-ended questions were coded, that is, responses were given numeric/alphabetic codes that provided labels for data entry and analysis. Student's paired *t-tests* (PHStat2 program) were used to analyze differences between mean pain and anxiety scores before and during-; before and after-; and before and 30 minutes after the physiotherapy session (significant level $\alpha = 0.05$). 95% confidence intervals (CIs) around the mean differences were calculated. In addition, descriptive statistics incorporating the median and range were also done, to illustrate changes in severity of pain and anxiety during physiotherapy.

**Below is an outline of the process of phase one of the main study.

FLOW DIAGRAM FOR MAIN STUDY: Phase one

The following diagram outlines the process of phase one of the main study.



REFERENCES

Finch E, Brooks D, Stratford P, Mayo N, 2002: Physical rehabilitation outcome measures: A guide to enhanced clinical decision making. 2nd edition. Canadian Physiotherapy Association, BC Decker Inc, Canada

Hoffman H, Patterson D and Carrougher G. Use of virtual reality for adjunctive treatment of adult burn pain during physical therapy: a controlled study. *Clin J Pain* 2000b; 16(3):244-250

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Taal L and Faber A. The burn specific pain anxiety scale: introduction of a reliable and valid measure. *Burns* 1997; 23(2):147-50

APPENDIX D3: FULL METHODOLOGY PROCEDURE OF CHAPTER 4

Study aim

The aim of the main study was to provide a preliminary analysis of the effect of a low-cost VR system, and possibly present it as an adjunct to the usual pain management strategies currently being utilized in the Tygerberg Hospital's (TBH) adult burn unit for pain and anxiety management in adult burn patients undergoing physiotherapy management.

Research questions

The primary research question was:

What is the effect of a low-cost VR system, used in conjunction with pharmacologic analgesics on reducing the pain and anxiety experienced by adult burn injury patients undergoing physiotherapy management in the TBH adult burn unit, compared to pharmacologic analgesics alone?

Study objectives

The primary objectives of the main study were:

- To provide descriptive data regarding the personal and demographical information, burn injury information, pharmacologic analgesic information and physiotherapy treatment information of the adult burn injury patients participating in the VR within-subject trials. (The time that the subject was given the last dosage of pharmacologic analgesics and when the physiotherapy treatment session commenced and ended was noted).
- To ascertain the effect of a low-cost VR system, in conjunction with pharmacologic analgesics, compared to pharmacologic analgesics alone, on reducing the pain intensity experienced by adult burn injury patients, during physiotherapy management at the TBH adult burn unit
- To ascertain the effect of a low-cost VR system, in conjunction with pharmacologic analgesics, compared to pharmacologic analgesics alone, on reducing the level of anxiety experienced by adult burn injury patients, during physiotherapy management at the TBH adult burn unit

Research team and their roles

- Principle researcher: recruited subjects, obtained consent from subjects, explained study procedures, data collection forms and scales to subjects, collected data from subjects, administered the VR to subjects, and conducted data storage, extraction and analysis. In addition, if the subject was English speaking, the principle researcher acted as blinded measurer/assessor on the randomization of the VR trials
- Research assistant: assisted in recruiting subjects, obtaining consent from subjects, explaining study procedures, data collection forms, and scales to subjects, also assist in data collection, storage and extraction. In addition, if the subject was Afrikaans or Xhosa speaking, the research assistant acted as blinded measurer/assessor on randomization of the VR trials
- Translator: assisted in professional translation of instructions regarding procedures, data collection forms, and scales and in obtaining informed consent from subjects. Also assisted in translating feedback and information retrieved from subjects.
- Qualified Physiotherapist: conducted the physiotherapy treatment.

METHODOLOGY

Study Setting

The TBH Adult Burn Unit is a ward located in the TBH, Tygerberg, South Africa, on the 1st floor. The ward currently consists of 22 beds, 5 of which are in the Intensive care unit (ICU). Depending on the demand, the male and female are allocated to designated wards accordingly. An average of 20 to 30 patients is admitted per month, with approximately 50% admitted to ICU. The staff consists of one sister and two nurses in the High Care Unit and 2 sisters and 3 nurses in the ICU. The head of department is Dr E van der Merwe and she is assisted by two to three other doctors. The pain management protocol for patients admitted to the burns unit consists of 24-hour administration of pharmacologic analgesics. Patients receive wound dressing changes daily, and physiotherapy is prescribed if necessary.

Study design

A randomized (condition allocation), single-blinded (assessor blinded only), single-subject, pre-post experimental case series (within-subject) design was implemented in this study.

Study population

The study population consisted of adult burn patients undergoing physiotherapy management admitted to the TBH adult burn unit.

Sample recruitment method and identification process

The adult burn injury patients admitted to the TBH adult burn unit between mid-November 2008 and December 2008 were sampled consecutively and recruited by the principle researcher and research assistant for this study.

Sample size

Eleven eligible subjects were recruited from the TBH adult burn unit and agreed to participate this VR trial study.

Sample inclusion criteria

- Adult male and female patients aged 18 years and over, who had sustained a burn injury via any cause or mechanisms such as fire, chemicals, hot liquids or substances, abrasions, electricity or coal.
- Patients who had sustained burn injuries to the lower limbs, (unilateral or bilateral) which cross the hip, knee or ankle joint, or upper limb (unilateral or bilateral, which cross the shoulder, elbow and wrist joints, but not bilateral hands. Patients may have had, in addition, sustained burn injuries to other parts of the body (excluding the face and bilateral hands), but must have had a lower limb or upper limb burn injury to be eligible for participation.
- Patients who had sustained burn injuries of any percentage of their total body surface area.
- Patients who had sustained burn injuries of any degree (first, second or third degree, or a combination of these classifications) or any depth (superficial, partial or full thickness, or a combination of these classifications).
- Patients who were within any phase of healing of the burn wound.
- Patients who either had had or had not had skin grafts, or any other reconstruction surgery.
- Patients who were undergoing post-burn physiotherapy at the time of data collection.

- Patients, who spoke, comprehended and were proficient in the English, Afrikaans or Xhosa language.
- Patients who received pharmacologic analgesics up to 2½ hours prior to commencement of physiotherapy session.

Sample exclusion criteria

- Patients whose medical condition was deemed unstable.
- Patient who had any cognitive deficits and are unaware of their surroundings.
- Patients who had sustained burn injuries to the face as the VR head-mount display was contraindicated in the use of facial burns.
- Patients who had sustained bilateral hand burn injuries as they had no comfortable means of maneuvering the VR input device.
- Patients may not have received any other interventions, besides pharmacologic analgesics prior to study.

Duration of phase

The data collection process of this phase of the study took approximately 4 weeks and took place from mid-November 2008 to mid-December 2008.

Instrumentation

The low-cost VR equipment and accessories used in this study consisted of the following:

- An **eMagin Z800 3DVISOR** (see figures 1 and 2 below) head-mount display with 2 high-contrast eMagin SVGA 3D OLED microdisplays, 24-bit color for more than 16.7 million colors, 0.59 inch diagonal eMagin OLED displays, 40 degree field view, and 800 x 600 triad pixels per display (figure 1 and 2)
- An ASUS F5SL Business series laptop, 2.00GHz, 2GB DDR2 667Mhz (2x1GB), 8 x DVD Super Multi, 1.3 MP Webcam, Radeon Mobility HD3450 256MB, gigabit LAN, Modem, Wireless 802.11a/b/g, Bluetooth (figure 3)
- A LOGIK PC ATTACK 3 joystick (figure 3)
- Walt Disney's Chicken Little PC game (software)



Figure 1: The eMagin Z800 3DVisor Virtual reality system, including the head-mount display and the control unit (source: <http://www.vrlogic.com/html/emagin.html>)



Figure 2: A female and male individual wearing the eMagin Z800 3DVisor head-mount display (source: http://www.3dvisor.com/pdf/Z800_datasheet.pdf)



Figure 3: The VR laptop and joystick

Possible side-effects of VR

Little information has been published on the side-effects of VR administration, of which nausea is hypothesized as the most likely problem, due to motion-sickness (Regan et al 1994). Although, Hoffman et al (2004) found no evidence of VR-induced nausea in his studies of adult burn patients, the possible effects for nausea will be compensated for by asking the subjects whether they feel 'sick', 'dizzy' or 'nauseous' at any time during the administration of VR (The principle researcher or research assistant may ask the patient, or if required, a translator may be used). The subjects were told that if they feel nauseous they should inform the principle researcher, research assistant or translator immediately, and the cause for the nausea would be established. Any adverse effects/side-effects reported by the subject or observed by the principle researcher/research assistant were documented on the data collection form.

Data collection tools

The previously constructed **data collection form** (Appendix A) was used to collect information relating demographical, personal, burn, analgesic and physiotherapy treatment information.

Outcome measurement tools

- A self-report **numeric pain rating scale** (NPRS) was used to subjectively measure intensity of pain experienced by subjects, before, during, after and 30 minutes after physiotherapy management (appendix B). *The NPRS is a self-report or interviewer-administered subjective measurement of pain intensity, whose developers are unknown. It consists of an 11 point scale (0 to 10) with the extreme anchors of “no pain” (0) and “pain as bad as it can be” (10). On the horizontal line are 1 cm intervals, indicating levels of pain. Subjects are presented with a copy of the NPRS and are asked to circle the number corresponding to their perceived level of pain intensity (0 to 10). Scoring is simply the response circled out of 10. For interviewer administration, the interviewer verbally describes the NPRS and then asks the patient for a verbal rating of his/her perceived pain. The patient’s verbal response is then his/her pain intensity out of 10 (Finch et al 2002). **Reliability testing:** In previous published literature the intraclass correlation coefficient (ICC) was 0.76 and the test-retest reliability of the NPRS measurements was high (0.90) (Mawdsley et al 2002).*
- A self-report **Burn Specific Pain Anxiety scale** (BSPAS) was used to subjectively measure the level of anxiety experienced by subjects before, during, after and 30 minutes after physiotherapy management (appendix C). *The BSPAS was developed by L.A. Taal and A.W. Faber, in the Netherlands in 1997. The BSPAS consists of nine items which describe: (1) feelings of worry about wound healing; (2) tension and fear of losing control during dressing changes; (3) anxious anticipation of pain during or after medical procedures; and (4) a generalized feeling of being ‘keyed up’ or ‘on edge’ because of enduring pain. The items are scored on a 10cm visual analogue line, with 1cm intervals between 0 and 10. The reference points are identified by these numbers and also by the expressions ‘not at all’ (0) and ‘the worst imaginable way’ (10). In the instructions, patients are explicitly requested to scale the strength of their feelings relative to the 11 reference points (Taal et al 1997). The highest total score was 90, indicating high anxiety levels. **Reliability testing:** In previous published literature, the Cronbach’s coefficient α was found to be quite high, 0.94, suggesting that the nine BSPAS items as a whole measure the same construct (reliability was considered to be acceptable when α was 0.70). The Pearson correlation coefficient, between the score on each individual item and the sum of the scores on the remaining items was 0.76 ($p < 0.0001$) with a range of 0.71 –*

0.82 (all $p < 0.0001$) (Taal et al 1997). **Validity testing:** in previously published literature the concurrent validity was measured by determining the correlation of the BSPAS with the State-trait anxiety inventory (STAI-S). Correlation between the STAI-S and the BSPAS (0.58, $p < 0.005$) indicated a statistically significant degree of co-variation between the two anxiety scales (Taal et al 1997).

Pilot study

The objective of the pilot study was to determine if the population for which the low-cost VR system was intended, comprehended the concept of the VR system and game. The time duration of the entire procedure was determined from this pilot study, for estimation of the time frame necessary in the main study. Two subjects undergoing physiotherapy management, and meeting the study inclusion criteria, were recruited from the TBH adult burn unit by the principle researcher in November 2008. The study procedure was explained to the subject in the language of their choice (English, Afrikaans or Xhosa) by the principle researcher, research assistant or the translator. Once the subject agreed to participate in this pilot study, they were requested to read and sign an informed consent form (Appendix F). A data collection form was completed for each subject, so that demographical, burn injury and analgesic information could be collected. In addition, the last administration time of analgesics, the time of the physiotherapy session, as well as area of body treated was noted. A NPRS and BSPAS form was administered to each subject prior to the commencement of the physiotherapy treatment session to collect baseline outcome measurement data. The subject had the opportunity to ask any questions and to ask for clarification of any misunderstandings. The comments and suggestions made by the subject were documented and addressed accordingly. The VR was pilot tested during the physiotherapy management sessions.

Published literature was consulted regarding the physiotherapy procedure (Hoffman et al 2000; Sharar et al 2007). The physiotherapy treatment session consisted of passive range of movement stretches of the lower limb or upper limb only. Slow passive stretching of the selected extremity to the end range of the affected joint, in all possible planes of movement was performed. The same passive ROM exercises were performed in the same planes, same number of repetitions, and same duration of stretch time in each component of physiotherapy treatment. When more than one joint was involved, the proximal joint was ranged first,

followed by the distal joint. The maximum duration of the treatment session was 20 minutes and was divided into two components (stage one and stage two) by time (as pre-determined by the physiotherapist), thus each component was approximately the same duration.

