RESTORATIVE VIRTUAL ENVIRONMENTS FOR REHABILITATION: INTERACTIVE TECHNOLOGIES FOR ENHANCED EARLY RECOVERY FOLLOWING CRITICAL ILLNESS AND INJURY

By

CHARLOTTE LUCY SMALL

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Abstract

The expectation for patients surviving admission to the Intensive Care Unit (ICU) is that they make the best possible functional recovery. Rehabilitation from the point of physiological stability is directed at reducing the impact of the consequences of critical illness. It was proposed that interactive technologies (iTech) could be used by patients on the ICU to enhance their trajectory and experience of recovery. The aim of this research was to develop and evaluate methodologies to investigate the feasibility of introducing novel iTech-based systems to the ICU. Four novel Virtual Natural Environments were combined with commercial-off-the-shelf technologies to produce interventions to improve pain management and sleep and enhance deep breathing and cycling exercises. Cohort and intervention choice were informed by the development of programme theories describing how the interventions might work. These were further developed and used to investigate mediators and modifiers of response to the interventions. Human Centred Design and Usability Engineering techniques were combined with methods to evaluate complex interventions in clinical settings. The four feasibility studies developed and refined methodologies to evaluate their usefulness and effectiveness. This research concludes with lessons learned and a guide to inform future development and implementation.

The flow chart on the next page shows the structure of the thesis and the content of each chapter.

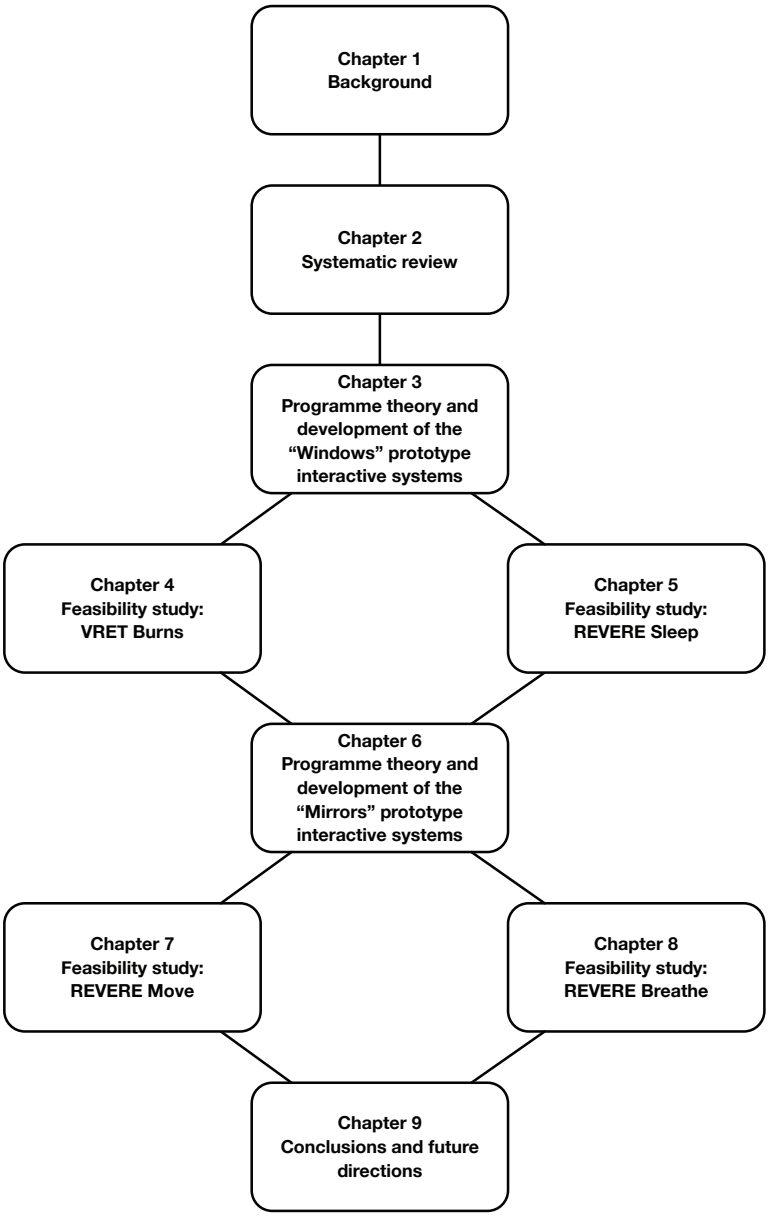

Figure 1 Thesis roadmap

Acknowledgements

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I would like to thank the study Principal Investigators, Dr Catherine Snelson, Dr Tom Bowden and Miss Olga Tucker who have always given their time with patience and cheerfulness. The fantastic group of Consultants in Intensive Care at QEHB has provided relentless support, kindness and practical help for all the clinical trials. David McWilliams, Fiona Howroyd, Charlotte Jones, Jon Weblin and the rest of the ICU physiotherapy team have inspired me and kept me smiling whilst giving the research project their expertise, time and invaluable opinions.This research has been funded by the Defence Medical Services Research Group. I would like to thank Dr Amarjit Samra for her support and the

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Dedication

For my incredible husband and children. I couldn’t have done this without you.

Awards and public engagement

This research has been the subject of two awards:

1. Royal College of Anaesthetists/National Institute of Health Research Clinical Research Trainee of the Year Award 2017 - Charlotte Small, Chief Investigator.
2. NIHR Clinical Research Network Patient and Public Involvement Award 2017 - Duncan and Lisa-Marie Buckley, ReVERe programme PPI leads.

This research has been presented by the Chief Investigator at a number of national and international conferences, including those of the United Kingdom Intensive Care Society, the European Society of Intensive Care Medicine Conference, the British Pain Society as well as local and departmental meetings. Local public engagement has been provided by the annual research showcase events organised by the NIHR SRMRC.

Alongside Professor Bob Stone, it was the subject of a presentation titled “New Rehabilitation Therapies and Virtual Pain Management” at the National Theatre in London, supporting the production of “Ugly Lies The Bone” , starring Kris Marshall.

The research has received interest from written, radio and television media. The ReVERe Sleep study was the subject on an interview for the Radio 4 Today programme and the ReVERe Move was featured by ITV Midlands Regional News.

Publications

Small, C., R. Stone, J. Pilsbury, M. Bowden and J. Bion (2015). "Virtual restorative environment therapy as an adjunct to pain control during burn dressing changes: study protocol for a randomised controlled trial." Trials 16(1): 48.

Stone RJ, **Small C**, Knight JF, Qian C, Shingari V. Virtual Natural Environments for Restoration & Rehabilitation in Healthcare. In: Ma M, Jain LC, Andersen P (editors). Virtual and Augmented Reality in Healthcare. Heidelberg: Springer-Verlag; pp. 497–521.

Presentations

Mustafa Y, **Small C**, Bowden M. Pain management during burns dressing changes Paper presented at Association of Anaesthetists of Great Britain and Ireland Group of Anaesthetists in Training Conference; Oxford, UK; 2013 Apr 3-5.

Small C, Pilsbury J, Snelson C. Impact of patient environment on neuropsychological symptoms in critical care. Paper presented at Intensive Care Society State of the Art Meeting; London, UK; 2014 Dec 16-18.

Pilsbury J, **Small C**, Snelson C. Sleep and delirium in critical care: does patient environment matter? Paper presented at European Society of Intensive Care Medicine; Paris, France; 2013 Oct 6-9.

Small C, Stone R, Qian C, Weblin J, Tucker O, Bion J, Snelson C. Restorative Virtual Environments for Rehabilitation-ReVERe Breathe. Paper presented at Kings Fund Integrating Care Conference; London, UK; 2016 Feb 9.

C Small, R Stone, C Snelson, P Mahoney, J Bion. Interactive Technologies in Critical Illness: A framework for evaluation. Paper presented at Intensive Care Society State of the Art Meeting; London, UK; 2016 Dec 5-7.

C Small, R Stone, P Mahoney, J Bion .Virtual Restorative Environment Therapy as an adjunct to conventional analgesia for procedure related pain in burns patients: a feasibility study. Paper presented at Pain Science in Motion Conference; Stockholm, Sweden, 2017 March 24-25.

C Small, R Stone, V Shingari, C Qian, M Bowden, J Pilsbury, A Bamford, J Bion. Virtual Restorative Environment Therapy as an adjunct to pain control during burns dressing changes:A feasibility study of a novel prototype system. Paper presented at British Pain Society Annual Scientific Meeting; Birmingham, UK; 2017 May 3-5.

C Small, R Stone, C Bullock, C Qian, V Shingari, J Knight, P Wood, J Bion, P Mahoney. Development of Virtual Reality Distraction Therapy for Military Combat Casualties: Usability study of Commercial-Off-The-Shelf Input Devices for navigating Virtual Environments. Paper presented at British Pain Society Annual Scientific Meeting; Birmingham, UK; 2017 May 3-5.

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List of abbreviations

BBC British Broadcasting Corporation

BSI British Standards Institution

CE Conformité Européenne

EI Effort/Importance (Domain on the Intrinsic Motivation Index)

GRS Graphical Rating Scale

HCD Human Centred Design

HMD Head Mounted Display

HRA Healthcare Research Authority

ICU Intensive Care Unit (syn. Critical Care Unit)

ICUAW Intensive Care Unit Acquire Weakness

IE Interest/Enjoyment (Domain on the Intrinsic Motivation Index)

IEC International Electrotechnical Commission

IMI Intrinsic Motivation Index

ISO International Organization for Standardisation

iTech Interactive Technology

MHRA Medicines and Healthcare products Regulatory Agency

MIC Maximum Inspiratory Capaty

MMS Manchester Mobility Score

MRC Medical Research Council

NHS National Health Service

NICE National Institute for Health and Clinical Excellence

NIHR National Institute of Health Research

NRS Numerical rating scale

PC Perceived Competence (Domain on the Intrinsic Motivation Index)

PCh Perceived Choice (Domain on the Intrinsic Motivation Index)

PT Pressure/Tension (Domain on the Intrinsic Motivation Index)

QEHB Queen Elizabeth Hospital Birmingham

RCSQ Richard Campbell Sleep Questionnaire

REC Research Ethics Committee

ReVERe Restorative Virtual Environments for Rehabilitation

SBT Spontaneous Breathing Trial/Test

SF 36 Short Form 36

SIRS Systemic Inflammatory Response Syndrome

SRMRC Surgical Reconstruction and Microbiological Research Centre

SUS System Usability Scale

UK United Kingdom

VAT Visual Analogue Thermometer

VE Virtual Environment

VIDD Ventilator Induced Diaphragmatic Dysfunction

VNT Virtual Nature Therapy

VR Virtual Reality

VRET Virtual Restorative Environment Therapy

VRET-I Interactive Virtual Restorative Environment Therapy

VRET-P Passive Virtual Restorative Environment Therapy

VU Value/Usefulness (Domain on the Intrinsic Motivation Index)

CHAPTER 1: INTRODUCTION

The first chapter of this thesis presents the aims of the research following an introduction with background and context, proposing the concept of the use of interactive technologies to enhance rehabilitation from critical illness and injury on the Intensive Care Unit (Figure 1).

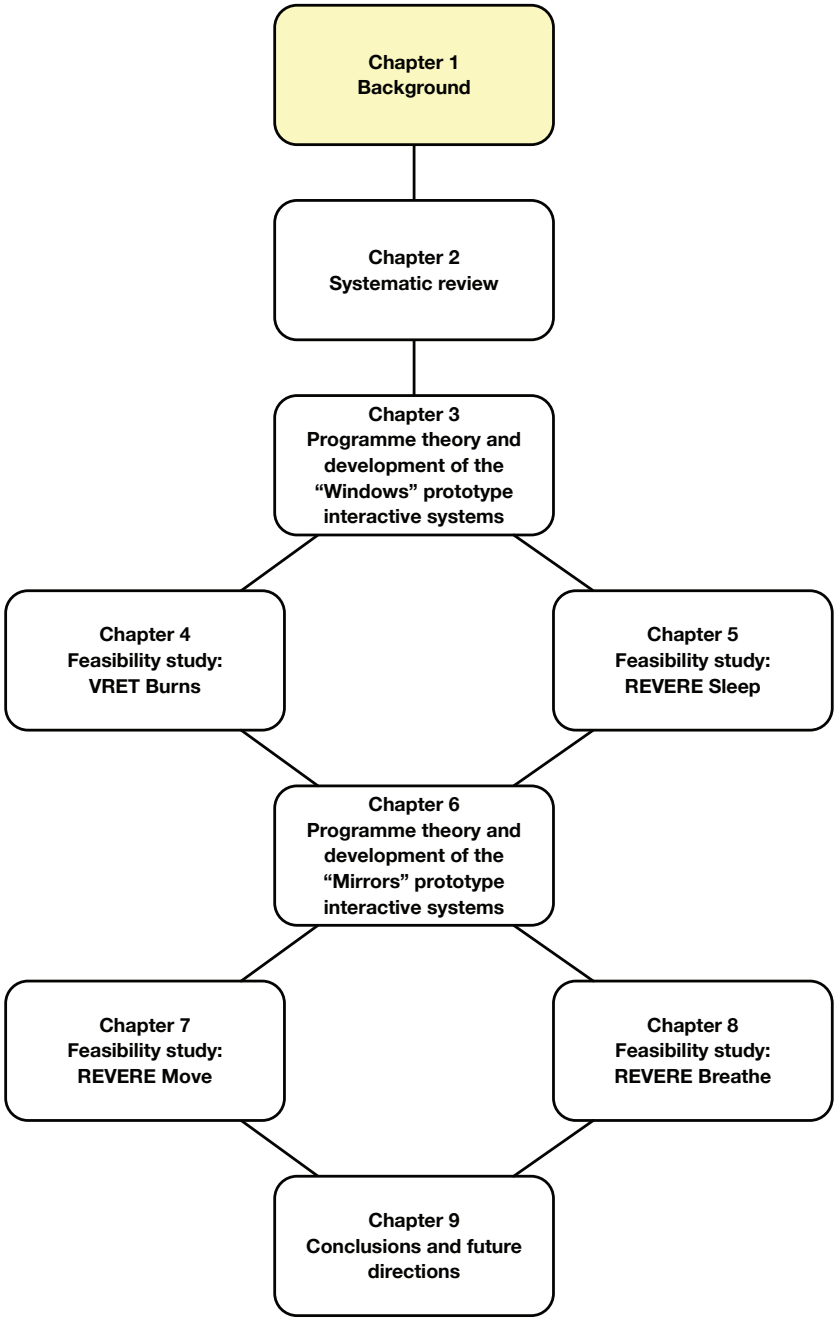


Figure 1.1 Thesis roadmap - Chapter 1

1.1 Setting the scene: The legacy of survival from critical illness

Over 150,000 adults are currently admitted to United Kingdom (UK) National Health Service (NHS) adult Intensive Care Units (ICUs)[1] suffering from critical illness each year, of whom over three quarters survive to discharge from hospital.(1) Critical illness is a term which encompasses life-threatening conditions, including major surgery, complex trauma and severe burns. Intensive Care Units provide advanced levels of organ monitoring and support, both pharmacological and mechanical. Recovery from critical illness is often inconsistent and incomplete, with patients following different trajectories of recovery; from the “big hit” model of major physiological insult with subsequent recovery, to the “slow burn” model of progressive decline, and the relapsing recurring course of acute exacerbations and partial recovery.(2)

[1] Intensive Care Unit (ICU) will be the term used to include intensive care, critical care, high dependency, level 2 and 3 care and specialist burns care.

1.1.1 Anthony’s story (From ICU Steps Patient Survivor Group)

“In March 2010 I came down with a nasty stomach bug whilst on holiday in France. By the time I got home a few days later I felt weak and feverish; my chest was aching. I spent 2 days in bed at home thinking I had a bad dose of man-flu. But my respiratory rate then started to climb and my wife took me to the John Radcliffe hospital in Oxford.

I was diagnosed with community acquired pneumonia in both lungs and put on antibiotics. I remember a consultant saying to me "you've got pneumonia, its a bit rubbish, and you're going to be here for a few days, and then you're going to need to take it easy for a few weeks". I remember thinking "I hope you're right, because I feel truly awful". Unfortunately he was wrong. It was about then that I first realised I was having to fight more and more with each passing hour to get oxygen into my lungs. Slow suffocation from the inside is very frightening.

That night I deteriorated on the ward and was moved to ICU first thing the next morning. I remember, as do many who have posted on the ICUSteps website, the passing ceiling lights as you're wheeled down the hospital corridors. I don't remember much after that, except trying to breath (sic). I fought for breath on a tight fitting mask for 4 days but then my CO2 levels started to rise, I was weakening and so I was sedated, intubated and put on a ventilator. I remained ventilated and sedated in an induced coma for 23 days whilst I and the Oxford ICU team fought my pneumonia. After 18 days I had chest surgery to drain effusions from around both my lungs and my heart. The infection and effusions at last abated and on day 24 I was extubated. But I couldn't cope off the ventilator so I was intubated and sedated again and the following day I had a tracheostomy. I then spent a week being weaned off the ventilator.

From the moment I was extubated on day 24, I was completely delirious, and although its over 3 years since I left hospital, the nightmares are as clear as ever. They revolved around me fighting for breath, fighting to stay with my family, believing many of my friends and family had died due to a global pandemic, travelling to far flung corners of the world to try to get treatment and on several occasions believing that I had run out of options and so having to come to terms with death. I never stopped fighting, but sometimes it felt like check mate. And then I wouldn't die, and the dream would continue.

My wife kept a diary, and I can now reconcile the actual events in the ICU unit and therefore the stimuli around me, with my dreams. The stimuli included all

the ventilator alarms, the other devices keeping you and the other patients around you alive, the conversations around the bed, the phones ringing, and all the blinking monitors and flashing lights.

I post-rationalise now (though there is no science behind this) that my nightmares were the result of my pickled brain trying to make sense of the ICU environment and stimuli and the circumstances I found myself in.

But the nightmares were so real that it needed to be explained to me over and over again in the week after I had come round that my friends and family were alive, that I was in Oxford not South Africa, and that millions of people around the world hadn't died. My wife gave me a radio to listen to, and it was probably the normality of listening to the BBC that convinced me that I had just been really ill. Nothing more, nothing less.

I quickly went from feeling very unlucky to have been critically ill, to very lucky to be alive. But I totally underestimated in my own mind quite how disabled I was. I couldn't walk, couldn't sit up, couldn't speak (until I was allowed a speaking valve in my tracheostomy). Trying to make sense of the world when you can't speak or write is hard - I had so many questions which I couldn't ask. I couldn't move my shoulders - they were totally frozen - and every time I was rolled in bed by the nurses my left leg delivered sharp shooting pains, due to some ossification in a muscle in my left hip, which I have since learnt happens to some people when the body undergoes extreme trauma. I remember sitting in a special chair next to my bed (which the nurses had lifted me into) and I couldn't handle it for more than an hour as the weight of my knees was too much for my wasted calf muscles to bear. I cried to be put back to bed. I was 34 but I felt 94.

None of us think we'll end up in a wheelchair or on a Zimmer frame learning to walk again - until it happens. And even then its very surreal. I couldn't get up off a floor for about 3 months after I came out of hospital. My core muscles were so destroyed that 4 months after coming home I slipped a disc in my lower back which ultimately required micro-discectomy surgery to fix a year later.

I have been very fortunate to have had a lot of help and support through my illness and recovery, and even with that, it was a really long slog. I now have a total appreciation for what people in permanent pain have to endure. I have since made a full recovery, but for some scars and a loss of some flexibility. I have been very lucky." (3)

Reduction in functional ability and quality of life in survivors of critical illness are consequences of persistent physical and non-physical (psychological and cognitive) impairments.(4) In many patients, psychological, cognitive and physical impairments co-exist and interact, with greater physical decline predicting a higher prevalence of adverse psychological symptoms.(5, 6) For the purpose of this research, the adverse consequences of critical illness have been categorised as skeletal muscle performance, respiratory muscle performance, mental wellbeing and pain, with multiple aetiologies contributing to each (Figure 1.2).

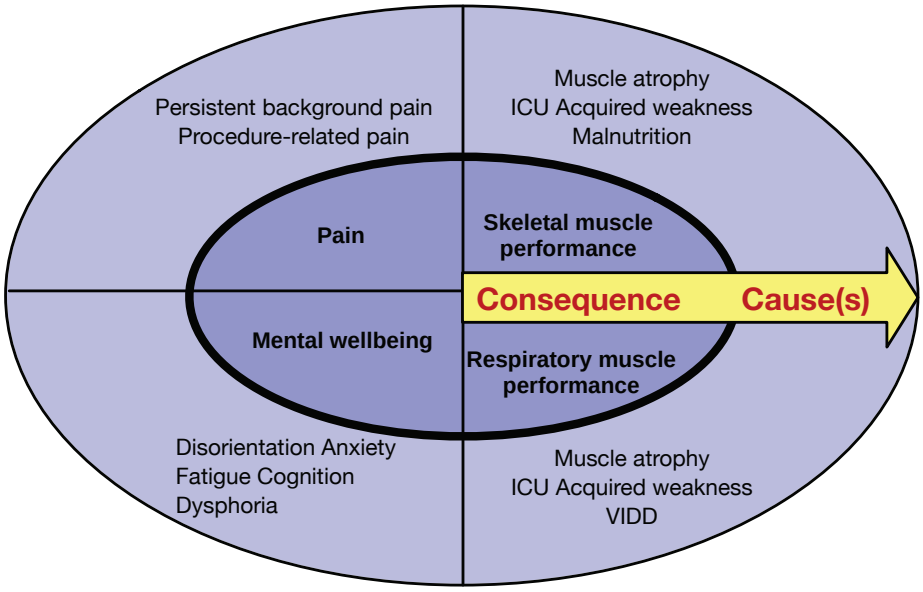


Figure 1.2: Categories of adverse consequences of critical illness and associated causes
ICU Intensive Care Unit, VIDD Ventilator Induced Diaphragmatic Dysfunction

1.1.2 Physical consequences of critical illness

Physical outcomes in patients recovering from Acute Respiratory Distress Syndrome have been shown to be significantly impaired at 12 months and have failed to return to age-matched norms up to five years after discharge from the ICU.(7) Survivors of critical illness have greater ongoing healthcare needs and are less likely to return to work than their peers.(8) Prolonged length of stay and associated immobility are independent risk factors for poor physical outcome following critical illness.(9)

One of the most common physical complications of critical illness, associated with prolonged ICU and hospital stay, is Intensive Care Unit-acquired weakness (ICUAW). This syndrome is evident in 50% of patients who are mechanically ventilated for greater than five days. Defined as bilateral symmetrical limb weakness, ICUAW is an umbrella term encompassing muscle atrophy, polyneuropathy and myopathy and is characterised by loss of muscle filaments, fasciitis and necrosis.(10-12) The aetiology of ICUAW is multifactorial with the main risk factors being duration of the Systemic Inflammatory Response Syndrome, multi-organ failure and mechanical ventilation, with one study reporting 100% incidence in patients suffering sepsis complicated by multi-organ failure.(13)

Impaired respiratory muscle performance is experienced alongside skeletal muscle impairment. This is exacerbated by diaphragmatic dysfunction caused by positive pressure mechanical ventilation, one of the most common therapies

required for patients on the ICU is mechanical ventilation. Although a small minority of ICU patients require prolonged mechanical ventilation, of more than 14 days, they occupy almost a third of ICU bed days, stay longer in hospital and are more likely to die in hospital during their illness.(14) Dependence on ventilatory support is compounded by co-existing lung parenchyma injury, excessive extra-vascular fluid and infection.

1.1.3 Non-physical consequences of critical illness

The most prevalent complications of critical illness include neuropsychological complications, most commonly psychiatric conditions such as somatic-type depression and post traumatic stress disorder, but also cognitive decline.(15) Neuropsychological symptoms are likely to be due to a combination of inflammation, drugs, pain, sleep deprivation and environmental stressors.(9, 16, 17) Depressive symptoms in the ICU predict prolonged dependence on mechanical ventilation and a higher likelihood of death.(18) Long-term brain dysfunction, which manifests as poor executive function and memory deficits, is associated with acute brain dysfunction, such as delirium and coma in the ICU in both short and long stay ICU patients.(19-21)

Patients report that pain is one of the greatest stressors whilst recovering on the ICU.(22) Pain, either intermittent or persistent, is ubiquitous for patients on the ICU. Pain is suffered as a direct consequence of the reason for admission (disease, surgery or trauma) and thereafter as a consequence of treatment. Invasive vascular access, percutaneous tracheostomies and nasogastric

feeding tubes provide continual discomfort for many, exacerbated by therapeutic practice such as suctioning of the trachea. Ineffective pain control has immediate and long term adverse consequences. Pain is associated with mood disturbance whilst on the ICU (23) and recall of pain associated with development of PTSD and anxiety symptoms following recovery and discharge. (24, 25)

1.2 Rehabilitation on the Intensive Care Unit

Whilst death from critical illness has long been the focus of interest for research and quality improvement on the ICU, there is increasing recognition of the importance of improving the quality of survival, regaining and maintaining quality of life, with international stakeholder groups recommending strategies to address both individual and clusters of complications.(5, 26)

The National Institute for Clinical Excellence states, in their Clinical Guideline 83, “Rehabilitation after critical illness":(27)

> *“optimisation of recovery as a therapeutic objective, rather than mere survival, has developed increasing prominence” …“poor-quality rehabilitation and impaired recovery from severe illness should be regarded as a major public health issue”.*

Effective rehabilitation requires a multi-modal, holistic approach, whereby all aspects of the patients’ function are considered, complications recognised and treated in order to enable efficient movement through rehabilitation milestones (Figure 1). Psychological wellbeing can be overlooked in favour of the focus on

achieving skeletal and respiratory muscle performance goals. Mood disorders, fatigue and pain may directly impede physical activity, as well as hindering engagement and motivation.(27)

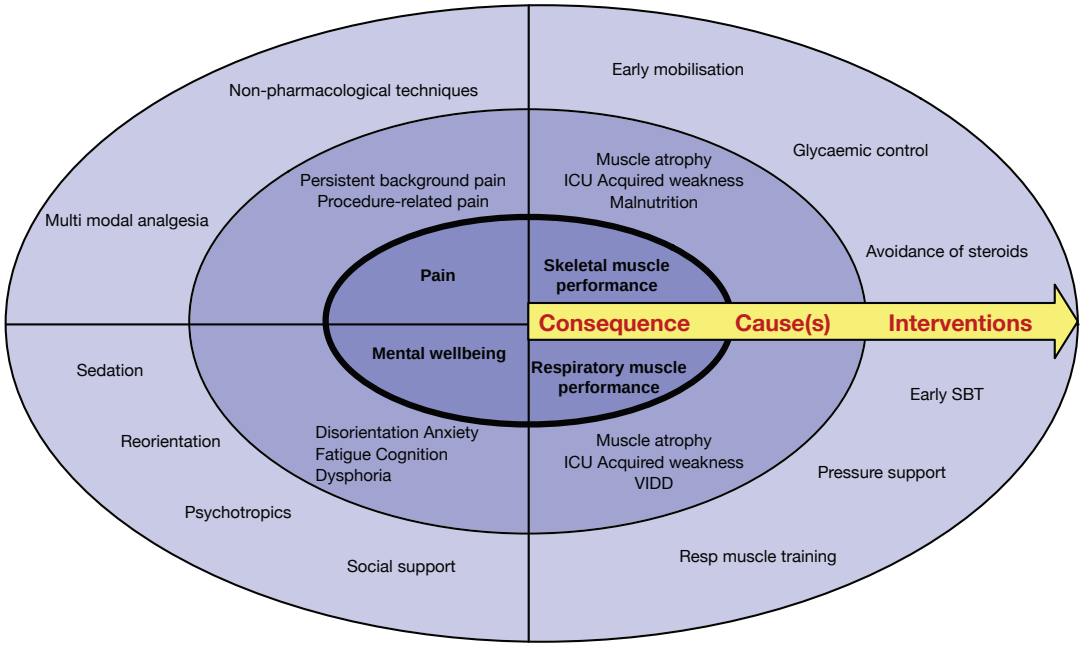


Figure 1.3: Rehabilitation on the ICU: Most common categories of adverse consequences of critical illness, their aetiologies and examples of interventions or treatment strategies
ICU Intensive Care Unit, SBT Spontaneous Breathing Test/Trial,
VIDD Ventilator Induced Diaphragmatic Dysfunction

The National Institute for Clinical Excellence Clinical Guideline 83: “Rehabilitation after Critical Illness” (27) proposed a number of research themes, including:

- In patients at high risk, which therapeutic strategies are the most clinically and cost effective at reducing the prevalence and severity of critical illness-associated physical morbidity, psychological morbidity and cognitive dysfunction?
- In patients with established morbidity, which specific therapeutic strategies are the most clinically and cost effective at reducing the magnitude of critical illness-associated physical morbidity, psychological morbidity and cognitive dysfunction?

Delivery of physical rehabilitation and psychological therapies to patients on the ICU requires staff time and cost, equipment cost and maintenance and the need for the conscious patient to be engaged, motivated and able to perform to the best of their ability. It is, therefore, of importance to ICU patients and their carers that innovative ways of delivering rehabilitation therapies are investigated.

1.3 Introducing Interactive Technologies to aid rehabilitation on the ICU

A potential adjunct to current physical, respiratory, pain and mental well being strategies to aid rehabilitation from critical illness is the application of interactive technologies (iTech). ITech is an umbrella term which includes virtual reality (VR), video games, serious games and cybertherapy. Interactive technologies have been exploited for a variety of medical conditions across a range of healthcare settings. The field of inpatient rehabilitation has seen a number of iTech-based interventions developed to aid management of a variety of conditions; each utilising different interfaces[2] with varying levels of interactivity, complexity and cost.

Developments driven by the computer gaming industry have resulted in rapid advancements in computer systems available to the commercial market. These advances, coupled with increased affordability, portability and accessibility of such equipment, present opportunities to use commercial-off-the-shelf products to develop novel iTech systems for use by patients recovering from critical illness. The complex nature of the rehabilitation needs of the ICU patient lends itself to some of the potential capabilities of an iTech based system, such as versatility and adaptability. The opportunities of using iTech to modify the patient environment and experience in a myriad of ways are appealing, but limitations may prevent their effective use (Figure 1.4).(28) A meticulous, human-centred approach to interactive system design with rigorous evaluation of effectiveness is required to ensure benefit.(29, 30)

[2] An interface device is a hardware components or system that enables interaction with software.

There are, currently, no recognised standards or guidelines informing how iTech systems should be designed, and their use evaluated, specifically for patients recovering from critical illness in hospital. This thesis will explore potential exploitation of iTech for such patients, focussing on the development and prototyping of research methods, which will be used to inform best practice guidance for future research.

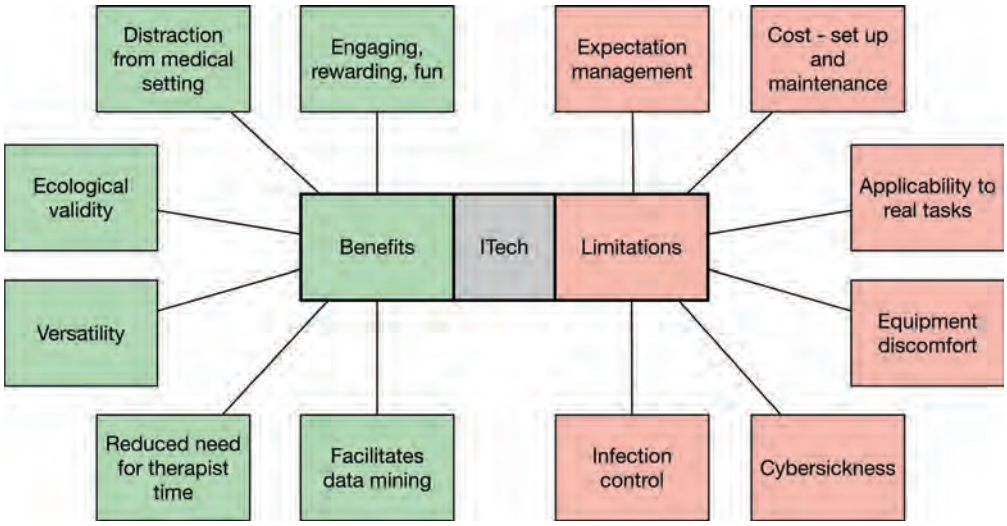


Figure 1.4: Examples of potential benefits and limitations of iTech-based therapy

1.4 Research Programme Aims

The overarching aims of the programme of research are to:

1. Develop prototype research methodologies to aid the design and implementation of prototype iTech-based systems to enhance the rehabilitation of patients recovering from critical illness in the ICU.
2. Evaluate the prototype methodologies developed to aid design and implementation of novel iTech-based systems for use by patients in the ICU.

1.5 Introduction to Human Centred Design and Usability Engineering processes

Human Centred Design (HCD) is an ergonomic-based, multi-stage approach to engineering and design process. Driven by human need rather than technological capability, the aims of HCD are to ensure that novel technology matches the needs and capabilities of the user, is safe and effective in providing the task required of it and is appropriately cost-effective.(30, 31). The principles and activities within HCD are guided by the British Standard, implementing, "Ergonomics of human system interaction."(30) The key tenet of HCD is the process of iteration within the design cycle of a system. This process is supported by methodologies informing design specification, including ergonomic task analysis, user knowledge, skills and attitudes assessment and prototype modelling (Figure 1.5).(32)

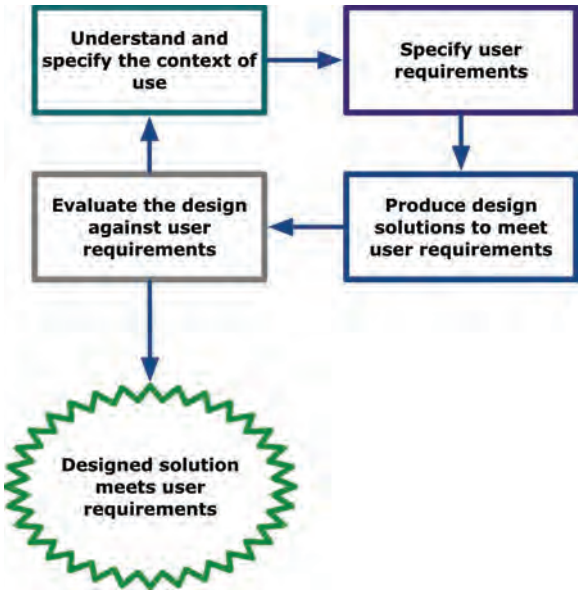


Figure 1.5: Summary of Human Centred Design activities.(BSI, 2010)

In order for an ITech based system to provide benefit it has to be usable and acceptable by the patient and carers within the ward environment.(33) System developers introduced the term “Usability Engineering Process”, described in relation to medical devices within the International Standard “Medical Devices - Application of Usability Engineering Process."(29) This document guides researchers and manufacturers on taxonomy, the strategies recommended to ensure devices are effective, efficient, safe and easy to use, as well as the evidence required by the regulatory authorities of the country of origin or intended distribution to validate and verify claims made about the device.

Widespread demand for iTech devices has produced a vast range of commercially available products with a wide variety of potential applications within the clinical field. Many such devices, including computer gaming consoles, have been evaluated for specific conditions or within specific clinical settings.(34-36) Whilst appealing due to their comparably low cost, these devices have usually been designed to meet the requirements and aspirations of the general public within a domestic setting. Their application within a clinical environment, for patients and staff with differing requirements and capabilities, can be problematic. One such example is the introduction of the Nintendo Wii gaming system to provide rehabilitation exercises within the Intensive Care Unit (ICU). Whilst the use of the system was deemed to be feasible and safe, only 5% of patients receiving physiotherapy on the ICU received the Wii system. For the most part this was due to usability constraints. The patients needed to be standing unassisted to play the games, with many being too weak to manage

this. The system itself was also found to be time consuming to set up, so its use was restricted where, in common with many settings, physiotherapy sessions were time-limited.(37) For the use of a device to be feasible, it has to be accepted by its users. The technology acceptance model states that technology uptake is affected by a variety of factors, including perceived usefulness, computer skills and self-efficacy. These may be evident in both the patient users and their carers.(33, 38)

As well as adapting commercial-off-the-shelf products, bespoke systems have been developed for use in the clinical settings. The advantages of such systems are that equipment can be designed specifically to meet the capabilities and requirements of the user. These are often more expensive and require specialist skills to use and maintain.(28) An example of such a system is the Computer Assisted Rehabilitation Environment system [Motek BV, Amsterdam, The Netherlands]; composed of a large 120 - 360 degree curved screen on which virtual reality projections are imposed, a six degree of freedom motion platform and a motion analysis system, which enables the user to interact contemporaneously with the VR environment for balance and prosthesis training. (39, 40) Whilst impressive and potentially beneficial to those who can access it, the size, cost and accessibility of such a suite limits its applicability to most institutions, with less than 20 units currently installed across the world.

1.6 Building the research framework: Interactive systems as complex interventions

The use of an interactive system by patients will be influenced by its context of use; the ward environment, the support provided by staff caring for the patient and the attitudes of the patients themselves to the perceived benefit of the intervention. Thus, such a system is described as a “complex intervention.” Guidance for the development and evaluation of complex interventions has been produced by the Medical Research Council (Figure 1.6).(41, 42)

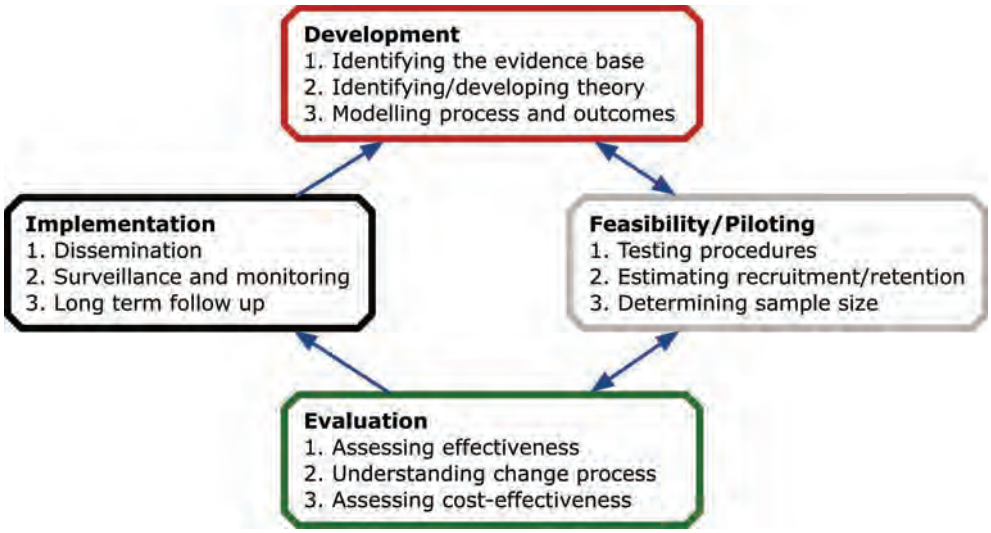


Figure 1.6: Outline of Medical Research Council framework for evaluation of a complex intervention.

The first methodological outcome for the research programme was the creation of a framework, combining HCD process with programme theory and evaluation via a clinical research trial, to be used at the commencement of the design process (Figure 1.7).

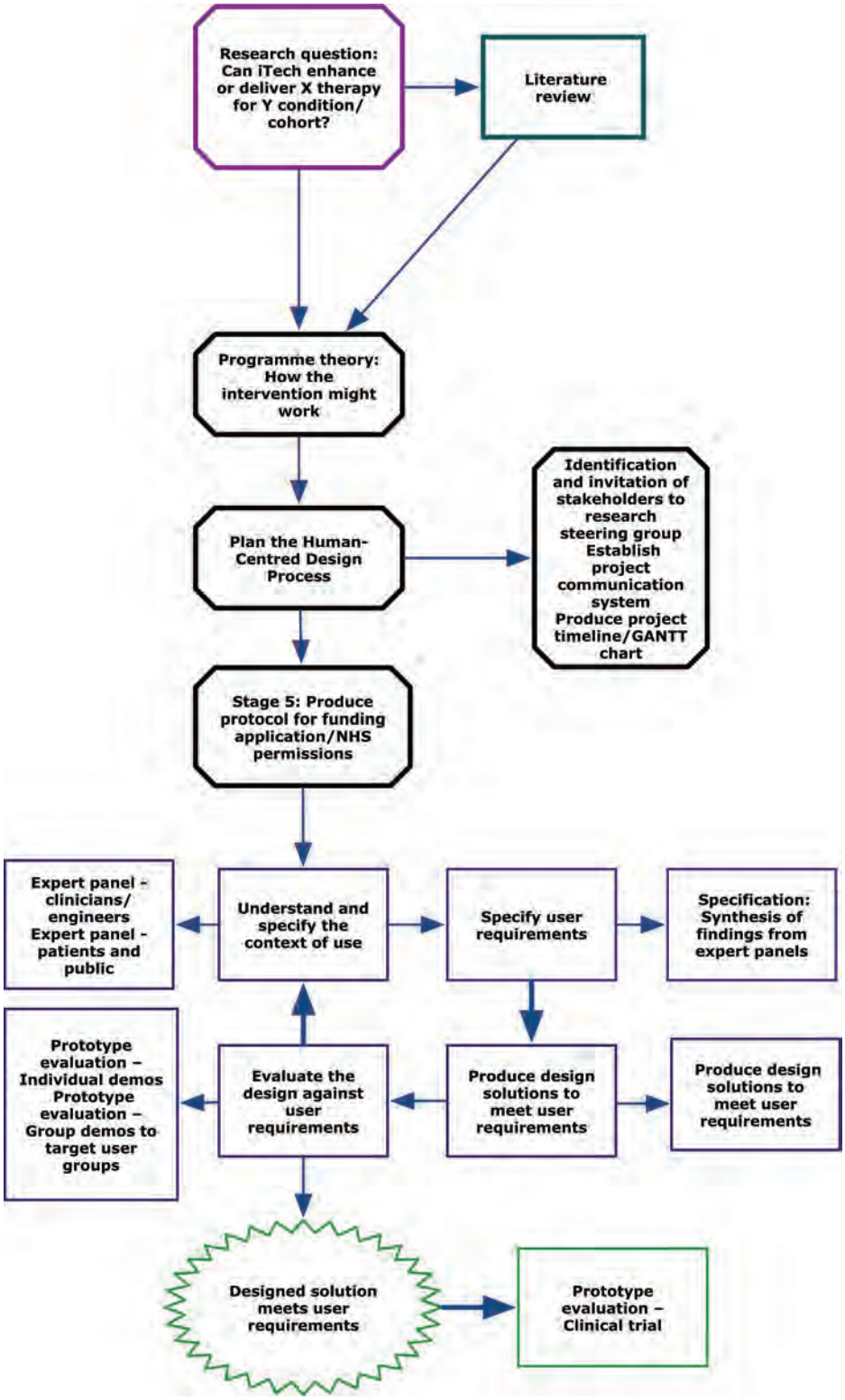


Figure 1.7: Framework for the development and evaluation for novel interactive systems for patient use

The thesis structure presents a series of studies recording the development of the processes within the aforementioned framework (Figure 1.7). Each chapter details the development of methodologies, their exploitation within the context of the research questions and clinical scenarios, followed by post hoc evaluation in order to provide a narrative of lessons learned informing application for future research.

After setting the research questions, the next stage in the process was to undertake a review of the current evidence in the field of interest in. For clinical research, the “gold standard” approach is to complete a systematic review. For this research, the systematic review would need to evaluation of both clinical effectiveness and the design and implementation science.

The next stage of the research critiques the current knowledge on the exploitation of interactive technologies for use on the ICU, in particular the methodologies used for system design and implementation, whether they were safe and usable in the ICU environment, whether, how and when they worked.

CHAPTER 2 SYSTEMATIC REVIEW OF THE FEASIBILITY AND EFFECTIVENESS OF INTERACTIVE TECHNOLOGIES TO AID PATIENT TREATMENT AND RECOVERY IN AN ACUTE HOSPITAL SETTING FROM ILLNESS, INJURY OR BURNS

Chapter 2 presents a systematic review of the feasibility and effectiveness of interactive technologies to aid patient treatment and recovery in an acute hospital setting from illness, injury or burns (Figure 2.1).

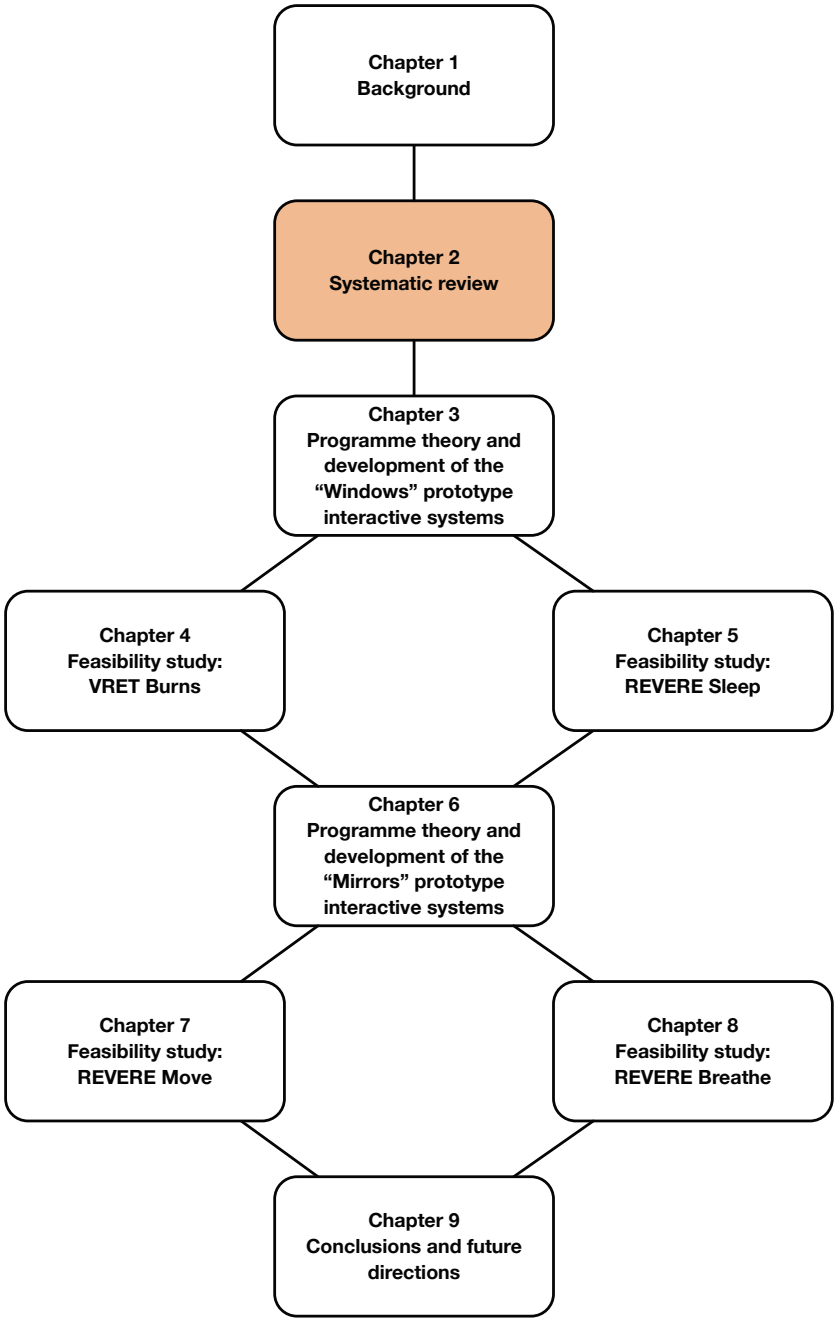


Figure 2.1 Thesis roadmap - Chapter 2

2.1 Introduction

Prior to the development of iTech systems for use on the ICU, it was necessary to synthesise and critique current evidence relating to the use of interactive devices by patients recovering from critical illness. A scoping review identified only four studies undertaken in adult ICUs. As this research is interested in the feasibility of introducing iTech to a clinical environment, particularly relating to development and evaluation process, there are sufficient similarities in the context of use and user capabilities to allow comparison across all inpatient patient groups. Thus, this review examines the feasibility and effectiveness of interactive technologies to aid patient treatment and recovery in acute hospital inpatients (adults and children) receiving interventions or treatment in an acute hospital setting, including critical care, for illness, injury or burns compared to standard care (Table 2.1).

2.2 Objectives

1. To determine the design and engineering processes integrated into the prototype design and trial protocol of iTech systems to aid patient recovery.
2. To examine the effectiveness of providing patients iTech-based interventions to improve their physical or non-physical recovery.
3. To synthesise a framework to describe the mechanisms of iTech-based interventions and their contextual mediators.

Table 2.1: PICO tool developed to inform the methodology of the systematic review

Participants	Acute hospital inpatients (adults and children) receiving interventions or treatment in an acute hospital setting, including critical care, for medical illness, injury or burns.
Interventions	Interactive technology (iTech)-based devices; including computer games, video games and virtual reality systems, where the patient interacts with the device.
Comparators	Standard care, to include: 1. Where the iTech device has been developed as an equivalent or superior alternative to an accepted clinical intervention. 2. Where the iTech intervention has been developed as an adjunct to standard care.
Outcomes	Primary outcome(s) I. Use of a human-centred design process to inform prototype development II. Feasibility of the use of iTech devices within the physical environment of the acute hospital setting. III. Usability of iTech devices by patients during early rehabilitation from illness, injury or burns. IV. Usability of iTech devices by staff caring for patients during early rehabilitation from illness, injury or burns. V. Safety of iTech device use by patients during early rehabilitation from illness, injury or burns. VI. Safety of iTech device use by staff caring for patients during early rehabilitation from illness, injury or burns.
	Secondary outcomes I. Effectiveness of ITech devices to improve non-physical recovery from critical illness, major trauma or severe burn, to include pain, sleep, mood, cognition and communication. II. Effectiveness of ITech devices to improve physical recovery from critical illness, major trauma or severe burn, to include mobility, balance, strength, coordination and cardiorespiratory fitness. III. Mediators and contextual modifiers of user acceptance.

2.3 Review questions

I. With respect to the use of interactive technologies to aid patient recovery in the acute inpatient setting:
    1. Were HCD or usability engineering processes used during prototype development?
    2. Are interactive technologies feasible for use in the physical environment of the acute hospital setting?
    3. Are interactive technologies usable by patients?
    4. Are interactive technologies usable by staff caring for patients?
    5. Are interactive technologies safe for use by patients?

II. Are interactive technologies effective in aiding patient non-physical recovery from illness, injury and burns?

III. Are interactive technologies effective in aiding patient physical recovery from illness, injury and burns?

IV. How might the iTech interventions work and what are the potential mediators and contextual modifiers affecting the likelihood of successful adoption of iTech based systems for patient use in an acute hospital setting?

2.4 Methods

2.4.1 Guidelines and protocol registration

The Preferred Reporting Items for Systematic Reviews and Meta-analyses checklist for reporting systematic reviews was adhered to during the design and execution of this review.(43) A full description of the systematic review methodology was published as a protocol in advance of commencement of the database searches on PROSPERO, the International Register of systematic reviews (protocol number CRD42017072074).

2.4.2 Information sources and searches

The thesis author (CS) completed searches of all databases listed in table 2.2, using the search strategy and search terms listed in Appendix 1. The final search was completed on the 30th November 2017. Studies were entered into EndNote X7 and duplicates removed.

Table 2.2: Sources searched for literature

Sources	Unpublished studies
1. PUBMED 2. CINAHL 3. AMED 4. Scopus 5. PEDRo 6. Science direct 7. Web of Science 8. Google scholar 9. Ovid 10. IEEE 11. Cochrane/CENTRAL	1. clinicaltrials.gov 2. Current controlled trials 3. WHO Clinical Trials Registry 4. EU Clinical Trials register 5. Grey literature • ResearchGate • Conference proceedings • Direct author communication

2.4.4 Inclusion and exclusion criteria

Screened trials included all those with acute hospital inpatient populations, both adults and children, published in the English language. The intervention was defined as any interactive device, used by the patient with a therapeutic objective, such as video games, cybertherapy and virtual reality (VR). All trial designs, apart from study protocols, opinion papers and non-systematic reviews without original participant data, were included with no date restriction.

Well-subject, bench tests and laboratory based studies, interventions incorporating hypnotherapy and those where the invention intent was to manage chronic, degenerative disease in adults or congenital neuromuscular conditions in children were excluded. Studies where the sole cohort were stroke survivors were excluded, as stroke patients were the subject of a recent Cochrane review.(35)

2.4.5 Study selection

The titles and abstracts were screened by two independent reviewers with reference lists of retrieved papers hand searched for additional studies (CS, Catherine Snelson (CSn)). Online trial registries were screened for ongoing and unpublished studies and the corresponding authors contacted for further trial information as required.

2.4.6 Data extraction and risk of bias in individual studies

A data collection form was used to extract all data. The data extraction form was based on the following published risk of bias tools:

1. Randomised Controlled Trials: The Cochrane collaboration risk of bias tool and (http://handbook.cochrane.org/chapter_8/table_8_5_d_criteria_for_judging_risk_of_bias_in_the_risk_of.htm).(44)
2. Case series: Criteria from Chambers et al (45), based on Cochrane Handbook for Systematic Reviews of Interventions.(44)
3. Qualitative studies: The CASP tool for qualitative studies (http://media.wix.com/ugd/dded87_29c5b002d99342f788c6ac670e49f274.pdf).

This form was piloted independently by two reviewers (CS, Joyce Yeung (JY)), using three papers, and amended prior to use for subsequent completion of data extraction. Data extraction was completed by two reviewers for each paper, then compared (CS, CSn, JY, Rochelle Velho (RV), Joe Alderman (JA)).

Data from studies with multiple publications were extracted and reported as a single study. In cases of data discrepancies the most recent publication was utilised. Disagreements about study selection and data extraction were resolved by a third independent reviewer (Julian Bion (JB)). In the event of inconsistent, incomplete or ambiguous data, the corresponding author was contacted for clarification.

Data extracted included:

1. Characteristics of the trial participants, including the location and type of facility.
2. The intervention type and fidelity, in an attempt to ascertain precisely what the participants were exposed to, analogous to the dose of a drug, as well as the control condition.
3. Processes undertaken to inform and evaluate the design specification or selection of iTech intervention.
4. Outcome measures used: type and timing of use, both clinical (measures of effectiveness and side effects) and non-clinical relating to, for example, usability and safety.
5. Qualitative data on factors influencing successful use and effectiveness of the technology.

For the purpose of this review the process and methodology described in each study were categorised as follows:

Human Centred Design Process:

1. Complete: Adherence to an international or national standard (eg BS EN ISO 9241-210 (30)) where the standard is referenced and there is evidence of adherence.
2. Partial: HCD process used, adhering to some elements of an international or national standard.
3. None: No evidence of HCD approach to device design.

Usability Engineering Process:

1. Use of usability assessment tool(s) which has/have been validated for use in an acutely ill patient population.
2. Use of usability assessment tool(s) are validated/undergo analysis of reliability during the study.
3. Use of a non-validated instrument to assess usability.
4. No usability assessment.

2.4.7 Synthesis of results

An early scoping review identified that study types were varied, with a predominance of mixed methods case reports, case series, feasibility and pilot studies and discrete yet heterogeneous study populations and interventions. A meta-analysis was not appropriate because of the heterogeneity in study design and measures. We therefore employed narrative synthesis of quantitative data (46) on user experience, safety and effectiveness, and qualitative data on human centred design, usability engineering process and user experience.

Textual narrative synthesis allocates studies into homogeneous groups and facilitates explanation of findings whilst comparing similarities and difference across different studies. It is most useful for synthesising highly heterogeneous evidence, where use of methods leading to the development of theoretical models, such as meta-ethnography, may generate misleading results and have limitations in terms of reproducibility and transparency.(46, 47) In these settings textual narrative synthesis generates a coherent account of research findings,

processes and structures used to develop and evaluate novel systems. Qualitative data underwent thematic analysis ,(48) using NVivo for Mac software (QRS International), to synthesise a framework illustrating mechanisms of effect, contextual modifiers, barriers and enablers to use of iTech in an acute hospital setting.

2.5 Results

2.5.1 Study selection and characteristics

Database searches identified 7761 papers with a further 43 relevant publications identified via hand searching of bibliographies. Following removal of 1472 duplicates, 6332 titles and abstracts were screened. A total of the 61 publications met the inclusion criteria for review of the full paper, of which 31 were excluded (Figure 2.2).

Studies were categorised according to intended treatment benefits of the iTech intervention:

1. Studies where the aim of the iTech intervention was to improve non-physical consequences of illness.
2. Studies where the aim of the iTech intervention was to improve the physical consequences of illness.

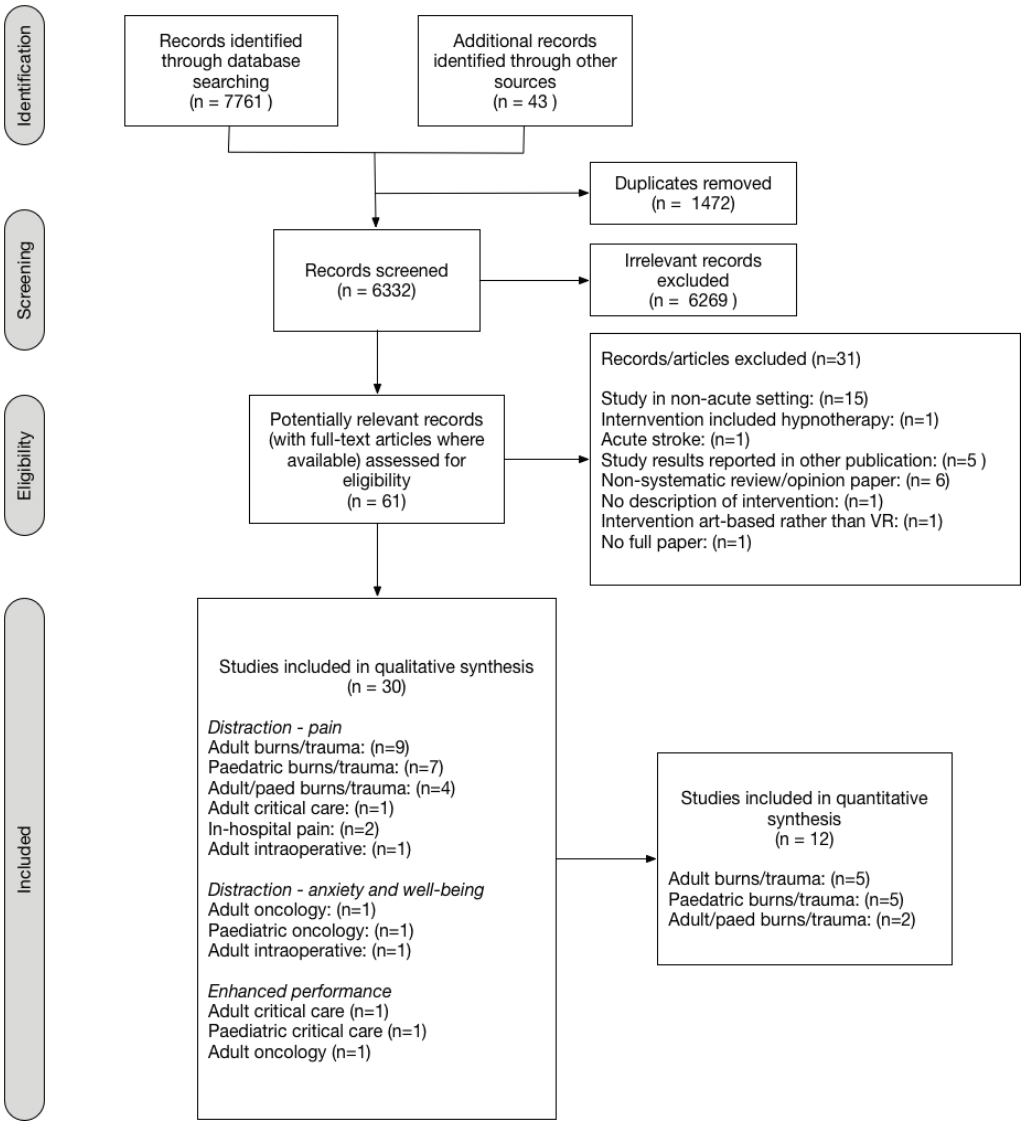


Figure 2.2: Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram

2.5.2 Description of included studies

There were 27 studies addressing the management of non-physical consequences of illness (hereafter referred to as “non-physical studies”), the majority investigating the effectiveness of iTech for distraction during painful procedures, with three studies addressing anxiety and mental wellbeing. (Appendix 2) Of these, 13 were used during wound care, including one operative repair following childbirth (episiotomy). Six papers reported devices designed to ameliorate pain during physical therapy for restrictive injuries and three were used for patients in pain due to medical illness.

There were 14 controlled trials, including four pilot (49-52) and eight complete RCTs with a total of 255 patients (Table 2.3).(53-60) There were four feasibility studies.(61-64) Of the studies investigating the use of iTech to alleviate anxiety, two were carried out in oncology units (65, 66) and one used intraoperatively during joint replacement under regional anaesthesia.(67)

Three studies addressed the management of physical consequences of illness (hereafter referred to as “physical studies”) (Appendix 2). One mixed methods exploratory study investigated the use of an interactive system to enhance physical function during treatment for cancer.(68) There were two ICU-based feasibility studies, one adult (37) and one paediatric (69) cohort, one adult and one paediatric, with a total number of 22 and 12 patients respectively.

Table 2.3 Description of Randomised Controlled Trials of ITech to relieve procedure-related pain

Study	Cohort	Centre	n	Intervention	Pain outcome tool
Carrougher 2009	Adult burns	Harborview Medical Centre, Seattle, USA	41	SnowWorld	0-100 GRS
Das 2005	Paediatric burns	Women and Children's hospital, Adelaide, Australia	9	Point and shoot video game	FACES 0-10 VAS
Chan 2007b	Paediatric burns	Chang Gung Memorial Hospital, Tao-Yung, Taiwan	8	Point and shoot video game	FACES
Hoffman 2000b	Adult burns	Harborview Medical Centre, Seattle, USA	12	SpiderWorld	100mm VAS
Hoffman 2008	Adult/ paediatric burns	Harborview Medical Centre, Seattle, USA	11	SnowWorld	0-10 GRS
Hua 2015	Paediatric wound care	Wuhan Medical Care Centre for Women and Children, Hubei, China	65	Ice Age 2 video game	FACES
Kipping 2012	Paediatric burns	Royal Children's Hospital, Royal Brisbane and Women's Hospital	41	Chicken Little video game	10cm VAS
Maani 2011a	Adult burns	Brooke Army Medical Center, Texas. USA	12	SnowWorld	0-10 GRS
Parker 2016	Adult burns	Royal Perth Hospital, Western Australia	22	Nintendo Wii	0-10 VAS
Schmitt 2011	Paediatric burns	Harborview Medical Centre, Seattle, USA	54	SnowWorld	0-100 GRS
Van Twillert 2007	Adult/ paediatric burns	Martini Hospital, Groningen, Netherlands	19	SnowWorld	10cm VAT
Voon 2016	Adult burns	Royal Perth Hospital, Western Australia	30	Nintendo Wii	0-10 VAS

2.5.3 Description of Interventions for non-physical consequences

Applications of iTech to improve non-physical consequences of illness were categorised into two groups; relief of pain and anxiety and mental wellbeing. Systems varied in complexity and cost. The lowest cost systems used commercial-off-the-shelf video games, often delivered via Head Mounted Display (HMD), with the premise that these increase effectiveness of the distraction.(59, 60, 62, 70) Other groups used HMDs to deliver novel purpose built games.(49, 50)

The pain relieving studies were dominated by Hunter Hoffman's team, who have developed the SnowWorld system (Figure 2.3). The team first developed SpiderWorld as psychological therapy to treat arachnophobia, but then investigated its potential to distract the user from acute procedure-related pain during burns dressing changes.(53, 71)

Figure 2.3: Screenshot from SpiderWorld

Laboratory testing supporting their hypothesis that exposure to a cold virtual environment produced analgesic effects in the thermally injured lead to their next prototype system, SnowWorld. This system was adapted for use in a functional Magnetic Resonance Imaging (fMRI) scanner (72) and the hydrotank, where immersion in water is used to facilitate dressing removal and debridement.(73) SnowWorld and SpiderWorld have been delivered via a variety of systems, including different visual displays and interface devices. Early studies used an HMD with external position sensors to enable motion tracking.(53, 55, 58, 63, 71) with later studies using either HMDs with embedded tracking systems.(56, 58, 61, 74, 75) or a bespoke waterproof HMD for use in the hydrotank.(54, 57, 76)

Another approach to delivery of virtual reality-based experiences was the use of “cybertherapy” environments, developed for healthcare uses, including a multi-environment system produced by the team at the Virtual Reality Medical Centre in San Diego, and used on one of the ICU-based studies.(77) Their initial feasibility study used a commercial-off-the-shelf Virtual Environment (VE) system,(64) in advance of their comparative cohort trial using the purpose built system “Pain RelieVR.”(78)

The use of VR systems delivered by HMD to elucidate relaxation were used by the two adult studies investigating their effect on anxiety during inpatient treatment.(66, 67) The most complex of the iTech interventions evaluated was a therapeutic play system, where video projectors, computer visual algorithms

and real-time special effect systems of video games are used to transform walls, ceilings and floors into interactive playgrounds for children undergoing treatment for cancer.(65)

2.5.4 Description of Interventions for physical consequences

All the trials investigating the use of iTech to enhance physical recovery used the Nintendo Wii gaming console with a variety of games marketed for fitness and entertainment. Only one trial stipulated the game chosen by all patients,(69) others used a variety of games depending on the body area to be exercised. In all but one study,(52) direct supervision was provided by the physiotherapist, in one case with the researchers participating in the exercises themselves.(68)

Although commercially designed as “exergaming” systems, an Australian team examined the exploitation of the Nintendo Wii Sports Pack to improve patient experience during active physiotherapy following burn injury. The choice of game was determined by the location of the burn and exercise goal, eg, tennis and boxing for upper limb and step up or yoga for lower limb.(51, 52)

2.5.5 Description of control conditions

The majority of the “non-physical” controlled trials used standard clinical care, eg protocol-driven analgesia, as their control condition. Some of the VR-based trials used alternative methods of distraction, including non-VR video games, for comparison, such as the Nintendo 64 based “Wave Race 64”,(53) or two-

dimensional videos.(78) The controlled pain studies exhibited variation in duration of exposure to intervention and the relationship between intervention and control. For example, many of Hoffman's early studies divided each wound care session into two three-minute segments, with control and VR exposure provided in random order.(54, 71, 79) Later trials also used a within-subject design, but alternated the intervention between sessions.(55, 59-61, 74, 75, 80)

2.5.6 Synthesis of results

2.5.6.1 Use of Human Centred Design and Usability Engineering process

The majority of studies used elements of Human Centred Design (HCD) process to inform the design or choice of system (Figure 2.4) (Appendix 3).

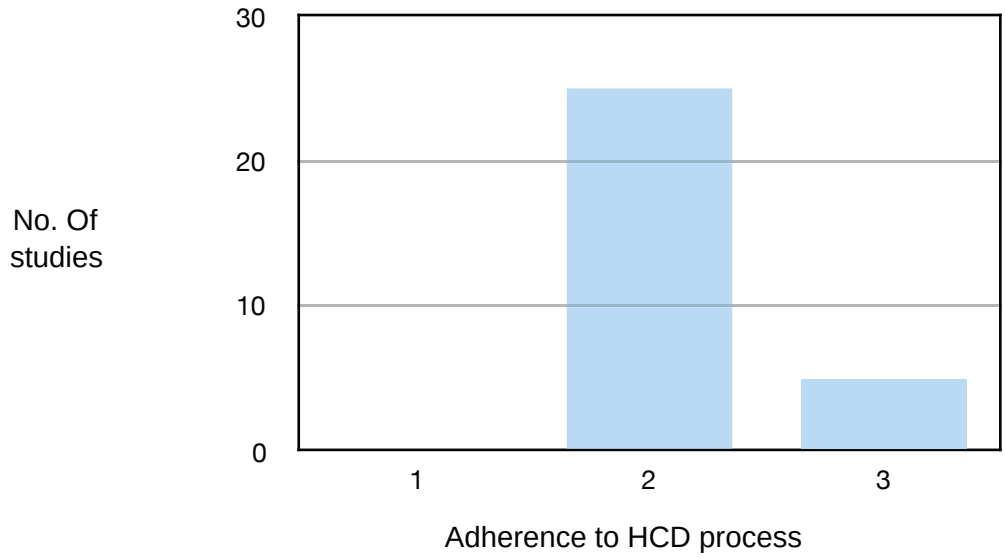


Figure 2.4: Number of studies reporting Human Centred Design process

1. Complete: Adherence to an international or national standard (eg BS EN ISO 9241-210 (BSI, 2010)) where the standard is referenced and there is evidence of adherence.
2. Partial: HCD process used, adhering to some elements of an international or national standard.
3. None: No evidence of HCD approach to device design.

Overwhelmingly, these processes were scanty in content and description, mainly limited to choosing systems which were affordable and designed for comparable purpose in general, domiciliary use.(37, 51, 52, 68) The research group investigating the use of “Wii-Hab" for patients on paediatric ICU did consider the environmental context of the intervention, in selecting games appropriate for use in bed,(69) noting that it was challenging to select a video game which a patient is able to play whilst receiving treatment and medication.

Within the context of this review, the exemplar reports of HCD process have been submitted by the developers of SnowWorld, describing in detail bench testing and usability assessments of hardware and the virtual environments.(72, 81, 82) Their approach has been to develop a system for use in burns patients which, whilst does not reference any HCD standards, follows many of the recommendations, including iterative design cycle informed by a multidisciplinary team.

Other teams who designed bespoke systems also described HCD process, including the Australian study, which stated:

> *“The developers considered the applicability of the game through varying age groups, gender, intelligence and intellectual capacities, while designing the game. The game tried to achieve effective distraction via immersion without violence and a simplified game structure requiring minimal control by the player, to allow the smallest possible movement during the dressing change procedure.”(49)*

One research group designed their “ice cream factory” software based on Hoffman’s principles of exposure to cold environments increasing thermal pain tolerance. Their research used a two phase approach, with phase one describing the prototype development. Their reported HCD processes included:

> *“The design of the game took into account the children’s age group, their psychomotor developmental abilities, the intellectual capabilities of the prospective players and the complexity of the game…all of the motions were designed to be in a continuous flow. An input device with the use of a mouse facilitated ease of control through a gentle pressing movement. Hence, abrupt and possibly jerky movements from the manoeuvre were minimized.”(80)*

The PainRelieVR system was developed with some consideration to its usability and usefulness:

> *“We selected the Samsung Gear because it is commercially available, widely used, relatively inexpensive, has minimal visual latency, and offers a generally positive patient experience based on our previous research. Higher-end tethered headsets, such as the Oculus Rift, are currently more expensive and onerous to use at scale in an inpatient setting.”(78)*

With VR modules,

> *“selected because they contain minimal triggers of emotional distress or motion sickness, present a wide range of visual and auditory stimuli, and are considered pleasant experiences by typical users…We placed sanitary disposable fabric covers on the VR goggles for each individual user, and fitted head caps on patients to minimize direct contact with the device—precautions recommended by our infection control department.”(83)*

Most studies assessed some aspect of device usability, although many limited the assessment to successful and unsuccessful use, often related to patient refusal, or overall satisfaction (Figure 2.5)(Appendix 3).

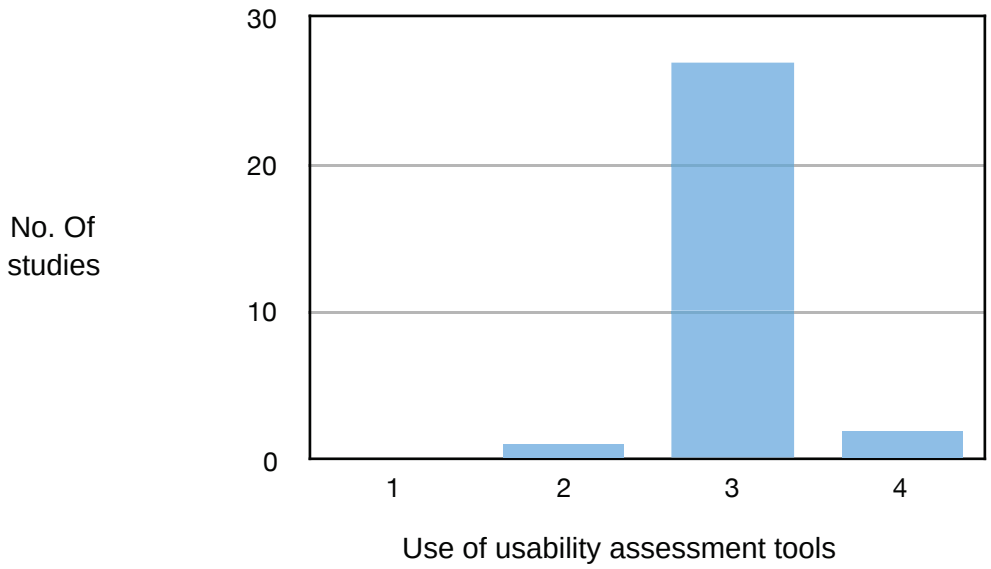


Figure 2.5: Number of studies reporting Usability Engineering process
1. Use of usability assessment tool(s) which has/have been validated for use in an acutely ill patient population.
2. Use of usability assessment tool(s) are validated/undergo analysis of reliability during the study.
3. Use of a non-validated instrument to assess usability.4. No usability assessment.

Hoffman's research evaluated presence, the sense of "being there" in the virtual environment and realism in many of their studies.(84, 85) Whilst these metrics are specific to the concept of virtual reality, their evolution does inform knowledge on user experience.

An important descriptor when considering feasibility of an intervention is set up time, particularly in the ICU setting, where therapist time its limited and patients are most dependent. Kho's paper reported that set up time was a negative

factor for the physiotherapists choosing the Nintendo Wii for the therapy session,(37) although others reported that no additional time was required during the physiotherapy session.(86)

The most rigorous of usability assessments was carried out by Chan et al.(80) who used and modified via an iterative process analysing reliability, the usability and modified presence questionnaires.

2.5.6.2 Feasibility in an acute hospital setting

The conclusions of all the feasibility and controlled trials were that the systems were feasible for use, but many defined this on the basis of absence of safety events rather than to the higher standard of whether a device was usable in routine practice (Appendix 4). Faber et al. (63) demonstrated that their system was used repeatedly, with 17/36 patients completing three or more sessions of VR-based distraction during their inpatient stay. In her ICU paper, Michelle Kho declared the Nintendo Wii intervention feasible, yet only recruited of 5% of patients screened over 11% of total physiotherapy interventions. This was largely due to physiotherapist opinions of the patients' therapy needs and time taken to set up.(37) The majority of papers reported very low drop-out rates during their studies, and those that did cited reasons such as medication-related drowsiness, clinical deterioration , discharge from ICU and device-related discomfort.(49)(69)(66) All reports of discomfort related to the use of Head Mounted Displays causing pain or nausea.(66-67,83) The highest refusal rate was noted in the HMD VR-based study of medical inpatients by Mosadeghi et al

(83), whose recruitment rate of 5.9% of 510 screened included a 66% refusal rate. Reasons for refusal included poor understanding of the purpose of VR, anxiety about using the HMD, fatigue, fear of losing control and concerns that the trial of VR was a psychological experiment. Those who were willing to take part were younger than the refusers (mean 49.1, SD 17.4 years versus mean 60.2, SD 17.7, p=0.01).

2.5.6.3 Usability by patients and staff

Some papers discussed device usability but few evaluated it systematically(Appendix 4). One aspect of staff usability is the ease of set up, which has been reported favourably for gaming systems in terms of no additional time required treatment delivery (62) and unfavourably for bespoke medical VR systems, due to technical difficulties and cumbersomeness.(49, 61) Choice of HMD as the visual display, as well as hand controllers as the interface device for distraction-based interventions excluded those with facial, ear, scalp or hand wounds from participating in a number of studies.(49, 55, 56, 58, 59, 61, 62, 78, 83) In the study by Jahn et al (68) 28 participants completed semistructured cognitive debriefing interviews. Patients reported few issues with usability, apart from difficulties in achieving focus on the images. In their study of the impact of the iTech-based intervention “Visual Parks” on well-being during inpatient treatment for cancer, Banos et al.(67) reported results of 10 point Visual Analogue Scales measuring user-reported satisfaction with the device, in addition to supporting evidence from pre- and post intervention questionnaires. All satisfaction scores were greater than 5/10, but with negative comments

reporting difficulties with navigation restrictions, and use of the system whilst lying in bed. Concentration whilst using the device was hampered by disturbance by noise from the ward environment.

There were very few negative reports of usability using gaming systems, with parent-supported independent use of a Nintendo Wii by children on ICU.(69) Patients were able to use a Microsoft Xbox system independently on the ward, reporting high user satisfaction scores (mean 8.3/10).(52)

2.5.6.4 Safety

All papers reported the patients' experiences of side effects and device-related adverse events.(Appendix 4) Consideration was given in some reports to contextual risk such as infection control (51, 52, 61, 78, 83) and the potential risk of seizures, with exclusion of those at high seizure risk from trial participation in all studies. Hoffman's research team report an almost complete absence of unwanted effects, including nausea, during their evaluation of SpiderWorld and SnowWorld.

Whilst the concept of cybersickness, thought to be attributed to sensory conflict theory,(87) has been reported during the use of VR systems, it was absent in most studies. This may be a consequence of improved software design and responsiveness to head tracking, or the exclusion of those patients at highest risk of cybersickness, such as those susceptible to motion sickness.(52, 58, 78, 83, 88) Within the 67 patients who experienced the relaxing "cybertherapy"

environments developed by the Virtual Reality Medical Centre in San Diego, three reported nausea.(77) Oncology patients reported tiredness relating to the required positioning during the hour-long exposure to “Emotional Parks.”(66) In their evaluation of the use of Nintendo Wii for children (median age 11 years, range 3-16 years), mean parental assessment of intervention safety was 6.9/7 (SD 0.4), although there were no reported adverse events and their participant numbers very small.(69) The Nintendo Wii was shown to be safe for distraction and physical therapy in both adult and paediatric ICU environments, even with patients who were awake but mechanically ventilated.(37, 69, 77)

2.5.6.5 Effectiveness of ITech interventions to aid non-physical recovery

Meta analysis of results was not possible due to differences in outcome measures and study interventions. Hoffman’s team assess pain in a triad of components, affective (unpleasantness/bothersome), cognitive (time spent thinking about pain) and sensory (worst/average). All studies reported positive findings in terms of improvements of pain experience. While they presented a statistically significant reduction in group difference in pre- and post-intervention scores, Parker et al’s (51) 13mm reduction is below the clinical threshold of 33%.(89) Similarly, Kipping defined their sample size based on a 2/10 point reduction in pain scores, reducing the clinical applicability of results.(59) Nonetheless, two studies reported both clinical and statistically significant improvements.(55, 58)

Pain following sternotomy and cardiac surgery can lead to cardiovascular and pulmonary complications if poorly managed. In their pre- and post-exposure analysis, Mosso-Vasquez (77) demonstrated reduction in pain scores in 88% of those exposed to one of six virtual environments for 30 minutes, with a mean reduction of 3.75 on a 10-point pain Likert scale. In a similarly designed trial, Tashjian (78) exposed medical inpatients, suffering from moderate or severe pain, to “Pain RelieVR”, viewed via HMD for 15 minutes, and compared its impact on pain with a high definition video. Both control and VR groups reported reduced pain scores ($p<0.001$ for both), but the effect was greater in the VR group ($p=0.008$).

