The feasibility of implementing a novel electrical stimulation device in the self-management of hand burn pain

Katrina Liddiard

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The feasibility of implementing a novel electrical stimulation device
in the self-management of hand burn pain
Katrina Liddiard

A report submitted in Partial Fulfilment of the Requirements for the Award of Bachelor of Health Science, Honours, Faculty of Health, Engineering and Science, Edith Cowan University.
Submitted March, 2015

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The feasibility of implementing a novel electrical stimulation device in the self-management of hand burn pain

Abstract

Burns are widely acknowledged as one of the most painful injuries experienced, and poorly controlled pain following burn injury has been linked to reduced psychological adjustment, lower quality of life, and increased risk of developing a chronic pain state. Transcutaneous electrical nerve stimulation has been used for pain relief in a range of medical conditions, and may have the potential to reduce pain and analgesic consumption for burns patients. The burn care environment presents unique challenges to the introduction of new interventions, and the feasibility of introducing a novel form of electrical stimulation into this environment has not been tested.

This single case experimental design study explores the feasibility of engaging burns patients and staff in the use of a novel electrical stimulation device, which may offer solutions for some of the limitations previously identified with traditional electrical stimulation. Four outpatients, with minor hand burns, self-applied the device over a period of up to 13 days. Multiple sources of data were gathered, both at home, and in the clinic during wound care procedures; from participants, nursing staff and the researcher, to obtain different perspectives.

Each case was analysed separately regarding changes at the time the device was introduced. Data collected included ratings of pain, anxiety and confidence in the ability to manage their own pain. Participant and staff ratings on ease of use and interference of the device with regular activities were also explored, along with the level of motivation to use the device. Analysis of trends and relationships between multiple data sources demonstrated that, for these participants with hand burns, the self-application of a novel electrical stimulation device was feasible. Recommendations for further research and clinical practice are outlined.

Katrina Liddiard
Dr Janet Richmond
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1 INTRODUCTION

1.1 THE PROBLEM

A burn injury is widely acknowledged as one of the most painful experiences (Connor-Ballard, 2009; Lončar, Braš, & Mičković, 2006; Patterson, Hoffman, Weichman, Jensen, & Sharar, 2004). Patients often suffer significant pain and distress through both the injury and the recovery processes, such as wound management and rehabilitation (Fauerbach, Pruzinsky, & Saxe, 2007; Ferguson & Voll, 2004; Solowiej, Mason, & Upton, 2010; Soon & Acton, 2006). Pain can be considered a stressor, activating biological stress mechanisms including increased heart rate and breathing, increased blood pressure and metabolic rate (Connor-Ballard, 2009). This stress has an adverse effect on the immune system, producing negative consequences for wound healing, as shown by Kiecolt-Glaser, Marucha, Mercado, Malarkey, & Glaser (1995) through experimental research in humans. Further, a longitudinal study that reviewed 122 burns patients up to two years after discharge from hospital, suggested that acute pain during early wound care may impact on long term psychological adjustment (Patterson, Tininenko, & Ptacek, 2006). Current pain management methods in burns are weighted towards medication (Stoddard et al., 2002; Wiechman Askay, Patterson, Sharar, Mason, & Faber, 2009), however, many analgesics, in particular opioids, carry unpleasant side-effects that can slow rehabilitation and recovery (Ferguson & Voll, 2004; Richardson & Mustard, 2009; Szeto & Nyquist, 1983).

Hand injuries are common among burn admissions because of the involvement of hands in most functional tasks that can cause burn injuries, for example cooking, and also because they are frequently used protectively, for example covering the face when confronted with a fire or explosion (J. Edwards & Mason, 2013). While hand burns on their own are rarely
life-threatening, they can have a significant impact on functional outcomes following injury, so wherever possible full hand function should be maintained after burn injury (Umraw, Chan, Gomez, Cartotto, & Fish, 2004). Paradoxically, the therapy and wound care procedures* that are aimed at achieving functional recovery are often the cause of considerable pain (Richardson & Mustard, 2009; Summer, Puntillo, Miaskowski, Green, & Levine, 2007; Wiechman Askay et al., 2009). The high density of nerve endings in hands is one potential cause of the high levels of pain experienced following hand burns (J. Edwards, 2001). Partial-thickness burns involve both the epidermal and dermal tissues. Partial-thickness injuries to the hand can be extremely painful as a result of both the exposed nerve endings (Connor-Ballard, 2009), and the oedema that is quickly established following a burn injury. This oedema has a direct impact on pain, as well as contributing to pain through a cycle of immobility, stiffness and loss of function (J. Edwards & Mason, 2013). Additionally, burns to the hands may have a significant impact on quality of life, affecting social reengagement through scarring and deformity, and functional recovery through restricted hand use (Williams et al., 2012).

Although representing only a small surface area, hand burns are considered complex injuries because of the high potential for pain and impact on quality of life, (J. Edwards & Mason, 2013). Minor, partial-thickness hand burns are frequently seen in burns units; can be extremely painful; and have the potential to significantly impact on quality of life outcomes, therefore improved options for pain management in this population warrant further investigation.
* Wound care procedure – describes an invasive procedure usually carried out by nursing staff, and consisting of the removal of old dressings; cleaning of the wound; debridement of any dead tissue; and application of new dressings.
1.2 SIGNIFICANCE AND SCOPE

Pain has historically been considered a linear or direct measure of the amount of tissue damage (Lončar et al., 2006), however, pain is now becoming widely accepted as a complex and adaptive concept (Brown, 2006; Phillips et al., 2008; Stoddard et al., 2002). As well as representing the extent of tissue damage, the experience of pain reflects emotional and cognitive processing of this nociceptive input (Richardson & Mustard, 2009; Stoddard et al., 2002; Tunks, Crook, & Weir, 2008). Injury, disease or surgery may cause pain in the first instance, but when the pain extends beyond the timeframe generally accepted for a condition, it is termed chronic or persistent pain. Chronic pain can cause major disruption to the overall well-being of an individual, their family and society as a whole (Gureje, Von Korff, Simon, & Gater, 1998).

A report utilising Australian Bureau of Statistics National Health Survey data (Access Economics, 2007), estimated that 3.2 million Australians were living with chronic pain in 2007, and that this figure is likely to increase to 5.0 million by 2050 if left unchecked. The report estimated the annual cost of chronic pain in Australia to be around $34.4 million in 2007 (Access Economics, 2007). Of particular concern from a public health perspective, is that chronic pain is over-represented in populations that may already be disadvantaged or marginalised. This includes older Australians; individuals living with a profound or severe disability; those from lower socioeconomic groups; individuals with a lower level of education; those with mental health conditions, in particular depression; those in receipt of a government pension or benefit; and the unemployed (Blyth et al., 2001; Croft & Rigby, 1994; Hagen, Zwart, Svebak, Bovim, & Jacob Stovner, 2005; Henderson, Harrison, Britt, Bayram, & Miller, 2013; Tunks et al., 2008). Many of these disadvantaged populations are also over-represented in burn injuries (Edelman, 2007; J. Edwards, 2001), due to their
reduced mobility or cognitive ability, and because they are therefore less able to avoid danger, or more likely to pursue risky behaviours.

A survey of 358 burns survivors (Dauber, Osgood, Breslau, Vernon, & Carr, 2002), identified that 11 years after injury, on average 52% of respondents still suffered ongoing or chronic pain. The presence of poorly-controlled acute burn pain has been shown to increase the likelihood of developing chronic pain and associated depression (R. R. Edwards et al., 2007), and has been linked to an increased incidence of post-traumatic stress disorder (Summer et al., 2007).

This study contributes to the understanding of the acute pain experience for the patient with minor partial-thickness hand burns, and some of the factors that may impact on their ability to engage with a novel form of self-managed pain relief, supported by the occupational therapist.

Occupational therapists (OTs) in the burn care environment are commonly concerned with an individual’s ability to reengage in life following an often life-changing event, intervening in a variety of occupational areas such as self-care, work or leisure (Pessina & Orroth, 2014). The lengthy process of rehabilitation following a burn injury can, for many, become a form of occupation in its own right, learning to incorporate dressings procedures and rehabilitative tasks into their standard self-care tasks, and developing techniques to adapt their usual self-care routines to work around bulky dressings or less mobile body parts (Pessina & Orroth, 2014). Observing a patient’s performance during self-care tasks and then adjusting the way that they carry out the task, or adapting environmental factors to encourage engagement in occupation is the particular domain of the occupational therapist. One of the likely barriers to engagement with a new device in the highly stressful burns environment...
environment will be the motivation of patients and staff to engage with and continue to use the device. Occupational therapists offer a unique and valuable perspective on the human construct of motivation.
1.3 RESEARCH HYPOTHESIS AND QUESTIONS

Burn care team members encourage patients to make effective use of pain medications, however, these carry a range of side-effects such as nausea and constipation, and may limit function (Ferguson & Voll, 2004; Fiorelli et al., 2012; Hewitt et al., 2014; Richardson & Mustard, 2009). Self-managed pain relief choices in burn care are limited. Non-invasive methods such as relaxation may be self-administered, but do require a degree of training and practice for proficient use (Ferguson & Voll, 2004), so the introduction of a method of non-invasive, self-administered pain relief that can be taught rapidly and carries minimal side-effects, may improve the sense of self-control over pain for patients and provide overall benefit (Bachiocco, Morselli, & Carli, 1993; Wiechman Askay et al., 2009).

A novel transcutaneous electrical nerve stimulation (TENS) device has demonstrated benefits in post-operative orthopaedic populations in randomised controlled and clinical trials (Gorodetskyi, Gorodnichenko, Tursin, Reshetnyak, & Uskov, 2007; Nigam, Taylor, & Valeyeva, 2011). These benefits include reduced post-operative pain, oedema and analgesic consumption, while increasing range of movement in hip, knee and ankle surgery (Gorodetskyi et al., 2007; Gorodetskyi, Gorodnichenko, Tursin, Reshetnyak, & Uskov, 2010; Nigam et al., 2011). Reduction of pain and oedema, while increasing range of movement, are all primary goals of hand therapy post-burn (Amis & Klein, 2012), thus, replication of these physiological changes would be clinically beneficial in the burn injured population.

The burn care environment, whether an inpatient ward or an outpatient clinic, has several unique features as compared to other medical environments. The most apparent is the rigorous infection control requirement to exclude pathogens where the protective skin barrier is lacking. Without adequate respect for infection control procedures in a burn care
environment, the introduction of a new intervention may increase the risk of deeper wounds, delaying healing and increasing morbidity and scarring (Baker, Townley, McKeon, Linge, & Vijh, 2007; Gauglitz, Shahrokhi, & Jeschke, 2012).

Another important feature of the burn care environment is the necessity for potentially painful and anxiety-provoking interventions such as wound dressing changes and rehabilitation (Stoddard et al., 2002; Wiechman Askay et al., 2009). In the burns environment, the relationship between patient and staff often continues over an extended timeframe and requires a considerable amount of trust. This relationship may be affected by a painful and unpleasant experience (Lončar et al., 2006; Stoddard et al., 2002), potentially causing reduced compliance with treatment, and further pain and anxiety (Richardson & Mustard, 2009). Pain and anxiety will be discussed in greater detail in the next chapter.

Based on literature reviewed in the following section regarding the potential positive effects of electrical stimulation, there is good reason to hypothesize that the self-application of a novel electrical stimulation device, non-invasive interactive neurostimulation (NIN), would be beneficial in a burn care environment, with patients suffering small, partial-thickness hand burns (see Appendix A for a scientific argument overview). Prior to exploring efficacy, however, the potential impact of introducing NIN into the already challenging burn care environment must be investigated. The primary research hypothesis was therefore:

*The self-application of a novel electrical stimulation device would be feasible in a burn care environment with patients suffering small, partial-thickness hand burns.*

For this study, feasibility is defined as an assessment of whether the proposed system is operationally viable and will fit in with current procedures without causing harm. Therefore, the primary concerns of feasibility for this study were that the intervention:
a. can be physically achieved without undue interference to current processes, or causing application problems for patients and staff

b. does no harm, by causing the patient increased anxiety or pain; reducing the patient’s confidence in their ability to manage their pain; or increasing the risk of infection, and

c. is sufficiently motivating for patients and staff to use it.

To address this issue of feasibility, the following secondary research questions were explored within each individual case study:

1. Did pain or anxiety increase in response to the introduction of NIN?

2. Did the patient’s confidence in their ability to manage their own pain change in response to introduction of NIN?

3. Did NIN interfere with the work of nursing staff or with patient activities?

4. Was the device easy to use?

5. Was the patient motivated to use the NIN device?

6. Is the NIN compatible with post-burn infection control procedures?
2 REVIEW OF THE LITERATURE

2.1 BURNS AND PAIN

2.1.1 Burn care environment

The situation in which burns patients find themselves, usually unexpectedly, is one that is often without parallel. Their sense of control over their pain, their healing and even their daily schedule is quickly usurped (Stoddard et al., 2002; Wiechman Askay et al., 2009; Wikehult, Hedlund, Marsenic, Nyman, & Willebrand, 2008). All this occurs in a situation where they are in pain, on medication, and dealing with reduced functional ability (Wiechman Askay et al., 2009), thus the relationship that they have with the burns staff becomes vitally important for recovery and return to normal life. Helping patients to gain a degree of control in this environment can provide benefit, both psychologically and in their experience of pain (Fauerbach et al., 2007; Wiechman Askay et al., 2009).

One of the most prominent features of a burn injury is the experience of pain, which initially arises from tissue damage but may also be further inflicted by the staff who are providing vital care (Fauerbach et al., 2007; Lončar et al., 2006; Stoddard et al., 2002; Ulmer, 1997; Wiechman Askay et al., 2009). Negative experiences of pain during dressings or rehabilitation procedures, can lead to a loss of confidence, damaging the relationship between patient and staff, and eventually leading to reduced compliance with treatment (Lončar et al., 2006; Stoddard et al., 2002). The provision of adequate pain relief can be challenging because the requirement for analgesia varies widely between patients (Choiniere, Grenier, & Paquette, 1992), and pain management plans need to be individualised (Richardson & Mustard, 2009). The distress and anxiety caused by pain can have an impact on patients, and in many instances their family members, which in turn may
have a negative impact on the perception of pain (Lončar et al., 2006; Stoddard et al., 2002; Ulmer, 1997). This will be discussed in greater detail later in the chapter.

Depending on the circumstances surrounding the event, the initial injury may also have caused considerable emotional trauma (Stoddard et al., 2002), and even patients with minor burns may experience psychological issues up to 6-8 months after hospitalisation (Ulmer, 1997). However, patients who are engaged in their care, and make efforts to have some influence over their rehabilitation may adapt better to life outside of the hospital (Dahl, Wickman, & Wengström, 2012; Ulmer, 1997).

2.1.2 Hand burns

In burn admissions, hands are more frequently represented than other body areas (Cartotto, 2005) because they are used protectively, and are involved in most functional tasks, exposing them to greater risk (J. Edwards & Mason, 2013). Considerable pain is elicited by the hand therapy and daily activities aimed at achieving functional recovery, however, full hand function needs to be maintained if possible to ensure the best outcome following hand burns (Umraw et al., 2004). Small, partial-thickness hand injuries can cause significant pain, due to the high density of exposed nerve endings in hand burns (Connor-Ballard, 2009; J. Edwards & Mason, 2013).

Following burn injury oedema develops immediately and over subsequent days, as fluid leaking from microvessels cannot be transported out of the area rapidly enough by lymphatic vessels (Omar, El-Badawy, Borhan, & Nossier, 2004). In confined areas such as in hands, the additional pressure placed on tissues by oedema is known to contribute both to pain, and to poorer hand function as a result of reduced mobility (J. Edwards & Mason, 2013). Oedema remaining in tissues for an extended time, along with immobility, can
impact on hand range of movement post-burn, as interruption to normal tissue gliding may lead to the formation of adhesions (Omar et al., 2004).

Hand burns are considered complex injuries (J. Edwards & Mason, 2013) as they can have a significant impact on quality of life, social reintegration and functional ability (Williams et al., 2012), and may be extremely painful regardless of burn size.

2.1.3 Pain management in burns

Burn injured patients commonly experience pain from several different sources (Connor-Ballard, 2009; Fauerbach et al., 2007; Stoddard et al., 2002; Wiechman Askay et al., 2009). A baseline level or background pain, may be overlayed by the procedural pain experienced during wound care or rehabilitation, and other breakthrough pain which may relate to touch or movement causing mechanical hyperalgesia (Stoddard et al., 2002; Summer et al., 2007), but which may also be experienced without an obvious cause (Summer et al., 2007; Wiechman Askay et al., 2009).

Thermal injury causes an inflammatory response which is considered the most likely mechanism of the initial severe pain experienced in burn injury (Stoddard et al., 2002). This inflammatory response usually resolves in time, therefore burn pain is often assumed to be a temporary problem (Patterson et al., 2006). However, the degree of pain experienced by burns patients is highly individual and influenced by pain perception, which is modulated by the central nervous system (Richardson & Mustard, 2009; Stoddard et al., 2002). Thus the inflammatory response and resultant nociceptive input is only part of the pain mechanism. If burn pain is allowed to continue unchecked, as with other forms of acute pain, central nervous system adaptation may occur in response to the repeating or ongoing stimulus. This may result in even greater elevation in hyperalgesia and risk the development of a chronic
pain state, related depression and further suffering (Lončar et al., 2006; Mahar et al., 2012; Richardson & Mustard, 2009; Stoddard et al., 2002).