The subject was given the opportunity to trial the VR game before the pilot procedure commenced. Once the subject was familiar with game, which did not take longer than five minutes, the procedure commenced. The order of the intervention (VR, with analgesics) and control (analgesics alone) conditions was randomized, so that each treatment condition had an equal chance of occurring first or second for each patient. Randomization of the trial conditions was conducted using a coin toss - 'heads' was no VR (analgesics only), and 'tails' was VR with analgesics. One of the following scenarios occurred depending on the randomization of the trial conditions:

- Stage one of the physiotherapy treatment procedure was conducted and the VR, in conjunction with analgesics, was administered. After approximately 5-10 minutes, stage one was stopped on indication from the physiotherapist and the VR was stopped, and a NPRS and BSPAS form was administered to the subject. Stage two of the physiotherapy treatment was then conducted, with no VR being administered (analgesics alone) for the rest of the physiotherapy management session. At the completion of the physiotherapy treatment session, a final set of the NPRS and BSPAS forms were administered to the subject.
- Stage one of the physiotherapy treatment procedure was conducted and the no VR (analgesics only) was administered. After approximately 5-10 minutes, stage one was stopped on indication from physiotherapist, and a NPRS and BSPAS form was administered to the subject. Stage two of the physiotherapy treatment was then conducted, with VR being administered in conjunction with analgesics for the rest of the physiotherapy management session. At the completion of the physiotherapy treatment session, a final set of the NPRS and BSPAS forms were administered to the subject.

After completion of the VR pilot study during physiotherapy management, the subject was asked the following questions:

1. Did you enjoy the VR experience?

2. Was the instructions given to you on how to use the VR equipment and play the VR game easy to understand?
3. Was the VR equipment easy to use?
4. Was the VR game easy to play?
5. Did you feel more or less pain while playing VR game?
6. Would you have liked to play the VR throughout the entire physiotherapy treatment session?
7. Is there anything else that you feel can be improved regarding the VR?

Outcomes of pilot study

The pilot study gave a clear indication as to how the subjects had to be instructed on using the VR equipment and game, and also identified any potential problems with the VR equipment and game. Any potential problems were addressed before the main study commenced.

Study procedure (main study)

The exact duration of the study procedure was determined by the pilot study's outcomes. It was determined that to trial the low-cost VR system on one subject would take approximately 40 minutes, including informing the subject and explaining the study procedure, setting up the VR equipment, and allowing the subject to test the VR game. The study was conducted on one subject at a time. This meant that one subject was sampled, recruited, informed, gave informed consent, completed a data collection form, completed outcome measurement tools (NPRS and BSPAS), and received VR intervention, at one time.

This initial phase was conducted by the principle researcher (a translator was present if required), and lasted for approximately 5 minutes. Each subject was briefed on the process of the study procedure individually in their preferred language which was either English, Afrikaans or Xhosa. It was ensured that each subject completely consented to the study and that he/she comprehended the process of the study. The subject was asked to read and sign an informed consent form (appendix G).

A data collection form was completed for each subject by a blinded assessor, so that demographical, burn injury, and analgesic information could be collected for each eligible

subject. Descriptive data was collected once for each subject, before the physiotherapy treatment. The data collected set a profile of the subject. In addition, the last administration time of analgesics was recorded. The NPRS and BSPAS were thoroughly explained to each subject. Baseline outcome measurement data (data from the NPRS and BSPAS was collected before the procedure commenced. The principle researcher or research assistant set up the VR equipment and informed the staff that that particular subject would undergo VR during a stipulated time period. Each of the eligible subjects were instructed on how the VR equipment worked and the VR procedure. The subject was instructed to use a joystick to maneuver the game. The subject was at this point asked if they still consented to participating in this study. If so, the procedure continued. As mentioned earlier the VR intervention followed a single-subject experimental case series (within subject) study design. In other words, each subject acted as his/her own control.

Blinding of assessor process

Depending on the language of the subject, either the principle researcher or research assistant acted as the blinded assessor. If an English or Afrikaans speaking subject was trialed, the research assistant acted as the blinded assessor and waited outside the treatment area. The research assistant only entered the treatment area once summoned, and quickly administered the outcome measurement tools (the NPRS and BSPAS) to the subject. The research assistant was blinded to which condition (the VR with analgesics or analgesics alone) had been applied prior to his entry. If the subject was Xhosa speaking, the principle researcher acted as the blinded assessor and waited outside the treatment area. The translator was used if required. The principle researcher only entered the treatment area once summoned, and quickly administered the outcome measurement tools (the NPRS and BSPAS) to the subject. The principle researcher was blinded to which intervention (the VR with analgesics or analgesics alone) had been applied prior to her entry. In this way at least the outcome measurement assessor could be blinded.

Study procedure

Published literature was consulted regarding the physiotherapy procedure (Hoffman et al 2000; Sharar et al 2007). The physiotherapy treatment session consisted of passive range of movement stretches of the lower limb or upper limb only. Slow passive stretching of the

selected extremity to the end range of the affected joint, in all possible planes of movement was performed. The same passive ROM exercises were performed in the same planes, same number of repetitions, and same duration of stretch time in each component of physiotherapy treatment. When more than one joint was involved, the proximal joint was ranged first, followed by the distal joint. The maximum duration of the treatment session was 20 minutes and was divided into two components (stage one and stage two) by time (as pre-determined by the physiotherapist), thus each component was approximately the same duration.

The subject was given the opportunity to trial the VR game before the procedure commenced. Once the subject was familiar with game, which did not take longer than five minutes, the procedure commenced.

The order of the intervention (VR with analgesics) and control (analgesics alone) conditions was randomized, so that each condition had an equal chance of occurring first or second for each patient. Randomization of the trial conditions was conducted using a coin toss method - 'heads' was analgesics alone condition, and 'tails' was VR with analgesics condition. On completion of the baseline NPRS and BSPAS, one of the following scenarios occurred depending of the randomization of the VR intervention:

- Stage one of the physiotherapy treatment procedure was conducted and the VR with analgesic condition was administered. After approximately 5-10 minutes, stage one was stopped on indication from the physiotherapist and the VR was stopped. A blinded assessor entered the treatment area at this stage and administered the NPRS and BSPAS to the subject to complete. The subject could not inform the assessor of anything that occurred in the room. Once the NPRS and BSPAS had been completed, assessor left the room and stage two of the physiotherapy treatment would then be conducted. The no VR (analgesics alone) condition was administered. After approximately 5-10 minutes, stage two was stopped on indication from the physiotherapist, and the blinded assessor entered the treatment room and administered the final set of the NPRS and BSPAS to the subject to complete.
- Stage one of the physiotherapy treatment procedure was conducted and the no VR (analgesics alone) condition was administered. After approximately 5-10 minutes, stage one was stopped on indication from the physiotherapist, and a blinded assessor entered the

room and administered the NPRS and BSPAS to the subject to complete. The subject could not inform the assessor of anything that occurred in the room. Once the NPRS and BSPAS had been completed, the assessor left the room and stage two of the physiotherapy treatment was then conducted. The VR with analgesics condition was now administered. After approximately 5-10 minutes, stage two was stopped on indication from the physiotherapist and the VR was stopped. The blinded assessor entered the room and administered the final set of the NPRS and BSPAS to the subject to complete.

Any adverse effects/side-effects due to the VR, reported by the subject or observed by the principle researcher/research assistant were documented on the data collection form at the end of the physiotherapy treatment session. On completion of the physiotherapy session, the patient had the opportunity to receive active and active-assisted range of movement exercises, functional and flexibility exercises from the physiotherapist.

Sources of data

Data collected from medical folder of subject

The following information was extracted from the medical folders (if possible) by the principle researcher or the research assistant:

- personal and demographic information
- burn injury information
- analgesics information

Data collected from the subject

The following information was collected from the patient (if possible) by the principle researcher, research assistant or translator (if required):

- any information not available in medical folder
- pain intensity measured using the NPRS
- anxiety levels measured using the BSPAS
- adverse effects

Data collected through observation

The following information was collected through observation by the principle researcher:

- physiotherapy information pertaining to duration of treatment, time treatment commenced and area treated.
- adverse effects

Data storage

The informed consent forms, data collection forms, NPRS and BSPAS forms for each subject, were filed in a subject-specific folder. Each subject was allocated a variable record/ reference number (VR2-01, VR2-02, etc.) and this number was clearly marked on the cover of the folder, so that the subject could remain anonymous.

Data analysis

Data was collated, extracted and entered into a purpose-built Microsoft Excel worksheet. Each record was given a variable record/reference number and this number was entered into excel. Incorrectly completed forms was discarded and not used for data analysis; however a record was kept of all eliminated and unusable questionnaires.

Data were entered into the following categories in the worksheet: variable record/reference number, date of data collection, procedure, gender, age, ethnic group, occupation, marital status, dependents, date of burn injury, total body area of burn, specific area of burn on body, degree/depth of burn, mechanism/cause of burn injury, type and dosage of analgesics, frequency of administration of analgesics, intensity of pain experienced immediately before and immediately after the VR with analgesics or analgesics alone condition, the level of anxiety experienced immediately before and immediately after the VR with analgesics or analgesics alone condition and adverse effects. Responses to close-ended questions were coded, that is, responses were given numeric/alphabetic codes that provide labels for data entry and analysis.

Due to the small sample size and the fact that NPRS and BSPAS scores were skewed, the data extracted in this study were analyzed in a number of ways using PHStat2 program.

For categorical pain data, the NPRS was divided into 3 categories: mild (0-3); moderate (4-6) and severe (7-10). For categorical anxiety data, the BSPAS was divided into 5 categories: very low (0=18); low (19-36); moderate (37-54); high (55-72) and very high (73-90).

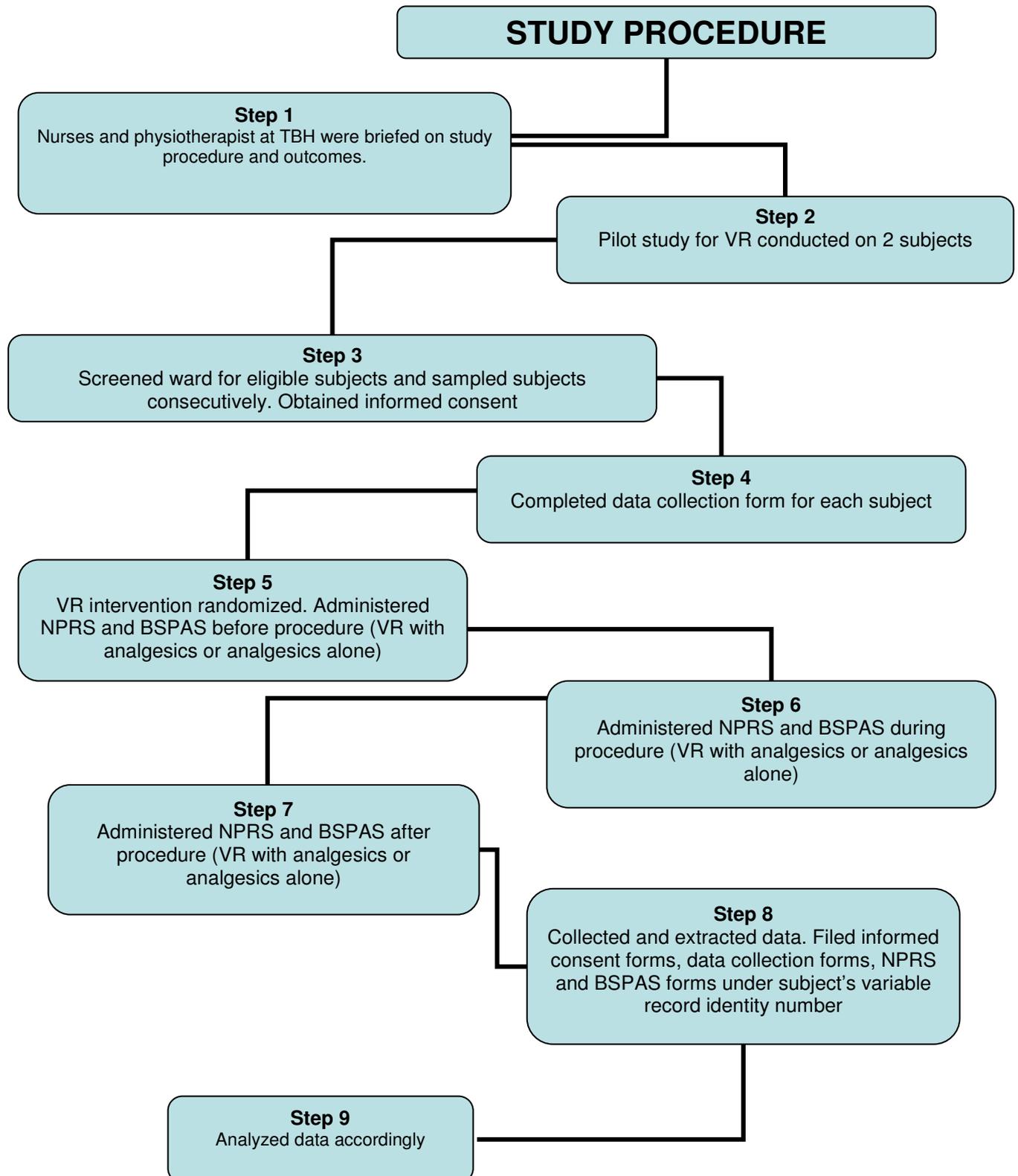
Statistical analysis of the difference in pain and anxiety categorical scores between the two

conditions (analgesics alone or VR with analgesics) was performed using these abovementioned categories in the Chi-square test analysis (significance level $p=0.05$). Student's paired *t-tests* were used to analyze differences between mean pain and anxiety scores before and during-; before and after-; and before and 30 minutes after the physiotherapy session (significant level $\alpha = 0.05$). 95% confidence intervals (CIs) around the mean differences were calculated. In addition, descriptive statistics incorporating visual descriptions of the change in pain and anxiety scores were illustrated using the box-and-whisker plot method. The lower hinge, median, and upper hinge of the box correspond to the 25%, 50%, and 75% percentiles, respectively. Descriptive data such as age, gender, etc. were narratively described.