Operative procedures can be undertaken on awake patients using either regional or localised infiltration of a local anaesthetic agent, creating loss of pain sensation in the operative field. Although not usually painful, patients can find such procedures distressing due to abnormal sensations and the unfamiliar surgical environment. An Iranian study demonstrated that iTech delivered via Vusix video glasses reduced pain experience when compared to usual care during repair of episiotomy wounds ($p=0.038$), with 20% of those receiving VR reporting severe pain during the procedure, compared to 60% of controls. Chan et al. (67) provided patients undergoing lower limb joint replacement under regional anaesthesia with a passive simulation based on SnowWorld, delivered via an Oculus Rift HMD. When compared to standard care, there was no difference in requirements for intravenous sedation or analgesia, although all 19 participants reported that they would be willing to use the VR system for awake

procedures in the future. This suggests that, despite not delivering clinically significant results, the intervention may improve the patient experience.

The use of the “Emotional Parks” system by patients with metastatic cancer, viewed on a 32in television screen for approximately half an hour each session, invoked statistically significant improvements in subjective ratings of general mood ($p=<0.001$), relaxation ($p<0.05$), sadness ($p<0.003$) and joy ($p<0.009$), when compared to pre-intervention testing.(67) Patients reported that they found the intervention meaningful, purposeful, entertaining and pleasant. Whilst the study design intended the participants to receive four sessions over a week, only 11/19 completed all four sessions, with attrition due to discharge (n=4), discomfort (n=2), other worries (n=1) and voluntary withdrawal (n=1). This draws attention to analysis which relies on a within-subject, repeated-exposure design, where the changing condition of the patient impacts on successful trial delivery.

2.5.6.6 Effectiveness of ITech interventions to aid physical recovery

Feasibility of using gaming systems has been evaluated in two studies, with one each set in adult and paediatric ICU (Appendix 4). Both studies recruited similar patient groups, in terms of dependence and treatment objectives, in that all were awake and cooperative and were considered to be in the rehabilitation phase of treatment.(37, 69) The Nintendo Wii was feasible and safe to use in patients requiring mechanical ventilation and sedation, and neither study reported any adverse events, although the paediatric group of seven patients

was small. Although caregivers reported that the children appeared to enjoy the activity, and accelerometry confirmed that use of the iTech improved activity levels, there was no improvement in hand grip strength measured over the three day intervention.

2.5.7 Risk of bias

Risk of bias assessments for the non-RCT studies are summarised in figures Appendix 5. The Cochrane risk of bias tool was used for the pilot RCTs and RCTs, and summarised using Review Manager (RevMan) software (Version 5.3) (Figures 2.6 and 2.7). The high risk of bias was incurred, for the most part, due to lack of blinding of participants and observers to intervention and data collection, small cohort size, failure to describe the iTech intervention in sufficient detail (with one team using different system iterations within one study, (58) non-standardisation of control condition, interpretation of non-clinically meaningful reductions in pain scores and absence of information on recruitment process. Use of within-subject, crossover design counteracted the confabulator of daily fluctuations in pain, however using three-minute segments of iTech intervention and control condition limited the applicability of results to clinical practice.(54)

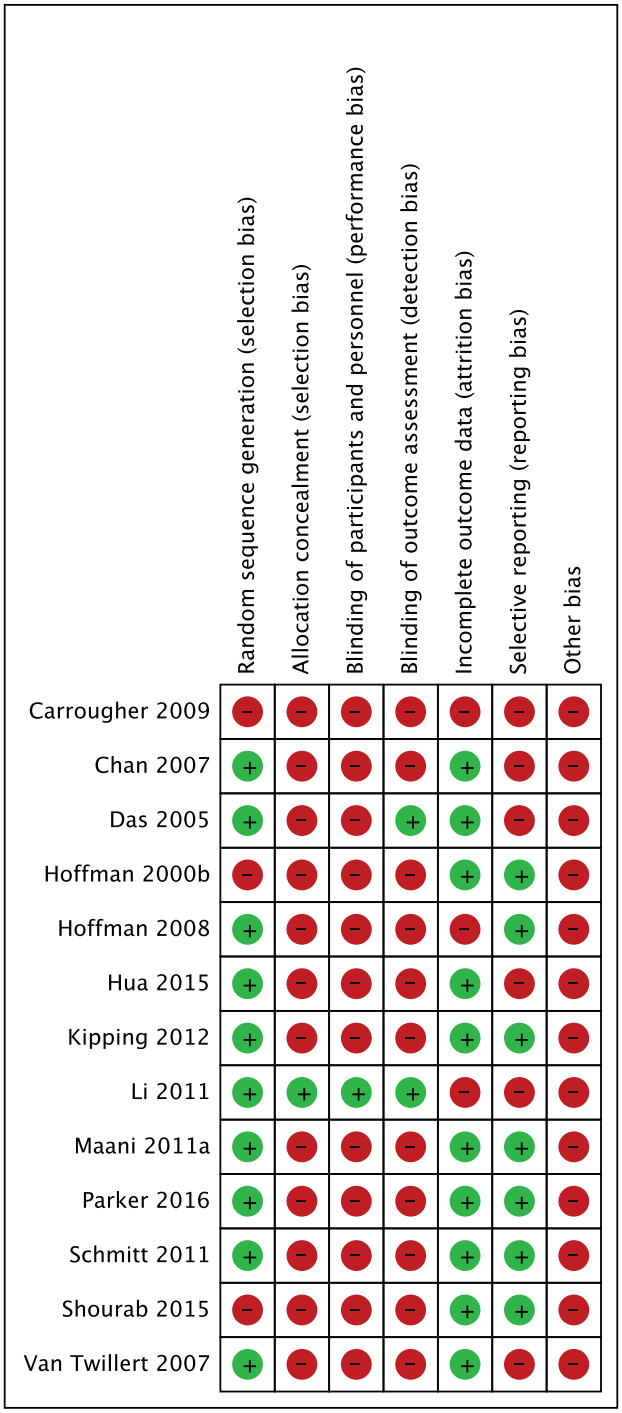


Figure 2.6: Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

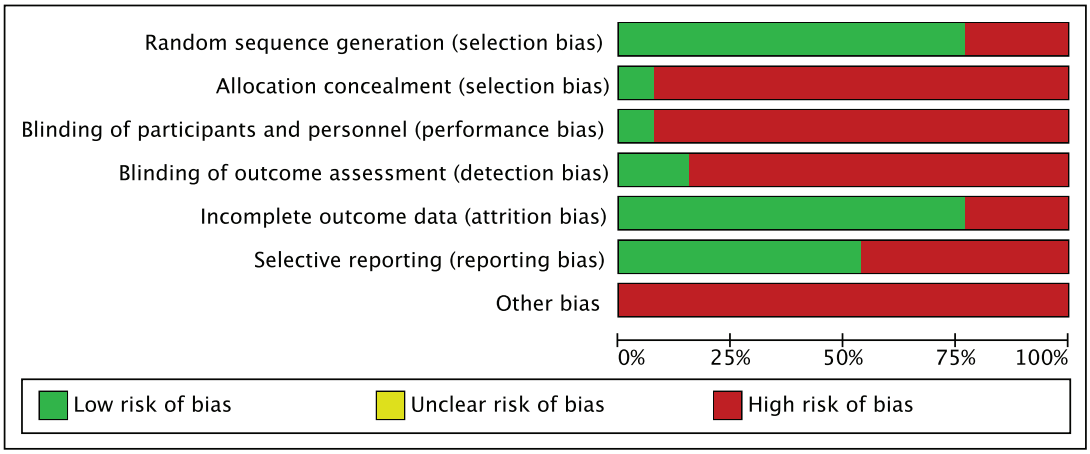


Figure 2.7: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

2.5.8 Mechanisms of effect

Synthesis of both quantitative and qualitative findings, using a nodal and sub-nodal textual narrative and thematic approach (Figure 2.8) within the studies was undertaken to inform the construction of a model of mechanistic effect (Figure 2.8).

Understanding the mechanism of effect requires answers to two questions:

1. What do iTech interventions do?
2. How do iTech interventions work?

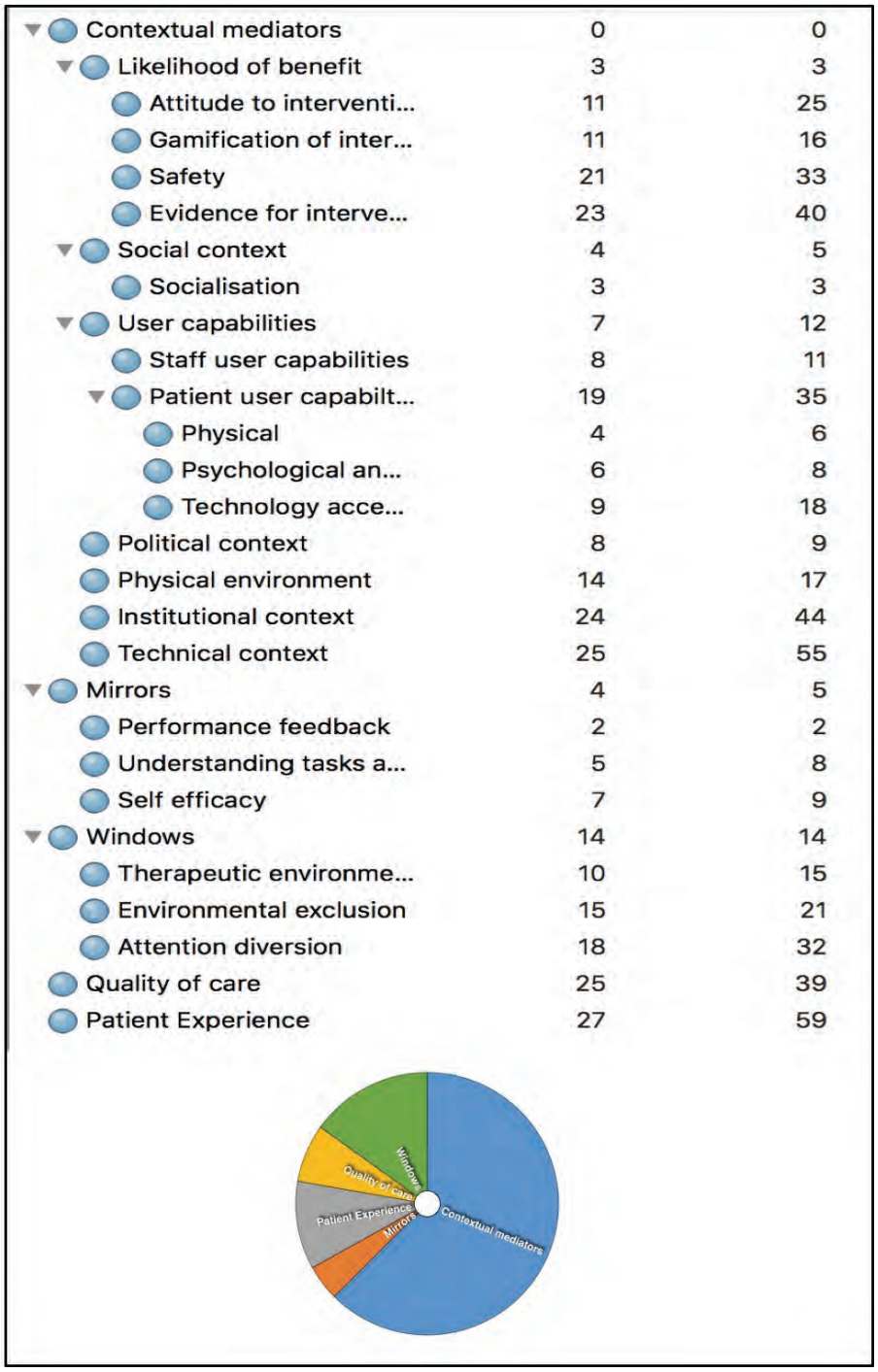


Figure 2.8: Nodal map for synthesis of qualitative data for the systematic review, left hand column denotes number of sources, right hand column denotes number of references. Pie chart represents number of references (produced in NVivo for Mac)

2.5.8.1 What do iTech interventions do?

At the top of the mechanistic hierarchy, two major themes were identified, describing what iTech devices do; enhancing quality of care or effectiveness of treatment and improving patient (and carer) experience of care (Figure 2.9). These themes harmonise with two of the three elements described by Ara Darzi in his definition of quality in healthcare.(90)

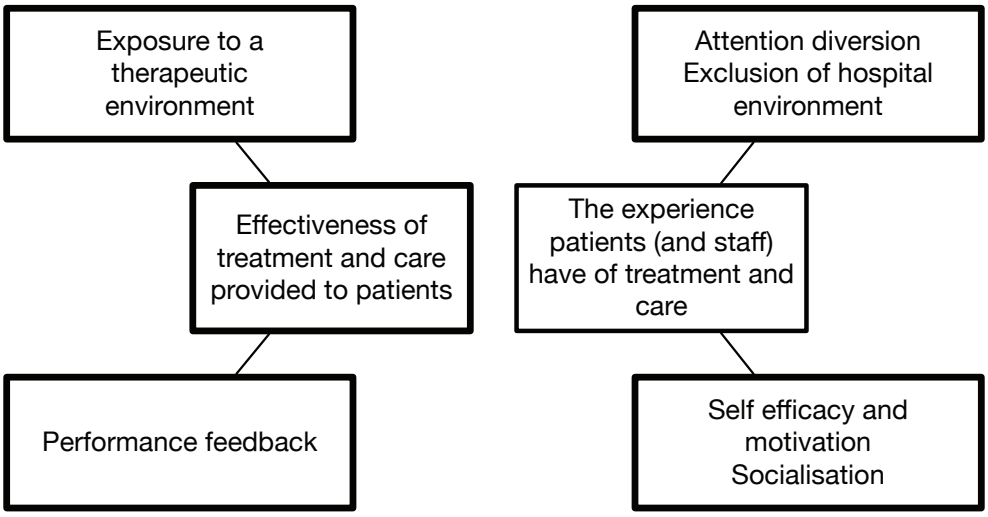


Figure 2.9: Illustration of mechanistic effect of iTech-based intervention to aid patient recovery in an acute hospital setting based on Ara Darzi's definitions of quality in healthcare

Theme 1: Enhancing quality of care

ITech was used in many studies to enable improvements in quality during routine care, such as dressing changes and physical therapy, or as an independent intervention to improve movement or encourage increased physical activity.

Pain negatively impacts on patient recovery.(91) Qualitative descriptions of pain experience as a consequence of medical illness or during painful interventions, whilst using iTech-based distraction, reported reductions in pain intensity, although not all patients responded positively.(53, 54, 57, 58, 60, 78, 80) Some patients experienced less pain and required less sedation and analgesia, with potential reduction in associated side effects, whilst using iTech distraction during wound care and operative procedures.(49, 59, 88)(67)

ITech improved compliance and achievement during passive stretching exercises and physical rehabilitation (51, 58, 74, 86) and increased quantity of limb movement and overall physical activity.(52, 68, 69). Use of iTech systems improved well being with reduced symptoms of depression and anxiety (65), although some patients reported that the system could increase anxiety.(83) A limitation of the gaming systems was that they had not been designed for patient rehabilitation, therefore did not provide tools to enhance the prescribed exercises, or means to effectively record progress.(52)

Theme 2: Patient (and carer) experience

ITech was used to improve patent experience, enhancing their overall hospital experience and moderating the impact of unpleasant procedures.

> *"It provides a separation from what's going on…Good distraction..welcome distraction…fun detour. Because it's boring here in the hospital." (83)*

Exposure to virtual environments invoked pleasant sensations, including reduced boredom, improved relaxation, enjoyment and fun, and helped patients to cope with the stress of hospitalisation.(65, 68)

Pain is a sensory experience, influenced by the patients' emotional and cognitive processes. Evaluations of SnowWorld reported reduced cognitive and emotional components of pain.(53, 54, 57, 58, 71, 75, 85) Fear avoidance behaviour was reduced in children during painful dressing changes, which extended to reports of improved emotional well-being and "fun" in some cases. (58, 60) Throughout the trials evaluating iTech-based distraction for wound care, there were consistent reports of improved compliance with treatment, thus reducing the time taken to complete the change of dressing, with additional benefit of a reduction in patient perception of duration of intervention.(51, 55)

> *"…two nurses said they found that the overall efficiency of the wound dressing procedure actually increased because, in the control situation, some of the children would kick and scream…"(80)*

There was no conclusive evidence that the impact of iTech was due to the design of the game, or merely distraction by the moving image. Further work is

needed to determine the effect of all the components, both software and hardware, of an iTech system.

2.5.8.2 Mechanism of effect: How do iTech interventions work?

The concept of utilising iTech interventions to improve non-physical and physical consequences of illness was distilled into two paradigms, “Windows” and “Mirrors.”

Theme 1: “Windows”

The “Windows” paradigm describes interventions which alter the patients’ perception of their environment, through giving them a view onto another world or excluding the unpleasant clinical environment around them. Within “Windows”, three sub-themes were identified, attention diversion, environmental exclusion and therapeutic environment (Appendix 6).

Attention diversion

Patients were able to forget their surroundings whilst using iTech. Virtual environments were engaged with at varying levels, from visual-only to multi-source feedback systems, providing the patient control over their virtual environment. Success of the intervention appears to depend on the balance of attentional resources required by the game with the intensity of unpleasant stimulation, or conditioned fear and anxiety.(49, 77, 78, 80)(67) Highly interactive systems were required to provide analgesia during procedure-related pain,(60) as opposed to passive, visual only, systems providing relaxation to

patients with background pain or poor well-being.(67) The majority of studies used normal clinical care as a control condition. A study using television watching as the control condition failed to demonstrate overall superiority of the more interactive VR system, with the authors drawing the conclusion that expensive interactive systems may not be necessary.(55)

Environmental exclusion

Use of head mounted displays (HMD), noise cancelling headphones or whole-room virtual experiences were techniques used to exclude the external environment, potentially increasing immersiveness and perception of presence.(54, 65, 78) Low tech HMDs, however, have a limited field of view, with patients able to see their room in their periphery.(56) Patients felt more anxious when they saw their wounds.(49) It is yet to be determined as to whether the effectiveness of HMD-based interventions is due to inability to see the wound or procedure, or viewing of the virtual world:

> *"there was no way of knowing if the computer simulation in the goggles itself accounted for the apparent reduction in sedation, or if the effect was achieved simply through the removal of auditory and visual stimuli and could have been achieved with a blindfold and earplugs" (67)*

Therapeutic environment

Interactive systems allowed patients to "visit" different places, with virtual environments often nature-based, designed to induce positive emotional states, invoking pleasant memories.(67) The bespoke medical application Pain RelieVR was described as:

> *“ a non violent and non competitive game that incorporates motivational music and features positively reinforcing sounds, animation and direct messages to patients.”(78)*

SnowWorld has been developed using the theory that exposure to cold environments reduces feelings of thermal-induced pain.(54) The effectiveness of Its predecessor, SpiderWorld, in reducing procedure-related pain experience, demonstrates that the virtual environment does not necessarily need to be pleasant to prove effective.(79)

Theme 2: “Mirrors” - providing a patients with feedback on progress and goals

The “Mirrors” paradigm describes interventions which provide the patient with a view of themselves, commonly during episodes of physical therapy. Three sub-themes were identified; performance feedback, self efficacy and socialisation.

Performance feedback

The video games may provide some degree of motor learning opportunities, where the patient receives immediate visual and auditory feedback on their performance, with patients more likely to achieve mastery of technique.(37, 69) Some ITech interventions provided training and improved patients’ technique, (37) and could be used to provide individualised standards for comparison of treatment response. However, although bespoke systems can be individualised and used flexibly,(65) gaming systems are not designed to aid rehabilitation from illness, and would need to be adapted to include specific physiotherapy

goals in order to reach their full potential.(51, 52) Use of iTech gaming systems appeared to improve “buy-in” by parents of children on the ICU.(69)

Self efficacy

ITech systems enhanced motivation to perform, improving confidence and independence, albeit with caregiver support in the most dependent patients.(37, 51, 52, 69) Children gained a greater sense of self control, increasing their ability to engage their coping mechanisms.(65) Children were able to use some of the more familiar gaming systems independently, being allowed to put on the HMD themselves and choose the game to play.(70)

Socialisation

In the most capable inpatients, gaming systems allowed opportunities to compete against others undergoing similar rehabilitation, for similar diagnoses or participate with friends and family.(52, 65, 68)

Mediators and contextual modifiers influencing effectiveness of ITech-based systems.

As discussed previously, iTech systems are complex interventions and their feasibility and effectiveness is influenced by their context of use.(42) Synthesis of the findings of the studies included in the review elucidated mediators and contextual modifiers (Appendix 7):

- Biological plausibility, or likelihood of the intervention to be effective. This modifier was further subdivided into:

    - Patient and staff attitude to the intervention.
    - Evidence for effectiveness of the intervention; whether the iTech system was enhancing the effectiveness of standard care or providing a novel therapy.
    - “Gamification” of the intervention; whether it was feasible and appropriate to convert a treatment modality into an interactive system.
    - Risk versus benefit; whether the iTech systems reduce harm, or provide no risk in the context of benefit.
- User capabilities. This modifier was further subdivided into:
    - Patient physical capabilities.
    - Patient psychological and cognitive capabilities
    - Patient technology acceptance, based on their knowledge, skills and attitudes to technology.(33)
    - Carer/staff user capabilities, encompassing elements above.
- Physical environment; the hospital, ward and bed-space of the patient, considering safety, ergonomics and human factors.
- Institutional context; case mix, hospital process and structures, patient flow through the hospital, financial, political, training and staffing enablers and barriers.
- Technical context: Complexity, familiarity and reliability of the iTech system and consequences of required training and support, availability of immediate engineering support, hospital policy on adoption of novel devices, facilities to charge and maintain systems.

2.6 Discussion

The objectives of this review were to determine the degree that Human Centred Design and Usability Engineering processes are integrated into the prototype design and trial protocol of iTech systems to aid patient recovery, examine the effectiveness of providing patients iTech-based interventions to improve their physical or non-physical recovery and to synthesise a framework to describe the mechanisms or mediators of iTech-based interventions and their contextual modifiers. Although other systematic reviews have investigated the effectiveness of iTech-based therapies for inpatient groups,(35) this is the first review to critically evaluate the methodologies informing design and implementation and the models of mechanistic effect.

This review has highlighted that few research teams have presented descriptions of design process or evaluation in any detail. The use of interactive systems in an acute hospital setting requires careful consideration of the user requirements and context of use. Although detailed guidance on adherence to international standards in human centred design and usability is provided,(29, 30) neither standard recommends specific tools to gather data during each phase of the design cycle, and there is no specific guidance on the process for device use by patients. Each aspect lends itself to usage of different types of tool, for example a risk analysis chart and monitoring of adverse events can be used to evaluate the safety of the device. There are a number of usability assessment tools, the most frequently applied is the System Usability Scale

(SUS),(92) although this has not yet been validated in a patient population. Thus, there exists a need and opportunity to develop and evaluate tools to assess usability in patient populations.

Synthesis of data on the effectiveness of iTech systems to improve non-physical and physical consequences of illness, injury or burns in an acute hospital setting, has been hindered by the overall poor quality of research to date, a finding replicated by other systematic reviews for the subject of iTech-based medical therapies.(93)(35) Resource allocation has led to two types of approaches; the use of commercial-off-the-shelf gaming systems and the development of bespoke “medical” interactive systems, usually by academic institutions. Effectiveness of gaming systems are, for the most part, impaired by the fact that they are designed for domestic use, rather than rehabilitation in hospital. Thus they are unable to deliver, or enhance delivery of, prescribed therapeutic strategies. This causes poor uptake as they are perceived by therapy staff not to be useful. Indeed, personal communication with the rehabilitation teams at Birmingham Children’s Hospital supports this, with therapists reporting that gaming systems are used for fun, but not for targeted physical therapy. Evidence for the use of bespoke systems is drawn, largely, from investigations into the use of SnowWorld, the lead researchers for most studies being the designers and owners of the system. Their data is almost universally positive, but the applicability of their results to widespread practice must be considered in the context of large expense, and, particularly in the

exploitation of the waterproof system, cumbersome and requiring dedicated space for use.

Critical analysis of the quantitative and qualitative data has informed the development of a “top level” model of mechanistic effect (Figure 2.9). This model illustrates the proposed theory that iTech-based interventions could enhance effectiveness of treatment and care via exposing the patient to a more therapeutic environment and enhancing performance feedback, whilst improving the experience of the user by diverting attention from the hospital environment and enhancing self efficacy, motivation and socialisation. This model also introduces the paradigms of “windows” and “mirrors” to describe how iTech could be used to change ones view of the world or reflect on ones effort and progress.

2.7 Limitations of the review

The studies retrieved examined the use of iTech for a number of discrete, yet diverse populations, from military complex trauma to paediatric oncology, limiting the generalisability of results to many of the readers.

Difficulty in interpretation of findings arose from the variation in study methods and outcome measures. Limited description of intervention fidelity renders none of the papers reproducible, albeit the review authors do appreciate that this is not necessarily an easy undertaking for authors within publishing requirements.

2.8 Conclusions

Overall, this systematic review provides some evidence to support the perception that use of iTech based systems is feasible for use in acute hospital settings, by patients with varying diagnoses and capabilities, including those in ICU. There is a distinct lack of high quality data with further rigorous studies required to evaluate the feasibility and effectiveness of such systems.

Research in this field would benefit from the rigorous application of Human Centred Design-based methodologies to ensure that devices developed are useful and usable. This review demonstrates the impact of the lack of specific guidance informing iTech design and implementation in hospital settings. Lack of use of International standards informing iterative product design processes may reflect lack of awareness or a perceived inaccessibility by clinical researchers with enthusiasm for using iTech in clinical settings. Patient factors, such as frailty and cognitive impairment may have deterred researchers from undertaking formal analysis of moderators of iTech use, where questionnaires used for well subjects may be considered overly burdensome.

Future work in this area should include accurate descriptions of the iTech interventions and their fidelity of use. The mechanistic model constructed within this review illustrates opportunities and strategies for further exploitation of iTech, with the framework of contextual modifiers illustrating considerations that need to be made throughout the design and implementation cycle.

2.9 Reflection and key methodological lessons learned

- Undertaking a systematic review provides a rigorous method for evaluating the evidence on clinical effectiveness of a proposed intervention.
- The systematic review can be used to inform the development of the programme theory, explaining biological plausibility and contextual modifiers of response.
- The challenge when using this approach for evaluating iTech is the variation in type, mode of delivery and outcome measures between each study, reducing generalisability and the ability to perform meta-analysis.
- Clinical trials rarely report detail in the methodologies used to inform iTech design and system development, so the completion of a systematic review produces limited meaningful data.

CHAPTER 3 PROGRAMME THEORY AND DEVELOPMENT OF THE PROTOTYPE INTERACTIVE SYSTEMS

Chapter 3 presents the development of the programme theory informing the development of the novel iTech-based devices, introduces the design and regulatory processes and presents the novel “Windows” prototype interactive systems (Figure 3.1).

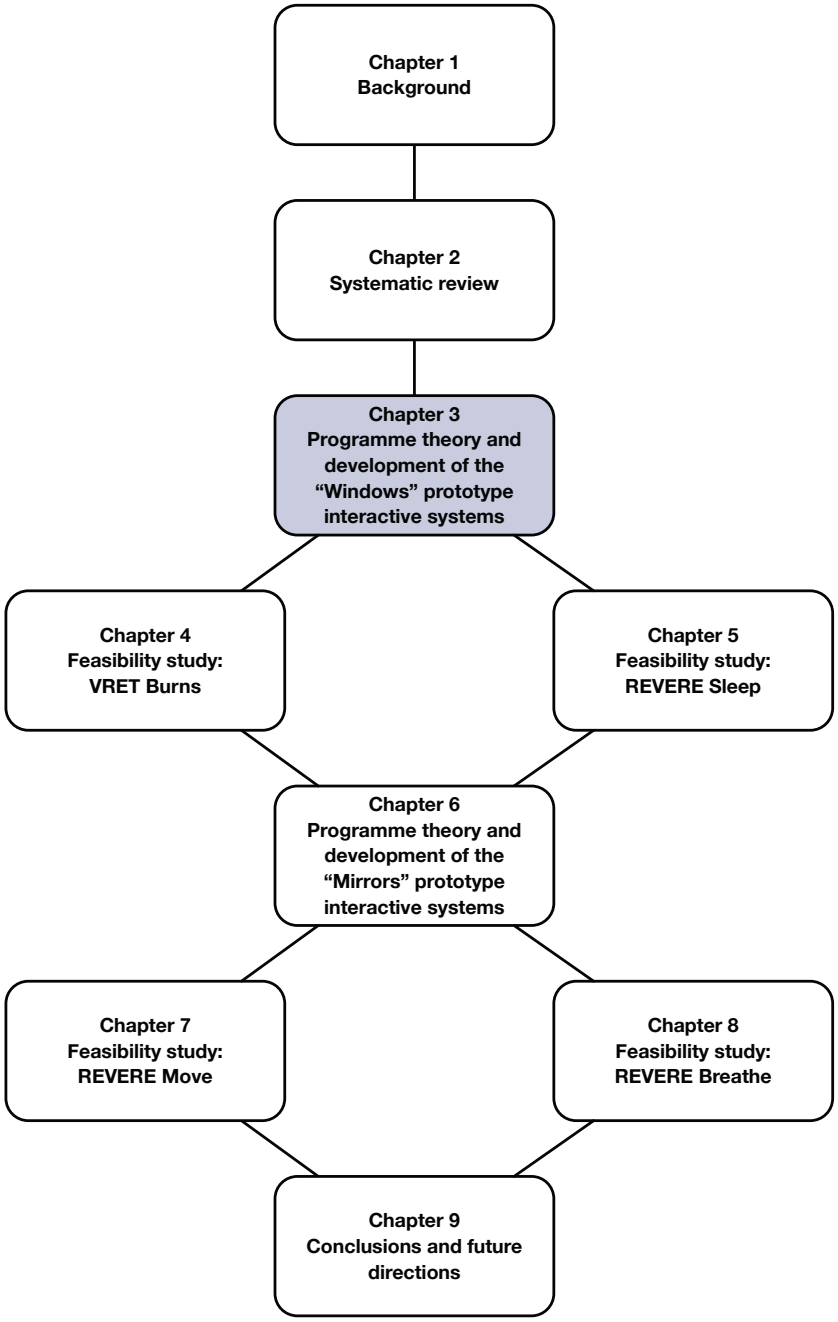


Figure 3.1 Thesis roadmap - Chapter 3

3.1 Building the programme theory of the novel ITech-based interventions

Underpinning the development and evaluation of any complex intervention is the programme theory (Figure 3.1). Programme theories are theoretical constructs that have evolved from social science disciplines and can be used prospectively to inform the development of hypotheses describing how complex interventions might work, to guide research methodology or to evaluate a programme retrospectively.(94)

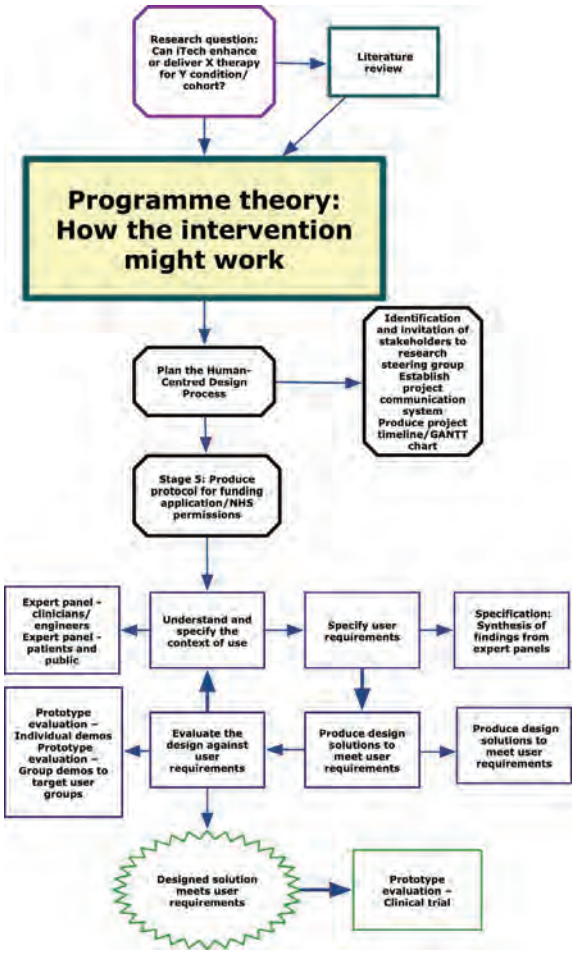


Figure 3.2 Programme theory within the research framework

The programme theory is also used to analyse the fidelity of the intervention, linking biological theory with implementation and evaluation of effectiveness. (95) The Medical Research Council's guidance asks:

> *"Can you describe the intervention fully, so that it can be implemented properly for the purposes of your evaluation, and replicated by others ?"(42)*

The programme theory for this research was developed in stages, the simplistic first stage model considers the use of interactive technologies by patients within the healthcare system, with a more detailed model then being constructed to consider the use of iTech for the critical care population. The sources used to develop the programme theory were NHS policy documents and reports,(27, 90) research summarised within the systematic review and concept mapping exercises undertaken by the research group.

Ara Darzi's NHS Next Stage Review Final Report "High Quality Care for All" details the ideal model of healthcare wherein patients should not only expect to receive the highest standards of medical treatment, but also receive that treatment in a manner that considers the patient experience, such as their physical environment and personal and social needs.(90) The synthesis of findings of the systematic review in Chapter 2 described how iTech interventions might enhance care and experience for hospitalised patients, introducing the effect paradigms of "Windows", the alteration of the patient's environment to provide distraction from their surroundings, and "Mirrors", the provision of feedback or self-assessment to the patient on their activity or performance.

The review also considered what the contextual modifiers of these potential intervention strategies might be. By combining these elements with the tenets of Darzi's model of care, a high level programme theory was constructed, illustrating what iTech interventions might do and how they might work within healthcare and rehabilitation setting (Figure 2.9).

A more detailed programme theory was then developed to describe how the interventions might work for patients recovering from critical illness. The cornerstone of this was the framework of consequences of critical illness, their aetiologies and current interventions used in clinical practice presented in Chapter 1 (Figure 1.3). The construction of this model was informed by a combination of expert opinion and guidelines on the components of critical illness and constituents of critical care and early rehabilitation.(27)

A key determinant of measurable success in implementation of novel systems in healthcare is ensuring innovation is driven by "human-pull" rather than "technology-push."(31) Thus, early engagement was sought with patient and public users of healthcare to further inform utility and utilisation. Prototype virtual environments were presented to national and local Patient and Public Involvement (PPI) groups of survivors of critical illness (ICU STEPS), trauma and burns (QEHB Pathfinder), with their feedback sought on potential exploitation for acutely unwell patients receiving care in hospital (Appendix 8). This information was summarised and further informed the process of mapping which components of recovery could potentially be modified using iTech,

combining explanation of biological plausibility with the model of mechanistic effect of iTech-based interventions (Figure 3.3). Each of these will be described in more detail in subsequent sections and chapters.

The programme of research was then divided into two phases, the first being “Windows” interventions, the second being “Mirrors” interventions. Within each research phase, further audit-based work was carried out to determine the most appropriate interventions for prototype development, with two clinical scenarios described within each theme.

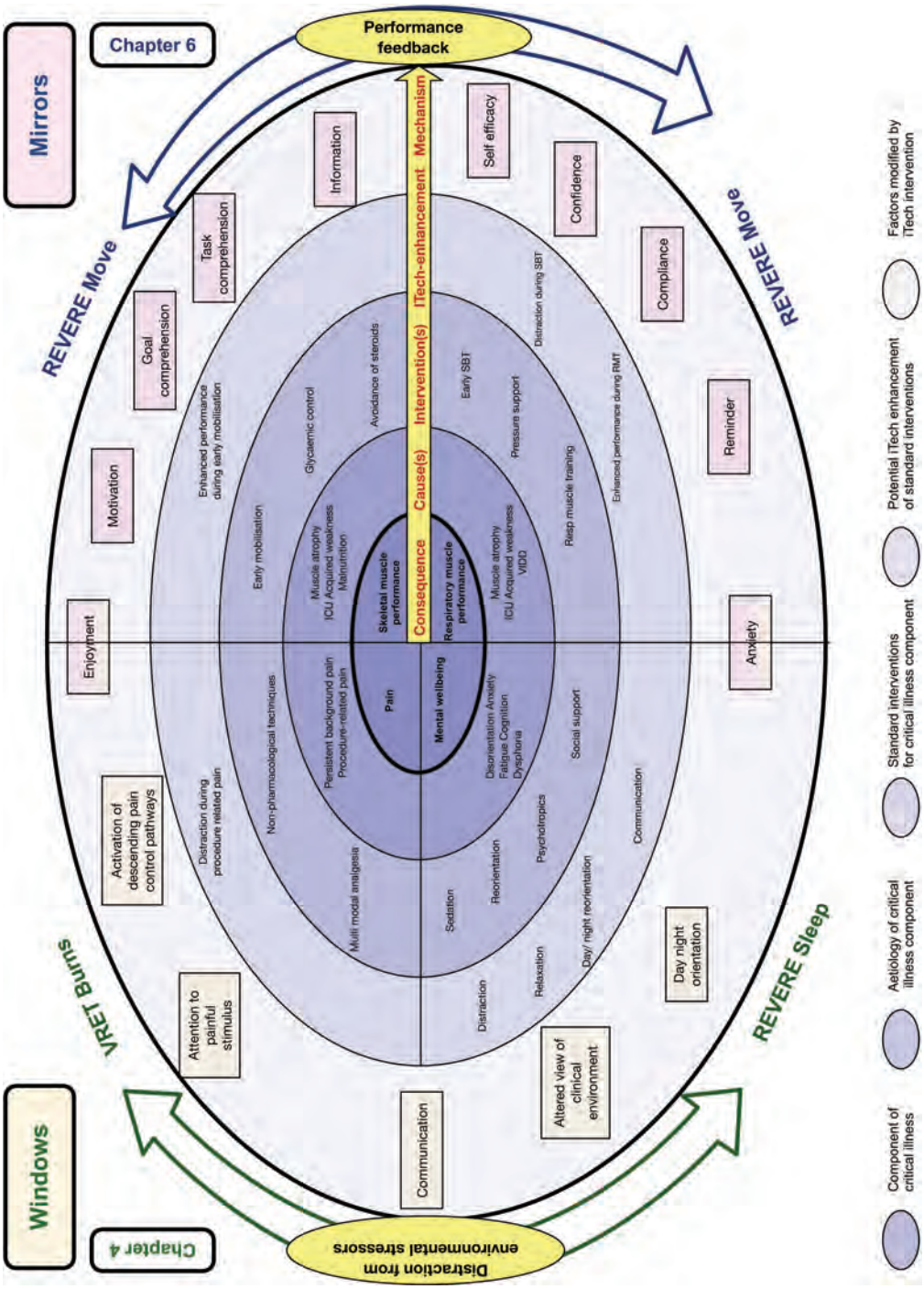


Figure 3.3 Conceptual model of components of critical illness, aetiology of consequences, current interventions and potential use of interactive technologies

3.2 Planning the Human Centred Design process

The research framework for this programme of work incorporates the guidance of the industry standard BS EN ISO 9241-210:2010 “Ergonomics of Human-Centred Interaction: Human-centred design for interactive systems.”(30)

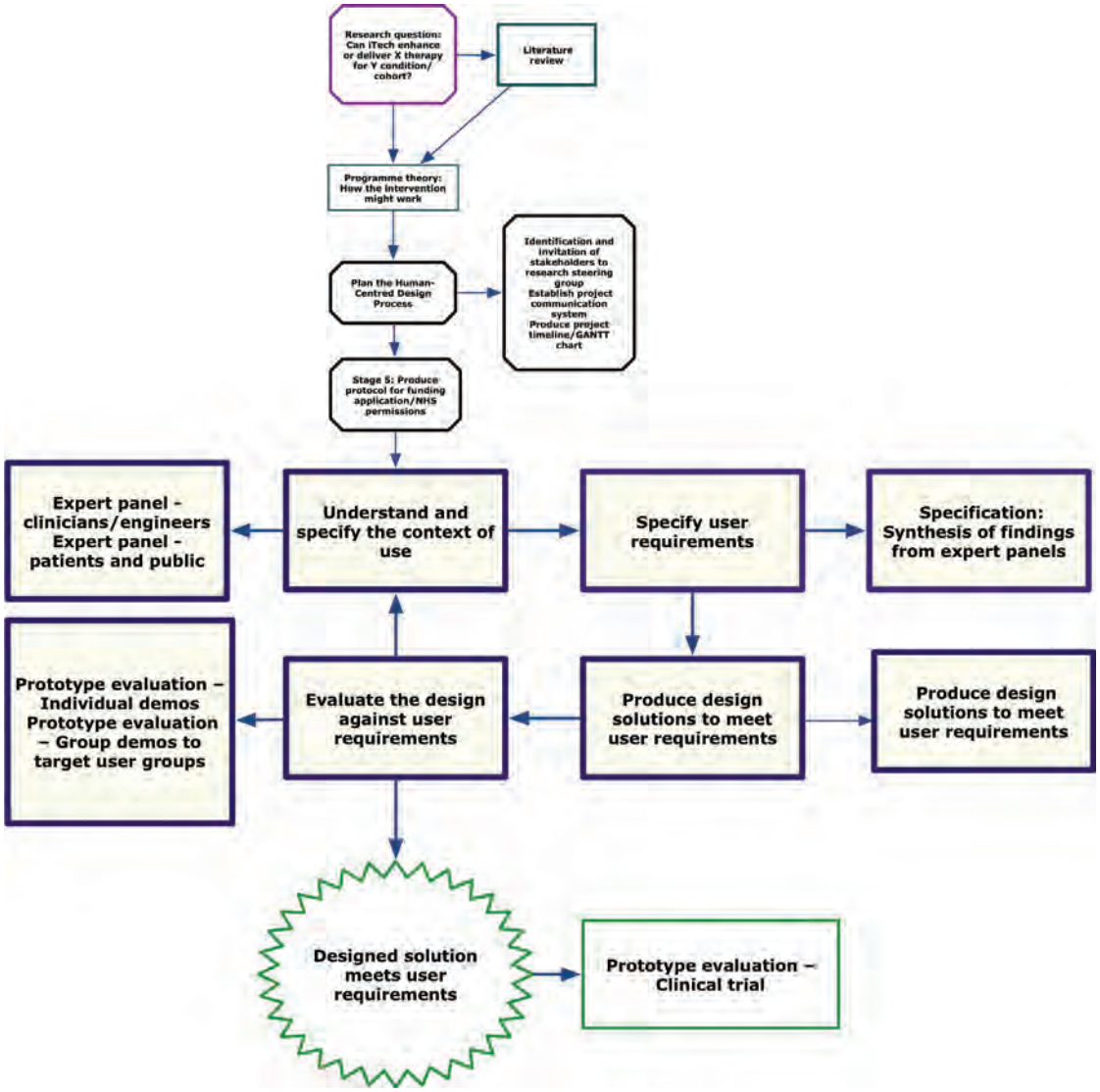


Figure 3.4: Iterative design cycle within HCD process

Recommendations for HCD processes and outputs include the clear description of the device's context of use, an understanding of the needs of the user groups, their characteristics in relation to device use and the tasks the device is required to assist with, in order to achieve pre-defined goals. This information informs the specification of user requirements, which combines the aforementioned detail with other contextual factors, including ergonomic assessments of the user environment and organisational factors affecting the usability of the system (Figure 3.4).(30) For the purpose of this research ISO 9241-201 was used in conjunction with the International standard IEC 62366 "Medical devices - application of usability engineering to medical devices"(29), which details recommendations of design inputs and outputs to ensure usability and safety of devices under development.

Throughout this research programme, the patient is the core around which the rest of the development process is built. Each patient receives a management plan of interventions prescribed to treat the causes and consequences of their critical illness (Figure 3.3). Some of these may be suitable for replacement or enhancement using an iTech-based system. For this to be feasible, there needs to be a logical "game-play" concept, or "gamification" of the planned intervention.

Interactive systems are complex interventions and their utility is influenced by their context of use.(42) Understanding of contextual modifiers, as identified from the systematic review, further informs the specification of user requirements. These modifiers have been categorised as user capabilities and the patient context (Figure 3.5). The user capabilities vary between patient users and fluctuate within each patient's admission. During the early design phase, capabilities were described in general terms during the initial design process, with generalisations provided by experience of the adult critical care population and evaluated during the clinical trials in order to assess associations between usability, intervention delivery and effectiveness.

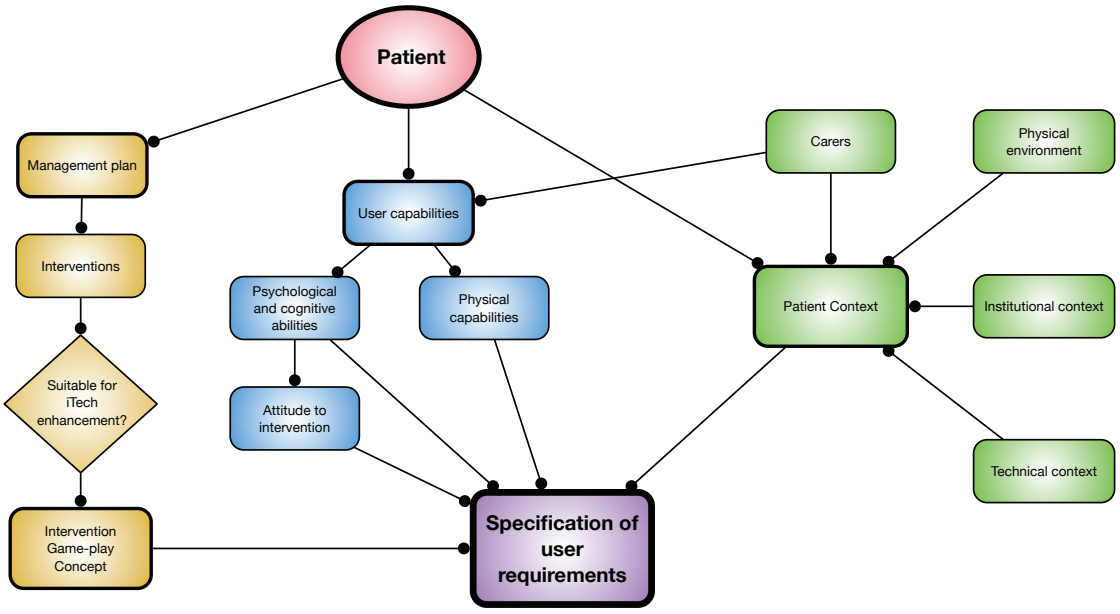


Figure 3.5: Contextual modifiers of iTech interventions to aid recovery from illness in an acute hospital setting

3.3 Development of medical devices for clinical use

Once a prototype system reaches an appropriate level of maturity in the iterative design process, it can then undergo assessment by well-subject and staff groups prior to a clinical feasibility trial under the regulations of the NHS Health Research Authority.

Novel medical devices undergo the scrutiny of multi-phase clinical trials to rigorously evaluate efficacy, safety and cost-effectiveness, in order for permission to be granted to proceed to manufacture and distribution in the medical setting. It is necessary to evaluate in “real-world” settings in order to verify and validate novel systems. However, in order to ensure public safety and avoid exposure to unnecessary harm, bench testing, particularly of the software, should be undertaken during prototype development. This is performed to ensure verification (meets the user requirements) and validation (fits the intended use), prior to testing by patients in the clinical setting.(30, 31)

The planning, delivering and reporting of clinical trials of medical devices is regulated by UK and International law, and is supervised in the UK by the collaboration of governing bodies, including the Medicines and Healthcare products regulatory Agency (MHRA), Research Ethics Committees, NHS and University governance department, with oversight provided by the NHS Health Research Authority (HRA) (Figure 3.6).

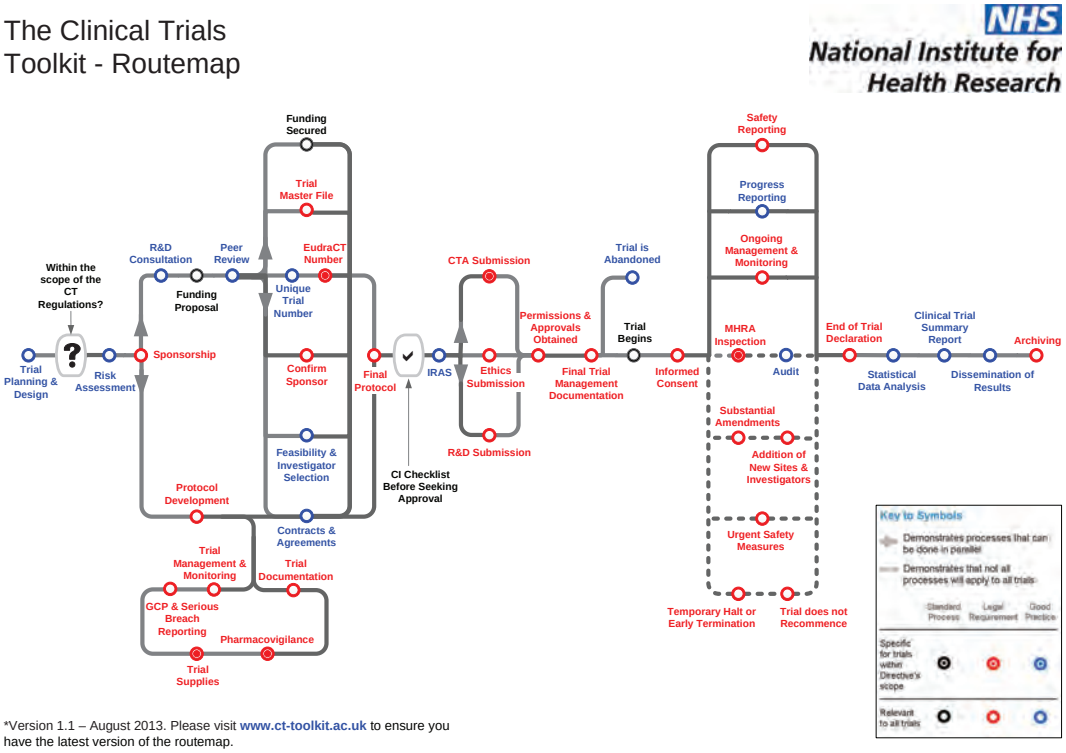


Figure 3.6: The Clinical Trials Route map

Accessed at (http://www.ct-toolkit.ac.uk/routemap/)

In order for a medical device to be legally manufactured used in clinical practice, it must be awarded a Conformité Européenne (CE) certificate. United Kingdom legislation requires the manufacturer to demonstrate compliance with essential requirements of European directives.(96, 97) This means either demonstrating equivalence to another already CE-marked device, or by providing data from a clinical investigation to support its safety and performance during patient use.

3.4 Introduction to the Virtual Environments

Prior to the establishment of their collaboration with the QEHB and Defence Medical Services research teams, the Human Interface Technologies team at the University of Birmingham had developed two virtual reality-based simulations of natural environments which they called “Virtual Burrator” and “Virtual Wembury.” “Virtual Burrator” is a virtual environment based on Burrator Reservoir, on the southern aspect of Dartmoor (Figure 3.7).

Figure 3.7: Screenshot of Virtual Burrator

The Wembury Bay virtual environment is based on the South West coastal path around Wembury Bay, near Plymouth.(98, 99) Both virtual environments were developed using industry-standard three-dimensional modelling and run-time software to achieve real-time, explorable scenarios (Figure 3.8). A detailed description has been written by the academic lead for Virtual Wembury,

Professor Bob Stone (Appendix 9). A sequence from Virtual Wembury can be accessed at https://www.youtube.com/watch?v=tyH-4IGrPnE.

Figure 3.8 Screenshot of Daytime Virtual Wembury Scene

At the inception of the research programme, Virtual Wembury was the most sophisticated of the two software systems, possessing dynamic environment effects, ranging from wave motion and sounds to a variety of animals.

The virtual environment could be synchronised with the real time of day and features sunrise and sunset events together with sun and moon movement during the day and night (Figure 3.9).

The software was designed to be compatible with a wide variety of virtual reality display and control devices, from head-mounted displays to gaming controllers,

body motion and gesture capture systems. The software components were designed to be reusable and easy to modify, facilitating the addition of new three dimensional models and environmental effects.

Figure 3.9: Virtual Wembury Sunrise

The therapeutic potentials of Virtual Wembury and Virtual Burrator were explored initially on the basis of evidence suggesting that exposure to nature, be it real or artificial, could have health benefits to patients, particularly in relation to the management of pain and psychological well-being.(100-105)

This evidence was underpinned by the concept of “Biophilia”, a term used to describe humans’ innate attraction to views of nature.(106)

3.5 Designing the “Windows” interventions

The adaptability of the Human Interface Technologies team’s virtual environments made them suitable for further development into nature-based therapeutic systems for use by patients recovering from critical illness. The many opportunities afforded by the potential to adapt methods of interaction were further increased by the software’s capacity to record experience and use in the support of clinical trials.

The research team determined that pain and sleep disturbance were the non-physical sequelae most appropriate for the development of iTech interventions based on Virtual Natural Environments (Figure 3.10). These were chosen due to:

1. High prevalence of sleep disturbance and poorly controlled pain in patients recovering from critical illness, complex trauma and severe burns. Despite Consultant-led, multi-modal pain management, this was known to be particularly problematic for the military complex trauma patients.
2. Evidence suggesting feasibility of using iTech systems to aid the relaxation, distraction and procedure-related pain in hospital settings (Chapter 2).

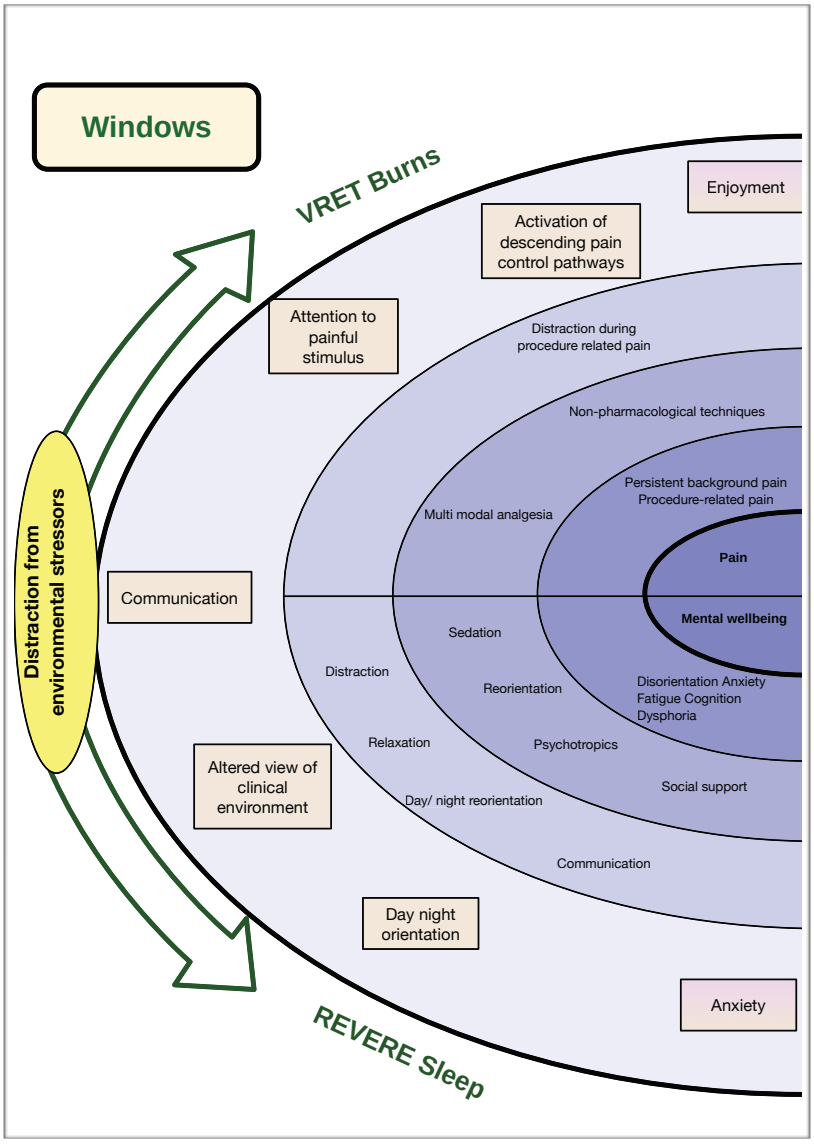


Figure 3.10: Conceptual model of components of critical illness, aetiology of consequences, current interventions and potential use of interactive technologies: Pain and Mental Wellbeing

3.6 Clinical Scenario 1:

Procedure-related pain following burn injury

3.6.1 Background

The management of severe burns involves meticulous wound care in order to prevent infection, with debridement and dressing changes occurring almost daily, for a period of weeks or months.(107) This wound care is recognised as one of the most painful procedures that can be undertaken, with most patients reporting severe to excruciating pain.

Poor acute pain management can have long-lasting consequences, being associated with later psychological sequelae such as depression, post-traumatic stress disorder and suicidal ideation.(108) Opioid analgesia, in conjunction with other agents such as paracetamol, are used for pain relief during ward-based wound care, but these agents have multiple unpleasant side effects. An audit of pain management during ward-based wound care was undertaken at the Queen Elizabeth Hospital Burns unit in 2011. Forty-two patients were reviewed over a four week study period. Of these, seven were excluded from the study as they had received ketamine (amnesic effects reducing reliability of subjective pain recall). Of the remaining 35, eight patients (22.9%) reported an average pain score of greater than 4/10, 13 patients (37.1%) reported a worst pain score of greater than 4/10 experienced at some point during the procedure.

3.6.2 Context of use

A project stakeholder group was formed, consisting of the lead researcher (C Small), the Defence Professor of Anaesthesia and Critical Care, Consultants in

Anaesthesia and Pain Medicine and Nursing staff from the Acute Pain Service, ICU and Burns nursing and therapy staff and the University of Birmingham Human Interface Technologies team.

3.6.2.1 Description of the user group

The intended patient user group included patients admitted to QEHB for management of burns. It was decided during early discussions that, as the first clinical trial delivered by the research team, it was more feasible to undertake the trial on the the Burns Unit rather than the ICU, to improve patient participation and facilitate consent.

The pattern of injury varies between every patient. Some patients had restrictions to movement and hand or arm function. Interface devices, such as commercial-off-the-shelf hand controllers, needed to be chosen or modified to allow optimum use by those with the greatest functional deficits. Some analgesics, for example opiates and antidepressants, might affect perception and coordination.(109) These factors were considered in the development of the virtual reality-based system, particularly with regard to the fidelity of the images presented and the mapping of the functions of the control devices used onto the computer-generated objects displayed on-screen.

The environmental context was a teaching hospital, specialist unit receiving both NHS and military patients. Most patients were in generously proportioned single rooms, but many lacked windows with a view or natural light. Use of

devices procured by the hospital trust for patient care was presided over by the trust medical device team, whose roles including the monitoring of electrical safety, technical support and storage.

3.6.2.2 Task description

The intervention was to be used by the patient during ward-based wound care, usually involving removing the dressing(s), cleaning the wound(s) and reapplying clean dressing(s), sometimes on multiple sites of the body. A priority of prototype design was to ensure that usual clinical care, in this case the process of changing the dressing, was in no way hindered. The layout of the patient, bed, equipment trolley and nursing staff varied depending on the location of the wounds.

3.6.3 User specification

As discussed in the systematic review, effectiveness of the system was to be influenced by the design of the software content and interaction. The system would need to integrate competitive, engaging distraction therapy and multi-sensory inputs with the development of virtual environments, designed to appeal to adults and include the following key features:

- Portable, mobile and easily moved between patient bed-spaces
- Ease to use by patients and ward staff
- Affordable
- Configured to allow flexibility in screen location and patient access.
- Compliance with hospital infection control policies

During well-subject trials of virtual reality systems to enhance pain tolerance researchers have sought to establish which aspect of the system improved its efficacy, from the quality of the computer-user interface (81) to the person view of the avatar.(110) The common theme elucidated from these studies was that engagement in the virtual activity, as opposed to realism of the virtual scenario, had the greatest impact on efficacy.

3.6.4 Potential design solutions: Principles of VR-mediated distraction from pain

Pain can be enhanced by anxiety, fear and distress caused by environmental and visual inputs. The underlying principle of virtual reality-based therapy is that attention is diverted from the painful stimulus (Figure 3.11). Functional magnetic resonance imaging studies undertaken during virtual reality-based distraction from experimental pain have demonstrated enhancement of the descending cortical pain-control system, via activation of the perigenual anterior cingulate cortex and periaqueductal grey.(111)

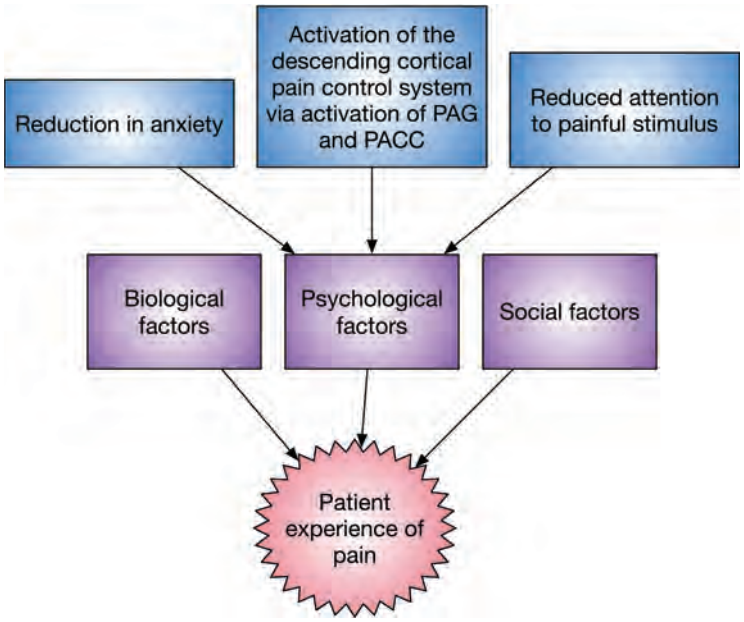


Figure 3.11: Principles of how VR-based distraction might improve pain experienced during wound care

3.6.5 Piloting the system and user interfaces

The first iteration of a prototype iTech system used both “Virtual Wembury” and “Virtual Burrator” displayed on a head mounted display or laptop screen with exploration of the virtual environment enabled by control devices. The specification of user requirements, relating to software development and selection of displays and interface devices, was informed by the results of small scale trials which had been undertaken the previous year (Figure 3.12).

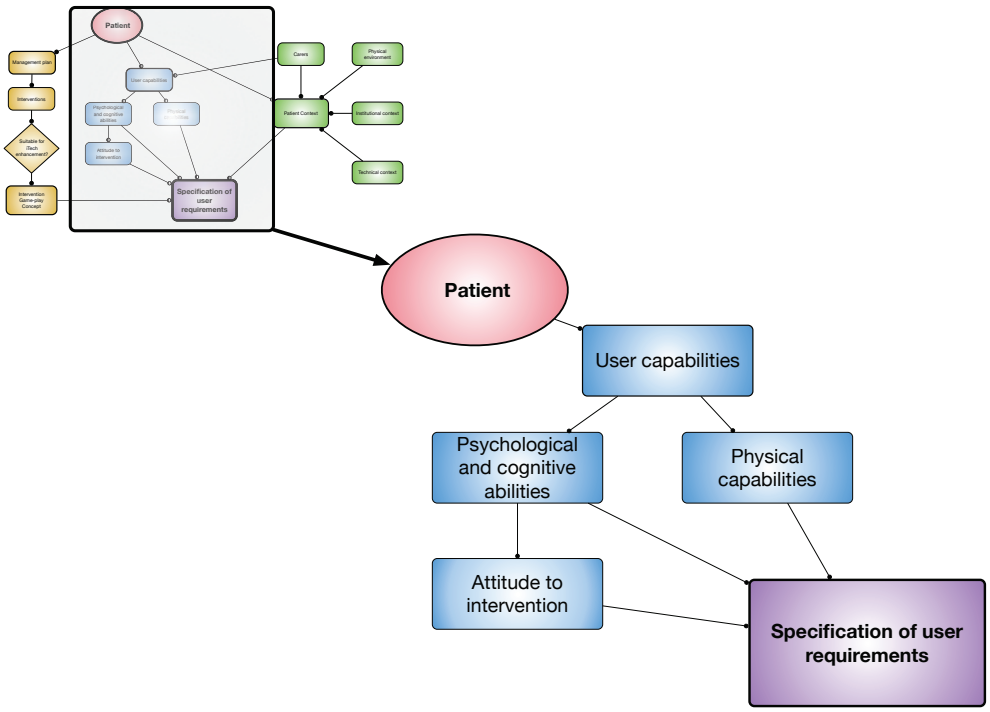


Figure 3.12 Patient factors informing specification of user requirement

This work had been carried out to inform the design of another iTech-based system developed to aid pain management and phantom limb pain in military amputees following combat trauma (Appendix 10). These studies determined patient user capabilities and preferences for the virtual environment content and interaction.

The patient cohort on the QEHB Burns unit was deemed sufficiently comparable to the military combat casualties to:

1. Provide the patient cohort for the clinical feasibility study of the novel iTech system.
2. Utilise the task description, context of use and user capability data described above to inform the system design.

3.7 The first prototype: Virtual Restorative Environment Therapy

3.7.1 Description of the Virtual Restorative Environment Therapy (VRET) system

Integration of the results informing the user specification informed the design of the first prototype Virtual Restorative Environment Therapy (VRET) system, which consisted of the software, display, controller and support stand components.

3.7.1.1 Software

The game software was based in the seascape of Virtual Wembury and was run on an Alienware laptop. Users drove a speed boat, in third person view, around a circular course, collecting lifesaving floats and avoiding obstacles, such as buoys and others boats. A point was scored for each float collected. The activity had multiple sensory inputs, encouraging maximum attention, yet was simple enough to be undertaken by those with impairment due to physical limitations and performance limitations such as opiates, pain and sleep deprivation.

The game was single gamer use only and had two modes of use

1. During passive video (VRET-P) participants looked at a static image of a virtual seascape.
2. In the interactive (VRET-I) treatment participants were able to navigate the virtual world, travelling in a speedboat around the waters offshore in Virtual Wembury (Figure 3.13).

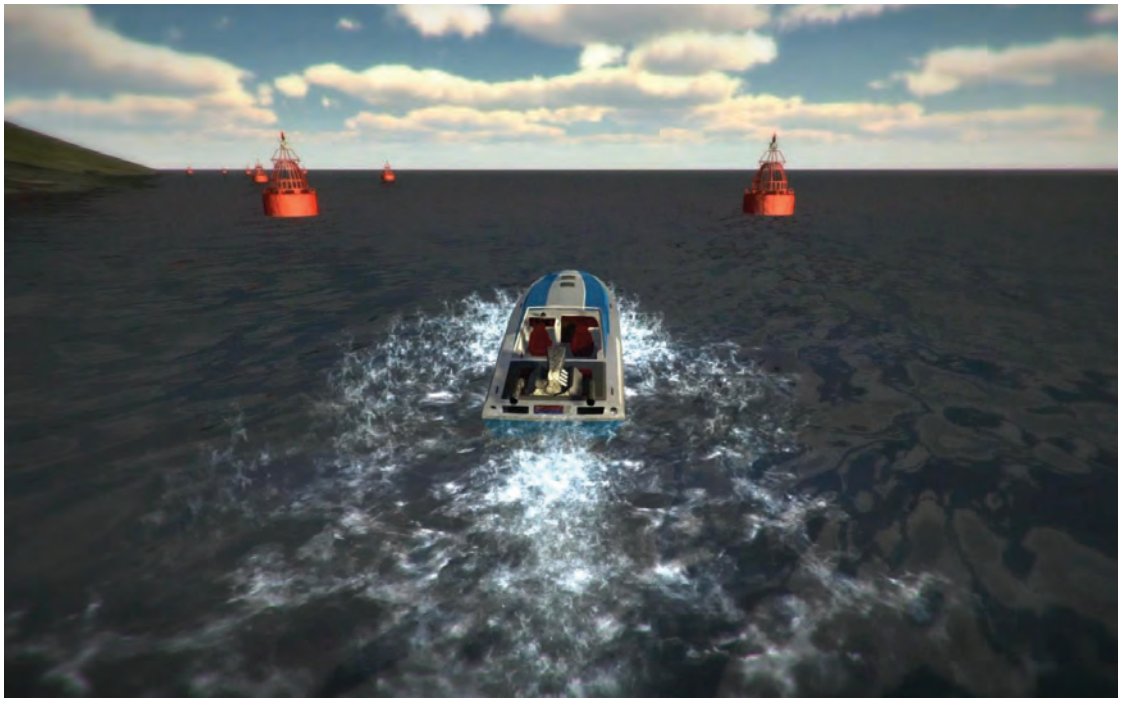


Figure 3.13 VRET: Screenshot of speedboat game

3.7.1.2 Controller

Human-Computer Interaction was provided via a single handed controller with thumb-operated joystick.

3.7.1.3 Display

Display of the virtual environment was provided via a 32 inch high definition television screen and noise cancelling headphones. Use of head mounted display was considered but deemed to be unacceptable due to potential discomfort, hygiene issues and the inability of patients with facial or scalp burns to use such a device.

The authors were aware that previous research has suggested that the use of head mounted displays may improve immersion, the amount of stimulation imposed by the VR system on the body's sensory inputs, and presence, the sense of "being there" in the virtual world.(112) Thus, the study design included the assessment of presence for each patient following the VRET interventions.

3.7.1.4 Support stand

Wound care was carried out in the patient bed space, thus the prototype was mounted on a wheeled stand to allow safe, easy manoeuvrability around bed spaces and between doors (Figure 3.14).

Figure 3.14 The Virtual Restorative Environment Therapy (VRET) system:
Left: whole system,Top right: controller, Bottom right: visual display TV screen

The reported of the study "VRET burns" Virtual Restorative Environment Therapy as an adjunct to pain control during burns dressing changes: A feasibility study of a novel prototype system" is presented in chapter 4.

3.8 Clinical Scenario 2:

Sleep disruption on the Intensive Care Unit

3.8.1 Background

Sleep disruption is a common problem for patients in the ICU. Characterised by disruptions of sleep architecture and circadian rhythms, its causation is likely to be a multi-factorial combination of the consequences of critical illness, sedation and the ICU environment.(113, 114) Sleep is an essential physiological process and sleep deprivation impairs processes such as immune function and wound healing.(115, 116), and may also delay successful weaning from mechanical ventilation.(117, 118) Disturbed sleep patterns are one of the greatest perceived stressors for patients in critical care and are associated with other unwanted and potentially avoidable symptoms, such as delirium, low mood and anxiety. (119-122) The critical care environment is, for many patients, highly stressful and has a detrimental impact on sleep. In particular, high noise levels are associated with disrupted sleep architecture (123, 124), with many critical care units having a higher noise levels than the 35 decibel limit recommended by the World Health Organisation for hospitals. Other environmental factors include lighting, ambient temperature and absence of time indicators.(125)

3.8.2 Context of use

The intended patient user group for a novel iTech-based device to enhance sleep was those requiring ICU-based care, but were conscious and aware of their surroundings. The ICU environment is focused primarily on providing safe organ-system support to preserve life. Non-pharmacological approaches to enhance patient comfort and improve sleep on the QEHB ICU include the

presence of the bedside nurse, friend and family contact and environmental modification of the bed space, including light, noise and temperature levels.

3.8.3 Specification of user requirements

As discussed in the systematic review, for the novel system to provide benefit it would need to provide engaging, relaxing therapy and multi-sensory inputs with the development of virtual environments, designed to appeal to adults be:

- Portable, mobile and easily moved between patient bed-spaces
- Easy to use by patients and ward staff
- Affordability
- Usability by those with complications of critical illness, such as ICU-acquired weakness
- Configured to allow flexibility in screen location and patient access.
- Compliance with hospital infection control policies

3.8.4 Potential design solutions: Principles of VR-mediated sleep enhancement

It was proposed that a virtual reality-based intervention could improve sleep on the ICU, by combining the elements of distraction from the clinical environment with enhancement of psychological well-being via induction of relaxation and pleasure to provide a virtual “Window” onto a different world (Figure 3.15).

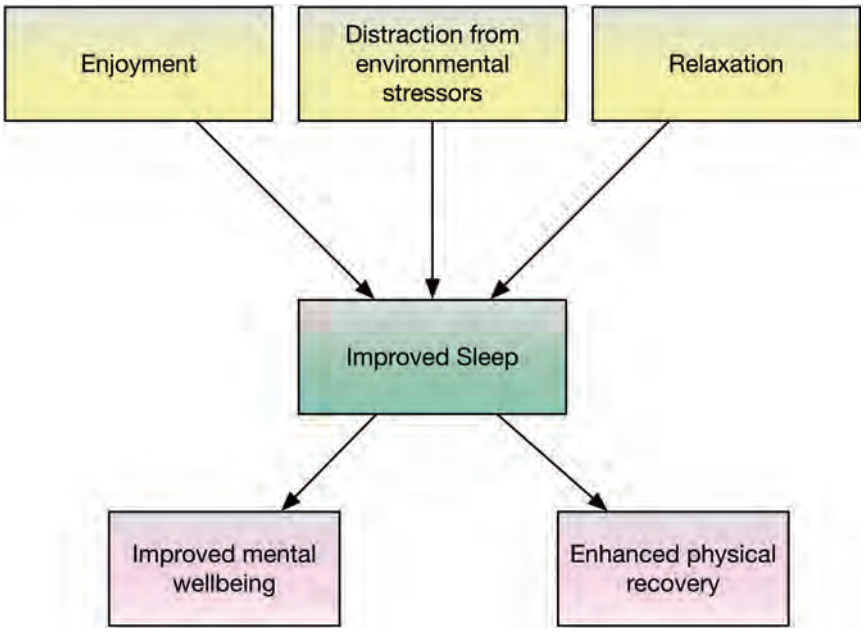


Figure 3.15: Principles of how a virtual reality-based intervention might enhance sleep and improve mental wellbeing and physical recovery

The iTech-based intervention was termed “Virtual Nature Therapy” or VNT and presented the patient with exposure to the sights and sounds of Virtual Wembury at sunset, in the evening prior to intended sleep. Hand controllers could be used to interact with the virtual environment, allowing the patient to explore the virtual world, increasing engagement and distraction from the clinical surroundings.

3.8.5 Piloting the system and user interfaces

3.8.5.1 Staff testing of the Virtual Nature Therapy prototype

An iterative design process utilises user feedback from prototype demonstrations. In hospital settings, these users can be patients, staff or others (eg friends and family). The first prototype of VNT was designed by the research team and consisted of a navigable version of Virtual Wembury at sunset viewed on a 50 inch television screen on a wheeled support stand. In order to gather early feedback on usability and context of use (Figure 3.16), the first prototype was demonstrated to a focus group of ICU doctors, nurses and physiotherapists on the QEHB ICU.

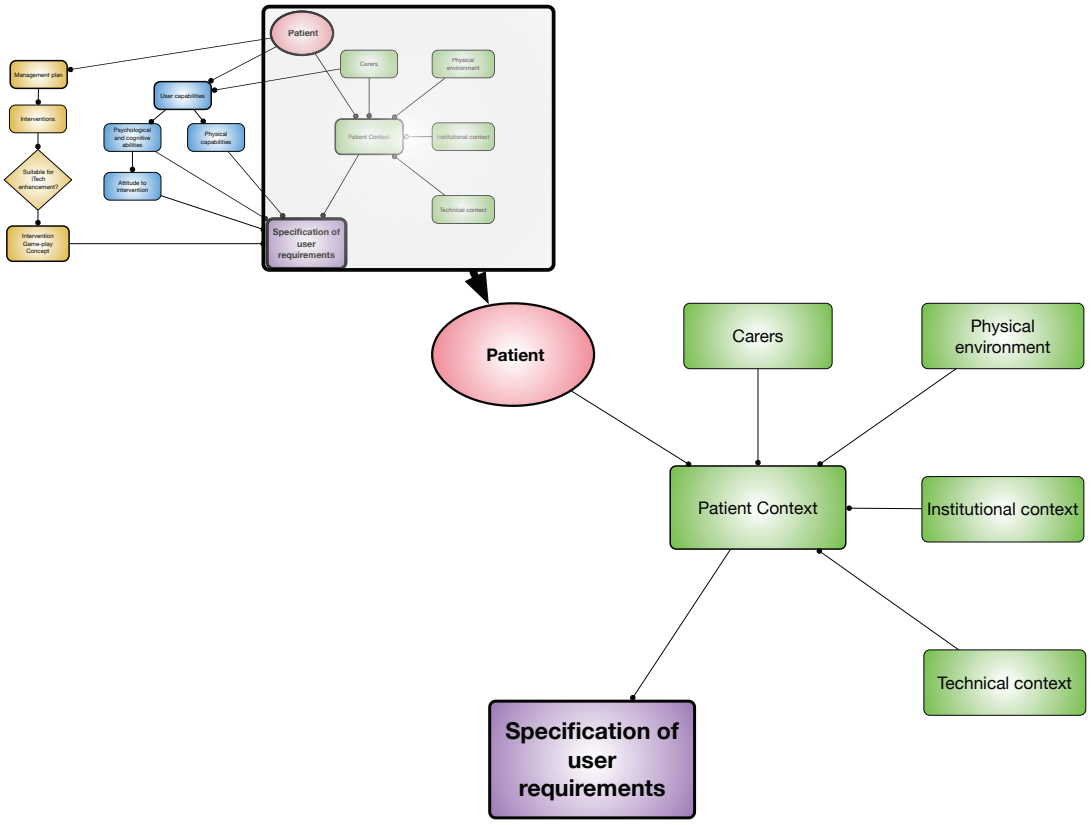


Figure 3.16: Understanding context of use to inform specification of user requirements

3.8.5.1.1 Aims

The aims of the staff demonstrations were to:

1. Determine the ergonomic limitations of the prototype design in terms of use within the ICU bed-space.
2. Evaluate staff attitudes to the device, including design of the software and selection of system components of the VNT.