The pain of a burn injury may not correlate directly with the size or depth of the burn (Richardson & Mustard, 2009; Stoddard et al., 2002), and it is generally accepted that small, partial-thickness burns have the potential to be extremely painful (Connor-Ballard, 2009). In a seminal study, Ptacek et al. (1995) explored psychological adjustment following burn injury, and found that regardless of the total body surface area* burned, or length of hospital stay, procedural pain during hospitalisation was the strongest predictor of psychological adjustment one month after leaving hospital.

Often the management of burn pain is primarily pharmacological, but in some instances analgesic medications cause side effects such as constipation, itching, nausea or dizziness (Dahl et al., 2012; Hewitt et al., 2014; Richardson & Mustard, 2009; Wiechman Askay et al., 2009) and may not be sufficient to fully eliminate pain (Wiechman Askay et al., 2009). Studies support the view that the best pain outcomes for burns patients can be achieved when the approach is multi-modal, including pharmacological and non-pharmacological options (Wiechman Askay et al., 2009), and multi-disciplinary, with the relief of pain placed as a high priority by all staff (Richardson & Mustard, 2009).

To establish a clearer picture of the neurophysiological processes at play both for acute burn injuries and the chronic pain that some patients may then develop, an understanding of the current paradigm of pain is essential and will now be examined.

* NB/ Total body surface area, or TBSA determines percentage of body burned based on the Lund-Browder chart, where 1% TBSA equates to roughly the surface area of the patient’s palm (Hettiaratchy & Papini, 2004).
2.1.4 Pain neurophysiological mechanisms

In 1965 Melzack and Wall first described some of the central nervous system mechanisms responsible for interpretation of noxious stimuli (Loeser & Melzack, 1999). With the advent of technological advances such as functional Magnetic Resonance Imaging it is now more broadly acknowledged that pain is the combined expression of nociceptive input along with emotional and cognitive evaluative activity in the central nervous system (Lončar et al., 2006; Richardson & Mustard, 2009; Stoddard et al., 2002; Tunks et al., 2008).

In the immediate post-burn phase, various inflammatory cytokines invade the injured tissue, creating a so-called "inflammatory soup" (Loeser & Melzack, 1999, p. 1607), establishing the cascade of chemicals that over the following hours, days and weeks create a run of finely tuned tissue healing events (Stoddard et al., 2002). These chemicals set up a process of sensitivity in the peripheral nervous system (Mahar et al., 2012; Summer et al., 2008), elevating the responsiveness of the nociceptors (sensory receptors that are sensitive to various potentially damaging inputs such as excessive heat or mechanical pressure), and in the first instance ensuring that the individual protects the vulnerable body part (Connor-Ballard, 2009; Matsuzaki & Upton, 2013). Multiple areas of the central nervous system then become more sensitive to input from that body part (Mahar et al., 2012; Ossipov, DuSSor, & Porreca, 2010). According to the current view of pain as a neuroplastic construct, when a state of peripheral and central sensitization remains unrelieved over an extended period of time, the activation of these neural pathways essentially becomes a learned response by the nervous system. The pain experience is then activated by lower levels of stimulation (Lončar et al., 2006; Stoddard et al., 2002).
Understanding the neurophysiology of pain is essential in establishing a study such as this one. In a study that surveyed 358 burns survivors, Dauber et al. (2002) found that pain worsened as a result of interventions such as surgery, wound care and rehabilitation, and also through “fear of pain, lack of communication and psychological stress” (Dauber et al., 2002, p. 9). This finding reinforces the concept of pain as an experience involving emotional and cognitive processing in the brain, and not merely simple nociceptive input (Stoddard et al., 2002).

Based on the earlier review of pain literature, it is apparent that the neurophysiological processes at work during wound care procedures and burn rehabilitation are multi-factorial. The impact that pain has on the body’s healing process will now be explored.

2.1.5 The impact of pain on healing

Psychological adjustment up to two years following burn injury is significantly related to the degree of pain experienced during wound care (Patterson et al., 2006), however, not all patients perceive wound care as stressful (Solowiej et al., 2010). The pain experienced during wound care procedures can have a significant impact on the body’s repair processes (Connor-Ballard, 2009; Gardner et al., 2014) and while patients may be prescribed analgesic medications, these are often not sufficient (Gardner et al., 2014), particularly for the most painful aspect of burn recovery, procedural pain (Connor-Ballard, 2009). The anticipation of pain in the lead up to dressing changes, often causes anxiety and distress (Lončar et al., 2006; Soon & Acton, 2006) and can have as much of an impact on quality of life as the wound care pain itself (Soon & Acton, 2006).

Pain is known to activate the body’s stress response, increasing heart rate and breathing, elevating blood pressure and basal metabolic rate (Connor-Ballard, 2009), and at the same
time causing the patient to withdraw or restrict movement and guard against the pain (Connor-Ballard, 2009), all of which are not desirable following burn injury. In a pioneering study, Kiecolt-Glaser et al. (1995) evaluated the negative impact of pain and stress on wound healing, using an acute punch biopsy experimental wound in 13 healthy female long-term caregivers. They compared results against 13 control subjects, and found that wound healing took significantly longer in the individuals who were experiencing elevated levels of stress. The authors suggest that altered immune function related to stress may have implications for wound healing, and other studies support the idea that pain should therefore be monitored closely and managed well to minimise stress and encourage faster wound repair (Gardner et al., 2014; Solowiej, 2010).

2.1.6 Pain and self-control

Wound care procedures provoke anxiety, which in turn can cause greater pain (Lončar et al., 2006). In a formative study on the impact of burn injury, Ulmer (1997) found that moderate to severe pain which was not relieved, affected the patient’s belief in their ability to control their own pain. Due to the nature of burn care; the unfamiliar environment; reliance on others to provide care; and the lack of certainty about the future, burns treatment itself may reduce a patient’s resources for coping and sense of control over their activities (Stoddard et al., 2002; Wiechman Askay et al., 2009). In addition to the trauma experienced as a result of the burn incident, this perceived loss of control may further increase distress (Fauerbach et al., 2007; Stoddard et al., 2002).

In an experimental study with 15 healthy male volunteers (Mohr, Leyendecker, Petersen, & Helmchen, 2012), where participants either had the opportunity to control the removal of a noxious stimulus, or the control over the stimulus was retained by the researcher,
participants reported a greater degree of pain from a stimulus over which they had no control. In important early research, Bachiocco, Morselli and Carli (1993) studied 126 postsurgical patients, grouping them according to their expectation of self-control. Their results showed that participants who actively participated in the control of their own pain, required less analgesics than those who relinquished control to others. As a way of returning a degree of control over pain to the burns patient, some studies have looked at the use of patient controlled analgesia (Choiniere et al., 1992; Richardson & Mustard, 2009; Wiechman Askay et al., 2009). Their results show that patient-controlled analgesia (PCA) offers flexibility in dosing, which is vital in a burn care environment (Choiniere et al., 1992), although some limitations exist in the use of PCA in burns. These limitations include the impact of reduced manual dexterity in some burns patients when operating the PCA controls (Richardson & Mustard, 2009), the requirement to have access to trained staff (Gallagher, Rae, Kenny, & Kinsella, 2000), and that some patients do not like to have intravenous lines inserted (Stoddard et al., 2002).

The current view in burn care generally, is that patient distress should be minimised (Stoddard et al., 2002), and that wherever possible, staff should work together with patients in an effort to increase their sense of control over their situation, including their pain (Fauerbach et al., 2007; Richardson & Mustard, 2009; Wiechman Askay et al., 2009). This in turn should help with a more positive overall pain experience and psychological outcomes (Ulmer, 1997; Wiechman Askay et al., 2009). Ideal pain relief would be potent, acting for short periods of intense pain, while not impacting on the patient’s alertness at other times (Richardson & Mustard, 2009). Richardson and Mustard (2009) state that good analgesia is necessary for burns patients, to speed rehabilitation, but that it needs to be titrated to an
effective level to be useful. Therefore the potential use of self-administered electrical stimulation for pain management in burns will now be explored.

2.2 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

Transcutaneous electrical nerve stimulation (TENS) describes a range of battery powered electrical stimulation devices applied directly to intact skin, delivering electrical current to peripheral sensory nerve fibres (M. I. Johnson, 2014; M. I. Johnson & Bjordal, 2011) to elicit physiological responses, most commonly pain relief (M. I. Johnson & Bjordal, 2011; Kimball, Drews, Walker, & Dimick, 1987). The application of TENS is relatively widespread, but despite this, many practitioners remain uncertain about the usefulness of TENS in clinical settings (M. I. Johnson, 2014), and parameters for use in clinical settings remain inconsistent (Aarskog et al., 2007; M. I. Johnson, 2001). Literature relating to the use of TENS in burn pain is extremely limited. It is therefore necessary to draw some parallels with studies in other populations as well, to best inform the discussion.

2.2.1 Transcutaneous electrical nerve stimulation in burns

Kimball et al. (1987) conducted a study comparing TENS with morphine in burn wound care, while using an enzymatic debridement technique to remove dead tissue from the wound. The authors acknowledged that despite the lack of statistically significant difference in pain response between the users of morphine and TENS in their study, clinically, TENS should be “strongly considered” (Kimball et al., 1987, p. 30) as a viable non-addictive form of pain relief in burns.

A wound care study that included both chronic and acute wounds, but excluded burn injuries, examined the relationship between procedural and wound care factors, and analgesic intake (Gardner et al., 2014). The study was conducted in two phases, the first
(n=57) to identify those participants who had experienced the highest levels of pain, and the second (n=23) applying electrical stimulation with these participants. Gardner et al. (2014) showed that the specific type of high-intensity TENS used, may serve to reduce pain during wound care procedures, over and above analgesic medication. However, the authors suggested that the additional time involved in setting up traditional TENS may have acted as a deterrent, and may have contributed to the lack of clinical uptake of TENS in wound care.

The pain experienced in burn injury is “intense and prolonged” (Lončar et al., 2006, p. 319), similar to that of musculoskeletal pain, and Summer et al. (2008) reported that mechanical hyperalgesia in burn injuries is also a primary mechanism of pain, in particular during periods of intervention such as wound care where touch or movement evokes a painful response. Together this suggests that in the absence of a large body of evidence about the use of TENS in burns, cautious application of some non-burn related literature may help inform the study of TENS in a burns population.

2.2.2 Efficacy

Until recently, the view that TENS lacked efficacy was compounded by a lack of consistency in approaches to using TENS, both clinically and in research as discussed by various authors (Bjordal, Johnson, & Ljunggreen, 2003; Breit & Van der Wall, 2004; Fiorelli et al., 2012; Walsh, Howe, Johnson, Moran, & Sluka, 2009). A Cochrane review on acute pain in adults (Walsh et al., 2009) determined that there was insufficient evidence of TENS efficacy to be considered as a stand-alone treatment, however, it is worthwhile looking further into the literature to review the potential for TENS as an adjunct to analgesic medications. A number of authors have discussed shortcomings such as under-dosing through insufficient intensity of stimulation (Bjordal et al., 2003; Sluka, Bjordal, Marchand, & Rakel, 2013); inappropriate
placement of electrodes (Aarskog et al., 2007; Moran et al., 2011); negative interactions with long term opioid usage (Sluka et al., 2013); and underpowered randomised controlled trials (M. Johnson & Martinson, 2007). These shortcomings have resulted in a failure of many studies to demonstrate the benefits of TENS, which have now been clearly identified by others (Bjordal et al., 2003).

In recent years several strong studies and metanalyses (Bjordal et al., 2003; Sbruzzi, Silveira, Silva, Coronel, & Plentz, 2012) have produced promising evidence that TENS may have efficacy in specific conditions such as post-surgical pain, thoracotomy pain or chronic musculoskeletal pain (Fiorelli et al., 2012; M. Johnson & Martinson, 2007; Sbruzzi et al., 2012), and for specific benefits such as the reduction of analgesic medications and associated reduction in side-effects (Bjordal et al., 2003; Kalra, Urban, & Sluka, 2001). In a metanalysis of 11 studies post-thoracotomy, Sbruzzi (2012) found that when combined with analgesic medication, active TENS provided better pain relief than placebo TENS.

As discussed earlier, side-effects of analgesic medications can be unpleasant, therefore reduction in analgesic consumption may be beneficial for burns patients. A meta-analysis of post-operative TENS, involving 21 randomised controlled trials, and 1350 patients, used reduction in analgesic consumption as the primary measure, and found that TENS was an effective intervention (Bjordal et al., 2003). In the meta-analysis, a subgroup of patients who had received stimulation at a level considered by the authors to be optimal - “strong subnoxious with adequate frequency” (Bjordal et al., 2003, p. 181) – demonstrated a highly significant, 35.5% reduction in analgesic consumption over placebo.

Fiorelli (2012) also examined the effect of TENS in post-thoracotomy pain and found that by combining TENS with analgesia, the same analgesic benefit was achieved while maintaining
patients on lower medication dosage, therefore encouraging faster recovery and return to function. In a literature review of post-thoracotomy studies, a similar result was observed by Freynet and Falcoz (2010), where seven out of the nine studies reviewed favoured TENS in combination with narcotics for improved outcomes. Freynet and Falcoz noted that in cases of mild pain TENS could be used alone to good effect, however, in the management of severe pain, TENS without medication was insufficient (Freynet & Falcoz, 2010).

Thus it appears that for the size of the potential benefit, TENS is a low-cost, non-invasive pain management technique that can be self-administered in many instances, with very few side-effects (Bjordal et al., 2003; Fiorelli et al., 2012; M. I. Johnson, 2014), and as such warrants further research. As a better understanding of the probable mechanism of action and advances in technology come together, there is increasing potential for TENS technology to be considered among the range of clinical pain management tools currently available, alongside pharmacological and psychological strategies (M. I. Johnson, 2014; M. I. Johnson & Bjordal, 2011).

2.2.3 Transcutaneous electrical nerve stimulation - mechanism of action

TENS has been in use clinically for pain relief for more than 30 years, but despite this, the exact mechanism of action remains unclear (Sluka & Walsh, 2003).

Evidence in human and animal model studies points towards a range of possible neurophysiological responses in both peripheral and central nervous systems. Walsh et al (1998) applied TENS over the superficial radial nerve in healthy human volunteers. By altering the parameters of the TENS, the observed effects on nerve conduction suggested that TENS had, at least partly, a direct action on the peripheral nervous system. Research in the rat model (DeSantana, Santana-Filho, & Sluka, 2008), demonstrated that TENS reduces
hyperalgesia through the release of endogenous opioids in the central nervous system.
Additionally, Sluka et al. (2013) discuss the combined evidence from studies by several authors (DeSantana et al., 2008; Kalra et al., 2001; Sluka, Vance, & Lisi, 2005), which all point to a possible effect of TENS on the central nervous system, reducing overall excitability and restoring the inhibitory action of the central nervous system on nociceptive input with ongoing use. Sluka et al. (2013) hypothesise that the effects seen in each of these studies with repeated use of TENS, is in effect like “re-booting” (Sluka et al., 2013, p. 1398) the nervous system to impact on one or more aspects of the sensitization processes. They also note that an important factor in the results seen with TENS may come from a circular process whereby reducing pain allows increased physical activity, which then has a positive action and further decreases pain.

In a study of post-thoracotomy patients, Fiorelli et al. (2012) observed that serum cytokine levels were significantly lower in TENS treated patients over placebo. The cytokines measured in this study are commonly known to impact on hyperalgesia in the “acute-phase inflammatory and immunologic response” (Fiorelli et al., 2012, p. 866), and while it is still unclear how TENS had this effect, the implication is that the reduction in serum cytokine levels may be a beneficial response in a post-operative thoracotomy patient (Fiorelli et al., 2012).