**Below is an outline of the process of phase two of the main study.

FLOW DIAGRAM FOR MAIN STUDY: Phase two

The following diagram outline phase two of the main study.



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Finch E, Brooks D, Stratford P, Mayo N, 2002: Physical rehabilitation outcome measures: A guide to enhanced clinical decision making. 2nd edition. Canadian Physiotherapy Association, BC Decker Inc, Canada

Hoffman H, Patterson D and Carrougher G. Use of virtual reality for adjunctive treatment of adult burn pain during physical therapy: a controlled study. *Clin J Pain* 2000b; 16(3):244-250

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Taal L and Faber A. The burn specific pain anxiety scale: introduction of a reliable and valid measure. *Burns* 1997; 23(2):147-50

APPENDIX E1: INFORMED CONSENT FORM

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Audit study

REFERENCE NUMBER: N08/01/019

PRINCIPAL INVESTIGATOR: Mrs. Linzette D Morris-Smith

ADDRESS: 140 Spencer Street, Goodwood, 7460

CONTACT NUMBER: 0845885826 or 0215925132

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part. This study has been approved by the **Committee for Human Research** at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The study will take place at the Tygerberg Hospital's adult burn unit. We are hoping to include at least 15 to 20 adults who have suffered a burns injury to assist us with this study. The overall study aims to analyze the effectiveness of a new technology, namely **Virtual Reality**, on reducing the pain and anxiety that adult burn patients experience when they undergo physiotherapy treatments. The Virtual reality will help distract the burns patient from the pain they are feeling. The reason for us wanting to do this study is to help a person who has suffered a burn injury to be able to cope with the treatment and procedures that they have to go through daily. The pain medication that is often given to burns patients is sometimes not enough and may have side-effects. By trying to find another way of helping a burns patient have less pain during physiotherapy treatment, we are hoping that the experience is easier for the patient and the health professional. However, before we can do this study we have to first collect some information and that is why you are invited to take part in this phase of the study. This part of the study will help us identify how burn patient cope with their pain on analgesics alone.

The procedure for this part of the study is as follows: the study subjects will be sampled and recruited from the patients admitted to the Tygerberg Hospital's adult burn unit. Once a selection of the study subjects have been made, the study subjects will be informed of the study procedures, and should they agree to participate in the study, each participant will have to sign this form so that it can be assured that they understand and are willing to take part in this study. A form will be completed for each study subject to collect information regarding themselves, their personal details, their burn injury, as well as whether they had surgery and about the pain medication they are given. Some information will be collected from the medical folder and some will be collected from the study subject. The study subject will then be given a set of pain and anxiety questionnaires to complete before, during, immediately after and 30 minutes after the physiotherapy treatment session. Each questionnaire and form will be explained to the participant before the procedure starts. All the information gathered from the form, pain and anxiety questionnaires will be filed under the allocated study subject's record/reference number and not under the study subject's name. In this way, no one, but the study leaders, will have access to the information.

Why have you been invited to participate?

You have been invited to participate in this study because you are an adult, over the age of 18 years old, you have suffered a burn injury and you are now admitted to the Tygerberg Hospital's adult burn unit.

What will your responsibilities be?

To be able to fully participate in this study we need you to do a few things for us. We would like you to follow the instructions that we give you carefully. If you do not understand let us know immediately. Your main responsibility will be to complete the data collection form, as well as the pain and anxiety questionnaires. You will also have to provide us with details of yourself and of your medical history.

Will you benefit from taking part in this research?

You will not benefit from this study financial, but you will benefit from the study knowing that you have contributed to helping us find an alternative way of treating burns patients like yourself to cope with the pain that they feel when they undergo physiotherapy treatments.

Are there in risks involved in your taking part in this research?

There are no risks involved in this section of the study.

If you do not agree to take part, what alternatives do you have?

If you do not want to take part in this study, you have every right to tell us, and we will not include you in the study.

Who will have access to your medical records?

The only people that will have access to your medical records, is myself and the people directly involved in the study. The information collected from you medical records will be treated as private and will be protected from others who should not see them. When the information is printed in the study thesis and is published to help other health professionals, your name or details will not appear in the paper and there will be no indication that it was your information.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study and there will be no costs involved for you, if you do take part.

Is there any thing else that you should know or do?

- You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

DECLARATION BY PARTICIPANT

By signing below, I agree to take part in a research study entitled

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2008.

.....
Signature of participant

.....
Signature of witness

DECLARATION BY INVESTIGATOR

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a translator. (*If a translator is used then the translator must sign the declaration below.*)

Signed at (*place*) on (*date*) 2008.

.....
Signature of investigator

.....
Signature of witness

DECLARATION BY TRANSLATOR

I (*name*) declare that:

- I assisted the investigator (*name*) to explain the information in this document to (*name of participant*) using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) on (*date*) 2008.

.....
Signature of translator

.....
Signature of witness

APPENDIX E2: INCWADANA ENGOLWAZI NGOMTHATHI-NXAXHEBA KUNYE NEFOMU YESIVUMELWANO

ISIHLOKO SEPROJEKTHI YOPHANDO:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Audit study

INOMBOLO YONXULUMANO: N08/01/019

UMPHANDI OYINTLOKO: Mrs. Linzette D Morris-Smith

IDILESI: 140 Spencer Street, Goodwood, 7460

INOMBOLO YOQHAGAMSHELWANO: 0845885826 or 0215925132

Uyamenywa ukuba uthathe inxaxheba kwiprojekthi yophando.

Nceda thatha ixesha lokufunda ulwazi oluvezwe apha, oluza kuthi luchaze iinkcukacha zale projekthi. Nceda buza nayiphina imibuzo emalunga nayiphi na indawo ongayiqondiyo ngokupheleleyo kwabo basebenza ngesi sifundo okanye kugqirha. Kubaluleke kakhulu ukuba waneliseke ngokupheleleyo yinto yokuba ucacelwe kakuhle ukuba yintoni unobangela wobukho besi sifundo kwaye ungabandakanyeka njani. Kwakhona, ukuthatha kwakho inxaxheba **ukwenza ngokuzithandela unganyanzelwanga** kwaye ukhululekile ukuba ungarhoxa ekuthatheni inxaxheba. Ukuba uthi hayi, oku akusayi kuchaphazela ukungavumi kwakho nangayiphi na indlela. Ukwakhululekile ukuba uyeke kwesi sifundo nanini na, nokokuba wavuma ukuthatha inxaxheba ekuqaleni.

Olu phando luvunywe ziinqobo ezisesikweni **zeKomiti yoPhando ngomntu kwiYunivesithi yaseStellenbosch** kwaye luza kwenziwa ngokwemigaqo esesikweni lophando elamkelekileyo kwiSaziso seHlabathi sika-Helsinki, iMigaqo eLungileyo yoMzantsi Afrika yokuSebenza eKliniki kunye neBhunga lezoPhando ngamaYeza (MRC) iMigaqo yeNqobo yezoPhando.

Simalunga nantoni esi sifundo sophando?

Isifundo siza kwenzeka kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo. Sinethemba lokuba siza kubandakanya ubuncinane abantu abadala abali-15 ukuya kuma-20 abanomonzakalo wokutsha ukuba basincede kwesi sifundo. Eli linqanaba lokuqala lesona sifundo siphambili. Sisonke isifundo sijolise ekucaluleni ukusebenza kobuchwephesha obutsha, ekungabalulwa i**Virtual Reality**, ekunciphiseni iintlungu nexhala eliviwa ngabantu abadala abazizigulane xa betshintshwa amabhandeji naxa benyangwa ngokwenza imithambo. Le *Virtual reality* iza kunceda ukususa iintlungu zokutsha eziviwa sisigulane. Isizathu sokuba sifune ukwenza esi sifundo kukufuna ukunceda umntu owenzakele kukutsha ukuba akwazi ukumelana nonyango nemigaqo ekufuneka beyilande yonke imihla. Amayeza eentlungu asoloko enikwa izigulane ezitshileyo amaxesha amaninzi abanezinye iziphumo. Ngokuzama ukufumana enye indlela yokunceda izigulane ezitshileyo engenazintlungu zingako xa kutshintshwa amabhandeji naxa kunyangwa ngokwenziwa kwemithambo, sinethemba lokuba oku kuxhotyiswa ngamava kuza kwenza kube lula kwisigulane nakwingcali yezempilo. Kanti, phambi kokuba sisenze esi sifundo kuza kufuneka siqale siqokelele ezinye iinkcukacha kwaye yiyo loo nto uye wamenywa ukuba uthathe inxaxheba kweli nqanaba lesi sifundo. Eli nqanaba lesi sifundo liza kusinceda sichonge ukuba loluphi uhlobo lokutsha esingamelaniyo nako isigulane neentlungu abazivayo kwisibulali zintlungu kuphela.

Imigaqo yeli nqanaba lesi sifundo yile ilandelayo: abathathi-nxaxheba baza kuba liqela elikhethwe lagaywa kwizigulane ezingeniswe kwicandelo labadala abatshileyo kwisibhedlele saseTygerberg. Emva kokuba amaxhoba esifundo ekhethiwe, amaxhoba esifundo aza kuchazelwa ngemigaqo yesifundo, kwaye ukuba ayavuma ukuthatha inxaxheba kwesi sifundo, umntu ngamnye othatha inxaxheba kuza kufuneka atyikitye le fomu ukuze kuqinisekise ukuba bayaqonda kwaye banomdla wokuthatha inxaxheba kwesi sifundo. Ifomu iza kuzaliswa ngexhoba ngalinye lesifundo ukuqokelela ulwazi malunga nabo, neenkukacha zabo, ngomenzakalo abanawo wokutsha, kunye nokuqonda ukuba bakhe batyandwa kusini na namalunga namayeza abawanikiweyo eentlungu. Ezinye iinkcukacha ziza kufumaneka kwifayile yabo yengxelo yonyango kwaye ezinye ziza kufunyanwa kubathathi-nxaxheba besifundo. Umthathi-nxaxheba kwisifundo uza kunikwa iphepha lemibuzo malunga neentlungu nexhala abanalo. Iphepha ngalinye lemibuzo nefomu ziza kucaciselwa lowo uthatha inxaxheba phambi kokuba inkqubo iqaliswe. Zonke iinkcukacha ezifunyenwe kwifomu, kwiphepha elinemibuzo malunga neentlungu nokuxhalaba ziza kugcinwa phantsi kwenombolo yengxelo/yesalathisi ebekelwe esi sifundo, hayi phantsi kwegama lexhoba lesi sifundo. Ngale ndlela, akukho namnye, ngaphandle kwabo bakhokela esi sifundo abaza kufikelela kwiinkcukacha.

Ukuba uthatha inxaxheba kwisifundo sokulinga kweli nqanaba, kuza kubakho okongezelweyo okufuna ukuba uphawule ngendlela engasokolisiyo yokuzalisa iifomu zokuqokelela iinkcukacha nephepha lemibuzo ngeentlungu nexhala, nokuba kube lula na ukuyiqonda imiyalelo enikiweyo ziinkokheli zesi sifundo.

Kutheni umenyiwe ukuba uthathe inxaxheba?

Umenyiwe ukuba uthathe inxaxheba kwesi sifundo kuba ungumntu omdala ongaphezu kweminyaka eli-18 ubudala, unomenzakalo wokutsha kwaye ngoku ungeniswe kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo.

Luza kuba yintoni uxanduva lwakho?

Ngokuthatha inxaxheba ngokupheleleyo kwesi sifundo sifuna usenzele izinto ezimbalwa. Singathanda ukuba ulandele imiyalelo esikunika yona ngenyameko. Ukuba awuyiqondi siselele ngokukhawuleza. Olona xanduva lwakho iza kuba kukuzalisa iphepha lemibuzo ngeentlungu nokuxhalaba kwakho. Kuza kufuneka usinike iinkcukacha ngawe nengxelo yakho yezempilo.

Ingaba uza kuzuza ekuthatheni inxaxheba kolu phando?

Awuzi kuzuza mali kwesi sifundo, kodwa uza kuzuza kwesi sifundo ngokwazi ukuba ubenegalelo lokusanceda ukufumana enye indlela yokunyanga ukutsha kwesigulane njengawe bakwazi ukumelana neentlungu abazivayo xa betshintshwa amabhandeji naxa benikwa unyango ngokwenza imithambo.