3.8.5.1.2 Methods

Staff participants were recruited from the QEHB ICU over a period of three days. Attendance was voluntary and no financial compensation was provided. Participants attended the demonstration individually and were introduced to the VNT system by a member of the research team. A clinical member of the research team then presented the concept for use on the ICU.The participant was then invited to navigate the virtual environments using the hand controllers, for up to 20 minutes. Following the demonstration, the participant was invited to write free text comments to the following questions:

- Do think you would be able to use the VNT system within the ICU environment?
- What are your views of the VNT system and how it has been designed?
- Do you think any of your patients might benefit from using VNT?

Responses were coded in NVivo and underwent thematic analysis.

3.8.5.1.3 Results

Eleven participants took part in the study. None experienced nausea or other side effects whilst navigating the VNT system. All completed the written questionnaire, although most only wrote brief comments. All participants stated that they thought the device would might be beneficial to some of their patients. The participants' comments were coded according to themes of whole system, software and interface devices (Table 3.1).

Table 3.1: ICU staff comments following demonstration of VNT

Theme	Comments
Whole system	Needs to be easy to manoeuvre, especially in emergencies. Should be a self contained unit. The whole system is too large.
Software	Very pleasant to look at. Very relaxing. Needs more wildlife, it's a bit post-apocalyptic.
Interface	The screen was too large. Good resolution on the screen Could be mounted on the bed or drip stand. The hand controller is easy to use. Should definitely be on wheels.

3.8.5.1.4 Discussion

The results obtained from this study supported further development of the prototype. Modifications made were based on comments on increasing interest within the software content and adjusting the support stand to facilitate manoeuvrability within the confines of the ICU bed space.

3.8.5.2 Case report: Patient testing of the VNT prototype

3.8.5.2.1 Aims

To explore usability and side effects of the VNT system by a typical long term patient on the ICU

3.8.5.2.2 Methods

The VNT was demonstrated to a patient on the ICU. The patient was an elderly female, who had spent six weeks being cared for on QEHB ICU, following complex intra-abdominal surgery, complicated by multi-organ failure. She had a tracheostomy tube inserted through her neck into the trachea to facilitate the process of liberation from mechanical ventilation and was receiving supplementary oxygen support. She was awake, alert and cooperative, with no signs of confusional state and had capacity to consent to participate in the demonstration. She was willing to take part, and her family members were present throughout. She was advised that the VNT system may cause nausea and, in this event, to advise a member of the research team who would terminate the demonstration.

Genius ring mouse	Wii Nunchuck	Joystick
		

Figure 3.17: Control devices tested during patient demonstration of VNT on the ICU

The patient was invited to explore the VNT virtual environment for an unlimited time, trialling three different hand controlled interface devices; a joystick, “Nun chuck” thumb controller and ring mouse (Figure 3.17). She was supervised at all times by a member of the research team.

She was then asked to provide free comments to a member of the research team about her views and experience of the VNT system. Qualitative data was coded using thematic analysis in NVivo.

3.8.5.2.3 Results

The participant used the VNT system for 15 minutes, trialling all three hand controllers (Figure 3.18).

Figure 3.18: First patient demonstration of Virtual Nature Therapy (VNT)

The participant's comments were coded according to themes of whole system, software and interface devices (Table 3.2). She experienced nausea whilst her family members were navigating the virtual environment using the controller themselves whilst she was watching.

Table 3.2: ICU patient comments following demonstration of VNT

Theme	Comments
Whole system	I find it tiring to use. I would be keen to try it again. It was a nice distraction and a nice change from watching television.
Software	I would have preferred to look at more greenery. I liked that the time of day (sunrise/sunset) could change on the screen according to the actual time of day. I think I would find it more relaxing without the movement. The movement on the screen made me feel sick whilst others were using the controllers.
Interface	The screen was too large. I enjoyed the sounds via the headphones. I didn't mind being able to hear background noises whilst I was using the headphones. The small controllers were easier to use than the joystick.

3.8.5.2.4 Discussion

The researchers were able to demonstrate the first prototype VNT system to both staff and patient. Access to staff feedback was facilitated by using the research team to provide direct patient care allowing the staff member to attend the demonstration sessions. Overall, staff were enthusiastic about taking part. Acquiring patient feedback was less straightforward, as few patients were medically and cognitively fit enough to both the system and provide detailed, constructive feedback. Rigour was necessary to ensure the patient did not feel

coerced into participating, nor did the experience hinder their care. The following modifications to the system were made:

1. Amendments to VR Content:

- Removal of artefacts, including a plank and static birds
- Removal of flags on the default start-up sequence.
- Movement of the moon to enable it to rise in the correct location
- Balancing of sound in both earphones (to avoid “one ear deafness” effects). Revision of the volume of the ocean sounds and volume thereof with respect to distance from shoreline
- Provision of a function where six viewpoints can be instantly selected (NO “fly-to” sequences) via a single (toggling) button-press.
- Reduction of viewpoint rotation speed

2. Alterations to system design to address ergonomic Issues prior to deployment on the ICU:

- Reduction of screen size and stand
- Television screen to be used in preference to head mounted display
- Avoidance of on-screen glare (artificial and natural lighting sources) and mesh-like objects in line with the lighting source
- Management of smearing caused by antibacterial wipes.
- Information to be provided for relatives to discourage them from “having a go”, due to the risk of patient disorientation and nausea.
- Information to be provided to the staff to ensure that set-up procedures are undertaken with the screen turned away from the patient,
- Selection of audio headphones of the larger padded ear surround type.

3.9 The second prototype: Virtual Nature Therapy

3.9.1 Description of the Virtual Nature Therapy System

Integration of the factors informing the user specification informed the design of the prototype Virtual Nature Therapy (VNT) system, which consisted of the software, display, controller and support stand components.

3.9.1.1 Software

The "Wembury Bay" virtual environment was used and presented sunset events together with sun and moon movement (Image 3.19).

Figure 3.19 Virtual Nature Therapy: Virtual Wembury at sunset

The virtual environment also featured a small number of animal representations, including rabbits, horses and seagulls, which moved in a random fashion.

Exposure to VNT comprised:

- Viewing the Virtual Wembury scene on the screen.
- Listening to the sounds of the Virtual Wembury environment using noise-cancelling headphones (the noise-cancelling function could be switched off at the patient's request)

Three conditions were used in sequence. Each condition represented increasing complexity VNT and potential engagement therein. Participants offered condition B or C were able to revert to condition A by not using their hand controllers if they wished

3.9.1.2 Display

"Virtual Wembury" was hosted on a Dell Inspiron i7 laptop equipped with a powerful Nvidia graphics processing unit, displaying real-time images of the virtual environment to users via a 50-inch television screen.

3.9.1.3 Controllers

Two control devices were offered for conditions VNT B and VNT C (Table 3.3).

Table 3.3 ReVERe Sleep: Description of the Virtual Nature Therapy Interventions

Condition	Description	Controller
VNT A	Static image. Patient unable to navigate within Virtual Wembury but objects within the VNT move; including sun setting, sea wave motion and animal movements.	Nil
VNT B	Toggle view with 180 degree viewing motion. Patients will be able to toggle between different viewpoints and look around from a static position. Reverts to VNT A if controller not used.	 Genius ring mouse
VNT C	Interactive version of VNT, whereby patients can navigate Virtual Wembury. Reverts to VNT A if controller not used.	 Wii Nunchuck

3.9.1.4 Support stand

The system was to be used in the patient bed space, thus the prototype was mounted on a wheeled stand to allow safe, easy manoeuvrability around bed spaces and between doors.

The report of the study Restorative Virtual Environments for Rehabilitation - Does Virtual Nature Therapy enhance sleep on the Intensive Care Unit? Is presented in Chapter 5

3.10 Reflections and key methodological lessons learned

- Design and development of iTech-based interventions for use by patients recovering from critical illness and injury can be informed by evaluation of clinical practice, via clinical audit.
- Small cycle testing can be used within an interactive process to refine system design. Access to patient user feedback is, however, limited due to physical and cognitive limitations of the target patient cohort and safety constraints of exposing vulnerable individuals to potential risk of immature technologies.

CHAPTER 4 VIRTUAL RESTORATIVE ENVIRONMENT THERAPY AS AN ADJUNCT TO PAIN CONTROL DURING BURNS DRESSING CHANGES: A FEASIBILITY STUDY OF A NOVEL PROTOTYPE SYSTEM.

Chapter 4 presents the report of the first study “VRET Burns,” Virtual Restorative Environment Therapy as an adjunct to pain control during burns dressing changes: a feasibility study of a novel prototype system (Figure 4.1). This study methodology is based on a clinical feasibility study to determine the likelihood of completing a proposed future randomised control trial to determine effectiveness.

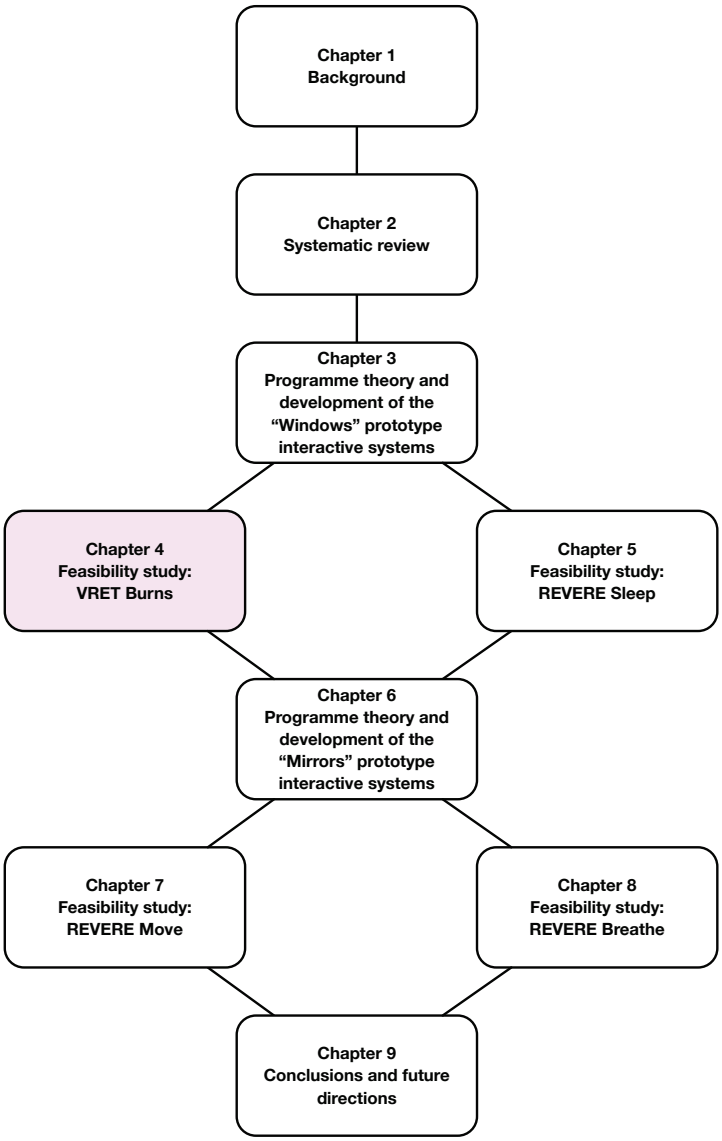


Figure 4.1 Thesis roadmap - Chapter 4

4.1 Introduction

The pain of a severe burn injury is characterised by an unremitting background pain, coupled with severe exacerbations associated with essential procedures such as dressing changes. The experience of pain is affected by patients' psychological state and can be enhanced by anxiety, fear and distress caused by environmental and visual inputs.(107) The underlying principle of VR is that attention is diverted from the painful stimulus. Functional MRI studies undertaken during VR distraction from experimental pain have demonstrated enhancement of the descending cortical pain-control system.(111) The prototype system integrates distraction therapy with the development of virtual restorative environments. We have termed our system "Virtual Restorative Environment Therapy" (VRET). Evaluation of effectiveness of a novel medical device requires the completion of a phase III randomised controlled trial. Prior to this, it was necessary to perform a feasibility study to inform the design and methodology of the definitive trial, as well as determining that the prototype system was usable and safe. Use of tools to evaluate usability in well subjects, such as the SUS (92), are likely to be overly burdensome in this patient cohort so simple methods should be used.

4.2 Hypotheses

1. When compared to standard analgesia alone or passive viewing of a virtual environment, exposure to the Virtual Restorative Environment Theory (VRET) system will reduce pain during ward-based burns dressing changes in adults.
2. System usability can be evaluated using simple Likert item questions and free text qualitative feedback.

4.3 Aims

To assess:

- The effectiveness of the novel VRET system in terms of the effects on pain and anxiety experienced by patients during dressing changes.
- The evaluation of patient acceptance and usability of the VRET system.
- The evaluation of clinical staff acceptance and usability of the VRET system.

4.4 Methods/Design

This study evaluated the feasibility of introducing a novel, the VRET system to the Burns Unit at the Queen Elizabeth Hospital Birmingham (QEHB) for dressing changes. A three arm, randomised, within-subject crossover design was used to compare three conditions:

1. Interactive VRET (VRET-I) plus conventional analgesics.
2. Passive VRET (VRET-P) plus conventional analgesics.
3. Conventional analgesics alone.

This study was sponsored by the University of Birmingham, reviewed by the National Research Ethics Service Committee South Birmingham (Reference 13/WM/0205), approved by the UK Health Research Authority and registered with the UK Clinical Research Network portfolio (Study ID 15785) and Current Controlled Trials (ISRCTN23330756). The study was designated as a trial of a class 1 medical device, not for commercialisation, thus received a letter of no objection from the (MHRA).(96, 97)

4.4.1 Study participants

The study was undertaken in the Queen Elizabeth Hospital Birmingham (QEHB) Burns Unit, a tertiary admitting centre for the management of adult patients with burns, including a level 1/2 high dependency area.. Eligibility for enrolment in the study was determined using the following criteria:

4.4.1.1 Inclusion criteria

Patients with burns (any cause) admitted to the QEHB Burns Unit, who required:

- at least three in-patient dressing changes.
- opioid based analgesia (e.g. oral morphine, codeine phosphate or tramadol) or inhaled nitrous oxide (entonox) for the dressing change (i.e. patients who have previously or might potentially experience moderate or severe pain).

4.4.1.2 Exclusion criteria

- Inability to use or interact with the VRET system (e.g. blindness, severe bilateral hand injuries).
- Requirement for general anaesthesia or analgo-sedation with Ketamine or Midazolam.
- Poor cognitive state (e.g. severe dementia or delirium or severe).
- Multi-drug resistant infection.
- Dressing changes requiring overhead showering.

4.4.1.3 Randomisation process

The order of intervention was randomised using block allocation, as was appropriate for the small sample size. A computer-generated randomisation sequence (www.randomization.org) used a block size of six, which was to be repeated four times.

4.4.2 Sample size

Using a Monte Carlo method, we estimated that a sample size of 25 patients would provide 99% power to detect a clinically important effect of a reduction in pain scores of a third.(89) The data and assumptions underlying the calculation were as follows:

- The observed distribution of 33 pain scores in the preliminary department audit was the true distribution of the ‘control’ value.
- The mean percentage reduction from the control value was 30 for VRET-I.

- The mean percentage reduction from the control value was 15 for VRET-P (assuming a lesser effect than VRET-I).
- Both percentage reductions were normally distributed with a standard deviation of 25.

4.4.3 Study procedure

4.4.3.1 Recruitment

Patients were informed of the study by their clinical team. Patients meeting the inclusion criteria were invited to participate by the research team and provided with a patient information sheet, following which they had up to 24 hours to decide whether they wish to enrol in the study, at which point written informed consent was taken. Each patient received each condition; VRET-P, VRET-I and control. The intervention order was randomised prior to the first procedure. A retrospective review of admissions and length of stay was undertaken to identify the likely accrual rate. Assuming a 50% refusal rates, it was estimated that 25 patients would be recruited over a three month period.

4.4.3.2 Intervention

During passive VRET (VRET-P) patients looked at a static computer-generated image of Wembury Bay. In the active treatment (VRET-I), patients were able to navigate the virtual world, travelling in a speedboat. Analgesia was provided as per ward protocol for each intervention and patient requirement prior to the dressing change. Dressing changes were carried out as usual by ward staff. Regular analgesics were given at set times according to the prescription (e.g.

0700, 1200, 1400, 1700, 2200) and, as required, analgesia was given 30 to 60 minutes prior to dressing change. Breakthrough pain was managed by nurse-titrated boluses of intravenous morphine. There was no standard analgesic protocol, although most patients received regular paracetamol, a non-steroidal anti inflammatory and a weak opiate (codeine or tramadol) with as required oral of intravenous morphine.

For conditions utilising the VRET equipment, a member of the research team set up the equipment in the patient room/bed space and patients received a short tutorial and demonstration prior to their dressing change. The setup procedures for the VRET system were demonstrated to the nurse undertaking the dressing change to allow evaluation of nursing perception of the system, including ease of use.

A member of the research team remained in the room whilst the dressing change was undertaken by a member of the burns unit's nursing team in order to detect adverse events or troubleshoot where required. Their interaction with the patient or staff was minimised as far as possible in order to allow normal clinical proceedings. Following the dressing change, a member of the research team removed the equipment from the patient's bed space/room, decontaminated it and stored it safely.

After each dressing change nursing staff completed a short usability questionnaire and patients were assisted to complete a questionnaire on their

experience of pain, anxiety and nausea during their dressing change. Despite the disadvantage of relying on recalled pain by the patient, it was felt that asking patients questions during the distraction activity would impact on the efficacy of the analgesic intervention. At the end of the study period, patients were offered the use of the VRET system for future dressing changes if they found it beneficial.

4.4.3.3 Criteria for discontinuing for a given trial participant:

- Patient refusal to continue receiving VRET.
- Patient becoming unable to use VRET or participate in data collection. This may be due to clinical deterioration or delirium.

4.4.4 Data collection

4.4.4.1 Primary outcome:

Worst pain score experienced during burn dressing change using an 11 point (0-10 where 0 is no pain and 10 is most severe) numerical rating scale (NRS). The NRS was selected as the patient may not have to be able to write, as is required for a graphical rating scale.(126)

4.4.4.2 Secondary outcomes:

1. Pain score one hour after dressing change (NRS).
2. Anxiety score during dressing change (NRS).
3. Patient satisfaction with pain control (Likert scale).
4. Patient satisfaction with VRET system (Likert scale).

5. Patient usability assessment of VRET system (Likert scale).
6. Patient enjoyment during use of VRET system (Likert scale).
7. Patient sense of presence during use of VRET system (Likert scale).
8. Nausea (Likert scale).
9. Nursing satisfaction with VRET system (Likert scale)Demographic data, including patient age, gender, size of burn and pain score before dressing change, was also collected.

Quantitative data was analysed using Graphpad Prism. Data was assessed for normality and between group analysis undertaken using paired t tests for normally distributed data and Wilcoxon sign rank test for non-normally distributed data. The qualitative interview data from patients and staff was coded using NVivo for Mac (QSR international).

4.5 Results

Two hundred patients were screened over an 18-month period, with 42 approached, of whom eight were enrolled (Figure 4.2). Reasons for the low accrual rate included patient refusal (28/34) and a change in practice whereby patients were more likely to be discharged home, returning for their dressing changes in outpatient clinic.

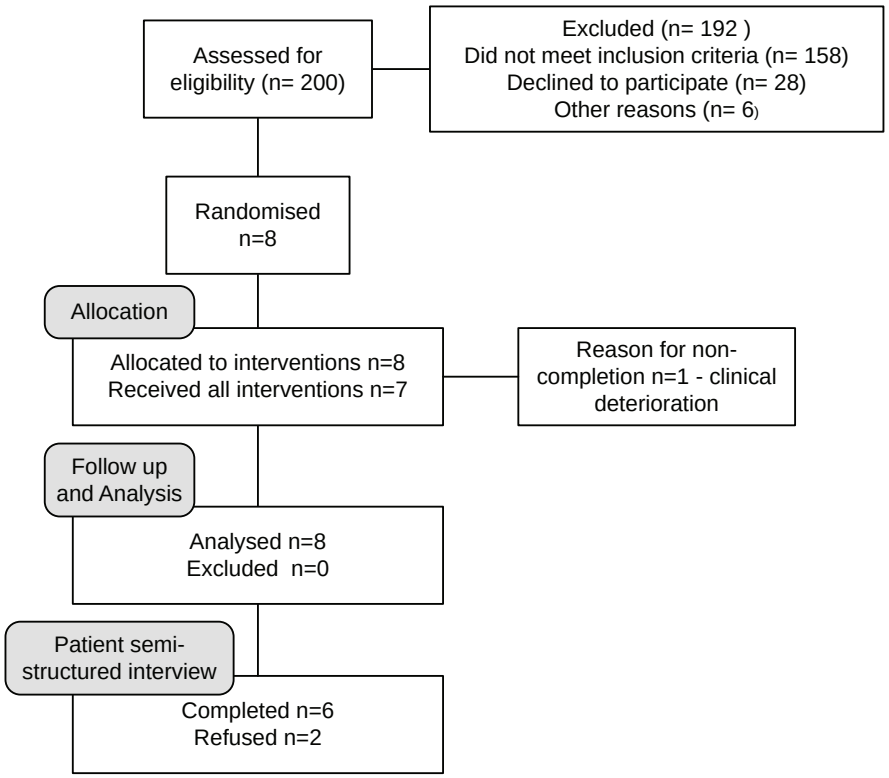


Figure 4.2 VRET Burns Consort diagram

The mean participant age was 47, range 21 to 83 years. Cause of burn included house fire, accidental self immolation, immersion in hot cooking oil and fall with long lie against radiator. Mean burn percentage body area was 22.2%, range 4 to 90%.

Seven patients completed all interventions with one patient completing just the VRET-I intervention before experiencing clinical deterioration. He was readmitted to the critical care unit for 11 days and on return to to the burns unit no longer required analgesia for dressing changes. His pain and anxiety scores were not included in the analysis due to the requirement of complete data sets

to undertake the statistical tests, however the qualitative and usability data data was included in analysis.

One patient requested to use the VRET-I intervention for all dressing changes after completion of the trial, accumulating over 6 hours of game-playing prior to discharge home. Only 2/7 patients wished to use the noise-cancelling headphones, the majority preferring to listen to sound via the LCD display screen.

Although pain increased during the dressing changes for all interventions, neither VRET conditions had an impact on pain compared to control conditions (Figure 4.3), although anxiety was significantly reduced during the VRET-I intervention compared to control (Figure 4.4).

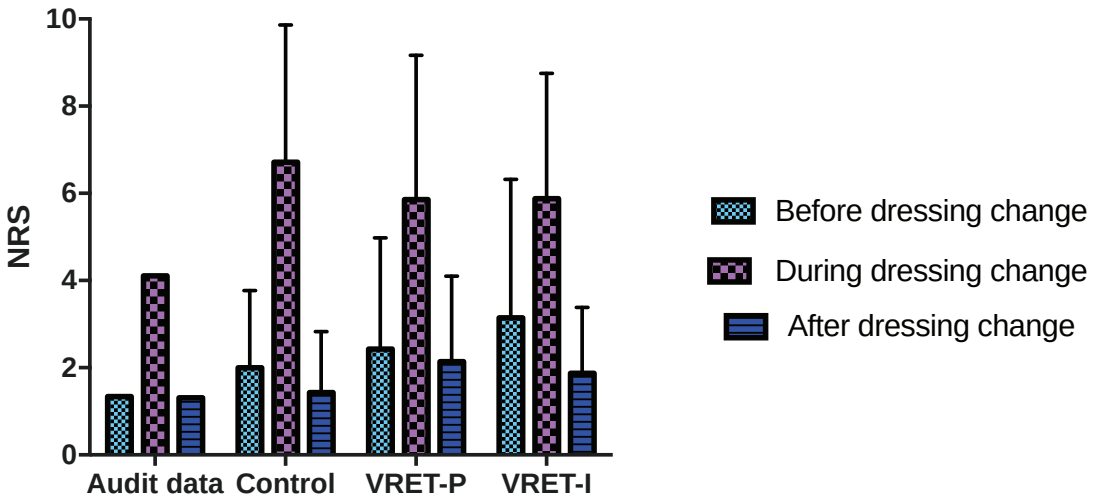


Figure 4.3: Comparison of worst pain before during and after dressing changes for each intervention.

Mean and 95% confidence intervals (n=7) Mean only for audit data.
No difference between interventions control vs VRET-P, control vs VRET-I, VRET-P vs VRET- for before, during and after dressing change pain scores $p>0.05$ for each comparison - paired t tests, normality confirmed by Shapiro-Wilk test
NRS Numerical Rating Scale for pain where 0 no pain, 10 most severe pain.

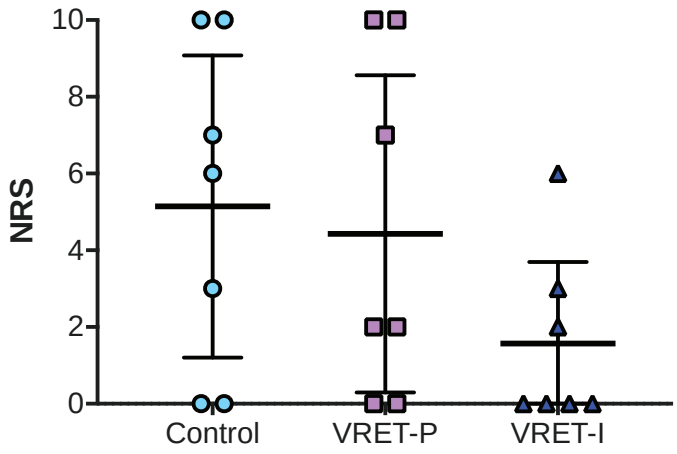


Figure 4.4 VRET Burns anxiety scores during dressing change.

Individual data points with error bars showing mean and 95% confidence intervals
Difference between Control and VRET-I, p=0.04. No difference between control vs VRET-P and VRET-P vs VRET-I, p>0.05 for each comparison. Paired t tests, normality confirmed by Shapiro-Wilk test.
NRS Numerical Rating Scale for pain where 0 no anxiety, 10 most severe anxiety.

No patients reported nausea during or after either VRET-P or VRET-I exposure. Patient reported that they were more satisfied with their pain relief following VRET interventions but this was only statistically significant when comparing control conditions with VRET-I (Figure 4.5).

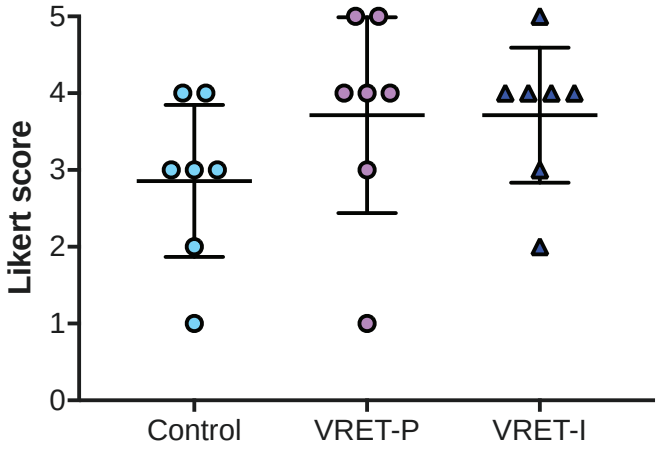


Figure 4.5: VRET Burns overall satisfaction with pain relief during the dressing change.

Individual data points with error bars showing mean with 95% confidence intervals. Difference between Control and VRET-P, p=0.02. No difference between control vs VRET-I and VRET-P vs VRET-I, p>0.05 for each comparison. Paired t tests, normality confirmed by Shapiro-Wilk test.
Likert score: 1=not at all, 5=very much

Patient usability assessments of the VRET prototypes are summarised in table 4.1, with all but one patient reporting that they enjoyed using the system “somewhat” or “very much.

Table 4.1 VRET Burns summary of satisfaction, usability, enjoyment and presence Mean (SD) of Likert Items where 1 not at all, 5 very much

Domain	Questions	VRET-P,n=8	VRET-I,n=7
Satisfaction	How satisfied were you with the virtual reality system during your dressing change?	3.37(1.50)	3.14(1.46)
Usability	To what extent did you feel the VR equipment was easy to use?	4.75(0.46)	5.00(0.00)
Enjoyment	Have you enjoyed this VR session?	3.75(1.28)	3.71(0.76)
Presence	To what extent did you feel you “went into” the virtual world?	2.38(0.92)	2.00(1.00)

All the patients reported that both VRET-P and VRET-I were “somewhat” or “very much” easy to use. Only one patient experienced “presence” or the feeling of going into the virtual world. The summary of the thematic analysis from patient and staff interviews is presented in tables 4.2 and 4.3. Two patients refused to participate in the semi-structured interviews and questionnaires following the interventions as they felt “too tired.”

The qualitative interview data from patients and staff was coded using NVivo for Mac (QSR international). Comments were classified by source into two categories, patients and staff. They were then coded by two main themes, positive and negative. Within the negative comment theme, three sub-themes were then identified, effectiveness and appeal, system ergonomics and usability and use errors (Table 4.2). Positive sub-themes were appeal and impact on mood, distraction and system ergonomics and usability. Within these sub-themes comments were further categorised by intervention type.

Table 4.2: Summary of qualitative feedback on the VRET systems - negative themes

Themes	Patients	Staff
Effectiveness and appeal	**VRET-P** Video was too simple for me so it didn't distract me from the pain at all. The picture was very nice and it was nice to imagine I was there, it wasn't enough to make a difference to my pain. It might have been better if the scenery changed/things happened to make it more interesting - eg people, animals, activities. Not very distracting I was disappointed with the video compared to the game **VRET-I** Didn't feel that is was distracting. Didn't seem to make a difference to my pain Lost interest in the game after 5 minutes Didn't want to use the computer as he never played computer games and doesn't want to start now Wasn't for me.Never been into video games.	**VRET-I** Patient seemed to prefer talking to us rather than playing the game. Sound not accurate - ok when watching it but annoying when just listening - sounds a bit repetitive.
System ergonomics and usability	**VRET-P** It might have been better if the screen was closer (in the shower) **VRET-I** Would have liked the sound to be louder Nurses got between me and the screen making it difficult to concentrate and steer the boat Steering needs to be more responsive. Turning circle too wide	**VRET-I** Does get in the way a bit when moving trolleys at the end of the bed when trying to avoid touching things Difficult for the patient when lying down Difficult to use the system when lying down Very weak hands therefore needed some assistance to hold the controller
Usage errors	**VRET-I** Need to fix the boat being able to jump the barriers	**VRET-I** Distracting only when comments made from "operator" to the patient.

Table 4.3: Summary of qualitative feedback on the VRET systems - positive themes

Themes	Patients	Staff
Appeal and impact on mood	**VRET-P** Better than the game, more relaxing, likes the sea Pleasant to watch **VRET-I** Enjoyed the game, Found it very relaxing, fell asleep after using it	**VRET-P** Very relaxing Lovely to look at **VRET-I** Very relaxing
Distraction	**VRET-P** Good for the first few minutes then was distracted by the nurses chatting **VRET-I** My best dressing change so far because I wasn't really thinking about the pain. I was addicted to getting the score up. Having something else to think about really helped.	**VRET-P** The patient was distracted by it as he chatted about it to the nurses during the dressing change
System ergonomics and usability	**VRET-P** Very professional system **VRET-I** Controller was simple and easy to use. Easy to get the hang of, even though not a regular gamer. Easy to manage with one hand. Easy to understand how to play the game	**VRET-P** Sounds didn't distract from work **VRET-I** Equipment was not obstructive for this dressing change as I had my back to the terminal and was only dressing one limb Very useful for this patient. Perfectly positioned for this patient even though he was in the shower. Easy to set up Manageable with careful use in the shower

Most patients reported that there were no usability concerns with the VRET-P intervention, but that they did not feel it was very distracting or effective at reducing pain. The VRET-I intervention appeared to be more effective for the users who were familiar with computer gaming systems and were able to use the system more easily.

None of the staff reported that the system interfered with clinical care, although one noted that recumbent patients found it difficult to see the screen when the system was positioned at the end of the bed. One one occasion, the VRET-P system was used safely within the bed-space shower area, where lower limbs only underwent dressing change assisted by flowing water (Figure 4.6).

Figure 4.6: Use of VRET-P during dressing change in the bedside shower area

All staff users reported that both VRET-P and VRET-I systems were “somewhat” or “very” easy to use and did not interfere with clinical care (Figure 4.7). There were no adverse events attributed to the use of the VRET system.

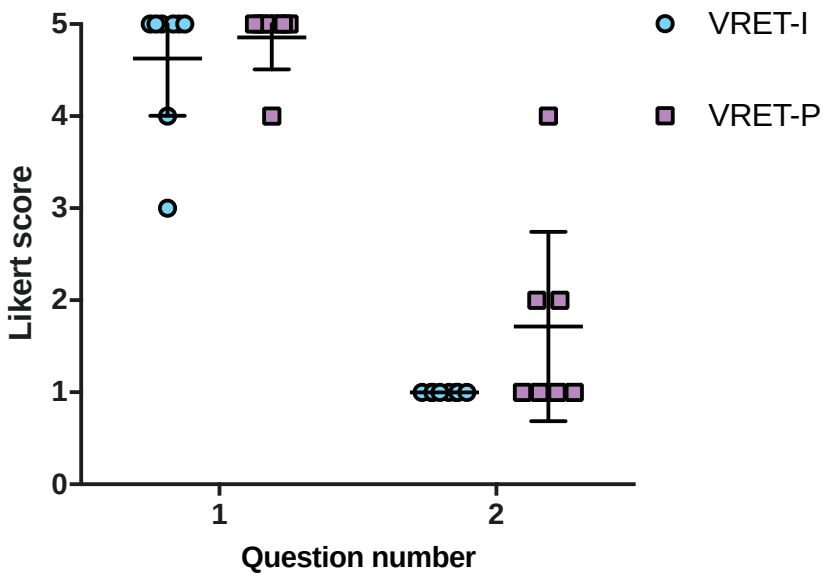


Figure 4.7 VRET Burns Staff user acceptance scores

Individual data points with error bars showing mean and interquartile range Question 1: To what extent did you feel the VR equipment was easy to use?
Question 2: To what extent did you feel the VR equipment interfered with clinical care?
Likert score: 1 not at all, 5 very much

4.6 Discussion

This study set out to establish the feasibility of introducing Virtual Restorative Environment Therapy to enhance pain management during dressing changes for burn wounds. The research group hypothesised that providing patients with an interactive, virtual reality-based game would provide distraction from pain during dressing changes and improve their experience of care.

4.6.1 Study recruitment

The study accrual rate was much slower than predicted by previous audits of admission data, with only 4% of screened patients recruited to the trial. This low recruitment rate has been seen in other trials of VR-based interventions for acute pain management and rehabilitation.(37, 83) A review of the screening log found that recruitment was limited by the nature of burns care, the ability of burns inpatients to provide informed consent due to psychiatric illness, requirement for overhead showering and the ability of patients to use the VR equipment. The cohort of patients recruited had higher pain scores than those included in the audit, with larger burns, reflecting their need to receive inpatient treatment.

The order-randomised, within-subject design with graded exposure to the VRET intervention was chosen to reduce bias within the study. Unfortunately this design may have consequently reduced the feasibility of accruing participants. Each patient had to receive at least three inpatient dressing changes not requiring a general anaesthetic or ketamine. Those patients who were

otherwise well enough were discharged home then returned to outpatient clinic for dressing changes, so many only underwent a single study-appropriate dressing change following skin grafting and prior to discharge. For logistic reasons, the study environment could not relocate to the outpatient clinic. The majority of surviving patients with the longer length of stay were the elderly frail (Image 4.2), those with medical co-morbidities and those with large burns.(127) Whilst increasing age is associated with higher mortality for a given percentage of burn, this rate is improving and there are increasing numbers of elderly survivors of burns.(128)

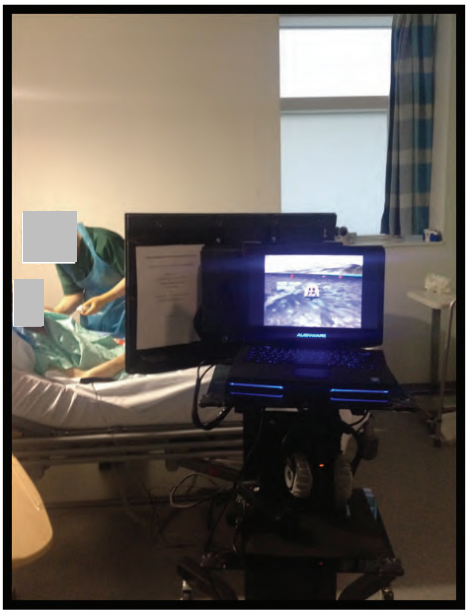


Figure 4.8: Use of the VRET-I system by an elderly patient during dressing change

Over half of the over 65s admitted to the burns unit are treated conservatively. (127) All these patients were screened, and many underwent the prerequisite number of appropriate dressing changes, however many were found to be too frail to attempt to use the VR system. A relatively high proportion of burns

patients with longer lengths of stay had self-harmed (mean 22 days). Of all burns patients, 82% suffer from mental illness,(129) with many excluded from the study due to inability to provide informed consent or unwillingness to take part. Prior to the introduction of novel interactive technologies for patient use, the characteristics and capabilities of the target population needs to be better evaluated, to ensure that the interface devices and simulations are usable.

4.6.2 Effectiveness

Failing to meet the recruitment target renders this study under-powered to assess its primary outcome of a 33% reduction in worst pain score during the dressing changes between the VRET interventions and control condition. There was a trend for reduction in pain scores between the control and VRET interventions but these were neither statistically nor clinically significant. No patients reported more than a one point increase in worst or average pain scores between control and VRET interventions. Whilst some patients reported that the VRET-P intervention was pleasant, none reported a noticeable difference in their pain scores.

The patient who reported the greatest efficacy of the VRET-I intervention was also the patient whose semi-structured interview data contained the most positive comments; he was a computer gamer prior to his burn injury and was keenest to avoid use of side-effect causing analgesics, such as morphine and entonox. Conversely, the patient who reported the least impact on pain experience using the VRET systems was a habitual user of heroin prior to

admission and, despite agreeing to participate in the study, reported that he had no wish to explore distraction-based strategies during his dressing changes.

Effectiveness of VR-based interventions may be associated with the sensation of “presence.” Presence may be enhanced by greater immersion in the VE, particularly with the use of head-mounted displays which obscure the view of the clinical area.(112) We did not use head mounted displays, or “goggles” as part of the prototype design as they are cumbersome and uncomfortable, with limited field of view and unsuitable for those with head or facial burns.(83)(67) (66) Future versions of these devices may render them suitable for testing within the next iteration of the prototype system.

This study only evaluated the sensory aspect of pain experience, alongside anxiety, during the dressing changes. It may have been valuable to collect data on other experiential factors, such as patient perception of duration of dressing change and compliance with treatment.(51, 55)

4.6.3 Safety

There were no safety concerns reported during the trial, neither as a consequence of patient exposure to the VRET causing cybersickness, nor as a consequence to patient or staff users via the moving and handling of the system.

Exclusion of patients with multi-drug resistant infection reduced the risk of harm due to transmission of infection between patients, though it was noted that we were not performing microbiological testing, such as surface swabs, to check for contamination after use and after cleaning.

4.6.4 Usability - patients

This first feasibility study of the research programme used a simplistic, unstructured method of assessing patient usability in the form of free text feedback. The expectation was that this would generate rich, qualitative data. This was an incorrect assumption, with most patients producing very restricted feedback, mostly due to fatigue and poor engagement. Future studies would benefit from a more structured approach, including quantitative tools.

Although no formal assessment of technology acceptance (33) was performed during the study, qualitative data from the semi-structured interview identified patients whose acceptance of the VRET systems was influenced by their prior exposure to, or opinion of interactive technologies. Response to the game design within VRET-I was mixed, with positive comments about ease of learning, and negative comments about repetition and boredom. Funding and time restrictions limited the complexity of the game, future iterations could allow for multi-level play, particularly for patients who wish to use the system for repeated dressing changes.

4.6.5 User errors - patients and research staff

The user error rate of the VRET systems during the trial was low, most likely due to the trial design where the study investigator set up the system and supervised the patient using the VRET during their dressing changes. Rather than user errors, it is more useful to consider whether the system was used in the way it was designed. It was noted by the staff and investigator that, particularly during the VRET-V interventions, patients were not watching the screen, therefore were not actually receiving the intervention. Part of the effectiveness of the VR-based systems using HMDs may have been due to the patients' inability to see their wounds.(49)

Consideration must be made during future design processes of the potential to incorporate functions which can monitor patient exposure to the VRET as this is crucial when attempting to determine the fidelity of the intervention.

4.6.6 Usability - staff

All staff members involved with patient care during the trial agreed to allow the VRET systems to be present during the dressing change and completed the semi-structured interviews following the dressing changes. Quantitative data, in the form of two Likert items, produced data of limited use. Qualitative data collected was sparse, the investigator allowed the staff to write their comments on the data collection form, with many just writing "no issues" and not providing detailed opinion. Future trials would benefit from having a detailed interview schedule in order to improve the richness of the data.

Staff user acceptance was influenced by two factors; their perception of the acceptance of the patient user and by the interference of the VRET device with clinical care, which depended on the location of the burn on the patient's body. Bilateral dressing changes and those requiring the patient to lie flat generated the most negative comments in relation to system design and ergonomics. Indeed, discomfort by patients exposed to interactive technologies on a conventional TV screen has been reported before. (66) Future trials would benefit from use of video capture to objectively assess the relationship between equipment, staff and patient positioning to reduce the burden of the VR-based intervention on clinical care.

4.6.7 Cost effectiveness

Cost effectiveness was not calculated within the scope of this study. However, the cost of the equipment was over £2000, even though commercial-off-the-shelf interface devices were used, and the development costs of staff time and overheads significantly exceeded this. The study data suggests that the usefulness of the VRET intervention, albeit in its first iteration, is limited to all but a small minority of burns patients. Once developed and determined to be effective, ongoing costs would be generated by the need to update software and replace damaged or redundant component parts.

4.6.8 Study limitations

The main limitation of this study is the lack of blinding for both participants and researchers, increasing risk of observer bias. The repeated measures design encouraged selection bias as only patients who were remaining in hospital for treatment for a length of stay greater than five days were enrolled. This led to preferential screening and recruitment of the elderly frail, those with the most severe burns, and those unable to self care at home, such as those suffering from severe mental health conditions. Whilst it was unfeasible to relocate the trial to the outpatient department, this should be investigated for future trials in order to improve the generalisability of the results to the burns patient population.

4.7 Conclusions

This study failed to recruit the target number of participants due to changes in clinical process, including the patient journey, presence of psychiatric illness preventing study participation and limited usability of the VRET system by burns patients. However, from the data collected VRET appears to be acceptable and safe and may be non-inferior to standard analgesic techniques when used as an adjunct. Overall, the VRET system was not a useful technology for the inpatient cohort of burns patients for management of pain during dressing changes though it may be most useful for patients in whom anxiety is heightening their pain experience. However, future prototype and trial development must include in-depth understanding of patients' physical capabilities and attitude to technology-based analgesic techniques to increase

usability and cost effectiveness of the technique. The methods used to analyse usability were feasible to use but were overly simplistic, lacking sufficient depth , and overly compromised the process required to usefully inform prototype development. Future studies will explore the use of tools validated in well-subjects, such as the System Usability Scale.(92)

4.8 Reflections and lessons learned

- Utilising the clinical feasibility study design where the number of participants is determined by the power calculation, based on a clinical primary outcome measure, risks undermining the iterative design process by delaying analysis and conclusions needed to inform prototype design. Time to target recruitment must be built into the methods to ensure the feasibility study is completed within a sensible time frame to enable timely progression.
- Over simplification of usability evaluation reduces the generalisability of results and threatens the usefulness of the study, potentially wasting time and exposes the healthcare consumers and system to unacceptable risk versus benefit.
- Use of surrogate cohorts, who may ostensibly have sufficiently similar characteristics to inform user specification, jeopardises the system design process from the earliest stages if assumptions are not adequately informed.

CHAPTER 5 RESTORATIVE VIRTUAL ENVIRONMENTS FOR REHABILITATION - DOES VIRTUAL NATURE THERAPY ENHANCE SLEEP ON THE INTENSIVE CARE UNIT?

Chapter 5 presents the report of the second feasibility study ReVERe Sleep: Restorative Virtual Environments for Rehabilitation - does Virtual Nature Therapy enhance sleep on the Intensive Care Unit? (Figure 5.1). This study methodology is based on a clinical feasibility study to determine the likelihood of completing a proposed future randomised control trial to determine effectiveness.

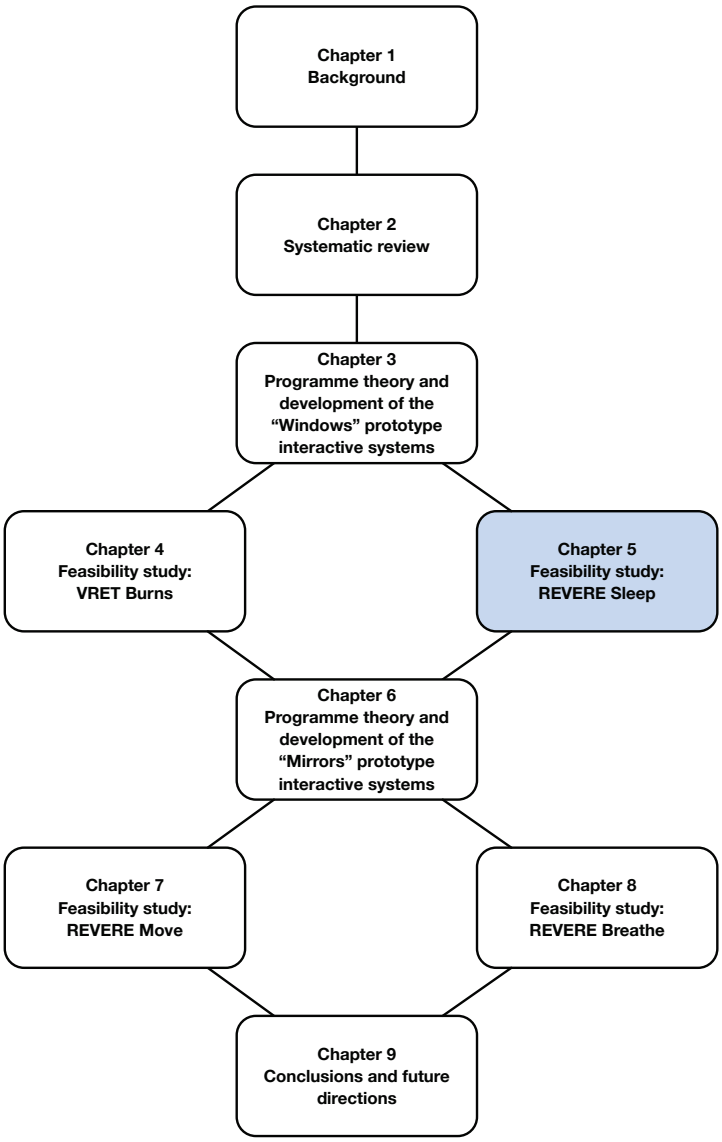


Figure 5.1 Thesis roadmap - Chapter 5

5.1 Introduction

Poor sleep during recovery from critical illness is common and causes a range of immediate and long-term detrimental effects.(130) Causation is multi-factorial and includes the impact of the patient's sensory environment.(131) Modifying a patient's immediate visual and auditory environment within the ICU is challenging.(132) Virtual environments (VEs) offer patients a non-pharmacological approach to modifying their environment. They have been used with some success in the reduction of pain and anxiety for patients undergoing dressing changes and dental procedures, although to date no study has explored the use of such systems for sleep improvement.(56, 133)

This study develops the HCD methods used during the VRET burns study, utilising the SUS tool (92), which, whilst the most contemporary method in use, has been validated for use in well-subjects and was identified by the research team as likely to be simple enough for use by patients on the ICU. Embedded usage software was also identified as being able to provide objective data on usage and preference, and would accumulate "passively" without the need for additional patient contact time by the researchers, limited burden of research participation.

5.2 Hypotheses

1. The use of the novel prototype system, Virtual Nature Therapy (VNT), by patients recovering on the ICU would improve subjective assessment of patient sleep quality.
2. Structured data collection tools and embedded software are feasible for use to inform prototype design in order to subjectively evaluate usability and objectively evaluate user preferences.

5.3 Aims

The primary aims of this study were to

1. Evaluate if VNT was feasible and safe on the ICU.
2. Evaluate whether engagement with this form of simulated environment lead to improvement in self-assessed sleep quality (determined by the Richard Campbell Sleep Questionnaire RCSQ).(134)

Secondary aims were to:

1. Determine the feasibility of using subjective, structured data collection tools to evaluate user (patient and staff) acceptance and use of VNT for patients within the ICU.
2. Determine the feasibility of using embedded usage software to evaluate user (patient) preferences for the types of engagement and levels of interactivity with VNT.

5.4 Methods

This study was a mixed methods feasibility study, using a within-subject design, where participants were presented with a graduated level of interaction with the prototype Virtual Nature Therapy (VNT). In addition to data related directly to intervention delivery, the study accumulated information on context and process to recognise potential implementation failure.

Development of the study design was informed by the Medical Research Council recommendations for developing and evaluating complex interventions, (42) the British Standard EN ISO 9241-210 “Ergonomics of human-system interaction.”(British Standards Institute 2010) and the international standard IEC 62366, “Application of usability engineering to medical devices”.(29, 30)

This study was sponsored by the University of Birmingham, reviewed by the National Research Ethics Service Committee South Birmingham (REC Ref 14/ WM/0058) approved by the UK Health Research Authority and registered with the UK Clinical Research Network portfolio (Study ID 16714) and Current Controlled Trials (ISRCTN63077147). The study was designated as a trial of a class 1 medical device, not for commercialisation, thus received a letter of no objection from the MHRA.(96, 97)

5.4.1 Study participants

The study was undertaken in the Queen Elizabeth Hospital Birmingham (QEHB) Intensive Care Unit. This is an 86-bed, mixed-level 2 and level 3 adult teaching

hospital ICU that admits medical, surgical, trauma, burns, liver, cardiac and neurosurgical patients. Eligibility for enrolment in the study was determined using the following criteria:

5.4.1.1 Inclusion criteria

- Conscious and able to communicate verbally.
- Aged over 18 years.
- Richmond Agitation Sedation Score -1 to +1.
- Considered unlikely to be discharged from ICU for five days.

5.4.1.2 Exclusion criteria

- Bilateral upper limb paralysis, or limb loss, preventing ability to use hand controller.
- Severe visual or hearing loss.
- Severe cognitive impairment including delirium, dementia or hepatic encephalopathy.
- Active infection or colonisation with multi-drug resistant organism.

5.4.2 Sample size

There is no established clinically significant change in RCSQ scores. Based on Kamdar et al.(135) quoting 27.1 as the standard deviation of the baseline RCSQ scores in one group of patients and 27.3 as the standard deviation of the final scores in a different group of patients, we estimated the standard deviation of the change in score to be 38.5 (i.e the square root of 2 x 27.2). Assuming that

the change in score in the ‘paired’ study has the same variability as the change in score in the unpaired study a sample size of 30 would provide an 80% power to detect a mean change of 20.4 (5% significance, two-tailed test).

5.4.3 Study procedure

5.4.3.1 Recruitment

QEHB critical care research nurses screened all patients daily for potential participation in the ICU’s research programme. Data on patient screening was collected electronically. Patients meeting the inclusion criteria received written information on the study and, following opportunity for discussion with the research team, had 12-24 hours to decide whether to participate. At this point, written consent was taken.

5.4.3.2 Intervention

Exposure to virtual nature therapy (VNT) comprised:

- Viewing the virtual reality scene (Virtual Wembury (Image 4.3) – a virtual reality reconstruction of the South Devon coastal path) on a 32in computer screen. The sun set over the sea during the intervention.
- Listening to the sounds using noise cancelling headphones or the screen speakers.

Participants received the VNT intervention for up to two hours in the evening, after the nursing handover at 19:30. Three VNT conditions were used in sequence between two nights of control conditions (no VNT) (Figure 5.2).The study period lasted five nights for each patient, though these were not always

consecutive due to changes in the clinical condition of the patient. Patients would not be woken up to receive VNT. Should patients have fallen asleep before receiving VNT and woken before 04:00, they were offered VNT if they wished to try to go back to sleep. Timings of sleep and the offering of VNT was to documented by the nurse caring for the patient.

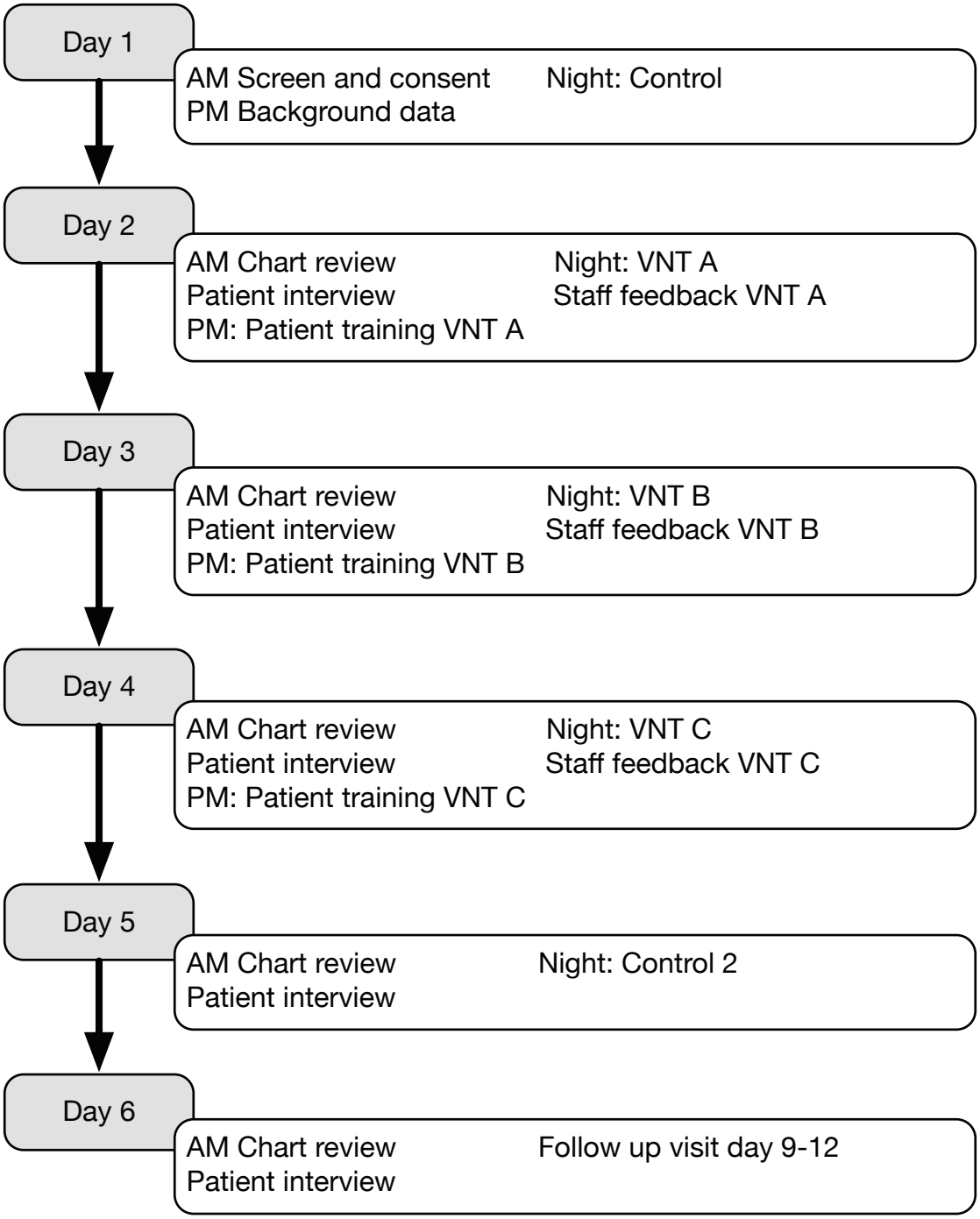


Figure 5.2: ReVERe Sleep study flow chart

5.4.3.3 Criteria for discontinuing or modifying allocated interventions for a given trial participant:

- Patient refusal to continue receiving VNT.
- Patient becoming unable to use VNT or participate in data collection. This may be due to clinical deterioration or delirium.

5.4.4 Data collection

Data collection provided subjective and objective evidence from patient and staff user perspectives. Data collection was carried out each morning following each condition and consisted of interrogation of the bedside notes and patient information and communication system accompanied by questionnaires for both patient and staff users. (Figure 4.8). Usability assessments combined the System Usability Scale (SUS) (92) with additional open questions providing triangulation.

5.4.5 Primary outcome

Patient reported sleep quality as measured by Richards Campbell Sleep Questionnaire (RCSQ).

5.4.6 Secondary outcomes (where overnight is 20:00 – 08:00):

- Hours of sleep recorded by nursing staff.
- Systolic blood pressure, pulse rate, respiratory rate.
- Presence of delirium, identified by a positive Confusion Assessment Method-ICU or Richmond Agitation Sedation Score >2 or <-2.(136)

- Pain scores overnight – Numerical Rating Scale 0-3 used by the QEHB ICU.
- Nausea, sickness and anti-emetic use.
- Patient usage of VNT – duration and type of activity, downloaded directly from embedded software within the VNT system.
- Staff feedback on usability and ergonomics (Table 5.1)

Table 5.1 ReVERe Sleep staff questionnaire on Usability and Ergonomics

Question	Comments
Did the VNT system cause you or the patient any problems, side effects or adverse events?	
Did you feel the patient benefitted from using the VNT system?	
Did the patient seem relaxed whilst using the VNT system?	
Did the patient seem uncomfortable whilst using the VNT system?	
Was the VNT system easy to use?	
Would you recommend VNT for other patients?	

To determine whether the system was acceptable to the patients and to identify usability issues, a range of assessment methods were employed, based on the Technology Acceptance Model.(33) These included:

1. Patient estimation of duration of system usage.
2. Participant usability ratings, using a modified version of the System Usability System (Likert) Scale (Table 5.2).(92)
3. Identification and recording of usability issues and incidents by hospital staff.
4. Automatic system tracking of users' navigation within the Virtual Environment (Table 5.3).

Table 5.2 ReVERe Sleep: System Usability Scale

Each statement is scored using a 1-5 likert scale where
1 strongly agree, 5 strongly disagree.
To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7 and 9 the score contribution is the scale position minus 1. For items 2,4,6,8 and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of system usability.
SUS scores have a range of 0 to 100.

Item	Statement
1	I think that I would like to use this system frequently
2	I found the system unnecessarily complex
3	I thought the system was easy to use
4	I think that I would need the support of a technical person to be able to use this system
5	I found the various functions in this system were well integrated
6	I thought there was too much inconsistency in this system
7	I would imagine that most people would learn to use this system very quickly
8	I found the system very cumbersome to use
9	I felt very confident using the system
10	I needed to learn a lot of things before I could get going with this system

The experimental protocol followed an ordered repeated measures design, whereby each subsequent condition introduces a further level of available functionality (Table 4.5). The evaluation of the VNT system’s usability had to accommodate this change and so, for each condition, different elements of user evaluation were included (Table 5.3).

Table 5.3: ReVERe Sleep usability variables for each condition

Automatic Tracking		Condition			
Interaction Function	Interaction Variable	Control	VNT-A	VNT-B	VNT-C
View status	Curtains open / closed	-	✓	✓	✓
Location selection	No. of location changes	-	-	✓	✓
	Choice of location	-	-	✓	✓
	Time spent at each location	-	-	✓	✓
View panning	No. of view direction changes	-	-	✓	✓
	Preferred view for each location	-	-	✓	✓
Free-roam	Time spent in free roam	-	-	-	✓
	Route mapping	-	-	-	✓
	Location of resting spots	-	-	-	✓
Perceived usage		Condition			
Usage element	Metric	Control	VNT-A	VNT-B	VNT-C
Visual content	Categorical estimate of time	-	✓	✓	✓
Audio content	Categorical estimate of time	-	✓	✓	✓
Usability		Condition			
Component	Assessment aspect	Control	VNT-A	VNT-B	VNT-C
Perceived ease of use	Viewing the screen	-	✓	✓	✓
	Listening to virtual sounds	-	✓	✓	✓
	Controller usability	-	-	✓	✓
	VE navigation	-	-	-	✓
Perceived usefulness	Visual content	-	✓	✓	✓
	Audio content	-	✓	✓	✓
Satisfaction and attitude towards use	Visual content	-	✓	✓	✓
	Audio content	-	✓	✓	✓
	Location selection function	-	-	✓	✓
	View panning function	-	-	✓	✓
	Free-roam function	-	-	-	✓

5.4.7 Data Analysis

5.4.7.1 Primary Outcome

Sleep quality was measured by Richard Campbell Sleep Questionnaire (RCSQ) completed by the patient. Generalised Estimating Equations were used to compare each VNT condition to the control conditions across the duration of the study.

5.4.7.2 Secondary Outcomes

- Hours of sleep as recorded by nursing staff between 20:00 and 08:00.
- Correlation of patient-estimated duration of usage of VNT system with usage data collected from the automated tracking system.
- Patient and staff perception of usability using the System Usability Scale (SUS).

Usage and usability data were analysed at a descriptive level to determine mode and spread of responses, and at a qualitative level to identify positive and negative issues in the design and implementation of the VNT system. Patient interview data included factors affecting the previous night's sleep, feedback on the prototype VNT system and suggestions for improvement, adverse events and side effects. This data was analysed alongside patient activity data, including physiotherapy, level of organ support, significant event overnight and change in patient location for associations. Quantitative data was analysed using GraphPad Prism. Qualitative data was analysed via NVivo for Mac, using thematic analysis.

5.5 Results

Thirty patients (18 males) were recruited to the trial from 14 medical and surgical specialties (Figure 5.3), with over half admitted under cardiothoracic surgery or general medicine. The mean age was 58 (range 19-79), mean length of ICU stay was 26.6 days (SD 36.7).

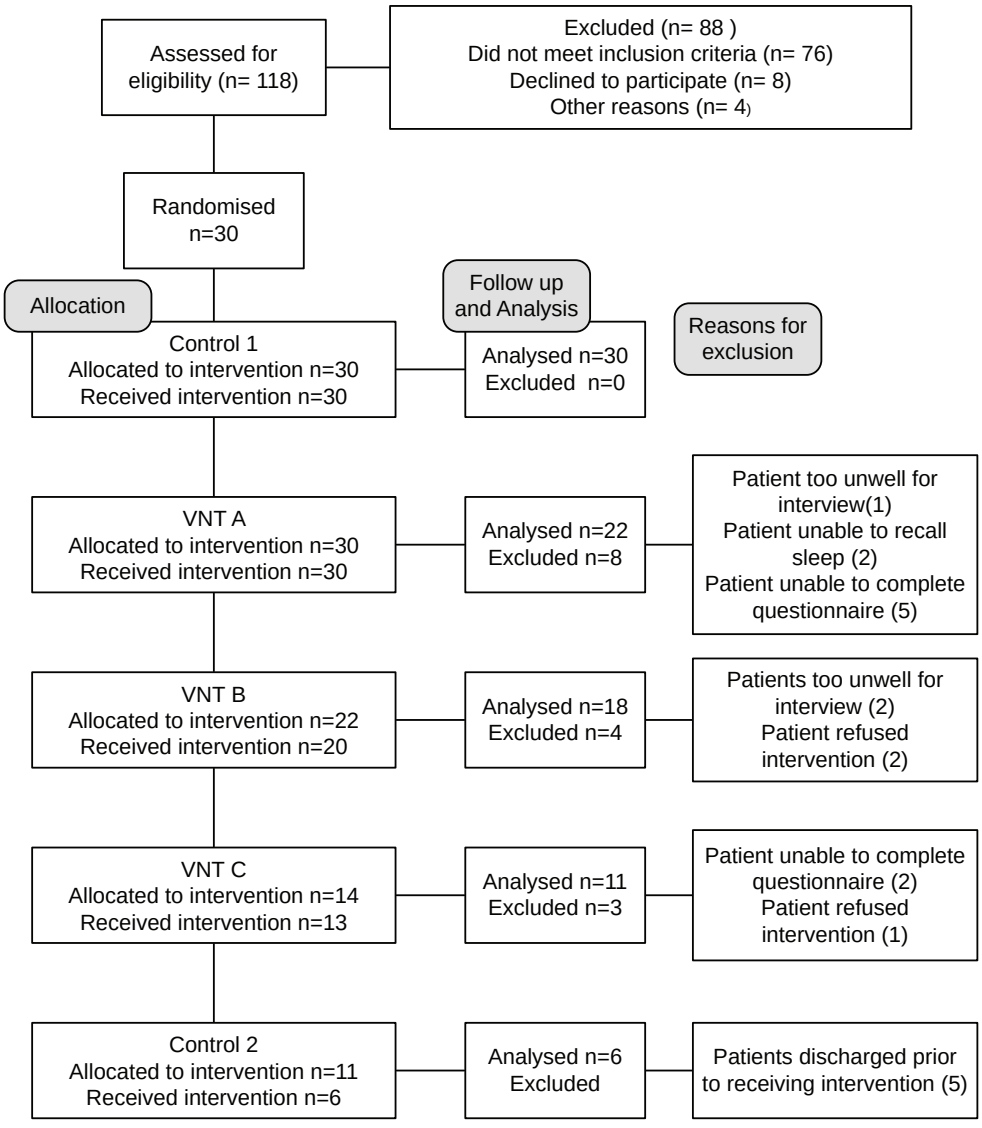


Figure 5.3: CONSORT diagram of the ReVERe Sleep study participation

Only six patients completed all VNT intervention and control nights. There were no reported adverse safety events from patient or staff users. One patient felt nauseated whilst the nurse was navigating in VNT C mode, which settled after 15 minutes. One patient reported that the sounds made her feel cold. Three patients (10%) did find the system unappealing, and refused to receive further exposure to VNT.

More patients experienced improved sleep during the nights following VNT exposure, although the differences were non significant (Figure 5.4). There was no correlation of RCSQ scores against systolic blood pressure, pulse rate, respiratory rate, pain scores, presence of delirium, night sedation, anti-emetic use or bed location (single room or main unit) between the control and VNT conditions. One patient developed delirium on the morning following exposure to VNT A. This patient was diagnosed with sepsis the same day and did not receive any further VNT interventions.

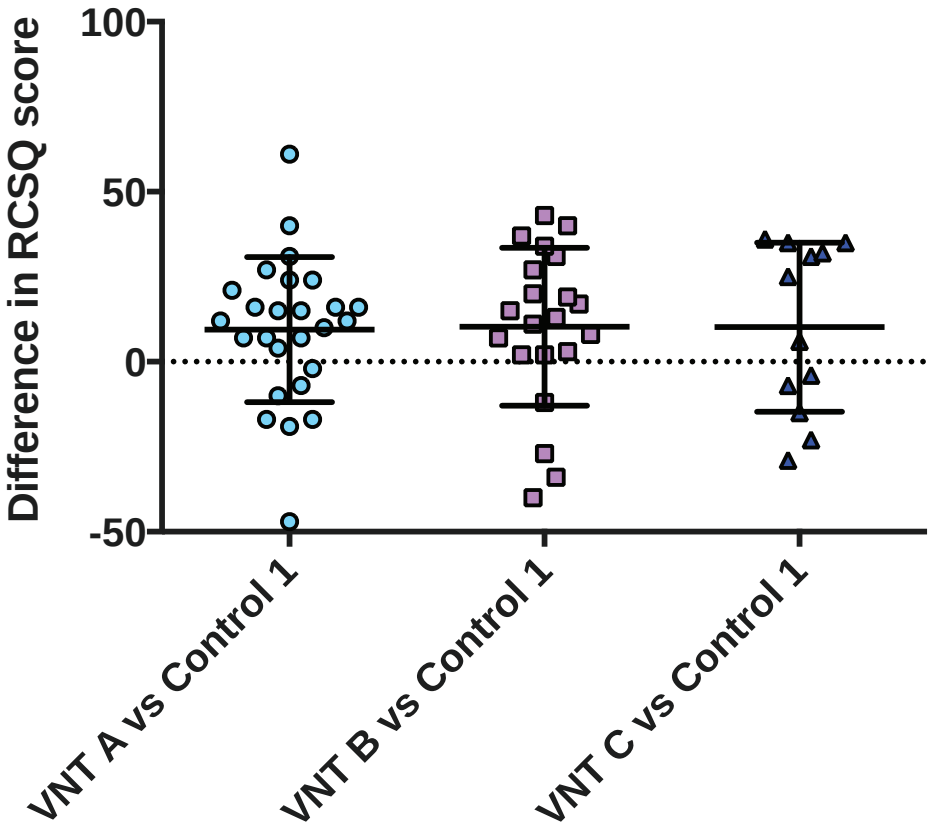


Figure 5.4: ReVERe Sleep Comparison of RCSQ sleep scores on nights following VNT exposure with nights without (Control)

Individual data points with error bars showing mean and standard deviation
Use of a Generalised Estimating Equation (allowing for analysis including incomplete datasets where patients did not complete all interventions) to compare RCSQ across all study nights showed a significant condition effect (p=0.039). Two pairwise comparisons were significant, control 1 versus VNT A (p=0.0093) and control 1 versus VNT B (p=0.0087). Following adjustment for multiple comparisons these were no longer significant.

The fidelity of the intervention was determined by patient report of time spent watching and listening to the VNT, including whether they fell asleep using the system (Table 5.4). All patients reported that they spent the same time watching as listening. All but one patient declined to use the noise cancelling headphones, preferring to use the sound from the television speakers.

Table 5.4: Estimated usage of VNT by patients

	Estimated time watching Mean (SD) mins	Estimated time listening Mean (SD) mins	Fell asleep using VNT
VNT A	88.3 (36.9)	88.3 (36.9)	50%
VNT B	88.2 (72.5)	88.2 (72.5)	55%
VNT C	71.1 (63.3)	71.1 (63.3)	43%

Usability assessments varied between systems variants and between user groups. The mean System Usability Scale (SUS) scores were highest for VNT A (Table 5.5). Some patients reported that they did not understand statements 3, 4 and 8, electing the “neither agree nor disagree” option.

Table 5.5: System Usability Scale Score for each VNT condition.
Mean (SD) sum of Likert Items. Maximum score 100.

	VNT A	VNT B	VNT C
Staff	74.8 (16.1)	69.7 (11.3)	68.9 (18.1)
Patients	69.8 (17.1)	76.5 (15.7)	73.4 (10.4)

There was no significant difference between staff and patient SUS scores (Figure 5.5). A score of over 70 is deemed to be acceptable for most products. (137)

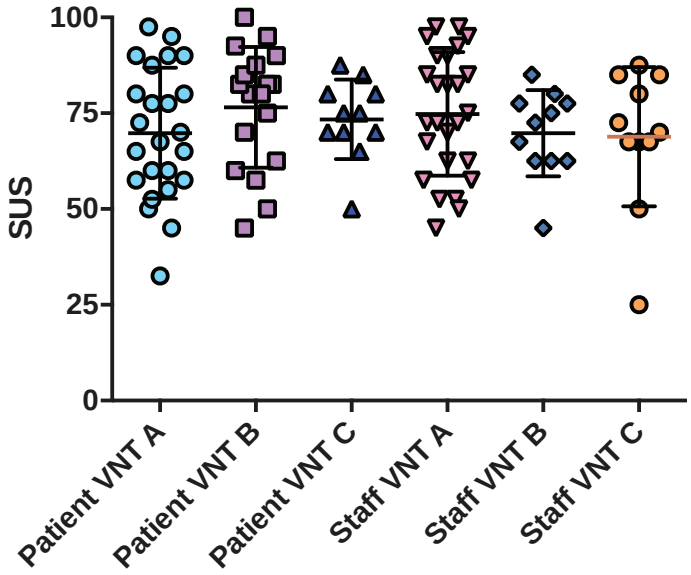


Figure 5.5: System Usability Scale (SUS) score for each VNT condition.

Individual scores, with error bars representing mean and standard deviation. Maximum score 100.

Patient interview and staff questionnaire data was used to aid interpretation of the user data. Elucidated themes were categorised as “positive” and “negative”. Sub-themes were elucidated and the three most common sub-themes for each positive and negative are listed, with example quotes given, in tables 5.6 and 5.7.

Patients with greater capability to use the interface devices, either due to maintained muscle strength and coordination or greater technology acceptance, preferred the interactive VNT,

> *“This system was loads better, the controller was much easier to use and I enjoyed exploring the virtual world” (VNT C).*

In answer to the staff question “Would you recommend the VNT system to other patients?” there were 34 positive responses, four negative responses and six respondents were unsure.

Table 5.6: Summary of ReVERe Sleep thematic analysis of qualitative data - positive themes

Themes	Patients	Staff
1. Impact on mood	54 uses of the words relax/relaxed/relaxing across all VNT interventions. Distracting (VNT A) Pleasant to watch (VNT A) Entertaining (VNT B) Calming (VNT B) Good for anxiety (VNT B) Made my mood better (VNT C)	
2. Distraction	Distracting from what was going on around me/in next bed space (VNT B) More engaging than the video last night (VNT B)	I think it has provided distraction from his current situation and surroundings for a short period of time (VNT B)
3. Ergonomics/usability	Easy to use, happy with it (VNT A) Not too intrusive (VNT A) Got on better with the controller for VNT C Easy to change the view but preferred the view form the beach (VNT B)	“System was easy to use, instructions were easy to follow” (VNT C)

Table 5.7: Summary of ReVERe Sleep thematic analysis of qualitative data - negative themes

Themes	Patients	Staff
1. System appeal and effectiveness	Video needs to be more realistic (VNT A) Was a bit disorientating when I woke up and it was still on (VNT A) I was really disappointed as I thought it would be much more interactive with a headset/goggles. (VNT A) A bit annoying as it didn't do anything (VNT A) More useful for children (VNT B) Boring (VNT B) Went dark too quickly (VNT C) Parts of the path are too long, there is too much shrubbery (VNT C)	Patient didn't like it as it kept her awake (VNT A)
2. System ergonomics	"Not high enough" (VNT A)	"The only issue was the size of the system, as the room is already full of other equipment" (VNT C)
3. Usability of interface devices	"Ring mouse was too tight." (VNT B) Didn't think the controller was very good, didn't work reliably (VNT B) Liked the video of the sunset but found it hard to use the controller (VNT B) The thumb mouse was difficult to use so I gave up quickly (VNT B)	"Hand aching after use – felt he would like a steering wheel" (VNT C)
4. Usage errors	"Woke up when the system ?crashed and desk top came on, increasing light levels in the bed space." (VNT C) Felt nauseated when the nurse was navigating (VNT C) Failed some nights so was not interactive enough (VNT C)	Screen went off in the middle of night and the computer screen – bright light – woke patient up. (VNT C)

5.6 Discussion

This study set out to establish the feasibility of introducing Virtual Nature Therapy to conscious patients on the ICU. The research group hypothesised that providing patients with a virtual view of nature would provide distraction from environmental stressors of their immediate surroundings, enhancing relaxation and sleep.

5.6.1 Study recruitment

This study met its recruitment target, albeit six months beyond the anticipated closure date. The main reason for exclusion of potential participants was the anticipated likelihood of discharge within five days once the patient had met the criteria for inclusion, there was often too small a window between the patient being sufficiently recovered to consent and participate and them then being fit for discharge to the ward, a research method limitation reported by others.(66) Reasons for slow accrual also included staff availability, where research staff were not available to supervise the research over the weekend and having only one VNT system.

5.6.2 Safety

Feasibility of the VNT was supported by a lack of adverse events attributed to use of the VNT system. The absence of nausea or cybersickness during VNT use, which may be attributed to the use of television display screens rather than head mounted displays. As with the VRET Burns study, the exclusion of patients with known multi-drug resistant colonisation or infection reduced the risk of

pathogen transmission attributed to the VNT system, although this was not confirmed microbiologically with equipment or patient swabs.

5.6.3 Effectiveness

Self-reported sleep scores improved over the duration of the study, although this was not statistically significant following adjustment for multiple comparisons. Intuitively, it might not be expected that the patients' sleep would improve over this period, so this adjustment may not be necessary. Any improvement seen was, at best, modest. Any benefit from the system may have been lost in the multitude of factors impacting on sleep quality. Noise was quoted as a frequent reason for poor sleep and future work should include objective measurements of this and other environmental confounders. There was no discernible impact on physiology, including blood pressure or pulse rate. Although used to measure effect in other studies of VR-based interventions on the ICU (138), these parameters are controlled pharmacologically in many patients so would be unlikely to reflect patent relaxation. Collection of this data was time consuming and of limited value for interpretation. The balance of burden on the researchers, appropriateness of collection of personal patient data and usefulness should be considered carefully for future trials.

The fidelity of the system was determined by the patients' self-reported exposure to the VNT, combined with usage analysed by embedded software. Usage reports varied between 15 and 360 minutes, where the intervention was designed to last approximately two hours. Those exposed to the VNT for longer

than recommended may have suffered disturbed sleep as a consequence of increased light levels in the bed space, those exposed to the VNT for a much shorter period of time may not have received its intended benefits. The embedded usage software indicated that many of those purportedly experiencing VNT B or C actually remained at one view point, typically the view of the subset over the beach, thus actually experienced the VNT A version of the system. Some patients reported in their interview that the exploratory function would be more appealing as entertainment during the day, rather than as a relaxing mode at night time. Three participants reported that they would have preferred a choice of scenes to view, and the potential for visualising nature-based art work was discussed as potentially appealing, as has been evaluated in an earlier study of patients undergoing stem cell transplantation. (139)

5.6.4 User acceptance and usability - patients

This was the first time VNT had been introduced into an ICU setting, where the restrictions of the environmental context and capabilities of the patient users impact heavily on usability and acceptability. Such factors are highlighted in previous research exploring commercial-off-the-shelf technologies for patient use in the ICU, with a very small proportion of patients able to use systems designed for whole population use.(37) Three patients withdrew from the trial citing discontent with the system. For some, VNT provided yet more imposing technology that was neither comforting nor relaxing. Learnability is a core feature of human-centred design. Patients experiencing critical illness may not

have the capacity or wish to learn how to use novel systems, which may explain the higher user acceptance scores for the more passive VNT A system.