Many of the effects of TENS shown in the literature translate well to desirable responses in burn injuries. It is important to explore the specific TENS parameters that have been seen to increase successful outcomes.
2.2.4 Transcutaneous electrical nerve stimulation - parameters for success

The limitations of many TENS studies relate to inconsistencies in the parameters selected (M. I. Johnson & Bjordal, 2011), thus to ensure success with TENS, it must be approached in the same way that pharmacological pain relief is approached; administering sufficiently strong stimulation; for long enough; to relevant locations; and with sufficient regularity to avoid under-dosing (Claydon, Chesterton, Barlas, & Sim, 2008).

a) Dose dependent effect:

Many studies discuss the dose dependent effect of TENS (Aarskog et al., 2007; Claydon et al., 2008; Moran et al., 2011; Sato, Sanada, Rakel, & Sluka, 2012; Sluka et al., 2013) whereby insufficient intensity of the signal, at or below sensory level, has been shown to have no significant analgesic effect (Bjordal et al., 2003; Moran et al., 2011), and a strong but sub-noxious level of sensation has been shown to significantly reduce the need for analgesic medication (Bjordal et al., 2003). Pantaleão et al. suggested that activation of a larger number of deeper tissue afferents can result from higher pulse amplitudes (Pantaleão et al., 2011). In seminal work, Melzack (1975) demonstrated that only high-intensity, strong, sub-noxious TENS would produce a prolonged analgesic effect.

b) Upward titration during treatment:

In addition to setting intensity high enough, numerous researchers (Liebano et al., 2009; Moran et al., 2011; Pantaleão et al., 2011; Sluka et al., 2013) stress the importance of titrating TENS upwards throughout treatment to retain the maximum analgesic benefit. Accommodation of sensory input can occur as a result of elevated threshold potentials in the nerve membrane, which then require greater stimulation to activate a nerve impulse to the central nervous system (Pantaleão et al., 2011). Accommodation has traditionally been
seen as a limitation of TENS devices (Pantaleão et al., 2011), as the stimulation becomes ineffective when the nervous system begins to effectively ignore the incoming sensation. Pantaleao (2011) suggests that the decreasing TENS sensation, effectively caused by accommodation, may in fact allow the patient to increase stimulation amplitude (titrating upward), and therefore potentially increasing the efficacy of the treatment while preventing analgesic tolerance (Liebano et al., 2009).

c) Modulation of high and low frequencies

Some evidence exists for the benefit of combining high intensity with modulation of TENS frequencies, both to improve the hypoalgesic effect (DeSantana et al., 2008) and to delay the onset of analgesic tolerance (DeSantana et al., 2008; Lima et al., 2014), which can occur with TENS in a similar way to the development of opioid tolerance (DeSantana et al., 2008). In a traditional TENS device this may require manual adjustment of settings (M. I. Johnson, 2001).

d) Optimal electrode positioning

Optimal positioning of TENS electrodes, as a critical factor for success (M. I. Johnson & Bjordal, 2011; Moran et al., 2011; Szeto & Nyquist, 1983), is discussed in numerous articles, suggesting that:

- placement within the same sensory dermatome or segment as the pain site may help to achieve maximum hypoalgesia (Claydon et al., 2008; M. I. Johnson & Bjordal, 2011);
- placement over the site of pain or the nerves proximal to the site of pain is common in clinical practice (M. I. Johnson & Bjordal, 2011);
• placement at locations of higher nerve density, indicated by lower skin resistance, may improve efficacy and limit skin irritation (Kolen, de Nijs, Wagemakers, Meier, & Johnson, 2012; Prokhorov, Llamas, Morales-Sánchez, González-Hernández, & Prokhorov, 2002);
• avoiding repeated placement at exactly the same location, and with the same parameters, may reduce development of analgesic tolerance (M. I. Johnson, 2014; Liebano et al., 2009).

Array or matrix electrodes, are a technological advancement that may address some of these placement issues. The arrays are designed in such a way that multiple active electrodes are contained within a specific area, and activated by the area of lowest tissue impedance (Bjordal et al., 2003; Kolen et al., 2012). This new development in TENS technology was an integral part of the novel TENS device used in this study and will be discussed later.

e) Training requirements

Traditionally TENS devices require manual adjustment of various parameters (M. I. Johnson, 2001), and the low uptake of TENS into clinical environments may in part, have been limited by the time required to set up the device. In addition, the work involved in training patients in the correct use of the equipment to ensure a successful result, may be a barrier to ongoing use (Bjordal et al., 2003).

In summary, TENS shows potential to assist with pain reduction, and to increase patient self-control over burn pain. However, a form of TENS that is easy to apply, with limited training, and that can be rapidly adjusted may be even more valuable in such a challenging care environment.
2.3 NON-INVASIVE INTERACTIVE NEUROSTIMULATION

Non-invasive interactive neurostimulation (NIN) is a relatively new development in transcutaneous electrical nerve stimulation which may offer solutions to many of the application problems described with conventional TENS above. The device used in this study (InterX®; Neuro Resource Group Inc.: Plano, Texas) which has been referred to in the literature as NIN (Biggs, Walsh, & Johnson, 2012; Clark, Magee, & Pyne-Geithman, 2010; Gorodetskyi et al., 2007, 2010; Nigam et al., 2011) or Interactive Neurostimulation (INS) (Schabrun et al., 2012), and also by the commercial name InterX (Biggs et al., 2012; Bjordal et al., 2003), offers a high amplitude current, and biphasic, pulsed sinusoidal damped waveform (Biggs et al., 2012) (full device specifications can be viewed in Appendix B).

Literature on the efficacy of NIN is limited, however, this study is based on the view that NIN is a novel TENS device which may address some of the application challenges presented by conventional TENS, and therefore justifies the use of NIN with burns patients.

2.3.1 Non-invasive interactive neurostimulation efficacy

Two randomised clinical studies on NIN (Gorodetskyi et al., 2007, 2010), and a randomised controlled trial (Nigam et al., 2011), show promising results when applying the device with post-operative orthopaedic patients. These studies demonstrate statistically significant changes in pain, range of motion, oedema and analgesic consumption, all of which would be clinically beneficial in the burns population. The results of one of these studies will be discussed in detail to demonstrate why the investigation of NIN in burns is warranted.

In a prospective, randomised clinical trial of 60 patients with surgically repaired, bimalleolar ankle fractures (Gorodetskyi et al., 2010), participants were treated (30 active; 30 sham) for
20 minutes, twice daily, over both injured and contralateral ankles, while participating in the standard post-operative rehabilitation protocol. Following a single course of treatment, the mean pain visual analogue scale (VAS) score dropped 28% for the active group from 8.40 ± 1.02 to 6.0 ± 0.91, compared to the control group which had only a 3% drop of mean pain VAS from 8.20 ± 0.92 to 7.90 ± 0.98. Measures of total range of motion at the same time point improved by more than 50% in the active group, as compared to the control group with no change in total range of motion at the same time point. Mean difference in ankle circumference (injured to uninjured) at the end of the fifth morning session, was used as a measure of oedema reduction, and this demonstrated a 38% reduction in the active group against 12% in the control group at the same point. In the NIN study in ankle fractures, over the 10 day period of the study, mean total analgesic consumption was reported as 112.0 ± 33.4mg for the active group, versus 209.0 ± 32.9mg for the control group (Gorodetskyi et al., 2010). Importantly, analgesic consumption was identified by (Bjordal et al., 2003) as the most appropriate measure of TENS efficacy.

The authors of this study acknowledge limitations which include the lack of long term follow up (Gorodetskyi et al., 2010). However, the reduction in analgesic consumption, alongside significant reduction in pain and oedema, and increased range of motion, suggest that NIN should be considered as a potentially useful TENS device for application in burns.

2.3.2 Relationship to transcutaneous electrical nerve stimulation

According to the literature (Biggs et al., 2012; Gorodetskyi et al., 2010; Nigam et al., 2011), non-invasive interactive neurostimulation differs from conventional TENS in both the electrode configuration and the inbuilt circuitry that enables automatic adjustment to changing tissue impedance; together these result in the delivery of higher density and
amplitude of stimulation than is currently available with conventional TENS device specifications and electrode configurations (Trowbridge & Magee, 2010).

To examine the efficacy of NIN compared to TENS, in a poster presented at the 13th World Congress on Pain, Montreal, 2010, Clark, Magee & Pyne-Geithman (2010) conducted a pilot study into genetic and cytokine markers in blood following NIN stimulation. They proposed that the higher density and intensity of current provided by NIN compared to TENS, as well as optimal positioning of electrodes may account for the differences they observed. The study demonstrated that along with other results, a significantly greater physiological response was elicited with NIN (476.2% increase in lymphocyte respiration following activation with Glutamate), than with TENS (21.7% increase in lymphocyte respiration under the same conditions) (Clark et al., 2010). The outcomes of the Clark et al study need to be viewed with considerable caution as the results are based on very small numbers, and have not yet been published in a peer-reviewed journal, however, the authors encourage further study to shed further light on the difference in mechanism of action for conventional TENS devices and the NIN device. These outcomes, and the proposed differences in the NIN mechanism over conventional TENS, suggest that the application of NIN in burns should be further investigated.

2.3.3 Non-invasive interactive neurostimulation parameters

Studies conducted using NIN suggest possible reasons for application advantages of NIN over TENS. These have been grouped according to the TENS parameters identified earlier as important for successful stimulation:
a) Dose dependent effect:

Earlier discussion covered the need for effective dosing with TENS to ensure adequate tissue response, by using the highest possible amplitude, or strong subnoxious stimulation (M. I. Johnson & Bjordal, 2011; Sluka et al., 2013). Current dispersed via large, widely-spaced electrodes as is required with TENS, may limit the amplitude that can be applied as the current may travel deeper into tissue and elicit muscle contraction (Nigam et al., 2011).

The NIN configuration of small, closely spaced electrodes, and short pulse width, ensures that the electrical stimulation can be delivered at a high intensity and amplitude without causing muscle contraction (Schabrun et al., 2012), or patient discomfort (Trowbridge & Magee, 2010). Biggs et al. (2012) describe NIN as delivering stimulation to create a strong non-painful parasthesia, similar to the recommendation in the literature regarding effective TENS parameters (M. I. Johnson & Bjordal, 2011; Sluka et al., 2013).

b) Upward titration during treatment:

Regular upward titration, or increasing intensity of TENS throughout treatment, is recommended to ensure that sufficient depolarisation of nerve endings will occur. As described earlier in the TENS discussion, manually adjusting the intensity of the TENS signal may also reduce the likelihood of nerve accommodation (the tendency of the nervous system to adjust to, and block out a constant, unchanging stimulus) (Pantaleão et al., 2011). In an industry white paper outlining the optimization of electrical stimulation treatment parameters for NIN, Trowbridge and Magee (2010) suggest that the interactive nature of NIN, where the waveform adjusts
automatically to changes in tissue impedance, may help to reduce accommodation for a similar reason.

c) Modulation of high and low frequencies:

The NIN device model used in this study (InterX® 900), which was designed for patient self-application rather than therapist-delivered stimulation, operates a preset cycle of varying stimulation parameters in an effort to maximise the tissue response. This feature may have the additional benefit of helping to reduce the build-up of analgesic tolerance to the electrical stimulation (Nigam et al., 2011), which would mean that stimulation using the NIN could continue over days or weeks without losing effect.

d) Optimal electrode positioning:

Nigam (2011) suggests that with the unique NIN electrode configuration, current follows the path of least resistance in the tissue, according to the physical principle of Ohm’s Law, therefore automatically delivering the stimulation to sites of lower impedance. The use of array electrodes (Kolen et al., 2012; Kuhn, Keller, Micera, & Morari, 2009) has been discussed by Johnson and Bjordal (2011) as a beneficial advancement for TENS; simplifying the application of electrodes, and potentially improving clinical efficacy. The NIN device used in this study adopts new technology incorporating single-patient use array electrodes (an image of the electrode arrays can be seen in Appendix B). The proposed advantage of array electrodes is that they may automatically direct current to areas of lower impedance, which have been found to correspond to optimal treatment locations, such as areas of higher nerve density (Lee, Kim, Park, Park, & Cho, 2003).
2.4 SUMMARY OF LITERATURE REVIEW

Transcutaneous electrical nerve stimulation has been in use for several decades. Despite evidence of efficacy of TENS in non-burn populations, it has made only limited inroads into the burn care environment. It is unclear whether barriers to applying TENS devices in burns, relate to perceived lack of efficacy; the physical challenge of introducing the intervention in this environment; or some other reason. Based on the review of literature relating to TENS, and the possibility that non-invasive interactive neurostimulation may overcome some of the limitations seen in TENS, further investigation of this device in the burns population is warranted.
3 THEORETICAL FRAMEWORK AND RESEARCH DESIGN

3.1 THEORETICAL FRAMEWORK

The basic tenet of occupational therapy is that occupation is not merely something we do, it is a driving force for our development as human beings, physically; cognitively; emotionally; and spiritually. In 1946 the World Health Organisation (WHO) defined health as “a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity.” (World Health Organisation [WHO], 1948). Individuals who have had their lives and occupational identities interrupted by an event such as a burn injury, can benefit from occupational therapy involvement, helping them to restore balance to many different aspects of well-being. Occupational therapists may be guided in their practice by a number of different theories. One of the best known and most widely used of these theories is the Model of Human Occupation (MOHO).

3.1.1 The Model of Human Occupation

Originally proposed by Kielhofner and further developed and refined by Kielhofner and others (Kielhofner & Forsyth, 1997), the Model of Human Occupation (MOHO) (see Appendix C for a diagrammatic representation of the MOHO) recognises human occupation (productive activity such as work or volunteering; play such as hobbies or sport; and self-care) as a dynamic system that helps to shape human physical, cognitive and emotional capacities and behaviours (Kielhofner & Forsyth, 1997). Using a MOHO framework, the occupational therapist sees performance of, or engagement in, occupation as a product of the internal workings of the person such as cognitive or physical attributes, abilities, and motivations, influenced by the environment and the task itself. The ability of the occupational therapist to influence the behaviour of others and engage individuals more
completely in an occupation rests heavily on the understanding of these principles. The view of occupational therapists, underpinned by the MOHO principles, is that human occupation is not simply a by-product of living, but an active driving force in the development, well-being and health of individuals, and that “through our occupational behaviour, we create our motor abilities, our self-concepts and our social identities” (Kielhofner & Forsyth, 1997, p. 104).

The model proposes that human engagement in occupation is a complex combination of three subsystems, the performance capacity subsystem, the habituation subsystem and the volition subsystem (Kielhofner, 2008; Kielhofner & Forsyth, 1997), carried out within a social and physical environment or context. Following a traumatic event such as a burn, individuals are often faced with an unfamiliar environment while experiencing pain, not only from the burn but also from the treatment procedures. In such a situation, each of the components described in the Model of Human Occupation are likely to be significantly interrupted.

Examples of this might include:

a) the **performance capacity subsystem** may be altered whereby physical function with bulky dressings, oedema and pain becomes much more challenging. Cognition or attention may also be adversely affected by pain;

b) the **habituation subsystem** is likely to be interrupted where the usual habits of getting out of bed, going to the toilet and having breakfast to start the day may now be replaced by a whole different routine involving stiff, and painful movement and taking medication; and

c) the **volition subsystem**, which relates to motivation, will be affected by a complex interplay of factors such as knowing that painful dressings changes are required, but instinctively wanting to avoid a task that will cause further pain; finding the visual impact of
open wounds unpleasant or even frightening; and potentially lacking any sense of control over the situation.

Engagement in the occupation of self-care, and the task of self-management of pain, is being viewed through the lens of the MOHO for this study. In order to implement a new pain self-management intervention in the challenging burn care environment, patients and staff will need to be highly motivated to overcome any obstacles. One of the most complex aspects of feasibility is the motivation for patients to engage with the NIN device, the volition subsystem will be explored in greater detail, while acknowledging the other two subsystems of performance capacity and habituation.

3.1.2 The volition subsystem and motivation

In clinical settings, patient motivation is acknowledged as an important determinant of the outcome of therapy (Maclean & Pound, 2000). In a review of physical rehabilitation literature, Maclean and Pound (2000) found that, anecdotally, motivated patients were believed to demonstrate better performance in rehabilitation, however, the concept of motivation can be viewed from different perspectives, and clinicians may not always agree on the meaning of motivation. According to Maclean and Pound (2000) some clinicians see the internal aspects of the patient, such as their inherent personality, as the key to motivation in therapy, assuming that if the personality of an individual is not conducive to engagement then there is little point in persisting with an activity. Others suggest that external factors such as the social context prior to and during therapy may be more important (Maclean & Pound, 2000), so a greater understanding of the factors that may be influencing motivation may allow clinicians to alter or manipulate certain aspects of an intervention, subsequently increasing the potential for engagement.
Motivation, or the drive of an individual to carry out an occupation or activity, cannot itself be directly seen. However, evidence of underlying motivation may be observed through volitional behaviours (Chern, Kielhofner, de las Heras, & Magalhaes, 1996). The MOHO (Kielhofner, 2008) view is that volition is a stable configuration, made up of the individual’s emotional and cognitive disposition and awareness of self, overlayed by a flexible and changing process of “anticipating, choosing, experiencing and reflecting on one’s actions” (Chern et al., 1996, p. 516).

To help understand the concepts of disposition and volitional self-awareness, there are three components that determine the degree of volition in an individual (De las Heras, Geist, Kielhofner, & Li, 2003). These are:

a) whether an individual has a personal interest in an activity – either an innate tendency, or developed after experiencing enjoyment when initially engaged in the activity,

b) whether an individual sees value in engaging in the activity – based on internal beliefs and shaped by cultural or social experiences, and

c) whether they believe in their own ability to effect a desired outcome, termed “personal causation” (Chern et al., 1996, p. 516) – based on a self-assessment of physical, intellectual and social capacity, and likely effectiveness at achieving a result.

The Volitional Questionnaire which has been adopted as one of the measures in this study, is based on the MOHO view of volition, and will be addressed in greater detail in the Methodology section.
3.2 RESEARCH METHODOLOGY

This study addressed hand burns in an effort to relate the study to one of the most frequently seen, and therefore relevant, populations in clinical practice. A single case experimental design was adopted.

3.2.1 Single Case Experimental Design

Single case experimental design (SCED) is described by Creswell (2013) as using mixed methods to explore a small number of cases in depth, and in the real-life setting (Yin, 1994). SCED is unable to provide a broad perspective of any field of study, however, it allows a detailed perspective of individual cases, which when taken in context can help to inform clinical practice (Rassafiani & Sahaf, 2010). In clinical populations, Kazdin (1978) and Rassafiani and Sahaf (2010) suggest that this research design can be very effective where the nature of the diagnostic group limits availability of participants, as is the case with the very specific depth and percentage of hand burns chosen for this study.