Ingaba zikho iingozi ezibandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?

Abukho ubungozi obubandakanyekayo kweli candelo lesifundo

Ukuba awuvumi ukuthatha inxaxheba, loluphi olunye unyango onalo?

Ukuba awufuni kuthatha inxaxheba kwesi sifundo, unelungelo lokusixelela oko kwaye asizi kukubandakanya kwesi sifundo.

Ngubani oza kufumana ingxelo yakho yamayeza?

Abantu ekukuphela kwabo abaza kwazi ukufumana iingxelo zakho zonyango ndim nabantu ababandakanyeka ngqo kwesi sifundo. Iinkcukacha eziqokelelweyo kwiingxelo zakho zezonyango ziza kugcinwa ziyimfihlelo kwaye ziza kukhuselwa kwabanye ekungafanelekanga ukuba bazifumane. Xa iinkcukacha zishicilelwe kwisifundo sethisisi kwaye zipapashiwe ukunceda ezinye iingcali zempilo, igama lakho okanye iinkcukacha zakho azizi kuvela ephepheni kwaye akukho nto iza kubonakalisa ukuba ezo nkcukacha zezakho

Ingaba uza kuhlawulwa ngokuthatha inxaxheba kwesi sifundo kwaye ingaba kukho iindleko ezibandakanyekayo?

Hayi, awuzi kuhlawulwa ngokuthatha kwakho inxaxheba kwesi sifundo. Akuzi kubakho zindleko oza kuzihlawula ukuba uthatha inxaxheba.

Ingaba ikho enye into ekumele uyazi okanye uyenze?

- Ungaqhagamshelana neKomiti yoPhando ngomntu kwa-021-938 9207 ukuba unenkxalabo okanye izikhalazo ezingasonjululwanga kakuhle ngugqirha wakho wesifundo.
- Uza kufumana ikopi yolu lwazi kunye nefomu yesivumelwano ukwenzela iingxelo zakho.

Isifundo somthathi-nxaxheba

Ngokuytyikitya ngezantsi, Mna ndiyavuma ukuthatha inxaxheba kwisifundo sophando semfuzo esibizwa ngokuba

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy'

Ndazisa ukuba:

- Ndilufundile okanye ndalufunda olu lwazi kunye nefomu yesivumelwano kwaye ibhalwe ngolwimi endilwaziyo nendikhululekileyo kulo
- Bendinalo ithuba lokuba ndibuze imibuzo kwaye yonke imibuzo yam iphendulwe ngokwanelisayo.
- Ndiyakuqonda ukuba ukuthatha inxaxheba kolu phando kube **kukuzithandela kwam** kwaye andikxange ndinyanzelwe ukuba ndithathe inxaxheba.
- Ndingakhetha ukusishiya isifundo nanini na kwaye andisayi kohlwaywa okanye ndigwetywe nangayiphi indlela.
- Ndisenokucelwa ukuba ndisishiye isifundo phambi kokuba siphele, ukuba ugqirha wesifundo okanye umphandi ukubona kuyinzuzo kum, okanye ukuba andisilandeli isicwangciso sesifundo, ekuvunyelenwe ngaso.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomthathi-nxaxheba

.....
Utyikityo lwengqina

Isifungo somphandi

Mna (*igama*) ndiyafunga ukuba:

- Ndizicacisile iinkcukacha ezikolu xwebhu ku-.....
- Ndimkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndiyaneliseka kukuba uyakuqonda ngokwanelisayo konke okumalunga nophando okuxoxwe ngasentla.
- Ndisebenzise/andisebenzisanga toliki. (*Ukuba itoliki isetyenzisiwe kumele ityikitye ngezantsi.*)

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomphandi

.....
Utyikityo lwengqina

Isifungo setoliki

Mna (*igama*) ndazisa ukuba:

- Ndicende umphandi (*igama*) ekucaciseni iinkcukacha ezikolu xwebhu ku-(*igama lomthathi-nxaxheba*) ndisebenzisa ulwimi lwesiBhulu/lwesiXhosa.
- Simkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndimxelele eyona nto iyiyo malunga nokunxulumene nam.
- Ndiyaneliseka kukuba umthathi-nxaxheba ukuqonda ngokupheleleyo okuqulathwe lolu xwebhu lwesivumelwano eyazisiweyo kwaye nemibuzo yakhe yonke iphendulwe ngokwanelisayo.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lwetoliki

.....
Utyikityo lwengqina

APPENDIX E3: DEELNEMERINLIGTINGSBLAD EN -TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Audit study

VERWYSINGSNOMMER: N08/01/019

HOOFNAVORSER: Mrs Linzette D Morris-Smith

ADRES: 140 Spencer Street, Goodwood, 7460

KONTAKNOMMER: 0845885826 or 0215925132

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daarvoor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die Komitee vir Mensnavorsing van die Universiteit Stellenbosch goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).

Wat behels hierdie navorsingsprojek?

Hierdie studie sal by die Tygerberg Hospitaal se volwasse brand eenheid plaasvind. Ons hoop om tenminste 15 tot 20 volwassenes wie 'n brandwond op gedoen het te benader om in hierdie studie deel te neem. Dit is fase 1 van die hoof studie.

Die algehele studie be-oog om te bepaal of 'n nuwe tegnologie, naamlik Virtual reality, effektief is om pyn en angs in volwassenes met brandwonde kan verlig. Die Virtual reality sal moontlik die brandwond pasiënt se aandag aftrek van die pyn wat hulle voel en dus die fisioterapie behandeling vergemaklik. Die pyn medikasie wat gereeld vir brandwond pasiënte gegee word is nie altyd voldoende nie en het nuwe-effekte. Dus, aangesien ons 'n alternatiewe manier wil implementeer, sal dit moontlik die pyn wat die brandwond pasiënt tydens hul fisioterapie behandeling verlig, en hopelik die ervaring vir die pasiënt en gesondheids professioneel vergemaklik. Voor ons hierdie studie kan begin, moet ons eers informasie versamel en dit id hoekom jy genooi is om deel te neem in hierdie fase van die studie. Die fase van die studie sal ons help identifiseer hoe brandwond pasiënt hul pyn met die normale pyn medikasie hanteer.

Die proses van hierdie fase van die studie is as volg: die studie deelnemers sal gewerf word by die Tygerberg Hospitaal se volwasse brand eenheid, en enige persoon wat voldoen aan die insluitings kriteria en toestemming gee, mag dan aan die studie deelneem. 'n Vorm sal vir elke deelnemer ingevul word wat informasie sal versamel oor hul self, hulle persoonlike besondere, hul brandwond besering, die pyn medikasie wat hulle ontvang, en of hulle enige chirurgie gehad het. Sekere informasie sal vanaf die mediese leër verkry word en die res van die informasie sal direk van die deelnemer versamel word. Die deelnemer sal dan 'n pyn en angs vraelys gegee word (voor, gedurende, dadelike na, en 30 minute na die fisioterapie behandeling), wat hulle sal voltooi. As die deelnemer nie die vraelys kan self antwoord nie, sal die projek leier dit vir die deelnemer voltooi. Elke vraelys en vorm sal verduidelik word aan elke deelnemer voor die proses begin. Al die informasie wat versamel word van die vorms en vraelys, sal onder die deelnemers se rekord/verwysing nommer geliaseer word nie onder die deelnemers se naam nie. Dus sal niemand, maar die projek leiers, toegang tot die informasie het nie.

Waarom is u genooi om deel te neem?

U is genooi om deel te neem aan hierdie studie omdat u 'n volwassene oor die onderdom van 18 jaar is, u 'n brandwond besering opgedoen het, en in die Tygerberg Hospitaal se volwasse brand eenheid opgeneem is.

Wat sal u verantwoordelikhede wees?

U word verwag om die instruksies wat ons aan u gee noukeurig te volg. As u nie iets verstaan nie, moet u dadelik vir ons laat weet. U hoof verantwoordelikheid sal wees om die vorms, asook die pyn en angs vraelyste volledig te voltooi. U word versoek om besonderhede van u self en u mediese geskiedenis aan ons te verskaf.

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

Nee, u sal nie finansiëel voordeel trek deur aan hierdie studie deel te neem nie, maar u hulp sal bydra om 'n alternatiewe behandeling vir ander brandwond pasiënte soos u die pyn wat hulle verduur tydens verband veranderinge en fisioterapie behandelinge beter hanteer.

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

Nee, daar is geen risiko's verbonde aan u deelname aan hierdie studie nie.

Watter alternatiewe is daar indien u nie instem om deel te neem nie?

As u nie wil deelneem aan hierdie studie nie, is u welkom om ons in te lig en dan sal u die normale en beste behandeling ontvang.

Wie sal toegang hê tot u mediese rekords?

The enigste mense wie toegang tot u mediese rekords sal hê, is die mense wie direk betrokke is in hierdie studie. Die informasie wat van u mediese lêer versamel sal word sal privaat gehanteer word en van anders beskerm word. Wanneer die informasie in die studie tesis gedruk en gepubliseer word, sal u naam en besonderhede nie verskyn nie en daar sal geen indikasie wees dat dit u informasie was nie.

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

U sal nie betaal word vir deelname aan die navorsingsprojek nie en deelname aan die navorsingsprojek sal u niks kos nie.

Is daar enigiets anders wat u moet weet of doen?

- U kan die Komitee vir Mensnavorsing kontak by 021-938 9207 indien u enige bekommernis of klagte het wat nie bevredigend deur u studiedokter hanteer is nie.
- U sal 'n afskrif van hierdie inligtings- en toestemmingsvorm ontvang vir u eie rekords.

Verklaring deur deelnemer

Met die ondertekening van hierdie dokument onderneem ek,, om deel te neem aan 'n navorsingsprojek getiteld

“Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

Ek verklaar dat:

- Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in 'n taal geskryf is waarin ek vaardig en gemaklik mee is.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.
- Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van deelnemer

.....
Handtekening van getuie

Verklaring deur navorsers

Ek (*naam*) verklaar dat:

- Ek die inligting in hierdie dokument verduidelik het aan
- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie 'n tolk gebruik het nie. (*Indien 'n tolk gebruik is, moet die tolk die onderstaande verklaring teken.*)

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van navorder

.....
Handtekening van getuie

Verklaring deur tolk

Ek (*naam*) verklaar dat:

- Ek die navorsers (*naam*) bygestaan het om die inligting in hierdie dokument in Afrikaans/Xhosa aan (*naam van deelnemer*) te verduidelik.
- Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek 'n feitelik korrekte weergawe oorgedra het van wat aan my vertel is.
- Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van tolk

.....
Handtekening van getuie

APPENDIX F1: INFORMED CONSENT FORM FOR MAIN STUDY (PILOT)

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Pilot study for VR

REFERENCE NUMBER: N08/01/019

PRINCIPAL INVESTIGATOR: Mrs Linzette D Morris

ADDRESS: 140 Spencer Street, Goodwood, 7460

CONTACT NUMBER: 0845885826 or 0215925132

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Committee for Human Research** at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The study will take place at the Tygerberg Hospital's adult burn unit. We are hoping to include at least 12 adults who have suffered a burns injury to assist us with this study. The overall aim of the study is to analyze the effectiveness of a new technology, namely **Virtual Reality**, on the pain that adult burn patients experience when they have to go through physiotherapy treatments. The Virtual reality will help distract the burns patient from the pain they are feeling. The reason for us wanting to do this study is to help a person who has suffered a burn injury to be able to cope with the treatment and procedures that they have to go through daily. The pain medication that is often given to burns patients is sometimes not enough and may have side-effects. By trying to find another way of helping a burns patient have less pain during the physiotherapy treatment, we are hoping that the experience is easier for the patient and the health professional. However, before we can implement this new technology, we need to know if it is easy to use and if it is easy to understand the instructions that we give. Therefore, we need your help in this pilot study.

The pilot study will give a clear indication as to how the subjects have to be instructed on using the VR equipment and game, and will also identify any potential problems with the VR equipment and game. These problems will be addressed before the main study commences.

A form will be completed for each study subject to collect information regarding themselves, their personal details, their burn injury, as well as whether they had surgery and about the pain medication they are given. Some information will be collected from the medical folder and some will be collected from the study subject. As this pilot study is solely to test the ease of using the VR equipment, no further data will be collected. The subject will have the opportunity to ask any questions and to ask for clarification of any misunderstandings. The comments and suggestions made by the subject will be documented and addressed accordingly. The VR will be tested during the physiotherapy management sessions. After the virtual reality has been used, the study subject will be asked a few questions as to how easy it was to use the virtual reality equipment, if they enjoyed it, if they felt less pain, if the game was easy, and if they would change anything.

Why have you been invited to participate?

You have been invited to participate in this study because you are an adult, over the age of 18 years old, you have suffered a burn injury and you are now admitted to the Tygerberg Hospital's adult burn unit.

What will your responsibilities be?

To be able to fully participate in this study we need you to do a few things for us. If for some reason you are unable to make it that specific day, please call us and let us know. We would also like you to follow the instructions that we give you carefully. If you do not understand let us know immediately. You will have the responsibility of completing the data collection form, pain and anxiety questionnaires. You will have the responsibility of playing the virtual reality game while undergoing physiotherapy treatment. You may not tell the research assistant what was done when he/she enters the room.