Some patients were unable to use either hand controller, particularly the thumb mouse. Whilst both had been selected as being suitable for patients with muscle weakness, patients did not have adequate dexterity to use them effectively, reducing enjoyment and engagement with VNT. Future work could endeavour to provide closer matching of technology properties to user requirements. The rate of commercial development of technologies may allow the researchers to horizon scan for products to match such needs.

The SUS was completed by all patients. Some patients reported that they did not understand items 5 (I found the various functions in this system were well integrated) and 6 (There was too much inconsistency in the system) and the median score for each time was 3 (neither agree nor disagree. The SUS used was not checked for face validity during protocol design. The sample size was too small to validate the questionnaire but future use of the SUS should be informed by review of the terminology used to ensure understanding and validate reliability.

The lack of structure for the semi-structured patient and staff interviews restricted the quality of data. There was a failure to evaluate factors such as perceived usefulness, satisfaction and ease of use in any detail. Future studies should include methods to capture this data appropriately.

5.6.5 User errors - patients and staff

There were a number of user errors with the VNT system. The most notable was during the use of VNT A, where, for one patient, the video was allowed to reset to the start of the sequence and run again and again all night. The consequence bright sunlight disturbing the patient every two hours. This occurred despite the staff member caring for the patient overnight receiving a user demonstration at the start of the shift, written instructions provided alongside the system, research staff contact numbers available and the use of seemingly familiar components, such as the television screen, which should have been easy to switch off. This event led to the patient's voluntary withdrawal from the trial due to distress following overnight disturbance and had a detrimental impact on staff perception of the study overall.

5.6.6 User acceptance - staff

The user acceptance questionnaires were only completed by the minority of nursing staff caring for the patients whilst the VNT was in use. This occurred despite regular verbal and written encouragement by the research team at the start and end of every shift and attempted follow up after the shifts. A number of non-compliers with the research process were agency staff, who may not have fully understood the research objectives or received adequate face to face training about VNT. Overall, however, the systems were well received and reported as easy to use and set up. Most staff were happy to rearrange the bed space such that the VNT system was at the end of the bed, replacing the

observation chart. Video capture would have been useful to objectively evaluate any interference from the VNT system during patient care.

5.6.7 Study limitations

The main limitation of this study is the non-blinding of researchers and participants, leading to potential observer bias. The high drop out rate during the trial resulted in a small minority of patients receiving all interventions, under powering the study and increasing the risk of a type 2 error during statistical analysis. The within-subject nature of the methodology reduced variation and reduced the sample size required, but ultimately led to the trial being undeliverable as the window between patient recruitment and ICU discharge was narrower than the study duration. Future trials to determine effectiveness would need to be between subject, albeit with a larger sample size.

5.7 Conclusions

In conclusion, whilst an improvement on patient sleep was not shown, this study demonstrated the feasibility and safety of introducing the VNT interactive technology system within the particularly challenging environment of the ICU. The system was usable by a variety of patients towards the end of their critical care admission and well accepted by nursing staff working alongside the system. Evaluation of usage and usability was improved in comparison to the VRET Burns study, but the appropriateness of the SUS for this cohort is questioned.

5.8 Reflections and key methodological lessons learned

- As with the VRET burns study, utilising the clinical feasibility study design where the number of participants is determined by the power calculation, based on a clinical primary outcome measure, risks undermining the iterative design process by delaying analysis and conclusions needed to inform prototype design.
- This learning point is extended here where the within subject, repeated measures design exaggerated the impact of slow recruitment on the study results by reducing the number of participants who completed all interventions.
- Exposing each participant to all proposed versions of an interactive system is useful in terms of informing preference of types of engagement and further exploration of mediators of response. The value of each participant could be increased by increasing the depth of evaluation at each intervention, whilst considering patient capability to reliably provide feedback using a range of data collection tools.
- Embedded software is useful for collecting data on user preference, and may have greater use, including collection of clinical outcome measures.

CHAPTER 6 DESIGNING THE “MIRRORS” INTERVENTIONS: DEVELOPMENT OF THE PROGRAMME THEORY AND MODIFICATION OF THE DESIGN PROCESS FOLLOWING EARLY CLINICAL TRIALS.

Chapter 6 describes how the “Mirrors” interventions might work with reflection and scrutiny of the methodological “lessons learned” from the earlier phase of work, informing improvements to the design and evaluation process of two novel iTech systems to enhance physical rehabilitation on the ICU (Figure 6.1).

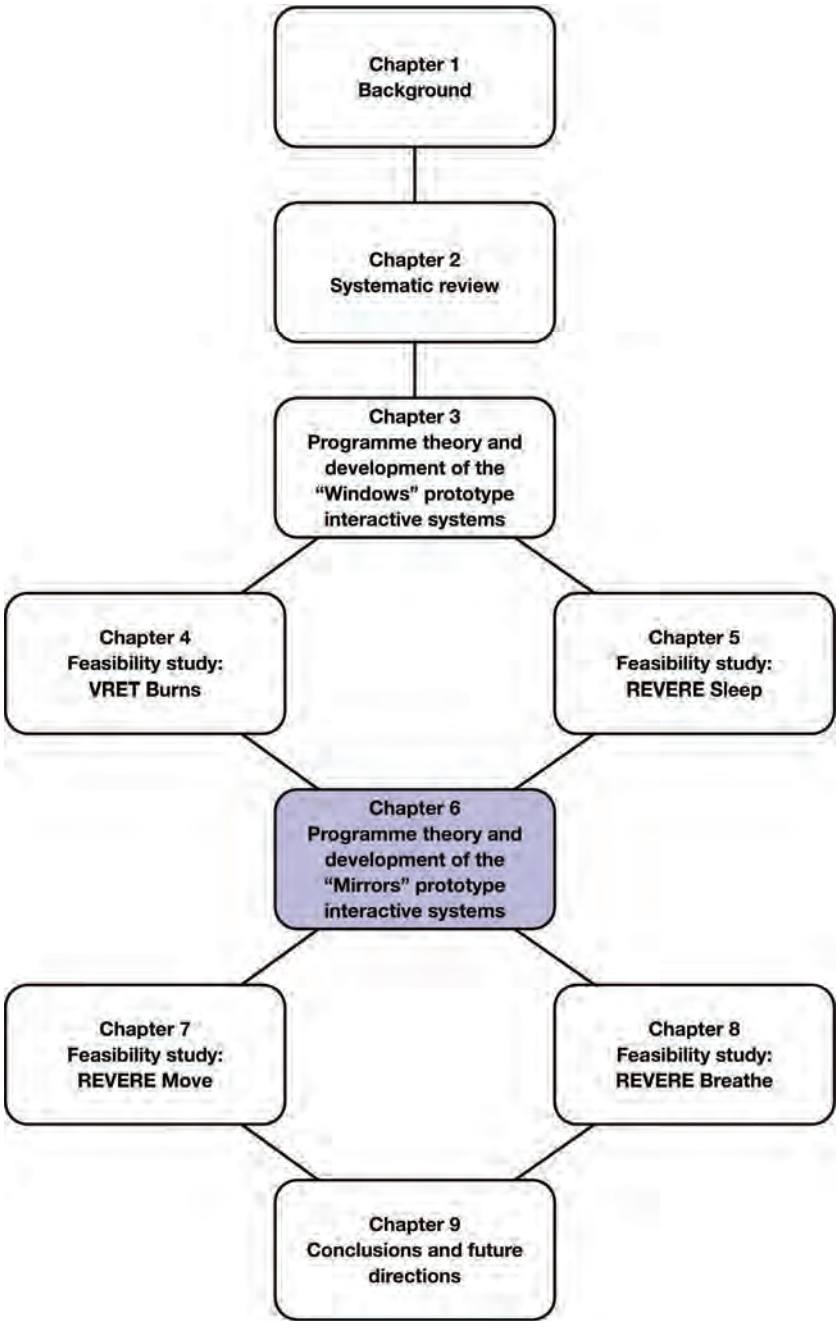


Figure 6.1 Thesis roadmap - Chapter 6

6.1 Programme theory of the “Mirrors” interventions

The rehabilitation strategies for ICU patients at the Queen Elizabeth Hospital Birmingham (QEHB) are individualised to their condition and stage of recovery (Figure 6.2).

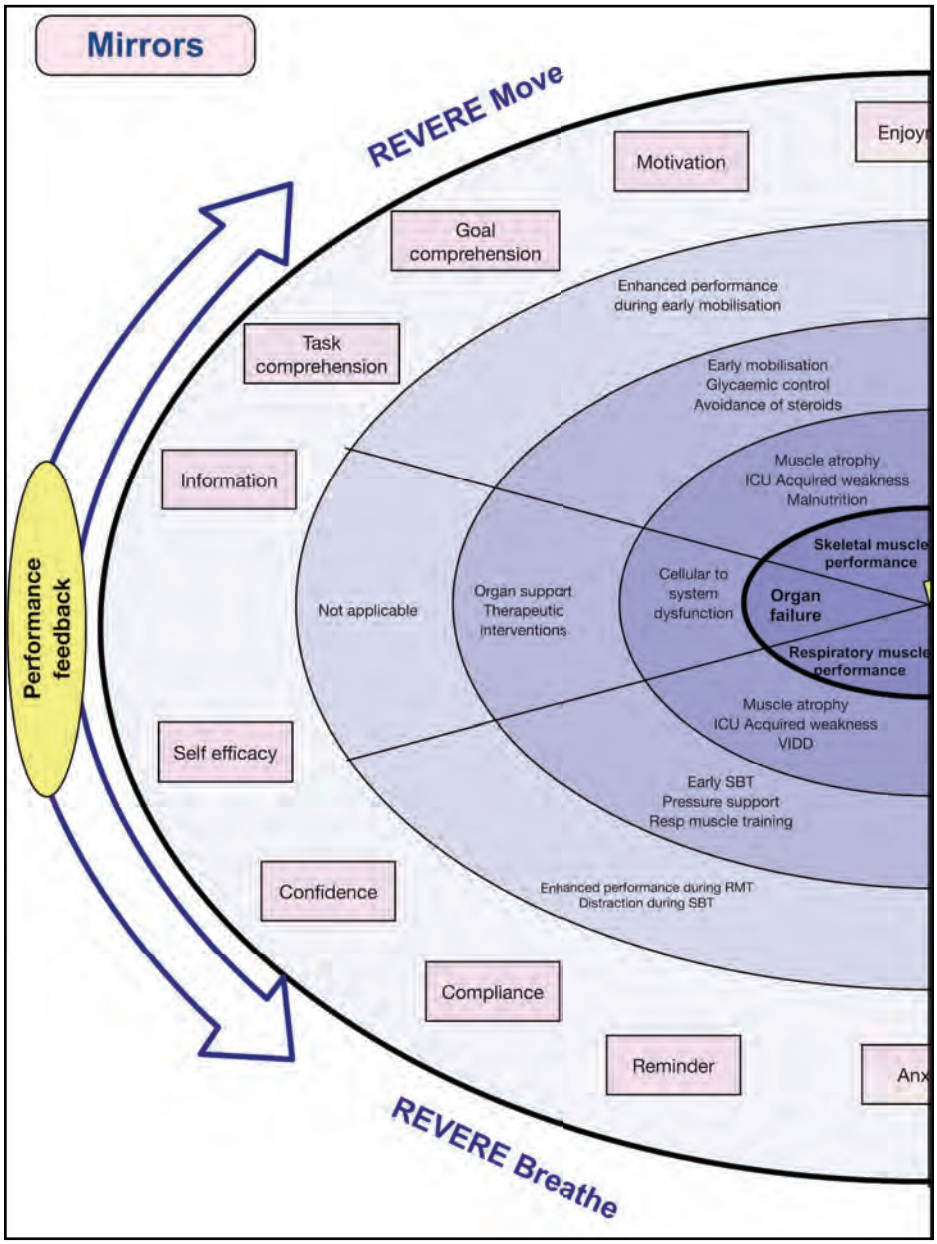


Figure 6.2 Conceptual model of “Mirrors” interventions

The ICU physiotherapy team use a range of interventions, including passive and active physical therapy, targeted at improving skeletal and respiratory muscle performance (Figure 6.2), with the main objective being return to the best possible function prior to discharge to the medical or surgical ward for ongoing care prior to discharge home.(27)

Participation in active rehabilitation is influenced by patient adherence behaviour. Adherence behaviour is, in turn, influenced by psychosocial factors including self-efficacy, motivation, depression, anxiety, pain response, personality and social support.(140, 141) Interactive systems, from video games to robotic assistance devices, have been used for a variety of heath and exercise applications, some of which have been designed to modify exercise-related behaviour.(142)

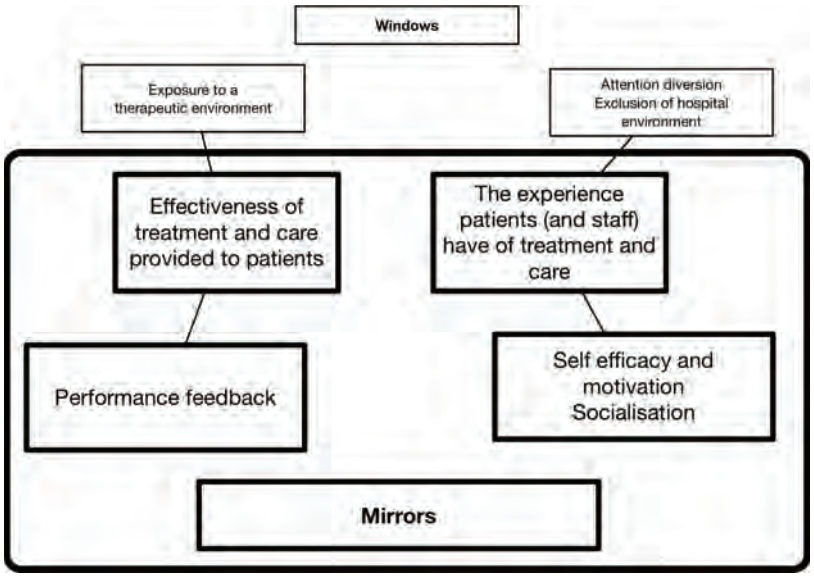


Figure 6.3 Illustration of mechanistic effect of the Mirrors iTech interventions

The simplistic model of mechanistic effect developed earlier in the research process suggested that the concept of “looking back at yourself” in a virtual mirror might improve effectiveness of physical rehabilitation. (Figure 6.3) Webb et al (143) published a systematic review and meta-analysis of the impact of internet-based rehabilitation interventions to promote health behaviour change. They concluded that the development of a detailed programme theory, particularly incorporating behaviour change techniques, to inform system prototype design was associated with significantly improved effect size. Thus it was necessary to scrutinise current scientific literature to produce a more detailed model.

Performance during exercise and rehabilitation sessions is influenced by psychosocial factors as well as physical capacity. Scobbie at al (146) identified seven theoretical constructs shown to influence behaviour during rehabilitation (Table 6.1). The relationships between three core tenets of performance motivational theory, goal-setting, expectancy and self-efficacy, and personality have been examined outside the critical care setting.(145) Neuroticism is negatively related to motivation while conscientiousness is positively related. Patient motivation is adversely affected by the neuropsychological consequences of critical illness, including sleep deprivation, pain, mood disorders and cognitive impairment. (155) The critical care environment amplifies these unfavourable conditions by reducing patient autonomy and creating disempowerment.(156)

Table 6.1 Description of theoretical constructs shown to influence behaviour during rehabilitation
From Scobbie et al (155)

Theoretical constructs	How they are expected to influence behavioural change.
Self-efficacy	Motivate goal-related intentions and behaviour
Outcome expectations	Encourage striving to achieve more difficult goals Increase resilience in the face of setbacks
Goal attributes (eg difficult/ specificity)	Maximise persistence and effort during goal pursuit Direct attention towards goal relevant activities Encourage use of strategies relevant to goal attainment.
Action planning	Promote translation of goal intentions into goal-related behaviour.
Coping planning	
Appraisal	Reveals progress and relation to goals Enhances goal-related performance Motivated adjustments to goal-related behaviour
Feedback	

Research in sports and work performance, elderly exercise and rehabilitation programmes suggests that the patient's personality and disposition may play a role in response to different types of motivational games.(145) Performance feedback may enhance the patient's self efficacy as they can visualise progress.(157) The presence of competitive avatars increases the performance of elderly subjects during upright cycling, but only in those with competitive personality traits.(158) Conversely, competitive avatars may be not effective for patients with neurotic personality traits and may reduce enjoyment and motivation.(159)

The process of goal-setting and achievement, including goal negotiation, planning, action, appraisal and feedback, is fundamental to rehabilitation practice. In order to optimise goal-setting, patients are required to understand

the goals that have been set and to be able to self-monitor their accomplishments and progress.(146)

Perception of success during a task enhances self-efficacy.(156) During their development of an intervention for upper limb stroke rehabilitation, Gorsic et al (153) concluded that patients recovering from stroke enjoyed competitive and cooperative games more than exercising alone, but that extrovert, competitive participants preferred competitive rehabilitation games and exercised significantly more intensely while introvert, uncompetitive patients preferred cooperation. The research groups early pilot work had suggested that competitive scenarios might be stressful or unpleasant for uncompetitive personalities,(160) although this concern was not borne out in their later study. (153)

Motivation is a key determinant of rehabilitation outcome.(150) Self-Determination Theory's taxonomy declares three human needs (Figure 6.4); autonomy (self-governance), competence (feeling capable and effective, self efficacy) and relatedness (sense of belonging, connectedness to others), and describes motivation as being the expression of three sub-types; amotivation, intrinsic motivation and extrinsic motivation.(144, 149) The former refers to a lack of intention to act, the latter emphasises consequences apart from engagement with activity, such as threats or rewards. The reward of ICU and hospital discharge deliver high levels of of extrinsic motivation. The majority of behaviour change research examining the impact of exercise-based

interventions in healthcare settings focuses on the manipulation of intrinsic motivation. Intrinsic motivation is the product of satisfaction, enjoyment and interest experienced during an activity.

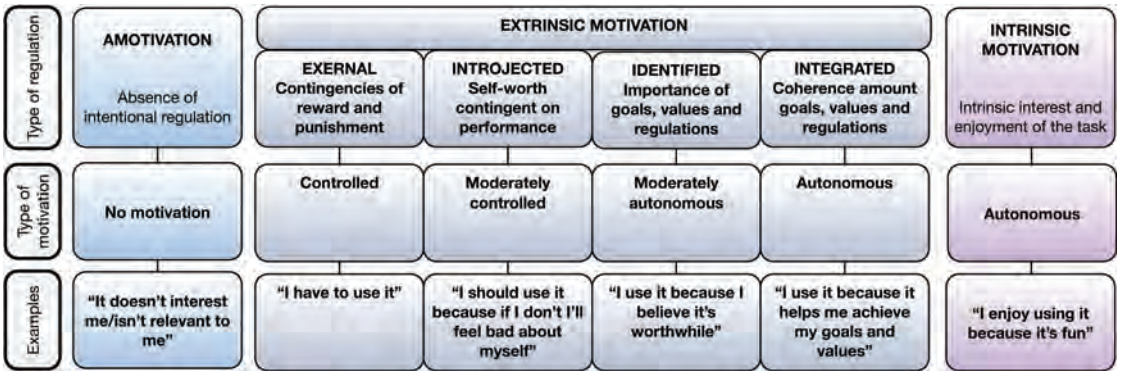


Figure 6.4 Taxonomy of Human Motivation
Adapted from Ryan and Deci (7)

The concepts of Self-Determination Theory can be used to evaluate motivational change over time during a rehabilitation intervention.(152, 154) Intrinsic motivation can be assessed using qualitative data from semi-structured interviews or a structured measurement tool,(152, 154) most commonly based on the Intrinsic Motivation Inventory.(142, 151, 153, 161) The Intrinsic Motivation Inventory is a multidimensional measurement tool developed to evaluate subjective experience in relation to an activity.(144) It measures six scales; interest/enjoyment (scores intrinsic motivation), perceived competence (positive predictor of intrinsic motivation, self efficacy), effort/importance (positive predictor of intrinsic motivation) and pressure/tension (negative predictor of intrinsic motivation), perceived choice (positive predictor of autonomy) and value/usefulness (positive predictor of extrinsic motivation).

In their introduction to their paper describing a novel interactive game for stroke rehabilitation “Message in a bottle’, Mihelj at al. (151) summarised the elements that are considered to make video game-playing most fun and engaging (Table 6.3) Whilst these design elements are based on motivational theory, it must be noted that they have been developed for healthy users. The clear differences in comprehension and motor capabilities between healthy subjects must be considered during the design process. Whilst games requiring higher order thinking and creative problem solving are preferred by well subjects they may not be suitable for patients with cognitive dysfunction, who may require low complexity systems.

Table 6.2 Intrinsic Motivation and Video game design

Adapted from Mihelj (14)

Elements enhancing enjoyment (intrinsic motivation)	Elements supporting intrinsic motivation	Goals and interaction	Characteristics of game design
Challenge Fantasy Control Curiosity Cooperation Recognition Competition	Improving your highest score Getting your name in the hall of fame Mastery of the machine Role play Narrative arcs Challenges Interactive choices within the game Interaction with other players	Short term goals (lasting a few seconds) Medium term goals (lasting a few minutes) Long term goals (lasting the length of the game) Complete freedom of interaction	Realism Customisation Winning and losing Variety of control option

The components above have been incorporated into a programme theory to describe how an interactive system might work to increase the impact of a rehabilitation intervention on the ICU (Figure 6.5). In addition, distraction from pain has been included. Uncontrolled pain is one of the most commonly reported unpleasant experiences for ICU survivors,(23, 162) and has negative psychosocial impact on motivation.(163) Although not mentioned in any of the sourced literature on motivational theory, the consensus of the QEHB ICU structured rehabilitation team is that pain associated with critical illness and associated interventions is a frequent barrier to effective exercise completion during rehabilitation sessions.

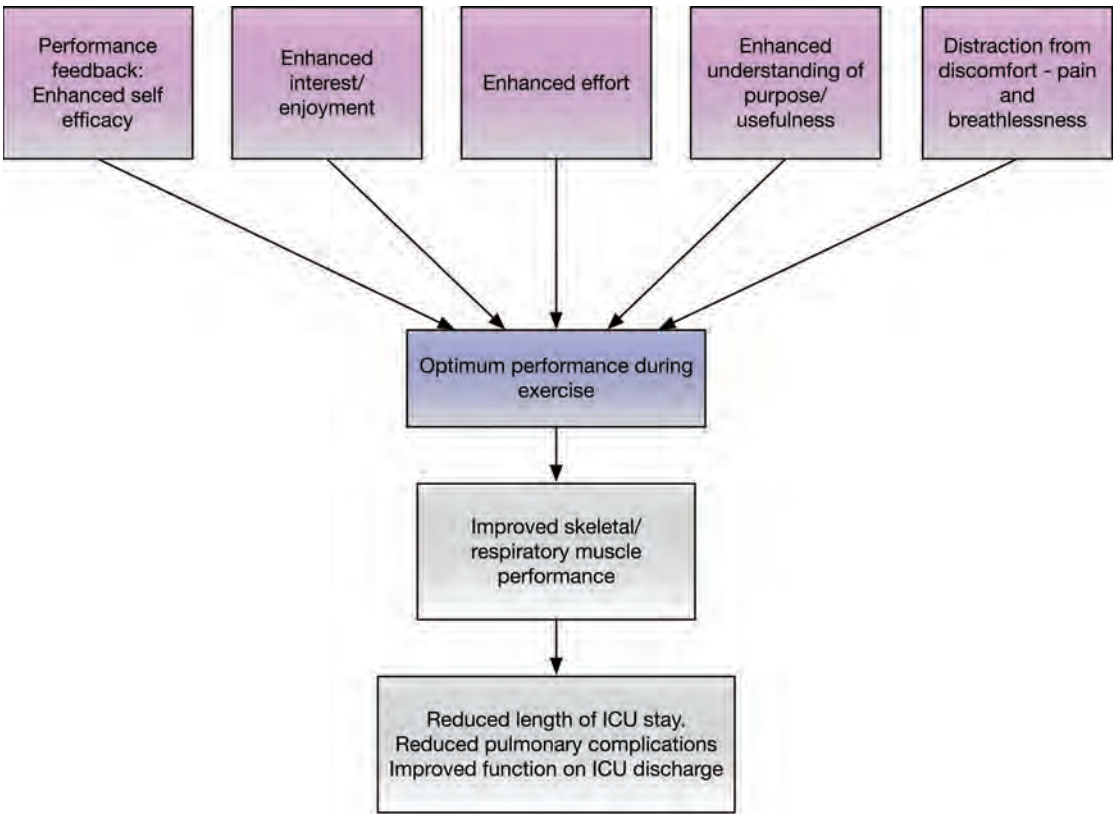


Figure 6.5: Programme theory for the “Mirrors” interventions

The limitations of the development of the programme theory are the paucity of relevant literature concerning motivational theory in rehabilitation on the ICU and the consequent use of study material from alternate patient groups. It may also present an overly simplistic model. There are cultural, environmental and institutional barriers to the delivery of effective rehabilitation on the ICU.(164) Patient motivation is adversely affected by the neuropsychological consequences of critical illness itself; including sleep deprivation, pain, mood disorders and cognitive impairment.(155) The critical care environment amplifies these unfavourable conditions by reducing patient autonomy and creating disempowerment.(165) The ReVERe Sleep study (chapter 5) illustrated that the impact of an interactive intervention may be too small to cause significant improvements in patient experience amongst the noise of their context of care.

The multi-factorial approach of the programme theory holds similarities to the oft-quoted “sum of marginal gains” described by the head of performance for British Cycling, Sir Dave Brailsford, in their training programme prior to their overwhelming success at the London Olympics in 2012.(166) The adaptability of interactive systems should enable design specification to address all the elements of improved performance feedback, enjoyment, effort, understanding and distraction from pain in turn.

6.2 Developing methodology to inform specification of user requirements

6.2 1 Factors predicting effective use of the technology

Predicting the success or failure of a device at the implementation phase of research is dependent on adherence to the specification of user requirements (Figure 6.6).

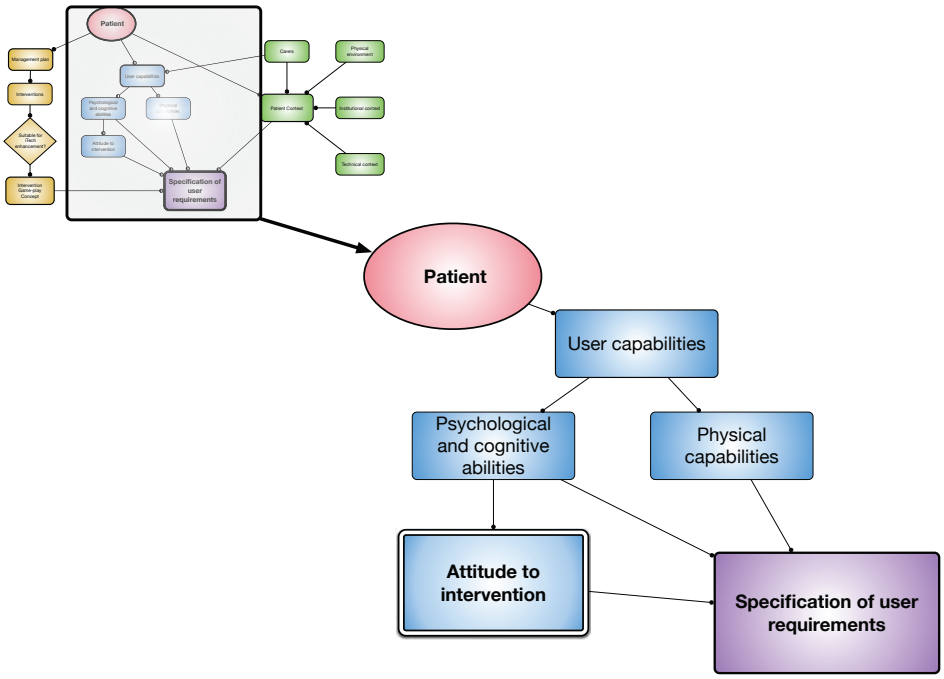


Figure 6.6: Contextual modifiers of iTech interventions to aid recovery from illness in an acute hospital setting

Widespread non-use will reduce the applicability and cost-effectiveness of any novel system.(167) The design of the VRET Burns and ReVERe Sleep systems was informed by small studies investigating the capabilities of the patient and staff users. The feasibility studies of both devices identified patient non-acceptance of the devices as a barrier to use. Non acceptance of novel technologies has also been reported by other research groups developing novel

interactive systems. Technology acceptance is defined as the intention to use or the actual use of a technology and is influenced by the attitude of the user to the intervention.(168, 169)

Literature describing the predictors and explanations of user-centred technology acceptance across a range of domains, including healthcare, present a variety of models based on differing intellectual theories. Most are underpinned by the Technology Acceptance Model (170) and the Unified Theory of Acceptance and Use of Technology.(171) The original construction of which was based on the Theory of Reasoned Action and Theory of Planned Behaviour.(172)

There has been widespread application of the Technology Acceptance Model and its derivatives in the field of healthcare technology research, the majority presented in the context of healthy subjects and staff users of technology, in particular the implementation of Electronic Health Records.(172) During their development of HeartCare, a web-based health information system for patients with congestive heart failure, Calvin Or and his research team have presented a model to explain the determinant of technology acceptance in patient groups. Their Patient Technology Acceptance Model included four core determinants; facilitating conditions, social influence, effort expectancy and performance expectancy with an additional domain of patient centred factors (Figure 6.7).(33) Or’s model was tested during the HeartCare II study, where they determined that perceived usefulness, perceived ease of use, subjective norm and healthcare knowledge most strongly predicted variance in the patient

acceptance and use of the HeartCare web site.(167) Other researchers have demonstrated that these determinants exert interdependence, with perceived ease of use being significantly associated with perceived usefulness.(173) And perceived health threat influencing perceived usefulness and behavioural intention.(174) In common with predictors of motivation for rehabilitation, user self efficacy predicts technology adoption, having a direct influence of perceived ease of use.(173, 174)

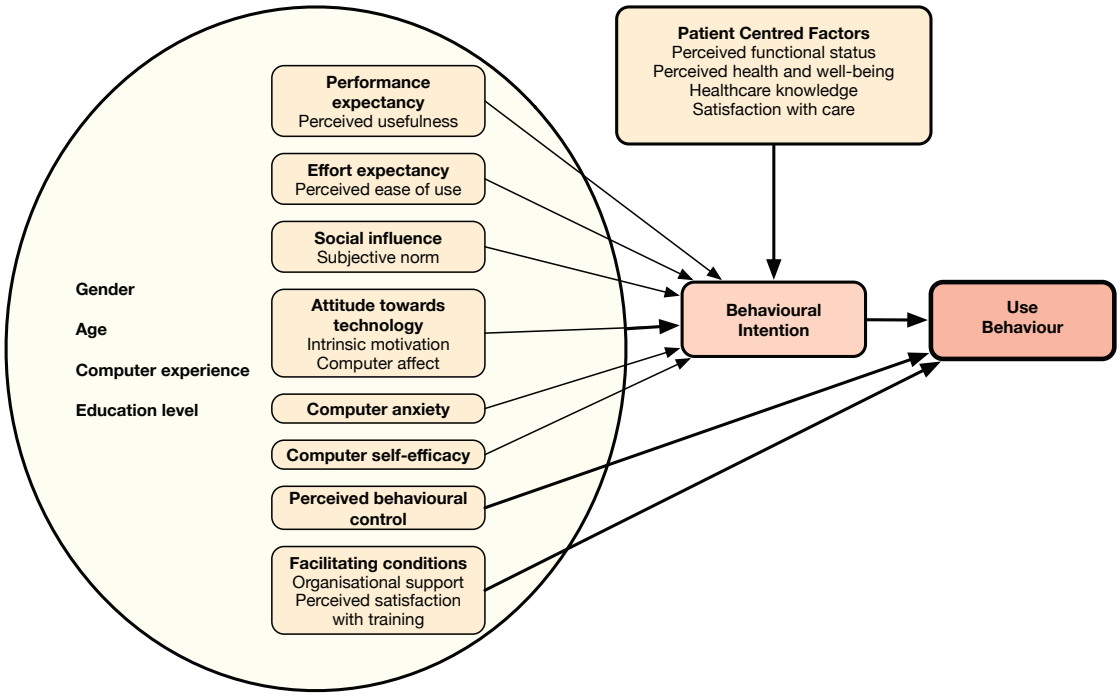


Figure 6.7 The Patient Technology Acceptance Model (168, 171)

Respondent demographic data predicting technology acceptance include gender, age, educational level, having school age children at home, computer experience and device usage.(171) Their effect-size and direction of effect, particularly in relation to age, are inconsistent, vary across studies and are accompanied by incomplete explanation of the the mechanisms of effect.(175)

Both quantitative and qualitative methods have been used for assessing technology acceptance in the development and implementation phases of healthcare technology research.(169)

Table 6.3 Definition of variables used in Technology Acceptance Models
Adapted from Holden (172)

Variable	Definition
Behaviour	The action, specific or general, whose prediction is of interest
Use	One specific behaviour of interest performed by individuals with regard to come interactive technology (iTech) system
Attitude	An individual’s evaluative judgement of the target behaviour on some dimension.
Perceived ease of use	An individual’s perception that using an iTech system will be free of effort.
Perceived usefulness	An individual’s perception that using an iTech system will enhance task performance
Facilitators	An individual’s perception of how easy it will be to perform the target behaviour (self-efficacy), of factors that may impede or facilitate the behaviour

6.3 Modification of the research methodology: Human Centred Design process and feasibility study design

6.3.1 Background

In light of the conclusions of the earlier clinical trials of the “Windows” interventions, it was necessary to review and improve the design processes used by the research team in order to improve the usability and acceptance of the new “Mirror” interactive systems.

6.3.2 Methods

Critical reflection following the completion of the VRET Burns and ReVERe Sleep studies was undertaken to identify lessons learned concerning both the design processes and clinical trial methodologies. The key guidance documents for interactive system and medical device design, ISO 9241-210 (30) and IEC 62366 (29), were scrutinised alongside published literature on early device testing to identify design inputs and outputs for each stage of the prototype development and trial delivery process.

6.3.3 Results

6.3.3.1 Lessons learned from early clinical trials

The lessons learned are summarised in table 6.4. Early device development relied on assumptions in the prototype design. Particularly limiting was the assumption of adequate similarity in user characteristics between the military battle-injured patients who performed the early interface usability testing and

the cohort of burns patients who were the subjects of the VRET Burns clinical trial.

A key limitation of the first two studies was the approach of attempting to answer the question of effectiveness within the primary outcome of the feasibility study. The use of a clinical outcome measure as the primary outcome drove decisions on target cohort size and the interventions design, control and sequence of exposure, at the expense considering whether the intervention could be implemented at all. A better approach would be to use the first study to determine the feasibility and acceptability of the the intervention, process and measurement tools required to deliver a future definitive trial, thus defining the primary outcome as the ability to recruit participants to the study and participant completion of the study protocol.

Table 6.4 Lessons learned from VRET Burns and REVERE Sleep studies

	Definition	**VR Burns**	**REVERE Sleep ICU**
Accessibility	Usability of a product, service, environment or facility by people with the widest range of capabilities.	Device not accessible to those with hand or facial injuries, visual loss, or those needing to lie flat.	Patients had inadequate dexterity to use the hand controllers.
Effectiveness	Accuracy and completeness with which users achieve specified goals.	No restrictions to dressing changes, but no significant reduction in pain experience.	No significant improvement in sleep experience.
Efficiency	Resources expended in relation to the accuracy and completeness with which users achieve goals.	Small minority of patients were recruited to the study. Accessibility issue compounded by methodological limitation of study requiring repeated exposure to intervention.	
Satisfaction	Freedom from discomfort and positive attitudes towards the use of the product.	High satisfaction from patient and staff uses despite lack of effectiveness.	
Usability	Extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use	Poor usability for some patients restricted the potential effectiveness of the intervention, which depended on immersion in the interactive world to enhance immersion.	
User experience	Person's perceptions and responses resulting form the use and/or anticipated use of a product, system or service.	Mixed user experience - varied depending on the user expectations of the device and their anticipation of being part of the clinical trial.	
Correct use/ Use error		Correct use by patients under supervision. Error within the software that allowed the boat to fly over barriers.	Use errors by nursing staff on set up and shut down due to lack of familiarity and device training.
Learnability	The time needed to become acquainted with the medical device and its operation	Close supervision reduced need for learnability, but game was quickly learned by most.	Once set up, the system was intuitive to use by patients but some staff members required repeated training.
Workload	Cognitive and/or physical efforts associated with using the medical device	Some patents reported fatigue from using the device. Patient group is generally easily fatigued as a consequence of illness and management.	
Safety	The attributes of the medical device that could compromise safe use	No safety issues identified during the feasibility studies.	

6.3.3.2 Modification of the design process

As discussed in chapter 3, the recommendations of the key standards for development of interactive systems and medical devices are complex and detailed. (29)(30) Both standards provide guidance for approaches to system design, but neither recommend methodologies, such as measurement tools. The research team reviewed each stage of the research framework (Figure 6.8) and made recommendations for design inputs and outputs at each stage.

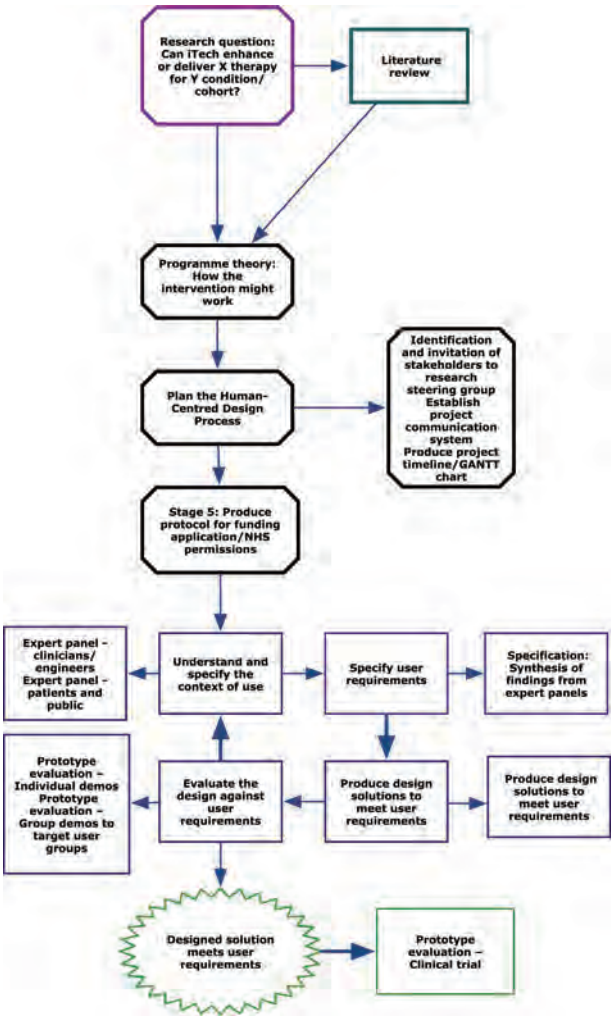


Figure 6.8 Framework for the development and evaluation for novel interactive systems for patient use

6.3.3.3 Recommendations for design input

These recommendations included:

1. Expansion of the stakeholder members to include an appropriate Patient and Public Involvement group, who were consulted at all stages from device conceptualisation to writing the patient information sheet.
2. Detailed description of the context of use, particularly relating to the ICU environment and anthropometric use (Table 6.5). Further information of influences of environmental context and the impact of the systems on task completion could be determined by the inclusion of video capture and link analysis into the subsequent clinical feasibility trials.
3. Development of a “Statement of User Requirement” template document, with detailed description of user characteristics, tasks and goals.
4. More extensive bench testing of system usability at each stage of prototype design.

Table 6.5 Template context of use document

1	Describe the users and other stakeholder groups	Identify relevant groups and their relationship with the proposed development described in terms of key goals and constraints
2	Describe the characteristics of the users or groups of users (there may be different groups of users with differing capabilities etc)	Include: Knowledge. Training Skill. Experience Education. Physical attributes Habits Preferences Capabilities
3	Describe the goals and tasks of the users	Interdependencies Activities to be carried out in parallel Potential adverse consequences Risks of task being carried out inaccurately
4	Describe the environment of the system	Physical, Social, Cultural, inc work practices, organisational structure and attitudes

6.3.3.4 Recommendations for design output

These recommendations were informed by the usability engineering techniques recommended for development of medical devices.(29)

1. Diversification of usability assessment processes beyond the Systems Usability Scale employed during the earlier clinical trials, to include more detailed qualitative data.
2. Further use of rapid prototyping in relation interface and screen use, to facilitate patient access to the interactive system.
3. Clinical trial research protocols to include rigorous hypothesis-based approach, to include assessment of proposed modifiers of behavioural change. Careful consideration of feasibility of trial delivery and completion to time and cost restrictions.

6.3.4 Discussion

The objective of this phase of research was to reflect on the methodological “lessons learned” of the previous phases of prototype device development and clinical trial delivery in order to produce a more rigorous structure for the design process of “Mirrors” interactive technology-based systems.This was done by revisiting the key industry standards, considering how their recommendations could best be applied to support the aims of the research.

The next phase of the research was to determine the most appropriate target physical rehabilitation strategies for enhancement by interactive technology-based systems.

6.4 Designing the “Mirrors” interventions

In the context of generous, yet not unrestricted, research funding, it was essential to consider feasibility of device design and trial delivery. In order to decide which physical rehabilitation interventions could potentially be enhanced using iTech the stakeholder group of clinicians, physiotherapists and the Human Interface Technologies team listed all current interventions in clinical practice then evaluated them against a matrix to determine their feasibility for iTech enhancement (Table 6.6).

Table 6.6 Matrix of ICU rehabilitation interventions and their feasibility
(Green = low risk, yellow = medium risk, red = high risk)

Intervention	Recruitment	Cost	Practicality
Respiratory Muscle Performance			
Weaning from mechanical ventilation			
Post operative/intubation incentive spirometry			
Respiratory muscle training			
Cough assist			
Skeletal Muscle Performance			
Core stability/balance			
Upper limb skeletal muscle training			
Lower limb skeletal muscle training - assisted walking			
Lower limb skeletal muscle training - recumbent cycling			

Feasibility was described in terms of three domains; ease of patient recruitment (number of patients receiving the intervention), cost (commercial off the shelf device/interface available or modifiable, likely complexity of the technology) and practicality (ability to measure outcome variables, evidence for use). Each domain was colour coded as red (poor/low), green (good/high) and yellow (mixed/medium). Interventions with red domains were excluded.

Recumbent cycling was selected under the skeletal muscle performance category as an intervention used frequently by the ICU rehabilitation team, requiring adaptation of an electronic device and being easy to measure performance due to data capture by unit's MotoMed recumbent cycling device. The chosen intervention to enhance respiratory muscle performance was discussed at length, with clinical preference for weaning (liberation) from mechanical ventilation. It was decided that the requirement for the device to integrate within the ventilator gas delivery circuit rendered the project unfeasible due to the high cost and regulatory procedures required for the risk associated with such a device. Thus, the group decided to develop a device to enhance the use of the "Spiroball", a non-invasive, non-electronic incentive spirometer.

6.5 Clinical scenario 3

Rehabilitation and Intensive Care Unit-acquired weakness

6.5.1 Introduction

Rehabilitation in those diagnosed with intensive care unit-acquired weakness (ICUAW) focuses on whole-body muscle and cardiorespiratory training (176) aiming to improve functional status, shorten time to independent ambulation and accomplishment of activities of daily living prior to discharge to a general ward.(177) There are few technologies evaluated to aid rehabilitation on ICU. (178) Those too weak to attempt step transfers out of bed or walking undergo sessions of recumbent cycling, which has been demonstrated to improve peripheral muscle strength, functional status and subjective wellbeing at hospital discharge in patients with prolonged ICU stay.(179) Recumbent cycling is utilised at QEHB for patients with ICUAW using the Reck MotoMed Letto or “MotoMed”. Patients diagnosed with ICUAW are referred to the ICU Supportive Rehabilitation Team, a multidisciplinary team lead by physiotherapists with expertise in the management of complex and long-stay ICU patients. These patients undergo cycling sessions of up to 20 minutes every 2-4 days until able to step transfer with assistance. The practice is reported elsewhere.(37) The MotoMed device has three modes of use; passive, active-assist and active (with adjustable resistance). Patients are instructed to actively pedal for as long as they are able, after which the Motomed reverts to a passive mode whereby the pedals continue to rotate slowly until the end of the prescribed session. The active-assist mode is not used.

6.5.2 Methods

6.5.2.1 Stakeholder group

- Chief Investigator: Dr Charlotte Small
- Lead expert (Patient/ICU Complex Trauma Survivor): Duncan Buckley
- Lead expert (Friends and Family): Lisa Buckley
- Patient and Public Involvement Group: QEHB Critical Care Survivors Group
- Human Factors & Simulation Lead: Prof Bob Stone
- Technology Development, Integration and Evaluation: University of Birmingham Human Interface Technologies Team: Dr Cheng Qian, Mr Vishant Shingari
- Principal Investigator (Queen Elizabeth Hospital Birmingham): Dr Catherine Snelson
- Lead physiotherapist: David McWilliams
- Research Physiotherapists: Charlotte Jones, Fiona Howroyd
- Nursing advisor: Sister Jennifer Williams, QEHB Critical Care and Follow up
- Sponsor: Dr Sean Jennings, University of Birmingham.

6.5.2.2 Context of use

In accordance with the programme theory (Figure 6.5), it was proposed that the interactive system could be used as an adjunct to the MotoMed to enhance adherence behaviour via improvements in intrinsic motivation, performance feedback and distraction from pain (Figure 6.9).

The novel system could provide meaningful imagery of activity and accomplishments. The task would be completion of an exercise session, according to the QEHB MotoMed protocol for use (Figure 6.10) The intended operating conditions would be the ICU patient bed space. The limitations on space have been discussed during the ReVERe Sleep study, and ergonomic considerations were particularly important given the size of the MotoMed. The device needed to meet the requirements of the QEHB trust infection control policy.

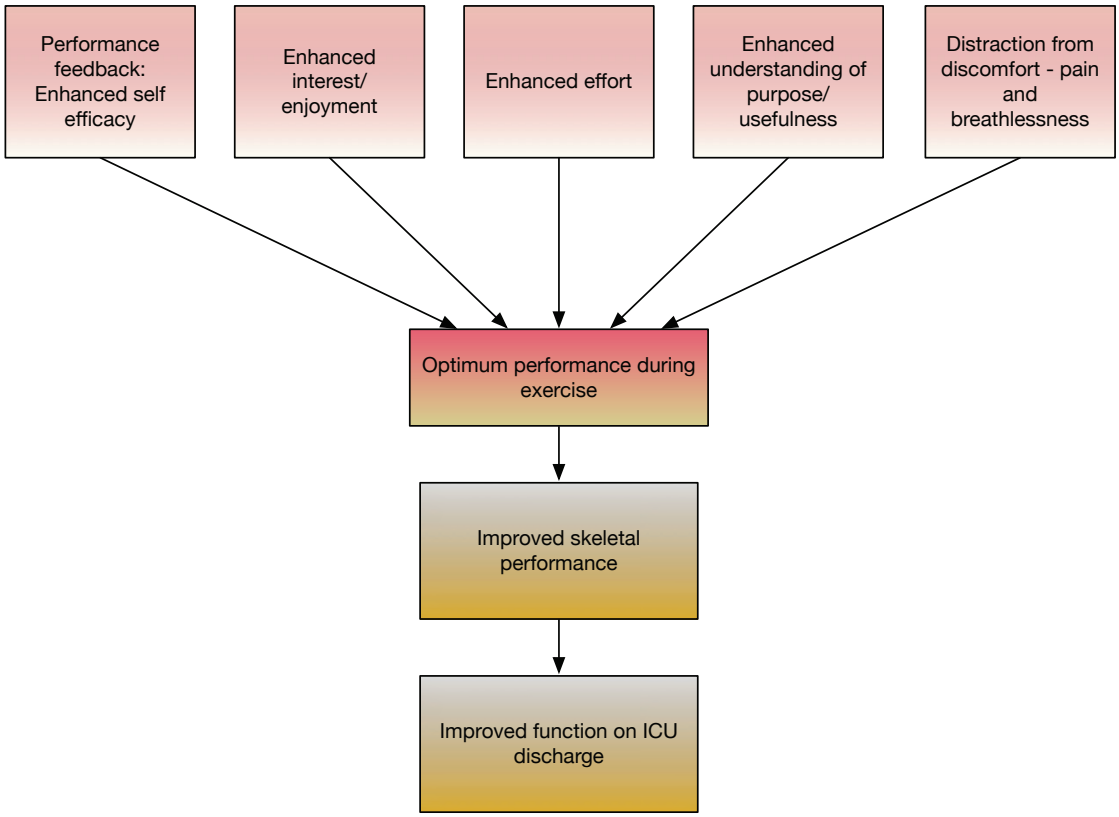


Figure 6.9: Causal Model to illustrate the theoretical process whereby the use of iTech-enhanced recumbent cycling might enhance the target behaviour goals, increasing the likelihood of accomplishing the therapy goals and achieving the therapy outcome.

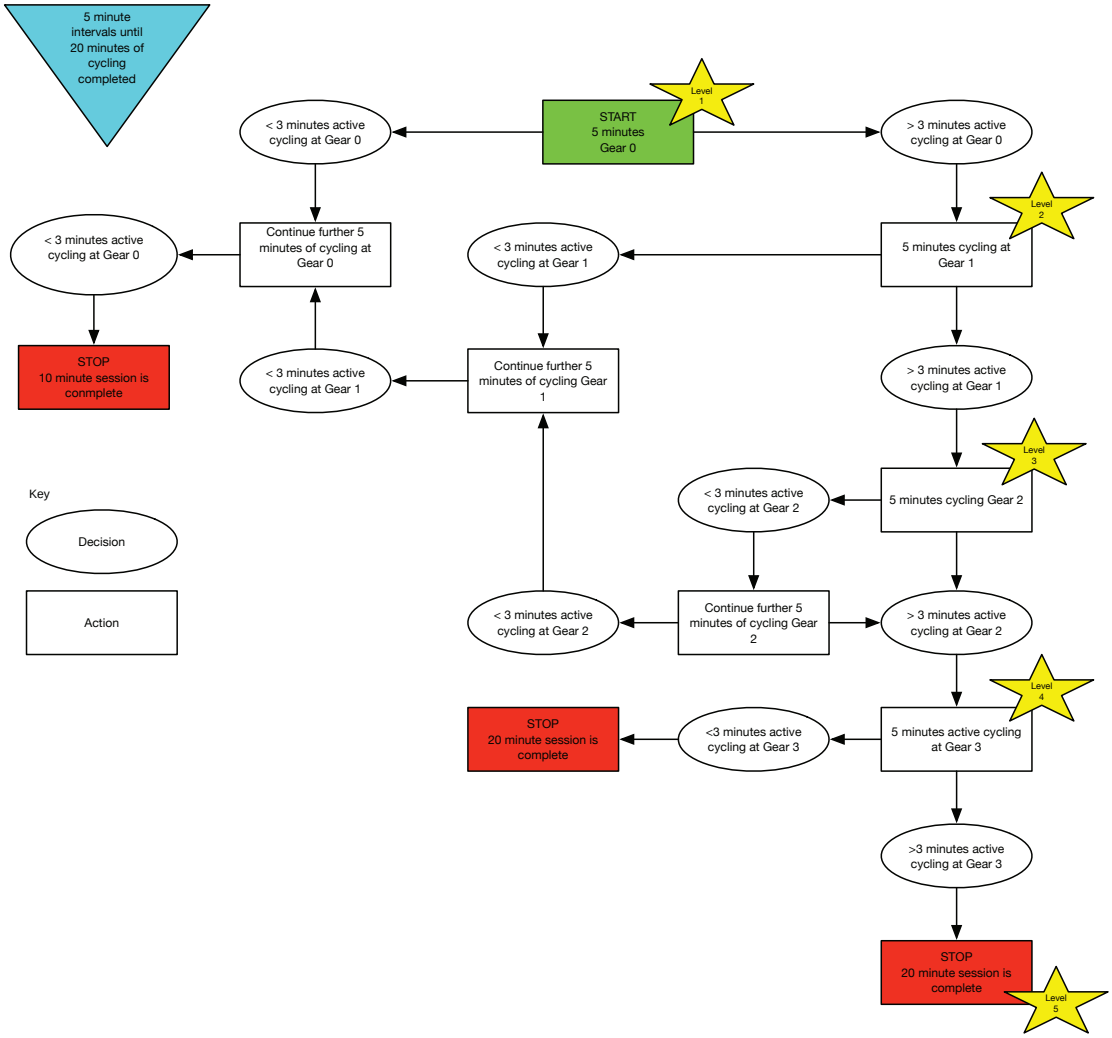


Figure 6.10 QEHB protocol for recumbent cycling using the Reck MotoMed Letto

Two versions of interactive feedback were developed, one distraction-based and one competition-based, designed to appeal to non-competitive and competitive personality types. The dashboard presented an ecologically relevant activity; recumbent cycling along a the coastal path in Virtual Wembury.

6.5.2.3 User research

The interactive device was designed to be used in conjunction with the Reck MotoMed Letto (Figure 6.11).

Figure 6.11 Reck MotoMed letto

Image reproduced courtesy of http://www.mediotronics.co.za/recumbent_rehabilitation

Although improving patient autonomy was considered, enhancing independent use of MotoMed by patients was not thought to be practical or safe. Patient user requirements were considered in relation to their interaction with the software. In order for the interactive intervention to be accessible, the patients would need an appropriate visual display, ideally supported by auditory input. Anthropometric testing was undertaken to establish best screen size and focal distance. Haptic feedback would be provided by the MotoMed system.

The user characteristics and capabilities of the physiotherapist were considered when designing the manoeuvrability and set up processes of the system. Two research therapists were involved in device design at all stages of the design process. Validation and verification was carried out during cognitive walk-though of the software procedures and during system prototype demonstrations.

6.5.2.4 Safety

The use of the MotoMed system has been established as being safe for use during early rehabilitation on the ICU, and is used within the standard care provided to patients requiring rehabilitation from ICU-acquired weakness on the QEHB ICU.(180, 181) Whilst the interactive system was designed to enhance motivation and performance, exercising to the limits of physiological capability may not be appropriate in the critical care setting so the protocols for MotoMed use in the QEHB was to be followed (Table 6.7). The novel system did not interact with the MotoMed software thus, in the event of failure the MotoMed could be used alone to enable to exercise session to be completed.

Table 6.7 Criteria for discontinuing MotoMed sessions

Discontinue exercise if there is an abnormal physiological response:
• Heart Rate greater than 70% predicated maximum • Decrease in HR by 20% • Systolic Blood Pressure above 180 • 20% decrease in systolic or diastolic • SpO2 90% or signs of respiratory distress • Arrhythmias • Symptoms of myocardial ischaemia

6.6 The third prototype : VeloVR

The prototype interactive system to enhance the use of the Reck MotoMed let recumbent cycle (Figure 6.11) was designed and constructed by the University of Birmingham Human Interface Technologies Team and named “VeloVR.” The active element of the intervention is the VeloVR software or “game”, the interface components, display and controllers, facilitate user access to the intervention.

6.6.1 Software

The software used was an extensively modified version of “Virtual Wembury” used for the ReVERe Sleep study. Users visualised themselves in a recumbent bicycle, cycling along the coastal path by Wembury Bay. A cadence tracking system (Garmin) tracked the MotoMed pedal movement. This data was entered, via custom-built mid-ware, into the VeloVR game. VeloVR had two game modes:

1. Distraction mode – patients pedalled along the coastal path of Virtual Wembury (Figure 6.12). Speed along the path was determined by cadence speed. As the gear is increased, as per the protocol, the change in effort was represented within the VeloVR game by an increase in speed. An image of their progress around the virtual “track” was provided in the top left hand corner.
2. Competition mode – patients pedalled and competed against a cycling avatar, attempting to move faster than them along the coastal path. The avatar speed and progress was that achieved by the patient during the previous session in distraction mode. Thus, they were aiming to perform

better than during the previous session. Visual feedback of their progress was provided by the virtual track in the top left hand corner, with a green dot indicating their current position and a red dot indicating the position of their competing avatar.

The software was opened via a laptop, accessed by the therapist in the bed space. The patient had no control over timing or method of interaction with the software, except via requests to the therapist.

Figure 6.12 Screenshots of VeloVR game

6.6.2 Interface devices

6.6.2.1 Visual output

The software was displayed on a 32 inch LCD television screen. The screen was mounted on a display stand, that also housed the laptop and power supply. The screen was positioned in front of the MotoMed controls, above the users' legs. The stand had wheels to facilitate manoeuvrability and allow the screen to be moved closer to or further away from the user as preferred.

6.6.2.2 Auditory output

VeloVR provided the sounds of nature associated with Virtual Wembury. Patients in the ReVERe Sleep study had a preference for auditory input via the television speakers. It was a requirement of physiotherapists that they could communicate with the patient during the MotoMed session so headphones were not included in the prototype system.

6.6.2.2 Haptic output

Haptic feedback was provided by the pedals of the MotoMed system.

6.6.4 User testing

User testing was performed at multiple stages of the iterative design process. Testing procedures included expert reviews, clinical scenario-based and real-environment testing by healthy subject users on the ICU (Figure 6.13). User testing by patients was performed during the clinical feasibility study.

6.6.5 Clinical trial protocol design

The protocol for the feasibility study was designed by the multi-disciplinary stakeholder group. The research methods built on those applied to the VRET Burns and ReVERe sleep studies, considering the lessons learned and evolving the HCD processes to improve the quality of the data collected, whilst maintaining the feasibility of data collection for the ICU context. Local and Health Research Authority permissions were secured, with a letter of no objection from the MHRA provided on the grounds that the device was being tested in the manufacturers institution only, without current intent to commercialise or seek CE marking.(96, 97) The protocol from the study "Restorative Virtual Environments for Rehabilitation: Feasibility of the use of interactive technology-enhanced recumbent cycling to aid mobilisation on the Intensive Care Unit" is described in detail in chapter 7.

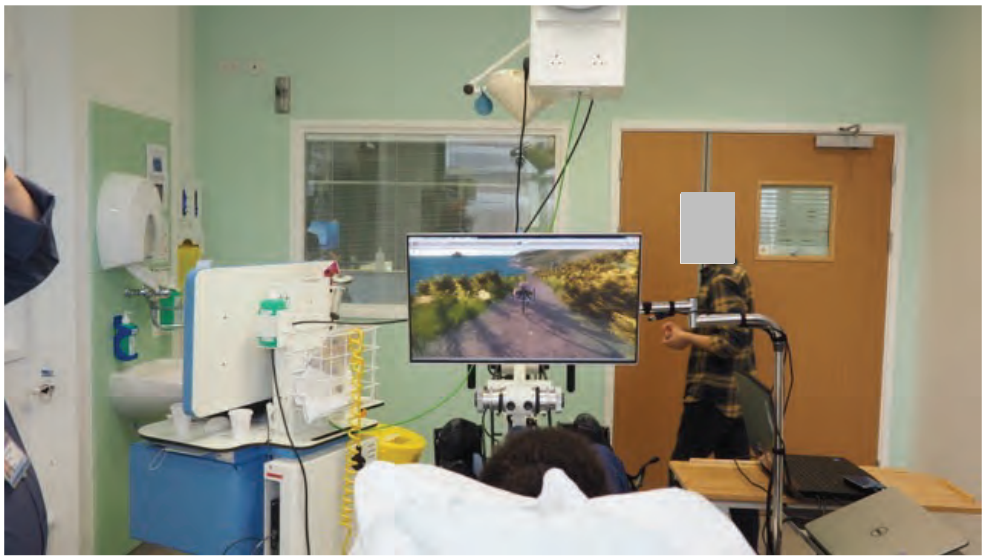


Figure 6.13: VeloVR from the patient point of view, undergoing bench testing by the research team

6.7 Clinical scenario 4:

Post operative pulmonary complications following major upper gastrointestinal surgery

6.7.1 Introduction

The ICU at QEHB routinely admits patients following major upper gastrointestinal surgery for post operative care. Patients who have undergone oesophagectomy or total gastrectomy for cancer treatment are at high risk of developing postoperative pulmonary complications (PPCs) due to intra-operative lung deflation, post-operative pain inhibiting deep breathing and cough, and poor physical state following neo-adjuvant chemotherapy.(182) The purpose of incentive spirometry is to recruit collapsed small airways, re-inflate the lung bases and encourage expectoration of airway secretions.

The next novel interactive technology-based intervention was designed to meet the user requirements of patients in their early phase of recovery from elective major upper gastrointestinal surgery (oesophagectomy or total gastrectomy) for cancer treatment, whilst on critical care. The aim was to develop a device which was superior to the current alternative, non-electronic, visual feedback devices, the Leventon Spiroball Incentive Volumetric Exerciser (Figure 6.14). These devices provide simple imagery to encourage correct action (breathing in rather than breathing out) but do not provide prompts to carry out the exercises, nor do they record patient activity, thus preventing objective usage or performance data collection when incentive spirometry is carried out independently. The absence of such capabilities has contributed to the methodological limitations of studies evaluating the efficacy of regular post operative incentive spirometry. (182)

Figure 6.14 Spiroball Incentive Volumetric Exerciser

Image reproduced from http://www.leventon.es/products/respiratory/spiro-ball.aspx

6.7.2 Methods

6.7.2.1 Standards

The MHRA determined that the prototype would be a Class 1 medical device. The research team decided to attempt to perform the required processes to secure a CE mark. The development process was conducted to meet the standards set out by:

1. University Hospitals Birmingham NHS Foundation Trust and Heart of England Foundation Trust policies on:
   A. Use of medical devices
   B. Infection control

2. Medicale Devices Directive 2007/43/EEC.(96)

3. British Standard ISO 9241:210 - Ergonomics of Human System Interaction, Human-Centred Design for Interactive Systems.(30)

4. IEC 62366_2007: Medical devices – Application of usability engineering to medical devices (International Electrotechnical Commission).(29)

5. ISO 14971 Risk management for medical devices.(183)

6.7.2.2 Stakeholder group

- Chief Investigator: Dr Charlotte Small
- Lead expert patient: Duncan Buckley
- Lead expert relative: Lisa Buckley
- Patient and Public Involvement Groups: QEHB Oesophagectomy Survivors Group and QEHB Critical Care Survivors Group
- Human Factors & Simulation Lead: Prof Bob Stone
- Technology Development, Integration and Evaluation: University of Birmingham Human Interface Technologies Team: Dr Cheng Qian, Mr Vish Shingari
- Principal Investigator (Queen Elizabeth Hospital Birmingham): Dr Catherine Snelson
- Principle Investigator (Birmingham Heartlands Hospital): Miss Olga Tucker
- Research physiotherapists: Jonathan Weblin, Charlotte Jones, Fiona Howroyd
- Nursing advisor: Sister Jennifer Williams, QEHB Critical Care and Follow up
- Consultants Upper GI surgery: Mr John Whiting QEHB), Ms Olga Tucker (BHH).
- Sponsor: De Sean Jennings, University of Birmingham.

6.7.2.3 Context of use

The novel interactive system was designed as a bedside device for use in patients required to undertake incentive spirometry. Incentive spirometry is the term used to describe the process of taking a deep breath to maximum inspiratory capacity followed by a non-forced exhalation. This is in comparison to vital capacity breathing which includes a forced expiration. In order to inform the game play algorithm, a literature search was undertaken to gain detailed information on maximum inspiratory capacity volumes following major upper gastrointestinal surgery, including pre-operative and post-operative values and the rate of improvement during recovery.

The clinical members of the stakeholder group completed the “Statement of User Requirement” to detail all aspects pertinent to design, including task description, user groups and context of use.(Appendix 11) The gameplay design was informed by instructions provided by the physiotherapists to ensure the game encouraged intuitively the correct breathing action and rewards when the correct action had been completed. Synthesis of user acceptability and user knowledge/skills/attitudes (KSA) from previous research by the group, alongside recommendation by the Upper Gastrointestinal Surgery Patient and Public Involvement (PPI) representatives informed the description of user requirements.

The programme theory for the “Mirrors” interventions (Figure 6.5) was developed further to improve its specificity to the intervention (Figure 6.15).

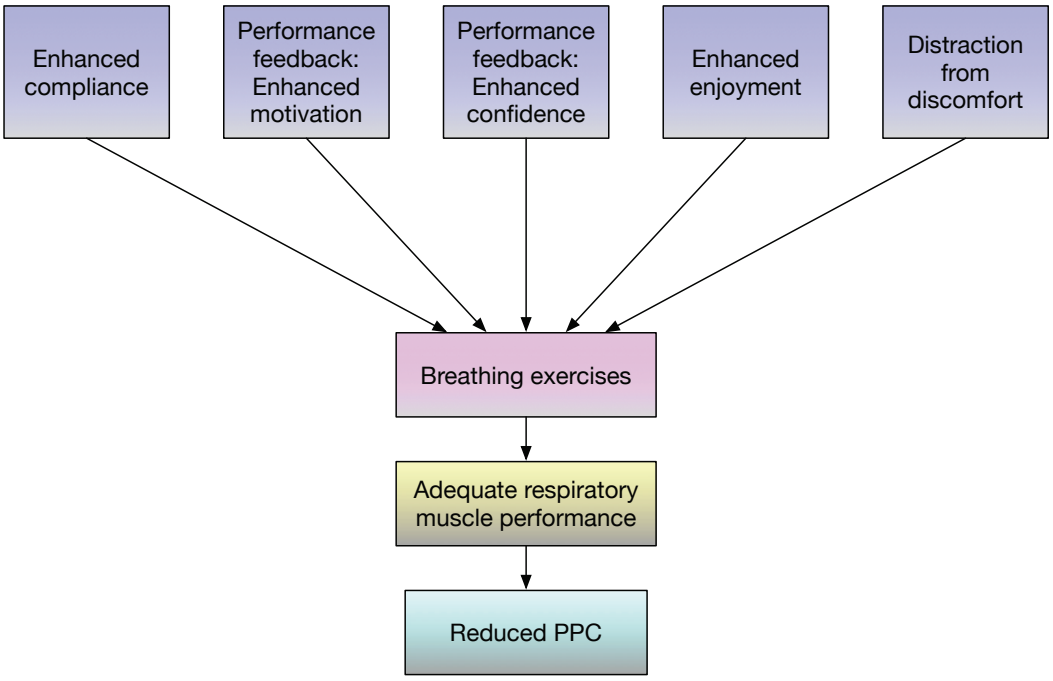


Figure 6.15: Causal Model to illustrate the theoretical process whereby the use of InspireVR will enhance the target behaviour goals, increasing the likelihood of accomplishing the therapy goals and achieving the therapy outcome.

6.7.2.4 User research

Validation and verification procedures were completed according to the essential requirements of the MHRA, in accordance to the Medical Devices Directive MDD 2007/47/EEC (96, 97), prior to their approval to undertake a clinical investigation. The novel system was subjected to electronic and software tests within the team's laboratory of the University of Birmingham (Figure 6.16). Testing sessions took place every two days for two weeks, with five sessions held per day, and included:

- Repeated power-on (boot-up) procedures,
- Repeated power-off (shut-down) procedures,
- Performance and stability during system set-up procedures,
- Performance and stability during periods of active use,
- Performance and stability during a 12-hour period of non-use (i.e. standing idle with the software running),
- Review of fault detection logs (an integral component of the run-time software used in this project).

During these tests, the integral logging system reported zero crashes, zero faults.

Figure 6.16 Novel iTech system undergoing bench testing by Dr Cheng Qian

6.7.2.5 Safety

In order to comply with the requirements of the MHRA Clinical Investigation, a full risk assessment was completed (Appendix 12).(96, 97) The Spiroball was to be available throughout the trial of InspireVR to ensure the patients were able to complete their exercises in the event of system failure. Data security was essential. Non-essential USB ports were deactivated during software installation, with override requiring a password held by the research team. The laptop was set up so only the study device software was accessible. The Windows operating system firewall was set to block external internet access. Enterprise software was installed to lock all access to patient data. At no times would patient identifiable data be stored on the system; data stored would only include inspiratory volumes achieved with each use and the time of each use.

6.8 The fourth prototype: InspireVR

The prototype system was called “InspireVR.” The system combined a commercially available spirometer (Vitalograph Pneumotrac 6800) with software, based on Virtual Wembury, delivered via a personal computer (Microsoft Notebook).

6.8.1 Software

The novel software for the InspireVR was designed to facilitate patient performance of incentive spirometry. The software had the following core features:

1. Reminders to the patient to complete incentive spirometry. The frequency of the reminders was determined by the clinical setting and indication.
2. Intuitive gameplay to encourage accurate maximum inspiratory capacity efforts at each session of incentive spirometry.
3. Performance feedback of each incentive spirometry session to provide the patient and clinicians with information on maximum inspiratory capacity achieved and the number of MIC efforts.

The incentive spirometry gameplay concept was a representation of a trebuchet (medieval catapult) which retracts on patient inspiration, firing a boulder into the sea at the end of maximal inspiration (Figure 6.17). The larger the maximum inspiratory capacity, the further the boulder would travel. Large maximum inspiratory capacity efforts were rewarded with boats sinking.

Figure 6.17 Screenshots of InspireVR

The design process of InspireVR considered the following:

1. Usability: Game play that was designed to be usable and achievable by the patients recovering from oesophagectomy or total gastrectomy on the ICU.
2. Applicability: Game play that replicates, exactly, the manoeuvre required during incentive spirometry. The patients' ability to score points during the game was dependent only on their ability to take a deep breath (aiming to increase their maximum inspiratory capacity with each effort), rather than requiring additional cognitive abilities or other skills.
3. Personalisation: All patients should have had the potential to progress through the levels of the game. This allowed tolerance for inter-user and daily variability in patient status. Success was measured by meeting a target maximum inspiratory capacity above baseline. Once a target was met, the patient would proceed to the next level for the next session, with an associated higher target capacity. The target maximum inspiratory capacity would be set for each patient at the start of each day (calibration). The patient would be prompted to provide three best effort maximum inspiratory capacity breaths. The targets for each level would

be calculated based on the highest volume achieved over the three attempts during morning calibration (Figure 6.18)

4. Feedback for clinicians. Patient maximum inspiratory capacity values were stored in an excel file.

Although preoperative Forced Vital Capacity and Forced Expiratory Volume in one second measurements are included in some papers discussing pulmonary complications of major upper gastrointestinal surgery,(184, 185) there was no published data of individual or serial maximum inspiratory capacity values following major upper gastrointestinal surgery. Local data recorded that patients with preoperative values of approximately 2000ml only achieve maximum inspiratory capacity values of 500ml in the first day postoperatively. There was no data to inform likely progress of maximum inspiratory capacity increase during early postoperative recovery. Hence, a pragmatic, consensus opinion-based approach was taken when defining each level of progress within the game. The clinical investigation would then collect data from each participant to inform future modification of the game algorithm.

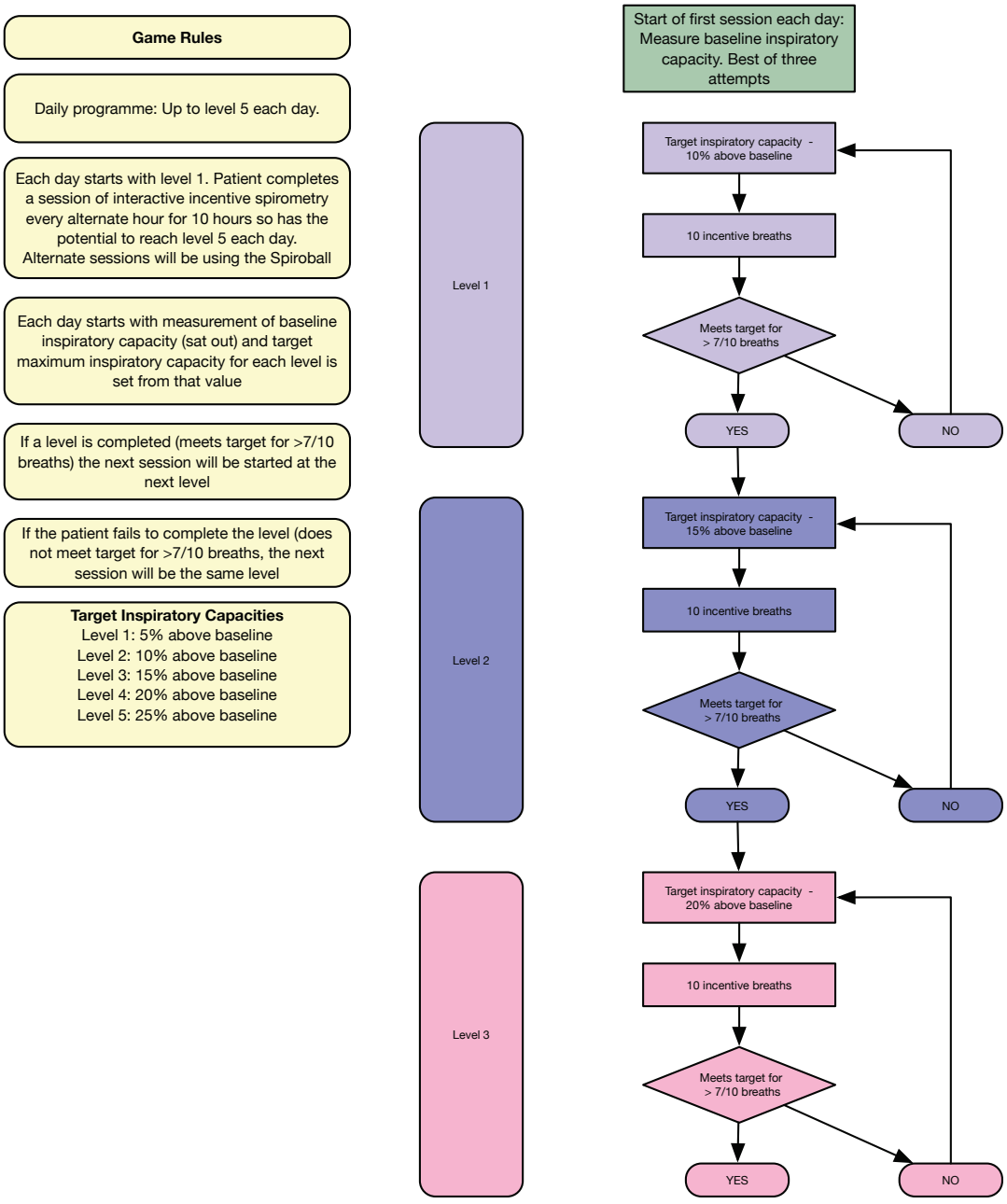


Figure 6.18 InspireVR game rules

6.8.2 Interface devices

6.8.2.1. Visual output

The visual display was provided via a touch screen Microsoft Notebook personal computer, attached to a stand on wheels. These components were selected to enable patients to use the device independently, whilst providing minimal inconvenience to bedside nursing and clinical staff.

6.8.2.2 Auditory output

Auditory output, including sounds of the trebuchet drawing back and the boulder splashing into the sea, was provided by the computer speakers.

6.8.2.3 Haptic output

The Vitalograph Pneumotrac 6800, when combined with Spirotrac software, has been designed for bedside, clinic or home use, for the measurement of pulmonary function. The main component parts of the Pneumotrac 6800 are the mouthpiece, Fleisch type pneumotachograph flowhead, twin tubing flow sampling and USB data output cable.

The external surfaces of the InspireVR system components could be cleaned using 70% isopropyl. alcohol wipes.The spirometer itself could be sterilised if exposed to pathogens of concern as per the manufacture’s instructions for use.

6.8.3 User testing - evaluation of the prototype REVERE Breathe system by the research stakeholders

User testing was completed by clinical members of the stakeholder group. InspireVR was subjected to “hands-on” experiences for the users, designed to evaluate usability and acceptance issues, operational procedures and basic troubleshooting. The outcome of these early tests included modifications to the system to improve the patient interface and to rectify issues with the game-based simulation (Table 6.8) and whole system (Table 6.9).

Table 6.8 Results of early user testing of InspireVR - game design

Issue raised	Modification made
InspireVR needs to launch every 2 hours, not every 1 hours	Algorithm changed
Clear instructions need to be provided at launch and at each activation of the game.	Text provided and incorporated into software.
First person-only view of the trebuchet and boulder makes interpretation of distance travelled by boulder difficult, particularly when the boulder falls short between the cliff edge/ beach and the sea.	To provide side-on or birds eye view as well as first person view.
The emoticons chosen to illustrate successful/ unsuccessful meeting of maximum inspiratory capacity target are unclear. To consider alternatives.	Smiling and sad emoticons chosen - more clear.
It is not possible to ascertain if boats to be sunk are occupied or not, thus suggesting sinking of people and boats and associated suggestion of loss of life.	To convert to images to open “rowing” boats and buoys to be sunk.
Unable to see the boulder clearly due to lack of contrast with surrounding ground.	Boulder colour changed to increase contrast.
Unable to see boats clearly due to lack of contrast with surrounding sea.	Boat colour changed to increase contrast.
It is not intuitive as to whether the patient has to inhale or exhale first.	Onscreen instructions modified and instructions for use improved. Protocol modified to include the need for clear instructions and supervision given to patients during use of the device.
The emoticons are too small for the patients to be able see clearly	Emoticon size increased by 50%
Placing the system on the tray table is not the ideal solution as the table is used for drinks, magazines etc.	To use stand not requiring use of the tray table

Table 6.9 Results of early user testing of InspireVR - whole system

Issue raised	Modification made
All desktop icons visible on laptop from pre-loaded software. Users may attempt to assess these.	All non-essential software rendered unusable/inaccessible and invisible on home screen. Only icons relating to InspireVR launch visible
Current spirometer only suitable for single patient use (no filter) and will need to be disposed of in whole if exposed to respiratory pathogens (PASPort), therefore does not meet technical requirements	Alternative spirometer sourced which meets requirements (Pneumotrac)
Development platform need to upgraded from Unity 3 to Unity 5 because: 1. Unity 5 has fixed some issues in data transfer which are necessary for the communication between Virtual Wembury and the spirometry interface. 2. Unity 5 has the ability to enhance visual fidelity.	Upgrade to Unity 5 complete
System unreliable if patient exhales prior to inhaling	Midware modified
Data storage files need to be password protected	Password protection for data storage file
The stand needs to be modified to allow adjustment of height for bed space (semi recumbent)/seated position	Appropriate stand selected to allow alteration in height
Placing the system on the tray table is not the ideal solution as the table is used for drinks, magazines etc.	To use stand not requiring use of the tray table

6.8.4 Clinical trial protocol design

The protocol for the feasibility study was designed by the multi-disciplinary stakeholder group. The research methods built on those applied to the VRET Burns and ReVERe sleep studies, considering the lessons learned and evolving the HCD processes to improve the quality of the data collected, whilst maintaining the feasibility of data collection for the ICU context. Local and Health Research Authority permissions were secured, with a letter of approval for the Clinical Investigation provided by the MHRA.(96, 97) The protocol for the study “Feasibility of the use of Interactive Technology-enhanced Incentive Spirometry (InspireVR) to reduce post-operative pulmonary complications following elective oesophagectomy and total gastrectomy” is described in more detail in chapter 8

6.8.5 Conclusions

This chapter has described the development of two novel interactive technology-based systems “VeloVR” and “InspireVR” to enhance physical recovery from critical illness and injury on the ICU. A programme theory was developed to illustrate how the interventions might work and to provide a framework for design and evaluation. Design processes were modified in the light of lessons learned from the prototype development and feasibility studies of the “Windows” interventions. The following chapters report the clinical feasibility studies of the two systems.