In medical research, randomised controlled trials (RCTs) are generally acknowledged as the gold standard for informing an evidence-based approach (Tate, McDonald, Perdices, Togher, Schultz, & Savage, 2008), however, in certain populations or situations, group designs such as RCTs may not capture a clear picture of the individual experience, and when conducted appropriately, single case experimental design may offer some advantages (Tate et al., 2008). Rapoff and Stark (2008) discuss some of the strengths of SCED as being flexible; able to be applied where small patient numbers limit large RCTs; appropriate where the withholding of medical care may be ethically unacceptable; capable of highlighting individual variations rather than just a merged group perspective; and offering the potential
for clinicians to directly interpret results for themselves and to use them to inform clinical practice (Rapoff & Stark, 2008).

SCED differs from the anecdotal reporting seen in clinical case studies. Clinical case studies offer a retrospective review of note-worthy medical cases (Perdices, 2009). In contrast, SCED uses a prospective study of individuals, with planned manipulation of carefully chosen variables, and measured observation and analysis of the data produced (Perdices, 2009; Tate et al., 2008). SCED offers the flexibility to be adjusted according to individual clinical need, whilst continuing to rigorously document interacting variables (Perdices, 2009).

In SCED, an ABA design is the gold standard to ensure rigour (Zhan & Ottenbacher, 2001). This is where the baseline behaviour or measurement is determined to be stable (A); then the dependent variable is introduced and behaviour stability is again ensured (B); and the variable or intervention is then removed again to confirm that the change was indeed related to this variable (A) (Zhan & Ottenbacher, 2001). While this ABA design is preferred as it can increase internal validity (Kazdin, 1978), it may not be ethically acceptable in all clinical settings (Zhan & Ottenbacher, 2001). This was determined to be the case with the removal of NIN in this study should participants benefit from pain relief as demonstrated in other populations. As the population tested were expected to be healed within two weeks, there was insufficient time for a long baseline phase using multiple wound care procedures prior to introduction of the intervention. Alternatively, several authors (Rapoff & Stark, 2008; Smith, 2012; Zhan & Ottenbacher, 2001) suggest comparison of multiple sets of AB data, introduced at different time points, and using different target behaviours within each individual. Thus the rigour of SCED can be increased by ensuring certain features are included at the planning stage (Tate et al., 2008), and based on review of the above
literature, a multiple data set, single case experimental design was chosen for the present study.

3.2.2 Sample

In a purposive sampling method, the researcher and burns nursing and medical staff identified suitable candidates based on burn size (less than 4% total body surface area), location (distal upper limb burns including the hand) and depth of burn (no deeper than partial-thickness). The decision to include only these patients in the study was made in consultation with the third author who is also the director of the burns unit and consultant burns surgeon. By setting very specific diagnostic parameters, the number of variables that could influence outcomes was reduced. Hand burns were determined to be an appropriate focus because of their impact on quality of life outcomes as described earlier. The burn care team at Royal Perth Hospital adopts a progressive approach, so patients who present with full thickness burns are commonly treated surgically rather than conservatively to reduce healing time, potentially limiting hypertrophic scarring. The decision was made to include only partial-thickness burns for this study in order to remove the variable of surgical intervention.

The researcher screened all potential participants and discussed the purpose of the study with them prior to deciding whether to enrol them in the study. Figure 2 shows a flowchart of participant selection, and Table 2 outlines the details of all patients screened and reasons for inclusion or exclusion. Written informed consent was obtained according to the Royal Perth Hospital, Human Research Ethics Committee guidelines; all participants were provided
with a copy of the consent letter (see Appendix D) and informed of their right to withdraw from the study at any time.

During the data collection period of four weeks, the researcher attended the burns outpatient clinic three times per week to monitor for potential participants.

### 3.2.3 Intervention

The NIN device (InterX®, Neuro Resource Group Plano, Texas) was explained, which required 1-2 minutes for each participant, and included the instruction to keep the sensation at the highest level of intensity possible but without discomfort, as well as to adjust the intensity up or down as required, in accordance with evidence in the literature discussed earlier. Written instructions were also provided for participants to take home (see Appendix E).

The NIN electrode arrays were applied using a Velfoam strap or cuff that is provided with the device for single patient use. As the strap is of a universal design (see Appendix B), the length when opened out fully was approximately 70cms, which wraps around the average forearm more than twice.

The NIN single patient system array electrodes used in the study are made of two wipeable, bendable plastic and metal plates, each with nine electrodes, with two thin cables coming from each (see Appendix B). Participants were instructed on cleaning if required, and the option was available to replace the Velfoam strap should it become excessively soiled. These procedures were discussed with the Infection Control Nurse Manager during the design phase of the study, and no difficulties were anticipated as the array electrode straps are positioned on intact skin sufficiently proximal to the open wound to present no greater risk than a sphygmomanometer cuff used regularly during nursing observations (Appendix F contains a summary of the discussion and infection control risk analysis).
The NIN device requires only three selections to be made to commence operation. This was considered an advantage in the burn care environment, where the cognitive burden of learning a complex electrical stimulation device may add to the distress of patients, and add to the workload for staff. Participants were encouraged to commence use of the NIN stimulation prior to the dressings being removed, as this is often described as the most painful part of the procedure (Connor-Ballard, 2009). Depending on timing of clinic appointments, participants had between one and approximately ten minutes of stimulation prior to commencement of the dressing removal, except for Participant C where dressings were removed prior to enrolment in the study and commencement of NIN.

The NIN device cuts out automatically after an operation period of 20 minutes. Participants were instructed to use the NIN device at home up to five times daily, moving or rotating the electrodes around the arm on each treatment, and using maximum tolerable intensity, as required.

### 3.2.4 Data collection tools

To increase rigour through triangulation of the data, multiple sources (participant, nursing staff and researcher), and multiple time points were measured in each individual case (Figure 1), including:

1. **Participant diary Visual Analogue Ratings (VAS) over up to 14 days** - of a) pain; b) anxiety; c) confidence in ability to manage own pain; d) ease of use of NIN device; and e) motivation to use NIN device,

2. **Patient VAS ratings carried out before and after wound care procedures on two separate occasions** - of a) pain; b) anxiety; c) confidence in ability to
manage own pain; d) ease of use of NIN device; and e) motivation to use NIN device.

3. **Nursing staff VAS ratings** carried out before and after wound care procedures on **two separate occasions** - of a) patient’s pain; b) patient’s anxiety; c) patient’s confidence in their ability to manage their own pain; d) ease of use of NIN device for the patient; e) patient motivation to use NIN device; f) interference of the NIN device with nursing care; and g) nursing staff motivation to have patient use the NIN device in future.

4. **Participant comments** and **nursing staff comments** throughout the study period.

5. Administration of the **Volitional Questionnaire** by the researcher on **two separate occasions** during wound care procedures, to observe participant volitional behaviours around use of the NIN device.
a) Visual Analogue Scale

Wiechman Askay et al. (2009) found that in clinical practice, assessment tools should be selected for ease of administration and interpretation by both staff and patients. One of the most common, simple, reliable and valid (Hawker, Mian, Kendzerska, & French, 2011) measures of pain in research and clinical practice is the visual analogue scale (VAS) (Mahar et al., 2012; Marsh-Richard, Hatzis, Mathias, Venditti, & Dougherty, 2009). This entails the placement of a mark by the patient on a 100mm line, to indicate the degree to which a descriptor relates to their experience. Using the line without scale markings and with descriptors only at the extreme ends has been found to reduce the risk that the participant will make comparisons to past numeric ratings, and this is likely to increase accuracy (Price, McGrath, Rafii, & Buckingham, 1983).

VAS scales can be adapted readily to suit different measures such as anxiety, and can report on extremes of either a bipolar measure, for example ‘hot versus cold’, or a unipolar
measure such as ‘never versus not more than 5x/day’ (Marsh-Richard et al., 2009).

Completing a VAS scale is not arduous (Marsh-Richard et al., 2009) and if necessary a burn injured patient can still complete the measure by pointing and the researcher marking when bandaged hands limit the use of a pen (Kimball et al., 1987).

For this study, multiple VAS measures were required from the participant: a) pain; b) anxiety; c) confidence in ability to manage own pain; d) ease of use of NIN device; and e) motivation to use NIN device; and from the nursing staff: a) patient’s pain; b) patient’s anxiety; c) patient’s confidence in their ability to manage their own pain; d) ease of use of NIN device for the patient; e) patient motivation to use NIN device; f) interference of the NIN device with nursing care; and g) nursing staff motivation to have patient use the NIN device in future; and so it was decided that all VAS ratings would be aligned in the same direction (negative to positive) to reduce confusion, and then scores for confidence, ease of use and motivation were inverted at the data analysis stage (Appendix G and Appendix H contain samples of the participant and nursing staff questionnaires).
b) The Volitional Questionnaire

Checklists or interviews may provide valuable information on motivation when determining whether sufficient motivation exists to engage in a new treatment. However, these may not provide a complete picture, particularly where an individual lacks the self-awareness to describe detailed aspects of their motivation or lack of motivation to engage in the treatment. The Volitional Questionnaire (VQ) (see Appendix I for a sample of the Volitional Questionnaire recording sheet) was developed and validated as a Master’s thesis by de las Heras in 1993 (de las Heras, 2003) and revised by Chern (1996), enabling occupational therapists to evaluate motives for engagement in situations where self-report of volition is not viable or practical. Initially this was to assist with assessment of individuals whose self-report options were limited by severe physical or cognitive challenges, however, the tool may also be able to shed light on volitional behaviours of individuals in an environment where self-report is impractical (Kielhofner, 2008), such as the burns clinic at the height of a painful wound care procedure. One advantage of the VQ is that it has been validated in a normal therapeutic interaction rather than an experimental environment (Chern et al., 1996).

The VQ is based on the assumption that while underlying motivation to engage in a specific task or activity cannot be observed, the outward volitional behaviours of an individual, such as taking initiative, or smiling to indicate enjoyment may allow the trained clinician to make inferences about level of motivation (Chern et al., 1996). The 14 behaviours measured in the revised version of the VQ (Chern et al., 1996) are assessed by a four point scale based around the degree of spontaneity and autonomy observed, and an overall understanding of strengths and weaknesses in volition is then developed (Chern et al., 1996).
While validated, Chern et al. (1996) recommended that the VQ be acknowledged as a tool under development, and identified limitations including a significant ceiling effect, whereby behaviours of highly motivated individuals may not be adequately measured by the tool. It is also not yet clear whether reliability is assured with new users learning directly from the user manual rather than a workshop (Chern et al., 1996).

Chern explains that volitional behaviours assessed using the VQ can be seen as a continuum of change, rating the lower levels of volition as “exploration” behaviours, the next level as “competency” behaviours, and the highest level of motivation being represented by the “achievement” behaviours (Chern et al., 1996, p. 33).

c) Participant diary

Participant diaries (Appendix J contains a sample page from the diary) can be useful in qualitative research, to enable collection of multiple points of data and provide insight into experiences that occur beyond the clinical environment (van Eerde, Holman, & Totterdell, 2005). The purpose of single case experimental design research is to provide the reader with an in depth view of the case as it unfolds, so ratings of pain; anxiety; confidence in managing own pain; ease of use of the NIN; and motivation to use the NIN were taken on a daily basis, along with an opportunity for comments to clarify these ratings and provide greater detail.

3.2.5 Data collection procedures

On the day of presentation at the burns clinic, following explanation and enrolment in the study, participants recorded VAS ratings retrospectively to provide a baseline prior to introduction of the NIN. To strengthen the reliability of this retrospective information participants were encouraged to discuss with a family member, or nursing staff and
researcher the significant events of the days since injury, to recall in detail where they were during these days, and levels of pain; anxiety; and confidence in ability to manage own pain.

All dressing procedures were carried out in the morning clinic. Prior to commencing the dressing procedure, participants completed the pre-procedure questionnaire, and immediately afterward rated the same questions in the post-procedure questionnaire; while the nursing staff member completed the staff questionnaire (see Appendix H). As a result of their hands being occupied or bandages being too bulky, where participants or staff had difficulty writing, they dictated comments to the researcher, who then read comments back to confirm an accurate representation of their views. Participants and staff were in separate rooms when this occurred to avoid influencing the comments of the other party. All participants had sufficient control of a pen to be able to mark the VAS ratings themselves.

Participants were instructed to record diary entries at the end of each day where possible. Participants were instructed, when using the NIN device at home, to document VAS ratings as described previously, along with intake of substances that may impact on feelings of anxiety or pain, such as caffeine, prescribed medications and to comment in the participant diary (see Appendix J) whether any specific stimulus, such as pain, had motivated them to apply the NIN device.

### 3.2.6 Data analysis methods

Data analysis in this SCED study was carried out by graphic representation of the data with analysis of magnitude and direction of trends, and direct or inverse relationships between data. Data has been presented in full so that the reader can draw their own conclusions, thus helping to inform clinical practice without misrepresenting the ability of SCED study results to be generalised to the wider population (Zhan & Ottenbacher, 2001). To determine
the feasibility of introducing a novel electrical stimulation device into the burn care environment, data from multiple sources, within each individual case, were analysed. The research questions were grouped into related topics around impact on the patient experience; impact of practical use of the device; and whether sufficient motivation existed among patients and staff to use the NIN device (Table 1).

<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Data Sources Analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Did pain or anxiety increase following introduction of NIN?</td>
<td>* Pre &amp; post wound care procedure participant VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Post wound care procedure nursing staff VAS ratings</td>
</tr>
<tr>
<td>2) Did the patient’s confidence in their ability to manage their own pain change following introduction of NIN?</td>
<td>* Participant diary VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Participant and nursing staff comments</td>
</tr>
<tr>
<td>3) Did NIN interfere with the work of nursing staff or patient activities?</td>
<td>* Pre &amp; post wound care procedure participant VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Post wound care procedure nursing staff VAS ratings</td>
</tr>
<tr>
<td>4) Was the NIN device easy to use?</td>
<td>* Participant diary VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Participant and nursing staff comments</td>
</tr>
<tr>
<td>5) Was the participant motivated to use the NIN device?</td>
<td>* Pre &amp; post wound care procedure participant VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Post wound care procedure nursing staff VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Participant diary VAS ratings</td>
</tr>
<tr>
<td></td>
<td>* Participant and nursing staff comments</td>
</tr>
<tr>
<td></td>
<td>* Volitional Questionnaire</td>
</tr>
</tbody>
</table>

In the following sections, each individual case study will be explored in depth with results graphed for ease of visual analysis. Behaviours recorded in the Volitional Questionnaire have been displayed using a radar graph as all behaviours carry equal weighting. The observation of ‘passive’ which indicates minimal volition, is recorded in the centre of the circle, therefore if a patient demonstrates a high level of volition for behaviours and displays them ‘spontaneously’, a larger circle will be mapped. The behaviours indicated in the
Volitional Questionnaire graphs between 12 o’clock to 3 o’clock have been linked to an “exploration” level of motivation, 4 o’clock to 8 o’clock a “competency” level and 9 o’clock to 11 o’clock “achievement” level of motivation as discussed earlier (Chern et al., 1996, p. 33).
4 RESEARCH FINDINGS AND CASE STUDY DISCUSSION

4.1 DEMOGRAPHICS

During the data collection period of four weeks, the researcher attended the burns outpatient clinic three times per week to screen for potential participants. Recruitment notices were also placed in the burns outpatient clinic and inpatient burns unit (see Appendix K). Of the ten patients identified for screening (Figure 2), one 47 year old male was located in the inpatient burns unit and identified by the consultant for review but subsequently deemed to be unsuitable for enrolment. The remaining nine potential participants were located in the burns outpatient clinic.

One individual, participant B, was withdrawn from the study following his first wound care procedure (WCP), as he was scheduled for surgical debridement and grafting. His early data has been included in the study, and will be discussed in further depth in his individual case study discussion and the general discussion, as it illuminates some important considerations about motivation to use the device. A range of different occupations and causes of injury were represented in the patients screened for inclusion as can be seen in Table 2.
<table>
<thead>
<tr>
<th>Demographics</th>
<th>Occupation</th>
<th>Burn description &amp; mechanism</th>
<th>Inclusion/exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>29yo male</td>
<td>Boilermaker</td>
<td>Flame burn, rupture of oxyacetylene torch hose</td>
<td>Participant A</td>
</tr>
<tr>
<td>42yo male</td>
<td>Belt splicer</td>
<td>Flame burn, cigarette ignited solvent from mining conveyor belt splicing</td>
<td>Participant B</td>
</tr>
<tr>
<td>30yo female</td>
<td>Chef</td>
<td>Contact burn, hot pan slipped from commercial oven</td>
<td>Participant C</td>
</tr>
<tr>
<td>25yo male</td>
<td>Filmmaker</td>
<td>Hot oil burn, bilateral dorsal hand burns while cooking</td>
<td>Participant D</td>
</tr>
<tr>
<td>42yo male</td>
<td>Boilermaker, single father</td>
<td>Flame and diesel burn from fuel tank explosion, right hand 12 hours prior</td>
<td>Burn depth too shallow, unlikely to require ongoing dressings.</td>
</tr>
<tr>
<td>27yo female</td>
<td>Admin worker</td>
<td>Contact burn, cooking pan handle 48 hours prior</td>
<td>Burn depth too shallow, unlikely to require ongoing dressings.</td>
</tr>
<tr>
<td>47yo male</td>
<td>Self-employed labourer</td>
<td>Electrical burn, digging with metal spade and stuck electrical cable 24 hours prior</td>
<td>Self-admitted regular methamphetamine user, unreliable for return of NIN</td>
</tr>
<tr>
<td>17yo male</td>
<td>School student</td>
<td>Flame burn, tending to campfire.</td>
<td>Mother stated unlikely to carry out activities required for study based on past behaviour</td>
</tr>
<tr>
<td>39yo male</td>
<td>Immigration worker</td>
<td>Contact burn, cooking pan handle 72 hours prior</td>
<td>Long term user of narcotics for prior back injury, describes limited pain in hand</td>
</tr>
<tr>
<td>86yo male</td>
<td>Retired</td>
<td>Flame burn, cleaning chimney with petrol when paper dropped into warm grate and caused an explosion. Right hand and face burn</td>
<td>Describes having no pain and not wanting to enter the study. No pain behaviours observed during dressing change</td>
</tr>
</tbody>
</table>
4.2 COMMON FINDINGS

All participants demonstrated the ability to easily operate the NIN device with either injured or uninjured hand as required. Only minimal instruction about how to operate the device, which lasted around 1-2 minutes, was required by all participants.