Will you benefit from taking part in this research?

You will not benefit from this study financial, but you will benefit from the study knowing that you have contributed to helping us find an alternative way of treating burns patients like yourself to cope with the pain that they feel when they have to go through physiotherapy treatments.

Are there in risks involved in your taking part in this research?

There is a small possibility that the virtual reality may make you a little nauseous. Should you feel any nausea, let the study staff now immediately.

If you do not agree to take part, what alternatives do you have?

If you do not want to take part in this study, you have every right to tell us and then you may ask the hospital staff to give you some pain medication.

Who will have access to your medical records?

The only people that will have access to your medical records, is myself and the people directly involved in the study. The information collected from you medical records will be treated as private and will be protected from others who should not see them. When the information is printed in the study thesis and is published to help other health professionals, your name or details will not appear in the paper and there will be no indication that it was your information.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

It is unlikely that you will be injured while you are taking part in this study, as it primarily involves usual medical procedures.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study, and there will be no costs involved for you, if you do take part.

Is there any thing else that you should know or do?

- You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

DECLARATION BY PARTICIPANT

By signing below, I agree to take part in a research study entitled

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.

- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2008.

.....
Signature of participant

.....
Signature of witness

DECLARATION BY INVESTIGATOR

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a translator. (*If a translator is used then the translator must sign the declaration below.*)

Signed at (*place*) on (*date*) 2008.

.....
Signature of investigator

.....
Signature of witness

DECLARATION BY TRANSLATOR

I (*name*) declare that:

- I assisted the investigator (*name*) to explain the information in this document to (*name of participant*) using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) on (*date*) 2008.

.....
Signature of translator

.....
Signature of witness

APPENDIX F2: INCWADANA ENGOLWAZI NGOMTHATHI-NXAXHEBA KUNYE NEFOMU YESIVUMELWANO

ISIHLOKO SEPROJEKTHI YOPHANDO:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Pilot study for VR.

INOMBOLO YONXULUMANO: N08/01/019

UMPHANDI OYINTLOKO: Mrs. Linzette D Morris

IDILESI: 140 Spencer Street, Goodwood, 7460

INOMBOLO YOQHAGAMSHELWANO: 0845885826 or 0215925132

Uyamenywa ukuba uthathe inxaxheba kwiprojekthi yophando. Nceda thatha ixesha lokufunda ulwazi oluvezwe apha, oluza kuthi luchaze iinkcukacha zale projekthi. Nceda buza nayiphi na imibuzo emalunga nayiphi na indawo ongayiqondiyo ngokupheleleyo kwabo basebenza ngesi sifundo okanye kugqirha. Kubaluleke kakhulu ukuba waneliseke ngokupheleleyo kukuba uacelwe kakuhle ukuba yintoni unobangela wokwenziwa kwesi sifundo kwaye ungabandakanyeka njani. Kwakhona, ukuthatha kwakho inxaxheba **ukwenza ngokuzithandela unganyanzelwanga** kwaye ukhululekile ukuba ungarhoxa ekuthatheni inxaxheba. Ukuba uthi hayi, oku akusayi kukuchaphazela nangayiphi na indlela ngokungavumi kwakho. Ukwakhululekile ukuba uyeke kwesi sifundo nanini na, nokokuba ubuvumile ukuthatha inxaxheba ekuqaleni.

Olu phando luvunywe ziinqobo ezisesikweni **zeKomiti yoPhando ngomntu kwiYunivesithi yaseStellenbosch** kwaye luza kwenziwa ngokwemigaqo esesikweni lophando olwamkelekileyo kwiSaziso sehlabathi sika-Helsinki, iMigaqo eLungileyo yoMzantsi Afrika yokuSebenza eKliniki kunye neBhunga lezoPhando ngamaYeza (MRC) iMigaqo yeNqobo yezoPhando.

Simalunga nantoni esi sifundo sophando?

Isifundo siza kwenzeka kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo. Sinethemba lokuba siza kubandakanya ubuncinane abantu abadala abali-12 abanomonzakalo wokutsha ukuba basincede kwesi sifundo. Sisonke isifundo sijolise ekucaluleni ukusebenza kobuchwephesha obutsha, ekungabalulwa i**Virtual Reality**, ekunciphiseni iintlungu nexhala eliviwa ngabantu abadala abazizigulane xa betshintshwa amabhandeji naxa benyangwa ngokwenza imithambo. Le *Virtual reality* iza kunceda ukususa iintlungu zokutsha eziviwa sisigulane. Isizathu sokuba sifune ukwenza esi sifundo kukufuna ukunceda umntu owenzakele kukutsha ukuba akwazi ukumelana nonyango nemigaqo ekufuneka beyilandele yonke imihla. Amayeza eentlungu asoloko enikwa izigulane ezitshileyo amaxesha amaninzi abanezinye iziphumo. Ngokuzama ukufumana enye indlela yokunceda izigulane ezitshileyo engenazintlungu zingako xa kutshintshwa amabhandeji naxa kunyangwa ngokwenziwa kwemithambo, sinethemba lokuba oku kuxhotyiswa ngamava kuza kwenza kube lula kwisigulane nakwingcali yezempilo. Kanti, phambi kokuba sisebenzise obu buchwephesha butsha, sifuna ukwazi ukuba kulula na ukubusebenzisa nokuba kulula na ukuyilandela imiyalelo esiyinikayo. Ngoko ke, sidinga uncedo lwakho kwesi sifundo sokulinga.

Isifundo sokulinga siza kusinika isikhokelo esicacileyo ukuba amaxhoba angayalelwa njani ukuba asebenzise izixhobo zeVR nomdlalo, kwaye siza kuchonga iingxaki ezikhoyo kwizixhobo zeVR nomdlalo. Ezi ngxaki kuza kujongwana nazo phamb kokuba esona sifundo siphambili siqalise. Ifomu iza kuzaliswa ngomthathi-nxaxheba ngamnye wesifundo ukuqokelela ulwazi malunga nabo, nangeenkukacha zabo, ngomonzakalo abanawo wokutsha, kunye nokuqonda ukuba bakhe batyandwa kusini na namalunga namayeza abawanikiweyo eentlungu. Ezinye iinkcukacha ziza kufumaneka kwifayile yabo yengxelo yonyango kwaye ezinye ziza kufunyanwa kumaxhoba esifundo. Njengoko esi sifundo ikukuvavanya ubulula bokusebenzisa isixhobo seVR, azikho ezinye iinkcukacha eziza kufunwa. Ixhoba liza kubanethuba lokubuza nawuphi na umbuzo kwaye acele ukucaciselwa nantoni na angayiqondiyo. Izimvo neengcebiso ezenziwa ngabathathi-nxaxheba ziza kugcinwa kwaye kujongwane nazo ngendlela. Umthathi-nxaxheba uza kubuzwa ukuba ukhetha ukuvavanya iVR, ngokutshintshwa ibhandeji enxebeni okanye xa kuqhutywa iseshoni elawula ukwenza imithambo. IVR iza kuvavanywa xa kutsjintshwa amabhandeji okanye xa kuqhutywa iseshoni elawula ukwenziwa kwemithambo.

Kutheni umeniwe ukuba uthathe inxaxheba?

Umeniwe ukuba uthathe inxaxheba kwesi sifundo kuba ungumntu omdala ongaphezu kweminyaka eli-18 ubudala, unomenzakalo wokutsha kwaye ngoku ungeniswe kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo abangalaliswanga.

Luya kuba yintoni uxanduva lwakho?

Ukuze ukwazi ukuthatha inxaxheba ngokupheleleyo kwesi sifundo sifuna usenzele izinto ezimbalwa. Singathanda ukuba ulandele imiyalelo esikunika yona ngenyameko. Ukuba awuyiqondi sixelele ngokukhawuleza. Olona xanduva lwakho iza kuba kukuzalisa iphepha lemibuzo ngeentlungu nokuxhalaba kwakho, usinike iinkcukacha malunga nawe nangengxelo yakho yezempilo, nokuvavanya kwaye usebenzise izixhobo zezirtual reality nezemidlalo ngeli xesha kusenziwa oku. Uza kucelwa ukuba unike izimvo zakho zokuba ingaba imiyalelo obuyinikiwe ibicacile nokuba ingaba izixhobo zezirtual reality kulula ukuzisebenzisa kwaye ziyaqondakala. Ungacebisa ngotshintsho olunokwenziwa malunga nokuphucula le miyalelo.

Ingaba uza kuzuza ekuthatheni inxaxheba kolu phando?

Awuzi kuzuza mali kwesi sifundo, kodwa uza kuzuza kwesi sifundo ngokwazi ukuba ubenegalelo lokusinceda ukufumana enye indlela yokunyanga ukutsha kwesigulane njengawe bakwazi ukumelana neentlungu abazivayo xa betshintshwa amabhandeji naxa benikwa unyango ngokwenziswa imithambo.

Ingaba zikho iingozi ezibandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?

Abukho ubungozi obubandakanyekayo kweli candelo lesifundo.

Ukuba awuvumi ukuthatha inxaxheba, loluphi olunye unyango onalo?

Ukuba awufuni kuthatha inxaxheba kwesi sifundo, unelungelo lokusixelela oko kwaye asizi kukubandakanya kwesi sifundo.

Ngubani oza kufumana ingxelo yakho yamayeza?

Abantu ekukuphela kwabo abaza kwazi ukufumana iingxelo zakho zonyango ndim nabantu ababandakanyeka ngqo kwesi sifundo. Iinkcukacha eziqokelelweyo kwiingxelo zakho zezonyango ziza kugcinwa ziyimfihlelo kwaye ziza kukhuselwa kwabanye ekungafanelekanga ukuba bazifumane. Xa iinkcukacha zishicilelwe kwisifundo sethisisi kwaye zipapashiwe ukunceda ezinye iingcali zempilo, igama lakho okanye iinkcukacha zakho azizi kuvela ephepheni kwaye akukho nto iza kubonakalisa ukuba ezo nkcukacha zezakho.

Ingaba uza kuhlalulwa ngokuthatha inxaxheba kwesi sifundo kwaye ingaba kukho iindleko ezibandakanyekayo?

Hayi, awuzi kuhlalulwa ngokuthatha kwakho inxaxheba kwesi sifundo. Uza kufumana imbuyekezo yexabiso lokuya kwakho esibhedlele, xa kufuneka ubuyele esibhedlele ukwenza ezinye iimvavanyo. Akuzi kubakho ziindleko ziza kufunwa kuwe, xa uthatha inxaxheba.

Ingaba ikho enye into ekumele uyazi okanye uyenze?

- Ungaqhagamshelana neKomiti yoPhando ngomntu kwa-021-938 9207 ukuba unenkxalabo okanye izikhalazo ezingasonjululwanga kakuhle ngugqirha wakho wesifundo.
- Uza kufumana ikopi yolu lwazi kunye nefomu yesivumelwano ukwenzela ufumane iingxelo zakho.

Isifundo somthathi-nxaxheba

Ngokutyikitya ngezantsi, Mna ndiyavuma ukuthatha inxaxheba kwisifundo sophando semfuzo esibizwa ngokuba

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Pilot for VR

Ndazisa ukuba:

- Ndilufundile okanye ndalufunda olu lwazi kunye nefomu yesivumelwano kwaye ibhalwe ngolwimi endilwaziyo nendikhululekileyo kulo
- Bendinalo ithuba lokuba ndibuze imibuzo kwaye yonke imibuzo yam iphendulwe ngokwanelisayo.
- Ndiyakuqonda ukuba ukuthatha inxaxheba kolu phando kube **kukuzithandela kwam** kwaye andikhange ndinyanzelwe ukuba ndithathe inxaxheba.
- Ndingakhetha ukusishiya isifundo nanini na kwaye andisayi kohlwaywa okanye ndigwetywe kwangaphambili nangayiphi indlela.
- Ndisenokucelwa ukuba ndisishiye isifundo phambi kokuba siphela, ukuba ugqirha wesifundo okanye umphandi ukubona kuyinzuzo kum, okanye ukuba andisilandeli isicwangciso sesifundo, ekuvunyelenwe ngaso.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomthathi-nxaxheba

.....
Utyikityo lwengqina

Isifungo somphandi

Mna (*igama*) ndiyafunga ukuba:

- Ndilucacisile ulwazi olukolu xwebhu ku-.....
- Ndimkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndiyaneliseka kukuba uyakuqonda ngokwanelisayo konke okumalunga nophando okuxoxwe ngasentla.
- Ndisebenzise/andisebenzisanga toliki. (*Ukuba itoliki isetyenzisiwe kumele ityikitye isaziso ngezantsi.*)

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomphandi

.....
Utyikityo lwengqina

Isifungo setoliki

Mna (*igama*) ndazisa ukuba:

- Ndicende umphandi (*igama*) ekucaciseni ulwazi olulapha kolu xwebhu ku.....(*igama lomthathi-nxaxheba*) ndisebenzisa ulwimi lwesiBhulu/lwesiXhosa.
- Simkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndimxelele eyona nto iyiyo malunga nokunxulumene nam.
- Ndiyaneliseka kukuba umthathi-nxaxheba ukuqonda ngokupheleleyo okuqulathwe lolu xwebhu lwesivumelwano eyazisiweyo kwaye nemibuzo yakhe yonke iphendulwe ngokwanelisayo.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lwetoliki

.....
Utyikityo lwengqina

APPENDIX F3: DEELNEMERINLICHTINGSBLAD EN -TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy 1: Pilot of VR

VERWYSINGSNOMMER: N08/01/019

HOOFNAVORSER: Mrs. Linzette D Morris

KONTAKNOMMER: 0845885826 or 0215925132

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daarvoor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die Komitee vir Mensnavorsing van die Universiteit Stellenbosch **goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).**

Wat behels hierdie navorsingsprojek?