6.9 Reflections and key methodological lessons learned

- A key determinant of success in the development of an interactive system is the efficiency of the process whereby the user requirements are understood and met by the designers/manufacturers. This process was better formalised by the use of templates completed collaboratively detailing the essential and desirable specifications.
- Embedded software can be used to facilitate collection of clinical outcome measures, though its accuracy needs to be determined during the clinical studies.
- Patient representative groups (PPI) are a useful cohort to evaluate technologies during the iterative design process as they have insight into the experiences of the target patient group but have recovered sufficiently to provide useful feedback.

CHAPTER 7 RESTORATIVE VIRTUAL ENVIRONMENTS FOR REHABILITATION - FEASIBILITY OF THE USE OF INTERACTIVE TECHNOLOGY-ENHANCED RECUMBENT CYCLING TO AID MOBILISATION ON THE INTENSIVE CARE UNIT.

Chapter 7 presents the report of the third feasibility study “ReVERe Move: Restorative Virtual Environments for Rehabilitation - Feasibility of the use of interactive technology-enhanced recumbent cycling to aid (VeloVR) mobilisation on the Intensive Care Unit” (Figure 7.1). The methods used to evaluate the VeloVR system have been informed by the lessons learned from the VRET Burns and REVERE Sleep studies.

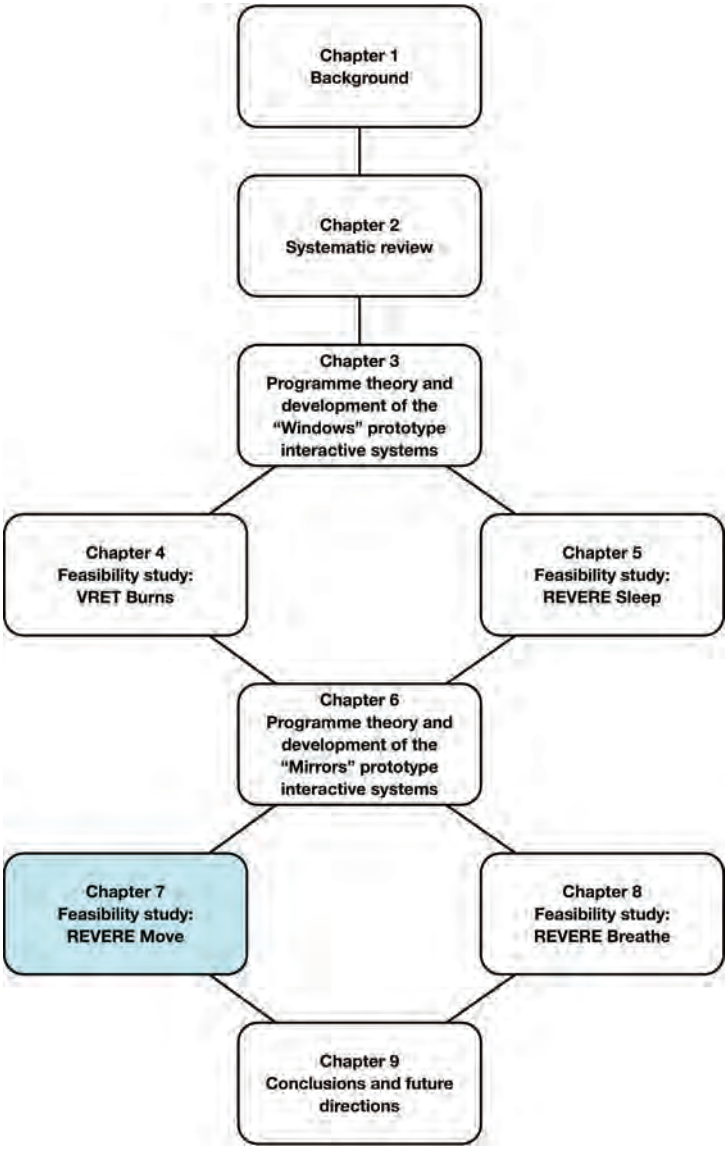


Figure 7.1 Thesis roadmap - Chapter 7

7.1 Introduction

A substantial proportion of survivors of injury or illness requiring treatment in the ICU suffer significant long-term adverse physical and psychological sequelae, reducing their health-related quality of life.(186) Physical disability is frequently a consequence of intensive care unit-acquired weakness (ICUAW), evident in 50% of patients who are mechanically ventilated for greater than five days.(187) Rehabilitation in those diagnosed with ICUAW focuses on whole-body muscle and cardiorespiratory training (176) aiming to improve functional status, shorten time to independent ambulation and accomplishment of activities of daily living prior to discharge to a general ward.(188) There are few technologies evaluated to aid rehabilitation on the ICU.(178) Recumbent cycling is utilised at the Queen Elizabeth Hospital Birmingham (QEHB) for patients with ICUAW using the Reck MotoMed Letto, or “MotoMed.” Patients diagnosed with ICUAW are referred to the ICU Supportive Rehabilitation Team, a multidisciplinary team lead by physiotherapists with expertise in the management of complex and long-stay ICU patients. These patients undergo cycling sessions of up to 20 minutes every two to four days until able to step transfer with assistance.

VeloVR is a novel interactive technology-based system, designed to be used with the MotoMed to enhance performance during recumbent cycling, The development of the VeloVR prototype has been described in detail in Chapter 6. The study protocol was written according to the Recommendations for Interventional Trials (SPIRIT) 2013 guidelines (189) and the CONSORT 2010 statement: Extension to randomised pilot and feasibility studies.(190)

7.2 Hypotheses

In patients with ICU-Acquired weakness on the ICU:

1. Interactive technology (iTech) can be used to enhance patient performance during recumbent cycling.
2. VeloVR-enhanced recumbent cycling hastens movement through mobility milestones.
3. VeloVR-enhanced recumbent cycling reduces ICU and hospital length of stay compared to standard recumbent cycling.

7.3 Aims

The aims of the research are to determine whether, in patients with ICUAW on the ICU:

- Interactive technology can be used to enhance patient performance during recumbent cycling.
- VeloVR reduces time to achieve mobility milestones.
- VeloVR-enhanced recumbent cycling reduces ICU and hospital length of stay compared to standard recumbent cycling.

To answer these questions a phase III multi centre randomised controlled trial (RCT) is needed.This protocol is designed to establish the feasibility of such a trial whilst evaluating the methodology and, therefore, its aims were to:

1. Estimate the likely rate of recruitment and retention of subjects to the proposed RCT.

2. Define the most appropriate clinical and patient reported outcome measures for the definitive trial. These will include short term measures to determine patient performance during cycling sessions, patient reported breathlessness and exertion, duration of cycling session, proportion of active versus passive cycling during each session and distance covered as measured by MotoMed device.
3. Evaluate the safety of, and adverse events related to, the use of VeloVR.
4. To assess the evaluation of ICU patient usability and user acceptance of the VeloVR device.
5. To assess the evaluation of rehabilitation staff usability and user acceptance of VeloVR.
6. Evaluate the programme theory (Figure 6.9) via assessment of the potential mediators of performance during during cycling sessions, to include perception of pain and patient-reported self efficacy and motivation.
7. Evaluate potential modifiers of response to the novel interactive system, including predictors of technology acceptance in patient users.

Clinical outcomes, including patient progression through mobility rehabilitation goals, patient mobility level and functional performance at discharge from ICU, duration of mechanical ventilation, tracheal intubation, ICU length of stay, hospital length of stay and in-hospital death will be included in the future clinical trial. These were not included in this feasibility study as the methods of data collection have been determined on previous studies on the QEHB ICU.(181)

7.4 Methods

This trial was a mixed methods feasibility pilot study of interactive technology-enhanced cycle (VeloVR). A within-subject repeated measures design was used to compare three different recumbent cycle interventions:

1. Standard use of MotoMed.
2. Distraction mode VeloVR.
3. Competition mode VeloVR.

This study was sponsored by the University of Birmingham, reviewed by the National Research Ethics Service Committee South Birmingham (Reference 17/WM/0007), approved by the UK Health Research Authority and registered with the UK Clinical Research Network portfolio (Study ID 33185) and Current Controlled Trials (ISRCTN18012197). The study was designated as a trial of a class 1 medical device, not for commercialisation, thus received a letter of no objection from the MHRA.(96, 97)

The use and effectiveness of VeloVR is influenced by its context of use. This defines it as a complex intervention. This study follows the guidance on developing and evaluating complex interventions provided by the Medical Research Council.(42)

7.4.1 Study participants

The study was undertaken on the Queen Elizabeth Hospital Birmingham (QEHB) ICU. This is an 86 bed mixed level 2 and 3 adult teaching hospital unit that admits medical, surgical, trauma, burns, liver, cardiac, transplant and neurosurgical patients.

7.4.1.1 Inclusion criteria

Patient admitted, with any diagnosis, to the QEHB ICU who were:

- Conscious and able to communicate
- Aged over 18 years
- Diagnosed with ICU-Acquired Weakness according to the MRC Sum score of 48 or more and exclusion of other causes of weakness.(10)

7.4.1.2 Exclusion criteria

- Severe visual impairment.
- Active delirium or psychosis at screening from the Richmond Agitation and Sedation Score and the Confusion Assessment Method for the ICU score. (136)
- Severe cognitive impairment or encephalopathy
- Patients with contraindication to mobilisation and recumbent cycling (e.g. pelvic / spinal fractures/lower limb external fixation).
- Poor prior level of mobility (<10yds)
- Expected withdrawal of treatment/palliative care in process.
- Previous participation in this study.

7.4.2 Sample size

For this feasibility study, no sample size was calculated. It was decided that a sample size of 20 would provide qualitative data saturation. The sample included all patients meeting the inclusion criteria up to a total of 20 patients, over a maximum period of 12 months.

7.4.3 Study procedure

7.4.3.1 Recruitment

The research physiotherapist identified all patients invasively mechanically ventilated for five days or more. Each of these patients was reviewed daily until they could be tested for ICUAW. Once ICUAW was diagnosed and there were no contraindications to the use of the recumbent cycle, the patients were then reviewed daily until they were cognitively able to receive information on the study. A letter of invitation and patient information leaflet were provided by the research physiotherapist, with opportunity given for the patient, their friends and family to discuss the trial with a member of the research team. At least 24 hours was given prior written informed consent being taken. In the context of ICUAW, some patients were unable to write and provide a signature. In this event, signed witness to consent was requested from a member of the patient's clinical team.

Staff members were invited to participate in the study. All physiotherapists supervising at least one VeloVR recumbent cycle session were invited to complete a questionnaire at the end of the study. Written informed consent was

taken from all staff participants prior to commencement of their first study cycling session.

7.4.3.2 Interventions

The VeloVR system is described in detail in chapter 6. Each cycling session used the same MotoMed device, either with or without the VeloVR system. The MotoMed ergometer was set to “Active” for each intervention. The duration of each intervention was a maximum of 20 minutes according to the standard QEHB recumbent cycling protocol (Figure 6.9). The protocol included four sessions of MotoMed, with two using VeloVR (Figure 7.2). All participants followed the same sequence of interventions with control non-VR sessions first and last to evaluate potential impact of training effect. The sequence of VeloVR interventions was always distraction followed by competition mode. This was due to the competition scenario requiring a preceding VeloVR session to record the avatar pace.

Participants were supervised by the physiotherapist, with full ICU bedside monitoring, during each intervention session of standard MotoMed or VeloVR (as is current standard practice). The patients were monitored for adverse events, including intravenous line dislodgement, and cardiovascular instability.

Participants were asked to complete a questionnaire before the first session and then another questionnaire and short semi-structured interview after each session, following a short period of rest and recovery (10-20 minutes).

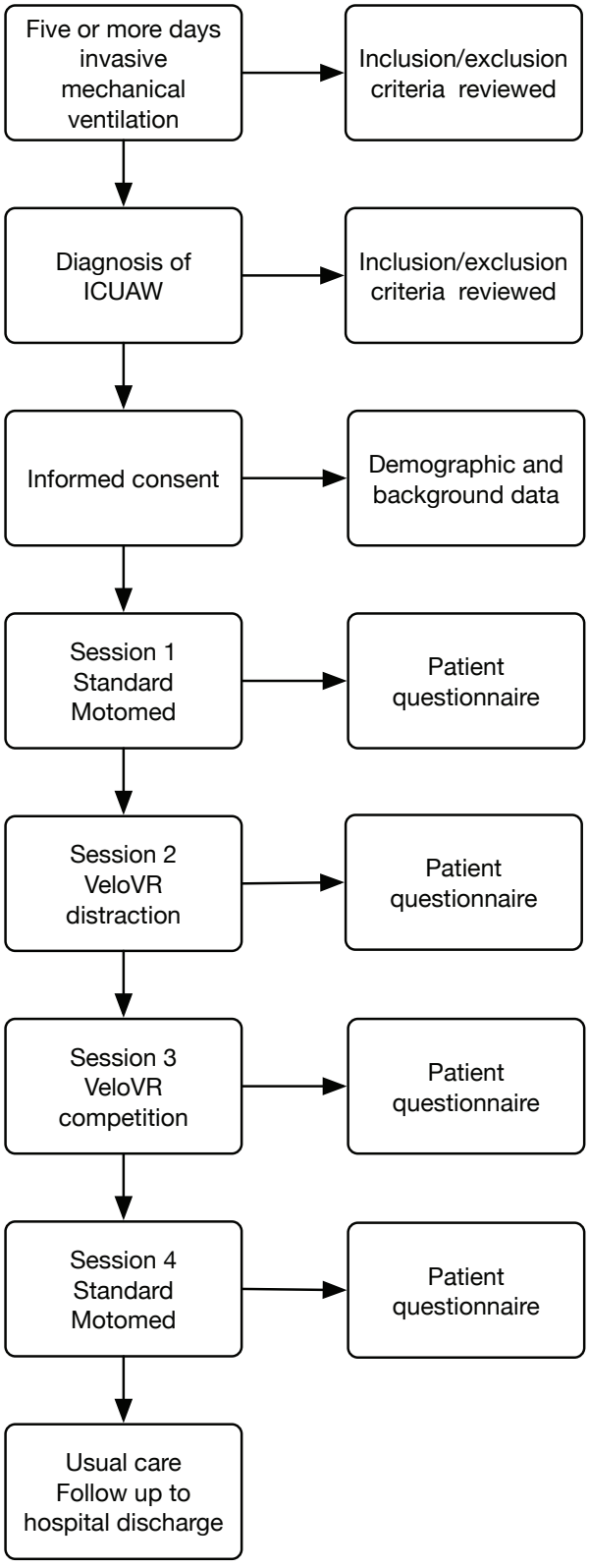


Figure 7.2 ReVERe Move Participant flow diagram

7.4.4 Data collection

7.4.4.1 Primary outcomes:

Feasibility and acceptability of the the intervention, process and measurement tools required to deliver a future definitive trial, defined as ability to recruit participants to the ReVERe Move study and participant completion of the ReVERe Move study protocol.

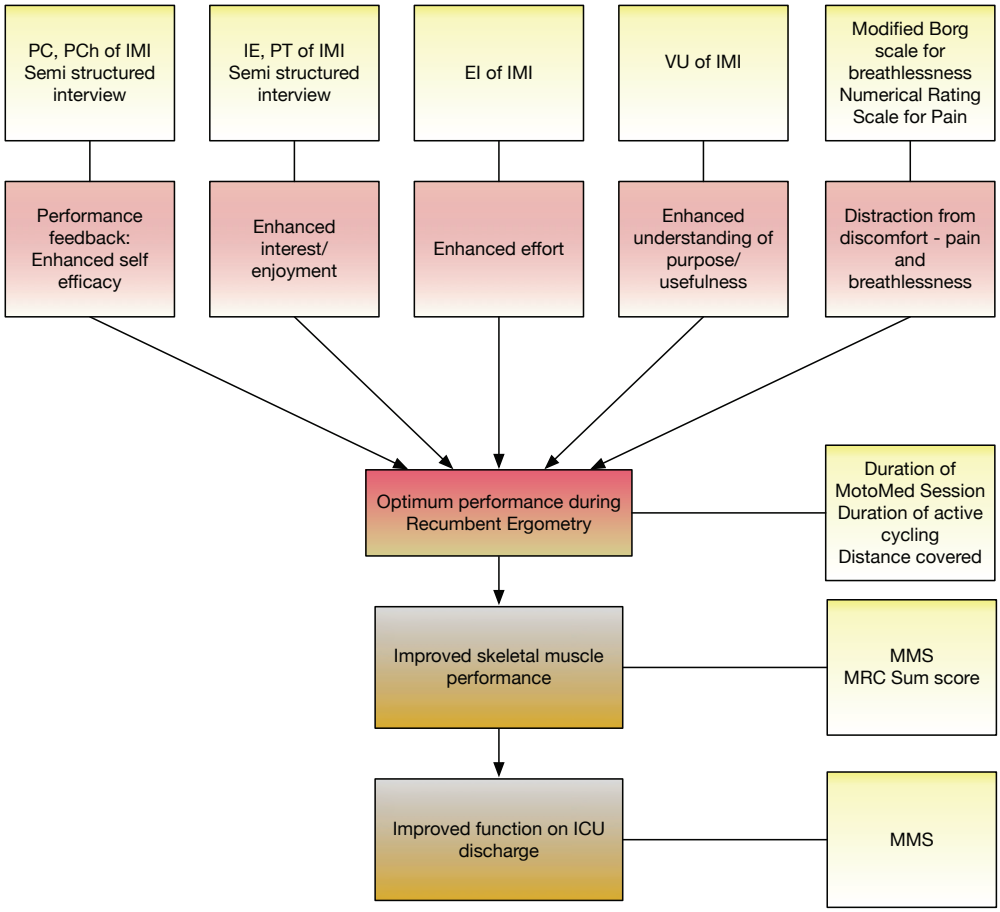


Figure 7.3 ReVERe Move study outcome measures mapped to Programme Theory

IMI: Intrinsic Motivation Inventory, IE: interest/enjoyment, PCh: Perceived Choice, PT: Pressure/Tension, EI: Effort/Importance, VU: Value/Usefulness

7.4.4.2 Secondary outcomes

The secondary outcomes were selected to establish the efficacy, usability, safety, and potential mediators of efficacy of the VeloVR system, underpinned by data on barriers and enablers influencing usage of the devices (Figure 7.3).

7.4.4.2.1 Efficacy of the VeloVR system

- Distance covered during each session (as measured by the MotoMed ergometer) in metres.
- Duration of active cycling during each session (seconds).
- Total duration of exercise during each MotoMed/VeloVR session.
- Perceived exertion during each cycling session (Borg Scale (191)).
- Perceived dyspnoea during each cycling session (Modified Borg Scale 1-10 (192)).
- Patient movement through mobility milestones: Manchester Mobility Score (Table 7.1).(193)

Table 7.1 Manchester Mobility Score (7)

1 In bed interventions (Passive Movements, Active exercise, chair position in bed)
2 Sit on edge of bed
3 Hoisted to chair (including standing hoist)
4 Standing practice
5 Step transfers with assistance
6 Mobilising with or without assistance
7 Mobilising more than 30m

7.4.4.2.2 Safety and usability of the VeloVR system by patient and staff users

- Safety, side effects and adverse events associated with use of the VeloVR system.
- Usability of the VeloVR system by patient users (semi-structured interview).
- Usability of the VeloVR by staff users (semi-structured interview).

7.4.4.2.3 Patient experience - evaluating barriers/enablers of optimum performance

- Pain experienced during each cycling session (Numerical Rating Scale).
- Modifiers of behaviour - Six sub-scales of the Intrinsic Motivation Inventory:
    - Interest/enjoyment (scores intrinsic motivation).
    - Perceived competence (positive predictor of intrinsic motivation, self efficacy).
    - Effort/importance (positive predictor of intrinsic motivation).
    - Pressure/tension (negative predictor of intrinsic motivation).
    - Perceived choice (positive predictor of autonomy).
    - Value/usefulness (positive predictor of extrinsic motivation).

7.4.4.2.4 Technology acceptance and attitude to the intervention

Based on the Patient Technology Acceptance Model (Figure 6.7).(33). The questionnaire was based on that used by Or et al (33) who based theirs on those presented by Venketash and Taylor.(171, 194)

- Technology/computer experience of patients prior to ICU admission.

- Technology acceptance and attitudes of patients prior to VeloVR use: Perceived usefulness, computer efficacy, perceived ease of use, attitude, attitude, habit, perceived norm, intention, facilitators and patient centred factors.
- Age, gender and presence of children under the age of 16 living at home with the patient prior to ICU admission.
- Competitive personality trait and attitude to exercise, including frequency of exercise prior to current hospital admission or onset of illness.

7.4.4.2.5 Patient experience and recommendations for future research

Patient experience during the MotoMed/VeloVR session and recommendations for future development of device and research (Semi-structured interview).

7.4.5 Data analysis

Data was pseudo-anonymised via a unique study identification number and collated on an Excel spreadsheet, stored securely on an NHS network computer. Descriptive statistics were analysed using Excel 2016. Quantitative statistical analysis was performed using GraphPad Prism and qualitative data was coded using thematic analysis via NVivo 12. Mean and standard deviation were calculated for continuous variables, which were compared between two interventions using a paired t-test or wilcoxon sign rank test and multiple interventions using one ay ANOVA (Analysis of Variation) Friedman test, depending on distribution of data, with p values of ≤ 0.05 considered significant.

7.5 Results

7.5.1 Patient characteristics

Sixty two patients were screened over a 12 month period, of whom 20 provided written informed consent to participate and received at least one intervention (Figure 7.4). Reasons for exclusion at the point of consent included delirium or severe cognitive impairment (48%) and prior poor level of mobility (31%). Three patients declined to participate, all of whom subsequently refused to use the MotoMed as part of their rehabilitation.

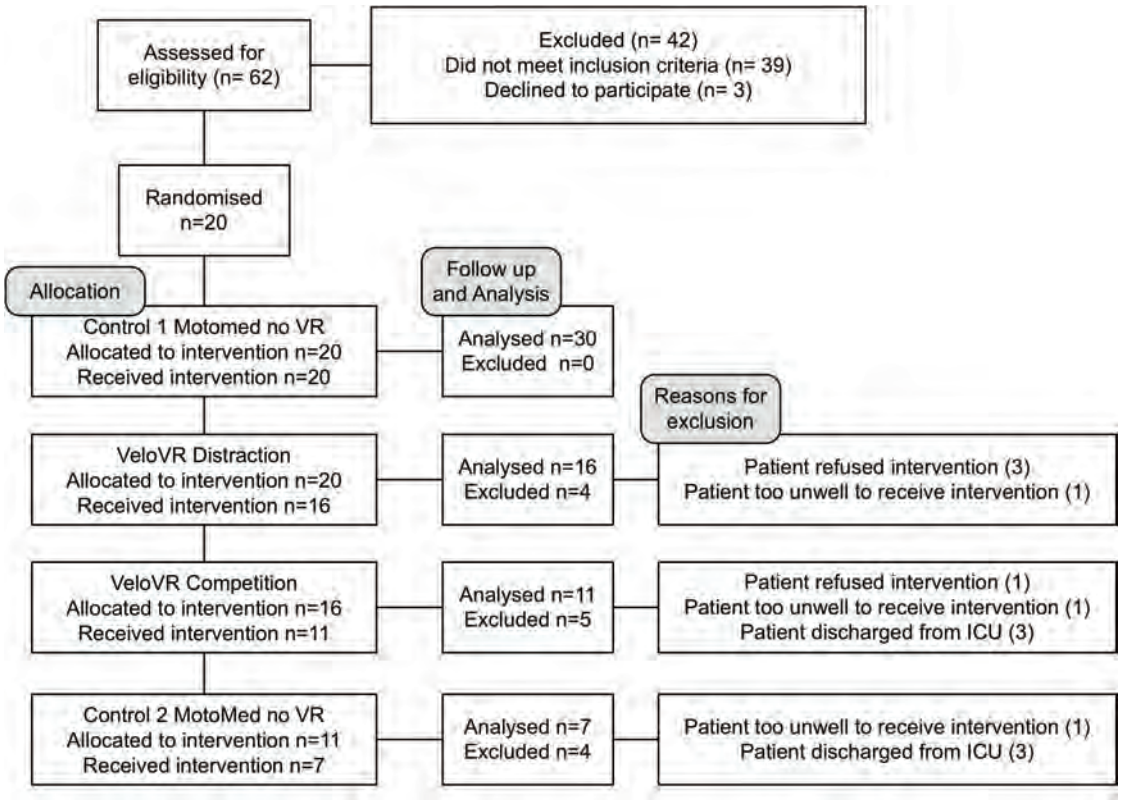


Figure 7.4 Consort diagram for the ReVERe Move trial

Patients were screened on all four ICU areas.Twelve patients were recruited from Area A (Hepatobiliary/Transplant/Gastrointestinal surgery/Medicine) and 8 patients from Area D (Cardiothoracic surgery including heart and lung transplant). The majority of patients were male (75%) and emergency admissions predominated (80%). Reason for admission included out of hospital cardiac arrest (two patients), solid organ transplant (6 patients), exacerbation of Chronic Obstructive Airway Disease (three patients) and elective major upper gastrointestinal surgery (three patients). The mean age was 54.35 (SD 16.97, range 26 to 79). The mean length of ICU stay at recruitment was 19.35 days (SD 10.55).

Most patients reported that their pre-admission functional status was normal (60%) or reduced for their age but were independent of activities of daily living (40%). All patients spoke English as their first language. The majority of patients had not entered higher education, and over half never exercised prior to onset of illness or hospital admission.(Table 7.2)

Table 7.2 ReVERe Move participant characteristics - education and exercise

Highest education level		Frequency of exercise	
Degree/equivalent	10%	Every day	20%
A level/equivalent	30%	1-5 times per week	20%
GCSE/equivalent	30%	Less than once a week	5%
No qualifications	30%	Never	55%

Whilst 20 patients were recruited and commenced the study interventions, only seven patients completed all four sessions. The reasons for attrition were similar to those of the ReVERe Sleep study reported in chapter 5. Six participants refused to engage with the cycling sessions with or without VeloVR. These patients were approached every week day until they were discharged from the ICU or declared that they wished to cease participation in the study. Reasons for refusal included fatigue, pain and the presence of visitors. Whilst some patients would agree to undertake cycling sessions on consecutive days, there were considerable delays in progress through the trial for some patients, with a trial duration range of 4 to 20 days. Some patients were discharged from ICU prior to completion of all interventions Three patients clinically deteriorated during the trial due to complications of their critical illness and subsequently died on the ICU. All patients were able to complete all the questionnaires until they completed, or were withdrawn from, the study.

The results below are presented as either whole datasets, including all 20 patients recruited to the trial or as data of the seven patients who completed all four sessions of the trial. This approach was taken to minimise the impact of the incomplete data on the statistical analysis of the effectiveness and impact of the VeloVR system whilst attempting to avoid the impact of data loss on items analysed using descriptive statistics.

Two research physiotherapists from the Supportive Rehabilitation Team completed all the study interventions during the trial and both completed the post-trial semi-structured interview.

Thematic analysis was used to evaluate the patient semi-structured interview responses and observations of research staff performing the MotoMed or VeloVR interventions. Statements were coded in NVivo and categorised according to the following emerging themes “Impact of VeloVR on the rehabilitation experience”, “Recommendations for improvements to the VeloVR system”, “Side effects and adverse events” and “Technical or process issues with the VeloVR system.” These results are presented alongside relevant quantitative data.

One patient was interviewed by ITV news during the study (Figure 7.4). The full report can be found at http://www.itv.com/news/central/2017-07-13/virtual-reality-project-helping-patients-to-cycle-the-coast-path/.

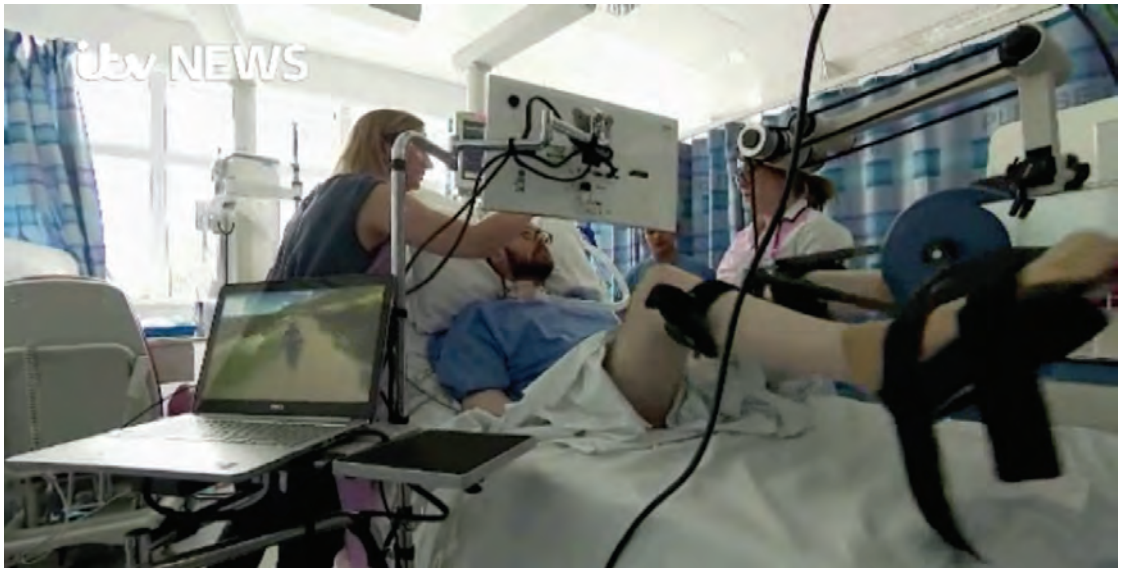


Figure 7.5: Patient participating in VeloVR study (image reproduced with patient consent, credit ITV news)

7.5.2 Efficacy of the VeloVR system

7.5.2.1 Performance during MotoMed and VeloVR sessions

In the seven patients who completed all four interventions, all but one increased their distance travelled on the MotoMed, with a significant increase between groups across all four interventions for total distance, total duration and duration of active cycling (Figures 7.5 to 7.7).

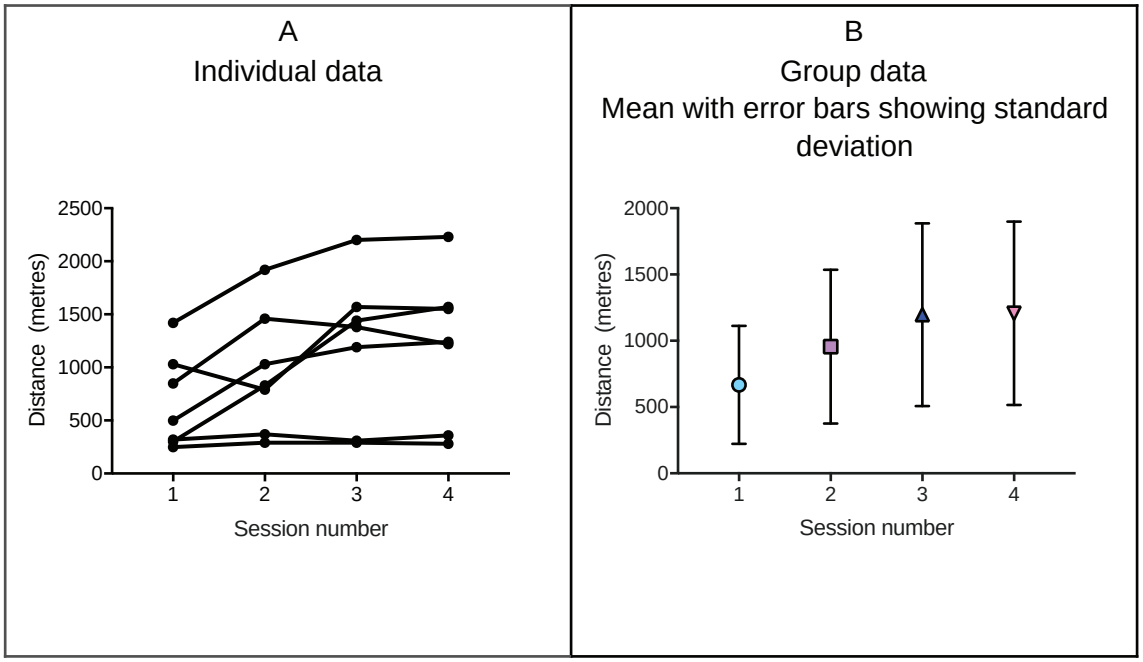


Figure 7.6 ReVERe Move Distance travelled on MotoMed

Dataset from participants who completed all four sessions, n= 7
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR

Significant difference between session numbers, p=0.01, repeated measures one way ANOVA.
Session 1 vs Season 2, p=0.06, Session 1 vs Session 3, p=0.01, Session 1 vs Session 4 p=0.02, Session 2 vs Session 3 p=0.10, Session 2 vs Session 4, p=0.13, Session 3 vs Session 4: p=0.78 paired t tests.
Normality assessed by Shapiro Wilk test

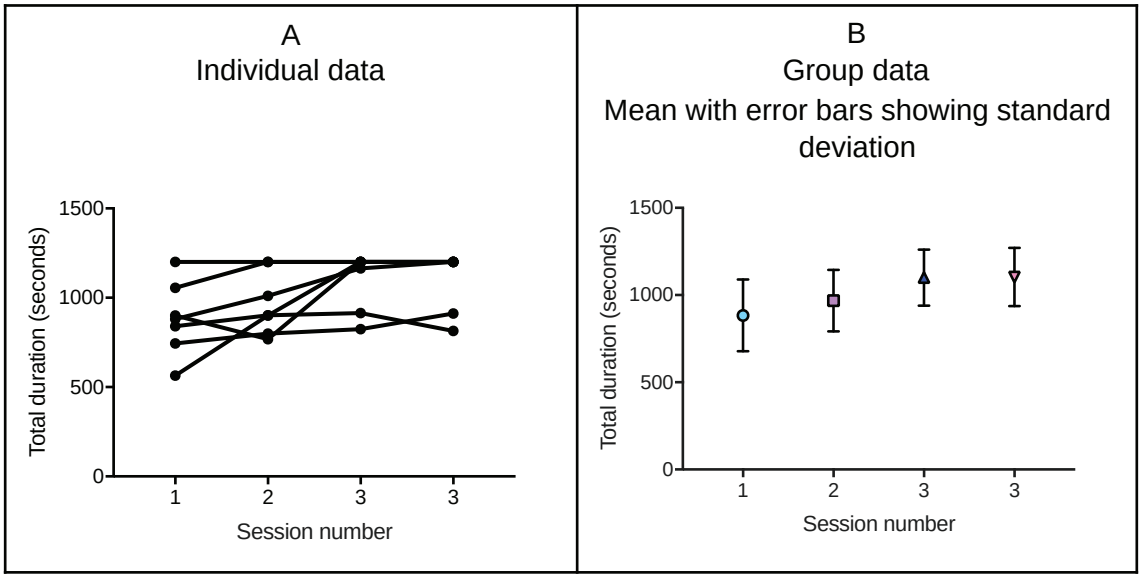


Figure 7.7 ReVERe Move total duration of MotoMed session

Dataset from participants who completed all four sessions, n= 7
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR

Significant difference between session numbers, p=0.02, Friedman test.
Figure 7.6: Session 1 vs Season 2, p=0.22, Session 1 vs Session 3, p=0.03, Session 1 vs Session 4 p=0.06, Session 2 vs Session 3 p=0.06, Session 2 vs Session 4, p=0.13, Session 3 vs Session 4: p>0.99 Wilcoxon matched pairs-signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

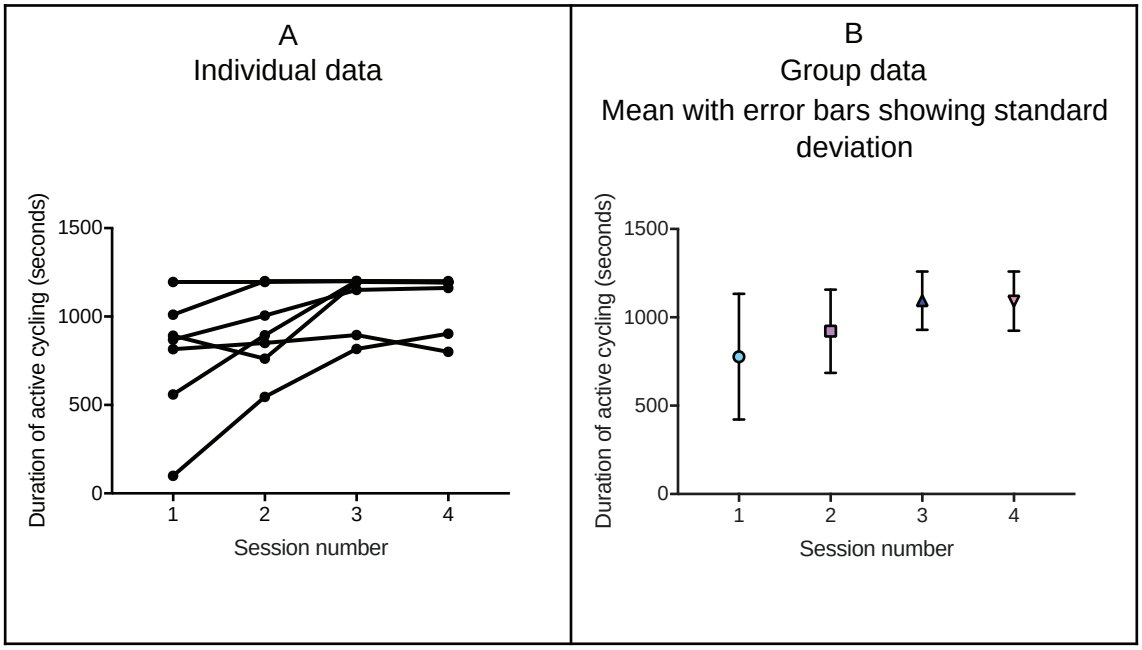


Figure 7.8 ReVERe Move Duration of active cycling MotoMed session

Dataset from participants who completed all four sessions, n= 7
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR

Significant difference between session numbers, p=0.02, Friedman test.
Session 1 vs Season 2, p=0.11, Session 1 vs Session 3, p=0.02, Session 1 vs Session 4 p=0.08, Session 2 vs Session 3 p=0.03, Session 2 vs Session 4, p=0.16, Session 3 vs Session 4: p=0.84 Wilcoxon matched pairs-signed rank test

Data not normally distributed as assessed by Shapiro Wilk test

7.5.2.2 Perceived breathlessness and exertion during MotoMed and VeloVR sessions

Patients reported more breathlessness during session 2,3 and 4 (Figure 7.8). There was variation, bit no significant difference, between subjective experiences of exertion (Figure 7.9).

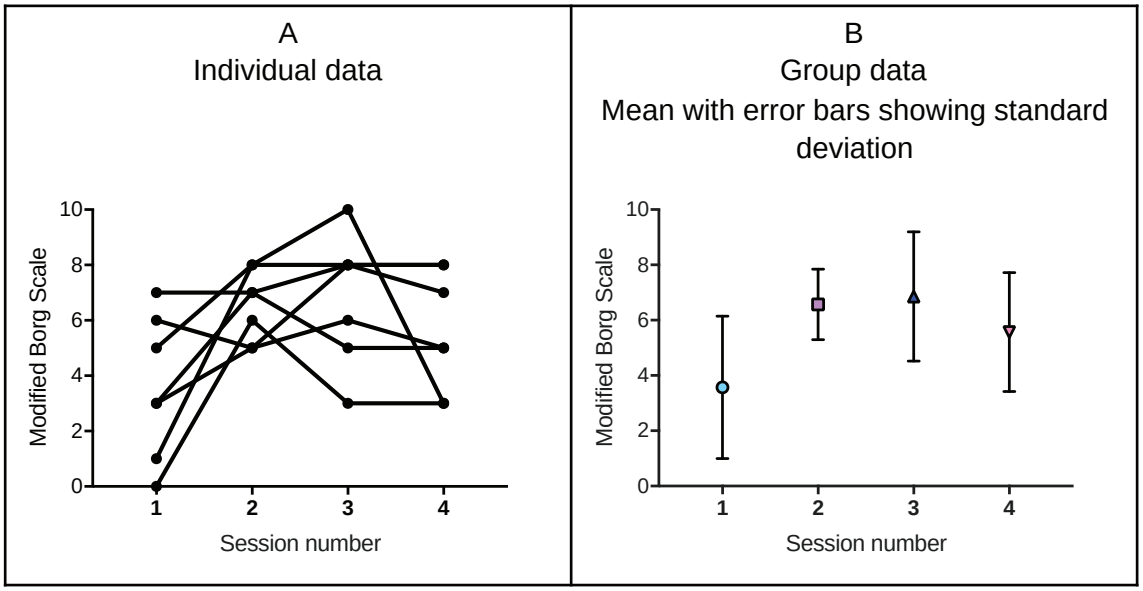


Figure 7.9 ReVERe Move Subjective breathlessness during MotoMed sessions

Dataset from participants who completed all four sessions, n= 7
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR

Significant difference between session numbers, p=0.03, repeated measures one way ANOVA.
Session 1 vs Season 2, p=0.04, Session 1 vs Session 3, p=0.04, Session 1 vs Session 4 p=0.03, Session 2 vs Session 3 p=0.74, Session 2 vs Session 4, p=0.35, Session 3 vs Session 4: p=0.23 paired t tests.
Normality assessed using Shapiro Wilk test

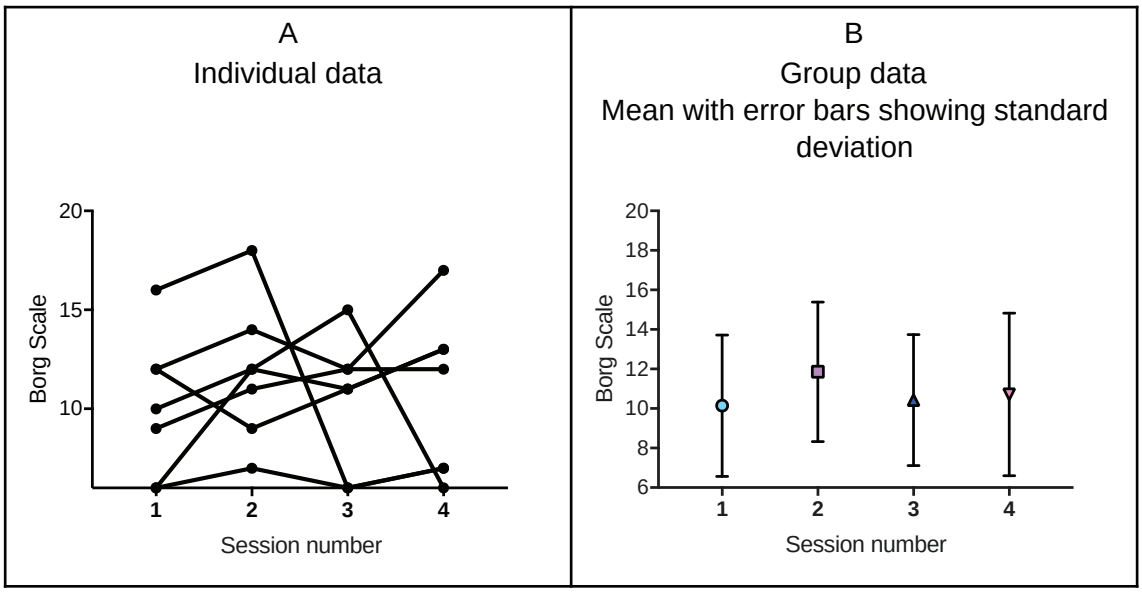


Figure 7.10 ReVERe Move Subjective exertion during MotoMed sessions

Dataset from participants who completed all four sessions, n= 7
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR

No significant difference between session numbers (p=0.72), repeated measures one way ANOVA.
Session 1 vs Season 2, p=0.14, Session 1 vs Session 3, p=0.90, Session 1 vs Session 4 p=0.78, Session 2 vs Session 3 p=0.48 Session 2 vs Session 4, p=0.62, Session 3 vs Session 4: p=0.87, paired t test.
Normality assessed using Shapiro Wilk test

7.5.2.3 Movement through mobility milestones

Patient movement through mobility milestones was measured using the Manchester Mobility Score (MMS), with a higher score denoting improved mobility. The mean mobility scores increased with a reduction in range across the study interventions (Figure 7.10).

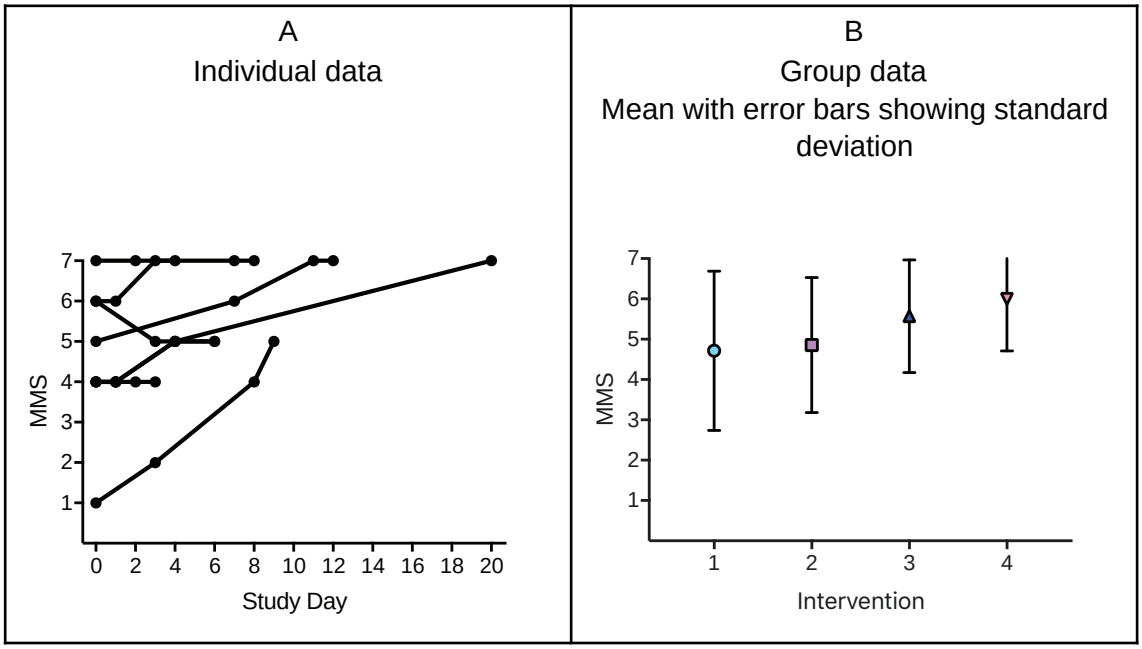


Figure 7.12 ReVERe Move Manchester Mobility Score (MMS) progression across interventions

Dataset from participants who completed all four sessions, n= 7
Graph A presents MMS plotted against participant study day, with each point representing a study intervention session.
Session 1: No VeloVR
Session 2:Distraction VeloVR
Session 3: CompetitionVR
Session 4: No VeloVR
Significant difference between session numbers, p=0.013, Friedman test.
Session 1 vs Season 2, p>0.99, Session 1 vs Session 3, p=0.25, Session 1 vs Session 4 p=0.06, Session 2 vs Session 3 p=0.12, Session 2 vs Session 4, p=0.06, Session 3 vs Session 4. p=0.50
All paired comparisons p>0.05, Wilcoxon matched pairs-signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

7.5.3 Safety and usability of the VeloVR system by patient users

There were no safety or adverse events associated with the VeloVR system during the ReVERe Move trial. There were no reports of tube dislodgement or interference with ventilation despite mechanical ventilation in use during 26% of interventions. No patients reported nausea.

During session 1 (MotoMed only) 13 patients requested to stop the intervention due to fatigue with three stopping due to discomfort. In session 2 (distraction VeloVR) eight patients stopped due to fatigue and two stopped due to pain from abdominal wound sites. All those who terminated session 3 (competition VeloVR) and session 4 (MotoMed only) prior to completion of the protocol cited fatigue only.

7.5.4 Usability of the VeloVR system by staff users

The two staff users reported that they quickly became confident using the VeloVR system, requiring only one or two sessions before they were able to use the system independently. The system was easy to set up and the software was easy to load, although positioning the cadence tracking system was difficult and sometimes hindered the set up process. The bulkiness of the device was reported to be problematic at times, particularly in the single occupancy rooms.

7.5.5 Technical or process issues with the VeloVR system

Due to the MotoMed and VeloVR running separate software operating systems, there were occasions of dyssynchrony and delay.

> *“ Sometimes it was difficult to time the start of the MotoMed to the start of the VR in competition mode as there was often a delay in loading the VR. This would mean the timer on the patients screen was different to the real time of treatment on the MotoMed.” Research Physiotherapist A*

The quality of the VeloVR intervention was reported to have been diminished during nine of the sessions. This occurred due to the VeloVR software being slow to load, particularly in competition mode, or spontaneously closing following start up. On one occasion it took a number of attempts to connect the wifi, with lack of connection stability causing tracking inconsistencies during competition mode. The sound function ceased mid-intervention during four sessions.

Environmental ergonomic issues were reported three times, twice due to the requirement to rearrange a number of large pieces of equipment in the bed space, and once due to screen glare necessitating the closing of window blinds. During two sessions the MotoMed system developed faults where it failed to calculate distance travelled and stopped functioning following start up.

“There was occasionally difficulty to pick up the signal from the monitoring device on the MotoMed, therefore the patient would be cycling but on the screen the VR would be stationary; it would therefore require position changes, re-adjustments and re-setting and this would be off-putting for the patient.” Research Physiotherapist B

7.5.6 Patient experience - evaluating barriers and enablers of optimum performance

7.5.6.1 Pain experience during MotoMed and VeloVR sessions

There was variation in subjective pain experience between and within subjects across the study interventions with patients reporting mild to severe pain during the cycling sessions. Pain was reported in legs and post-operative abdominal wounds. Four of the seven patients who completed all four interventions experienced no pain.

7.5.6.2 Exercise Behaviour

For each patient who completed the ReVERe Move protocol, experiencing all four interventions, each Likert item pair score on the Intrinsic Motivation Index was added together (in reverse for a negative question) as per the guidance for the tool.(144) This gave each domain a maximum of 10.

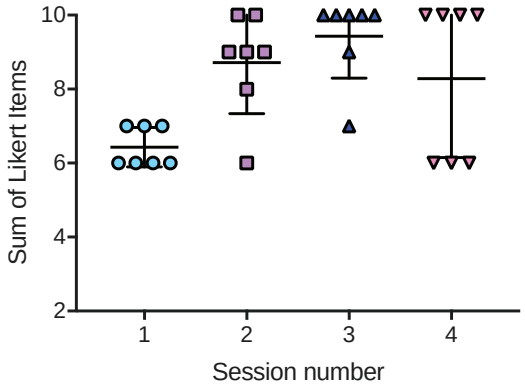
Interest/Enjoyment (IE)	
Statements: 1. I enjoyed doing this activity very much 2. I thought this was a boring activity Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.12 ReVERe Move Interest/Enjoyment (IE) dimension of the Intrinsic Motivation Index

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from two statements (no. 2 reversed): Maximum score of 10

Significant difference between session numbers, p=0.04, Friedman test.
Session 1 vs Season 2, p=0.03, Session 1 vs Session 3, p=0.03, Session 1 vs Session 4 p=0.16, Session 2 vs Session 3 p=0.50, Session 2 vs Session 4, p=0.35, Session 3 vs Session 4: p=0.63, Wilcoxon matched pairs-signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

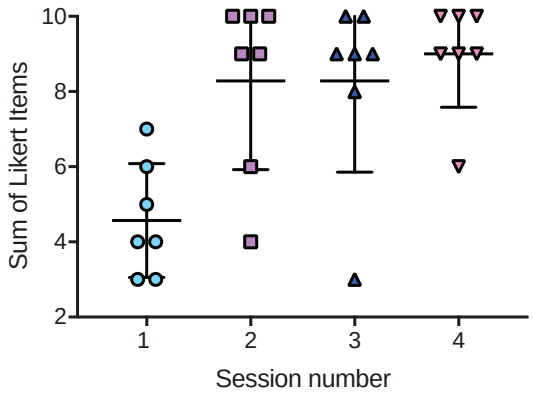
Pressure/Tension (PT)	
Statements: 1. I was very relaxed doing this activity 2. I felt very tense doing this activity Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.13 ReVERe Move Pressure/Tension (PT) dimension of the Intrinsic Motivation Index

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from two statements (no. 2 reversed): Maximum score of 10

No difference between session numbers, p=0.08, Friedman test.
Session 1 vs Season 2, p=0.02, Session 1 vs Session 3, p=0.03, Session 1 vs Session 4 p=0.16, Session 2 vs Session 3 p>0.99, Session 2 vs Session 4, p=0.75, Session 3 vs Session 4: p>0.99, Wilcoxon matched pairs-signed rank test.
Data not normally distributed as assessed by Shapiro Wilk test.

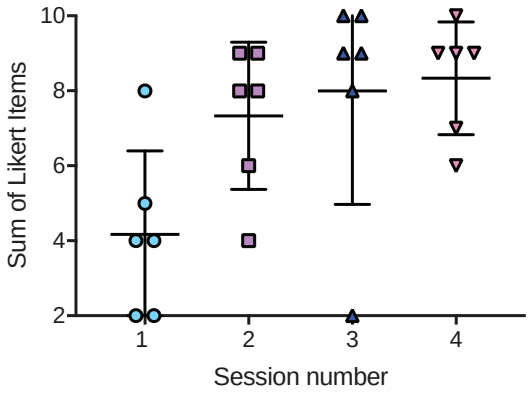
Perceived Competence (PC)	
Statements: 1. I am satisfied with my performance during this activity 2. This was an activity I couldn't do very well Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.14 ReVERe Move Perceived Competence (PC) dimension of the Intrinsic Motivation Index

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from two statements (no. 2 reversed): Maximum score of 10

No difference between session numbers, p=0.08, Friedman test.
Session 1 vs Season 2, p=0.06, Session 1 vs Session 3, p=0.19, Session 1 vs Session 4 p=0.06, Session 2 vs Session 3 p=0.75 Session 2 vs Session 4, p=0.63, Session 3 vs Session 4: p=0.82, Wilcoxon matched pairs signed rank test.
Data not normally distributed as assessed by Shapiro Wilk test.

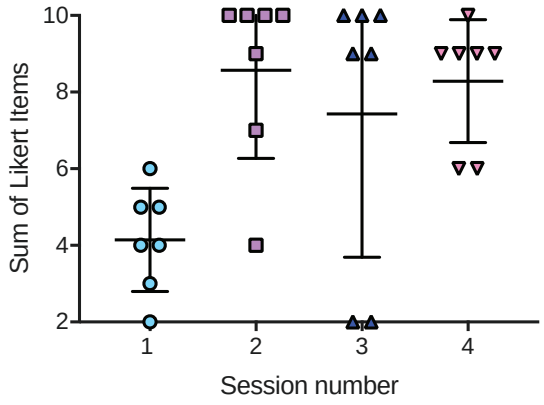
Effort/Importance (EI)	
Statements: 1. I tried very hard with this activity 2. I didn't put much energy into this Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.15 ReVERe Move Effort/Importance (EI) dimension of the Intrinsic Motivation Index

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from statements (no. 2 reversed): Maximum score of 10

No difference between session numbers, p=0.07, Friedman test.
Session 1 vs Season 2, p=0.06, Session 1 vs Session 3, p=0.06, Session 1 vs Session 4 p=0.02, Session 2 vs Session 3 p=0.78 Session 2 vs Session 4, p=0.84, Session 3 vs Session 4: p=0.75, Wilcoxon matched pairs signed rank test.
Data not normally distributed as assessed by Shapiro Wilk test.

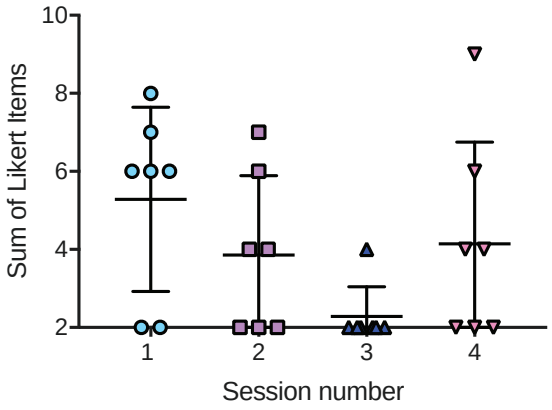
Perceived Choice (PCh)	
Statements: 1. I didn't really have a choice about doing this activity (n) 2. I did this activity because I wanted to. Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.16 ReVERe Move Perceived Choice (PCh) dimension of the Intrinsic Motivation Index (Mean and Standard Deviation)

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from two statements (no. 2 reversed): Maximum score of 10

Significant difference between session numbers, p=0.03, Friedman test.
Session 1 vs Season 2, p=0.06, Session 1 vs Session 3, p=0.19, Session 1 vs Session 4 p=0.06, Session 2 vs Session 3 p=0.75 Session 2 vs Session 4, p=0.63, Session 3 vs Session 4: p=0.82, Wilcoxon matched pairs signed rank test.
Data not normally distributed as assessed by Shapiro Wilk test.

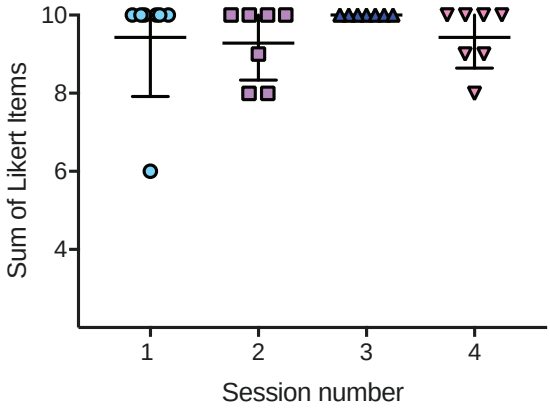
Value/Usefulness (VU)	
Statements: 1. I think this is an important activity 2. I believe doing this activity could help me Session 1: No VeloVR Session 2: Distraction VeloVR Session 3: CompetitionVR Session 4: No VeloVR Individual values with error bars showing mean and standard deviation	

Figure 7.18 ReVERe Move Value/Usefulness (VU) dimension of the Intrinsic Motivation Index (Mean and Standard Deviation)

Dataset from participants who completed all four sessions, n= 7
Sum of Likert items from two statements (no. 2 reversed): Maximum score of 10

No difference between session numbers, p=0.25, Friedman test.
Session 1 vs Season 2, p=0.88, Session 1 vs Session 3, p>0.99, Session 1 vs Session 4 p>0.99, Session 2 vs Session 3 p=0.25 Session 2 vs Session 4, p>0.99, Session 3 vs Session 4: p=0.25, Wilcoxon matched pairs signed rank test.
Data not normally distributed as assessed by Shapiro Wilk test.

7.5.6.3 Impact of VeloVR on the rehabilitation experience

From the semi-structured interview, patients used the word “enjoyed” or “enjoyment” positively during 17 sessions with VeloVR and only one session with MotoMed alone. Reasons for enjoyment included “it made the session more fun and interesting,” “I found it relaxing” and “It was more entertaining with the screen.” Five patients reported specifically that they liked the coastal virtual environment “I liked the sound of the sea and the waves.”

Four patients reported that the VeloVR improved their confidence in their ability to complete MotoMed sessions “Initially I thought “I can’t do this” until I had a go,” as well as reducing anxiety “I felt panicked before session. I felt anxious about cycling. I didn’t feel that during the VeloVR session, I was relaxed during the cycling. I didn’t feel tired, and could go at my own pace, I usually find rehab causes increased breathlessness and anxiety but I felt relaxed throughout.”

Staff felt that patient autonomy and independence was not improved with the VeloVR as the system required staff support for set up and intervention delivery.

Five patients who completed all four sessions during the study reported that the VeloVR system improved their motivation, although one reflected that the participation in the research study may have been more motivating that the intervention itself. One patient reported that they found the competition mode more engaging that the solo mode. One patient reported that they were sufficiently motivated by seeing progress in their overall mobility following

exercise and that the addition of VeloVR to enhance motivation was, for them, unnecessary. The physiotherapists reported that the patients who completed the trial were, overall, motivated to participate in their rehabilitation. Their enthusiasm for the study may have been partly driven by their belief that they would receive extra physiotherapy input.

Two patients described how it distracted them from their environment. Comments included “It was a good distraction from ICU and feeling depressed” and “I found the VR interesting, it was a good distraction while in hospital to lift my mood,” as well as the exercise “Good distraction from pedalling and time” and “I felt like I was engaging with the world outside the hospital.”

One patient found the VeloVR system unappealing, feeling that it reduced their ability to concentrate on the MotoMed exercise. Another patient reflected that the VeloVR system was unnecessary as they were sufficiently motivated by their perceived improvements in functional mobility following exercise and the additional of VeloVR to enhance motivation was unnecessary. One patient declined to use the system after the first MotoMed session, stating “I feel embarrassed and silly using cycling kit. I didn’t expect to be exercising on ICU.”

The physiotherapy staff users reported that it improved their experience of delivering rehabilitation on the ICU, providing enjoyment, fun and variety.

> *"It was also great to see such enthusiasm amongst wider members of the MDT too during the trial (not just physios but nurses and doctors too) …More often than not there was a great response and enthusiasm from patients, nursing staff and relatives…The VeloVR often attracted attention from staff members on the critical care and was seen as a positive addition to rehab – the doctors started to ask for it to be used with their patients." Research Physiotherapist B*

7.5.7 Evaluating modifiers of patient response to the VeloVR intervention

All 20 patients completed the pre-intervention questionnaires on technology exposure and acceptance. All patients used at least one interactive device prior to admission to hospital, although there was variation in the number of devices and associated confidence with using them. Those with more devices reported higher confidence scores, particularly those who owned video gaming systems.

All but one of the participants who completed the study protocol were male. All patients reported that their perceived pre-admission functional status was either normal or independent but reduced for their age. Two thirds of patients were in paid employment prior to admission with a quarter retired from employment and only one patient of working age reporting that they were unable to work due to their illness.

Overall, five patients reported that they had played competitive sport at a local level and only one who completed the protocol. Proportionally more patients with self-declared competitive personalities completed the protocol compared to all trial participants (43% and 30% respectively). Three patients had children age 16 or under living at home with them, one of those completed the trial protocol.

The results of the pre-intervention technology acceptance questions are summarised in figures 7.17 to 7.27. Likert items with positive statements are illustrated in blue, those with negative statements are illustrated in red. The acceptance of the VeloVR technology prior to interventions varied, particularly in patients' prior exposure to and confidence using technology and their expectation of using electronic devices as part of their rehabilitation from their current illness. Future use of the Technology Acceptance Model (TAM) will enable modelling of the interactions between the dimensions. However, this was not undertaken during the data analysis of this study due to small cohort size and awareness that the TAM has not been validated for use in the ICU population. As the purpose of the data collection was to assess the feasibility of use of the tool prior to future use and validation, descriptive statistics are presented for each dimension.

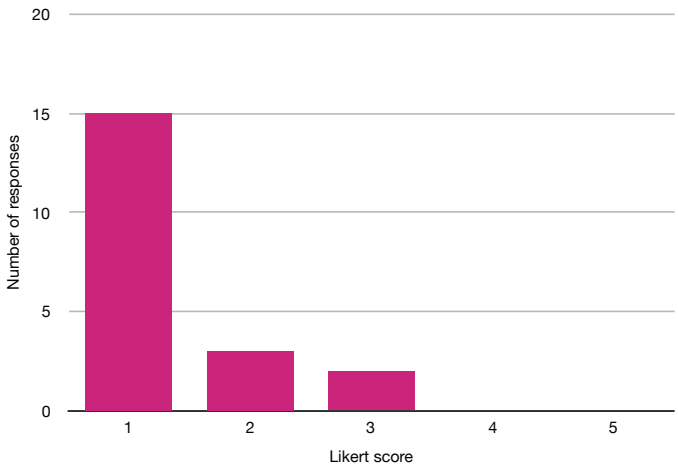
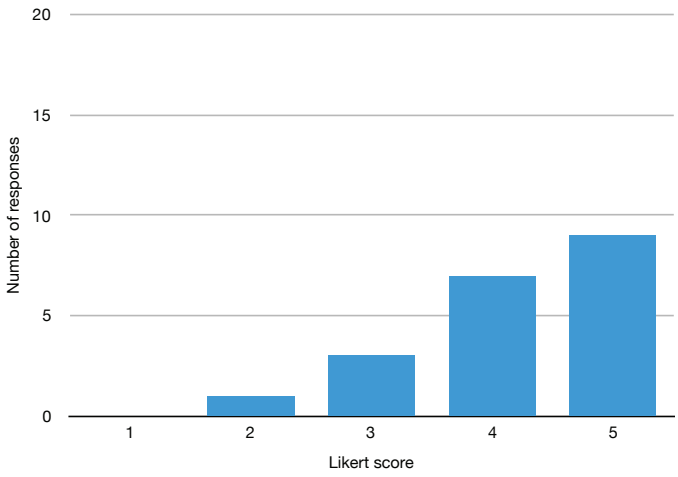
Attitude	
Statement: I am worried that VeloVR will cause me harm *Negatively phrased question* Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	
Statement: Use of VeloVR will help with cycling exercises Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.18 VeloVR Patient Technology Acceptance, Dimension: Attitude

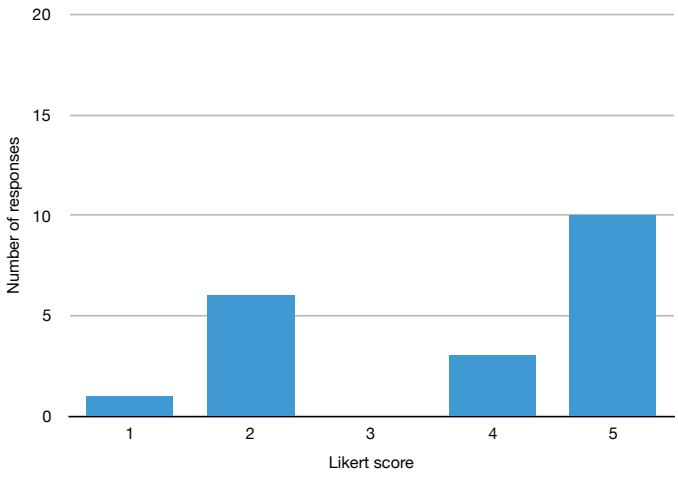
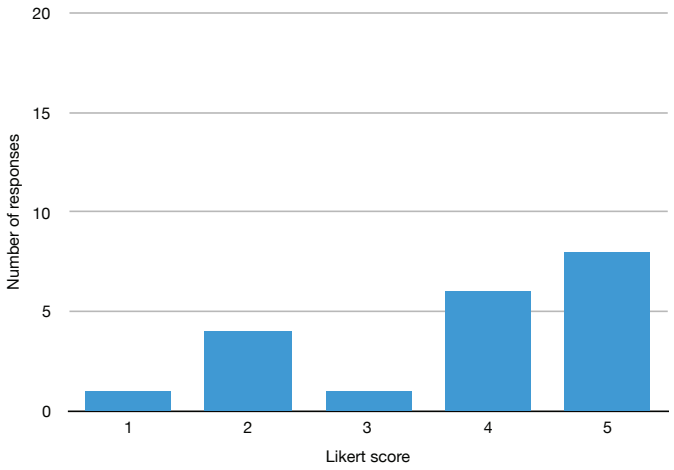
Habit	
Statement: I use computers and electronic gadgets in my everyday life Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	
Statement: I feel confident using computers and electronic gadgets Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.19 VeloVR Patient Technology Acceptance, Dimension: Habit

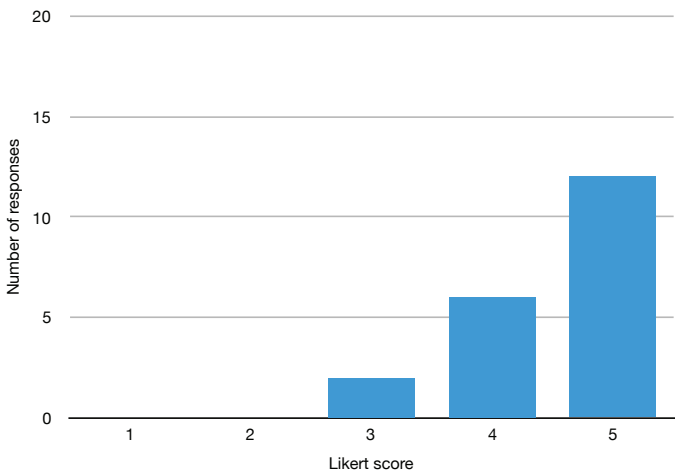
Perceived Usefulness	
Statement: VeloVR will help me to perform my best during the cycling session Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.20 VeloVR Patient Technology Acceptance, Dimension: Perceived usefulness

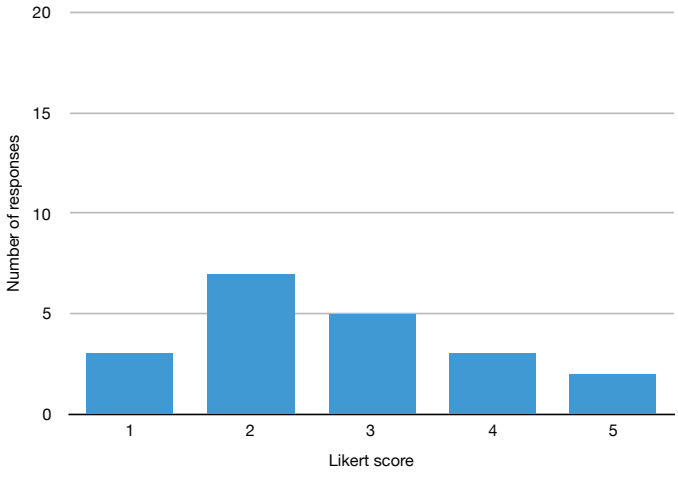
Perceived Norm	
Statement: I expect to be using electronic devices to help with my rehabilitation Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.21 VeloVR Patient Technology Acceptance, Dimension: Perceived norm

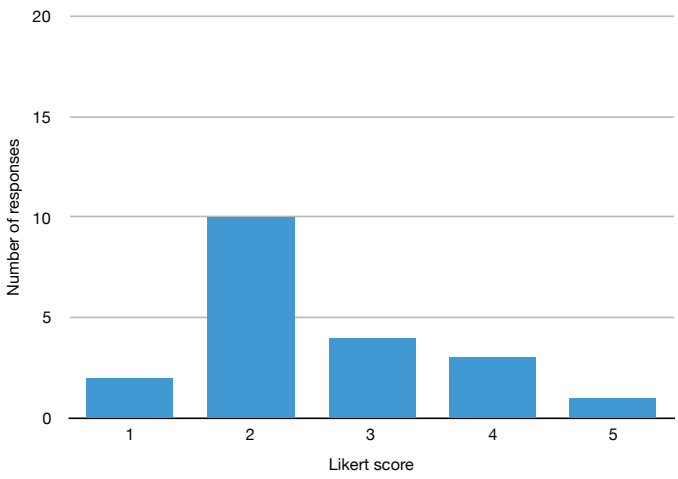
Intention	
Statement: I intend to use other electronic devices during my rehabilitation after my illness/ injury/operation Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.22 VeloVR Patient Technology Acceptance, Dimension: Intention

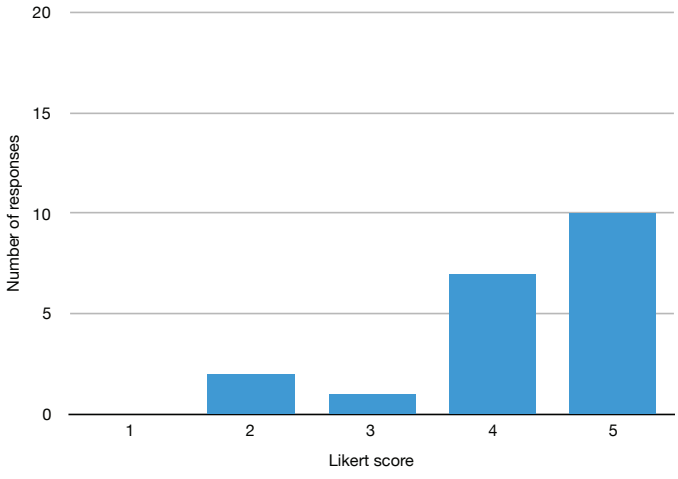
Facilitators	
Statement: I will have enough support to use VeloVR in hospital Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.23 VeloVR Patient Technology Acceptance, Dimension: Facilitators

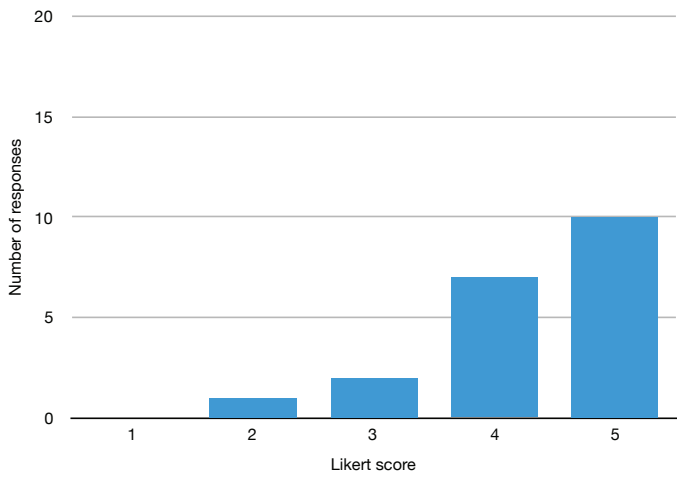
Computer Efficacy	
Statement: I could easily learn how to use VeloVR Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.24 VeloVR Patient Technology Acceptance, Dimension: Computer efficacy

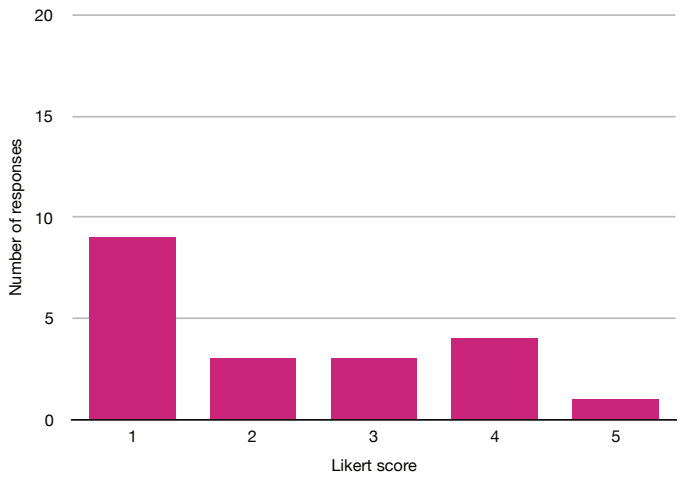
Computer Anxiety	
Statement: Learning to use new electronic devices makes me feel apprehensive *Negatively phrased question* Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.25 VeloVR Patient Technology Acceptance, Dimension: Computer anxiety

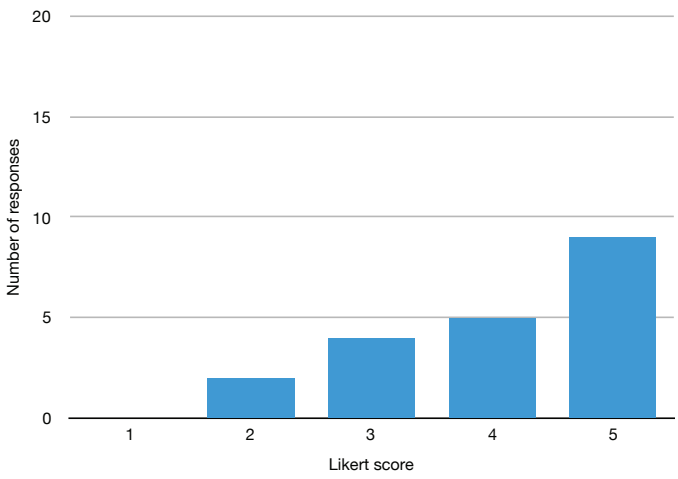
Perceived Ease of Use	
Statement: I feel confident I will be able to follow the instructions for using the VeloVR Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.26 VeloVR Patient Technology Acceptance, Dimension: Perceived ease of use

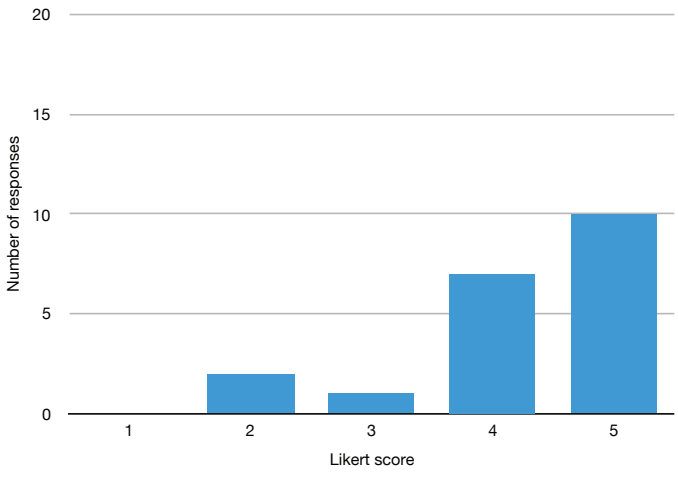
Intrinsic Motivation	
Statement: I am looking forward to using VeloVR Likert score Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.27 VeloVR Patient Technology Acceptance, Dimension: Intrinsic motivation

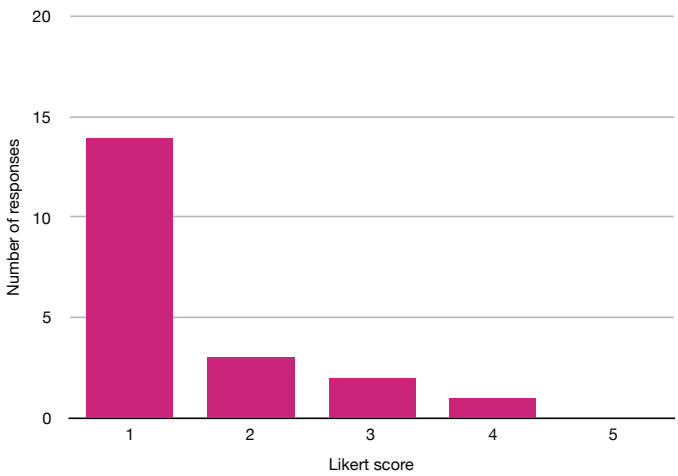
Patient Centred Factor	
Statement: I have a disability/ impairment which will prevent me from using VeloVR properly *Negatively phrased question* Likert score 1 strongly disagree 2 agree 3 neither agree nor disagree 4 agree, 5 strongly agree n=20, each patient provided one response	

Figure 7.28 VeloVR Patient Technology Acceptance, Dimension: Patient centred factor

7.5.8 Recommendations for improvements to the VeloVR system

Patients who completed all four MotoMed/VeloVR sessions during the study, experiencing both solo and completion VeloVR modes, recommend that the system should be further developed to include different virtual landscapes and actives to avoid boredom and maintain interest. Comments included “It would be useful to do different activities” and “I would like other activities - triathlon, swimming, competition games” as well as “I would like to have different views, I would find it more varied and interesting” and “It would be better to have more landscape to explore rather than going round in circles.” One patient stated that the VeloVR experience would be more realistic if viewed in first person rather than third. The two patients who enjoyed the competition mode most requested the ability to compete against other patients.