Participants offered comments in the diary and wound care procedure questionnaires to clarify VAS ratings and offer further insight into their activities with the NIN. Comments are provided in full in the tables for each participant (see Appendix L for a table of the behaviours observed using the Volitional Questionnaire).
4.3 CASE STUDY A – FINDINGS AND DISCUSSION

A 29 year old male boilermaker was working with an oxyacetylene welding torch when the hose ruptured and flame exploded down his right arm, inside his protective glove, blowing the glove off, and resulted in direct impact to the volar wrist which sustained a deeper burn (Figure 3). Cool water was applied for 5-10 minutes at the workplace and then for 20-30 minutes at the local hospital. The patient was transferred to the metropolitan area 1600kms away for specialist treatment at the Western Australian state adult burns facility. The participant was recruited into the study when he presented to the burns clinic on Day 5 post-injury and completed the study on Day 11 when being transferred back home to the country.

![Participant A - burn injury (Day 11)](image)

Figure 3: Participant A - burn injury (Day 11)

Image showing the remaining area of deeper injury at the volar wrist where the blast from the oxy-torch was concentrated inside the glove. The participant was discharged back to the rural community at this point and was to continue managing his own dressings for the remaining small wound.

After explanation of, and enrolment in the study, the participant was trained in application and operation of the NIN device, lasting around 1 minute. Due to time constraints the array electrodes were strapped around the participant’s forearm by the researcher. The
The participant was able to operate the NIN device independently, and the researcher then observed the participant’s interaction with the device using the Volitional Questionnaire. The participant’s wife, a trained nurse, and two year old daughter were present throughout; the burn care nurse entered the room and commenced the wound care procedure immediately after training was completed.

![Figure 4: FULL DATA - Diary VAS Ratings (Participant A)](image)

**Figure 4: FULL DATA - Diary VAS Ratings (Participant A)**

Trends —
Day of wound care procedure when NIN was first introduced (WCP1), compared to previous day:
- Pain = ↓11%; Anxiety = ↑68%; Confidence in ability to manage own pain = ↓50%
Day of wound care procedure when NIN was first introduced (WCP1), compared to following day:
- Pain = ↓27%; Anxiety = ↓88%; Confidence in ability to manage own pain = ↑52%

**Discussion of feasibility (Participant A)**

Did pain or anxiety increase in response to the introduction of NIN?

Pain and anxiety showed a direct relationship and followed a general downward trend over the period of the study (Figure 5), with the exception of Day 6 (WCP1) when the NIN was introduced.
Data on the participant's pain and anxiety have been separated off from the main graph to more easily view the relationship between them. Pain and anxiety followed a close direct relationship except for the day of introduction of NIN, when pain did not spike along with anxiety.

A hypothesis that may be considered for this finding is:

- The introduction of NIN did not cause an increase in pain, however, anxiety did increase as could be expected for a wound care procedure, or as a result of the introduction of NIN, or as a result of some other unknown variable.

Removal of old dressings and debridement of necrotic tissue is generally the most painful part of a wound care procedure (Stoddard et al., 2002), so pain and resultant anxiety around wound care is generally expected (Lončar et al., 2006).

On appraisal of other sources of data it appears that pain and anxiety VAS ratings recorded at home in the evening were different to those reported during the day at the wound care
procedures. Figure 6 shows that both pain and anxiety VAS ratings lowered from pre to post-dressing on both WCP1 and WCP2.

![Figure 6: Wound Care Procedure VAS Ratings (WCP1 & WCP2) (Participant A)](image)

Trends:
WCP1 (Pre to post dressing comparison) - Pain = ↓1%; Anxiety = ↓35%; Confidence in ability to manage own pain = ↑13%; Ease of use of NIN = ↑16%; Motivation to use NIN = ↑10%
WCP2 (Pre to post dressing comparison) - Pain = ↓11%; Anxiety = ↓13%; Confidence in ability to manage own pain = ↑46%; Ease of use of NIN = ↑3%; Motivation to use NIN = ↑2%

Based on this additional information the hypothesis can be modified:

- The participant responded with elevated anxiety at home on Day 6 in anticipation of the wound care procedure, and the introduction of NIN did not result in an increase in pain or anxiety in the clinic environment.

The comment recorded by the participant in the Diary: Day 6 entry (Table 3) “I used it once when I got home and it seemed to reduce pain. Had it on for 15 mins. Didn’t have much pain through the day.”, appears to support this modified hypothesis.
Did the patient’s confidence in their ability to manage their own pain change in response to introduction of NIN?

Based on the daily diary VAS ratings, the participant’s confidence in his ability to manage his own pain showed an upward trend over the course of the study, inverse to the downward trend of pain (Figure 7). This inverse relationship was most apparent for WCP0, when the procedure was carried out in the Emergency Department prior to referral to the specialist burns clinic. In this instance pain was extremely high (9.8/10) and confidence was extremely low (0.3/10). The inverse relationship was again very clear for WCP2, the second dressings procedure using the NIN, where pain was extremely low (1.8/10), and confidence extremely high (9.5/10). This finding is expected as, by this stage, the participant was more familiar with the burns clinic environment and knew largely what to expect from a wound care procedure; was familiar with the NIN device; and had a much smaller wound area.

For WCP1 when the NIN was introduced, confidence lowered (50%) similarly to the other wound care procedure days, however, pain also lowered (11%) and so the inverse relationship was not maintained on this day based on diary VAS ratings at home.

The following hypothesis is suggested based on the above collection of findings:

- The loss of confidence in ability to manage own pain experienced on each wound care procedure day may relate to increased pain or another unknown variable, however, the introduction of NIN did not negatively affect the participant’s confidence in his ability to manage his own pain.

<table>
<thead>
<tr>
<th>Data location</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diary: Day 6 (day of WCP1)</td>
<td>“I used it once when I got home and it seemed to reduce pain. Had it on for 15 mins. Didn’t have much pain through the day.”</td>
</tr>
<tr>
<td>Diary: Day 7</td>
<td>“Didn’t have much pain so didn’t have pain killers or NIN device.”</td>
</tr>
</tbody>
</table>

Table 3: TABLE OF COMMENTS - Participant A
<table>
<thead>
<tr>
<th>Comment from staff: On day of WCP1</th>
<th>“Remember you can use that [indicating NIN].”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments during WCP1:</td>
<td>“Next one [wound care procedure] will be fine. I managed this one.”</td>
</tr>
<tr>
<td>Diary: Day 8 (day of WCP2)</td>
<td>“Haven’t been in much pain during the day so haven’t needed pain killers or NIN device.”</td>
</tr>
<tr>
<td>Diary: Day 9</td>
<td>“Didn’t have much pain today, a little bit in my rist [sic] but not enough to need paid [sic] relief or NIN device.”</td>
</tr>
<tr>
<td>Diary: Day 10</td>
<td>“Not much pain at all today, haven’t had and [sic] pain killers or NIN device.”</td>
</tr>
<tr>
<td>Diary: Day 11</td>
<td>“Haven’t been in much pain today so haven’t had pain killers or NIN device.”</td>
</tr>
<tr>
<td>Diary: On completion of study</td>
<td>“When I was at home I couldn’t bring my hand down [indicating lowering hand to dependent position], but when I put it [NIN] on I could walk around and use my hand normally. It did the job.”</td>
</tr>
<tr>
<td></td>
<td>“I don’t know whether it worked in the way it was supposed to but I didn’t think about that [indicating burn injury], [while I was] thinking about that [indicating NIN].”</td>
</tr>
<tr>
<td></td>
<td>“The second [wound care procedure] was easier. I knew what to expect from the procedure and I knew it [indicating NIN] would work. I felt reassured I had some way of coping.”</td>
</tr>
<tr>
<td></td>
<td>“It was good that it [NIN] was instant. With Panadol you’re just waiting for it to kick in.”</td>
</tr>
<tr>
<td></td>
<td>“The [NIN] strap was really long. It would be good if it was able to be shortened.”</td>
</tr>
<tr>
<td>Comment from wife: On completion of study</td>
<td>“It would be good to have something that could be used in the shower. It [NIN] helped to reduce his anxiety and he would get more anxious with the shower, so it would be good to have something like the NIN that could help him feel reassured.”</td>
</tr>
<tr>
<td>Comment from staff: On day of WCP1</td>
<td>“It distracts the patient whilst dressings are done. The patient appeared anxious while dressings were taken down prior to using NIN. His behaviour included pulling away to avoid pain. When he was occupied with the NIN device he remained relatively still and appeared more relaxed.”</td>
</tr>
</tbody>
</table>

Looking to the VAS ratings (Figure 6) which were taken before and after the wound care procedures on days 6 and 8 (WCP1 and WCP2), the participant’s confidence in his ability to manage his own pain increased 13% from pre to post-dressing at the wound care procedure when NIN was introduced (WCP1) and confidence increased 46% on the second occasion (WCP2). Viewed along with the patient comment during WCP1 (Table 3) that “Next one [wound care procedure] will be fine. I managed this one.”, this data supports the above hypothesis.
Did NIN interfere with the work of nursing staff or patient activities? Was the device easy to use?

All data point towards no interference of NIN in the work of the nursing staff or patient activities. With the exception of a practical suggestion made by the participant in the comments at the completion of the study (Table 3) that “The [NIN] strap was really long. It would be good if it was able to be shortened.”

Nursing staff (Figure 8) rated the NIN extremely easy to use for this participant (10/10), and extremely low for interference in nursing activities (0/10), at both wound care procedures. Participant rating for ease of use was only recorded on the day of introduction of NIN (WCP1) and was high (8.9/10). As described in the participant comments (Table 3), the participant reported using the NIN on the day of introduction only, as his pain level was
sufficiently lowered to be able to cease both analgesic medication and the NIN, from Day 6 to Day 11 (Table 3). The participant therefore only used the NIN in the burns clinic during wound care procedures (WCP1 and WCP2). The following hypothesis is suggested:

- The introduction of NIN did not interfere with the activities of nursing staff or the participant, and was perceived by both as easy to use.

![Figure 8: Nursing Staff VAS Ratings for Wound Care Procedure 1 & 2 (Participant A)](image)

VAS ratings recorded by nursing staff following the wound care procedures.

Was the patient motivated to use the NIN device?

Data from several sources show that motivation to use the NIN was perceived as high (9/10) by the participant (Figure 6), on the day of introduction (WCP1) at the burns clinic, and also at home (9.9/10) on the same day (Figure 4). Observations of behaviour measured with the Volitional Questionnaire (Figure 9) lend support to the conclusion that the participant was highly motivated on this occasion. Nursing staff perception (Figure 8) was that the participant was extremely motivated to use the NIN (10/10), and that the nurse was also extremely motivated to have the participant use the NIN in future (10/10).
The Volitional Questionnaire on the day of the second wound care procedure (Figure 10) was of limited use, as few of the measureable behaviours were observed. This may be reflective of the fact that the task of applying the NIN was now very familiar to the participant, so there was no opportunity to observe behaviours such as ‘Tries new things’, ‘Shows curiosity’ or ‘Tries to correct mistakes/failures’. Alternatively this lack of data may reflect the insensitivity of the Volitional Questionnaire to behaviours of highly motivated individuals (Chern et al., 1996).

![Volitional Questionnaire Results for Wound Care Procedure 1 (Participant A)](image)

**Figure 9: Volitional Questionnaire Results for Wound Care Procedure 1 (Participant A)**

All data collected with the Volitional Questionnaire (VQ) on the day of introduction of NIN (WCP1) suggest a high level of motivation to use the NIN.
Few of the listed behaviours were observed during the second wound care procedure, possibly resulting from insensitivity of the assessment for the purpose of the study.

This data together leads to a hypothesis that:

- The motivation to use the NIN was high for both staff and participant.

On the second occasion using the NIN whilst in the burns clinic (WCP2), the participant (Figure 6), and nursing staff (Figure 8) VAS data shows that the participant had a high level of motivation, however, on the same day, the motivation to use the NIN in the home (Figure 4) was recorded as 0.2/10, and continued this way for the remaining days of diary data collection. Reduction in pain may have been as a result of normal healing processes; the introduction of NIN; or another unknown variable, however, Figure 11 shows the clear relationship between reduction in pain and a rapid decline in motivation to use the NIN in the home.
This suggests a modification of the above hypothesis:

- The participant and staff were motivated to use the NIN while pain was high, however, once pain became very low, there was insufficient internal motivation for the participant to continue using the NIN device at home. The participant was externally motivated to use the NIN in the clinic, regardless of low levels of pain, whilst in the presence of the staff and researcher.

These findings will be discussed further in the general discussion in context with the other cases.
4.4 CASE STUDY B – FINDINGS AND DISCUSSION

A 42 year old mining worker – employed as a conveyor belt splicing supervisor, was wearing protective gloves when he stepped in to assist with belt-splicing and his gloves were saturated with solvent. He then moved away from the conveyor belt and lit a cigarette which ignited his gloves and the surrounding area including the conveyor belt. The participant obtained a fire extinguisher and put out the fire prior to removing his gloves (approx. 15-20 seconds) resulting in circumferential skin loss over the proximal and middle phalanges of all fingers of the right hand, as well as small burns to fingertips of the left hand.

Figure 12: Participant B burn injury (Day 2)
The participant was enrolled in the study on the day following injury. His partner and adult step-daughter were present during the wound care procedure.

Following enrolment, the participant was provided with a brief explanation of the NIN device and how to apply and operate it, which took around 1-2 minutes. The array electrodes were strapped around the participant’s forearm by the participant with some assistance from his partner. With the bulky bandages and his difficulty manipulating objects, the participant’s partner explained that since his injury she had been assisting him with self-care tasks. The participant was able to operate the NIN device without difficulty, and the researcher then observed the participant during the wound care procedure using the Volitional Questionnaire.

During discussion with the participant and his partner, while waiting for the wound care procedure to commence, several important factors came to light which may have had a bearing on the study results:

- The participant reported taking the maximum dosage of his analgesic medication prior to attending the clinic, and stated that as a result he was experiencing almost no pain, even while the most-adhered dressings were removed.
- The participant was jovial and distracted for the first part of the appointment, talking of going to a favourite fast-food outlet unavailable in his rural hometown, as soon as he could leave the clinic.
- The participant was discussing a meeting scheduled with his work supervisors for after the clinic appointment, where he was expecting to be dismissed over safety concerns around his injury (on a subsequent visit to the burns clinic, the participant
explained that this had occurred). The participant and his partner showed obvious
distress at the financial burden his dismissal would cause, and the difficulty of
obtaining transport at great cost to return to the remote rural town where their
teenage daughter was looking after herself while they were in the metropolitan area.

The participant was later withdrawn from the study on Day 5 following injury, when the
surgeon determined that his right hand would require debridement and skin grafting, based
on the depth of injury and the likely healing time. As the participant felt that the NIN may
provide some pain relief during his recovery from surgery, he was allowed to continue use
after exclusion from the study as per the Royal Perth Hospital (RPH) ethics requirement. The
participant and nursing staff VAS ratings before and after the first wound care procedure,
and the Volitional Questionnaire were able to be reviewed as part of the study, however,
the participant was lost to follow up, and so patient diary data was not available for
inclusion for this case study.

Despite the fact that Participant B had to be withdrawn from the study once he was
scheduled for surgical intervention, some useful insight can be gleaned from his interaction
with the NIN device at his first wound care procedure.
**Figure 13: Wound Care Procedure VAS Ratings (Participant B)**

**Trends:**
- (Pre to post dressing ratings) - Pain = ↓15%; Anxiety = ↓4%; Confidence in ability to manage own pain = ↑36%; Ease of use of NIN = ↓1%; Motivation to use NIN = ↓3%

**Discussion of feasibility (Participant B)**

Did pain or anxiety increase in response to the introduction of NIN?

From results of the participant VAS ratings (Figure 13) it is apparent that both pain and anxiety were low and did not increase from pre to post-dressings ratings (Pain = ↓15%; Anxiety = ↓4%), on introduction of the NIN. This is supported by the nursing staff VAS ratings of both pain and anxiety at 0/10 following the wound care procedure (Figure 14).
The participant’s high level of analgesic medication prior to the wound care procedure may potentially have masked an increase in pain and resultant anxiety, however as this medication was taken prior to both pre and post-dressing data collection, it would have had an equal impact on both, therefore the most likely hypothesis seems:

- The introduction of NIN did not have a negative impact on the participant’s pain or anxiety.