Hierdie studie sal by die Tygerberg Hospitaal se volwasse brand eenheid plaasvind. Ons hoop om tenminste 3 tot 5 volwassenes wie 'n brandwond op gedoen het te benader om in hierdie studie deel te neem.

Die algehele studie be-oog om te bepaal of 'n nuwe tegnologie, naamlik Virtual reality, effektief is om pyn en ang in volwassenes met brandwonde kan verlig. Die Virtual reality sal moontlik die brandwond pasiënt se aandag aftrek van die pyn wat hulle voel en dus die fisioterapie behandeling vergemaklik. Die pyn medikasie wat gereeld vir brandwond pasiënte gegee word is nie altyd voldoende nie en het nuwe-effekte. Dus, aangesien ons 'n alternatiewe manier wil implementeer, sal dit moontlik die pyn wat die brandwond pasiënt tydens hul fisioterapie behandeling verlig, en hopelik die ervaring vir die pasiënt en gesondheids professioneel vergemaklik. Voor ons hierdie fase van die studie kan begin, moet ons eers weet of dit maklik is om die virtual reality te gebruik en of dit maklik is om die instruksies te volg.

Die proses van hierdie fase van die studie is as volg: die studie deelnemers sal gewerf word by die Tygerberg Hospitaal se volwasse brand eenheid, en enige persoon wat voldoen aan die insluitings kriteria en toestemming gee, mag dan aan die studie deelneem. 'n Vorm sal vir elke deelnemer ingevul word wat informasie sal versamel oor hul self, hulle persoonlike besondere, hul brandwond besering, die pyn medikasie wat hulle ontvang, en of hulle enige chirurgie gehad het. Sekere informasie sal vanaf die mediese leër verkry word en die res van die informasie sal direk van die deelnemer versamel word. Aangesien hierdie fase net is om te sien of die Virtual reality maklik is om te gebruik, sal niks ander informasie versamel word nie. The deelnemer sal die kans het om vrae te vra oor die Virtual reality en om iets wat hulle misverstaan die opklaar. Die kommentaar en voorstelle wat die deelnemers verskaf sal gedokumenteer word en verander word as dit nodig is. Die virtual reality sal gedurende die omruil van verbande or die fisioterapie behandelings gebruik word. Na die virtual reality getoets is, sal die projek leiers die deelnemer a paar vrae vra omtrent die gemak van die gebruik van die Virtual reality, of hulle dit geniet het, of hulle minder pyn gevoel het, of die speeletjie maklik was, en of hulle enige iets anders sal verbeter.

Waarom is u genooi om deel te neem?

U is genooi om deel te neem aan hierdie studie omdat u 'n volwassene oor die onderdom van 18 jaar is, u 'n brandwond besering opgedoen het, en in die Tygerberg Hospitaal se volwasse brand eenheid opgeneem is.

Wat sal u verantwoordelikhede wees?

U word verwag om die instruksies wat ons aan u gee noukeurig te volg. As u nie iets verstaan nie, moet u dadelik vir ons laat weet. U hoof verantwoordelikheid sal wees om die Virtual reality toerusting te toets en

kommentaar verskaf op hoe die instruksies of toerusting kan verbeter. U word versoek om besonderhede van u self en u mediese geskiedenis aan ons te verskaf.

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

Nee, u sal nie finansieel voordeel trek deur aan hierdie studie deel te neem nie, maar u hulp sal bydra om 'n alternatiewe behandeling vir ander brandwond pasiënte soos u die pyn wat hulle verduur tydens verband veranderinge en fisioterapie behandelinge beter hanteer.

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

Nee, daar is geen risiko's verbonde aan u deelname aan hierdie studie nie.

Watter alternatiewe is daar indien u nie instem om deel te neem nie?

As u nie wil deelneem aan hierdie studie nie, is u welkom om ons in te lig en dan sal u die normale en beste behandeling ontvang.

Wie sal toegang hê tot u mediese rekords?

The enigste mense wie toegang tot u mediese rekords sal hê, is die mense wie direk betrokke is in hierdie studie. Die informasie wat van u mediese leër versamel sal word sal privaat gehanteer word en van anders beskerm word. Wanneer die informasie in die studie tesis gedruk en gepubliseer word, sal u naam en besonderhede nie verskyn nie en daar sal geen indikatie wees dat dit u informasie was nie.

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

U sal nie betaal word vir deelname aan die navorsingsprojek nie en deelname aan die navorsingsprojek sal u niks kos nie.

Is daar enigiets anders wat u moet weet of doen?

- U kan die Komitee vir Mensnavorsing kontak by 021-938 9207 indien u enige bekommernis of klagte het wat nie bevredigend deur u studiedokter hanteer is nie.
- U sal 'n afskrif van hierdie inligtings- en toestemmingsvorm ontvang vir u eie rekords.

Verklaring deur deelnemer

Met die ondertekening van hierdie dokument onderneem ek,, om deel te neem aan 'n navorsingsprojek getiteld

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

Ek verklaar dat:

- Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in 'n taal geskryf is waarin ek vaardig en gemaklik mee is.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.
- Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van deelnemer

.....
Handtekening van getuie

Verklaring deur navorsers

Ek (*naam*) verklaar dat:

- Ek die inligting in hierdie dokument verduidelik het aan
.....
- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie 'n tolk gebruik het nie. (*Indien 'n tolk gebruik is, moet die tolk die onderstaande verklaring teken.*)

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van navorder

.....
Handtekening van getuie

Verklaring deur tolk

Ek (*naam*) verklaar dat:

- Ek die navorsers (*naam*) bygestaan het om die inligting in hierdie dokument in Afrikaans/Xhosa aan (*naam van deelnemer*) te verduidelik.
- Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek 'n feitelik korrekte weergawe oorgedra het van wat aan my vertel is.
- Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van tolk

.....
Handtekening van getuie

APPENDIX G1: INFORMED CONSENT FORM FOR MAIN STUDY

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Main study

REFERENCE NUMBER: N08/01/019

PRINCIPAL INVESTIGATOR: Mrs. Linzette D Morris

ADDRESS: 140 Spencer Street, Goodwood, 7460

CONTACT NUMBER: 0845885826 or 0215925132

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Committee for Human Research** at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The study will take place at the Tygerberg Hospital's adult burn unit. We are hoping to include at least 12 adults who have suffered a burns injury to assist us with this study. This is phase two of the main study.

The overall aim of the study is to analyze the effectiveness of a new technology, namely **Virtual Reality**, on the pain that adult burn patients experience when they have to go through physiotherapy treatments. The Virtual reality will help distract the burns patient from the pain they are feeling. The reason for us wanting to do this study is to help a person who has suffered a burn injury to be able to cope with the treatment and procedures that they have to go through daily. The pain medication that is often given to burns patients is sometimes not enough and may have side-effects. By trying to find another way of helping a burns patient have less pain during the physiotherapy treatment, we are hoping that the experience is easier for the patient and the health professional.

The procedure for phase two of the study is as follows: After we have informed the study subjects of the study procedure, and the study subject agrees to take part in this study, he/she will be required to sign this consent form. A form will then be completed for each participant before the main part of the study starts. This form will collect information about the study subject with regards to his/her personal and medical details. For the physiotherapy treatment the entire procedure will be divided into two stages. Stage one will be the first half of the treatment, and stage two will be the second half of the treatment. The treatment will consist of passive range of movement stretching of upper and lower limbs. The two stages of the physiotherapy treatment will randomly be assigned to either receiving virtual reality or to receiving no virtual reality (only pain medication). The study subject will have to complete a pain and anxiety questionnaire before, during, immediately after and 30 minutes after each stage of the physiotherapy treatment. Therefore you will complete 3 sets of the pain and anxiety questionnaires. A research assistant will come into the room to give you the pain and anxiety questionnaires to complete.

Why have you been invited to participate?

You have been invited to participate in this study because you are an adult, over the age of 18 years old, you have suffered a burn injury and you are now admitted to the Tygerberg Hospital's adult burn unit.

What will your responsibilities be?

To be able to fully participate in this study we need you to do a few things for us. We would also like you to follow the instructions that we give you carefully. If you do not understand let us know immediately. You will

have the responsibility of completing the data collection form, pain and anxiety questionnaires. You will have the responsibility of playing the virtual reality game while undergoing the physiotherapy treatment. You may not tell the research assistant what was done when he/she enters the room.

Will you benefit from taking part in this research?

You will not benefit from this study financial, but you will benefit from the study knowing that you have contributed to helping us find an alternative way of treating burns patients like yourself to cope with the pain that they feel when they have to go through physiotherapy treatments.

Are there in risks involved in your taking part in this research?

There is a small possibility that the virtual reality may make you a little nauseous. Should you feel any nausea, let the study staff now immediately.

If you do not agree to take part, what alternatives do you have?

If you do not want to take part in this study, you have every right to tell us and then you may ask the hospital staff to give you some pain medication.

Who will have access to your medical records?

The only people that will have access to your medical records, is myself and the people directly involved in the study. The information collected from you medical records will be treated as private and will be protected from others who should not see them. When the information is printed in the study thesis and is published to help other health professionals, your name or details will not appear in the paper and there will be no indication that it was your information.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

It is unlikely that you will be injured while you are taking part in this study, as it primarily involves usual medical procedures.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study, and there will be no costs involved for you, if you do take part.

Is there any thing else that you should know or do?

- You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

DECLARATION BY PARTICIPANT

By signing below, I agree to take part in a research study entitled

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way.

- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2008.

.....
Signature of participant

.....
Signature of witness

DECLARATION BY INVESTIGATOR

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a translator. (*If a translator is used then the translator must sign the declaration below.*)

Signed at (*place*) on (*date*) 2008.

.....
Signature of investigator

.....
Signature of witness

DECLARATION BY TRANSLATOR

I (*name*) declare that:

- I assisted the investigator (*name*) To explain the information in this document to (*name of participant*) using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) on (*date*) 2008.

.....
Signature of translator

.....
Signature of witness

APPENDIX G2: INCWADANA ENGOLWAZI NGOMTHATHI-NXAXHEBA KUNYE NEFOMU YESIVUMELWANO

ISIHLOKO SEPROJEKTHI YOPHANDO:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Main study

INOMBOLO YONXULUMANO: N08/01/019

UMPHANDI OYINTLOKO: Mrs. Linzette D Morris

IDILESI: 140 Spencer Street, Goodwood, 7460

INOMBOLO YOQHAGAMSHELWANO: 0845885826 or 0215925132

Uyamenywa ukuba uthathe inxaxheba kwiprojekthi yophando. Nceda thatha ixesha lokufunda ulwazi oluvezwe apha, oluza kuthi luchaze iinkcukacha zale projekthi. Nceda buza nayiphi na imibuzo emalunga nayiphi na indawo ongayiqondiyo ngokupheleleyo kubasebenzi besi sifundo okanye kugqirha. Kubaluleke kakhulu ukuba waneliseke ngokupheleleyo yinto yokuba ucacelwe kakuhle ukuba yintoni unobangela wesi sifundo kwaye ungabandakanyeka njani. Kwakhona, ukuthatha kwakho inxaxheba **ukwenza ngokuzithandela unganyanzelwanga** kwaye ukhululekile ukuba ungarhoxa ekuthatheni inxaxheba. Ukuba uthi hayi, oku akusayi kuchaphazela ukungavumi kwakho nangayiphi na indlela. Ukwakhululekile ukuba uyeke kwesi sifundo nanini na, nokuba ubuvumile ukuthatha inxaxheba ekuqaleni.

Olu phando luvunywe ziinqobo ezisesikweni **zeKomiti yoPhando Lomntu kwiYunivesithi yaseStellenbosch** kwaye luzakwenziwa ngokwemigaqo esesikweni lophando elamkelekileyo kwiSaziso sehlabathi sika-Helsinki, iMigaqo eLungileyo yoMzantsi Afrika yokuSebenza eKliniki kunye neBhunga lezoPhando ngamaYeza (MRC) iMigaqo yeNqobo yezoPhando.

Simalunga nantoni esi sifundo sophando?

Isifundo siza kwenzeka kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo. Sinthemba lokuba siza kubandakanya ubuncinane abantu abadala abali-12 abanomonzakalo wokutsha ukuba basincede kwesi sifundo. Eli linqanaba lesibini lesona sifundo siphambili.