Changes to the user-computer interaction were recommended by five patients. Three stated that they would have preferred to be able to control the direction of the bike. One patient would have preferred more visual information on progress and achievements, including lap times. Another patient requested the VeloVR system should be accessible to the patient via a touch screen, to enable control over the bike gear, direction of travel and virtual landscape. One patient specifically requested that the system not be over-complicated though, including the ability to steer the virtual bike. Staff reported that the avatar and position tracker was difficult to see for those with visual impairments and needed to be bigger or have greater colour definition.

The only comment regarding improvements to the ergonomics of the VeloVR system related to the proximity of the screen to the patient. Two patients with poor eyesight, not corrected by their spectacles, requested that the screen be moved closer to their face. This resulted in their knees hitting the screen when flexed during pedalling the cycle. Two other patients preferred the screen to be moved further away on initial set up as they felt it was “too bright and too close” and “made me feel a bit claustrophobic.” Five patients requested extra support or hand grips to improve upper body stability during MotoMed use.

7.6 Discussion

The objectives of this study were to evaluate the feasibility of a novel interactive device, VeloVR, designed to enhance performance during recumbent cycling for patients recovering from ICU-acquired weakness. It is important to consider optimising the rehabilitation process for these patients as those who develop ICU-acquired weakness suffer a longer duration of mechanical ventilation, longer length of ICU and hospital stay and higher one year mortality.(195)

The recruitment rate for this study was 32%, similar to that reported in another feasibility study of recumbent cycling, albeit at an earlier entry point of the first four days of mechanical ventilation.(196) The number of patients screened was lower than anticipated, with previous audit data suggesting that 300 patients a year would be eligible. The main reason was the inconsistent diagnosis and documentation of ICU-acquired weakness. This was usually only formally documented once the patients had been referred to the Supportive

Rehabilitation Team. Future trial design would need to include a more inclusive screening criteria, such as greater than five days of ICU stay, and formal testing for ICUAW as part of the screening procedure.

Of those recruited, only 35% completed all four interventions of the study protocol. The limitations of a within-subject repeated measures design study were discussed in chapter 5 and have been reported by other research groups. (66) As with the ReVERe Sleep study, the completion of trial protocol was negatively influenced by the often short time period between patient gaining capacity to provide informed consent prior to starting the first intervention and recovering sufficiently to be discharged from the ICU prior to the final intervention. Participant trial duration ranged from four to 21 days. This variation was due to patient capacity and willingness to engage in cycling sessions and staffing availability; the research physiotherapy team not being available most weekends. Patient variability will present a challenge to the future design should between-subject methods be used, particularly when considering matching of patient groups and exposure to the intervention.

All participants, including those who were unable to complete the study protocol, were able to complete the study questionnaires, supporting the feasibility of the data collection process and use of the IMI and TAM-based tools. Studies of early rehabilitation interventions at the author's unit have demonstrated feasibility of collection of a range of outcome data from this population.(181)

The effectiveness of the VeloVR intervention was defined as:

1. Increase in distance travelled as measured by the MotoMed system, which is a product of cadence speed, gear and duration.
2. Total duration of cycling session.
3. Duration of active pedalling during the cycling session.

The data from the seven patients who completed all four sessions of cycling was included in this analysis. This was unlike the ReVERe Sleep study where all patients were included in data analysis of effectiveness, regardless of the number of interventions they had received. The justification for the data analysis procedure for ReVERe Move was the confidence of the the fidelity of intervention the completing participants had received. The interventions delivered during all of the seven completing participant interventions were without error, increasing the likelihood that the data is robust, reproducible and accurately reflects the response to the intended intervention.

There was a significant improvement in distance travelled and time spent actively cycling between the first control MotoMed session and subsequent interventions both with and without VeloVR. The improvements, however, persisted during the final “control” MotoMed session, which may indicate that the increase in performance was due to the training impact of the MotoMed alone or the functional physiotherapy (sitting, standing, walking) received during the study period, rather than the VeloVR system. The movement through

mobility milestones may have been due to general physical improvement and recovery rather than the VeloVR intervention.

In order to prove the causative links between VeloVR, increasing cycling performance and enhanced physical recovery, it might be desirable to investigate change in skeletal muscle structure and function. The feasibility of this has been reported by other research groups and would be of great interest within the future definitive trial.(197, 198)

A safety consideration for future studies should the intent be to increase performance, is quantifying the benefit and potential risk of exercising during recovery from critical illness. It has yet to be established whether exercising to maximal exertion is beneficial or harmful to recovering muscle function and cardiovascular fitness.

The usability of VeloVR was highly promising. Unlike previous studies where the System Usability Scale (92) was used, information was collected from semi-structured interviews. Although, therefore, this study lacked a numerical assessment of usability, this approach generated a greater richness of data and was more suited to the style of the VeloVR system use, where only two physiotherapists performed the majority of the equipment “use” tasks, with the patients experiencing the intervention without the cognitive burden of set up. Future studies, where more staff members are operating the system, could integrate a version of the modified SUS from the ReVERe Sleep study. Another

useful method of evaluating the usability of the system would be to undertake task analysis, either within a clinical trial or during preceding bench testing. Tasks with associated usability goals could be identified with potential use errors informing design points and alterations in system plans.(29)

A number of the technical challenges relating to the system were due to the contemporaneous use of two separate systems, the MotoMed and the VeloVR system. The benefit of the current version of VeloVR is that it could potentially be used with any cycling system, allowing flexibility across departments using different equipment. However integration of the VeloVR system within the structure of a recumbent ergometer would likely increase ease of use and reduce the size of the combined systems.

The behavioural impact of the VeloVR interventions was assessed using a tool based on the Intrinsic Motivation Inventory (IMI).(144) Patients understood the questions asked and all parts of this questionnaire were completed. The scores for the domains of interest/enjoyment, perceived competence, effort/importance and value/usefulness all increased across the study interventions. This has been reported in another study investigating the impact of novel VR-based games on IMI in stroke patients.(151) This effect may have been due to the repeated nature of the MotoMed/VeloVR sessions and may have occurred with MotoMed sessions alone. The finding may also have been a research effect where, by nature of the provision of study information and enquiry by the patient, they were more informed about their condition and rehabilitation

process. Prior to a future definitive trial it would be valuable to re-evaluate this in a cohort of patients receiving MotoMed sessions alone.

Patients reported reduced scores in the Perceived Choice domain. Enabling patients to exercise when they wish would be an ambition but would require careful consideration of safety and avoiding any burden on nursing staff who may be called to assist in the absence of physiotherapist availability.

This study evaluated, albeit simplistically, patient personality traits mediating acceptance of the technology. A crude assessment of personality was made, based on patient reported “competitiveness.” A more thorough personality assessment relating to motivation type may be valuable when considering the most appropriate types of rehabilitation interventions for individual patients. This could be determined directly from the patient on the ICU, or prior to surgery necessitating ICU admission, or from the patients relatives or friends. More detailed tools to assess psychological needs and satisfaction in relation to technology acceptance have been validated in non-medical fields of research (142) and, with due consideration for data capture burden on patients, be a fascinating inclusion in studies informing future prototype evolution.

All but one of the participants were male. This study did not explore the possible effects of gender, but this should be explored during future trials.

There were many reports of patients enjoying both the distraction and completion mode of the VeloVR. Patients were not directly asked which mode of use they preferred, but most of those reporting preference unprompted all favoured the competition mode. The phrasing of such a question in a future trial would need to be considered to avoid patients arbitrarily choosing one option when they actually hold no preference.(153)

7.6.1 Study limitations

The study interventions and outcome measures were unblinded to both participants and researchers, therefore all outcome data must be viewed with due suspicion. Blinding of participants and researchers to the intervention will be considered for a future definitive study. Blinding methods could include random variation in mode of interaction, eg distraction or completion or “sham” interactive systems where the avatar behaves at random, rather than in response to patient effort.

This study suffered from incomplete data due to patient non-compliance during study participation and technical failures of both the MotoMed and VeloVR systems. In depth validation and verification testing of future prototypes may identify software instability prior to clinical trial commencement, although this occurred equally frequently with the established MotoMed system. The small sample size not only reduces likelihood of detecting a statistically significant difference in outcomes, but also reduced the likelihood of detecting low probability errors in device usage.(29) Any definitive trial of a future prototype

device would require a carefully delivered pilot study to identify such potential errors prior to widespread dissemination of the novel system.

7.7 Conclusions

This study demonstrated that the novel VeloVR was safe and feasible for use for patients recovering from ICU-acquired weakness undergoing rehabilitation on the ICU. Improvements in design process, informed by lessons learned from early trials, produced a novel system that was, for the most part, reliable, usable and accepted by patients and staff alike. Performance data and evaluation of behavioural responses and attitudes to the novel interactive system encourage further development of the device, with careful consideration required in the design of the definitive study to ensure successful recruitment and completion of the study protocol.

A future definitive trial would need to investigate the hypothesis that VeloVR improves performance in excess of the improvement seen by using the MotoMed alone. This will require a between subject study of well matched cohorts receiving identical study protocols. In the event that the technology is delivered in a consistent manner, the challenges of delivering a study of this nature are evident given the conflicts with patient autonomy and variations in patient journey during their recovery from critical illness or injury.

7.8 Reflections and key methodological lessons learned

- Patients recovering in the ICU have the ability to provide useful feedback using a range of quantitative data collection tools. Their ability to provide qualitative data is limited due to fatigue and communications difficulties, such as use of tracheostomy tubes for airway and ventilation support.
- As with the REVERE Sleep study, consideration must be mad eof the duration of the window between recruitment and discharge from the ICU and the impact of that window being too small to allow completion of all trial interventions. This factor could be ameliorated by extending the research environment beyond critical care, to the wards and even home.
- Participation in research may be compromised by the factors that the intervention itself is attempting to address, such as poor motivation and engagement, potentially leading to an “own goal” for the researchers as this issue should be identified early in the research process. This study suggests that getting patients to engage with any attempt at physical therapy is the challenge, rather than improving the effort in those who were already engaged. At this point, the programme theory needs to be revisited and refined.

CHAPTER 8 FEASIBILITY OF THE USE OF INTERACTIVE TECHNOLOGY-ENHANCED INCENTIVE SPIROMETRY TO REDUCE POST-OPERATIVE PULMONARY COMPLICATIONS FOLLOWING ELECTIVE OESOPHAGECTOMY AND TOTAL GASTRECTOMY.

Chapter 8 presents the report of the fourth, and final, study “ReVERe Breathe: Feasibility of the use of Interactive Technology-enhanced Incentive Spirometry (InspireVR) to reduce post-operative pulmonary complications following elective oesophagectomy and total gastrectomy” (Figure 8.1). The methods used to evaluate the VeloVR system have been informed by the lessons learned from the VRET Burns, REVERE Sleep and REVERE Move studies.

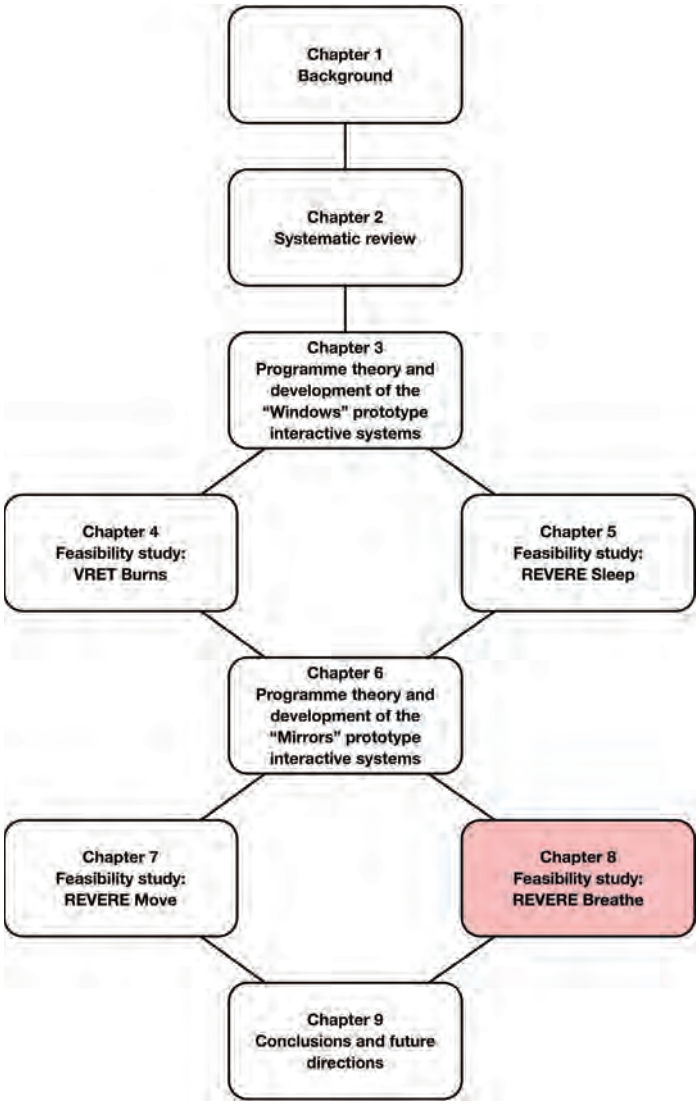


Figure 8.1: Thesis roadmap - Chapter 8

8.1 Introduction

Patients undergoing major upper gastrointestinal surgery for treatment of cancer of the oesophagus or stomach (oesophagectomy or total gastrectomy) are recommended to complete deep breathing exercises regularly during their early post-operative recovery on the ICU in order to reduce the risk of post operative pulmonary complications, such as lung infections.(199) Incentive spirometry, assisted by devices such as the Leventon Spiroball (Figure 6.13), is designed to encourage patients to take slow deep breaths in order to increase their lung volumes, thus reducing or reversing atelectasis (partial collapse of lung alveoli) and improving gas exchange. Patients are instructed to take a deep breath from rest to their maximum inspiratory capacity, before exhaling gently to their functional residual capacity (Figure 8.2).

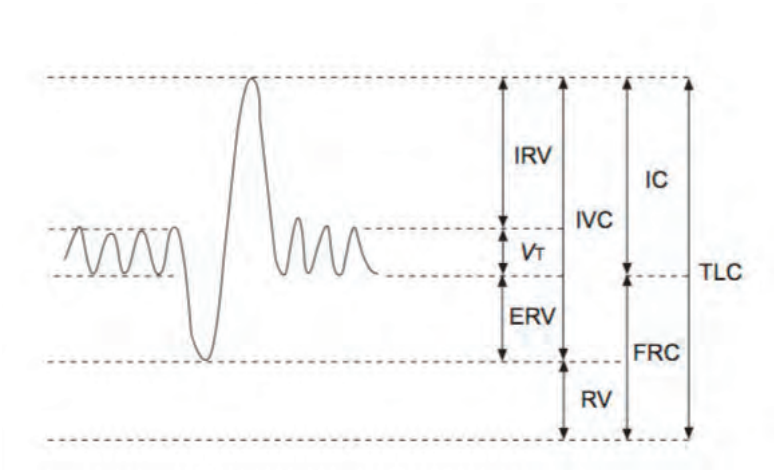


Figure 8.2 Static lung volumes and capacities based on a volume-time spirogram of an inspiratory vital capacity (IVC).

IRV: inspiratory reserve volume; VT: Tidal volume (TV); ERV Expiratory reserve volume; RV: residual volume; IC: inspiratory capacity; FRC: functional residual capacity; TLC: total lung capacity. From Wanger et al. (200)

Despite its use in routine practice, the evidence supporting the efficacy of incentive spirometry in the reduction of postoperative pulmonary complications is unconvincing. A Cochrane systematic review assessed the impact of incentive spirometry in comparison to other breathing exercises and no breathing exercises in upper abdominal surgery, and failed to demonstrate statistically significant benefit of the intervention.(182) Studies reviewed were reported to be lacking rigour; with high risk of bias associated with blinding and loss to follow up. The Cochrane reviewers concluded that, given the poor quality of evidence to date, further randomised trials were required to address the issue of compliance, as well as the standardisation of outcome measures and follow-up time points.

Interactive technology provides a potential solution to the these limitations. InspireVR is a novel interactive technology-based device developed by the research team using commercial-off-the-shelf interface devices combined with custom designed gaming software. The development of the InspireVR prototype has been described in detail in chapter 6.

In summary, InspireVR has been designed to:

1. Provide an incentive game to encourage compliance and improve performance during incentive spirometry for patients recovering from major upper gastrointestinal surgery on the ICU.
2. Support data gathering and provide data presentation to inform clinicians of compliance with, performance during and response to incentive spirometry therapy.

The study protocol was written according to the Recommendations for Interventional Trials (SPIRIT) 2013 guidelines (189) and CONSORT 2010 statement: extension to randomised pilot and feasibility studies.(190)

8.2 Hypotheses

1. InspireVR will provide objective usage and performance data to the patient, ICU therapists and clinicians.
2. Inspire VR will improve motivation and performance during incentive spirometry in patients recovering from elective oesophagectomy or total gastrectomy on the ICU in comparison to standard incentive spirometry using a Spiroball device.
3. InspireVR will reduce the incidence of post operative pulmonary complications in patients recovering from elective oesophagectomy or total gastrectomy in comparison to those receiving standard incentive spirometry using a Spiroball device.

8.3 Aims

The overall aim of this research is to determine whether the use of InspireVR after elective major upper gastrointestinal surgery for cancer results in reduced post-operative pulmonary complications compared to standard care, using a non-electronic incentive spirometry device, in adult patients. To answer this question a phase III multi-centre randomised controlled trial is needed. The proposed study will establish the feasibility of such a trial and, therefore, its aims were to:

1. Estimate the likely rate of recruitment and retention of subjects to the proposed randomised controlled trial.
2. Determine the effectiveness of using InspireVR to measure compliance and performance during incentive spirometry.
3. Evaluate the safety of, and adverse events related to the use of InspireVR.
4. Evaluate the usability and user acceptance of the InspireVR device by patients recovering from elective major upper gastrointestinal surgery (oesophagectomy or total gastrectomy) on the ICU.
5. Evaluate the programme theory via assessment of the potential mediators of compliance and performance during post-operative incentive spirometry, to include patient reported enjoyment and self efficacy.
6. Evaluate the impact of modifiers to patient response to the InspireVR intervention, including predictors of technology acceptance in patient users.

Clinical outcomes, including postoperative pulmonary complications, surgical complications, ICU length of stay, hospital length of stay and in-hospital death will be included in the future clinical trial, were not included in this feasibility study as the methods of data collection have been determined on previous studies on the QEHB ICU.(181, 201)

8.4 Methods

This trial was a mixed methods feasibility study of the novel interactive technology-enhanced incentive spirometry device (InspireVR). A within-subject design was used to compare InspireVR with the standard non-electronic spirometer, Spiroball.

This study was sponsored by the University of Birmingham, reviewed by the National Research Ethics Service Committee South Birmingham (Reference 16/WM/0458), approved by the UK Health Research Authority and registered with the UK Clinical Research Network portfolio (Study ID 32850) and Current Controlled Trials (ISRCTN14521547). The study was authorised as a clinical investigation to support the CE (Conformité Européenne) marking as a Class 1 medical device by the United Kingdom competent authority, the MHRA (CI/2016/0064), according to the Medical Devices Directive 2007.(96, 97)

8.4.1 Study participants

The study was undertaken on the Queen Elizabeth Hospital Birmingham (QEHB) and Birmingham Heartlands Hospital (BHH) critical care units. The

Upper Gastrointestinal (UGI) surgical team carry out approximately 70 oesophagectomies and 30 gastrectomies per year at QEHB and half those numbers at BHH. The median length of stay on the ICU following surgery is 3 days (QEHB mean length of ICU stay 6.6 days), with some readmitted during their hospital stay due to post-operative complications.

8.4.1.1 Patient Inclusion criteria

All consecutive patients undergoing completed elective oesophagectomy and total gastrectomy for cancer treatment on their first post-operative admission to the critical care units (intensive care or high dependency units) at QEHB or BHH. Only those patients undergoing surgery on a Monday or Tuesday at QEHB were enrolled due to lack of provision of research staff to support the delivery of this study at weekends.

8.4.1.2 Patient Exclusion criteria

The exclusion criteria reflect the inclusion of patients undergoing an uncomplicated early post-operative recovery:

- Severe cognitive impairment preventing incentive spirometry or verbal confirmation of consent.
- Known multi-drug resistant chest infection.
- Tracheostomy.
- Tracheal intubation for more than 24 hours post-operatively.
- Post operative tracheal re-intubation.

- Readmission to the critical care units for any cause following discharge to surgical ward.

8.4.2 Sample size

This study aimed to recruit all consecutive patients undergoing oesophagectomy or gastrectomy for cancer over a nine month period. Assuming the procedure rates stayed relatively constant at 150 per year, and allowing for a patient refusal rate of 33% and a pessimistic drop out rate of 50%, we anticipated that the target recruitment of 25 patients would be met over this period.

8.4.3 Study procedure

8.4.3.1 Recruitment

Patients were either sent a letter of invitation and a study information leaflet to their home address, or were approached directly at a surgical outpatient clinic visit prior to their preoperative assessment clinic visit. During the preoperative assessment clinic visit all patients were reviewed by the research physiotherapist (as is usual clinical practice) who provided them with information on post-operative incentive spirometry. All patients returned home with a Spiroball device to practice their incentive spirometry technique prior to admission. During the pre-operative assessment clinic visit the InspireVR device was demonstrated to the patient and all questions answered. Following this, written informed consent was taken. After the surgery was completed, a member of the research team visited the patient in the ICU, HDU or post-

operative care unit to confirm that the participant still met the inclusion criteria and confirmed verbal consent. At this point the patient was enrolled into the study (Figure 8.3). The intervention stage of the trial commenced on the day after surgery.

8.4.3.2 Allocation

All study participants received both the InspireVR and Spiroball interventions. Each patient was asked to alternate the use of Spiroball and InspireVR. In order to reduce bias associated with presenting one device before the other each day, two sequences were designed such that the first device presented each day was alternated. Patients were randomised to start on sequence A or B on day 1 of the trial (Table 8.1). A free online randomisation programme was used to generate the randomisation sequence (www.randomization.com). The patients then alternated between sequence A and B on a daily basis. The allocated sequence was provided to the patient in their bed space, as part of the case report form whereby they (supported by their bedside nurse or physiotherapist) documented their usage of each device.

Patients were offered the use of the Spiroball device if they were unable to use or did not wish to use the InspireVR device. This was an essential part of the risk mitigation of the study as it allowed the incentive spirometry intervention to delivered in the event of InspireVR system error or failure.(Appendix 12)

Table 8.1 ReVERe Breathe Sequence A and B order of interventions

	Sequence	
Session number	**A: Day 1 and 3, B: Day 2**	**A: Day 2, B: Day 1 and 3**
1	Spiroball	InspireVR
2	InspireVR	Spiroball
3	Spiroball	InspireVR
4	InspireVR	Spiroball
5	Spiroball	InspireVR
6	InspireVR	Spiroball
7	Spiroball	InspireVR
8	InspireVR	Spiroball
9	Spiroball	InspireVR
10	InspireVR	Spiroball

8.4.3.3 Interventions

The InspireVR device is described in detail in Chapter 6. Each patient followed the same study timeline (Figure 8.3) Following their surgery patients were recovered from anaesthesia, aiming for tracheal extubation with supportive oxygen provided by face mask, optimisation of fluid, cardiovascular and acid base status and pain control. They were then transferred from either the operating theatre or theatre recovery area to the critical care units at QEHB or BHH. Study participants were advised to attempt incentive spirometry sessions hourly from the morning after their operation (day 1), aiming for 10 sessions per day. Each incentive spirometry session consisted of 10 maximum inspiratory capacity breaths, with short intervals between to allow recovery if required.

On the day of the patient's surgery, a member of the ReVERe Breathe research team installed the InspireVR system into the patient bed-space, ready for use the morning after surgery. The InspireVR system was inspected for damage and cleanliness and the function of the game tested. The nurse receiving the patient onto critical care was informed of the patient's participation in the trial.

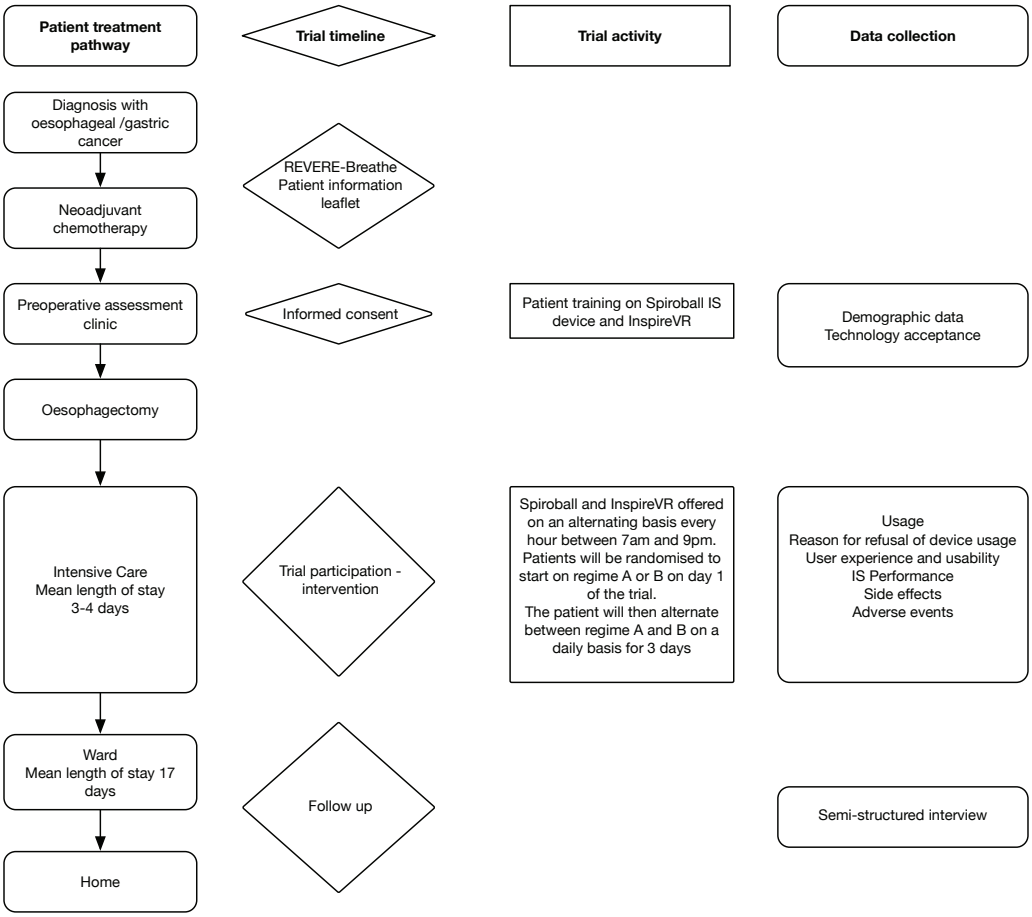


Figure 8.3 ReVERe Breathe Study timeline

Trial day 1 (Day after surgery)

Once alert and cooperative, they commenced their incentive spirometry breathing exercises using, alternately, Spiroball and InspireVR. A member of the research team visited at approximately 0800 to ensure both devices were in the bed-space and ready for use. The patient and nurse caring for them were reminded how to use each device and shown the case report form for the day. One table in section 4 of the case report form was completed each day (Table 8.2). A member of the research team visited the patient at least once during the day to check for problems, with documentation completed in the patient clinical record.

Trial day 2-3

The participants completed the study at the end of their third post-operative day, or on discharge to the surgical ward, whichever was sooner.

Trial Day 4

By day 4, the patients had completed the experimental phase of the trial. The patients were invited to participate in the semi-structured interview. The InspireVR device was removed from the patient bed-space, inspected for damage, cleaned and placed into storage in the critical care research offices.

InspireVR system instructions for use were provided to each participant and the bedside nursing staff A clinical investigators brochure, including details of trial procedures, system troubleshooting and processes for cleaning and decontamination were provided to each study site.

Table 8.2 Example of completed ReVERe Breathe study daily case report form

Day 1		Sequence A				
Session	Time	Device to be used	Device Used	Successful attempts	Pain	Comment
1	0800	Spiroball InspireVR		0/10	None	Patient asleep, session not completed
2	0910	Spiroball InspireVR		10/10	None	No problems
3	1010	Spiroball InspireVR		9/10	Mild	
4	1120	Spiroball InspireVR		8/10	Mild	InspireVR not working - Spiroball used
5	1200	Spiroball InspireVR		4/10	Moderate	Epidural topped up before use
6	1300	Spiroball InspireVR		7/10	Mild	
7	1405	Spiroball InspireVR		0/10	Mild	Unable to find Spiroball device
8	1500	Spiroball InspireVR		9/10	None	
9	1610	Spiroball InspireVR		10/10	None	
10	1700	Spiroball InspireVR		10/10	None	

8.4.4 Data collection

8.4.4.1 Primary outcomes:

Feasibility and acceptability of the the intervention, process and measurement tools required to deliver a future definitive trial, defined as ability to recruit participants to the ReVERe Breathe study and participant completion of the ReVERe Breathe study protocol.

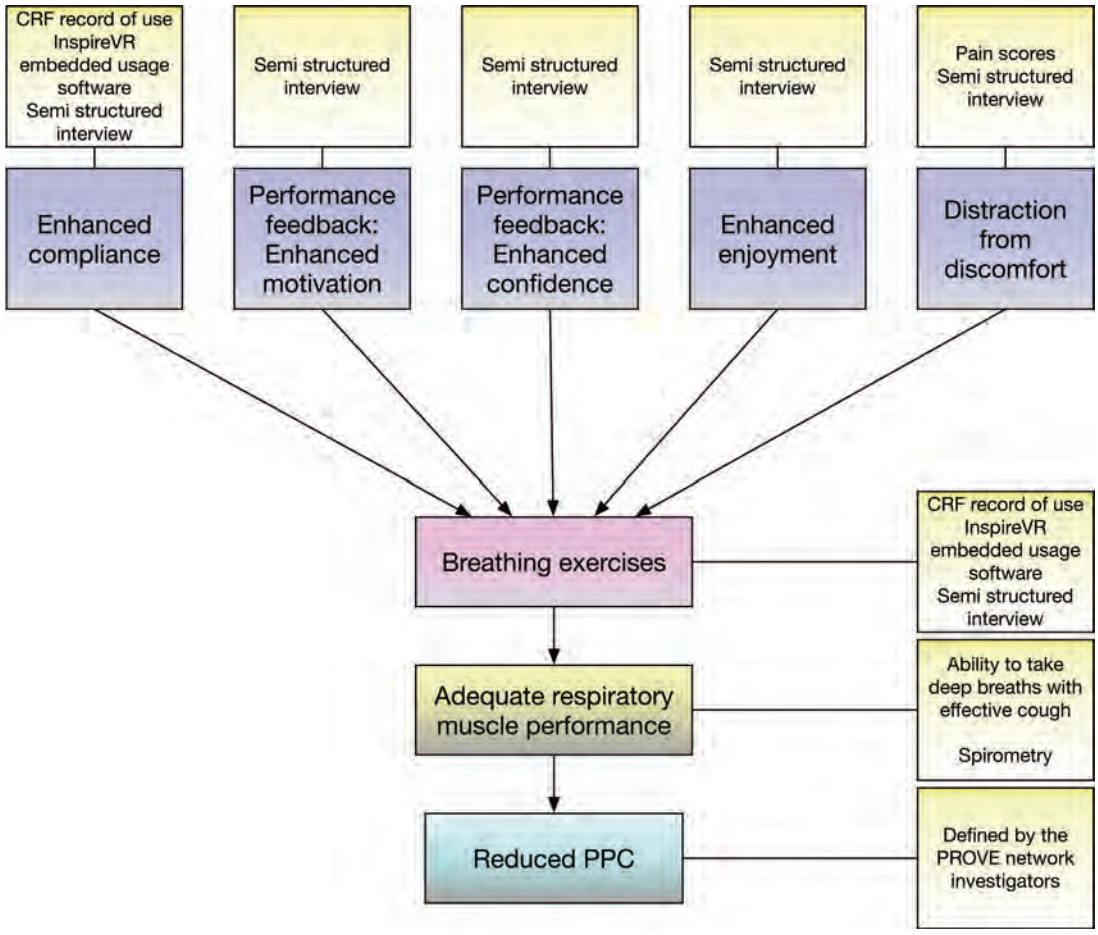


Figure 8.4 ReVERe Breathe study outcome measures mapped to Programme Theory
CRF Case Report Form, PPC Postoperative pulmonary complications

8.4.4.2 Secondary outcomes

The secondary outcomes were selected to establish the effectiveness, usability, safety, and potential mediators of efficacy of the InspireVR system, underpinned by data on barriers and enablers influencing usage of the devices (Figure 8.4).

8.4.4.2.1 Effectiveness of the InspireVR system

- Compliance with incentive spirometry, comparing InspireVR to Spiroball. Each InspireVR attempt was recorded by embedded software within the device. Use of both devices was recorded by the patient and on the patient nursing records (current standard practice).
- Effectiveness of InspireVR in delivering the components of the intervention, compared to the Spiroball device, including:
    - Ability of patient to attempt the incentive spirometry exercises.
    - Number of successful attempts at incentive spirometry.
    - Recording of patient compliance with incentive spirometry.
    - Recording of performance during incentive spirometry.
- Patient achievement of pre-specified targets for maximum inspiratory capacity on the InspireVR and Spiroball.

8.4.4.2.2 Safety and usability of the InspireVR device by patient and staff users

- Side effects and adverse events whilst using the InspireVR device.
- Patient usability and experience of the InspireVR device. The System Usability Scale for the ReVERe Sleep study was modified in view of ReVERe Sleep patient confusion over meaning of statements. (Table 8.3) Data from this was triangulated by qualitative data from a semi structured interview.

Table 8.3 ReVERe Breathe: Modified System Usability Scale

Each statement is scored using a 1-5 Likert scale where
1 strongly agree
5 strongly disagree.
To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7 and 9 the score contribution is the scale position minus 1. For items 2,4,6,8 and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of system usability. SUS scores have a range of 0 to 100.

Item	Statement	Likert score (1= strongly disagree, 5=strongly agree)				
1	I would recommend using InspireVR to others	1	2	3	4	5
2	I found InspireVR too complicated to use	1	2	3	4	5
3	I thought InspireVR was easy to use	1	2	3	4	5
4	I needed someone to help me use InspireVR	1	2	3	4	5
5	InspireVR helped me to do deep breathing exercises more effectively	1	2	3	4	5
6	I found InspireVR confusing to use	1	2	3	4	5
7	I think others would learn to use InspireVR quickly	1	2	3	4	5
8	I felt that InspireVR was too awkward to use	1	2	3	4	5
9	I felt confident using InspireVR	1	2	3	4	5
10	It took me a long time to learn how to use InspireVR	1	2	3	4	5

8.4.4.2.3 Patient experience - establishing patient preference for game elements and evaluation of barriers and enablers of optimum performance

Qualitative data describing patient experience of systems elements including:

- Activity reminders or prompts to enhance compliance.
- Game design elements to enhance enjoyment, self efficacy and performance.
- Patient experience of study participation.

8.4.4.2.4 Technology acceptance and attitude to the intervention

Based on the Patient Technology Acceptance Model:(33)

- Technology/computer experience of patients prior to ICU admission
- Technology acceptance and attitudes of patients prior to InspireVR use: Perceived usefulness, computer efficacy, perceived ease of use, attitude, attitude, habit, perceived norm, intention, facilitators and patient centred factors (Table 8.4).
- Age, gender and presence of children under the age of 16 living at home with the patient prior to hospital admission.

Table 8.4: ReVERe Breathe Questionnaire based on Technology Acceptance Model

Statement	Dimension	Likert Score (1=strongly disagree, 5=strongly agree)
InspireVR will help remind me to do my deep breathing exercises	Perceived usefulness	1 2 3 4 5
InspireVR will help me to do my deep breathing exercises more effectively		1 2 3 4 5
I could easily learn how to use InspireVR	Computer efficacy	1 2 3 4 5
Learning to use new electronic devices makes me feel apprehensive	Computer anxiety	1 2 3 4 5
I feel confident I will be able to follow the instructions for using the InspireVR	Perceived ease of use	1 2 3 4 5
Use of InspireVR will help with deep breathing exercises	Attitude	1 2 3 4 5
I am looking forward to using InspireVR	Intrinsic motivation	1 2 3 4 5
I am worried that InspireVR will cause me harm	Attitude	1 2 3 4 5
I use computers and electronic gadgets in my everyday life	Habit	1 2 3 4 5
I feel confident using computers and electronic gadgets		1 2 3 4 5
I expect to be using electronic devices to help with my rehabilitation after surgery	Perceived norm	1 2 3 4 5
I intend to use other electronic devices during my rehabilitation after surgery	Intention	1 2 3 4 5
I will have enough support to use InspireVR in hospital	Facilitators	1 2 3 4 5
I have a disability/impairment which will prevent me from using InspireVR properly (please describe)	Patient centred factor	1 2 3 4 5

8.4.5 Data analysis

Data was pseudo-anonymised via a unique study identification number and collated on an Excel spreadsheet, stored securely on an NHS network computer. Embedded usage data was downloaded from the InspireVR system. Usage allocation was cross-checked by comparing the date-time stamp on the data to the trial date recorded on the CRF. Data exported as a .csv file and imported into an Excel file, where it was manually cleaned by removal of all values less than 100ml.

The protocol included ten sessions of incentive spirometry each day, each one completing ten maximum inspiratory capacity efforts, alternating use of the InspireVR and Spiroball Devices. Thus, each participant should have completed a total of 15 sessions and 150 maximum inspiratory capacity efforts for each device over the three trial intervention days. Participant completion of ReVERe Breathe study protocol was calculated from the use documented on the case report form and was considered in three stages (see Table 8.5 for worked example):

1. Percentage of incentive spirometry sessions in the study protocol the InspireVR and Spiroball device were available compared to total number of sessions in the protocol (calculated as A/15 x 100 where A = number of sessions device available).
2. Percentage of incentive spirometry sessions in the study protocol the patient attempted each incentive spirometry session using either device whilst the

device was available (calculated as B/A x 100 where B = number of sessions device use was attempted).

3. Percentage of maximum inspiratory capacity breaths in the study protocol the patient completed with either device compared to the maximum required, according to the number of sessions the device was used (calculated as (C/Bx10) x 100 where C = number of maximum inspiratory capacity breaths).

Table 8.5: Worked example of participant completion of ReVERe Breathe study protocol

Participant 1				
A	Number of sessions InspireVR available	7	Percentage of sessions InspireVR available	47
B	Number of sessions InspireVR used	7	Percentage of sessions InspireVR used	100
C	Number of successful attempts of InspireVR	70	Percentage of successful attempts of InspireVR	100
A	Number of sessions Spiroball available	7	Percentage of sessions Spiroball available	47
B	Number of sessions Spiroball used	7	Percentage of sessions Spiroball used	100
C	Number successful attempts of Spiroball	36	Percentage successful attempts of Spiroball	51
Reasons for non-adherence to protocol: Patient preference for InspireVR, Loss of Spiroball				

Descriptive statistics were analysed using Excel 2016. GraphPad Prism was used to analyse quantitative data. Continuous data underwent assessment of normality using the Shapiro Wilk test. Null hypotheses were tested using paired t-tests for normally distributed paired samples, and Wilcoxon Signed Rank tests

for non-normally distributed paired samples where $p<0.05$ determined a statistically significant difference in values. Thematic analysis was used to evaluate the qualitative data using NVivo.

8.5 Results

The study experienced a slower than intended accrual rate, due to reallocation of patients at QEHB from Monday and Tuesday operating lists to Friday lists. A no-cost trial extension of three months was approved by the study sponsor, NHS Health Research Authority and NIHR Clinical Research Network.

8.5.1 Patient characteristics

Ninety-eight patients were screened over the 12 month period. Fourteen participants who provided consent at preoperative assessment were subsequently not enrolled. Reasons included failure to achieve tracheal extubation within 24 hours of completion of surgery, immediate post-operative complications (epidural haematoma) and non-availability of InspireVR system (Figure 8.5).

Each site recruited 10 patients each; six female and 14 male patients with a mean age of 68 years (range 46-81years). Oesophagectomy was performed in 14 patients, the remainder underwent total gastrectomy. All patients were admitted to Area A ICU (Hepatobiliary/Transplant/Gastrointestinal surgery/ Medicine) at QEHB or the High Dependency Unit (HDU) at BHH.

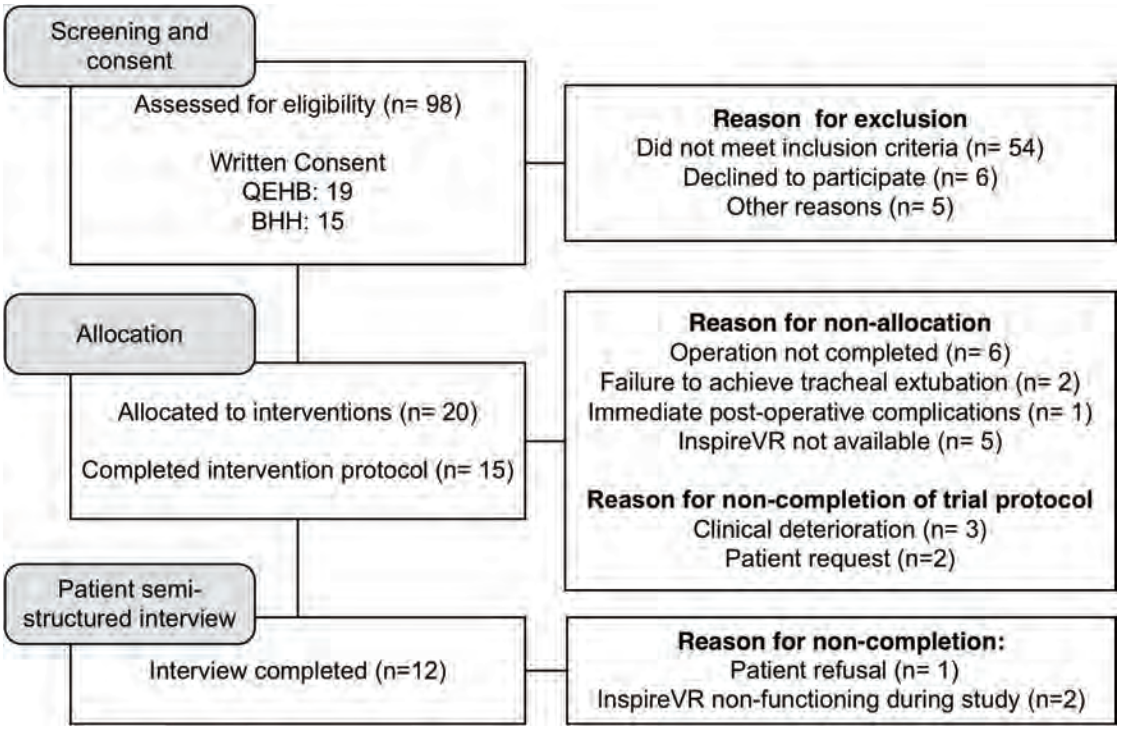


Figure 8.5 Consort diagram for the ReVERe Breathe trial

All but one of the patients spoke English as their first language, with one patient speaking Bengali as their first language accompanied by good spoken English. Half the patients declared they held no qualifications, two patients held higher degrees, three patients held Batchelor degrees. The remainder of patients had completed A level, O levels or equivalent qualifications.

8.5.2 Recruitment and retention of subjects to the proposed study

Fifteen patients participated in the study for all three days of the intervention period. Three patients were withdrawn from the study due to clinical deterioration, including post-operative pneumonia requiring tracheal reintubation and mechanical ventilation and post operative delirium due to sepsis. One patient completed the intervention phase but declined to complete the post operative semi-structured interview. Two further patients did not complete the post-intervention semi-structured interview or System Usability Scale as they had not been able to use the InspireVR device due to technical failure.

The InspireVR device suffered a technical failure preventing use during at least one entire session of the intervention period for six participants with two patients not able to use the InspireVR device at all during the intervention period. The Spiroball device was lost during part of the intervention period of the study for two participants (Figure 8.6).

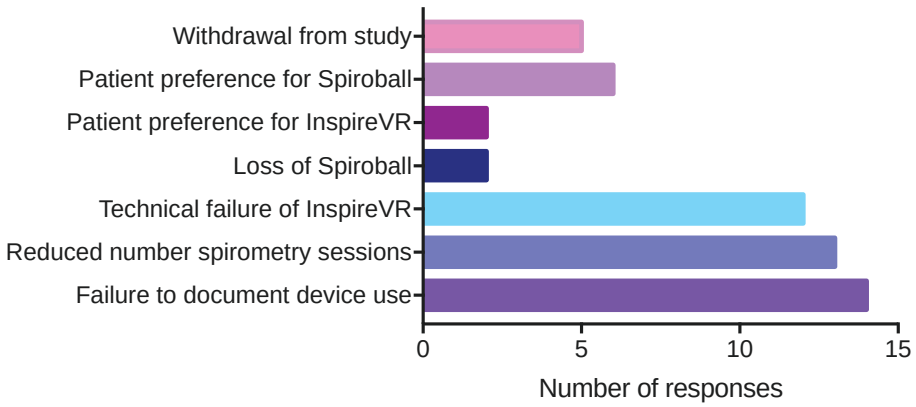


Figure 8.6: Reasons for non-adherence to ReVERe Breathe study protocol

Each participant allocated more than one response

8.5.3 Effectiveness of the InspireVR system

The Spiroball device was available to the patient for more sessions of incentive spirometry than the InspireVR (Figure 8.7).

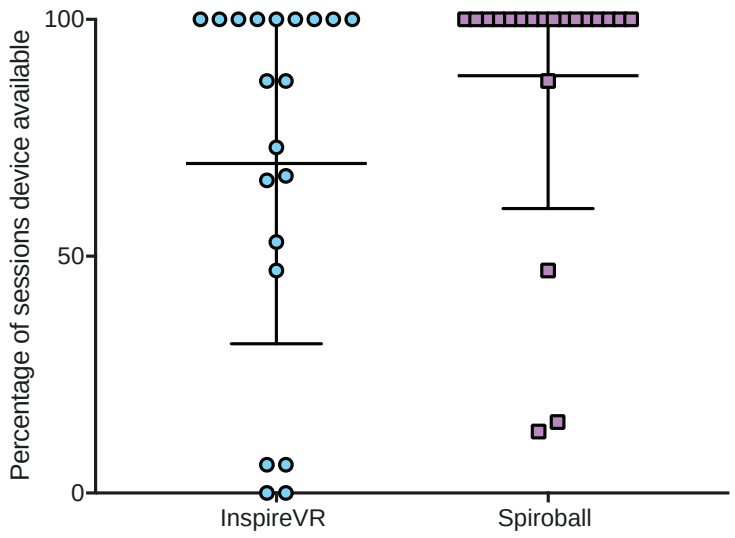


Figure 8.7: ReVERe Breathe Percentage of incentive spirometry sessions in the study protocol the InspireVR and Spiroball device were available compared to number of sessions in the protocol

Individual values with error bars showing can and standard deviation
Significant difference between devices, p=0.004, Wilcoxon matched-pairs signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

There was no difference in the percentage of incentive spirometry sessions attempted by the patient using either device whilst each device was available (Figure 8.8). The patients who recorded greater than 100% usage for the Spiroball had a preference for that device so used it instead of the InspireVR sessions. Documentation of usage appeared incomplete for 14/20 participants. For twelve of the patients the number of sessions where incentive spirometry was attempted was reduced by the requirement for medical interventions or imaging and sleeping or fatigue.

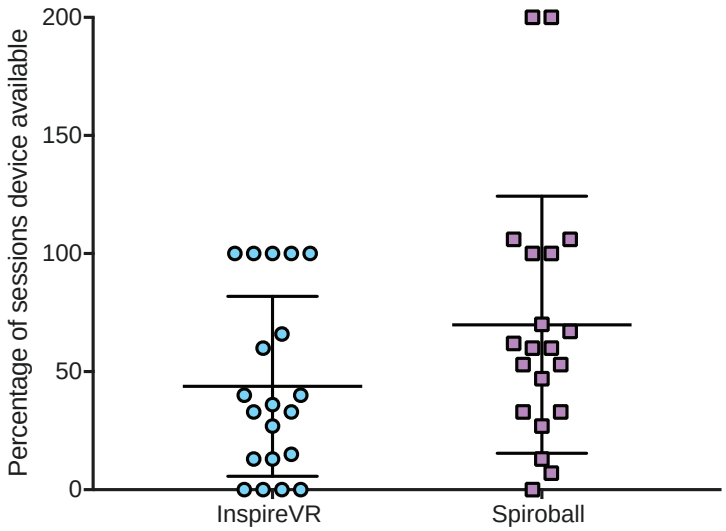


Figure 8.8 Percentage of incentive spirometry sessions attempted by the patient using either device whilst each device was available

Individual values with error bars showing mean and standard deviation
No significant difference between devices, p=0.052, Wilcoxon matched-pairs signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

There was no difference in the percentage of maximum inspiratory capacity breaths in the study protocol the patient completed each either device compared to the maximum required (Figure 8.9). Reasons for reduced number of maximum inspiratory capacity breaths included technical failure of the InspireVR device (n=9) and uncontrolled pain (n=4).

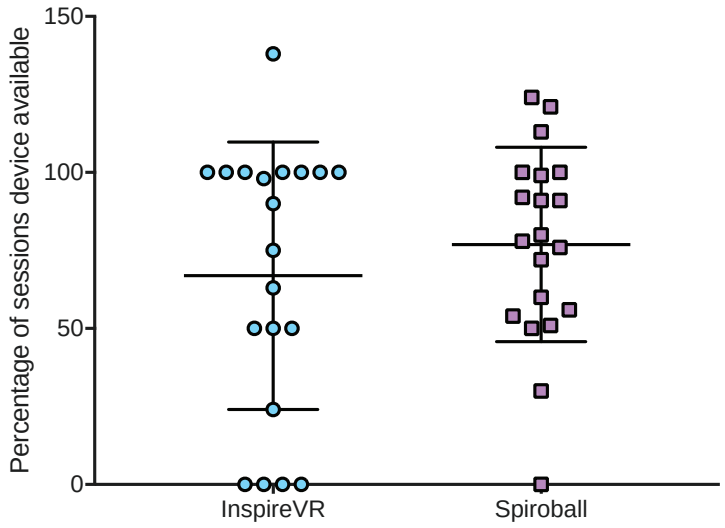


Figure 8.9 Percentage of maximum inspiratory capacity breaths in the study protocol the patient completed each either device compared to the maximum required, according to the number of sessions the device was used

Individual values with error bars showing can and standard deviation
No significant difference between devices, p=0.052, Wilcoxon matched-pairs signed rank test
Data not normally distributed as assessed by Shapiro Wilk test

The data analysed originated from that self-reported and documented on the case report form. InspireVR embedded usage data was collected in twelve patients. The reason for the missing data from eight patients has yet to be determined. There was a difference in the number of incentive spirometry breaths using the InspireVR recorded on the case report form and from the

embedded InspireVR software variation for every patient and on each side of the mean (Figure 8.10).

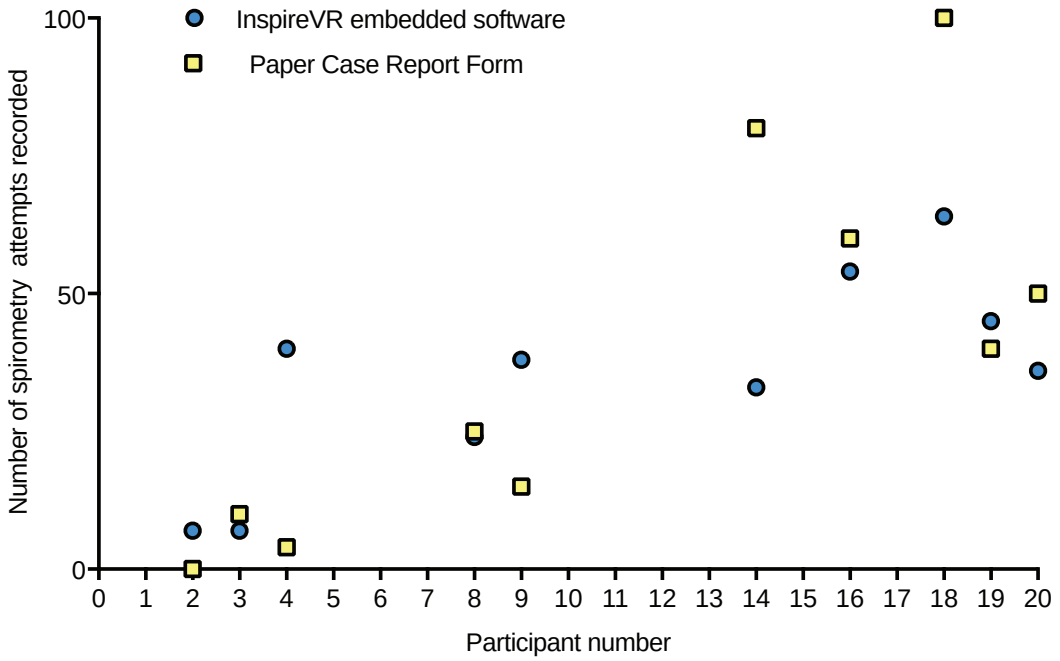


Figure 8.10: Number of InspireVR incentive spirometry breaths recorded according to the InspireVR embedded usage data and the paper case report form (n=10)

Maximum Inspiratory Capacity values were collected from the InspireVR device in twelve cases. The data from one patient has not been presented as most of the values were negative, due to the gas tubing being inserted incorrectly. The graphs below show the number of values collected, their mean values and spread and their change in value of maximum capacity as time progressed (Figure 8.11-8.13).

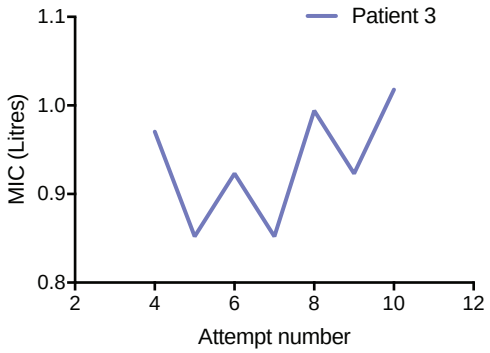
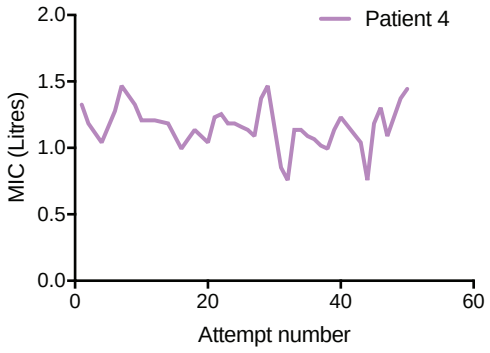
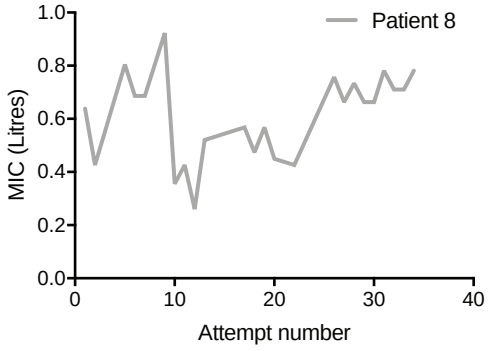
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.8521 0.8521 0.9231 0.9941 1.018 0.9332 0.06533
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.7574 1.065 1.172 1.249 1.467 1.159 0.1643
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.2604 0.4556 0.6627 0.7278 0.9231 0.6114 0.1638

Figure: 8.11 Maximum Inspiratory Capacity data from InspireVR embedded usage software

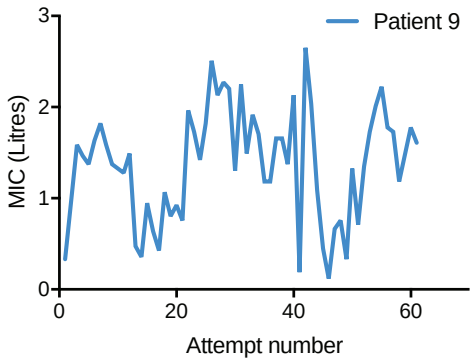
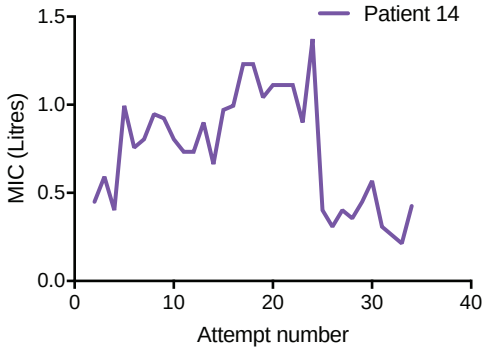
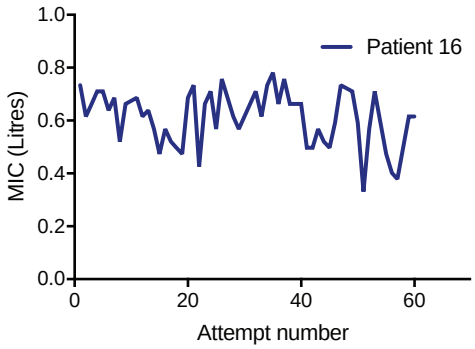
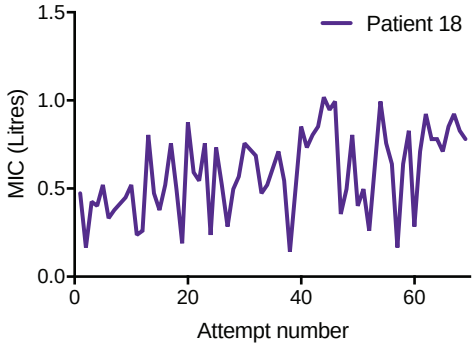
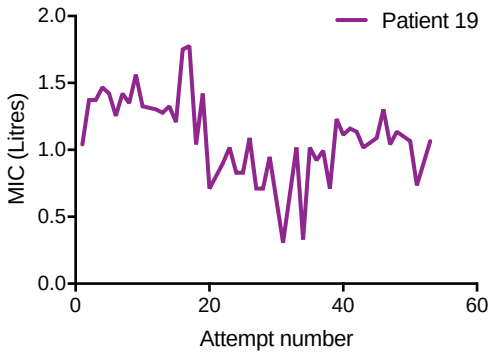
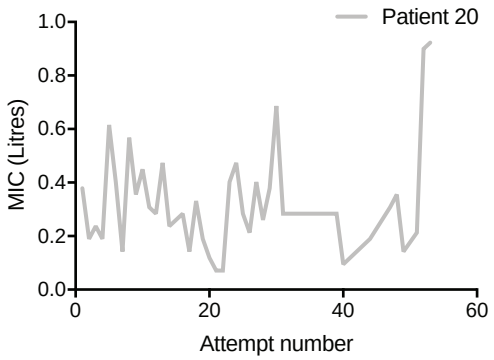
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.1183 0.8935 1.444 1.787 2.651 1.378 0.6236
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.213 0.4142 0.7574 0.9941 1.373 0.7416 0.3261
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.3314 0.5207 0.6154 0.6923 0.7811 0.6101 0.1054
	Maximum Inspiratory Capacity (MIC) Minimum: 25% Percentile: Median: 75% Percentile: Maximum: Mean: Std. Deviation:	Litres 0.142 0.4083 0.5562 0.7811 1.018 0.5913 0.2366

Figure 8.12: Maximum Inspiratory Capacity data from InspireVR embedded usage software



Maximum Inspiratory Capacity (MIC)	Litres
Minimum:	0.3077
25% Percentile:	0.9408
Median:	1.089
75% Percentile:	1.325
Maximum:	1.775
Mean:	1.105
Std. Deviation:	0.3082



Maximum Inspiratory Capacity (MIC)	Litres
Minimum:	0.1183
25% Percentile:	0.213
Median:	0.2959
75% Percentile:	0.4024
Maximum:	0.9231
Mean:	0.3498
Std. Deviation:	0.1924

Figure: 8.13 Maximum Inspiratory Capacity data from InspireVR embedded usage software

A summary of the data is presented in Figure 8.14.

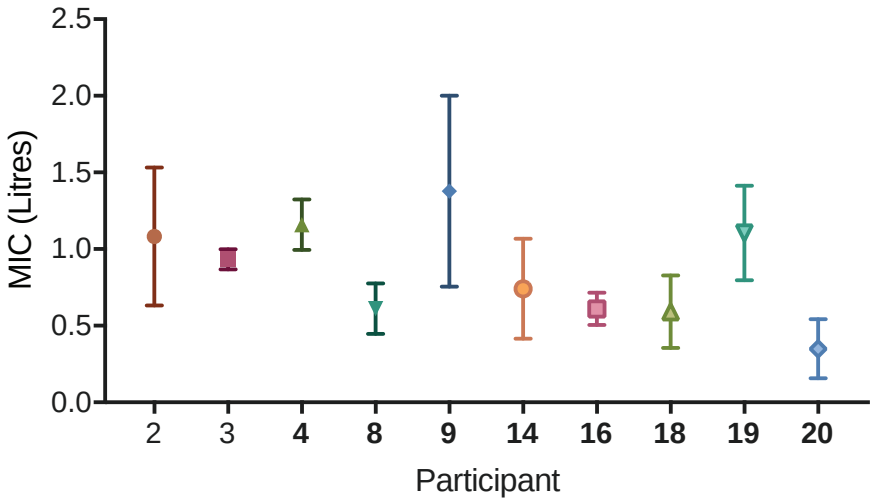


Figure 8.14 Summary of Maximum Inspiratory Capacity data from InspireVR embedded usage software (mean and standard deviation)

8.5.3 Safety and usability of the InspireVR system by users

There were no safety or adverse events associated with the InspireVR system or Spiroball during the ReVERe Breathe trial. There were no reports of intravascular line dislodgement or interference with equipment in the patient bed space. No patients reported nausea.

Subjective usability of the InspireVR device was assessed using a modified System Usability Scale, with ten Likert items presented to the patient user (Figure 8.15).

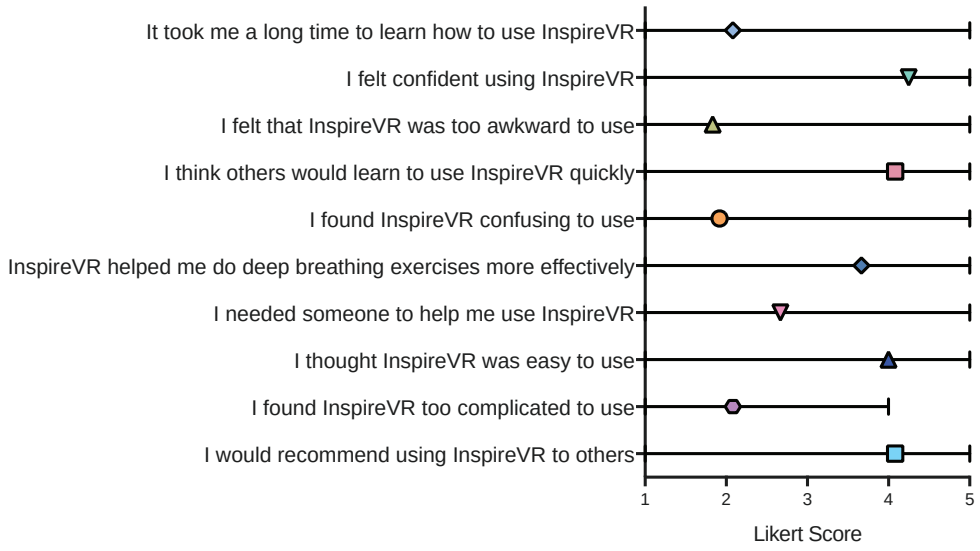


Figure 8.15 InspireVR System Usability Scale Likert Item

Mean with error bars showing range
Likert score
1 Strongly disagree
2 Disagree
3 Neither agree nor disagree
4 Agree
5 strongly agree

A score of over 70 is deemed to be acceptable for most products.(137) Twelve patients completed the questionnaire. The mean score was 73.8 (range 10-100) with seven patients awarding scores of greater than 70 (Figure 8.16).

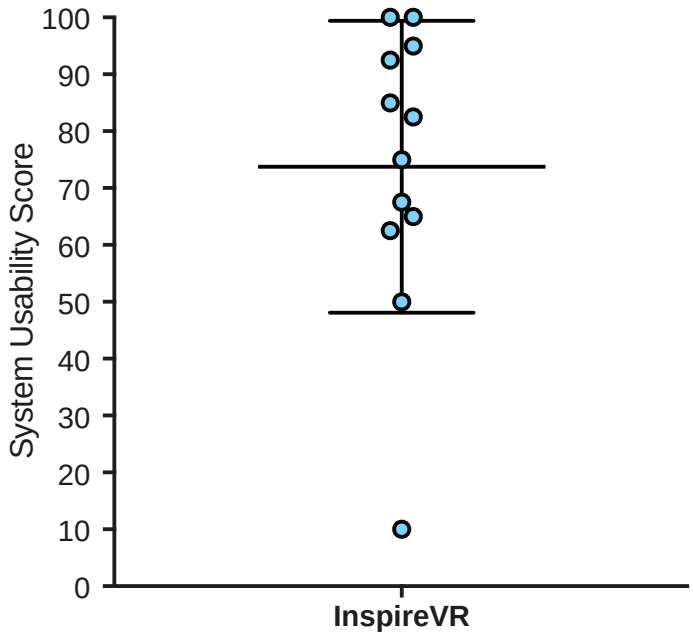


Figure 8.16 InspireVR System Usability Scale scores

Individual total scores
Error bars show mean and standard deviation. Maximum score 100.

Free text comments on the case report form and semi structured interview data was used to aid interpretation of the quantitative usability data. Elucidated themes were categorised as “positive” and “negative”. Sub-themes were elucidated and the three most common sub-themes for each positive and negative are listed, with example quotes given, in tables 8.6 and 8.7.

Table 8.6 ReVERe Breathe thematic analysis of qualitative data - positive themes of usability and ergonomics

Sub theme	Comments
1. Ease of use	Felt confident using after first go. Game was easy when it worked Understood the game well Understood what I needed to do Easy to use, smiling faces helped Both systems equally easy to use The InspireVR is easier to use than the Spiroball When system wasn't crashing it was quite easy to use I felt confident using it as I had support from the nurses Good as only needed to breathe in gently to make it work Easy to use once I got used to it Easy to use but did not interest me Could get a better seal on the InspireVR mouthpiece than the Spiroball Spirometer was heavier than the spiroball but not too heavy The more I used the InspireVR the easier it was to use Understood how device was supposed to work The spiroball was harder to use than InspireVR
2. Access and manoeuvrability	Not intrusive, didn't get in the way No problems having the machine in the bed space Not in the way of patients or staff It was not intrusive Easy to adjust, comfortable to use It was easier to use the InspireVR once I was sitting out of bed InspireVR didn't get in the way

Table 8.7 ReVERe Breathe thematic analysis of qualitative data - negative themes of usability and ergonomics

Sub theme	Comments
1. Instability of InspireVR software	Power saving function was a problem - kept turning off and resetting Game kept freezing Kept resetting itself The software was not user friendly Issues when the InspireVR froze Too early to use in the device's development Software was too sensitive - goes in and out of the programme - so not ideal for unwell people I wanted to throw the InspireVR out of the window System was hopeless After two hours the InspireVR would freeze or turn off so needed help to reset from the physios
2. Ease of use	More time for tuition is needed Not usable in the ICU setting Couldn't adjust the sound Device was harder to use post op than pre op Too many engineering design flaws to use it properly Not well presented The shape of the mouthpiece on the InspireVR made it harder to use than the Spiroball Spiroball was easier to pick up
3. Integration of system components	System kept falling apart The game was easy to follow but the stand wasn't right Too much of a "prototype" feel to it A good concept but needs a few tweaks Difficult to manoeuvre the stand - the keyboard fell off InspireVR Spirometer kept falling off its holder Keyboard not secure Filter kept falling off the InspireVR
3. Access and manoeuvrability	Device was too big and too hard to set up Device was in the way Intrusive and cumbersome Felt guilty that device was in staff's way Too big and bulky - should be more compact Accessing the device from the stand was quite difficult
4. Use errors	Made errors using it at the start - ie breathing out into mouthpiece. Errors generated from system not working properly.

Overall, there were more negative than positive comments on the usability and ergonomic considerations of the InspireVR device. Whilst there were a number of positive responses regarding ease of use, the instability of the InspireVR software generated the most negative comments from patient users. Only one patient reported that they had made a usage error whilst using the InspireVR device:

> *"At the beginning I wasn't using it properly and kept breathing into it, is I asked my daughter to write a reminder note which said "MOUTHPIECE IN, REMOVE, BREATHE OUT." (Participant 12)*

8.5.5 Patient experience - evaluating barriers and enablers of optimum performance

Qualitative data from the semi-structured interview and the comments sections of the case report form underwent thematic analysis. The elements of system design (Figure 8.4) were used as main themes, with each theme then subdivided into positive and negative sub themes. The main themes were activity reminders or prompts to enhance compliance, enhanced enjoyment, self efficacy and performance, distraction from discomfort and patient experience of study participation.

8.5.5.1 Activity reminders or prompts to enhance compliance

There were more positive than negative comments on the theme of activity reminders or prompts to enhance compliance (Table 8.8), particularly from patients with whom the InspireVR device had experienced fewer technical problems.

Table 8.8 ReVERe Breathe qualitative data on patient experience: Activity Reminder/ Prompt

Positive comments	Negative comments
InspireVR reminded me to do the exercises and made me want to do them. Patient more aware of rationale for deep breathing exercises. Felt InspireVR improved his compliance with the exercise programme and promoted me to do the exercise. Good feedback, encouraged more use. Useful to be reminded as easy to lose track of time. InspireVR helped remind me to do the exercises. I could see the countdown timer on the screen so I knew how long I had until the next session - spiroball doesn't do that. Countdown timer was a useful reminder. Good to know how long you get to rest between exercise sessions. Good that you can start the next session early if you want to. The prompts helped to remind me and the nursing staff. The prompt was most helpful to remind the nurses. Countdown did help to remind me to do the exercises.	Don't know why I had to do post op breathing exercises. The prompt did not really help as there was too much else going on. InspireVR did not encourage deep breathing exercises. Didn't improve compliance. Didn't find the reminders helpful. The timer didn't improve my compliance, I was already quite compliant.

8.5.5.2 Performance feedback and motivation

Patients reported positive and negative comments on the impact of the InspireVR game on their motivation to complete incentive spirometry sessions to the best of their ability, compared to the Spiroball (Table 8.9). A number of patients reported that they were already highly motivated to recover from surgery.

Table 8.9 ReVERe Breathe qualitative data on patient experience: Performance feedback and motivation

Positive comments	Negative comments
Improved my motivation, understood the scores and why they were important and looked forward to getting to the next level. Good incentive - wanted to improve. Felt more motivated to do the exercises Provided good motivation. The smiling faces helped to keep a record of what I'd done, I liked the feedback. I found the feedback helpful but don't think it improved my performance. Sinking the ships helped to egg me on. InspireVR helped to remind me of the importance of doing the exercises.	Did not affect motivation to do exercises Feedback was useful but game kept resetting so unable to progress through levels. Didn't really understand how to go up a level Already motivated by wanting to recover from surgery knowing the health benefits, game design did not help The lack of practicality meant that I was less motivated I felt more motivated with the spiroball InspireVR was a good distraction but I didn't think it was beneficial I was already motivated I didn't think the smiley faces improved my motivation Better feedback on spiroball which gave numbers rather than faces.

8.5.5.3 Enjoyment

There were more positive comments on perceived enjoyment whilst using the InspireVR system (Table 8.10). Lack of enjoyment was reported by patients who experienced technical problems with the InspireVR system.

Table 8.10 ReVERe Breathe qualitative data on patient experience: Enjoyment

Positive comments	Negative comments
I was disappointed on the last evening when the device was removed as I was just getting into it	Was not as exciting as I expected
I was already motivated to recover but the game made it more interesting	Not particularly enjoyable
I looked forward to using the InspireVR	Didn't find the game engaging
Enjoyed playing the game	Enjoyment didn't come into it
Liked the smiley faces	Game needs to be more interactive
Liked the game design	The volume was too loud
Looked forward to using it	Preferred spiroball
Liked sinking the ships and having a target or reward	The sound was loud and annoying
I enjoyed it once I had the additional instructions the I was well away	Found the system frustrating as it kept crashing
I didn't really enjoy using it much the first day but enjoyed it more the better I felt	Preferred the Spiroball
Feedback of the catapult made it more enjoyable	
I enjoyed the InspireVR more than the Spiroball	
The game was interesting and more enjoyable	
Enjoyed the greater feedback I got from the InspireVR	

8.5.5.4 Self Efficacy

There were more negative than positive comments on the impact of the InspireVR on self efficacy to perform incentive spirometry effectively (Table

8.11). Two patients reported that it had made them realise that they had been using the Spiroball incorrectly, using it to exhale into rather than inhale.

Table 8.11: ReVERe Breathe summary of qualitative data on patient experience: Self efficacy

Positive comments	Negative comments
The InspireVR gave me more confidence than the Spiroball. I could use both devices independently. Felt it made me more confident with the exercises. Easy to use independently. InspireVR made the exercises easier. Helped me understand what I was supposed to do and told me if I was getting it wrong. Helped remind me to do the exercises and reassured me I was doing them correctly.	Didn't improve my ability to manage my own recovery. Felt more confident with the Spiroball as InspireVR wouldn't work properly. Did not assist patients self-recovery as much as expected. Was able to use the device independently once set up but unable to troubleshoot. Required more training to use. I didn't have to think too much when using the spiroball. Both systems gave me the same amount of confidence. Spiroball was better as was practical and could be used independently, although appreciates that design needs to be improved. Needed the physios or nurses to help me reset it so couldn't really use the system independently. Need to be already quite independent to use InspireVR so not best suited for the first few post op days.

8.5.5.5 Distraction from discomfort

There was no difference in pain scores between sessions using InspireVR or Spiroball. Three patients reported during their semi-structured interview that the InspireVR device did not provide distraction from their discomfort.

8.5.6 Study experience

All the study participants reported that they enjoyed participating in the study, including those who did not enjoy using the InspireVR device. The participant who reported that he wished to throw the InspireVR device out of the window, when asked about his experience of participating in the ReVERe Breathe study stated:

> *"It was good to be part of something positive and to be able to help others down the line I didn't like the InspireVR system but liked being part of the research and giving feedback." Participant 6*

8.5.7 Technology acceptance and attitude to the intervention

All 20 patients completed the pre-intervention questionnaires on technology exposure and acceptance (Figure 7.20) None of the participants had a child aged 16 or under living in their home. All patients used at least one interactive device prior to admission to hospital, although there was variation in the number of devices and associated confidence with using them.

The results of the pre-intervention technology acceptance questions are summarised in figures 8.16 to 8.26. Likert items with positive statements are illustrated in blue, those with negative statements are illustrated in red. The acceptance of the InspireVR technology prior to interventions varied across all dimensions, particularly habit, perceived ease of use, perceived norm and intention. As with the REVERE Move study, descriptive statistics of each dimension are presented.