Comments by both the participant and nursing staff (Table 4) that the NIN intervention was seen in a positive light by the participant, seem to support this hypothesis.

Table 4: TABLE OF COMMENTS - Participant B

<table>
<thead>
<tr>
<th>Data location</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments during WCP1:</td>
<td>“[The NIN intervention] Sounds positive.”</td>
</tr>
<tr>
<td>Comment from staff: On day of WCP1</td>
<td>“Didn’t interfer [sic] at all. Patient was very compliant. Didn’t complain about treatment.”</td>
</tr>
</tbody>
</table>
Did the patient’s confidence in their ability to manage their own pain change in response to introduction of NIN?

The participant’s VAS rating increased by 36% from pre to post dressing with regard to confidence in ability to manage his own pain (Figure 13), and the nursing staff VAS rating placed his confidence high at 9/10 (Figure 14). Together this suggests the hypothesis:

• The introduction of NIN did not adversely affect the participant’s confidence in his ability to manage his own pain during this wound care procedure.

Did NIN interfere with the work of nursing staff or patient activities? Was the device easy to use?

Limited data was available from only one wound care procedure with regard to interference of the NIN device in activities, however, the nursing staff member gave a rating of 0/10 for interference with nursing staff activities on this occasion (Figure 14).

With regard to ease of use, data from both the participant (Figure 13), where ease of use was rated pre and post-dressing as 9.7/10 and 9.8/10 respectively, and from the nurse (Figure 14) where ease of use was rated at 10/10, suggest that the device presented no difficulties. Together this data, though limited, supports a hypothesis that:

• The NIN was viewed by both participant and staff as easy to use, and caused no interference in the activities of nursing staff or participant during this wound care procedure.

Was the patient motivated to use the NIN device?

Data from the participant (Figure 13) where motivation was rated as 10/10 pre-dressing, and 9.7/10 post-dressing, and also from the nurse (Figure 14) where motivation was rated at 10/10, would suggest that the participant was highly motivated to use the NIN. Looking further at the results from the Volitional Questionnaire, where the participant’s behaviours
were observed, suggested that in fact, the participant may be less motivated than he indicated verbally. As seen in Figure 15, the participant was observed to be passive or hesitant in several behaviours, and only spontaneous in the behaviours ‘seeks additional responsibilities’ and ‘tries to solve problems’, which occurred when he took the initiative to adjust the NIN positioning while assisting with the dressing.

![Figure 15: Volitional Questionnaire Results for Wound Care Procedure (Participant B)](image)

The graph is reflective of an individual of only moderate motivation, with behaviours rated on the lower level of the scale at ‘passive’ or ‘hesitant’, and only two behaviours rating the highest level of ‘spontaneous’.

As described earlier in the case study, the participant and his partner were both very distracted by their financial and social concerns throughout the clinic visit. The participant was willing to be involved in the study, and discussed the concept of the NIN intervention positively, as seen in the comment (Table 4). However, his degree of engagement was limited, and it is not known whether he would have continued to use the NIN had he remained in the study. The collective appraisal of all this data leads to the following hypothesis for this participant:
• The participant was sufficiently motivated to engage in the use of the NIN during the wound care procedure in the clinic, however, his motivation to continue using the NIN in the home environment cannot be determined because of limited data.

The participant was reviewed in the burns clinic when he presented 10 days after injury, for a wound care procedure after his skin grafts had taken, and to return the NIN device. The participant described using the NIN device during his first post-surgery dressings change, however, there was no verification of this, and the participant may have simply been motivated by a desire to please the researcher.
4.5 CASE STUDY C – FINDINGS AND DISCUSSION

A 30 year old female chef sustained a >1% burn when a metal pan slipped as she was removing it from the commercial oven, and the pan made contact with the dorsal surface of her left hand, over the area of the first metacarpal (Figure 16). Her injury occurred late in the evening and she managed her own wound care and pain over the first three days post-injury. During the baseline period, the participant presented to a general metropolitan hospital Emergency Department on Day 4, where a wound care procedure was carried out prior to referral to the specialist burns clinic, which she attended on Day 7. At this time she was entered into the study.

The participant described the reason for her initial attendance at the Emergency Department in her comments (Table 5) on Day 3: “My blister popped during the night and I woke up with more pain than the previous days. I put some Burnaid on my burn to try and calm the pain but it didn’t work. At night I took the dressing (fixomul) [sic] off after...”
showering and it was covered in a yellowish pus. I was a bit concerned that it might be infected so I was [sic] it well under cold running water trying to get rid of all the pus.

Afterwards I put some gauze [sic] on, (not fixomul) [sic] and took some panadol to sleep without pain.”

And Day 4: “I went to the hospital to check that my wound wasn’t infected. I was feeling a bit dizzy and unwell. I was concerned about not being able to work. I was supposed to go to work but couldn’t really move my hand well.”

The participant experienced discomfort with analgesic medication as evidenced by comments (Table 5) recorded by nursing staff on the day of the first wound care procedure and introduction of NIN (WCP1): “Pt [patient] was feeling sick on arrival probably due to analgesia”, and by the participant following the same wound care procedure: “I’m worried about pain relief. Panadol + codeine makes me feel unwell. Only panadol [sic] I’m not sure is enough.”

The participant was very willing to provide detailed information and took time to ensure accuracy in her comments throughout the data collection period.

Table 5: TABLE OF COMMENTS - Participant C

<table>
<thead>
<tr>
<th>Data Location</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diary: Day 2</td>
<td>“It was a bit hard to move my hand but overall was almost a normal day. I used my hand less than normal but still cooked, did some laundry etc.”</td>
</tr>
<tr>
<td>Diary: Day 3</td>
<td>“My blister popped during the night and I woke up with more pain than the previous days. I put some Burnaid on my burn to try and calm the pain but it didn’t work. At night I took the dressing (fixomul) [sic] off after showering and it was covered in a yellowish pus. I was a bit concerned that it might be infected so I was [sic] it well under cold running water trying to get rid of all the pus. Afterwards I put some gauze [sic] on (not fixomul) [sic] and took some panadol to sleep without pain.”</td>
</tr>
<tr>
<td>Diary: Day 4</td>
<td>“I went to the hospital to check that my wound wasn’t infected. I was feeling a bit dizzy and unwell. I was concerned about not being able to work. I was supposed to go to work but couldn’t really move my hand well.”</td>
</tr>
</tbody>
</table>
| Diary: Day 5  | “I barely left the bed all day. I felt unwell and sleepy. I didn’t move my hand at all. I used my right hand only. Didn’t do any house chores all day, only cooked at night. Covered my dressing with a latex glove but barely used my hand. Had to ask my
Diary: Day 6 (day of WCP1)

“The only not-so-easy part [of the NIN] for me is to strap the NIN around my arm with just one hand. Other than that quite easy. There was a moment when the tingling sensation was starting to hurt and I had to turn it down a little. It was around the 4th time that I was using it.”

“(burn) pain comes and goes but when it comes is sharp and annoying. I used NIN in those times of pain and it worked. The pain was gone a few minutes after using it [NIN].”

Comments during WCP1:

Pre-procedure VAS rating comments:
- Pain VAS: “It was really painful when the dressing was removed and the wound was cleaned [without NIN].”
- Anxiety VAS: “It concerns me how much pain will I feel. If I will be able to work or move my hand. I’m also feeling dizzy which doesn’t help.”
- Confidence VAS: “I’m worried about pain relief. Panadol + codeine makes me feel unwell. Only panadol [sic] I’m not sure is enough.”
- Ease of use VAS: “Doesn’t seem complicated.”

Overall comments: “If it can help me it’ll be great. If I can help so that others feel less pain that’s also great.”

Post-procedure VAS rating comments:
- Pain VAS: “There was not much touching so there wasn’t too much pain.”
- Anxiety VAS: “Some anxiety for pain and movement.”
- Confidence VAS: “I think with regular panadol [sic] during the day as recommended and the NIN I can manage the pain.”

Comment from staff: On day of WCP1

“Pt [patient] was feeling sick on arrival probably due to analgesia. Patient was visibly more relaxed by end of dressing.”

Diary: Day 7

“I don’t feel that I can use it [NIN] to do things. I think it will be uncomfortable carrying it around. Haven’t tried though.”

“I got anxious about being able to go back to work without pain and I’m wondering how long will this whole process be.”

Diary: Day 9 (day of WCP2)

“I used it [NIN] to be able to rehabilitate my hand by moving it without pain.”

Diary: Day 10

“Almost without pain, still used it [NIN] to exercise the hand.”

Diary: Day 11

“Pain is almost gone. Still used the machine to exercise just in case.”

Diary: Day 12

“Didn’t feel pain. Changed the bandage and the wound is almost healed. Still forced myself to exercise and used the NIN while I did it, just in case.”

Discussion of feasibility (Participant C)

Did pain or anxiety increase in response to the introduction of NIN?

Pain followed a downward trend over the duration of the study, with a period of elevated pain on days 4 and 5 corresponding to her attendance at the Emergency Room; at the same time anxiety increased in the first two days following injury, slowly reducing again over the remainder of the study period. Viewed together (Figure 18), there appears to be a loose
direct relationship between pain and anxiety for parts of the graph, and they diverge in other areas such as Day 1, Day 3, and Days 7 and 8.

**Figure 17: FULL DATA - Diary VAS Ratings (Participant C)**

Trends –
Day of wound care procedure when NIN was first introduced (WCP1), compared to previous day: Pain = ↓28%; Anxiety = ↓28%; Confidence in ability to manage own pain = ↑26%
Day of wound care procedure when NIN was first introduced (WCP1), compared to following day: Pain = ↓4%; Anxiety = ↑16%; Confidence in ability to manage own pain = ↓13%

Comments made in the diary on Day 3: “I was a bit concerned that it might be infected” and Day 7: “I got anxious about being able to go back to work without pain and I’m wondering how long will this whole process be”, could suggest that these elevations in anxiety were related to general anxiety surrounding the injury and implications for work, rather than anxiety specifically about the pain. A direct relationship between pain and anxiety is more
apparent on days 4 and 5, and 9-12 (Figure 18) when pain and anxiety were rated similarly, however, on days 7 and 8, the relationship between pain and anxiety was not clearly defined, as pain continued on a downward trend, while anxiety was once again elevated.

Figure 18: PAIN/ANXIETY RELATIONSHIP - Diary VAS Ratings (Participant C)
The graph shows the overall downward trend of pain and sections where anxiety followed a direct relationship with pain, as compared to sections where anxiety deviated from this relationship.

Whether this observation had any relationship to the introduction of the NIN device is not able to be determined, however, the following hypothesis around pain and anxiety is suggested:

- Increased anxiety at home on Day 5, resulted from either the introduction of NIN, the fears around injury and work described above, or some other unknown variable; however pain continued on a downward trend from Day 4 onward, and was not adversely affected by the introduction of the NIN on Day 6.
The VAS ratings recorded by the nursing staff (Figure 20) at this dressing (WCP1) suggested a moderate level of pain (3.5/10) and anxiety (5.9/10), and the participant VAS ratings (Figure 19) on the day of this wound care procedure (WCP1), showed reduction in both pain ($\downarrow$36%) and anxiety ($\downarrow$33%) from pre to post-dressings, supporting the hypothesis that the periods of elevated anxiety at home were not directly related to pain or the introduction of the NIN.

![Figure 19: Wound Care Procedure VAS Ratings (WCP1 & WCP2) (Participant C)](image)

Trends -
WCP1 (Pre to post dressing ratings) - Pain = $\downarrow$36%; Anxiety = $\downarrow$33%; Confidence in ability to manage own pain = $\downarrow$5%; Ease of use of NIN = $\uparrow$15%; Motivation to use NIN = $\downarrow$4%;
WCP2 (Pre to post dressing ratings) - Pain = 0%; Anxiety = $\uparrow$25%; Confidence in ability to manage own pain = $\downarrow$2%; Ease of use of NIN = 0%; Motivation to use NIN = $\downarrow$8%
Thus the above hypothesis has been modified to:

- Increased anxiety at home most likely resulted from fears around injury and work, while pain followed a downward trend and was not adversely affected by the introduction of the NIN.

Did the patient’s confidence in their ability to manage their own pain change in response to introduction of NIN?

Pain and the participant’s confidence in her ability to manage her own pain followed a fairly close inverse relationship (Figure 17). Looking at the trend in confidence around WCP0 the first procedure carried out in the Emergency Department, without specialist staff, and with fears about the wound and impact on work, the participant showed a decrease in confidence (Figure 21), (↓13% on Day 4 compared to Day 3; then ↑13% on Day 5 compared to Day 4). In contrast, on the day of introduction of the NIN, the participant’s confidence went up 26%, then dropped by 13% the following day. Whilst the reasons for these changes in confidence cannot be clearly determined, the hypothesis suggested is:
• That confidence in ability to manage own pain was not adversely affected by the introduction of NIN for this participant.

Figure 21: PAIN/CONFIDENCE RELATIONSHIP - Diary VAS Ratings (Participant C)
Showing the inverse relationship between pain and confidence in the ability to manage own pain.

Did NIN interfere with the work of nursing staff or patient activities? Was the device easy to use?

The nurse rated interference with treatment activities low at 1.8/10 (WCP1) and 1.6/10 (WCP2), but did not indicate through any specific feedback what the interference may have been.

Comments made by the participant, in the diary (Table 5) on Day 7, the day following introduction of NIN, suggest that interference with participant activities was minor, and related to a perception of difficulty carrying the NIN hand controller whilst continuing with daily activities: “I don’t feel that I can use it [NIN] to do things. I think it will be uncomfortable carrying it around. Haven’t tried though.”
In the clinic environment, based on data from the participant VAS ratings (Figure 17) and the nursing staff VAS data (Figure 20), both the participant and nurse rated the NIN high on ease of use following the first wound care procedure (WCP1) at 9.0/10 and 7.2/10 respectively. On the second occasion the participant rated ease of use at 10/10, while the nurse rated it at 8.2/10. Comments by the participant on ease of use at home suggest that any issues were related to fitting the device: “The only not-so-easy part [of the NIN] for me is to strap the NIN around my arm with just one hand. Other than that quite easy.”, and adjusting the intensity setting: “There was a moment when the tingling sensation was starting to hurt and I had to turn it down a little. It was around the 4th time that I was using it.” At the same time, the VAS ratings in the diary on ease of use (Figure 17), support the idea that on return home the participant found the device easy to use (9.7/10), and continued to do so with 10/10 for the remaining ratings.

When viewed overall, the data suggest the following hypothesis:

a) The NIN device was perceived by the participant and staff as easy to use, and did not interfere greatly with the activities of either participant or staff.

Was the patient motivated to use the NIN device?

Based on data from the diary (Figure 17), the participant’s motivation to use the NIN was fairly high (7.5/10) on day of introduction, but then dropped rapidly to 1.2/10 two days later. When viewed in relationship to pain (Figure 22), this reduction in motivation appears to parallel the reduction in pain, however, the day after the second wound care procedure (Day 10), there was a brief sharp rise in motivation (54% increase compared to Day 9), followed by an immediate correction (48% reduction compared to Day 10). A possible explanation for this may be a discussion that the participant and researcher had about the NIN, when the
participant was asking about the research findings in populations other than burns. The participant showed interest in the reduction in oedema and increased range of movement findings in post-operative orthopaedic studies, and may have viewed the NIN as having the potential to offer more than just pain reduction for her burn recovery. Comments in her diary on Day 10 (Table 5): “Almost without pain, still used it [NIN] to exercise the hand.”, may support this view.

![Graph of Pain/Motivation Relationship - Diary VAS Ratings (Participant C)](image)

**Figure 22: PAIN/MOTIVATION RELATIONSHIP - Diary VAS Ratings (Participant C)**

Explanation of graph detail

The nursing staff VAS ratings (Figure 20) in the clinic during both wound care procedures suggested a high level of motivation for the participant to use the NIN in future (9.2/10 and 9.0/10 for WCP1 and WCP2 respectively), as well as a perception that the participant was fairly highly motivated to use the device (8.2/10 and 8.3/10 for WCP1 and WCP2 respectively). The participant VAS ratings (Figure 19) show high motivation (8.8/10 and
8.4/10 pre and post-dressings for WCP1; 7.8/10 and 7.0/10 pre and post-dressings for WCP2), however motivation dropped from WCP1 to WCP2 (↓10% pre-dressing ratings; ↓14% post-dressing ratings).

Looking to the results of the Volitional Questionnaire for the first wound care procedure (Figure 23), the participant spontaneously demonstrated 12 out of the 14 behaviours, and only ‘shows pride’ and ‘seeks challenges’ were not in evidence because of a lack of opportunity.

The Volitional Questionnaire results for the second wound care procedure (Figure 24) shared a similar pattern, with two behaviours rated lower at ‘involved’, and all other behaviours that were observed remaining with a rating of ‘spontaneous’.

**Figure 23: Volitional Questionnaire Results for Wound Care Procedure 1 (Participant C)**

All data collected with the Volitional Questionnaire (VQ) on the day of introduction of NIN (WCP1) suggest a high level of motivation to use the NIN.
Initially the participant demonstrated a high level of motivation to use the NIN device in the clinic and at home, however the motivation to use at home changed over time, leading to the following hypothesis:

- The participant and staff were highly motivated for the participant to use the NIN in the clinic. In the home environment motivation reduced rapidly along with reduction in pain, and elevated again briefly in line with a discussion in the clinic about potential non-pain related benefits of NIN in orthopaedic literature.