Sisonke isifundo sijolise ekucaluleni ukusebenza kobuchwephesha obutsha, ekungabalulwa i**Virtual Reality**, ekunciphiseni iintlungu nexhala eliviwa ngabantu abadala abazizigulane xa betshintshwa amabhandeji naxa benyangwa ngokwenza imithambo. Le *Virtual reality* iza kunceda ukususa iintlungu zokutsha eziviwa sisigulane. Isizathu sokuba sifune ukwenza esi sifundo kukufuna ukunceda umntu owenzakele kukutsha ukuba akwazi ukumelana nonyango nemigaqo ekufuneka beyilandele yonke imihla. Amayeza eentlungu asoloko enikwa izigulane ezitshileyo amaxesha amaninzi abanezinye iziphumo. Ngokuzama ukufumana enye indlela yokunceda izigulane ezitshileyo engenazintlungu zingako xa kutshintshwa amabhandeji naxa kunyangwa ngokwenziwa kwemithambo, sinthemba lokuba oku kuxhotyiswa ngamava kuza kwenzakube lula kwisigulane nakwingcali yezempilo.

Imigaqo yeli nqanaba lesibini lesi sifundo yile ilandelayo: Emva kokuba abathathi-nxaxheba besifundo ekhethiwe, amathathi-nxaxheba besifundo baza kuchazelwa ngemigaqo yesifundo, kwaye ukuba bayavuma ukuthatha inxaxheba kwesi sifundo, umntu ngamnye othatha inxaxheba kuza kufuneka atyikitye le fomu yesivumelwano. Ifomu iza kuzaliswa ngomthathi-nxaxheba ngamnye phambi kokuba eyona ndawo iphambili kwesi sifundo iqaliswe. Le fomu iza kuqokelela iinkcukacha ngomthathi-nxaxheba wesi sifundo malunga naye neenkukacha zakhe zezempilo. Ixhoba lesifundo liza kuchongwa ukuba libekwiqela lokutshintshwa amabhandeji okanye libekwiqela lokunyangwa ngokwenza imithambo. Kwiqela elitshintshwa amabhandeji, inkqubo yokutshintshwa kwamabhandeji iza kwahlulwa ibenezigaba ezimbini. Isigaba sokuqala iza kuba kukususwa kwebhandeji elimdaka, isigaba sesibini ibekukucocwa kwenxeba lokutsha nokufakwa kwebhandeji elicocekileyo. Izigaba ezimbini zokutshintshwa kwamabhandeji ziza kuchongelwa ukufumana i**virtual reality** okanye zingafumani *virtual reality* (ibe ngamayeza eentlungu kuphela). Ixhoba lesifundo kuza kufuneka lizalise umlinganiseli weentlungu nowexhala phambi nasemva kwesigaba ngasinye sokutshintshwa kwamabhandeji. Ngoko ke uza kugqiba iiseti ezi-3 zemibuzo emalunga neentlungu nokuxhalaba onako. Umncedisi kolu phando uza kungena egumbini akunike iphepha lemibuzo ngeentlungu nangokuxhalaba ukuba ulizalise.

Kwiqela lokunyangwa ngokwenza imithambo, inkqubo iyonke iza kwahlulwa ibe zizigaba ezimbini. Isigaba sokuqala iza kuba sisiqingatha sokuqala sonyango, isigaba sesibini iza kuba sisiqingatha sesibini sonyango. Unyango luza kubandakanya uluhlu lokolula amalungu angezantsi uhleli phantsi. Izigaba ezimbini zonyango

lokwenza imithambo luza kuchongelwa ukufumana *ivirtual reality* okanye zingafumani *virtual reality* (ibe ngamayeza eentlungu kuphela). Umthathi-nxaxheba wesifundo kuza kufuneka azalise iphepha lemibuzo ngeentlungu nokuxhalaba phambi nasemva kwesigaba ngasinye sonyango ngokwenza imithambo. Ngoko ke uza kugqiba iiseti ezi-3 zemibuzo emalunga neentlungu nokuxhalaba onako. Umncedisi kolu phando uza kungena egumbini akunike iphepha lemibuzo ngeentlungu nangokuxhalaba ukuba ulizalise.

Kutheni umenyiwe ukuba uthathe inxaxheba?

Umenyiwe ukuba uthathe inxaxheba kwesi sifundo kuba ungumntu omdala ongaphezu kweminyaka eli-18 ubudala, unomenzakalo wokutsha kwaye ngoku ungeniswe kwisibhedlele saseTygerberg kwicandelo labadala abatshileyo.

Luza kuba yintoni uxanduva lwakho?

Ngokuthatha inxaxheba ngokupheleleyo kwesi sifundo sifuna usenzele izinto ezimbalwa. Singathanda ukuba utyelele isibhedlele ngeenjongo zesifundo ngemihla esikunike yona. Ukuba zikhona izizathu ongenakwazi ukuphumelela ngenxa yazo ngaloo mhla, nceda usitsalele umnxeba usazise ngoko. Singathanda ukuba ulandele imiyalelo esikunika yona ngenyameko. Ukuba awuyiqondi sixelele ngokukhawuleza. Olona xanduva lwakho iza kuba kukuzalisa iphepha lemibuzo ngeentlungu nokuxhalaba kwakho. Uza kubanoxanduva lokudlala umdlalo we*virtual reality* ngeli xa utshintshwa amabhandeji okanye unyangwa ngokwenziswa imithambo. Akufunekanga uxelele umphandi oncedisayo ukuba wenziwe ntoni xa engena kwelo gumbi

Ingaba uza kuzuza ekuthatheni inxaxheba kolu phando?

Awuzi kuzuza mali kwesi sifundo, kodwa uza kuzuza kwesi sifundo ngokwazi ukuba ube negalelo lokusinceda ukufumana enye indlela yokunyanga ukutsha kwesigulane njengawe bakwazi ukumelana neentlungu abazivayo xa betshintshwa amabhandeji naxa benikwa unyango ngokwenza imithambo.

Ingaba zikho iingozi ezibandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?

Bungakho ubungozi obuncinane kuba ivirtual reality ingakwenza ube nesicaphucaphu. Ukuba uziva unesicaphucaphu, xelela abasebenza kwesi sifundo ngokukhawuleza.

Ukuba awuvumi ukuthatha inxaxheba, loluphi olunye unyango onalo?

Ukuba awufuni kuthatha inxaxheba kwesi sifundo, unelungelo lokusixelela oko kwaye asizi kukubandakanya kwesi sifundo.

Ngubani oza kufumana ingxelo yakho yamayeza?

Abantu ekukuphela kwabo abaza kwazi ukufumana iingxelo zakho zonyango ndim nabantu ababandakanyeka ngoko kwesi sifundo. Iinkcukacha eziqokelelweyo kwiingxelo zakho zezonyango ziza kugcinwa ziyimfihlelo kwaye ziza kukhuselwa kwabanye ekungafanelekanga ukuba bazifumane. Xa iinkcukacha zishicilelwe kwisifundo sethisisi kwaye zipapashwe ukunceda ezinye iingcali zempilo, igama lakho okanye iinkcukacha zakho azizi kuvela ephapheni kwaye akukho nto iza kubonakalisa ukuba ezo nkcukacha zezakho.

Ingaba uza kuhlululwa ngokuthatha inxaxheba kwesi sifundo kwaye ingaba kukho iindleko ezibandakanyekayo?

Hayi, awuzi kuhlululwa ngokuthatha kwakho inxaxheba kwesi sifundo. Akuzi kubakho zindleko oza kuzihlawula ukuba uthatha inxaxheba.

Ingaba ikho enye into ekumele uyazi okanye uyenze?

- Ungaqhagamshelana neKomiti yoPhando Lomntu kwa-021-938 9207 ukuba unenkxalabo okanye izikhalazo ezingasonjululwanga kakuhle ngugqirha wakho wesifundo.
- Uza kufumana ikopi yolu lwazi kunye nefomu yesivumelwano ukwenzela iingxelo zakho.

Isifundo somthathi-nxaxheba

Ngokuyityikitya ngezantsi, Mna ndiyavuma ukuthatha inxaxheba kwisifundo sophando semfuzo esibizwa ngokuba (faka isihloko sesifundo).

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy

Ndazisa ukuba:

- Ndilufundile okanye ndalufunda olu lwazi kunye nefomu yesivumelwano kwaye ibhalwe ngolwimi endiliciko nendikhululekileyo kulo
- Bendinalo ithuba lokuba ndibuze imibuzo kwaye yonke imibuzo yam iphendulwe ngokwanelisayo.
- Ndiyakuqonda ukuba ukuthatha inxaxheba kolu phando kube **kukuzithandela kwam** kwaye andikhangane ndinyanzelwe ukuba ndithathe inxaxheba.
- Ndingakhetha ukusishiya isifundo naninina kwaye andisayi kohlwaywa ndigwetywe nangayiphi indlela.
- Ndisenokucelwa ukuba ndisishiye isifundo phambi kokuba siphele, ukuba ugqirha wesifundo okanye umphandi ukubona kuyinzuzo kum, okanye ukuba andisilandeli isicwangciso sesifundo, ekuvunyelenwe ngaso.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomthathi-nxaxheba

.....
Utyikityo lwengqina

Isifungo somphandi

Mna (*igama*) ndiyafunga ukuba:

- Ndilucacisile ulwazi olu kweli xwebhu ku-.....
- Ndimkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndiyaneliseka kukuba uyakuqonda ngokwanelisayo konke okumalunga nophando okuxoxwe ngasentla.
- Ndisebenzise/andisebenzisanga toliki. (*Ukuba itoliki isetyenzisiwe kumele ityikitye ngezantsi.*)

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lomphandi

.....
Utyikityo lwengqina

Isifungo setoliki

Mna (*igama*) ndazisa ukuba:

- Ndicende umphandi (*igama*) ekucaciseni ulwazi olulapha kolu xwebhu ku..... (*igama lomthathi-nxaxheba*) ndisebenzisa ulwimi lwesiBhulu/lwesiXhosa.
- Simkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndimxelele eyona nto iyiyo malunga nokunxulumene nam.
- Ndiyaneliseka kukuba umthathi-nxaxheba ukuqonda ngokupheleleyo okuqulathwe loluxwebhu lwesivumelwano eyazisiweyo kwaye nemibuzo yakhe yonke iphendulwe ngokwanelisayo.

Kutyikitywe e-(indawo) ngo-(umhla) 2008.

.....
Utyikityo lwetoliki

.....
Utyikityo lwengqina

APPENDIX G3: DEELNEMERINLICHTINGSBLAD EN -TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy: Main study

VERWYSINGSNOMMER: N08/01/019

HOOFNAVORSER: Mrs. Linzette D Morris

ADRES: 140 Spencer Street, Goodwood, 7460

KONTAKNOMMER: 0845885826 or 0215925132

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daarvoor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die Komitee vir Mensnavorsing van die Universiteit Stellenbosch **goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).**

Wat behels hierdie navorsingsprojek?

Hierdie studie sal by die Tygerberg Hospitaal se volwasse brand eenheid plaasvind. Ons hoop om ten minste 12 volwassenes wie 'n brandwond op gedoen het te benader om in hierdie studie deel te neem. Dit is fase 1 van die hoof studie.

Die algehele studie be-oog om te bepaal of 'n nuwe tegnologie, naamlik Virtual reality, effektief is om pyn en ang in volwassenes met brandwonde kan verlig. Die Virtual reality sal moontlik die brandwond pasiënt se aandag aftrek van die pyn wat hulle voel en dus die verband veranderinge en/of die fisioterapie behandeling vergemaklik. Die pyn medikasie wat gereeld vir brandwond pasiënte gegee word is nie altyd voldoende nie en het nuwe-effekte. Dus, aangesien ons 'n alternatiewe manier wil implementeer, sal dit moontlik die pyn wat die brandwond pasiënt tydens hul verband verandering en/of fisioterapie behandeling verlig, en hopelik die ervaring vir die pasiënt en gesondheids professioneel vergemaklik. Die proses van hierdie fase van die studie is as volg: die studie deelnemers sal gewerf word by die Tygerberg Hospitaal se volwasse brand eenheid, en enige persoon wat voldoen aan die insluitings kriteria en toestemming gee, mag dan aan die studie deelneem. Die deelnemers sal dan die VR eerder tydens die eerste helfte van die fisioterapie behandeling ontvang, of tydens die tweede helfte. 'n Vorm sal vir elke deelnemer ingevul word wat informasie sal versamel oor hul self, hulle persoonlike besondere, hul brandwond besering, die pyn medikasie wat hulle ontvang, en of hulle enige chirurgie gehad het. Sekere informasie sal vanaf die mediese leër verkry word en die res van die informasie sal direk van die deelnemer versamel word.

Tydens die fisioterapie sessies, sal die proses in twee gedeeltes word. Deel 1 sal die eerste helfte wees en deel 2 die tweede helfte. Die behandeling sal passiewe bewegings wees. Die twee gedeeltes sal eerder die VR of geen VR ontvang. Die deelnemer sal pyn en ang vraelyste voltooi voor en na elke deel. Dus, sal elke deelnemer 3 stelsels vraelyste voltooi. 'n navorsing assistent sal die vraelystes vir u gee. Elke vraelys en vorm sal verduidelik word aan elke deelnemer voor die proses begin. Al die informasie wat versamel word van die vorms en vraelyste, sal onder die deelnemers se rekord/verwysing nommer geliaseer word nie onder die deelnemers se naam nie. Dus sal niemand, maar die projek leiers, toegang tot die informasie het nie.