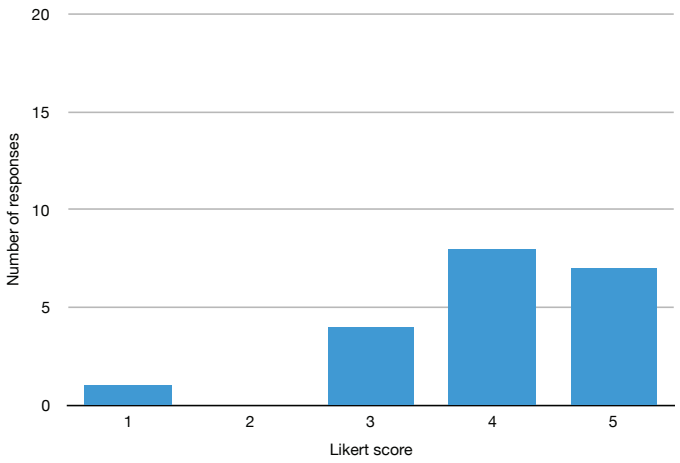
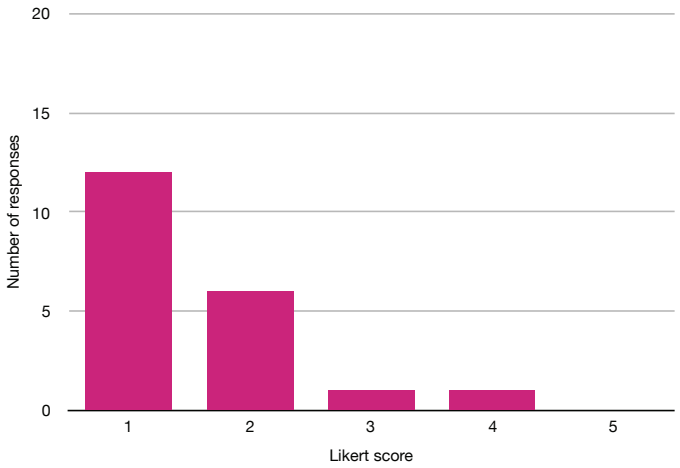
Attitude	
Statement: Use of InspireVR will help with deep breathing exercises Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	
Statement: I cam worried InspireVR will cause me harm *Negatively phrased question* Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.17 InspireVR Patient Technology Acceptance, Dimension: Attitude

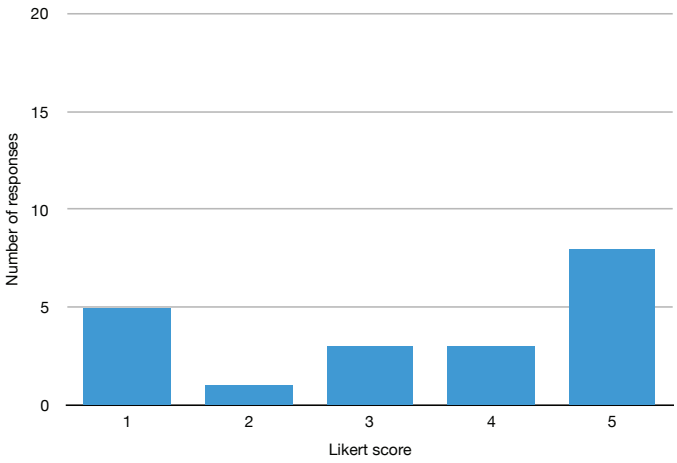
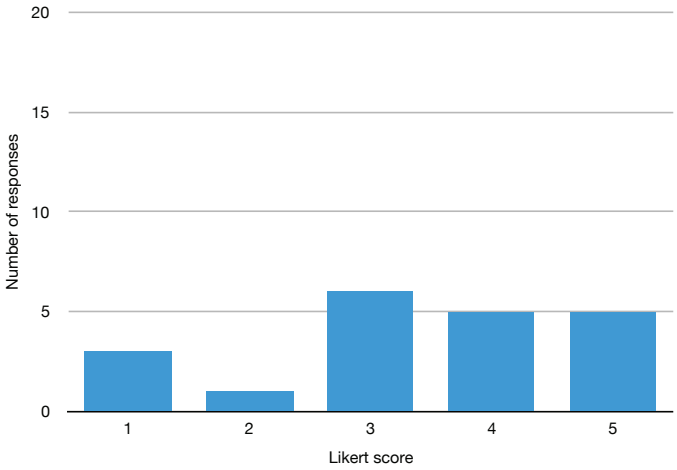
Habit	
Statement: I use computers and electronic gadgets in my everyday life Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	
Statement: I feel confident using computers and electronic gadgets Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.18 InspireVR Patient Technology Acceptance, Dimension: Habit

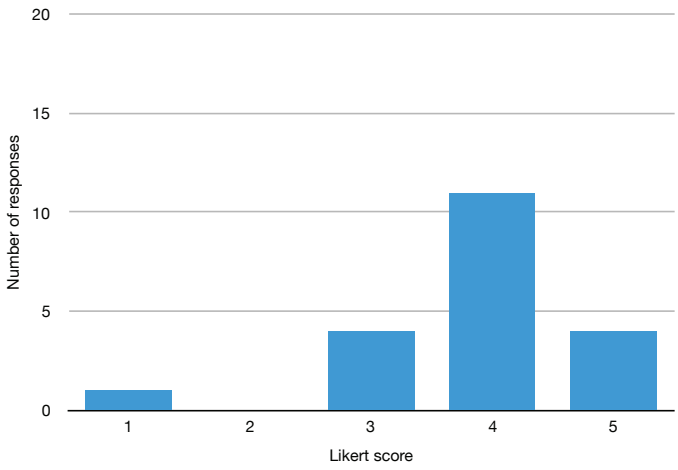
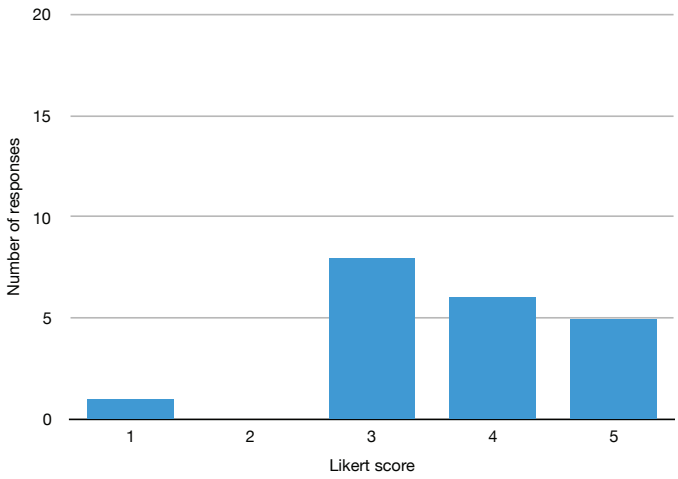
Perceived usefulness	
Statement: InspireVR will help remind me to do my deep breathing exercises Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	
Statement: InspireVR will help me to do my deep breathing exercises more effectively Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.19 InspireVR Patient Technology Acceptance, Dimension: Perceived usefulness

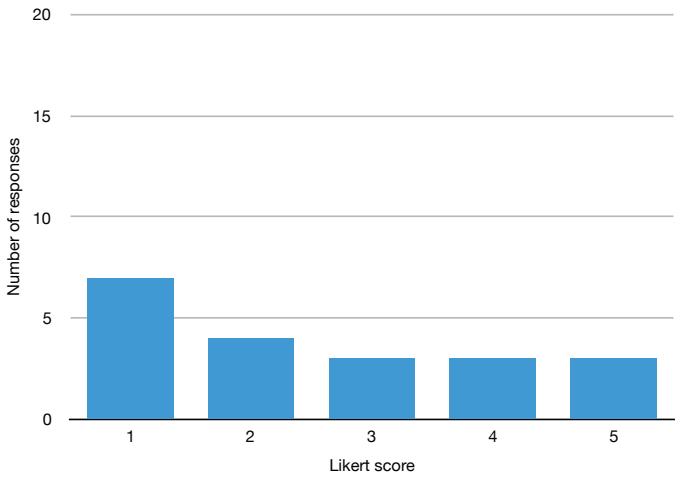
Perceived Norm	
Statement: I expect to be using electronic devices to help with my rehabilitation after surgery Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.20 InspireVR Patient Technology Acceptance, Dimension: Perceived norm

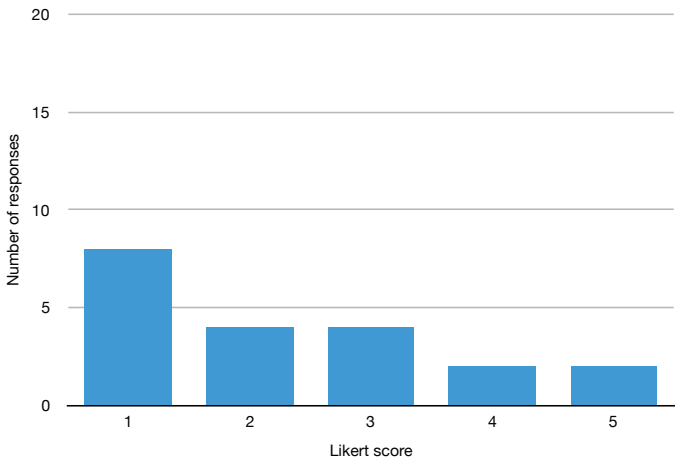
Intention	
Statement: I intend to use other electronic devices during my rehabilitation after surgery Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.21 InspireVR Patient Technology Acceptance, Dimension: Intention

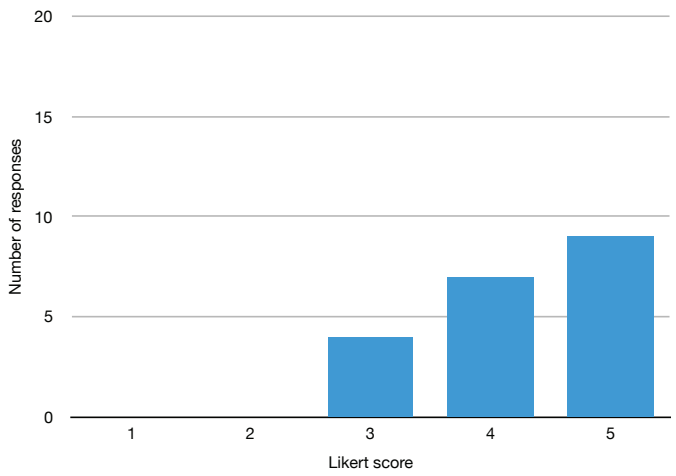
Facilitators	
Statement: I will have enough support to use InspireVR in hospital Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.22 InspireVR Patient Technology Acceptance, Dimension: Facilitators

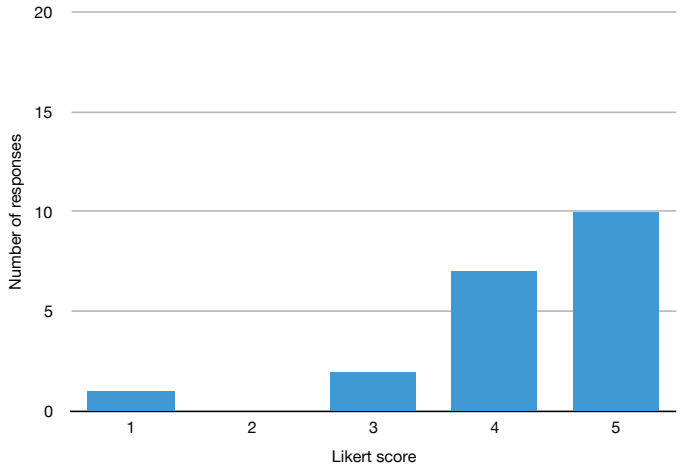
Computer Efficacy	
Statement: I could easily learn how to use InspireVR Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.23 InspireVR Patient Technology Acceptance, Dimension: Computer Efficacy

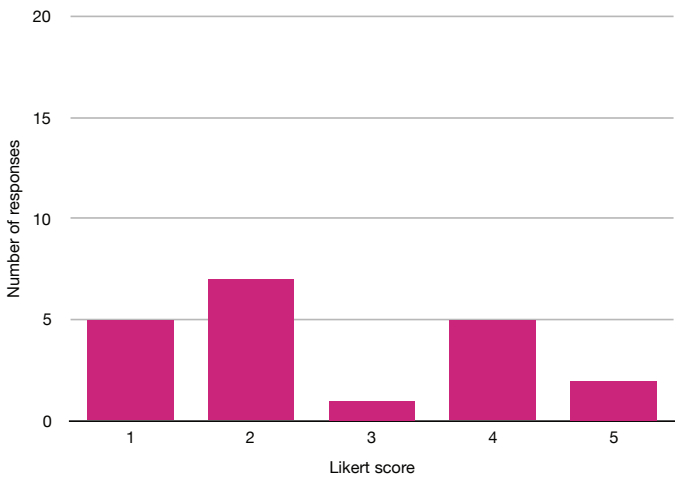
Computer Anxiety	
Statement: Learning to use new electronic devices makes me feel apprehensive *negatively phrased question* Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.24 InspireVR Patient Technology Acceptance, Dimension: Computer anxiety

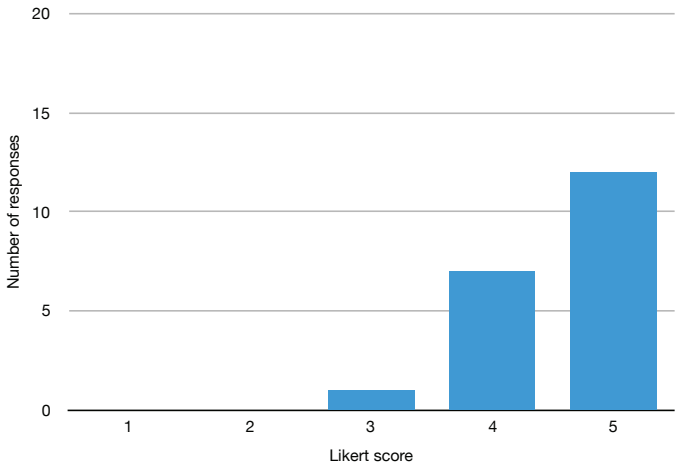
Perceived Ease of Use	
Statement: I feel confident I will be able to follow the instructions for using the InspireVR Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.25 InspireVR Patient Technology Acceptance, Dimension: Perceived ease of use

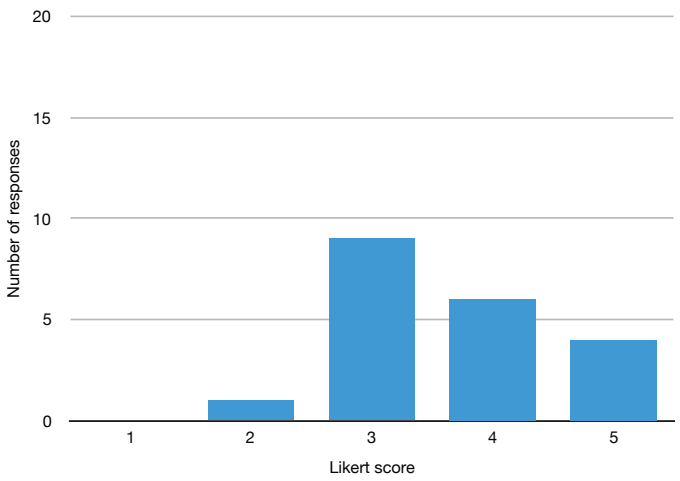
Intrinsic Motivation	
Statement: I am looking forward to using InspireVR Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.26 InspireVR Patient Technology Acceptance, Dimension: Intrinsic Motivation

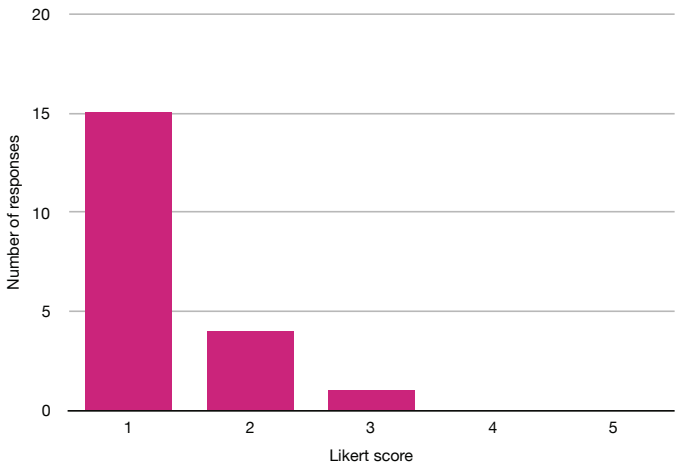
Patient-Centred Factor	
Statement: I have a disability/ impairment which will prevent me from using InspireVR properly *Negatively phrased question* Likert score 1=strongly disagree, 2=agree 3-neither agree nor disagree, 4=agree, 5=strongly agree n=20, each patient provided one response	

Figure 8.27 InspireVR Patient Technology Acceptance, Dimension: Patient centred factor

8.5.7 Recommendations for improvements to the InspireVR system

Six patients made suggestions for improvements for system design in the “other comments” section of their semi-structured interview (Table 8.12). Most comments were in relation to the design of the InspireVR game, with the remainder informing selection of interface and display components for future interactions of the InspireVR system.

Table 8.12 Recommendations for improvements to the InspireVR system

Understood the levels but wanted more numerical feedback, felt the face emojis were a bit childish.
Encourages improved performance to get though levels but probably needs better feedback visual to show you’ve reached each level.
Would be useful to see progress - spreadsheet/graphs and a report.
Visual element was not useful as it provided no data.
I wanted to do more than 10 deep breaths, which I could only do using the spiroball.
Needs to be fixed to one of the stands already in the bed space as it’s already quite crowded.
Different game scenarios would make it more fun.
Would prefer a small battery operated system - same size as spiroball but same game design as InspireVR.

8.6 Discussion

The purpose of the ReVERe Breathe study was to establish the feasibility of a phase III clinical trial to determine the effectiveness of a novel interactive technology-based device, InspireVR, to reduce post operative pulmonary complications following major upper gastrointestinal surgery. The study was designed to critically assess the development of the methods used to inform prototype design and evaluation.

There were no adverse events related to the use of the InspireVR, and no reported interference with clinical care despite the position of the system within the patient bed space (Figure 8.27).

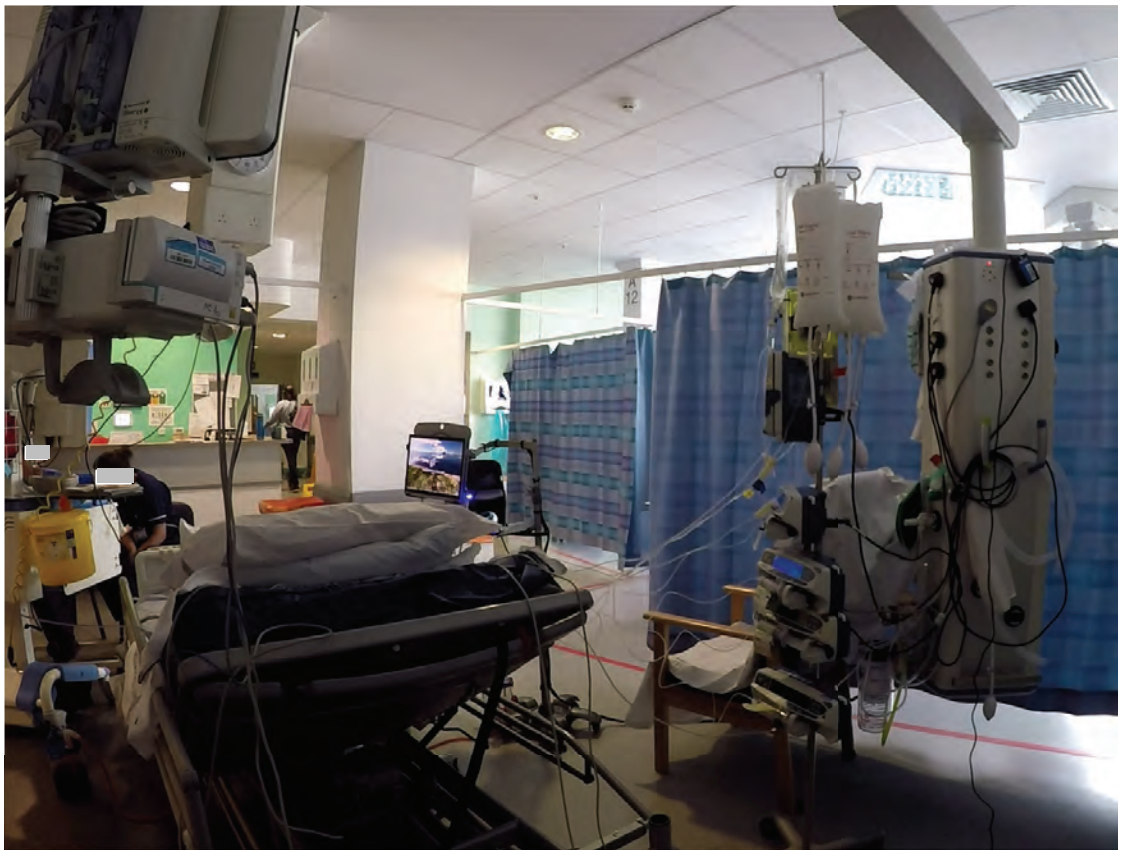


Figure 8.28 Image of InspireVR in ICU bed space during the ReVERe Breathe study

Although the accrual rate was slower than anticipated, the main reason for exclusion was due to the planned surgery date being a Friday at QEHB. These patients were excluded as there was no provision for research physiotherapy support at the weekend and the research team held the opinion that this was necessary to ensure the trial protocol was followed. It was also noted that, over the weekend, the delivery of post-operative physiotherapy was carried out by the “on-call” physiotherapy team, rather than the specialist Upper Gastrointestinal physiotherapists. Although a difference in outcome data for those receiving operations on Monday or Tuesday compared to Friday has yet to be established, the delivery of care was determined to be sufficiently different that they might be considered different patient cohorts in terms of context of care. This would need to be investigated in detail prior to the future definitive trial, particularly when considering multi-centre involvement.

The effectiveness of the InspireVR intervention was measured in terms of compliance with, and best possible performance during, incentive spirometry. During the design process of the system, the research team had carefully considered the design elements according to the programme theory of how the intervention would work. However, for a device to be effective, first and foremost it has to be available to be used. Hence, the first evaluation of the feasibility of device use for a future definitive trial was whether the novel system was available for use as often as the alternative device, Spiroball. During this feasibility study, the InspireVR device was available for use significantly less than the Spiroball, due to intermittent failure of the InspireVR software. There

were a number of reasons for this, including automatic software updates and user errors. The main lesson learned from this study is the importance of a thorough verification and validation process, with bench testing repeated until the required reliability of the software is achieved. This was the first device of its type that had been developed by the research team. The design of InspireVR device was the complex, with a novel game concept, algorithm of gameplay rules and virtual environment coupled with another medical device, the Vitalograph spirometer, necessitating the creation of midware to allow integration of the two systems.

The game algorithm had been designed based on the assumption that, given the purpose of incentive spirometry following major upper gastrointestinal surgery is to re-inflate collected airways and increase lung capacity, the maximum inspiratory capacity values would increase during serial uses of the InspireVR system. This assumption was not borne out by the data collected from the InspireVR system. This may be for a number of reasons. The assumption may not be correct, the patients may have been using the device incorrectly or the device may have not been recording the values correctly, due to a failure of the spirometer, midware or game software. Prior to further device development, it is essential to determine the progress of maximum inspiratory capacity values, using serial, accurate, spirometry measurements in a cohort of patients recovering from major upper gastrointestinal surgery on the ICU.

Despite the varied experiences of patients using the InspireVR system, over half the participants who completed the post-intervention questionnaire recorded System Usability Scale scores of more than 70, the accepted benchmark for device usability, with the statement “I would recommend using InspireVR to others” being awarded a mean score of more than 4 (agree to strongly agree).

The semi-structured interview data provided a rich source of information from patients on their opinions of the design elements of the the InspireVR game. It would have been useful to have collected more information on their subjective experience of the Spiroball system. Whilst the InspireVR device has been designed as an alternative, many patients reported that they preferred the use of the Spiroball and it would be useful to further understand which design elements, such as small size, numerical feedback and simplicity, should be incorporated into future device iterations.

All patients owned at least one interactive device prior to admission, with all but one reporting that they were at least moderately confident at using more than one interactive device. More patients reported confidence in computer efficacy and perceived ease of use than not and few had concerns over the safety of the InspireVR system. However, there was a more balanced response to questions on perceived usefulness, attitude and intrinsic motivation. This may have been due to the explanations provided by the patent information leaflet and the researcher providing information and answering questions prior to taking

informed consent. This study was the first undertaken by the research team where consent to participate was taken prior to ICU or hospital admission, with the patient yet to experience the condition leading to their recruitment to the study. This may explain the poor understanding of the need for the intervention and its potential benefits.

8.6.1 Study limitations

There were a number of limitations to this study. The first was the lack of completeness of data to enable accurate analysis of device usage. Documentation of usage appeared incomplete for 14 of the 20 participants. Whilst limitation of the requirement for written documentation of the Spiroball device was noted from study conception, this was not considered carefully enough when designing the study methodology, relying on completion of usage data by the busy clinical staff, or the patient themselves. A more robust manner of achieving data acquisition must be developed prior to further studies of this nature.

A second limitation was the lack of blinding of participants or researchers to intervention or outcomes, leading to potential recall bias of the participants and observer bias of the researchers. Two patients reported that whilst they had not enjoyed using the InspireVR system, they had enjoyed being part of the research, particularly the contact with the research staff. This effect must be considered in a study of this nature where considerable patient-researcher contact is required due to the requirement for technical support during device

use and daily data collection. Whilst it is the ambition of the research team that future iterations of the InspireVR allow greater independence of use, the impact of trial participation itself must be considered, particularly in the event of a multi-centre trial where variation in research staff activity and patient contact may affect outcome.

A third limitation was a consequence of having two centres recruiting patients simultaneously. The engineering support required from both centres was considerable, placing a previously unrecognised burden on the co-investigators from the University of Birmingham Human Interface Technologies team. The greater success in InspireVR device usage at QEHB may have been due to the presence of the Chief Investigator and research physiotherapists at the site who, having been stakeholders during the device development, were better able to troubleshoot problems.

The fourth limitation was the due to the assumption the patients would be able to use the device independently, thus staff usability and technology acceptance evaluations were not undertaken.

8.7 Conclusions

The ReVERe Breathe study was ambitious and the InspireVR device the most complex of those produced to date by the research team, whose efforts ensured successful trial launch, recruitment and adherence to trial protocol.

For the future, there were a number of lessons learned requiring the research team to carefully consider the design of the next iteration of the InspireVR system prior to, most likely, a repeated feasibility study prior to the definitive study to determine clinical effectiveness.

8.8 Reflections and key methodological lessons learned

- Poor reliability of technology undermines the entire research process. Whilst the requirements of the MHRA Clinical Investigation were arduous, they underline the absolute necessity of ensuring that the device is accurate, reliable and safe. Failure to deliver these exposes all participating in the study to harm, from time wasted to non-availability of a clinical intervention and tarnishes public opinion of the device and its associated research. Rigorous bench testing must be undertaken until all are satisfied that the prototype is fit for purpose prior to exposure to the clinical environment.
- Interactive technologies can be used to collect data to answer research questions were earlier models were unable to collect data on usage or performance.

CHAPTER 9 CONCLUSIONS AND FUTURE DIRECTIONS

This chapter presents a summary of the research findings, current ongoing research and suggestions for future development of the iTech interventions and the developmental methodology (Figure 9.1).

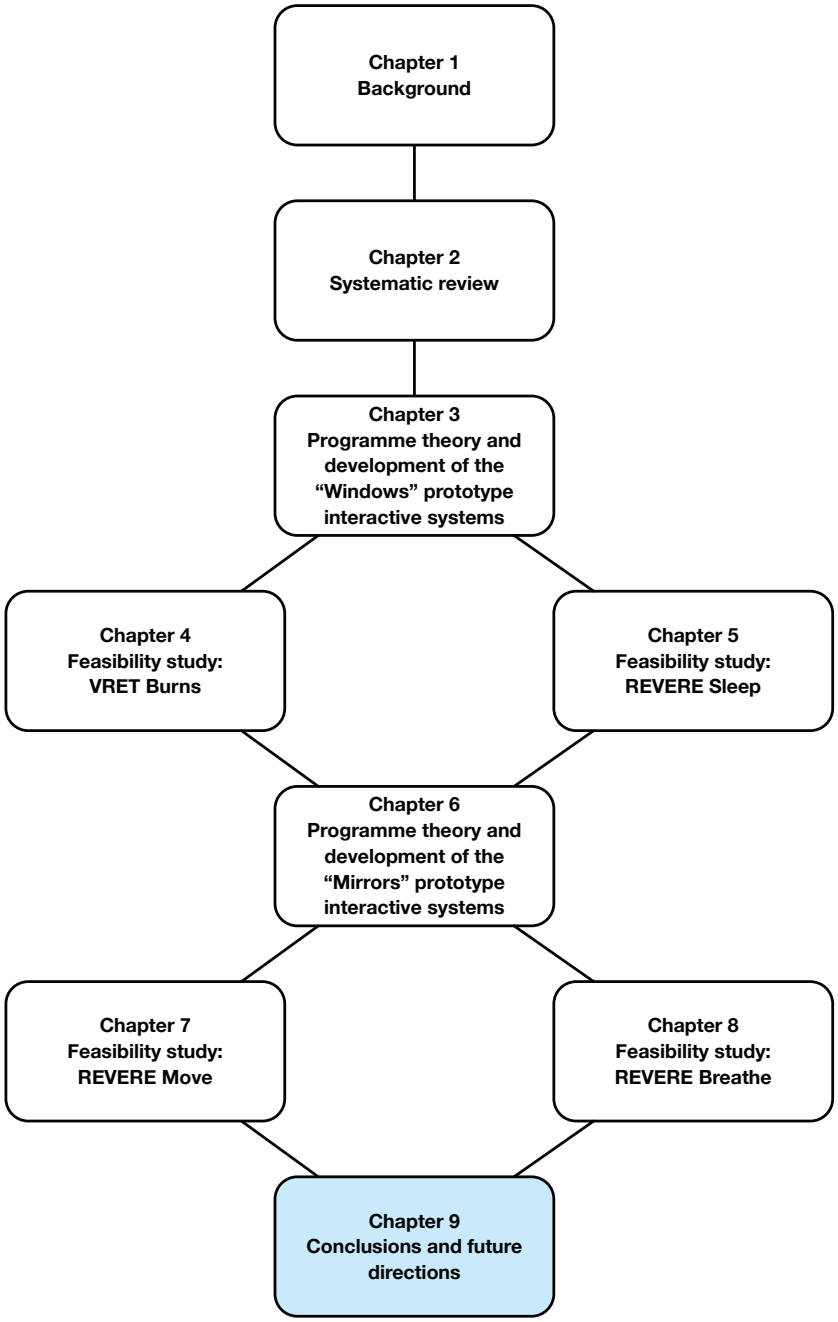


Figure 9.1 Thesis roadmap - Chapter 9

9.1 Summary

Effective rehabilitation on the ICU requires a holistic approach, combining therapies to address the physical and non-physical consequences of critical illness. This research programme proposed that interactive technologies (iTech) could be used to augment or replace such therapies for patients recovering on the ICU.

The aims of the research programme were to develop and evaluate prototype research methodologies to aid the design and implementation of novel iTech-based systems to enhance the rehabilitation of patients recovering from critical illness in the ICU.

The thesis structure presents a series of studies recording the evolution of the processes within the research framework (Figure 1.7). Each chapter detailed the development and refinement of methodologies, their exploitation within the context of the research questions and clinical scenarios, followed by post hoc evaluation in order to provide a narrative of lessons learned informing applications for future research.

The ReVERe research programme delivered four novel iTech systems and four feasibility studies. These studies demonstrated that the use of these technologies was feasible, safe and might improve patient trajectory of recovery and experience of care. The lack of participants recruited to, or completing, the

studies, limits the generalisability of the clinical findings of the studies, but all contributed to the lessons learned during the research programme.

9.2 Strengths and weaknesses of the ReVERe research programme

The selection of iTech interventions was informed by the conceptual model of components of critical illness, aetiology of consequences, current interventions and potential uses of interactive technologies (Figure 3.3). Whilst this provided an overview of critical illness, its defensibility is limited by the information use to construct it; local clinical stakeholder opinion combined with national guidance and a scoping review of literature on the process of recovery from critical illness and interventions to enhance recovery. The landscape of rehabilitation from critical illness is changing rapidly, with evolving understanding of factors underpinning the adverse consequences of critical illness and best practice for strategies to ameliorate them.(202) The model is limited by its simplicity and requires more rigorous development, including critical synthesis of the literature concerning all aspects of rehabilitation and recovery, expert consensus and understanding of local case-mix and healthcare delivery at potential sites of iTech exploitation.

Whilst considering how the interventions might work, the paradigms of “Windows” and “Mirrors” were introduced.(Figure 3.3) At the end of this phase of the research programme, this is still considered a useful way of describing why iTech interventions might be effective and the design process. This structure is particularly useful when considering the allocating of resources to

designing the elements of novel systems. For example, more resource might be allocated to quality of presentation of software for “Windows” interventions compared to “Mirrors” interventions where function might be prioritised over form.

During the design of each iTech system, the targets for modification, be they experiential or behavioural, were illustrated for each. Each was based on a combination of knowledge gained directly from the patient cohort, such as functional magnetic resonance imaging displaying the pain modifying effects of VR-based distraction, (72) indirectly from surrogate cohort, such as modifiers of motivation and performance in the elderly frail population (141) or based on local stakeholder clinical experience and opinion, such as the changes in maximum inspiratory capacity values following major user gastrointestinal surgery. None of the feasibility studies, or prior developmental work for each, fully established the accuracy of each theory. As such, the future development of each device would require scrutiny of each stage of the theory to enable evaluation of the fidelity of the intervention during a definitive trial.

The target for the “Mirrors” interventions was behavioural change. This inferred that recovery of skeletal and respiratory muscle is best achieved by exercise to maximum performance, an assumption not yet borne out by laboratory or clinical research. Indeed, even the usefulness of recumbent cycling on the ICU has yet to be established unequivocally.(203) Nonetheless, should the process of improvements in muscle performance reflect that seen in well subjects, it

would be valuable to explore the impact of iTech interventions on behavioural modification in detail, including the influence of patient trait personality type and changes in psychological state on rehabilitation-based behaviours. Validation of the Intrinsic Motivation Index was not performed during the ReVERe Move study due to small cohort size but should be considered in the future.

A framework of contextual influences, including physical and social environment, illustrated considerations that would need to be made throughout the design and implementation cycle (Figure 3.5) Although four different patient cohorts are studied, a strength of this research was the repeated use of the same clinical setting. This provided rich information on the impact of different types of iTech interventions on the patient environment and their carers and vice versa. The ICU bed-space is already a technology-rich setting with constant requirement for direct patient-carer contact and high levels of activity. The technologies were determined to be safe to use and were widely accepted by ICU nursing and therapy staff, despite their apparent interference and cumbersomeness.(Figure 9.2)

Figure 9.2 The typical ICU bed space during the ReVERe Breathe study illustrating nursing activity and technology-rich environment.
Permission for publication granted by patient and QEHB ICU nursing staff member

The research attempted to assess the factors that might mediate the effect of the interventions. The most complex element of all factors considered was the user characteristics, particularly in relation to knowledge, skills and attitudes to technology adoption. As well as the changes seen in mood and motivation during ICU stay, it has been observed that technology acceptance fluctuates with time.(169) Donald Norman, the once Vice President of Advanced Technology at Apple wrote, in The Design of Everyday Things:

> *"Why do we need to know about the human mind? Because things are designed to be used by people, and without a deep understanding of people, the designs are apt to be faulty, difficult to use, difficult to understand." (204)*

Longitudinal models of patient knowledge, skills and attitudes in relation to technology acceptance during recovery from critical illness would be of value to

inform how interventions can be designed and adapted for use throughout the patients recovery process, from the ICU to home.

The framework for the design methodology was based on international standards for device development and medical research standards for the evaluation of complex interventions (Figure 1.7). This structure was found to be useful, particularly when used to inform research timelines, resource allocation and preparedness for clinical trial delivery.

The templates of specification of user requirements facilitated increased precision of the descriptions of the target cohort, required tasks and intended goals. A potential limitation of increasing precision was the risk of reducing the applicability of the intervention to all but a small number of potential users. The ability to provide a specification of user requirements which was fit for purpose was challenging, particularly due to the heterogeneity of the patient cohorts in terms of physical and cognitive capabilities and attitude to the intervention. This suggests that flexibility of system design, from methods of interaction to software content and style, should be considered in the future design processes.

Early developmental work was based on usability heuristics. As the experience of the research team grew, informed by the results of early trials, the usability of the iTech devices improved. Validation of tools to evaluate usability, such as the System Usability Scale used during the ReVERe Sleep study and its modified

version used for the ReVERe Breathe study, were not validated due to the small cohort size, where between four to ten respondents per item are required to perform validation tests.(205) This limits the ability of the reader to validate these results. In view of the difficulties patients experienced in the comprehension of the System Usability Scale, future work may consider the use of other usability assessment tools, such as the approaches used for Outcome-Driven Innovation, where each task is broken down into a series of desired outcomes, and the iTech device is evaluated by scoring the observed delivery of each outcome.(206) This methodology may increase the accuracy of the assessment but is likely to be resource-intense as it usually requires external observation, which would be challenging in the ICU environment whilst considering space and patient privacy.

9.3 Methodological lessons learned and considerations for future research

Each chapter presented a summary of reflections of the research process and key methodological lessons learned. These included:

- Undertaking a systematic review provides a rigorous method for evaluating the evidence on clinical effectiveness of a proposed intervention.
- The challenge when using this approach for evaluating iTech is the variation in type, mode of delivery and outcome measures between each study, reducing generalisability and the ability to perform meta-analysis.

- The systematic review can be used to inform the development of the programme theory, explaining biological plausibility and contextual modifiers of response.
- Clinical trials rarely report detail in the methodologies used to inform iTech design and system development, so the completion of a systematic review produces limited meaningful data.
- Design and development of iTech-based interventions for use by patients recovering from critical illness and injury can be informed by evaluation of clinical practice, via clinical audit.
- Small cycle testing can be used within an interactive process to refine system design. Access to patient user feedback is, however, limited due to physical and cognitive limitations of the target patient cohort and safety constraints of exposing vulnerable individuals to potential risk of immature technologies.
- Utilising the clinical feasibility study design where the number of participants is determined by the power calculation, based on a clinical primary outcome measure, risks undermining the iterative design process by delaying analysis and conclusions needed to inform prototype design. Time to target recruitment must be built into the methods to ensure the feasibility study is completed within a sensible time frame to enable timely progression.
- Over simplification of usability evaluation reduces the generalisability of results and threatens the usefulness of the study, potentially wasting time and exposes the healthcare consumers and system to unacceptable risk versus benefit.

- Use of surrogate cohorts, who may ostensibly have sufficiently similar characteristics to inform user specification, jeopardises the system design process from the earliest stages if assumptions are not adequately informed.
- A within subject, repeated measures design exaggerated the impact of slow recruitment on the study results by reducing the number of participants who completed all interventions.
- Exposing each participant to all proposed versions of an interactive system is useful in terms of informing preference of types of engagement and further exploration of mediators of response. The value of each participant could be increased by increasing the depth of evaluation at each intervention, whilst considering patient capability to reliably provide feedback using a range of data collection tools.
- Embedded software is useful for collecting data on user preference, and may have greater use, including collection of clinical outcome measures.
- A key determinant of success in the development of an interactive system is the efficiency of the process whereby the user requirements are understood and met by the designers/manufacturers. This process was better formalised by the use of templates completed collaboratively detailing the essential and desirable specifications.
- Embedded software can be used to facilitate collection of clinical outcome measures, though its accuracy needs to be determined during the clinical studies.
- Patient representative groups (PPI) are a useful cohort to evaluate technologies during the iterative design process as they have insight into the

experiences of the target patient group but have recovered sufficiently to provide useful feedback.

- Patients recovering in the ICU have the ability to provide useful feedback using a range of quantitative data collection tools. Their ability to provide qualitative data is limited due to fatigue and communications difficulties, such as use of tracheostomy tubes for airway and ventilation support.
- As with the REVERE Sleep study, consideration must be mad eof the duration of the window between recruitment and discharge from the ICU and the impact of that window being too small to allow completion of all trial interventions. This factor could be ameliorated by extending the research environment beyond critical care, to the wards and even home.
- Participation in research may be compromised by the factors that the intervention itself is attempting to address, such as poor motivation and engagement, potentially leading to an “own goal” for the researchers as this issue should be identified early in the research process. This study suggests that getting patients to engage with any attempt at physical therapy is the challenge, rather than improving the effort in those who were already engaged. At this point, the programme theory needs to be revisited and refined.
- Poor reliability of technology undermines the entire research process. Whilst the requirements of the MHRA Clinical Investigation were arduous, they underline the absolute necessity of ensuring that the device is accurate, reliable and safe. Failure to deliver these exposes all participating in the study to harm, from time wasted to non-availability of a clinical intervention and

tarnishes public opinion of the device and its associated research. Rigorous bench testing must be undertaken until all are satisfied that the prototype is fit for purpose prior to exposure to the clinical environment.

- Interactive technologies can be used to collect data to answer research questions were earlier models were unable to collect data on usage or performance.

These lessons learned have been assimilated by the research team, who identify that many of the problems that beleaguered this programme were, ironically, identified during the systematic review undertaken early in the research process. The research methods utilised in the feasibility studies were heavily influenced by the approaches traditionally taken in clinical trials of non-technological interventions, a reflection of the experience of the clinical researchers and the expectations of medical journal editors who might be considering publication of the research reports.

Moving forward, a preferable approach might be to consider all the lessons learned and incorporate them into an alternative design process, such as the outcome-driven approach favoured by industry.(206) This would rely less on the clinical outcome measures as a means of judging product success in immature technologies, but would consider more closely the activities that the device is designed to support. This would increase the likelihood of success during patient studies and streamline progressive innovation.

Although the research framework (Figure 1.7) provides as useful and usable tool to inform design activities at each phase, it must be supported by the templates produced including the specification of user requirements (Appendix) and risk analysis (Appendix). Early Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis by an experienced team of research stakeholders might help to recognise vulnerabilities earlier in the process.

9.4 Contributions

Although the clinical feasibility studies reported inconsequential or negative clinical outcome findings, the main aim of the research was to develop prototype methodologies to design and evaluate novel interactive systems.

The key methodological research contributions of this thesis were:

1. Development of a research framework combining Human Centred Design processes with the recommendations of the Medical Research Council for the Evaluation of Complex Interventions
2. A systematic review establishing the current knowledge on the exploitation of interactive technologies for use in acute inpatient settings, considering how they were developed, whether they were safe and usable and whether they worked.
3. Descriptions of the processes behind the development of programme theories describing how iTech-based interventions might work in critical care settings to ameliorate physical and non-physical complications of critical illness.

4. Descriptions of methods used to develop interactive technologies, and evaluation of their strengths and weaknesses including:
    1. Stakeholder development of statements of user requirements.
    2. Small cycle testing using patient, patient representative and staff user groups to inform the iterative design process.
    3. Bench testing of interactive systems to ensure accuracy and reliability.
5. Development of the evaluation science via methodologies incorporated in a feasibility study of a novel iTech based intervention to enhance pain management during dressing changes for burns patients, including simple descriptive measures to evaluate usability.
6. Development of the evaluation science via methodologies incorporated in a feasibility study of a novel iTech based intervention to improve sleep for patients on the ICU, including use of the System Usability Scale to subjectively evaluate usability and embedded software to assess user preference.
7. Development of the evaluation science via methodologies incorporated in a feasibility study of a novel iTech based intervention to enhance recumbent cycling for patients on the ICU including use of embedded software to monitor performance and evaluation of the feasibility of the IMI and TAM questionnaire completion by ICU patents in order to model mediators and moderators of benefit in future studies.
8. Development of the evaluation science via methodologies incorporated in a feasibility study of a novel iTech based intervention to improve incentive

spirometry for patients recovering from major upper gastrointestinal surgery, including a modified SUS tool, embedded performance software and detailed semi structured interviews.

9. Descriptions of methods used to enhance delivery of clinical trials of interactive technologies, including staff engagement, understanding of the conflict between design process and expectations of all stakeholders, particularly in light of requirements of NHS funding bodies and medical journal editorial policy.

9.5 Ongoing research

9.5.1 The Digital Liberation from Ventilation System

Recognition that one of the early research objectives, enhancing the process of liberating patients from mechanical ventilation (termed “weaning”), was not deliverable during this research programme due to the complexity of the required intervention, has led to a programme of work collaborating with an industry partner, Cambridge Design Partnership.

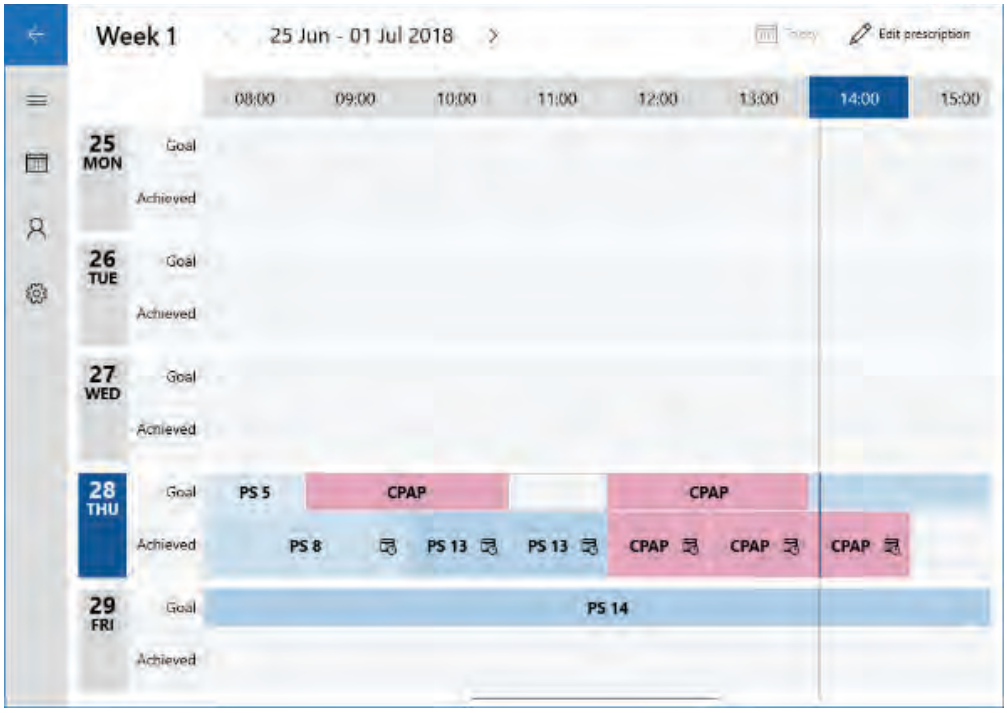


Figure 9.3 Screenshot of the DELVeS dashboard

Funded by the NIHR Surgical Reconstruction and Microbiological Research Centre the first prototype “DELVeS” the Digitally Enhanced Liberation from Ventilation System (Figure 9.3) has been developed.

The DELVe system combines a touchscreen interactive weaning chart, prescribed by clinical staff, with realtime and historical data feed from the mechanical ventilator, presented such that adherence and progress can be better understood.

Figure 9.4 Bench testing of the DELVE system in the simulation suite of the Medical Devices Testing and Evaluation Centre, QEHB

Bench testing has been supported by the Medical Device Technology Evaluation Centre at QEHB (Figure 9.4). The feasibility study, based on QEHB ICU, is due to open in December 2018. Future work streams will include the development of systems to enhance patient and carer understanding of weaning progress and goals and the use of data to model patterns predicting success of failure during the weaning process.

9.5.2 The ICU Communication WitH Acute Tracheostomy System

The Patient and Public Involvement representatives, led by Duncan and Lisa-Marie Buckley, have been vital members of the stakeholder groups for the three ReVERe studies. Over the course of the research, Duncan and Lisa-Marie have been supported in the development of their own idea for an intervention, influenced by their experience of care on the ICU. The ICU CHAT (Communication witH Acute Tracheostomy) has been developed to aid communication for voiceless patients on the ICU (Figure 9.5).

Figure 9.5 Screenshot form the ICU CHAT communication aid

The prototype development and feasibility study was funded by the NIHR SRMRC and was completed in August 2018. Further development of the device will be dependent on ongoing research funding.

9.6 Recommendations for future research

It is the first ambition of the ReVERe research group that a centre is formed with expertise on the design and evaluation of both novel, bespoke iTech systems and clinical applications of commercial-off-the-shelf devices. The clinical research team could collaborate with both academic and industry partners depending on the specification of each project and expertise required. This group would consolidate the lessons learned and produce recommendations for best practice in the development and evaluation of novel interactive systems for use by patients. They would also endeavour to influence the clinical academic community on the need to move away from the traditional feasibility study using clinical primary outcome measures, towards a more task outcome-focussed approach.

The evolution of the VRET, VNT, InspireVR and VeloVR systems will be influenced by funding opportunities but all have shown potential scope for development. The variation on presentation of patients on the ICU renders each iTech intervention potentially useful to some but not others. Thus, the second ambition of the ReVERe research group to develop a modular interactive system, incorporating the interventions designed to date and those of the future, to be used by patients throughout their journey through critical illness, from the ICU to home, as and when appropriate for each stage of recovery.

9.7 Conclusions

The impetus for this research was the collaboration between clinical academics at the Queen Elizabeth Hospital Birmingham, the Human Interface Technologies Team at the University of Birmingham, supporting by funding from the Defence Medical Services.

Over the eight years since the research programme was conceived, the team have achieved a significant number of milestones, with many lessons learned along the journey, from appreciation of the possible and impossible within each other's domain to the learning of a shared language. Moving forward, there are a number of key reflections from each study that must be considered.

As the research progresses, it is likely that the patient population, and those caring for them, become even more adept as use of technology, with greater acceptance of use as part of clinical care. This will present great opportunities but at the cost of even greater expectation. Continued horizon scanning will be needed to continue to match technological capabilities with the needs of the patients and healthcare systems, to enable the development of the disruptive not just disruption.

Appendix 1:Systematic Review search strategy and results

SEARCH NO.	DATABASE	SEARCH TERMS	RECORDS
1	PUBMED	Search ((((((((((((((((((((((((((inpatient[Title/Abstract]) OR hospital[Title/Abstract]) OR intensive care[Title/Abstract]) OR ICU[Title/Abstract]) OR critical care[Title/Abstract]) OR high dependency[Title/Abstract]) OR acute care[Title/Abstract]) OR ITU[Title/Abstract]) OR inpatient[MeSH Terms]) OR intensive care unit[MeSH Terms]) OR burn unit[MeSH Terms]) OR burn[Title/Abstract]) OR trauma[Title/Abstract]) OR surgery[Title/Abstract]) OR coronary care[Title/Abstract])) AND ((((((video game[Title/Abstract]) OR virtual reality[Title/Abstract]) OR computer game[Title/Abstract]) OR Wii[Title/Abstract]) OR Xbox[Title/Abstract]) OR interface, user computer[MeSH Terms])) AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) NOT (((simulator[Title/Abstract]) OR simulation[Title/Abstract]) AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) NOT (electronic health record[MeSH Terms] AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) NOT (electronic health record[MeSH Terms] AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp])))) NOT (psychiatric AND ((Case Reports[ptyp] OR Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase III[ptyp] OR Controlled Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp]))) Filters: Case Reports; Clinical Study; Clinical Trial; Clinical Trial, Phase III; Controlled Clinical Trial; Meta-Analysis; Randomized Controlled Trial	340

2	OVID inc. PsychARTICLES Journal@Ovid Full Text Embase Ovid MEDLINE PsychINFO	1. (critical care or intensive care or trauma or injury or burn*).ti. 2. (virtual reality or computer game* or video game* or user computer interface or interactive technolog*).ti. 3. limit 2 to human 4. limit 3 to humans 5. 1 and 4	3858
3	Web of Science	Keywords: (Video game* Kinect Xbox, Nintendo Wii, Gaming console, Interactive games, Gaming system, Interactive technology.) AND (Intensive Care, Critical Care, Critical Illness, Burn, Trauma, Injury)	739
6	PEDRo	Title or abstract: (video game* or computer game* or virtual reality of interactive technology)	11
7	IEEE	Keywords: (Video game* Kinect Xbox, Nintendo Wii, Gaming console, Interactive games, Gaming system, Interactive technology.) AND (Intensive Care, Critical Care, Critical Illness, Burn, Trauma, Injury)	436
8	Cochrane	Keywords: (Video game* Kinect Xbox, Nintendo Wii, Gaming console, Interactive games, Gaming system, Interactive technology.) AND (Intensive Care, Critical Care, Critical Illness, Burn, Trauma, Injury)	2377

Appendix 2: Systematic review: Study characteristics

Pain	Study	1. Location 2. Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
Adult Burns	Carrougher 2009	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Physical therapy 4. Not declared	Adults over age 20, requiring post burn physiotherapy, on two consecutive days during acute hospital stay.	Non english speaking, significant facial, ear or scalp injuries that prevented them wearing a helmet, seizure disorder, full joint range of movement.	• RCT • Within subject crossover. • VR for one complete PT session, control for the other session • Order randomised
	Hoffman 2000a	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Wound care 4. Not declared	Inpatients on burns unit	Not described.	• Two case studies • VR for half a session, control for the other half, order randomised.
	Hoffman 2000b	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Physical therapy 4. Not declared	Adult Inpatient on burns unit Previous reports of pain during physical therapy	Not described.	RCT Within subject, crossover
	Hoffman 2009	1. Harborview Medical Centre, Seattle, USA 2. Trauma Unit 3. Physical therapy 4. N/A	Inpatient on trauma unit	Not described.	• Single case study • VR for half a session, control for the other half.
	Maani 2011a	1. Brooke Army Medical Center, Texas. USA 2. Surgical research burns unit 3. Wound care 4. Not declared	Inpatient on burns unit Documented excessive pain during previous days wound care Aged 18 or over Able to operate a computer mouse or joystick	Susceptibility to motion sickness Open wounds on hands Anxiety on viewing SnowWorld on a desktop computer	• Prospective RCT, Within subject • VR for half a session, control for the other half, order randomised.
	Maani 2011b (ketamine)	1. Brooke Army Medical Center, Texas. USA 2. Surgical research burns unit 3. Wound care 4. Not declared	Inpatient on burns unit	No described	• Two case studies • VR for half a session, control for the other half.

Pain	Study	1. Location 2. Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
	Morris 2009	1.Tygerberg Hospital, near Cape Town, South Africa 2. Adult burns unit 3. Physical therapy 4. 2 months	Inpatient on burns unit Adult Receiving physical therapy	Facial or bilateral hand burns Epilepsy Medically unstable Cognitive deficits	• Feasibility study • Within subject, controlled
	Parker 2016	1. Royal Perth Hospital, Western Australia 2. Adult burns unit 3. Active Physical therapy 4. 24 months	Inpatient on burns unit Burn total body surface area </= 10%	Limb amputation Electrical injury Neurological condition affecting participation Non-english speaking Unable to complete study independently Superficial burn with anticipated admission < 7 days High risk of multi-drug resistant infection	• Prospective RCT • 7 day trial of 5 days of twice daily computer game activity Randomisation into intervention and control groups, and into upper and lower limb groups
	Voon 2016	1. Royal Perth Hospital, Western Australia 2. Adult burns unit 3. Active Physical therapy 4. 15 months	Inpatient on burns unit with burn TBSA 1-10% Aged 18 or over Burns affecting upper limb joints Pain score of >/= 3/10 Able to stand with normal power limb function Adequate fluency in spoken and written English	Cognitive, hearing or visual impairment Pre-existing joint pathology at joints of interest Concurrent cardio/ respiratory conditions Pregnant, limb amputation, high risk infections Seizure disorder, motion sickness, vestibular pathology	Pilot RCT, between subject Patients categorised as inpatients (>3 days in hospital) or short stay (<3 days). Short stay patients discharged before day 7 continued the study at home.
Adult and Paed Burns	Faber 2013	1. Martini Hospital, Groningen, Netherlands 2. Burns Unit 3. Wound care 4. 42 months	Inpatient on burns unit Able to communicate meaningfully Dutch speaking/ reading/writing ability Expected length of stay at least 4 days	Psychiatric illness Physical impairments that preclude VR use, eg facial burns Seizure disorders Admission to ICU	• Feasibility study • Within subject, within patient • Baseline post-treatment comparison

Pain	Study	1. Location 2. Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
	Hoffman 2008	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Wound care in the hydrotank 4. Not described	Inpatient on burns unit Requiring wound care in the hydrotank and had previously experienced significant pain.	Not described.	• RCT • Within subject
	Markus 2009	1.University of Wisconsin Hospital and Clinics. 2.Burn Center 3. Physical and occupational therapy 4. Not described	Inpatient on burns unit Aged over 8 Able to complete subjective evaluations of pain	Delirium, psychosis, organic brain disorder, seizure history. Susceptibility to motion sickness Facial burns Isolation for infection	Feasibility study to determine resources required and barriers to implementation.
	van Twillert 2007	1. Martini Hospital, Groningen, Netherlands 2. Burns Unit 3. Wound care 4. 42 months	Aged 8 or over Inpatient on burns unit Able to communicate meaningfully Dutch speaking/ reading/writing ability Expected length of stay at least 4 days	Psychiatric illness Physical impairments that preclude VR use, eg facial burns Seizure disorders Admission to ICU	RCT Within subject, crossover
Paeds Burns/ wound care	Chan 2007	Chang Gung Memorial Hospital, Tao-Yuan, Taiwan Paediatric Burns Unit Wound Care	Inpatient on burns unit Third to fifth day after burn Prior anxiety during dressing changes	Not described.	Pilot RCT Within-subject, crossover
	Das 2005	1.Womens and Children's Hospital, Adelaide, Australia. 2. Burns Centre 3. Wound care 4. Not described	Inpatient on burns unit Aged 5-18 years Burn TBSA >3% Requiring dressing changes	Burns to hands, face or head. Epilpsy Reduced intellectual capacity	Pilot RCT Within subject, crossover
	Hoffman 2014	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Wound care 4. Not declared	Inpatient on burns unit	Not described.	Case study

Pain	Study	1. Location 2. Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
	Hua 2015	1. Wuhan Medical Care Centre for Women and Children, Hubei, China 2. Paediatric unit 3. Wound care 4. 12 months	Aged 4-16 years Chronic wounds that required active dressing changes	Non-Chinese speaking Visual or auditory disability Receiving sedative medication Wounds requiring surgery	RCT Between subject
	Kipping 2012	1. Royal Children's Hospital, Royal Brisbane and Women's Hospital 2. Paediatric and adult burn centres 3. Wound Care 4. 15 months	Aged 11 to < 18 years Inpatient on burns unit First conscious change of dressing Burn wound TBSA >1%	Cognitive impairment preventing he use of outcome measures Visual/hearing impairment unable to be corrected Wound location impacting the ability to use the off-the-shelf VR device Non-English speaking Child safety and protection issues	RCT Parallel group design
	Scapin 2017	1. Childrens Hospital Joana de Gusmao, Florianopolis, Santa Caterina, Brazil 2. Burn Unit 3. Wound care 4. 3 months	Inpatient on burns unit	Not described.	Two case reports Within subject, crossover
	Schmitt 2011	1. Harborview Medical Centre, Seattle, USA 2. Burns Unit 3. Physical therapy 4. Not declared	Inpatient on burns unit Age 19 years and younger Requiring range of motion physiotherapy	Motion sickness Burns on body regions that preclude use of VR, eg ears Seizures	RCT Within subject, crossover

Pain	Study	1. Location 2. Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
Adult critical care	Mosso-Vasquez 2014	1. La Raza National Medical Center 2. Cardiac Surgery Department 3. Post cardiac surgery 4. Not declared	Inpatient on hyper acute cardiac surgery unit Within 24 hours of cardiac surgery, including valve replacement, coronary stent insertion, coronary revascularisation, tricuspid plasty, ventricular communication repair and bridge tricuspid resection Conscious, normal vision, free movement of limbs	Airway cannulation Haemodynamic disorder	Pre and post controlled trial
Adult medical	Mosadeghi 2016	1. Cedars-Sinai Medical Center, Los Angeles 2. Inpatient Specialty programme 3. Inpatients - mixed medical cohort 4. 4 months	Adults aged 18 or over Admitted to Inpatient Specialty Program	Unable to consent In contrast isolation Head wounds or bandages History of motion sickness or vertigo Active nausea and vomiting Seizures or epilepsy	Feasibility (usability), mixed methods
	Tashjian 2017	1. Cedars-Sinai Medical Center, Los Angeles 2. Inpatient Specialty programme 3. Inpatients - mixed cohort 4. 6 months	Adults aged 18 or over Admitted to Inpatient Specialty Program Pain score >/= 3 over the preceding 24 hours	Unable to consent In contrast isolation Head wounds or bandages History of motion sickness or vertigo Active nausea and vomiting Seizures or epilepsy	Comparative cohort trial
Adult intraoperative	Shoorab 2015	1. Omolbanin Hospital of Masshad, Iran. 2. Delivery suite 3. Episiotomy repair 4. 3 months	Primiparous women requiring repair of episiotomy following parturition. Iranian national Low risk pregnancy All stages of labour Spontaneous labour	History of mental illness, addiction, motion sickness, headaches. Apgar scores <7 at 1and 5 minutes of birth. Neonate anomaly Receiving higher than 5ml 2% lidocaine	RCT Sample size based on power calculation from previous plots tudy.

Anxiety/ other	Study	1.Location 2.Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
Adult oncology	Banos 2012	1. Hospital Clinica Benidorm 2. Cancer Centre 3. Inpatient oncology treatment 4. Not declared	Diagnosis of metastatic cancer Hospitalised for at least 1 week Karnofsky functionional state >/= 50	Serious psychopathology Legal incapacity Brain metastasis	Descriptive pilot study
Paeds oncology	Li 2011	1. Childrens Hospital,Hong Kong 2. Oncology Unit 3. Anxiety and depression during inpatient stay 4. 14 months	Inpatients on paediatric oncology ward for treatment of cancer Asked 8-16 years Able to speak Cantonese and read Chinese Have been diagnosed with cancer for at least 2 months and currently undergoing active treatment	Cognitive or learning problems,	• RCT • Non-equivalent control group, pre test-post test, between subject design Sample size determined to detect a medium effect size between groups, based on a prior study
Adult intraoperative	Chan 2017	1. St Vincents Hospital, Mebourne, Australia. 2. Operating theatre 3. Joint replacement surgery 4. 5 months	Patients receiving lower limb joint replacement surgery under regional anaesthesia English speaking	Significant cardiac or respiratory disease General anaesthetic Cognitive, visual or hearing impairment	• Pilot RCT • Between subject

Performance	Stdy	1.Location 2.Facility 3. Reason for intervention 4. Trial Duration	Inclusion criteria	Exclusion criteria	Design
Adult critical care	Kho 2012	1. Johns Hopkins Hospital, Baltimore, USA 2. Medical ICU 3. Physical Therapy 4. 12 months	Patients receiving physical therapy on the medical ICU	Physical therapy not indicated	Observational study, observing use and indications for using Nintendo Wii and Wii fit and occurence of adverse events
Paeds critical care	Abdul satar 2013	1.McMaster Children's Hospital, Ontario, Canada 2. Paediatric Critical Care Unit 3. Physical Therapy 4. 8 Months	Inpatients on PCCU with anticipated length of stay of >48 hours Age 3 to 18 years	Anticipated death or withholding life sustaining treatment Physical inability to mobilise Cardiorespiratory instability Language barrier Inability to comprehend instructions or perform the intervention	Feasibility study
Adult oncology	Jahn et al 2012	1. Martin Luther University 2. Oncology Unit 3. Physical therapy 4. 13 months	Patients admitted to unit for radiotherpay of radio-chemotherapy for at least 5 days Physical function status grade 2 or better	Insufficient proficiency in written or spoken German.	Mixed methods exploratory study

Appendix 3: Systematic Review: Description of intervention and HCD/UE process

Psin	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
Adult Burns	Carroughe r 2009	SnowWorld NVis NVisor HMD Physical therapy Therapist chose most painful/ troublesome joints to exercise during the sessions	10 minutes for both VR with standard analgesia and control session.	Standard analgesia - long acting opioid and a procedural short acting opioid. In dependent of study protocol and determined by local physician.	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
	Hoffman 2000a	SpiderWorld Head mounted display with external Polhemus 6df position sensors Wound care	3 minutes of VR with standard analgesia and 3 minutes of control during each session, order randomised.	Nintendo 64 video games; “Wave Race 64” and “Mario Kart 64”	2 System designed for phobia managemen t	3 Presence and realism assessed
	Hoffman 2000b	SpiderWorld Head mounted display with external Polhemus 6df position sensors Physical Therapy	3 minutes of VR with standard analgesia and 3 minutes of control during each session, order randomised.	Standard analgesia only	2 System designed for phobia managemen t	3 Presence and realism assessed
	Hoffman 2009	SnowWorld Rockwell Collins SR80 HMD with Intersense IC3 head tracker Wound care	5 minutes of VR with standard analgesia and 5 minutes of no VR on 2 consecutive days	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed

Psin	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
	Maani 2011a	SnowWorld Rockwell Collins SR80 HMD mounted on robot-like holding system Wound care	Approx 6 minutes of VR with standard analgesia and minutes of no VR	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
	Maani 2011b	SnowWorld Rockwell Collins SR80 HMD mounted on robot-like holding system Wound care	5 minutes of VR plus standard analgesia and 5 minutes of no VR with standard analgesia plus ketamine	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
	Morris 2009	Chicken Little PC game eMagin HMD with joystick Physical therapy	Half therapy session in VR with standard analgesia, half with standard analgesia only Mean session duration 18 minutes	Standard analgesia only	2 Consideration of cost only	3 Adverse events and time allocated to system set up
	Parker 2016	Nintendo Wii and a mobile TV Nunchuck controller for upper limb Balance board for lower limb Upper limb alternated between tennis and boxing from Wii Sports Lower limb used yoga, step up and sporting type exercises from Wii Fit	At least 5 days of twice daily sessions over a 7 day period Minimum of 2 mins per game then repeat the schedule.	Individualised exercise therapy assisted by physical therapist including mobilisation and range gaining exercises, with core stability and cardiorespiratory fitness training	2	3

Psin	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
	Voon 2016	Xbox Kinect Sports Pack, game chosen related to the location of the burn Patients unsupervised during exercise sessions	For a maximum of 7 days Two daily sessions of physical therapy, 15 minutes of self-directed exercise followed by 15 monies of Xbox Kinect	For a maximum of 7 days Two daily sessions of physical therapy, 30 minutes of self-directed exercise (prescribed on basis of location of burn)	2	3
Adult and Paed Burns	Faber 2013	SnowWorld Cybermind Hi-Res900 3D HMD with external Polhemus 6df position sensors	Each intervention lasted duration of dressing change, VR plus standard analgesia	First dressing change with standard analgesia only - done within first 14 days of admission	2	3
	Hoffman 2008	SnowWorld Custom built, water friendly HMD Microsoft Sidewinder joystick	Six minute segment of wound care chosen: Half this session used VR with standard analgesia (3 min), half with standard analgesia only (3 min)	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
	Markus 2009	SnowWorld Preview VO35vHMD Physical or occupational therapy	2-9 minutes, duration of therapy session	Nil	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed

Psin	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
	van Twillert 2007	SnowWorld Cybermind Hi-Res900 3D HMD with external Polhemus 6df position sensors Offered during one of the daily wound dressing changes during the first week	Duration of wound care	Standard care or alternative distraction, including music, television, non-medical conversation, distraction by a child care worker	2	4
Paeds Burns/ wound care	Chan 2007	Novel game designed for the study: based on an ice cream factory. Point and shoot. High resolution 3D glasses and mouse trigger Offered during one complete change of dressings.	Duration of wound care	Standard analgesia only	2 - but detailed description of development of game and hardware selection for the burns its	1 - usability and modified presence questionnaire (PQ) - reliability analysis undertaken for the study
	Das 2005	Novel game designed for the study: based on “Quake” by ID software. Point and shoot. IOGlasses HMD with Intersense IS300 tracking system. Mouse trigger Wound Care	During half the dressing change, order randomised	Standard analgesia only	2 - game designed by Dept of Computer and Information Sciences	3 Some description of the usability in the discussion
	Hoffman 2014	SnowWorld Oculus Rift HMD with robot-like arm goggle holder Physical therapy.	20 minute session during passive ROM physical therapy	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
	Hua 2015	Ice Age 2: The meltdown eMagin z800 HMD and joystick Wound care	Duration of wound care	Standard distraction - not described	3	3
	Kipping 2012	Chicken Little PC game - age 11-13 years, Need for Speed 14-17 years eMagin HMD with joystick Wound Care	Duration of wound care	Standard distraction - TV, stories, music, caregiver or no distraction plus analgesia	3	3

Psin	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
	Scapin 2017	3D rollercoaster ride Samsung Gear VR Innovator Edition for Note 4. Wound care	During half the dressing change	Nil	3	3
	Schmitt 2011	SnowWorld HMDs (selected based on availability at time of study): NVis NVisor HMD VR-1280 Pro-view XL ProView SR80 Polhemus Fastrack motion tracking system Physical therapy	Half of each PT session Once a day for up to 5 days	Standard analgesia only	2 Detailed description of reason behind software design and hardware selection/ design	3 Presence and realism assessed
Adult critical care	Mosso-Vasquez 2014	Five cyber therapy environments (developed by Virtual Reality Medical Centre in San Diego): Cliff, Dream castle, Enchanted Forest, Icy Cool World, Drive, Walk Bike.	30 minutes	Nil	3	3
Adult medical	Mosadeghi 2016	Samsung Gear VR Innovator edition goggles with Samsung Galaxy Note 4 VR software “experiences:” 1. Paint studio, 2. TheBluVR, 3. Cirque de Soleil, 4. Tours of Iceland	3-5 minutes per VR experience	Nil	2 Description of reason behind software and hardware selection/ design	3
	Tashjian 2017	Samsung Gear Oculus headset with Samsung Galaxy S7 phone VR experience: Pain RelieVR	15 minutes	2D High Definition video depicting relaxing nature scenes	2 Description of reason behind software and hardware selection/ design	3
Adult intraoperative	JahaniShoorab 2015	3D Bluray/DVD player connected to Vuzix video glasses, with external remote control device. Deliveries and repairs all completed by assistant researcher, using standardised technique and lidocaine infiltration	Duration of episiotomy repair	Standard care, repair of episiotomy - completed by same researcher for both groups.	3	3

ANXIETY/ OTHER	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
Adult oncology	Banos 2012	Emotional parks - “Walk through nature” Guided narratives and exercises designed to induce either joy or relaxation. Four sessions administered during one week, first and third were joy sessions and second and fourth were relaxation sessions. 32 in TV and computer with keyboard, mouse and headphones mounted on a trolley.	Each session lasting approximately half an hour	Nil	2 Consideration of usability, accessibility, and cost in design	3 Satisfaction VAS
Paeds oncology	Li 2011	VR enhanced Therapeutic play: PlayMotion system installed into a playroom. Playmotion uses video projectors, computer visual algorithms and real-time special effect systems of video games to transform walls, ceilings and floors into interactive playgrounds. Small groups - max 4 children plus research nurse	30 minutes, 5 times a week.	Standard care, no VR	2	4
Adult intraoperative	Chan 2017	Passive simulation modelled on SnowWorld played on Oculus Rift DK2 with classical music	After patient positioning before start of operation to end of operation	Standard care, no VR	2	3

Performance	Study	Intervention description	Duration of intervention	Control condition	Human Centred Design Process	Usability engineering process
Adult critical care	Kho 2012	Nintendo Wii and Wii Fit Set up and supervised by physiotherapist	Duration of physical therapy session	Standard physical therapy	2	3
Paeds critical care	Abdulsatar 2013	Nintendo Wii Boxing for trial, other games after 2 trial days, play time observed. Set up and supervised by physiotherapist	10 minutes of Nintendo, twice a day, for 2 days. After the trial patients could use the system when they wished	Nil	2 Games chosen to increase upper limb activity, suitable for use in bed	3 Parental evaluation of satisfaction and belief of benefit to child
Adult oncology	Jahn et al 2012	Nintendo Wii: Patient choice Wii Sports, Family Trainer, Sports Island, Family Ski and Snowboard Presented via video projector Researchers present during the sessions to help or participate.	30 minutes a day for a minimum of 5 days.	Nil	2 Games chosen to increase general activity Healthy volunteers used to provide data of degree of heart rate increase for each game	3 Qualitative evaluation of user satisfaction

Human Centred Design Process:

1. Complete: Adherence to an international or national standard (eg BS ENISO 9241-210 (30)) where the standard is referenced and there is evidence of adherence.
2. Partial: HCD process used, adhering to some elements of an international or national standard.
3. None: No evidence of HCD approach to device design.

Usability Engineering Process:

1. Use of usability assessment tool(s) which has/have been validated for use in an acutely ill patient population.
2. Use of usability assessment tool(s) are validated/undergo analysis of reliability during the study.
3. Use of a non-validated instrument to assess usability.
4. No usability assessment.

Appendix 4: Systematic review: Summary of study results

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Adult Burns	Carrougher 2009	100mm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain • Nausea • Goniometry Analysis: Students t-test	100mm GRS • Realism of virtual environment • Presence Analysis: Students t-test	1. 41 2. 89.7 % 3. 39 4. 39 5. Not documented	GRS scores lower during VR for worst pain (40 vs 55, p=0.004), pain unpleasantness (22 vs 32, p=0.031), time spent thinking about pain (26 vs 41, p=0.008). Opioid equivalents - no difference between groups No difference in ROM	VR only Realism - mean 25.6 (SD 23.5) Presence - mean 35.1 (SD 26)

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Hoffman 2000a	100mm VAS • Worst pain • Average pain • Pain unpleasantness • Time spent thinking about pain • Anxiety • Nausea	100 mm VAS • Realism of virtual environment • Presence	1. 2 2. 100 % 3. 16 and 17 years 4. 2 5. 2 6. N/A	<u>Case 1, session 1:</u> During VR: 80mm reduction for worst pain, 66mm reduction for average pain, 80mm reduction for unpleasantness, 98mm reduction for time spent thinking about pain, 58mm reduction in anxiety, <u>Case 1, session 2:</u> During VR: 30mm reduction for worst pain, 27mm reduction for unpleasantness, 53mm reduction for time spent thinking about pain, 22mm reduction in anxiety. No nausea in either session. <u>Case 2,</u> During VR: 47mm reduction for worst pain, 35mm reduction for average pain, 55mm reduction for unpleasantness, 61mm reduction for time spent thinking about pain.	<u>Case 1, session 1:</u> Realism: 55 mm for VE, 11mm for video game Presence 100 mm for VR, 17mm for video game. <u>Case 1, session 2:</u> Realism: 71 mm for VE, 2 mm for video game Presence 81 mm for VR, 11 mm for video game <u>Case 2</u> Realism: 35 mm for VE, 18mm for video game Presence 43 mm for VR, 0mm for video game.

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Hoffman 2000b	100mm VAS • Worst pain • Average pain • Pain unpleasantness • Time spent thinking about pain • Anxiety • Nausea Limb Range of Motion (ROM)	100 mm VAS • Realism of virtual environment • Presence	1. 12 2. 92% 3. 12 4. 12 5. N/A One patient refused to participate at approach/ consent	Pain: Statisitcally significant reduction in mean pain ratings in VR vs control for all pain measures. No significant difference in anxiety Mean nausea ratings zero	Mean presence: 63.67mm Mean realism 51.92mm
	Hoffman 2009	100mm VAS • Worst pain • Pain unpleasantness • Time spent thinking about pain • ROM • Nausea	100 mm VAS • Fun	1. 1 2. 100% 3. 32 4. 1 5. 1 6. N/A	Mean changes during VR: 17mm reduction for worst pain, 33mm reduction for unpleasantness, 47mm reduction for time spent thinking about pain No increase in ROM on day i, 15 degrees greater ROM during VR on day 2 No nausea .	33mm mean increase in fun during VR

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Maani 2011a	10cm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain • Nausea Analysis: Students t-test	10cm GRS • Fun • Realism • Presence	1. 12 2. 100% 3. 22 (range 20-27 years) 4. 12 5. 12 6. Not described	GRS scores lower during VR for worst pain (4.5 vs 6.25, $p<0.05$), pain unpleasantness (2.83 vs 6.25, $p<0.01$), time spent thinking about pain (2.17 vs 7.58,$p<0.001$) $p=0.008$). No nausea. Results non significant for worst pain or unpleasantness for participants with mild or moderate pain only.	Fun - 7.5 in VR, 0 without VR. Presence in VR - 5.33
	Maani 2011b (ketamine)	10cm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain • Nausea	10cm GRS • Fun • Realism • Presence	1. 2 2. 100% 3. Aged 21 and 41 4. 2 5. 2 6. Not described	<u>Participant 1</u> GRS scores lower during VR for worst pain (5 vs 8), pain unpleasantness (2 vs 8), time spent thinking about pain (2 vs 5). No nausea. <u>Participant 2</u> GRS scores lower during VR for worst pain (1 vs 6), pain unpleasantness (0 vs 6), time spent thinking about pain (1 vs 10). Nausea - 1/10	<u>Participant 1</u> Fun - 9 in VR, 0 without VR. Presence in VR - 5 <u>Participant 2</u> Fun - 10 in VR, 0 without VR. Presence in VR - 9

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Morris 2009	0-10 NRS for pain 0-100 Burn specific pain anxiety scale	Duration of set up time Adverse events	1. 11 2. 73% 3. 33 (range 23-54) 4. 11 5. 11 6. N/A	NRS for pain Lower median score with VR (3, range 0-10) than analgesia alone (6, range 2-10). BSPAS Lower median score with VR (33, range 6-78) than analgesia alone (44, range 14-87) Both non significant using students t-test and chi squared test when converted to categorical data.	No additional time allocated to treatment session No adverse events
	Parker 2016	Pain: 0-10 VAS, before and after exercise Fear avoidance: Pain Anxiety Symptom Scale (40 item Likert scale, 0-200) ROM: Goniometry	Nil	1. 22 2. 77% 3. 26 (median) range 16-59 4. 22 5. 22 6. N/A	Statistically significant (p=0.019) reduction in groupies difference in before/ after pain scores in ITech group compared to control. For those with pain 0-4/10 pre-exercise, pain was reduced in 9% of control and 17% of iTech group, but increased in 73% controls and 42% in intervention group. For those with pain >4/10 pre-exercise pain was reduced 52% in control group and 30% in intervention group, and increased in 35% controls and 25% intervention group. Non significant differences in PASS and ROM scores between groups.	Nil

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Voon 2016	Upper limb function: QuickDASH 0-100 Pain: 0-10 NRS Kinesophobia: TAMPA scale	Data collected by patient diary. Compliance: total time for each session Self reported satisfaction: VAS 0-10	1. 30 (15 in each group) 2. 67% (Xbox), 60% control 3. 31, 25-39 Xbox, 29, 23-40 control (Med, IQR) 4. 30 5. 30 6. N/A	QuickDASH score: Xbox 38, Control 43.7, p=0.75 Pain before: Xbox 4.28, control 3.44, p=0.019 Paon after: Xbox 4.58, Control 4.16 Pain (change over exercise): Xbox +0.303, control +0.726, p=0.111 TAMPA: Xbox 36.9, control 37.4, p=0.754	Mean daily activity (min) in Xbox 49.37, Control 26.7, p<0.0001 Satisfaction score Xbox 8.53, control 7.8, p<0.0001 No problems setting up the Xbox independently in the hospital or at home
Adult and Paed Burns	Faber 2013	Worst pain: 10cm VAT Within-subject paired t tests to compare VR sessions with baseline control (wound care session 1) Side effects	Number of VR sessions during wound care	1. 36 2. 83.3% 3. 27.7 (15.2) years 4. 36 5. 36 6. N/A	VAT scores were lower during all VR sessions compared to control, but this was only statistically significant when comparing the first three VR sessions with the control. (p=0.006, p=0.04, p=0.038) No nausea	Mean number of VR sessions: 2.8 (1.4) 36 completed one VR session 30 completed two or more 17 completed three or more
	Hoffman 2008	10cm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain • Nausea	10cm GRS • Fun • Realism • Presence	1. 11 2. 100% 3. 27, range 9-40 years 4. 11 5. 11 6. N/A	Overall, mean pain ratings lower for all pain measures. Worst pain: 5.1(2.6) for VR vs 7.6(1.9) for control, p=0.015 Pain unpleasantness: 4.1(2.8) for VR vs 6.7(1.6) for VR, p=0.017 Time: 3.6(2.5) for VR vs 7.6(3.1 for control, p<0.001 No nausea	Fun: 3.8(3.3) for VR vs 0.9(1.6) for control, p=0.015 Mean presence 3.4 Those with presence >3.4 had reduction in all pain ratings, those with presence <3.4 had no reduction.