The implications of this will be discussed in greater detail in the general discussion section.
4.6 CASE STUDY D – FINDINGS AND DISCUSSION

A 25 year old male filmmaker was cooking at home when he knocked the handle of the wok and tipped hot oil over both hands. He placed both hands in the swimming pool for 2-3 minutes but upon realising that blisters where already forming, discontinued cooling the burn and drove himself to the nearest hospital Emergency Department, around 20 minutes away. He sustained approximately 3% total burn surface area distributed fairly equally between the left and right hands.

The participant was enrolled in the study on Day 2 following the injury when he presented at the burns clinic and continued to collect data until Day 9 post-injury, when he went away for the Christmas holiday period and forgot to take the NIN device with him.

Figure 25 Participant D - burn injury (Day 2)

Showing deeper burn on the right hand.
Prior to taking down the dressings, the right hand was chosen to be the active or NIN treated hand, as the participant was right dominant and therefore more likely to involve this hand in function. Once dressings were removed, the nursing staff assessed all wounds and determined that the right hand had suffered a slightly deeper burn injury, however, burn size or depth is not indicative of the amount of pain a patient will experience (Connor-Ballard, 2009).

As a filmmaker, the participant had recently returned from a project in Mongolia where he joined a charitable motorbike ride, filming the ride as well as children with severe burn contractures. He was very interested in the wound care process and the concept of pain and asked questions of the nurse and researcher while the dressings were being changed. During these discussions he revealed that his usual pain coping style was to avoid looking at wounds or injuries, but that he felt he was able to be more involved in the procedure this time, stating that this was “maybe because of Mongolia, maybe because I drove [himself to hospital].” He explained that by this he meant that he may have developed a different perspective on his injury as a result of recent experiences challenging his view of himself as lacking courage with regards to pain.

Following feedback from the previous participants, the NIN strap was shortened so that it only wrapped once around Participant D’s arm, and the participant was instructed more strongly to keep adjusting the stimulus to a strong, sub-noxious sensation.

Participant diary data for the Left, untreated hand (Figure 26) versus the Right, treated hand (Figure 27) have been presented in two separate graphs for clarity. Data collected for Day 1 on pain, anxiety and confidence were rated the same for left and right hand, as it was decided that reliable ratings could not be determined retrospectively.
Figure 26: FULL DATA - Diary VAS Ratings (Participant D) Left, untreated hand

Trends –
Day of wound care procedure when NIN was first introduced (WCP1), compared to previous day: Pain = ↓39%; Anxiety = ↓72%; Confidence in ability to manage own pain = ↑30%
Day of wound care procedure when NIN was first introduced (WCP1), compared to following day: Pain = 0%; Anxiety = ↑1%; Confidence in ability to manage own pain = ↓12%
The graph for the left hand only includes ratings of pain, anxiety and confidence in ability to manage own pain as the NIN was not implemented in this hand. The two graphs show very similar trends for all three measures. The right hand graph (Figure 27) then shows additional data about the perceived ease of use of NIN and motivation to use the device.

**Discussion of feasibility (Participant D)**

Did pain or anxiety increase in response to the introduction of NIN?

To address the question of whether the participant’s pain or anxiety increased as a result of the introduction of NIN, it is necessary to look at multiple sources of data, first comparing the left, untreated hand with the right, treated hand.
Figure 28 and Figure 29 show clearly that ratings for left and right hands for both pain and anxiety followed a very similar path. Several hypotheses could explain this:

a) The NIN device had no impact on either pain or anxiety;

b) The response to NIN regarding pain and anxiety was equal, as a result of a cross over effect within the central nervous system, as described in the literature (Yuan et al., 2010);

c) The participant was unable to separate his experience of pain or anxiety sufficiently to determine any difference between left and right hands.

![Figure 28: PAIN - Left, untreated vs Right, treated - Diary VAS Ratings (Participant D)](image)

Daily pain scores were scored retrospectively for Day 1, using a common score, and thereafter scored separately. Left and right pain ratings showed a similar overall downward trend.

Looking to the participant VAS ratings for left (Figure 32) and right (Figure 33) hands, the pain scores from pre to post-dressing increased, potentially as a result of the disruption to
tissue during the procedure (Summer et al., 2007), however, the pain increased less for the right, treated hand (↑10%) than it did for the left, untreated hand (↑32%), and anxiety reduced for both right, treated (↓15%) and left, untreated (↓12%) hands.

Reviewing the diary data at home for this participant (Figure 30, Left hand) and (Figure 31, Right hand), a direct relationship between pain and anxiety is apparent. However, following his first visit to the burns clinic, anxiety dropped for both left and right hands, whilst he still rated his daily pain in the mid-range (between 6.3/10 and 3.8/10 for left; and between 6.5/10 and 3.5/10 for right) throughout days 2 to 9.
Figure 30: PAIN/ANXIETY RELATIONSHIP - Diary VAS Ratings (Participant D); Left, untreated hand
Pain and anxiety for the left hand showed a direct relationship with anxiety ratings lower than pain ratings.

Figure 31: PAIN/ANXIETY RELATIONSHIP - Diary VAS Ratings (Participant D); Right, treated hand
Pain and anxiety showed a direct relationship with anxiety ratings lower than pain ratings.
The participant comments in the diary (Table 6), on Day 2: “Using it [NIN] but not enough relief to not use drugs.”, Day 3: “Same as before – still need drugs.”, and Day 4: “Same as other days – need drugs still.”

Figure 32: Wound Care Procedure VAS Ratings (WCP1 & WCP2) (Participant D); Left, untreated
Trends:
WCP1 (Pre to post dressing ratings) - Pain = ↑32%; Anxiety = ↓12%; Confidence in ability to manage own pain = ↓27%
WCP2 (Pre to post dressing ratings) - Pain = ↓14%; Anxiety = ↓15%; Confidence in ability to manage own pain = ↑8%
Figure 33: Wound Care Procedure VAS Ratings (WCP1 & WCP2) (Participant D); Right, treated

Trends:
WCP1 (Pre to post dressing ratings) - Pain = ↑10%; Anxiety = ↓15%; Confidence in ability to manage own pain = ↑3%; Ease of use of NIN = ↑4%; Motivation to use NIN = ↓3%
WCP2 (Pre to post dressing ratings) - Pain = ↓18%; Anxiety = ↓6%; Confidence in ability to manage own pain = ↑3%; Ease of use of NIN = 0%; Motivation to use NIN = 0%

Table 6: TABLE OF COMMENTS - Participant D

<table>
<thead>
<tr>
<th>Data Location</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diary: Day 2 (day of WCP1)</td>
<td>“Using it [NIN] but not enough relief to not use drugs.”</td>
</tr>
<tr>
<td>Diary: Day 3</td>
<td>“Same as before – still need drugs.”</td>
</tr>
<tr>
<td>Diary: Day 4</td>
<td>“Same as other days – need drugs still.”</td>
</tr>
<tr>
<td>Comments during WCP1:</td>
<td>“[The dressing removal] stings but not unbearable so go for it.”</td>
</tr>
<tr>
<td>Comments during WCP2:</td>
<td>“I’d rather do something like that [NIN] and not use drugs at all.”</td>
</tr>
<tr>
<td>Diary: On completion of study</td>
<td>“Noticed that when wearing device [NIN], sometimes wound fluid would come out.”</td>
</tr>
<tr>
<td></td>
<td>“[I] would [choose to] use [the NIN in future] if wound and scar benefits were shown [and] if practical issues can be improved.”</td>
</tr>
<tr>
<td>Diary: Day 10 (Christmas Day)</td>
<td>“Forgot to use – too drunk!” (No further data collected beyond this point)</td>
</tr>
<tr>
<td>Diary: Day 11 (Boxing Day)</td>
<td>“Forgot to take down south [on holiday to southern area of the state].”</td>
</tr>
</tbody>
</table>
Based on the above analysis of all data, the following hypothesis is suggested:

- Pain and anxiety were not negatively impacted by the introduction of the NIN device, however pain increased in both left and right hands following the first wound care procedure, possibly related to the interruption of injured tissue, or another unknown variable.

Did the patient’s confidence in their ability to manage their own pain change in response to introduction of NIN?

The diary data on the participant’s confidence in his ability to manage his own pain (Figure 34) showed an obvious direct relationship between left and right hand, and no apparent difference around the day of introduction of NIN (WCP1). At the same time there is a clear inverse relationship for pain and confidence in ability to manage own pain for both left (Figure 35) and right (Figure 36) hands.

Figure 34: CONFIDENCE - Left, untreated vs Right, treated - Diary VAS Ratings (Participant D)

VAS ratings carried out at home showed that the participant’s confidence in his ability to manage his own pain was closely matched for left and right hands.
The participant’s confidence in his ability to manage his own pain was not different between the treated and untreated hand, the following hypothesis is suggested:

- The participant’s confidence in his ability to manage his own pain was not affected by the introduction of the NIN device.

Figure 35: Diary VAS Ratings – pain/confidence relationship (Participant D) Left, untreated hand
VAS ratings of the left hand at home showing a clear inverse relationship between the participant’s pain and confidence in ability to manage his own pain.
Figure 36: Diary VAS Ratings – pain/confidence relationship (Participant D) Right, treated hand

VAS ratings of the right hand at home showing a clear inverse relationship between the participant’s pain and confidence in ability to manage his own pain.

Did NIN interfere with the work of nursing staff or patient activities? Was the device easy to use?

The nursing staff (Figure 37) rated interference of the NIN device relatively low (2.3/10) for the first wound care procedure, and 0/10 for the second wound care procedure. No clarifying comments were provided.
Participant comments at the completion of the study (Table 6): “I would [choose to] use [the NIN in future] if wound and scar benefits were shown [and] if practical issues can be improved.”, indicated that some practical issues may have caused interference. Upon request for clarification, the participant indicated that, while they interfered only mildly, the following issues were a barrier to his use of the NIN:

- One-handed application of the strap was difficult
- Wires got in the way
- Positioning of the hand controller during activity was difficult

In the clinic, the participant was observed during administration of the Volitional Questionnaire, to have difficulty with positioning the hand controller during certain stages of the procedure, in particular when standing at the hand basin to take dressings down. He put the hand controller in his back trouser pocket and tucked the cable under his arm as a way of solving the problem. When he returned to his seat from a standing position the
participant sat on the controller, activating the buttons which he then had to turn down rapidly.

All participant VAS ratings of ease of use both at home (Figure 33), and in the clinic during dressings (Figure 27), remained high throughout (9.6/10 or above). Nursing staff also rated ease of use high (Figure 38) at 8.7/10 and 9.6/10 for the first and second wound care procedures respectively.

The following hypothesis is proposed based on the above data and observations:

a) The NIN interfered moderately in aspects of the participant’s activities, however, the device was perceived as easy to use by both participant and nursing staff.

Was the patient motivated to use the NIN device?

Reviewing the data from the participant diary for the right hand (Figure 27), the participant’s motivation to use the device was initially high and then steadily lowered in a loose direct relationship with lowering pain, seen more clearly in Figure 38.

During wound care procedures in the clinic, nursing staff perceived the participant to be highly motivated (Figure 37), although more motivated in the second procedure (9.9/10) than in the first procedure (8.8/10). At the same time the staff were highly motivated for the participant to continue using the device in future (9.4/10 for WCP1; 8.4/10 for WCP2).

Results of the VAS rating of participant motivation following the first wound care procedure (Figure 33) also showed the participant to be highly motivated (9.2/10) and rose to 10/10 following the second wound care procedure. This was supported by the participant comment (Table 6) during wound care procedure two: “I’d rather do something like that [NIN] and not use drugs at all.”. The results of the Volitional Questionnaire (Figure 39 and
Figure 40) showed mostly ‘spontaneous’ ratings of behaviours that were observed, however, 4 out of 14 (WCP1) and 5 out of 14 (WCP2) of the assessable behaviours were not seen at all so results of the Volitional Questionnaire should be viewed with caution.

![Graph showing pain and motivation relationship](image)

**Figure 38: Diary VAS Ratings – pain/motivation relationship (Participant D) Right, treated hand**

Motivation to use the NIN showed a downward trend after the first three days following introduction. Motivation showed a loose direct relationship with pain.

Finally, comments from the participant (Table 6) in the two days after data collection was ceased, suggested that his motivation to use the NIN was contingent on remembering to use it or having it with him: “Forgot to use – too drunk!” (Day 10, Christmas Day), and “Forgot to take down south [on holiday to southern area of the state].” (Day 11).

Comparison of all this data leads to the hypothesis:

- The participant was motivated to use the NIN while the pain level was sufficiently high, and other activities were not distracting him.
Figure 39: Volitional Questionnaire Results for Wound Care Procedure 1 (Participant D)
Data collected with the Volitional Questionnaire (VQ) on the day of introduction of NIN (WCP1) suggest a relatively high level of motivation to use the NIN, however, 4/14 behaviours were not observed so results should be reviewed with caution.

Figure 40: Volitional Questionnaire Results for Wound Care Procedure 2 (Participant C)
Data collected with the Volitional Questionnaire (VQ) on the day of the second wound care procedure (WCP2) still suggest a relatively high level of motivation to use the NIN, however, 5/14 behaviours were not observed so results should be reviewed with caution.
5 GENERAL DISCUSSION

This study has demonstrated that the self-application of non-invasive interactive neurostimulation by individuals with partial-thickness hand burns is feasible.

As a single case experimental design, the results apply specifically to the participants studied, however, with a degree of caution, it may be possible to use the results to inform clinical decision-making around the use of this novel form of electrical stimulation in this burns population. To assist in this process, results for each case study have been outlined in full, and hypotheses developed around the research questions relating to feasibility. Results from all the cases will now be discussed together in relation to the overall question of feasibility.

One of the elements discussed in the introduction as a key component of feasibility was infection control. It was determined that this should be addressed as a separate element outside of the data collected from participants and nursing staff. To this end a meeting was held with the infection control nurse manager prior to commencement of the study, and the overall risk factors and strategies to mitigate risk were discussed (the summary of this process can be found in Appendix F). The finding of this meeting was that the level of risk involved in introducing the NIN, appeared low in comparison to the potential benefit and the study should therefore go ahead.

A simple flow chart (Figure 41) explains the process by which the individual hypotheses developed for each case study, were used to inform the discussion on overall feasibility of self-application of the NIN device by the participants.
Figure 41: Summary of individual case study and overall hypotheses

This flow chart demonstrates the overall process that was followed to develop individual case study hypotheses and how this information has been reviewed to come up with an overall recommendation on feasibility.

5.1 INTERFERENCE WITH ACTIVITIES AND EASE OF USE

Data for all four participants, including information provided by nursing staff, suggest that the NIN device was very easy to use and interfered only to a limited extent in the activities of either participants or nursing staff. Participants provided qualifying information that
should assist clinicians to modify the way the device is used and tackle some practical application issues. These are discussed further in the final recommendations.

5.2 IMPACT ON PAIN AND ANXIETY

In each of the four cases, pain and anxiety followed an overall downward trend as would clinically be expected of an uncomplicated, healing burn wound. Each of the participants experienced elevations and reductions in both pain and anxiety, also to be expected during the post-burn recovery phase. Discussion of each case aimed to draw together multiple data sources, and to pose hypotheses to explain the individual pain and anxiety responses. Some of the common topics that warrant further discussion are:

5.2.1 Elevated pain following wound care procedures

Literature supports the view that wound care procedures are the most painful part of recovery following a burn injury (Connor-Ballard, 2009), as a result of interruption of the hyperalgesic tissue (Stoddard et al., 2002). As expected, some participants had elevated pain around the time of wound care procedures. The efficacy of NIN as a tool for the self-management of burn pain was not within the scope of this study and will be addressed in a planned later phase of research.

5.2.2 Elevated anxiety in response to wound care procedures

The link between the experience of pain and the central nervous system based cognitive and emotional processing of nociceptive input has been discussed in detail earlier. Whether participants’ increased anxiety at specific time points was a response to the anticipation of a painful procedure cannot be determined from this study. The interaction of pain and anxiety is very complex, with the physiological stress response activated by pain including elevated
heart rate, respiration and blood pressure (Connor-Ballard, 2009), being very similar to the physiological response to anxiety. The circular nature of the pain-stress-anxiety-pain cycle may take considerable research to fully understand, however, an important truth remains evident; that the guarded and stiff posture, or active withdrawal that is often adopted by patients experiencing pain and anxiety (Connor-Ballard, 2009), are not beneficial to recovering burns patients. Interventions that have the potential to reduce pain and/or anxiety to help break the cycle without adding to the trauma, warrant further investigation.

5.2.3 Elevation of anxiety regarding return to work and impact of injury

As discussed earlier, the occupational therapy Model of Human Occupation (MOHO) view is that human occupation is not only what people do with their time, but a shaping force helping individuals to develop and grow across the lifespan, making sense of their experiences and structuring their interaction with the world (Kielhofner & Forsyth, 1997). Even small burn injuries can significantly interrupt the human elements described by the MOHO theory of performance capacity (physical and cognitive capabilities); habituation (habits and roles that provide structure to daily life); and volition (the drive of an individual to carry out activities and occupations) (Kielhofner, 2008; Kielhofner & Forsyth, 1997). The depth of data provided by participant C offered insight into the anxiety generated when thinking about the impact of the injury on return to work and the interruption of productive occupation. Future studies in this area will need to consider the difficulty of separating sources of anxiety such as this from anxiety about the pain.