Waarom is u genooi om deel te neem?

U is genooi om deel te neem aan hierdie studie omdat u 'n volwassene oor die onderdom van 18 jaar is, u 'n brandwond besering opgedoen het, en in die Tygerberg Hospitaal se volwasse brand eenheid opgeneem is.

Wat sal u verantwoordelikhede wees?

U word verwag om die instruksies wat ons aan u gee noukeurig te volg. As u nie iets verstaan nie, moet u dadelik vir ons laat weet. U hoof verantwoordelikhede sal wees om die vorms, die pyn en ang vraelyste volledig

te voltooi, asook die virtual reality te gebruik. U word versoek om besonderhede van u self en u mediese geskiedenis aan ons te verskaf.

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

Nee, u sal nie finansieel voordeel trek deur aan hierdie studie deel te neem nie, maar u hulp sal bydra om 'n alternatiewe behandeling vir ander brandwond pasiënte soos u die pyn wat hulle verduur tydens verband veranderinge en fisioterapie behandelinge beter hanteer.

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

Nee, daar is geen risiko's verbonde aan u deelname aan hierdie studie nie.

Watter alternatiewe is daar indien u nie instem om deel te neem nie?

As u nie wil deelneem aan hierdie studie nie, is u welkom om ons in te lig en dan sal u die normale en beste behandeling ontvang.

Wie sal toegang hê tot u mediese rekords?

The enigste mense wie toegang tot u mediese rekords sal hê, is die mense wie direk betrokke is in hierdie studie. Die informasie wat van u mediese leër versamel sal word sal privaat gehanteer word en van anders beskerm word. Wanneer die informasie in die studie tesis gedruk en gepubliseer word, sal u naam en besonderhede nie verskyn nie en daar sal geen indikasie wees dat dit u informasie was nie.

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

U sal nie betaal word vir deelname aan die navorsingsprojek nie en deelname aan die navorsingsprojek sal u niks kos nie.

Is daar enigiets anders wat u moet weet of doen?

- U kan die Komitee vir Mensnavorsing kontak by 021-938 9207 indien u enige bekommernis of klagte het wat nie bevredigend deur u studiedokter hanteer is nie.
- U sal 'n afskrif van hierdie inligtings- en toestemmingsvorm ontvang vir u eie rekords.

Verklaring deur deelnemer

Met die ondertekening van hierdie dokument onderneem ek,, om deel te neem aan 'n navorsingsprojek getiteld

Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy.

Ek verklaar dat:

- Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in 'n taal geskryf is waarin ek vaardig en gemaklik mee is.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.
- Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van deelnemer

.....
Handtekening van getuie

Verklaring deur navorsers

Ek (*naam*) verklaar dat:

- Ek die inligting in hierdie dokument verduidelik het aan
.....
- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie 'n tolk gebruik het nie. (*Indien 'n tolk gebruik is, moet die tolk die onderstaande verklaring teken.*)

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van navorder

.....
Handtekening van getuie

Verklaring deur tolk

Ek (*naam*) verklaar dat:

- Ek die navorsers (*naam*) bygestaan het om die inligting in hierdie dokument in Afrikaans/Xhosa aan (*naam van deelnemer*) te verduidelik.
- Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.
- Ek 'n feitelik korrekte weergawe oorgedra het van wat aan my vertel is.
- Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te (*plek*) op (*datum*) 2008.

.....
Handtekening van tolk

.....
Handtekening van getuie

APPENDIX H: LETTER TO DR VAN DER MERWE – HEAD OF DEPARTMENT, TBH BURN UNIT

The Head of Department: Burns Unit
Tygerberg Hospital
Tygerberg
7505

Attention: Dr E van der Merwe

RE: PERMISSION TO CONDUCT STUDY IN UNIT

Dear Dr van der Merwe,

The proposed research project, **“Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn patients during physiotherapy”**, forms part of an MSc degree in Physiotherapy at the Stellenbosch University, in Cape Town, South Africa. The aim of the study is to analyze the effectiveness of a low-cost virtual reality system on the pain intensity and level of anxiety experienced by adult burn injury patients undergoing physiotherapy management at the Tygerberg Hospital’s adult burn unit.

Physiotherapists and other medical professionals often have to deal with non-compliance due to pain from burn injury patients undergoing painful procedures such as physiotherapy management, which can lead to a delay in wound healing and hinder function. In addition, the use of pharmacologic analgesics carries with them the added risk of side-effects and cannot be used for long periods of time. Alternatives to pharmacologic analgesics and techniques are therefore warranted. Virtual reality is a non-invasive, non-pharmacologic analgesic technique recently found to be useful in certain medical conditions and painful medical procedures. However, the usual Virtual reality systems trialed in international studies are expensive and not economically feasible for developing countries. It is hoped that the implementation of a low-cost Virtual reality into South African hospitals will improve medical services and outcomes of burn patients.

The main objective of the study is to analyze the effect of the low-cost Virtual Reality system on the pain intensity and anxiety experienced by the adult burn injury patients undergoing physiotherapy management.

I would hereby like to request permission to conduct my study in the Tygerberg Hospital Adult Burns Unit. I am currently awaiting ethics approval for this study and will only commence once I have authorization to do so. Should you have any enquiries regarding this study, please do not hesitate to contact me on the following numbers: 0219389084 or 0845885826.

Yours sincerely,

Mrs. Linzette Morris
BSc Physiotherapy (UWC)

Prof QA Louw
Supervisor (primary)

Mrs. L Crous
HOD Physio

APPENDIX I: ORIGINAL ELECTRONIC-MAIL (EMAIL) LETTER FROM DR VAN DER MERWE, HEAD OF TBH ADULT BURN UNIT GRANTING PERMISSION

Date:	Wed, 24 Oct 2007 11:41:38 +0200
From:	"Elbie Van der Merwe" <Elbievdm@pgwc.gov.za>  View Contact Details  Add Mobile Alert
To:	"Linzette Morris" <linzette_morris@yahoo.com>
Subject:	Re: letter requesting permission to conduct study in unit

Dankie ek liaseer die versoek en jy kan maar voort gaan met die studie.
Onthou my taak gaan streng klinies wees met pasiënt seleksie en ondersteuning.

Dr Elbie van der Merwe

>>> Linzette Morris <linzette_morris@yahoo.com> 10/22/07 1:07 PM >>>
Dear Dr van der Merwe,

Kindly find the letter attached requesting your permission to conduct my study regarding Virtual Reality in the Tygerberg Hospital Burns Unit and Outpatient department.

Thank you for you time and advice.

Regards,
Linzette Morris

APPENDIX J: LETTER TO INTERDISCIPLINARY PANEL OF EXPERTS

Mrs. LD Morris-Smith
140 Spencer Street
Goodwood
7460
Email: ldmorris@sun.ac.za
Tel: 0845885826

Date: _____

RE: Effect of a low-cost Virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy.

Dear _____

The above mentioned research project forms part of an MSc degree in Physiotherapy at the Stellenbosch University, in Cape Town, South Africa. The aim of the study is to analyze the effectiveness of a low-cost virtual reality system on reducing the pain intensity and level anxiety experienced by adult burn injury patients undergoing physiotherapy management at the Tygerberg Hospital's adult burn unit. Physiotherapists and other medical professionals often have to deal with non-compliance from burn patients undergoing painful procedures such as physiotherapy management, which can lead to a delay in wound healing and hinder function. In addition, the use of pharmacologic analgesics carries with them the added risk of side-effects and cannot be used for long periods of time. Alternatives or adjunctive therapies to pharmacologic analgesics and techniques are therefore warranted. Virtual reality is a non-invasive, non-pharmacologic analgesic technique recently found to be useful in certain medical conditions and painful medical procedures. However, the usual Virtual reality systems trialed in international studies are expensive and not economically feasible for developing countries. It is hoped that the implementation of a low-cost Virtual reality into South African hospitals will improve medical services and outcomes of burn patients.

The main objective of the study is to analyze the effect of the low-cost Virtual Reality system on the pain intensity and anxiety experienced by the adult burn injury patients undergoing physiotherapy management. A secondary aim of this study is to establish a profile of the adult burn injury patient admitted to the Tygerberg Hospital's adult burn unit which will incorporate demographical, personal and medical information, as well as the type and dosage of analgesics administered to adult burn injury patients attending the unit, will be established. For this purposes, a data collection form therefore has to be constructed and validated with which the information required for the profile can be collected and analyzed. However, to construct such data collection form, the expertise of professionals involved in burn wound care and burn rehabilitation is required. As we deem you an expert in your field, we humbly request your assistance in the construction and content validation of the proposed data collection forms. Please find attached a draft of the suggested data collection form.

Guidelines for evaluation of the data collection form:

- We ask that you review the data collection form and provide feedback regarding the construction of the data collection form and the content.

- Please bear in mind that the data collection form needs to collect information regarding the demographical, personal, burn injury, analgesic and physiotherapy treatment information of the subject
- The data collected from the form should provide enough information to establish a clear profile of the adult burn injury patient admitted to the Tygerberg Hospital adult burn unit.
- The data collection form should be able to retrieve information from the subject and the medical folder.
- The questions and sections should be appropriate and comprehensive.

Should you require any additional information, please do not hesitate to contact me.

Thank you for your time and participation.

Mrs. Linzette D Morris
BSc Physiotherapy UWC

Prof QA Louw
Supervisor

Mrs. LC Crous
HOD PT (co-supervisor)

APPENDIX K: SHORT CV OF PRINCIPLE RESEARCHER

Surname : Morris
Full first names : Linzette Deidré
Gender : Female
Nationality : South African citizen
ID number : 8108290879087
Date of birth : 29 August 1981
Address : 140 Spencer Street
Goodwood
7460
Contact numbers : +27 21 5925132 (home)
+ 27 845885826 (mobile)
+27 21 9389300 (work)
Email address : ldmorris@sun.ac.za
linzette_morris@yahoo.com
Qualifications : B.Sc. Physiotherapy (University of
Western Cape) 2004

Work experience

2007 to present Stellenbosch University (full-time researcher)
2007 Liezel Ross Physiotherapists (locum physiotherapist)
2006-2007 Stellenbosch University (part-time research assistant)
2006-2007 Dr Q Louw Physiotherapist (clinical physiotherapist)
2006 Gorman and associates (locum physiotherapist)
2005-2006 Pholosong Hospital, Gauteng (community physiotherapist)

Professional board memberships

Health professional council of South Africa reg. no. : PT 0088366
South African Society of Physiotherapy reg. no. : MOR010
Irish Society of Chartered Physiotherapists reg. no. : 11073

Publications in peer-reviewed journals

1. Louw QA, **Morris LD**, Grimmer-Somers K: The prevalence of Low Back Pain in Africa: A systematic review. BMC 2007;8:105
2. Louw Q, **Morris LD**, Sklaar J: Evidence of Physiotherapeutic interventions for acute low back pain. SAJP 2007;63(3):7-14
3. Hillier S, Louw Q, **Morris L**, Uwimana J, Statham S: Massage therapy for people with HIV (Protocol). Cochrane Library 2008, Issue 4. Art. No.: CD007502. DOI: 10.1002/14651858.CD007502.

4. **Morris LD**, Louw QA, Grimmer-Somers K: The effectiveness of Virtual Reality on alleviating pain and anxiety experienced by burn injury patients: a systematic review. *Clin J Pain* 2009;25:815–826
5. **Morris LD** and Louw QA: Physiotherapists are as effective as general practitioners in treating acute low back pain JBI Library of Systematic review 2009
6. Hillier S, Louw Q, **Morris L**, Uwimana J, Statham S: Massage therapy for people with HIV. *Cochrane Library* (in press)
7. **Morris L** and Louw Q: Effect of a low-cost virtual reality system on reducing pain and anxiety experienced by adult burn injury patients during physiotherapy management. (in press)
8. **Morris L** and Louw Q: Pain and anxiety levels of adult burn injury patients during physiotherapy at the Tygerberg Hospital, South Africa (in press).
9. Louw QA and **Morris LD**: Clinical evidence for the effectiveness of physiotherapeutic acute low back pain interventions in the private health sector of the Western Cape, South Africa. *SAJP* 2009 (accepted)

Publications under review or in process

10. **Morris LD** and Louw QA: The physiotherapeutic management of acute low back pain in the private health sector of the Western Cape, South Africa. *SAJP* (under review)

Conference proceedings

1. Louw Q, **Morris L** and Grimmer-Somers K (2007): The prevalence of low back pain in Africa – A systematic review. World Physiotherapy Conference. 14th -20th August 2006, Dar es Salaam, Tanzania
2. Louw Q, **Morris L** and Sklaar J (2007): Evidence-based practice for acute low back pain: A systematic review of the evidence. South African Society of Physiotherapy (SASP) National Congress 2007, Durban, September 2007
3. **Morris-Smith L** (2009): Virtual reality and Burns. SASP International Congress 1-3 May 2009, Cape Town (Somerset West), South Africa
4. **Morris LD** (2009): Virtual reality and Burns. Stellenbosch University Annual Academic day 2009. 12 and 13 August 2009, Tygerberg, South Africa (poster presentation)