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Markus 2009	Nil	Duration (to nearest minute) for 2 staff members • Equipment preparation • Patient instruction • Therapy during VR • Clean up	1. 10 2. 90% 3. 36 4. 10 5. 10 6. N/A	Nil	Duration (mean) Total set up time: 59 min (SD18) Set up time 23.8 min Teaching: 6.6 min Participation: 13.0 min Clean up: 16 min Technical difficulties caused variability in set-up time
	van Twillert 2007	Worst pain: 10cm VAT Anxiety: Dutch edition STAI	Perception of duration of dressing change	1. 19 2. 63% 3. 30 (range 8-65) 4. 19 5. 19 6. N/A	Pain: Reduction in pain during VR for 16/19 patients compared to control, in those 16 the mean reduction was 56%, overall pain scores reduced by 39% ($p < 0.01$). Pain scores increased the day following the intervention ($p<0.05$.) Anxiety: Non significant reduction of 2% with VR vs control.	Significant linear relationship between the discrepancy in time experience (lower) and VAT score reduction (Pearson's $r = 0.37$, $p < 0.05$)
Paeds Burns / wound care	Chan 2007	Pain:Self reported Faces scale, before during and after dressing change plus nurses' behavioural assessment. Semi-structured interview on pain relief for both conditions	Usability and modified presence questionnaire (PQ) - 7 point likert scale Semi-structured interview on the usability of the VR	1. 8 2. 88% 3. 6.54(2.27) 4. 8 5. 8 6. N/A	Pain: No statistically significant difference between groups at before, during or after. Nurses observed fewer anxious behaviours during the VR intervention. Shift in attention from dressing change during VR, with better behaviour and emotions	Mean presence: 4.81 (SD 1.05) Usability: mean (SD) Ease of operation: 3.13(0.718) Ease in learning: 3.5 (0.802) Comfort with glasses: 4.0 (0.598) Weight: 3.38(0.498) Would play the game again: 4.63 (0.460)

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Das 2005	Pain: Self reported modified Faces scale (combined with 0-10 VAS), average pain after each half of the dressing change	Usability observations by researchers	1. 9 2. 66% 3. 10 (3.7 for boys and 4.1 for girls) 4. 7, with a total for 11 trials 5. 7 6. Two participants withdrawn due to drowsiness after analgesia	Mean pain score differences between administrations was significantly less for VR than control ($p<0.01$) All but one child had a pain reduction of >2 on the faces scale for VR vs control	Device appeared cumbersome. requiring a number of wires to connect the HMD to the console. Would need a variety of games for all ages of children.
	Hoffman 2014	10cm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain	10cm GRS • Fun • Presence	1. 1 2. 100 3. 11 4. 1 5. 1 6. N/A	Pain: GRS ratings were lower for all pain measures.	Presence: 10 More fun in VR
	Hua 2015	Pain: Before, during and after. Self reported Faces pain score, Caregiver reported VAS, nursing staff reported FLACC Pulse rates, O2 sats	Duration of dressing change	1. 65 - 33 in VR group, 32 in control. No sig diff between groups 2. 48% 3. 8.72 (range 4-16) 4. 65 5. 65 6. N/A	Pain: FACES: significantly lower in VR group before ($p=0.016$), during ($p=0.001$) and after ($p=0.034$) wound care VAS: Significantly lower scores in the VR group before ($p=0.028$), during ($p=0.007$) and after ($p=0.001$) wound care FLACC: Significantly lower scores during ($p=0.001$) and after ($P=0.013$) wound care Pulse rates significantly lower in VR group ($p=0.013$)	Length of dressing change reduced in VR group ($p=0.003$)

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Kipping 2012	Pain: 0-10 VAS Self report for adolescents and caregivers FLACC for nursing staff All before, after dressing removal and after dressing application Heart rate and O2 sats Rescue doses of analgesia Nausea: 0-10 VAS	Adverse events	1. 41 - 20 intervention, 21 control 2. 68% 3. 13.08 (1.6) 4. 40 5. 40 6. 1 refused to complete intervention but results included in analysis	Pain: No difference in self reported or caregiver VAS at all time points Reduced nursing staff FLACC for intervention group vs control at dressing removal (p=0.02) No difference in heart rates or O2 sats More rescue doses of analgesia in the control group (p=0.05) Nausea <1/10	No adverse events
	Scapin 2017	Pain: Faces and NRS - assessed just before, during dressing change without VR, during dressing change with VR, after closing the dressing without VR. Nausea, dizziness	Fun Immersion	1. 2 2. 100% 3. Age 9 and 8 4. 2 5. 2 6. N/A	Pain: Reduced from (1) 10 to 4 and (2) 6 to 4. No nausea or dizziness	Children appears to be immersed and enjoying the VR

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Schmitt 2011	100mm GRS • Worst pain • Pain unpleasantness • Time spent thinking about pain • Nausea • Goniometry	100mm GRS • Realism of virtual environment • Presence • Fun	1. 54 2. 81% 3. 12(3.9) 4. 54 5. 54 6. N/A	Pain: Study day 1: Cognitive - 44% reduction with VR Affective - 32% reduction Sensory - 27% reduction p<0.05 for all No increase in joint ROM Nausea - 0-9 across 5 days	3 fold increase in fun for VR condition. Presence range 47-76 and realism range 35.1-46.4 across the 5 days
Adult crit care	Mosso-Vasquez 2014	Pain: Likert scale Respiratory rate Heart rate Mean arterial pressure Oxygen saturation Pain Nausea	Nil	1. 67 2. 56% 3. 67 4. 67 5. N/A	88% had reduced pain post VR therapy, mean decrease of 3.75 37.3% had reduced heart rate, 52.2% had reduced mean arterial pressure, 64% (of 22 patients) had reduced respiratory rate after VR. Reduction in respiratory rate correlated with reduction in pain likert score (R^2=0.925) Three episodes of nasuea One episode of cardiac arrhythmia requiring termination of VR	Nil

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Adult medic	Mosadeghi 2016	Patient perception of anxiety or pain during VR	Ability of patients to use VR Characteristics of VR participants versus VR non-participants Patient experience with VR	1. 30 2. 63% 3. 49.7 (17.4) 4. 28 5. 28 6. Nausea, weight of the goggles.	43% believed VR could change their anxiety level. 75% believed it could improve pain by distraction.	510 patients screened, 82.9% failed to meet inclusion criteria and of the eligible 87, 66% refused the participate in the trial - 5.9% overall. VR participants were significantly younger than the non-participants Participant VR experience: 86% of responses were positive VR hardware: 61% positive responses 57% preferred “Tours of Iceland”, least preferred was “Paint Studio.”

Pain	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
	Tashjian 2017	Pain: 11 point NRS, pre- and post intervention Adverse events Change in BP and HR in VR group.	Nil	1. 100, 50 in each group 2. 40% in VR group, 54% in control 3. VR: 54.48 (17.9), control 47.7 (15.2) 4. 100 5. 100	Within subject: significant drop in pain for both VR ($p<0.001$) and control group ($p<0.001$) Between groups: Difference in difference favoured VR ($p=0.008$) Using a binary responder definition there were more responders in the VR grope (65%) then the control group (40%), NNT = 4 Repeated measures ANOVA, sig decrease in pain in VR group ($p<0.001$) No adverse events No change in BP or HR in VR group	Nil
Adult intra-op	JahaniShoorab 2015	Pain: 0-100 NPRS before and during the four stages of repair	Patient estimated duration of repair	1. 32 total: 16 VR, 16 control 2. 0% 3. 24.1 (4.1) 4. 30 30 5. Yes (1 drop out from each group)	Groups matched for clinical and demographic data. Reduction in pain in VR vs control between groups ($p=0.038$) and at difference stages ($p<0.0001$) Severe pain reported in 60% of the VR group and 20% of the non VR group	Patient estimated duration of repair lower in VR group vs control ($p=0.013$)

Anxiety/ other	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants (%) 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Adult oncology	Banos 2012	Pre-and post-intervention questions Mood: 7-pointVAS of joy, sadness, anxiety, relaxation and vigour, general mood state and subjective mood Physical discomfort: 10 point VAS Side effects Open ended questions	Satisfaction with intervention: 10 point VAS, “Did you like today’s activity?” and “Do you thin that today’s session has been useful or beneficial?” Satisfaction with intervention scale: 10 point VAS, “How logical does this psychological program seem to you?”, “How satisfied are you with the psychological program?” “How confident would you be in recommending this psychological program to a friend experiencing a similar situation?” “How useful do you think this program has been for you?” “How annoying or uncomfortable has this program been for you?”	1. 20 2. 53% 3. 60.9 (14.54) 4. 19 - 5 received one session, 2 received two sessions, 1 patient received three sessions, 11 received all four sessions. 5. 19 6. Clinical deterioration, discharge, high physical discomfort, presence of other worries, voluntary withdrawal.	Statistically significant improvements in the second sessions in general mood ($p<0.001$), relaxation ($P<0.05$), sadness ($P<0.003$) and the fourth session, increase in joy ($P<0.009$). Side effects - four participants reported tiredness related to positioning during the intervention. One user reported increase in pre-existing dizziness.	All satisfaction scores were higher that 5/10. Participants did not rate the intervention as uncomfortable. Patients found the program meaningful, purposeful, entertaining and pleasant. Negative comments about navigation restrictions, lacking elements (people, vegetation) Performance difficulties improved with practice. Lying in bed made interaction with the device difficult. Clinician used the interaction device for patient in ICU, and another experiencing discomfort. Hospital context - disturbance and distraction by visitors and staff, other noises

Anxiety/ other	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants (%) 3. Age - mean(*SD*/range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Paeds oncology	Li 2011	State anxiety: CSAC-C, range 10-30 Depressive symptom scores: CES:DC Both on admission and at day 7	Nil	1. Total 122, 52 intervention, 70 control 2. 53.5% intervention, 52.9% in control group 3. 11.6(2.1) intervention, 12.1(2.3) in control group 4. 98% attrition in control group, 85% attrition in VR group.. Slow recruitment due to Influenza (H1N1) epidemic.	No difference between anxiety and depressive symptom scores between groups at day 7.	Nil
Adult intra-op	Chan 2017	Sedation requirements Nausea	Tolerance of VR Willingness to use VR for awake procedures in teh future	1. Total: 19, 9 VR and 10 control 2. 10.6% in control, 10.6% in VR 3. 19 4. 19 5. One VR simulation ended early due to google discomfort	No difference in doses of protofol, midazolam or fentanyl between groups. Sample size too small to detect statistically significant difference. No nausea	One patient was unable to complete VR session due to discomfort from HMD All were willing to use VR for awake procedures in the future

Performance	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants (%) 3. Age - mean(*SD*/ range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Adult crit care	Kho 2012	Demographic data, MICU admission details, baseline ambulation, hospital length of stay, hospital outcome For Nintendo sessions: adverse events, ICU treatment, sedation and delirium	Activities during PT and indications for VG use	1. 410 included 2. Of those receiving VG therapy, 64% were male 3. Age 52(median), 32-64 (IQR) 4. N/A 5. N/A 6. N/A	1. 22 (5%) patients received VG therapy, for 11% of total PT treatment sessions. These patients had longer MICU (8.5 days) and hospital (30.5 days) stay. 2. 90% has RASS sore of 0 3. None had delirium 4. None had vasoactive infusions 5. 45% occurring during mechanical ventilation 6. 2% had benzodiazepine and 7% had narcotic infusions 7. No adverse safety events	1. Median time from initial PT to VG therapy, median of 1 session of VG therapy a day, 2. Indications: balance (52%), endurance training (45%) 3. Most common activities: boxing (38%), bowling (24%) and balance board (21%). Also used tennsi, baseball, golf, soccer, skiing
Paed crit care	Abdulsattar 2013	Demographic and admission data Safety events Upper limb activity during the intervention - Actigraph GT3X accelerometer on each wrist, activity in 3 sec epochs Muscle strength - hand grip strength	Feasibility to recruit patients Caregiver and participant satisfaction 0-7 scale	1. 12 2. 42% 3. 11, 3-16 (median, range) 4. 8 5. 8 6. Discharged prior to intervention n=3, withdrew n=1	Mean upper limb activity higher during Wii sessions than rest of day (57.12 ± 46.60 vs 9.36 ± 4.12 counts, p = 0.049, n = 8). No significant change in grip strength Clinical safety events - none reported but data incomplete (n= 3) No correlation between severity of illness (PRISM III scroe and total Wii playtime	Caregiver feedback (6/8) Mean scores Enjoyment 5.7±1.8 Safety 6.9 ± 0.4 Potential benefit to child 5.3 ± 1.8 Strong correlation between total Wii play-time and caregiver perception of the child's enjoyment (p = 0.86, p = 0.02)

Performance	Study	Outcome measures (clinical)	Outcome measures (non clinical)	1.Participants recruited 2. Male participants (%) 3. Age - mean(*SD*/ range) 4.No. completed trial 5.No. completed follow up 6.Reasons for drop out	Results - clinical	Results - non-clinical
Adult oncology	Jahn et al 2012	Nil	Semi-structured interview of experience using Nintendo Wii - Mayring's method to analyse	1. 7 2. 71% 3. 56.7 (8.56) 4. 7 5. 7 6. 11 patients decided to participate	Nil	Themes: Physical activity as a game, relaxation and decrease of negative emotions, distraction while playing, positive self experience and interaction 3/7 would play the game as an inpatient again Older patients preferred less physically straining games Golf and bowling were the most popular games "Playing virtual physical activity games decreased strain-related distressing symptoms and led to subjective internal loss of control experiences." "Playing with the game console resulted in the experience of forgetting the hospital surroundings and what it was like to be an oncology inpatient for the majority of individuals." "The use of the motion-activated game console in a hospital environment was accepted positively."

Appendix 5: Systematic Review: Risk of bias of included studies (Non-RCTs)

Risk of bias non-RCTs	Study	Selection criteria adequately reported	Population representative of normal practice	Measure of variability	Loss to follow up explained	90% included at baseline followed up	Prospective recruitment	Consecutive recruitment	Relevant prognostic factors reported	Other
Adult Burns	Hoffman 2000									Authors suggest that it might have been the inability to see the wounds rather than the VR itself which has the analgesic effect
	Hoffman 2009									Single case Reason for case selection not specified
	Maani 2011b									?publication/ reporting bias. No discussion of reason for patient selection
	Morris 2009									Small sample, non significant trend for better pain with VR
Adult and Paed Burns	Faber 2013									Good description of those excluded. Lack of statistical significance in later sessions likely due to low numbers
	Markus 2009									
Paeds Burns/ wound care	Hoffman 2014									Case study
	Scapin 2017									
Adult critical care	Mosso-Vasquez 2014									Incomplete data and no reason given. Inadequate description of pain assessment “Likert”
Adult oncology	Banos 2012									
	Jahn et al 2012									Small sample, qualitative data only.
Adult critical care	Kho 2012									Observational study. Use influenced by time and opinion of therapists
Paeds critical care	Abdulsatar 2013									Incomplete data due to discharge prior to intervention starting and caregiver compliance with feedback (6/8)
Adult medical	Mosadeghi 2016									Only 5.9% of those screened were recruited
	Tashjian 2017									No screening figures

Appendix 6: Systematic Review: Mechanisms of effect

Sub theme	Description	References of primary studies
Theme 1: Enhancing quality of care		
	• Increased compliance and cooperation during wound care and PT reduces duration of intervention and increases efficacy of carers • Self reported pain intensity was lower using iTech during wound care, PT and operative procedures. • It is appealing to apply non-pharmacological techniques to therapy, distraction techniques reduced need for analgesia and sedation, with their unwanted side effects • Intense pain alone causes adverse sequelae beyond the effects of the cause of the pain • The game encouraged increased activity and limb movement • Patients that experience fun are more likely to comply with future treatment. • Children using therapeutic play exhibited fewer depressive symptoms after 7 days. • The Nintendo game has not been designed for rehabilitation	Abdulsatar 2013, Banos 2012, Chan 2007, Chan 2017, Das 2005, Hoffman 2000b, Hoffman 2008, Hoffman 2009, Hoffman 2014, Hua 2015, Jahn 2012, Kipping 2012, Li 2011, Maani 2011a, Maani 2011b, Morris 2009, Mosadeghi 2016, Mosso-vasquez 2014, Parker 2016, Scapin 2017, Shcmitt 2011, Shourab 2015, Tashjian 2017.
Theme 2: Patient (and carer) experience		
	• Perception of duration of wound care was shorter whilst using iTech • Some reported loss of sense of time during intervention • Emotional and cognitive components of pain were reduced whilst using iTech • The ITech was enjoyed and well tolerated • Therapeutic play helps children cope with the stress of hospitalisation. • Behaviours and emotions were improved following use of iTech during painful procedures • The game occupied time and gave the patient something to look forward to • The system allows the patient to escape their reality, providing separation from their hostile environment • Subjects reported increased fun during iTech interventions, even during painful procedures • Nurses reported that wound care sessions were easier and less stressful whilst the patient used iTech	Abdulsatar 2013, Banos 2012, Carrougher 2009, Chan 2007, Chan 2017, Das 2005,Hoffman 2000a, Hoffman 2000b, Hoffman 2008, Hoffman 2009, Hoffman 2014, Hua 2015, Jahn 2012, Kipping 2012, Li 2011, Maani 2011a, Maani 2011b, Morris 2009, Mosadeghi 2016, Mosso-vasquez 2014, Parker 2016, Scapin 2017, Shcmitt 2011, Shourab 2015, Tashjian 2017.

Sub theme	Description	References of primary studies
Theme 1: Windows		
Attention diversion	Patients able to forget their surroundings whilst using iTech Virtual environments were interacted with on may levels Children were engaged in game during the dressing change, particularly when the game appealed to them In some cases conditioned fear was more engaging than the virtual environment. There may be a threshold of attentional resources that needs to be attained before presence is achieved.	Banos 2012, Carrougher 2009, Chan 2007, Chan 2017, Das 2005,Faber 2013, Hoffman 2000a, Hoffman 2000b, Hua 2015, Kipping 2012, Li 2011, Morris 2009, Mosadeghi 2016, Mosso-vasquez 2014, Tashjian 2017, van Twillert 2007
Exclusion of hospital environment	Most patients find the clinical environment unpleasant Use of head mounted display or VR “helmets” that exclude external visual input Noise cancelling headphones exclude external auditory input Multi-Sensory inputs create a more engaging and immersive level of distraction. HMDs had varying fields of view, with some still able to see their hospital room, some were apart to exclude this. PlayMotion converted a whole room into a non-clinical, sensory environment for therapeutic play Patients report less pain when they are unable to see the wound, but there was no way to know if the effect was due to the computer simulation or just exclusion of visual cues, and whether the same effect could have been achieved with eye masks and ear plugs.	
Exposure to therapeutic environment	Ability to “visits” different nature-based virtual environments Some virtual environments designed to induce positive emotional states, some taken from domestic gaming systems where the design intent was fun rather than therapy The virtual environment provides positive reinforceng sounds, animation and direct messages SpiderWorld exposed the patients to a virtual guyana bird-eating tarantula	
Theme 2: Mirrors		
Performance feedback	Video games may provide motor learning opportunities Patients receive immediate visual and auditory feedback on their performance Patients more likely to achieve mastery of techniques with performance feedback	Abdulsatar 2013, Jahn 2012, Kho 2013, Li 2011, Parker 2016, Scapin 2017, Tashjian 2017, Voon 2016
Self efficacy and motivation	The iTech system enhanced motivation to perform Video games enhanced self efficacy, confidence and independence Children gained self control over their environment and procedures Potential for use with activity diaries, monitored by therapist Children were allowed to chose their favourite game, increasing fun Playing games led to subjective internal loss of control feelings	

Understanding rehab tasks and goals	Systems provide training and improve patients technique, providing individualised standards for comparison of treatment response COTS Gaming system are not designed for rehabilitation, but could be adapted to include specific physiotherapy goals in order to reach their full potential	
Socialisation	Opportunity to compete against others undergoing similar rehabilitation, for similar diagnoses or participate with friends and family	Jahn 2012, Li 2011, Voon 2016

Appendix 7: Systematic Review Contextual modifiers

Sub theme	Description	Primary studies
Theme 1: Plausibility of effectiveness intervention		
Attitude to intervention	The system was well developed and planned Caregivers reported less pain in their patients during iTech intervention Patients may motivate themselves by planning ahead and thinking about their exercises Patients found COTS gaming systems familiar and easy to use Some parents thought that resting rather than play was best for their children with cancer Fatigue impaired enthusiasm for the novel system Some patients reported that they were too old to use video games Patients refused to participate because they didn't understand the purpose of the game, or were anxious about side effects Some nurses reported that the intervention saved time of calming children before and after wound care, some stated that time taken to learn the game took as long as it did to coax the child to have their dressing changes Despite the positive views of the patients, the clinical results were non-significant	Abdulsatar 2013, Banos 2012, Carrougher 2009, Chan 2007, Chan 2017, Das 2005,Hoffman 2000a, Hoffman 2000b, Hoffman 2008, Hoffman 2009, Hoffman 2014, Hua 2015, Jahn 2012, Kipping 2012, Li 2011, Maani 2011a, Maani 2011b, Morris 2009, Mosadeghi 2016, Mosso-vasquez 2014, Parker 2016, Scapin 2017, Schmitt 2011, Shourab 2015, Tashjian 2017, van Twillert 2007, Voor 2016.
Evidence for effectiveness of intervention	iTech distraction explained using the gate control theory of pain Pain was reduced across most iTech distraction studies Children moved more during Nintendo Wii use then without Regular movement can reduce scar formation and loosen contractures There were fewer depressive symptoms following 7 days of PlayMotion use There was no difference in outcome measures for physical rehab on ICU Evidence for efficacy of early rehabilitation in paediatric ICU has yet to be systematically evaluated	
Gamification of intervention	Distraction or action can be gamified, but most COTS video game systems are not designed for physiotherapy Nintendo Wii Boxing used to improve core stability, upper arm strength and balance in ICU patients Balance boards were useful for proprioceptive feedback ITech may relax the patient and improve compliance with treatment, but effectiveness depends on balance of stimulus intensity	
Risk/benefit	Few safety and adverse events Discomfort most commonly due to HMD Some reports of nausea and dizziness, though those predisposed to motion sickness or seizures were excluded Some perception of concern over side effects of iTech Systems must meet infection control standards	
Theme 2: User capabilities		

Patient physical capabilities	Diverse patient groups were able to use iTech systems, including those who were bed bound and mechanically ventilated Study withdrawals were due to patients meeting their therapy goals SnowWorld has been customised to meet user requirements of patients will major burns/trauma, using HMD mounted on goggles No patients had exercised in the four weeks prior to hospital admission RCTs saw the majority of screened patents excluded Patients were exclude based on inability to use HMD, eg due to head wounds	Abdulsatar 2013, Carrougher 2011, Chan 2007, Chan 2017, Das 2005, Hoffman 2014, Kipping 2012, Li 2011, Maani 2011b, Markus 2009, Morris 2009, Mosadeghi 2016, Parker 2016, Scapin 2017, Shcmitt 2011, Shourab 2015, van Twillert 2007, Voor 2016.
Patient psychological and cognitive capabilities	Diverse patient groups were able to use iTech systems RCTs saw the majority of screened patents excluded Patients were excluded based on cognitive capacity and mental state, younger children were excluded as unable to complete questionnaires Effectiveness of distraction interventions will depend on patients coping strategy - approach versus avoidance. Patients were unwilling to complete the STAI Anticipatory fear reduced the impact of the intervention The child was not keen to try the iTech intervention as he was having a “bad day”	
Patient technology acceptance	Diverse patient groups were able to use iTech systems Patients who were recruited to the trial were younger than those who refused The system was well accepted as easy to use Exergames are popular amongst children and their peers Children were able to choose their favourite games The game choice did not appeal to all children, the older children found it less enjoyable than the younger ones Some patients refused because they feared losing control Older patients reported that they preferred the less physically straining and less complex games One report that VR was a “psychological experiment”	
Carer/staff user capabilities	Set up time did not extend procedure time Staff reported time to set up was too long	
Theme 3: Physical environment		
ITech interventions have been shown to be safe and feasible in an acute hospital environment, including adult and paediatric critical care, operating theatres and delivery suite. The system must see the requirements of space and infection control There was plenty of space on the hydrotherapy room Patients were excluded due to the need for wound care in the shower Waterproofing the system allowed it to be used through the entire dressing change, with wet debridement Patients in bed found it difficult to use the system Difficulties came from the hospital room context, distractions were frequent Hand tethered headsets, such as Oculus Rift, are not suitable for use in hospital rooms		Banos 2012, Carrougher 2009, Chan 2007, Chan 2017, Das 2005, Faber 2013, Hoffman 2008, Shourab 2015, van Twillert 2007. Voor 2016
Theme 4: Institutional context		

ITech systems were feasible for use in civilian and military institutions across the world, both urban and rural, including burns units, oncology units, operating theatres, delivery suite and in bed bound, mechanically ventilated patients on the adult and paediatric ICU The short duration of the intervention made incorporation into the hospital routine possible iTech systems were feasible for use in divers patient groups Average length of stay for patients using iTech devices ranged from a few days to many weeks Patients were discharged prior to completing the trial interventions as medically fit and no longer requiring acute/high dependency/ICU care There were fewer children meeting the inclusion criteria than anticipated The system needs to meet the hospital's financial requirements VR exercise is inexpensive and does not required specialised personnel or equipment	Abdulsatar 2013, Banos 2012, Chan 2017, Das 2005, Faber 2013, Hoffman 2009, Hua 2015, Jahn 2012, Kho 2012, Li 2011, Maani 2011a, Maani 2011b, Markus 2009, Morris 2009, Mosadeghi 2016, Mosso-vasquez 2014, Parker 2016, Scapin 2017, Shcmitt 2011, Shourab 2015, van Twillert 2007.
Theme 5: Technical context	
COTS gaming systems were easy to use and easy to learn how to use Some studies used bespoke "medical" software with COTS interface and displays, others used completely bespoke systems High tech VR systems are more effective than low tech systems Minimal visual latency reduced likelihood of cybersickness Use of a bespoke virtual interface affords flexibility and adaptation to therapeutic goals Savings made on purchasing low cost COTS systems will not result in meaningful reductions in pain Systems which are more immersive and generate greater presence are more effective at relieving pain and anxiety, even with repeated exposure Patients reported the HMD was too heavy Low tech HMDs do not obscure peripheral vision Hospital staff had to be available for each system set up The enrolment rate was slower then anticipated, mainly due to non-availability of research staff There was a detailed clean up process with disposal of components in skin contact with the patient Differences between VR and TV distraction were not significant Dressings prevented a user form accessing the Xbox Kinect motion sensor Restrictions in the sensors directional sensatevity and range prevented it being used in bed bound patients	Abdulsatar 2013, Banos 2012, Carrougher 2009, Chan 2007, Faber 2013, Hoffman 2000a, Hoffman 2000b, Hoffman 2008, Hoffman 2009, Hoffman 2014, Kipping 2012, Li 2011, Maani 2011a, Maani 2011b, Markus 2009, Morris 2009, Mosadeghi 2016, Parker 2016,, Schmitt 2011, Shourab 2015, Tashjian 2017.

Appendix 8 Patient and Public Involvement report

Thoughts and analysis on expansion of Virtual Reality Critical Care rehabilitation system following QIICC Pathfinder meeting on Friday 06 September 2013

by

Pathfinder members Lisa-Marie and Duncan Buckley

For the attention of:

Dr Charlotte Small

&

Professor Bob Stone
Director, Human Interface Technologies Team

on behalf of

University Hospitals Birmingham NHS
NHS Foundation Trust

1.0 Introduction

1.1 The aim of this report is to briefly add a patient's perspective to the presentation already given by Dr Small during the QIICC Pathfinder meeting on Friday 06 September 2013.

1.2 I am basing these thoughts upon my own personal experience which, it is assumed, is unique from the majority of inpatients to a Critical Care Department. Some of these thoughts may not be applicable in the general population of inpatients to that department, instead highlighting extreme and acute injuries that require interaction using these methods.

2.0 Background information

2.1 For this report, I feel that it is necessary to briefly cover the physical situations that I found myself in during my stay in critical care. This is so that it can be seen why, and how, I have drawn my conclusions and recommendations.

2.2 Following the car collision that I was involved in, my injuries were such that I was unable to move any of my limbs, or my head, only my eyes and my tongue. The total my injuries amounted to the following:

- Fractured skull
- Hairline fracture to one of my spine vertebrae
- Fractured sternum
- Broken ribs numbers 1, 2 and 7 Collapsed lungs
- Bruised heart
- Lacerated spleen
- Lacerated kidney
- Torn small intestine in several places
- Smashed left elbow
- Left arm radial nerve damage due to impact
- Broken left femur
- Smashed left patella (knee)
- Fractured right tibia
- Fractured right fibula in two places
- Fractured ankle

2.3 Once I was able to visually assess myself, I could see that I had an exterior fixate on my left arm which prevented any bending motion due to the damage to my elbow, exterior fixate to my left leg due to the damage of my knee and subsequent condyle displacement, and a full back slab cast from my right foot to my thigh following my tibia

and fibula breaks. My right arm was fortunately not injured in the collision, however the drugs and lack of movement had rendered it motionless.
2.4 As it was pointed out in the meeting by David McWilliams (physiotherapist), a long duration of inactivity had led to a vast amount of muscle wastage which severely prohibited any kind of physical movement whatsoever. Additionally, I had a tracheotomy which needed constant attention by the nursing team.

3.0 Thoughts and recommendations for additional virtual reality functionality

3.1 Introduction

3.1.1 I have tried to put myself in the place of a critical care patient with access to this technology, in the hope that I will be able to envisage additional uses for the equipment. Thinking back on my own stay within the Department, and long-term hospital duration, I am able to provide states of mind and considerations for use.

3.2 Diagnostic assessment

3.2.1 To reiterate the comments I made in the meeting, this technology would be very well served for aiding the clinicians to assess possible mental function following severe traumatic experiences.

3.2.2 For example, Prof Bion, during my own case needed to establish physical and mental capacity once I had been roused from my comatose state. At that stage, it was unknown whether the trauma I had received to my skull would have been the foundation for any mental impairment. Not being able to move any limbs, it was difficult to establish whether I was able to comprehend any instructions to move my arms and legs. Owing to the weakness I had developed, limb movement was restricted, which left my eyes and blinking together with my tongue, which was also difficult to move fully.

3.2.3 With current eye tracking technology, a possibility exists for integrating the motion tracking of a patient's eyes to help clinicians diagnose mental function and understanding to questions; perhaps even a yes or no answer box for the patient looking at a screen to determine questions put to them.

3.3 Communication

3.3.1 Due to the extent of my injuries, and my tracheotomy, verbal communication was also difficult. This led to an innovative two-dimensional solution my wife created, we nicknamed the alphabet board. The idea was to communicate with each other via my wife pointing to relevant letters on the board and myself to blink when the letter had been reached in order to spell out words.

3.3.2 This however, proved a difficult task to accomplish, which was a long winded method creating frustration for myself. However this concept could be translated to an electronic version for the patient which, when combined with the above eye tracking

scenario, a virtual keyboard could be created in which the patient would be visually look at which letter to select and blink to select it. To solve the problem of verbal communication, it could then be integrated with a screen reader that is synonymous with disability access for websites and home computing, which will read out any statement made by this method.

3.4 Integrated dexterity tests

3.4.1 Again, as mentioned in the meeting, the integration of passive and subtle logical puzzles within the virtual environment could also serve to not only help with patient interest, but also with clinicians obtaining patient progress and assessment.

3.5 Virtual locations

3.5.1 During the meeting on Friday, I discussed with Prof Stone the possibilities of having a small library of environments to suit different patient preferences. He advised me that there is also a forest location already in development/developed which would also complement the system, in addition to Virtual Wembury.

3.5.2 Some of the other environment I had thought of to add to this list were:

1. A stream walk through woodland with running water sounds, birdsong and other nature effects
2. A canal barge / walk among fields and woodlands
3. A town park with distant ambient sounds of traffic and bustling cityscape effects.
4. A castle walk
5. Stately homes set within gardens and grounds

3.6 Additional location

3.6.1 One additional location that I suggested in the meeting was that of the hospital where the patient was currently residing. I mention this because, as a long−term hospital patient, it became important to me to know where I was and what was around me. My immediate world became the bed I was lying in and my possessions that I had gathered. Seeing visitors attend my bedside day after day and leave for the evening without knowing what is around the corner became a mild anxious but inquisitive thought in my head.

3.6.2 I would therefore see a benefit to having a virtual hospital environment from the point where the bed is located. That is not to say that any external virtual doors would be able to be used within the simulation, but merely intended for the patient to be able to see where they are in relation to the rest of the building and what is around the corner and down the corridors.

3.7 Motivational inspiration

3.7.1 During the meeting on Friday, Lisa briefly discussed with Dr Small the use of the

system for a motivational inspiration to provide them with a sense of enjoyment for objectives and hobbies that they desired to do prior to the unfortunate circumstances that placed them within the Critical Care Department. The psychology behind this idea is to generate a driving force within the patient to want to succeed and want to get better to fully experience that desire for real outside the hospital environment. The equipment should therefore not be primarily used as escapism for the patient but also as a motivational aid to changing the mind−set of the patient in a positive way.

3.7.2 These motivational inspiration is could also have an integral progression for achieving markers of progress to enable a quicker exit from critical care. I recall during the meeting there was talk of a linked competition based system for patients against one another. Whilst I could see the advantages of this, it might also have detrimental effects on those patients who do not do particularly well and therefore only personal goals and individual achievement to better course of action for the patient.

3.7.3 An example of such motivational achievements might be:

1. Helicopter rides
2. Sporting activities linked to their injuries post release (for example it would not be wise to provide a running exercise for a patient who will be unable to run upon release from hospital but a cycling exercise)
3. Hobbies / pastimes the patient wanted to achieve prior to their own personal tragedy.

3.8 Staff progress

3.8.1 Not only can the patient be monitored and their progression tracked through their rehabilitation, but perhaps the equipment can also track the staff interaction and ensure they too are performing optimally to minimise a patient’s stay on the ward and improve their recovery.

4.0 Conclusions

4.1 This type of technology used in this application has very great potential for rehabilitation and also psychological improvement to the patient involved in acute trauma care. For my own situation, I'm sure that there will be more suggestions that I can bring to the fore once I have reminded myself about the state of mind I traversed on the state of mobility I progress through during my stay.

4.2 Patients that have each suffered acute and severe trauma will be experiencing various different mental states and attitudes that can be alleviated through this technology. As both Lisa and I discussed with Dr Small during the lunch break, a

patient that has endured that level of trauma with the knowledge that their physical, and mental, situation after hospital will be hindered possibly for the remainder of their lives will be emotionally grieving for the active life they had before (I know I did), which could lead to depression or severe anxiety if left without treatment. Helping them to deal with and change that attitude whilst in hospital will help the patient to come to terms with their situation and motivational the help and to involve a new approach to their circumstances.

Appendix 9: Virtual Wembury

The Virtual Environment Design & Construction Process – A Summary
Prof. R.J. Stone and Dr C. Qian (University of Birmingham)

Virtual Wembury is an example of a computer-generated, or "Virtual Reality" (VR) geographic environment that has been developed using a range of commercial off-the-shelf software products, coupled with bespoke, two- and three-dimensional assets, created using industry-standard design and image processing tools. Virtual Wembury, and its Virtual Burrator counterpart (Stone, 2015; Stone & Hannigan, 2014) have been developed to support a number of research projects at the University of Birmingham, ranging from hospital patient recovery and rehabilitation to the recreation of sites of historic interest ("Virtual Heritage").

Based on two real-world locations in South Devon, the environments were developed over a period of 3 years (2011-2014), and continue to be developed as new software products become available (thereby enabling the realism, or "fidelity" of the environments to be enhanced), or as new historic sites and artefacts come to light. Using the latest in commercially-available VR tools, environments such as Virtual Wembury and Virtual Burrator (Figure A1) enable end users to explore and interact with features in real-time using a wide variety of traditional computer devices (e.g. keyboard and mouse and screen) and "non-traditional devices" (Kortrum, 2008), including "wearables" such as head-mounted displays and instrumented glove controllers. In the main, integration of virtual environments with these devices is supported by the software libraries supplied with the commercial product, and updated regularly as new devices appear. However, in certain cases, unconventional interface devices require the development of additional midware in order for the user to take full advantage of the interactive qualities of the virtual environment.

Figure A1: Virtual Wembury and Virtual Burrator

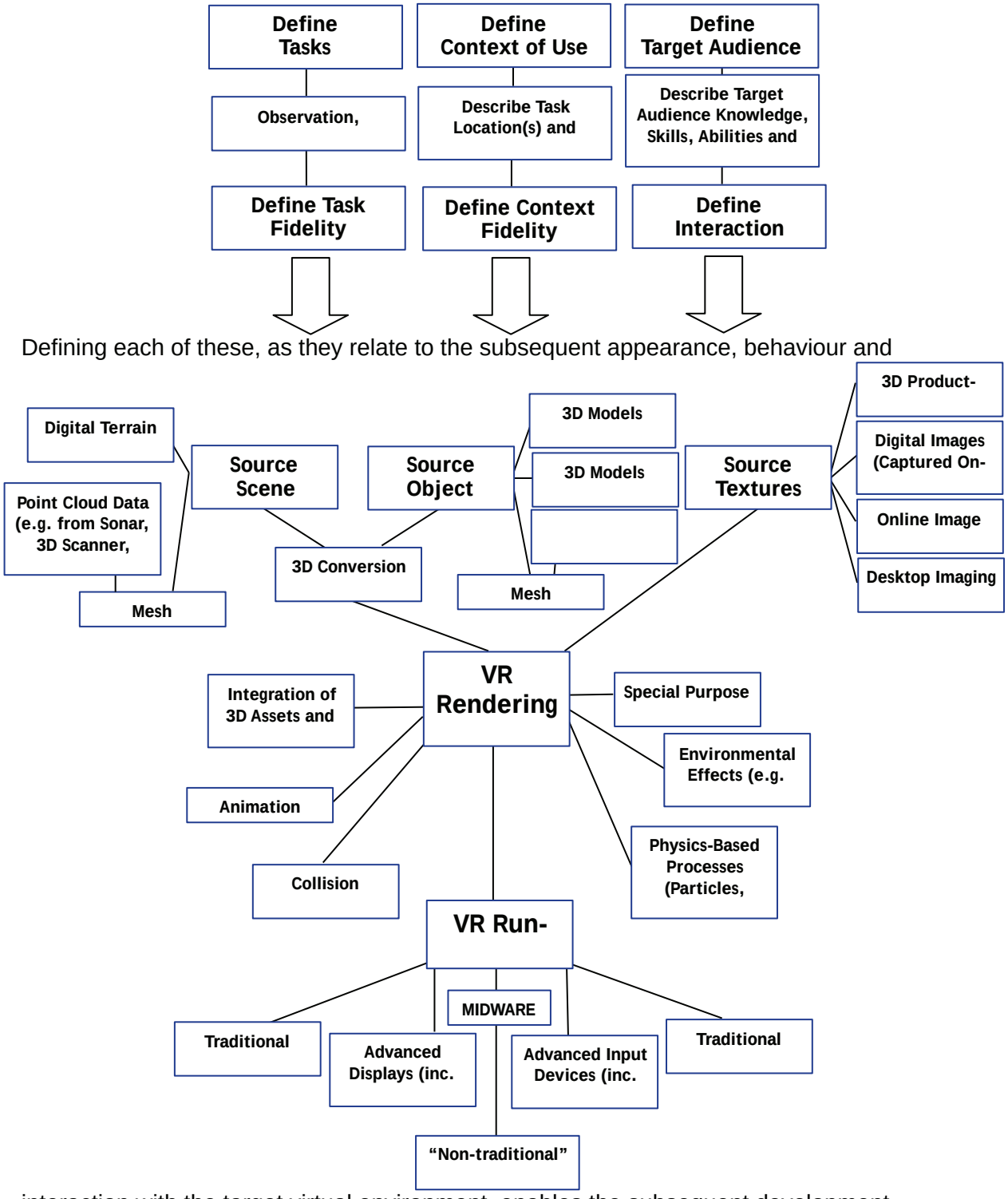
Both Virtual Wembury and Virtual Burrator environments have been “constructed” using similar processes and, whilst no formal techniques or software development standards exist within the international VR community for the production of such environments, the University of Birmingham has been instrumental in the demonstration and recording of “best practice” in the field of VR for the past 14 years, with particular emphasis on the exploitation of Human Factors knowledge in real-time, interactive 3D design (Stone, 2008; Stone, 2012).

As with other VR projects developed by the University of Birmingham team, the design process for any virtual environment begins with a fidelity analysis based on an understanding of the tasks to be undertaken, the context of use and the Knowledge, Skills, Abilities and Attitudes of the end user population (à la ISO9241, Part 210). Depending on the nature of the VR project, these early Human Factors issues can be obtained through early and iterative engagement with project stakeholders (e.g. military training specialists, healthcare professionals, educationalists, etc.), *in situ* observations of, and briefings with the end users undertaking activities in real-world settings, or structured task analyses (Figure 2).
The outcome of these activities are then used in the specification of three main categories of fidelity central to the successful design of a VR experience, especially in helping to ensure a high-level and application-centred balance of *physical fidelity* (how the virtual environment’s
component objects mimic the appearance and operation of their real-world counterparts) and *psychological fidelity* (the extent to which the end user perceives the virtual environment to be a believable surrogate for the real-world task, irrespective of how realistic it may look). These categories are (Stone, 2012 (Part One, Section 3)):

Task fidelity – the design of appropriate sensory and behavioural features within the VR task(s) that support the delivery of high psychological fidelity experiences.

Context fidelity – the design of appropriate “background” sensory and behavioural detail in virtual environments. Background effects and scenarios should complement – and not interfere with – the task being performed.

Interactive fidelity – the procurement, modification or bespoke design of appropriate data input and display technologies and their subsequent integration and use with the VR task(s) being undertaken.



Defining each of these, as they relate to the subsequent appearance, behaviour and interaction with the target virtual environment, enables the subsequent development process to be planned and executed, exploiting the most appropriate commercial off-the-shelf (COTS) software tools.

Figure A2: Virtual Wembury Fidelity Analysis and Subsequent Construction Process Flowchart

In the specific case of *Virtual Wembury* , the task fidelity category covers the definition of such virtual features as the style and sound of “walking” when exploring the virtual scenario, the level of physical fidelity (path textures, plants, etc.) close to and distant from the end user’s viewpoint, and the extent to which the end user can explore the virtual environment without experiencing unrealistic constraints and features.

For the context fidelity category, important features include the presence and change of ambient lighting and sound effects (especially in day-night cycles), the animation of plants to simulate wind effects, the accuracy of ocean and river sounds, and the presence (visual and auditory) of animals exhibiting believable behaviours.

Finally, for the category of interactive fidelity, consideration needs to be given to the type(s) of controls and displays that best suit the end user’s needs in their ability to explore and interact with features within the virtual environment. For example, for many this may simply take the form of a large, high-definition screen and Xbox-like games controller. For many patients in a hospital setting, depending on such factors as age and post-operative perceptual-motor capabilities, on-screen interaction may require a much simpler form of control – one that does not require the support or use of the whole hand (or both hands). For others, the most appropriate form of interaction may (as defined as an outcome of early Human Factors analyses; Stone, 2012), be delivered using a VR head-mounted display and part- or full-body motion tracking, or other form of wearable technology.

Once the target fidelities have been defined, then, again using the *Virtual Wembury* environment as an example, it is necessary to list the main natural and man-made features that will make up the simulated environment and to attribute levels of task and context fidelity to each feature. There are no fixed rules for attributing fidelity levels. Typically this has to be undertaken in close collaboration with end users and other stakeholders, or as part of an experimental investigation, as was the case with *Virtual Wembury* (Qian, 2015). In addition, extensive photographic, video and sound surveys need to be undertaken at different times of the day and during different seasons throughout the year.

Once these activities have been completed, it is possible to identify which of the man-made and natural features destined for reproduction within the virtual environment can

be sourced (freely or by purchasing) from online 3D and 2D (image/texture) asset databases and which of the features need to be developed from scratch (Figure A2).

The *Virtual Wembury* environment was developed using a variety of 3D modelling, image processing and run-time tools. The virtual topography of the environment was, at the time of development, based on commercially available Digital Terrain Model (DTM) data. DTM databases typically comprise dense fields of digital elevation points. In the case of the Wembury data, these were supplied (as a commercially available database from Getmapping.co.uk[3]) at a resolution of 5m and a vertical accuracy of 1m. Sometimes referred to as "Bald Earth" models, the DTM database is devoid of any trees, vegetation, buildings and other man-made features, providing developers with measurements relating only to the underlying terrain. In the case of *Virtual Wembury*, a DTM area of 3.5km^2 was obtained, covering Wembury Bay itself (including the Great Mewstone Island), the coastal path west to Heybrook Bay and Renney Rocks and a landmass area extending approximately 1km inland. The DTM model was then converted into a polygon-based mesh (Figure 3, Lower Segment), rendering the virtual terrain into a form suitable for importing into an appropriate COTS VR toolkit, in this case, *Unity3D* (https://unity3d.com/). *Unity* is a popular integrated authoring tool that supports the rapid development of both animated and interactive 3D worlds. *Unity* consists of an editing tool, supporting VE development activities such as those described here, and a powerful games engine, allowing end users to explore and interact with 3D scenarios in real time.

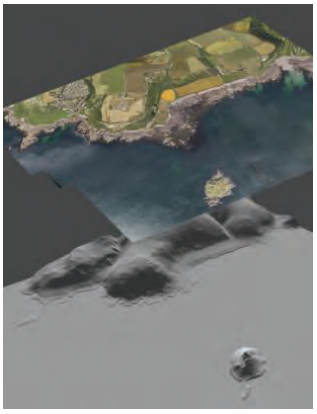


Figure A3: Converted Wembury Bay DTM Data (Lower Segment) and Corresponding Aerial Image (Upper Segment)

[3] Note that, at the time of writing, academic institutions can obtain DTM and other geometric datasets representing geographical areas, plus high—resolution aerial images free of charge from the online Digimap Collection (https://digimap.edina.ac.uk/).

The imported mesh was flat-shaded and endowed with a high-resolution texture map, itself generated from an aerial photograph of 12.5cm resolution (also sourced from Getmapping.co.uk[1]). This texture map (Figure A3, Upper Segment) provided the development team with a visual template which was invaluable in helping to locate key natural and man-made features identified during the fidelity analysis – trees, large plants, meadows, rocks, streams, buildings, paths and enclosures. The virtual counterparts of these and many other features were either sourced online, or "built" from scratch using such commercial 3D modelling (or "computer-aided design" (CAD)) toolkits as *3ds Max* or *SketchUp Pro*. Where possible (and to save development time) *SketchUp* 3D Warehouse models (https://3dwarehouse.sketchup.com/) were modified to closely approximate certain key buildings of the area, such as St Werburgh's Church, the local Marine Conservation Centre and the Old Mill.

As mentioned earlier, a series of photographic, video and sound surveys were also conducted at the Wembury Bay site. Digital photographic images were not only used for reference purposes during the development of *Virtual Wembury*. Suitably enhanced and manipulated using Adobe Photoshop or Paint.net, they also provided the development team with a rich source of detailed textures for natural and man-made objects. The recorded sounds were assessed to consider their appropriateness for the virtual scenario. Where background sounds, such as excessive noise caused by the prevailing winds, rendered an audio file unusable, alternatives were sourced online. Sounds of birdsong, waves, wind and footsteps were then programmed into the VE, to create a dynamic soundscape which varies depending on the end user's spatial location. Procedural time of day (24-hour day-night cycle) and weather effects were also implemented, using the commercial *UniSky* software system. Other effects, including particle-based sea mist (appearing in the early morning virtual scenery), were implemented using "plug-in" assets, also sourced or purchased online.

Virtual Wembury, as delivered as an integrated virtual environment hosted within the Unity engine, can be displayed to the end user using a range of devices, from head-mounted displays to LCD screens and data projectors. Exploration of, and interaction with the virtual environment can also be implemented using a range of devices, as appropriate, from basic keyboards and mice to multi-function hand controllers, gesture recognition devices and gamepads. For special cases where the virtual environment requires integrating with non-traditional input devices, then appropriate midware programs are required.

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Appendix 10: Small cycle testing to inform the early prototype development

These studies were undertaken during the development of interactive systems to alleviate acute phantom limb pain and procedure related pain in military combat casualties admitted to QEHB. All studies were undertaken in collaboration with Vishant Shingari, Jim Knight, Cheng Qian and Bob Stone.

Permission to undertake these studies was granted by the Ministry of Defence Research Ethics Committee (MODREC ref 288/PPE/11 and 289/PPE/11)

i. Testing the software

i.i Aims

1. To explore patient views on appeal of “Virtual Wembury” and “Virtual Burrator.”
2. To explore patient preference on interactive activities which could be integrated into the virtual environments.
3. To assess usability and user acceptance of the system display (Head Mounted) and interface devices (Nunchuck single handed controller and noise-cancelling headphones)

i.ii Methods

Over a two-day period, the research team approached military combat casualties on ward 412 (trauma/orthopaedic) at QEHB who had suffered multiple limb loss and were well enough to take part in the study. Written informed consent was taken prior to participation. “Virtual Wembury” and “Virtual Burrator” were demonstrated via both head mounted display and a lap top screen (Figure B1). Demonstrations lasted as long as the patients wished; to a maximum duration of 60 minutes. Following the demonstration, participants undertook a semi-structured interview. The first part of the interview appraised the virtual environment. Each was asked to rank the appeal of the two virtual environments and the appeal of activities that could be built into the virtual

environment. Patients were then invited to suggest ideas for other activities or virtual environments.

In the second phase of the interview, patients appraised the user experience of the system, using a modified System Usability Scale. The System Usability Scale (SUS) is an easy to use tool, which has been validated for the rapid and easy assessments of a broad spectrum of human-technology interface devices.(92) Free text comments allowed further explanation of allocated scores.

Figure B1: Patient demonstrations of Virtual Wembury using Head Mounted Display

i.iii Results

Data was analysed using Microsoft Excel. Five patients were enrolled in the study. Whilst it had been anticipated that ten patients would be required, data saturation was achieved with five. All the participants enjoyed using the equipment and were enthusiastic about its intended uses and potential benefits.

All participants found the coastal scenery of Virtual Wembury to be somewhat or very appealing. 3/5 patients found the reservoir scenery to be appealing. All the patients expressed enthusiasm for the virtual reality systems and intended uses, though some suggested that, with its lack of interactivity, they might become bored with it.

Nonetheless, all were satisfied with one of the virtual environments presented; Virtual Wembury.

All expressed enthusiasm for most of the suggested interactive tasks (Figure B2). Common suggestions for interactive tasks included sports and problem solving or “command" tasks. Only one patient requested a gun shooting-type game. Three participants suggested sporting activities.

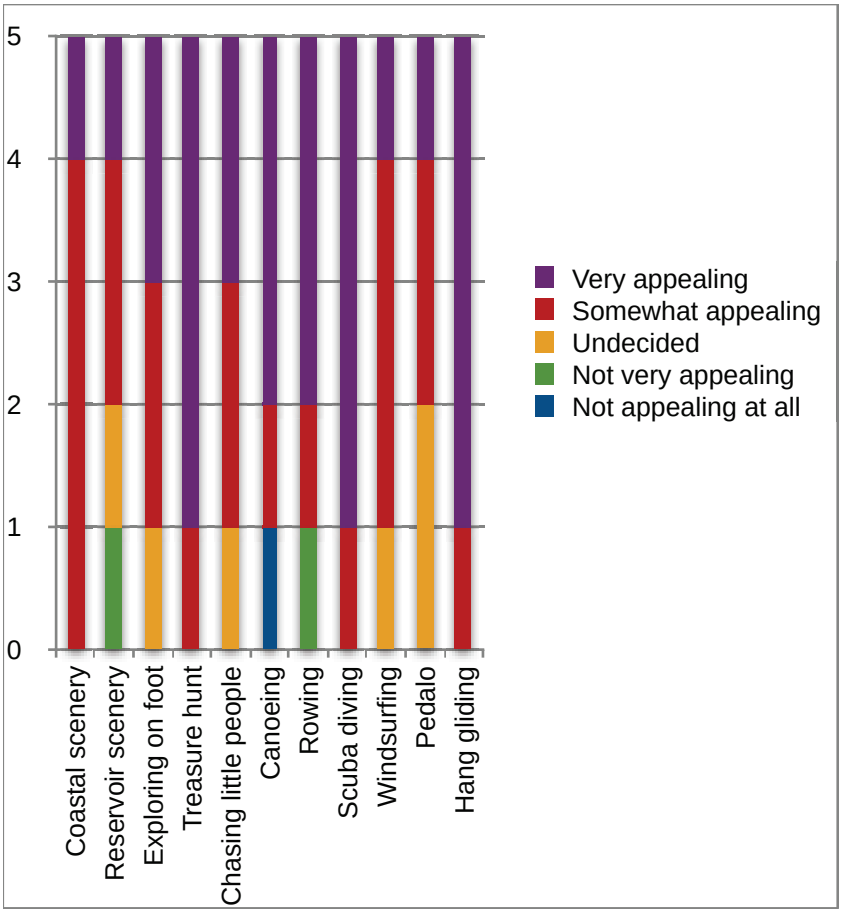

Figure B2 Patient preference for type of Virtual Environment

The usability results were largely positive (Figure B3). Due to the small number of participants, statistical analysis was inappropriate but, all participants felt they would use the system and all would recommend to others.

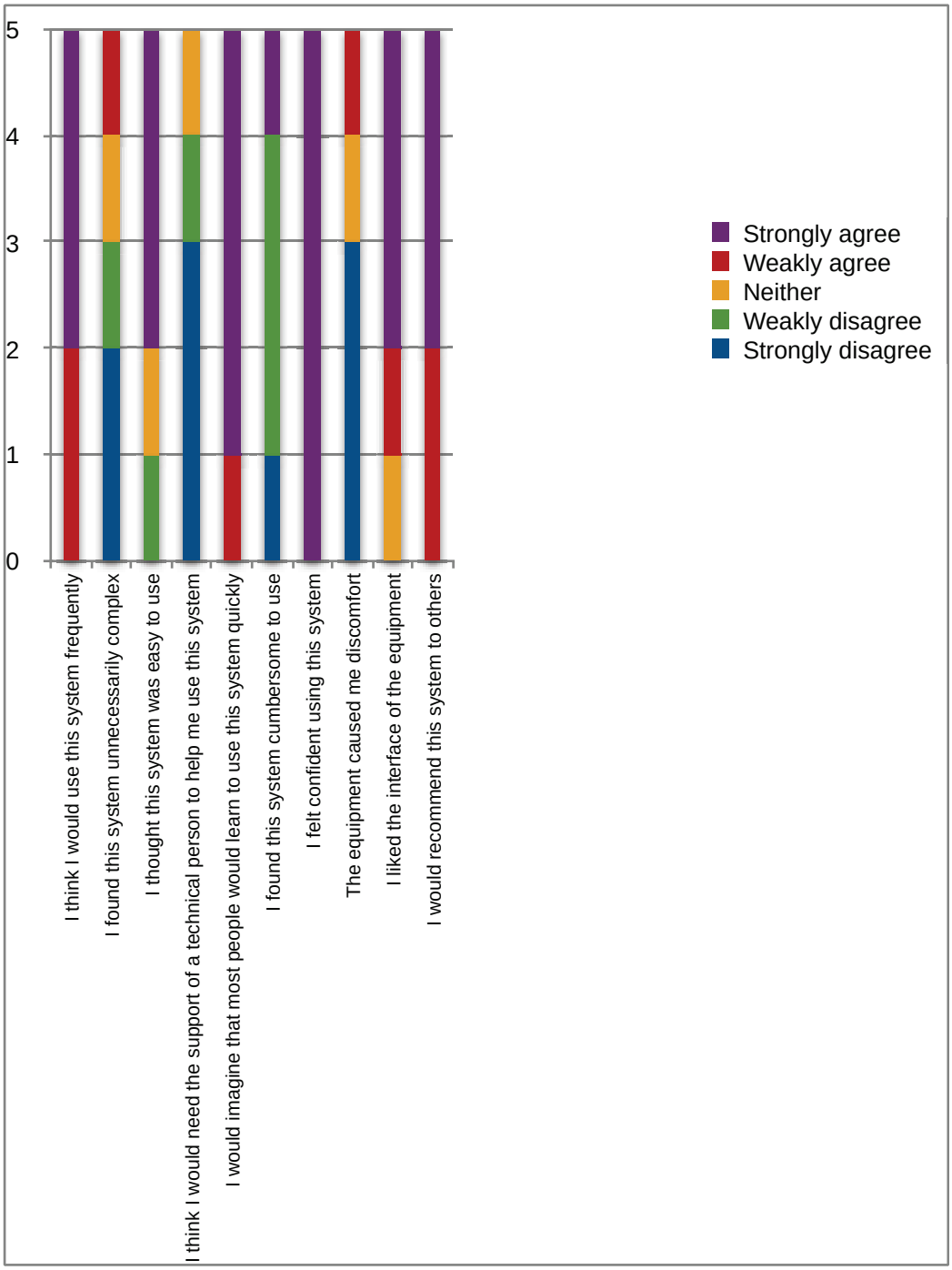

Figure B3: System Usability Scale assessment of first iTech-based prototype

Two patients reported that the head mounted goggles were bulky and uncomfortable and one patient, who was unable to sit independently, felt the headphones were uncomfortable when lying down.

i.iv Discussion

This first study of patient use of the virtual environments contradicted the anticipated findings that the military patients would prefer combat-based games, particularly given the ward had recently installed a large screen gaming system when first person combat games, such as “Call of Duty", were felt to be most popular. In addition, patients were not always keen on high-tech interface and display devices if they proved to be uncomfortable.

ii. Testing the hardware

ii.i Aims

1. To assess usability of interface devices selected to support patient interaction with the virtual environments.
2. To assess user acceptance of interface devices selected to support patient interaction with the virtual environments.

ii.ii Methods

The stakeholder group produced descriptors of the user characteristics and capabilities of battle-injured military inpatients on ward 412 at Queen Elizabeth Hospital Birmingham. These included patient specific factors that would hinder usability of devices; such as partial or complete loss of limb (actual or functional) and fatigue and those that favour usability; including familiarity with gaming systems. Generic factors, also relevant to other patient cohorts, were considered included avoidance of pathogen spread, room layout, access, power supply and availability of storage facilities. The HIT team then selected ostensibly appropriate hand controllers (Table B1) for formal usability appraisal by a sample of the target patient population. The hand controllers were integrated with a single television display device, using a navigable version of “Virtual Wembury.”

The research team approached military combat casualties with limb loss on ward 412 and written informed consent was taken prior to participation. All patients with capacity to consent to participate were approached, unless they fulfilled the following exclusion criteria:

1. No upper limb function, e.g cervical cord injury
2. Current physiological instability, e.g sepsis
3. Active infection/known colonisation with multi-drug resistant organism

Table B1 Input devices used in the Usability Studies

1	Keyboard and mouse (Logitech wireless combo MK260
2	One-handed handheld gaming controller (Nintendo Wii Nunchuck thumb controller)
3	Two-handed handheld gaming controller (Microsoft Xbox wireless controller)
4	Joystick (Speedlink)

Demographic data included computer game play experience to elucidate technology acceptance and familiarity. Using a within subject, repeated measures design, each participant trialled each of the four hand controllers in random order, over a four day period. This methodology was used to minimise potential bias caused by fatigue and learning effects.(207)

Prior to testing each device, the patients were allowed time to find the most comfortable way to use the system, whether sitting or recumbent, and to become familiar with its functions. The testing process required each participant to navigate three times from one end of the “Virtual Wembury” coastal path to the other, maintaining a central position on the path throughout. Each navigation attempt lasted approximately three minutes. An integrated user tracking system, measuring navigation trajectory and time to completion of task provided objective measures of user performance.

Following completion of the third navigation attempt for each device, subjective data were collected using a questionnaire incorporating:

1. Usability of the input device based on the VRUSE questionnaire; a tool designed specifically to assess usability of VR based systems.(208)
2. Ratings of workload based on the NASA Task Load Index (TLX).(209)
3. Discomfort rating – Borg Numerical Rating Scale.(210)

Free text comments allowed further explanation of scores, followed by a final ranking of order of preference of the four controllers.

ii.iii Results

Fifteen patients were enrolled in the study, with 12 completing all four device assessments. One patient withdrew following use of two controllers (Nunchuck Thumb controller and joystick) due to nausea induced while interacting with Virtual Wembury. Data from the 12 completed assessments was analysed.

There was a non-significant trend for navigation of the coastal path taking longer using the keyboard and mouse ($P>0.05$, paired t test), with less forward motion and more sharp turns, when compared to any of the other hand controllers.

The Xbox controller was rated as the most usable device overall (Table B2), although the joystick was awarded the highest usability scores by hand-injured patients. One way analysis of variation (ANOVA) testing showed a significant main effect on ratings of usability of the devices [$F(3,33) = 4.177$, $p=0.013$). There were significant differences on usability ratings between the Xbox and each of the other controllers (Joystick $p=0.018$, keyboard and mouse $p=0.033$, thumb controller $p=0.002$) , but no significant effects between the remaining three.

Table B2 Ratings of controller usability (1-7 Likert scale)
SD Standard Deviation

	All participants		Non hand injured		Hand injured	
	Mean	SD	Mean	SD	Mean	SD
Joystick	4.57	0.71	3.86	0.70	6.69	2.31
Keyboard and mouse	4.37	0.76	4.49	0.82	4.02	1.19
Thumb	4.51	0.81	4.40	0.91	4.86	0.98
XBox	5.93	1.65	6.04	1.83	5.61	1.81

The user preference results were seemingly influenced by hand function; in particular the joystick was least favoured by those without and most favoured by those with hand injury(Table B3). NASA TLX workload ratings were highest for the keyboard and mouse (Table B4), although one way ANOVA testing failed to demonstrate a statistically significant difference ([F (1.445,15.899) =2.246, p>0.05). Patients with hand injuries reported pain or discomfort using all devices, with no device being worse than the others.

Table B3 Ranking of user preference of each control device

	All participants		Non hand injured		Hand injured	
	Best	Worst	Best	Worst	Best	Worst
Joystick	2	5	0	5	2	0
Keyboard and mouse	1	4	1	1	0	3
Thumb	1	3	0	3	1	0
XBox	8	0	8	0	0	0

Table B4: Ratings of workload for each control device (NASA TLX)

	Mean	STDEV
Joystick	3.88	2.18
Keyboard and mouse	6.22	5.63
Thumb	4.53	2.64
XBox	3.01	1.61

i.iv Discussion

All devices except the keyboard and mouse allow the user to move forward and change direction simultaneously when using a one handed technique. This may account for the slow navigation and low usability scores of the former device by patients with hand injuries, in whom one-handed usage was unavoidable. The Xbox controller was favoured by many, even those with hand injuries who were able to adapt their position to use the device. This is unsurprising considering that use of Xbox, and similar, gaming systems is ubiquitous amongst the patient population, with most patients having use of such systems in their bed space or in the patient lounge on ward 412. This effect highlights the importance of considering the contextual environment, including institutional and social; not just the impact of injuries on usability.

iii. The end of OP HERRICK and introduction to an alternative patient cohort

Unbeknown to the research team at the time, the participants of this trial would be the last military patients to participate in the research programme. Shortly after the completion of the studies, combat operations in Afghanistan were drawn down and the reduction in combat casualty admissions rendered future clinical trials in this cohort unfeasible. Nevertheless, the programme of research continued, with an alternative patient group sought within the hospital.

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Appendix 11: InspireVR: Interactive System User Requirements

JUSTIFICATION FOR SYSTEM DEVELOPMENT
High rate of PPC amongst post-op oesophagectomy patients. One treatment strategy is post-operative incentive spirometry, prescribed hourly until discharge from hospital. Compliance and performance is patient-driven with variable reminders by therapists/nursing staff, Current devices do not provide continual reports of compliance and performance.

OUTCOME	**1. Describe the patient goal(s)?** Reduction in postoperative pulmonary complications (PPC) following major upper gastrointestinal (UGI) surgery. PPC include pneumonia, atelectasis (collapse of dependant lung tissue, usually the bases) and respiratory failure. The incidence of PPC following major UGI surgery is 60-75% and is associated with over 25% of early postoperative deaths, alongside patient morbidity and increased length of stay.
	2. Describe how achievement of the goal can be measured (how will the intervention been judged a success(1)**)** Incidence of post operative pulmonary complications

OUTPUT	**3. Describe the process of how the goal can be achieved.** Shallow, monotonous breathing resulting from immobility, pain and fatigue exacerbates atelectasis. Secondary infection of atelectatic lung can occur if this does not resolve spontaneously. Improved inspiratory effort/reduced expiratory muscle fatigue should result in: 1. Improved expectoration of secretions 2. Reduction in basal atelectasis/alveolar collapse NOTE: There is no clinical evidence to inform the type or duration of breathing exercises that result in maximum improvement in function. Different approaches are used in clinical practice to include informal “take 10 deep breaths every hour” to more formalised inspiratory muscle training. A limitation of the evaluation of many of these interventions is the inability to accurately record performance during exercises. The impact of these exercises on diaphragm and other respiratory muscle (intercostals/abdominals) has also not yet been determined, though there is ongoing research evaluating the use of non-invasive (e.g. ultrasound) based techniques to assess diapragm structure and function. For the purpose of this study a pragmatic approach will be taken whereby the chosen exercise strategy will be that used in current clinical practice, incentive spirometry. Future prototypes will be informed by the results of further trials evaluating the relative benefits of different respiratory muscle training.

TASK ANALYSIS (JSP 912)

4. Describe the task that encourages achievement of the goal.

There are a number of respiratory exercises that are carried out to improve inspiratory effort, both pre and postoperatively. These techniques include deep breathing, inspiratory muscle training and incentive spirometry. No technique has been demonstrated to be more effective than another(2).

Incentive spirometry (IS) is designed to mimic yawning or sighing; the body's natural technique for preventing alveolar hypoventilation. Non-electronic devices to aid IS include the Spiroball®. Following training, patients are encouraged to carry out IS independently.

The use of IS is recommended in combination with deep breathing techniques, early mobilisation, optimum analgesia and directed coughing following major abdominal surgery (3). A recent Cochrane Systematic review (4) concluded that current evidence did not support the use of IS (or sustained maximal inspiration) for prevention of PPC in UGI surgery. They did state that the evidence analysed was poor quality and recommended larger scale randomised controlled trials. A criticism of many of the trials was a lack of standardisation of technique and ability to monitor compliance. This was particularly the case for preoperative training, which, being carried out at home, was unsupervised following an initial training session for each patient. Lack of efficacy may have been due, therefore, to failure to carry out the exercises as prescribed.

The aims of the interactive task would be to:

1. Enhance performance during IS:
    - Provide performance feedback
    - Provide incentive to improve
    - Provide training/reminders/tips on technique

2. Enhanced compliance with an IS presciption:
    - Provide reminders/prompts

3. Provide clinician feedback re compliance and performance

5. Describe the rules and constraints of the above task. Time limits etc.

Based on the American Association for Respiratory Care Guideline: Incentive Spirometry 2011 (3)

- Sit in an upright position.
- Exhale normally.
- Place lips tightly around the mouthpiece.
- The patient inhales at a slow, steady rate.
- Feedback to the patient is provided as a measure of flow or volume.
- Breath hold for 3 - 5 seconds.
- Normal exhalation

There is no evidence for the frequency with which IS should be carried out. Regimes applies to clinical trials include:

- Ten breaths every one/two hours whilst awake.
- Ten breaths, five times a day.
- Fifteen breaths every four hours

The breaths do not have to be in succession, the patient may rest for a few seconds between each breath.

The target volume of the breaths needs to be individualised to the patient. There is no published date to track the progress of lung volumes in this cohort. Local data suggests that patients' maximum inspiratory capacity falls to approximately 500ml, from a baseline of approximatetely 2000ml. The rate of return to normal, and whether preoperative values are even acheived, has also not been determined. A pragmatic design of the software/game algorithm is suggested, which will be modified based on pilot patient data during early feasibility testing.

6. Describe how performance of this task can be assessed.

1. Compliance with prescribed IS schedule: number of attempted sessions, number of completed sessions.
2. Respiratory parameters to monitor baseline and response to intervention
    - Vital Capacity (Maximum inspiratory volume)
    - Forced expiratory volume in 1 second (FEV1)
    - Inspiratory and expiratory muscle strength (may need alternative device to measure this)
3. Performance during IS sessions:
    - Maximum inspiratory flow rate
    - Inspiratory capacity (volume)
    - Duration of breath hold

7a. USER CHARACTERISTICS: PATIENT (Please provide a representative range)	
Demographics	
Age	18-100
Gender	Both
Height (cm)	120-210
Weight (kg)	40-180
Language	All
Socioeconomic status	All
Employment	All
ANTHROPOMETRICS **Physical capabilities: *Based on assumptions made that patient was fit for surgery and able to consent to participation in InspireVR/ReVERe Breathe trial***	
Upper limb strength (Hand/Arm)	Normal/mild impairment
Upper limb movement (Hand/ Wrist/Elbow/Shoulder)	Normal/mild impairment
Lower limb strength (Foot/Leg)	Normal/mild impairment
Lower limb movement (Foot/Ankle/Knee/Hip)	Normal/mild impairment
Neck movement	Normal/mild impairment
Eye movement	Normal/mild impairment
Mouth/tongue movement	Normal/mild impairment
Speech	Normal/mild impairment
Skin integrity	Poor - following chemotherapy
Tissue oedema	Some/mild
Mental capabilities	
Hearing	Normal/mild impairment
Visual acuity	Normal/mild impairment/corrected
Field of view	Normal/mild impairment
Colour perception	Normal/impaired
Olfaction	Normal/impaired
Concentration	Normal/mild impairment
Coordination	Normal/mild impairment
Cognition	Normal/mild impairment

Alertness	Normal/mild impairment
Orientation	Normal/mild impairment
Familiarity with interactive technologies (self efficacy)	Varied - mixed demographic, many will be over 60.
Attitudes towards interactive technologies	Varied - mixed demographic, many will be over 60.
Equipment in contact with the patient (permanent/intermittent)	
Monitoring	ECG, NIBP, ABP, SO2
Therapeutic	O2, epidural catheter, intravenous line (upper limbs/hands, intraarterial catheter (wrist)

7b. USER DESCRIPTION: CARER
Familiarity with interactive technologies: Some familiarity with Virtual Wembury (See results of ReVERe Sleep).
Attitudes towards interactive technologies: Mixed (see results of ReVERe Sleep)

8. ENVIRONMENTAL CONTEXT
Floor plan
Room contents – some permanent and some intermittent/temporary.
Access – position and size of doors/corridors
Power supply Yes - standard
Temperature (controlled/uncontrolled)
Light – including windows - natural light in only a few bedspaces, most UGI patients in “inner ring”
Humidity - standard
Ambient noise - approx 60dB but frequently louder
ITech equipment storage facilities available. ICU Research Officer

Appendix 12: InspireVR Risk Analysis

Task	Hazard	Foreseeable sequence of events	Hazardous situation'	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
InspireVR placed into patient bedspace	Moving and handling	Patient carer, patient or visitor moves device in such a manner that requires lifting and excessive use of force	Musculo-skeletal injury to patient carer or visitor. Injury to patient	P, PC, V	Probable	Serious	12	InspireVR has been designed to minimise user load during moving and handling. Device training on moving and handling will be provided to patient carers. Moving and handling instructions will be provided with each InspireVR system.	3
	Damaged components	System receives structural damage on movement	Sharp edges of broken device cause personal injury	P, PC, V	Remote	Minor	4	Patient under constant supervision from nursing staff who can remove system from the bedspace should it become damaged. Trial participation is contingent on adequate patient cognition and cooperation - patients will be able to inform carers should damage occur. A member of the research team will inspect the system on a daily basis.	2
	Electro-magnetic energy	InspireVR becomes contaminated with water/other liquid	Electric shock	P, PC, V	Remote	Critical	8	Surge protection incorporated to mains power lead, to trip in the event of short circuit.	4
	Power loss/not charged	Device not placed onto charge during previous storage period			Occasional	Minor	6	Laptop is to be run on mains power to provide full graphical and processor power. User guide check list to include section on charging of laptop during down time.	2
InspireVR set up by user	System fault	InspireVR fails to switch on due to software malfunction - Microsoft Windows update, Operatig system crash, Midware failure	Patient failure to complete Incentive Spirometry (IS)	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2

Task	Hazard	Foreseeable sequence of events	Hazardous situation'	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
	System fault	System unable to connect to MiFi (WiFi)	Patient failure to complete Incentive Spirometry (IS)	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2
	Electro-magnetic energy	Short circuit while plugging in USB	Electric shock	PC	Improbable	Serious	12	In the event of short circuit due to the insertion of USB laptop will reboot automatically.	3
	Electro-magnetic energy	Electric shock from power adapter	Electric shock	PC	Improbable	Serious	12	Cease use of power adapter and call technical support for a replacement to be installed.	3
	System function	Failure to connect to MODEM	Patient failure to complete IS	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot the WiFi Modem 4. Check the signal strength of the WiFi Modem in the bed-space. 5. Over the phone/on site technical support available for duration of the study	2
Incentive spirometry carried out by patient	Poor device usability	Patient unable to complete IS using InspireVR. Patient physically or mentally unable to use device.	Patient failure to complete IS	P	Probable	Minor	12	1. InspireVR has been developed using a human centred design process. 2. Spiroball provided at all times to allow alternative method of delivering IS. 3. Second InspireVR system available for use. 4. User instructions provided to guide reboot. 5. Over the phone/on site technical support available for duration of the study	2

Task	Hazard	Foreseeable sequence of events	Hazardous situation'	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
	No output from spirometer	Patient unable to complete IS using InspireVR	Patient failure to complete IS	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2
	Device element failure	No audio		P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2
	Device element failure	InspireVR crashed when in use	Patient failure to complete IS		Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2
	Biological contaminant	Patient bodily fluids come into contact with system, e.g. patient expectorates into spirometer	Infected bodily fluids contaminate surfaces and enter spirometer mouthpiece. Potential cross-contamination of next patient user.	P	Probable	Serious	12	1. Device surfaces can be decontaminated using 70% isopropyl alcohol. 2. Single use bacterial-viral filters for spirometer mouthpiece. 3. Internal parts of spirometer mouthpiece can be autoclaved.	3

Task	Hazard	Foreseeable sequence of events	Hazardous situation'	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
Inspire VR in bedspace when not being used for IS	Data Security	Theft/loss of laptop	Patient data stored on laptop compromised	P	Improbable	Serious	12	Secure laptop to stand by means of physical lock. Encryption of patient data (.txt files) on laptop.	3
	Data Security	IS performance data downloaded for malicious purpose via USB/ external data storage system	Patient data stored on laptop compromised	P	Improbable	Serious	12	Install software to deactivate non-essential USB ports, and override using password. Install enterprise software to lock all access to patient data (.txt files) that contain patient data. Only allow access programs relating to the REVERE Breathe software.	3
	Data Security	IS performance data downloaded for malicious purpose via WiFi	Patient data stored on laptop compromised	P	Improbable	Serious	12	WiFi dongle attached to the laptop is set to WPA-2 wireless standard. Data sharing protocol is disabled. Use of Windows firewall to block external internet access.	3
Inspire VR moved into new bedspace/ placed into storage	Biological contaminant	InspireVR incorrectly decontaminated between patient use	Transfer ot biological pathogen between patient/ other user	P, PC, V	Occasional	Serious	9	External surfaces of system components can be decontaminated using 70% isopropyl alcohol wipes, in line with manufacturer instructions and NHS infection control guidelines. In the unlikely event of contamination of the spirometer by serious respiratory pathogen* (e.g mycobacterium tuberculosis), the spirometer can be sterilised as per manufacturer instructions. *Know active respiratory infection, or other infection with multi-agent resistant organism is a contraindication to major surgery	3
	Storage conditions	Device stored at extremes of temperature - too hot/too cold	Device failure	P	Improbable	Minor	2	Device to be stored on the critical care units, within bedspace or in medical device storage facility in controlled environmental conditions.	2

Occurence					
Frequent 5	Low 5	Medium 10	High 15	High 20	High 40
Probable 4	Low 4	Medium 8	Medium 12	High 16	High 32
Occasional 3	Low 3	Low 6	Medium 9	Medium 12	High 24
Remote 2	Low 2	Low 4	Low 6	Medium 8	High 16
Improbable 1	Low 1	Low 2	Low 3	Low 4	Medium 8
Severity	Negligible 1	Minor 2	Serious 3	Critical 4	Catastrophic 8

Occurrence/Severity table: From http://www.greenlight.guru/hubfs/Sales_Material/gg_guide_to_risk_management.pdf

Severity level	**Description**
Critical	Loss of limb, life-threatening injury
Major	Severe, long-term injury, potential disability
Serious	Short-term injury or impairment requiring additional medical intervention to correct. Includes psychological sequelae of personal data loss.
Minor	Slight inconvenience to user, little to no effect on product performance, non-vital fault
Negligible	No or negligible risk to patient

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