5.2.4 Differing ratings of pain between nursing staff and participants

Nursing staff and patient assessment of pain may not always be consistent (Wiechman Askay et al., 2009). Some of the staff involved in the study worked in both the burns
outpatient clinic where smaller burns are treated, and the inpatient burns unit where severe or massive burns are treated. This may account for some of the discrepancies between staff and participant responses to pain ratings. The experience with patients who have suffered much larger burns may have caused them to develop a degree of immunity to the pain experience of the participants who all had smaller burns. Also, the researcher being the clinician in this study may have had an impact on the data collected. It is plausible that participants and nursing staff responded in a manner that they believed to be helpful for the study, rather than with complete honesty.

5.3 IMPACT ON CONFIDENCE

Each of the four participants responded to the experience of burn injury, as could be expected, with reduced confidence in their ability to manage their own pain. On balance, the introduction of NIN in these four cases did not impact negatively on confidence in their ability to manage their own pain. As discussed earlier, the experience of pain and the anxiety that this may generate, are linked closely with the concept of self-control of pain. The level of acute pain experienced may be influenced by the individual’s perception that they have some control over their pain (Bachiocco et al., 1993; Gedney & Logan, 2007). While some studies have suggested the use of patient-controlled analgesia in burns in an effort to increase the opportunity for self-control of pain, they acknowledge that administration of this method is problematic. This study demonstrated that a handheld, patient operated device, with simple controls and rapid training is feasible for certain burns patients. With caution, the results of this study regarding confidence in ability to manage their own pain may be used by clinicians intending to implement a similar device in a burn care environment.
5.4 MOTIVATION TO USE THE DEVICE

For all participants, data pointed to a very high motivation to use the device when it was first introduced. At the same time, nursing staff generally demonstrated a high level of motivation for the participants to continue using the NIN. From a single source of data such as the pre and post-wound care procedure ratings, it would be possible to come to the conclusion that the motivation to use the NIN is high, and would remain high. The advantage of gathering multiple sources of data for each participant was greater clarity on the issue of motivation which is a highly complex one. Triangulating all the data on motivation highlighted two key issues to be discussed; the relationship between pain and motivation to use NIN; and the influence of external factors on motivation.

5.4.1 Relationship between pain and motivation to use non-invasive interactive neurostimulation

Motivation to use the device reduced rapidly in line with pain reduction. While this may seem an obvious conclusion, it is sufficiently noteworthy within the data, to warrant further discussion. The MOHO view of motivation (indicated externally through volitional behaviours), is that the values, interests and personal causation of the individual come together in the context of the physical and sociocultural environment, to determine engagement in activity or occupation (Kielhofner & Forsyth, 1997). Personal causation is the belief that an individual has about their likely effectiveness at achieving a desired outcome, based on a self-assessment of their own physical, cognitive and social capacities.

Examples of how these volitional factors played out during the study are:
• While the pain was high, all participants initially valued the device; however, as their pain levels subsided, the intervention was of less value and motivation lowered rapidly.

• Participant A, along with his wife who was a nurse, had a particular interest in how the device worked and what potential it may have in the burn care environment, and his motivation to use NIN was initially extremely high. As his interest was piqued, and his pain levels subsided, his motivation to use the device dropped dramatically.

• Participant D may have had low personal causation, or limited belief in his ability to impact on his pain using the NIN device. His motivation to use NIN was initially extremely high. As the study continued, even though his pain level was moderate, as other activities such as Christmas and drinking became more interesting to him, he was insufficiently motivated to remember to use the NIN and forgot to take it away on holiday with him.

5.4.2 Influence of external factors on motivation

To sustain the use of a self-managed pain relief device, internal motivators need to remain high as described above. External motivators alone, such as staff input may be sufficient to engage a patient while in the staff member’s presence, however, engagement will drop rapidly in the home environment unless internal motivation is also high. An example of this in the study was:

• Participant C, who was initially highly motivated, had a rapid reduction in motivation along with lowering pain, as described above. Her motivation to use the NIN increased briefly following her second visit to the clinic and then corrected the following day.

Triangulation of all the data as discussed in her case study, suggest that this spike in
motivation was as a result of discussion with the researcher about the results seen in non-burn populations and the reason for a study in burns. The researcher attempted to provide factual information during this discussion, and deliberately avoided coaching or influencing the participant with a biased opinion, to reduce influencing the data. Based on the data, this discussion appears to have influenced the participant to use the NIN device more in the following days, in case a benefit beyond pain relief may be obtained. Whilst this external influence (the researcher’s explanation) was sufficient to lead to a brief increase in motivation, it was clearly insufficient to be sustainable for the long term.

An individual assessment of internal and external motivators may be a key factor in the decision to provide a NIN device for home use, versus making it available only under the guidance of staff in the burns clinic or unit. This information will be incorporated into the decision-making for the next phase of research. Post-burn pain tends to be most severe during wound care procedures, or rehabilitation interventions such as physiotherapy or hand therapy (Fauerbach et al., 2007; Lončar et al., 2006; Stoddard et al., 2002), thus the use of the NIN only in the clinic environment may still be very valuable. As limited training is required to effectively operate the device, and it can be applied and in use within 1-2 minutes, this would add little burden to a wound care procedure for either patient or staff.

The use of the NIN only in the burns inpatient unit or ward may also be valid to consider, as patients in this environment may be less distracted by outside influences and activities, be more focused on the recovery processes, and therefore show higher levels of the value and interest aspects of volition.
The more complex aspect of personal causation will require further research to determine whether particular types of training or education, and other personal traits or coping styles may influence the individual’s belief in their own ability to have any impact on their pain, either using the NIN device or through other strategies.
5.5 SIGNIFICANCE OF THIS STUDY

This thesis has made an original contribution to the field of electrical stimulation in the hand burn population, using a novel form of transcutaneous electrical nerve stimulation that addresses some of the limitations of conventional TENS devices in a burn care environment. While this study is small and narrow in scope by necessity, the in-depth perspective offered by single case experimental design may help to inform clinicians and encourage further research in this field. It is not uncommon to come across burns patients who, for various reasons, cannot tolerate appropriate doses of specific analgesics, and this study may help the clinical reasoning process regarding the use of TENS as an adjunct to analgesics.

This study highlighted the need for careful consideration of patient and staff motivation to engage in new treatments, prior to the commencement of research. Before devoting valuable research resources to a large scale efficacy study of a new device such as NIN, a clear perspective of the likely uptake is required.

The application of the occupational therapy Model of Human Occupation in a burns population offers a unique perspective of the human factors that may influence uptake of new devices where engagement of the patient in the activity is critical to the success of the intervention. The use of MOHO as a framework for future studies in burns by occupational therapy researchers could provide valuable insight where analysis of complex human behaviour is required.

This study contributes in a small way to our understanding of the acute pain experience for burn injured patients. More broadly, the complex relationship of acute pain to the development of chronic pain, and the issue of chronic pain as a population health concern,
requires many different studies to continually expand the body of evidence, and to encourage a range of different research methods for varied perspectives.
5.6 LIMITATIONS

This study had a number of limitations:

Purposive sampling was necessary to ensure appropriate participants, and it should be noted that case study outcomes with different patients may have provided very different data for discussion. Consideration should be given to the fact that burn injuries frequently occur with individuals who engage in high risk activities. The individuals enrolled in this study were on the whole compliant and willing to engage with a new technology, however, this may not have been the case with an individual such as the regular illicit substance user who was excluded from the study as he did not meet inclusion criteria.

Additionally very tight diagnostic parameters were chosen for the study (partial-thickness burns to the hands, of less than 4% total body surface area) to restrict variability in the cases. Different findings may have resulted from the introduction of NIN to patients with deeper burns, burns requiring surgery, or burns to body areas other than the hands, and this must be considered in the next phase of research.

Single case experimental design was chosen to enable an in-depth exploration of the topic. By restricting the study to such a small number of cases, multiple data sources could be triangulated, which would not have been possible with larger numbers in the short timeframe available for the study. However, SCED does not allow the researcher to generalise the findings beyond the cases described. By presenting data in full, along with identification of trends and relationships, clinicians may come to their own conclusions, thus helping to inform clinical practice.
A pilot study would have been beneficial, allowing for adjustment of assessment and data collection procedures, however, this was not possible given the short timeframe (four weeks for data collection). While SCED is a prospective research design, it allows additional flexibility and interventions can be modified from one participant to the next, while changes are rigorously documented. One such example in this study was the modification of the NIN strap for Participant D following feedback from the previous participants that it was too long and difficult to apply. Retrospective collection of data was also necessary as a result of this short timeframe, and this may have had an impact on the reliability of this data. To achieve a more rigorous design a stable baseline would be required, however, multiple data sources and perspectives were used in an effort to offset the short timeframe and to increase rigour.

It was not possible to limit the variables by arranging to have a single nursing staff member attend all dressings for participants. The nature of the burn care environment is that patients will be seen by different staff at different clinic times, which may have added an unwanted variable. However, the aim of SCED is to study the individual in a real life environment, and it was necessary to work within the regular staffing arrangements.

Finally, the nature of an honours project is that the researcher must be hands-on in all aspects of the study. In this instance, the researcher was also an experienced occupational therapist with specialist knowledge in the burns field. This may have influenced the behaviour of both participants and staff, and potentially reduced the objectivity of the researcher. This limitation was discussed in relation to some of the individual case study findings earlier in an effort to increase transparency.
6 RECOMMENDATIONS AND CONCLUSION

There are a number of recommendations in relation to future research, and in the clinical application of the NIN device in a burn care environment:

**Research**

The short timeframe for this study, and the very narrow diagnostic group restricted the information that could be obtained. Future research with patients that are expected to have longer healing times, for example patients with larger and deeper burns, or post-surgical burns, may shed further light on the subject. The planned next stage of this research, which is intended to address the question of efficacy, will require collection of a different data set. Based on the results of this study, this could potentially include measures of functional outcomes; pain; analgesic consumption and side-effects; oedema; and range of motion. This study has also raised interesting questions around the effect of self-control of pain on the overall pain experience, and further research in this area for the burns population is warranted.

**Clinical application of non-invasive interactive neurostimulation in burns**

Several recommendations can be made regarding practical solutions for clinical burn care facilities that may consider using NIN:

- Shortening the electrode strap and using a D-ring fastening would allow the patient to slide the closed strap over the hand and simply tighten it on the arm. It would be possible to carry this out in any occupational therapy department.
- Fastening the NIN hand controller to the arm strap by attaching a hook Velcro adhesive patch to the back of the device would allow patients to place the device out
of the way. This modification could also be done on site. A more robust solution
long-term, would be if the manufacturer was to provide a holster to place the hand
controller in for clipping to clothing.

- If possible applying the NIN at least 10 mins prior to commencing dressing removal
would allow the participant to become familiar with increasing and decreasing the
intensity setting to maintain a strong, subnoxious stimulus, without the need for
reminders from staff.

Overall, while demonstrating feasibility in these cases, this study has raised some useful
questions on how and where the NIN device would be best used with burns patients, and
established that research into the efficacy of the NIN in this population is warranted.

In weighing up the impact of introducing a pain self-management option such as NIN, it is
important to consider the potential risk versus benefit ratio. In the cases studied, it was
found that the risk to the participant was low, and that engagement with the device was
high in the clinic setting. It is also important to recognise in future research that the
assessment of benefit may not come from simple reduction of pain, but should also
encompass other elements such as the impact on analgesic consumption and the impact of
the individual’s perception of increased self-control over their pain and their daily life.

This study, using a single case experimental design, explored the feasibility of patient self-
application of the new TENS development, non-invasive interactive stimulation. This thesis
outlines the importance of the field of study, based on a wide body of evidence. Data
collected from multiple sources were presented, and each case study analysed separately.
The thesis explores common findings from the four case studies to highlight considerations for future research. For these participants with hand burns, the self-application of a novel electrical stimulation device was found to be feasible.
7 REFERENCES


Croft, P. R., & Rigby, A. S. (1994). Socioeconomic influences on back problems in the community in Britain. *Journal of Epidemiology and Community Health, 48*(2), 166-170. doi: 10.1136/jech.48.2.166


Appendix A: Overall Scientific Argument Map
Appendix B: Product Specifications InterX® (Neuro Resource Group: Plano, Texas)

<table>
<thead>
<tr>
<th>Specification</th>
<th>Specification Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>215mm x 52mm x 43mm</td>
</tr>
<tr>
<td>Weight</td>
<td>~185gms</td>
</tr>
<tr>
<td>Operating / Storage Temperature</td>
<td>15°C to 40°C / -40°C to 60°C</td>
</tr>
<tr>
<td>Operating / Storage Humidity</td>
<td>5% to 85% relative humidity</td>
</tr>
<tr>
<td>Power Source</td>
<td>2 x AA alkaline batteries</td>
</tr>
<tr>
<td>Pulse Duration</td>
<td>10 to 500 microseconds</td>
</tr>
<tr>
<td>Single Pulse Frequency</td>
<td>15 to 350 pulses per second</td>
</tr>
<tr>
<td>Pulse Frequency in Burst Mode</td>
<td>120 to 480 pulses per second</td>
</tr>
<tr>
<td>Typical Skin Resistance</td>
<td>3000 Ohms</td>
</tr>
<tr>
<td>Typical Peak / Average Voltage Output (on skin)</td>
<td>70V / 12V</td>
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<tr>
<td>Typical Peak / Average Current Output (on skin)</td>
<td>50mA / 6mA</td>
</tr>
<tr>
<td>Waveform</td>
<td>Pulsed, damped, biphasic, sinusoidal</td>
</tr>
</tbody>
</table>

Images below show the bendable, wipeable electrode arrays attached to the Velfoam strap. The arrays can be curved to accommodate the shape of the arm. The strap, which is approximately 70cm long, can be shortened. The red and grey wires connect to the device cable. The electrode array strap can be left attached to the device between use for easier application.
The Model of Human Occupation (MOHO) is one of the most widely used models of occupational therapy. Occupation, which includes all activities of productivity, self-care and leisure, is viewed as an essential shaping force that influences the growth of an individual towards health, well-being and overall development. Occupation is made up of three subsystems: volition; performance capacity; and habituation. Each of these three subsystems has several components.

The volition subsystem, which determines an individual’s motivation to engage in occupation, is a complex interplay of values, interests and personal causation. Personal causation is the individual’s belief in their ability to affect a desired outcome based on a self-assessment of physical, cognitive and social capabilities and the likelihood of achieving a result.

The performance capacity subsystem is comprised of the physical and cognitive capacities of the individual.

The habituation subsystem involves the habits and ritual behaviours that an individual performs, to some extent automatically, in response to environmental cues.

All occupation is carried out within an environment. The environment, which includes both physical and social, helps to determine occupational behaviour, either by providing adequate opportunity for the behaviour, or forcing the individual to carry out occupation in a way that suits the environment (Kielhofner & Forsyth, 1997).
The feasibility of using non-invasive interactive neurostimulation (NIN) in acute distal upper limb burns.

Principal Investigator: Katrina Liddiard, Bachelor of Health Science Honours student, ECU
RPH Investigator: Prof Fiona Wood, Director Burns Service WA, Royal Perth Hospital

You are being invited to participate in a research study because you have a burn injury to the upper limbs. This information sheet explains the study and describes what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend or your GP.

Background and aim
The aim of this study is to find out how feasible it is to use a type of mild electrical stimulation called NIN, to help patients dealing with pain after hand and arm burns, to learn whether patients may be able to use the device on their own and to find out what impact this has on the work of the burn care nurses. The NIN device has been designed for use by patients after surgery, however, the purpose of this study is to identify whether limitations exist for use in the treatment of burn pain.

What participation in the study involves
If you choose to participate, I will:

- Carry out a short interview, lasting around 30 minutes to discuss the treatment and train you in how to use the device. During this time I will be happy to answer questions and explain more about how the device works. You will be able to contact me at any time during the study to ask more questions.
- Ask you to use the NIN device over a two week period in your hospital and/or home environment.
- Ask you to use the NIN device during a dressings change procedure, once in the first week of joining the study, and once in the second week. During these procedures I will attend for observation.
- Ask you to record your experiences in a diary during the two weeks of the study. This includes five quick ratings of:
  - how easy it is to use the device;
  - how confident you are that you can manage your own pain;
  - how motivated you are to use the device;
  - your level of pain;
  - your level of anxiety
  - plus any comments or observations that you may like to make.
- Ask you to record the same five short ratings before and after your two dressings procedures.
- Ask your permission for the nursing staff to also rate their experience of your use of the device during the dressings procedures.
- Photograph your burn wounds at three key points in the study.

Device appearance and operation
The NIN device includes a handheld machine, which can be operated using only four buttons, as well as two pads called array electrodes, which contain nine metal plates each and are strapped around the arm away from the area of burn injury. This electrode array design allows the current provided by the NIN device to be transferred across the skin in the location that is most effective for treating your pain. It also allows the sensation to be set at a comfortable level. You can see instructions on how the NIN device is applied at the end of this form.
Possible side effects and risks
The NIN device comes from a group of battery operated electrical stimulation devices called transcutaneous electrical nerve stimulation or TENS. TENS machines are well known to be very safe and can be bought by any member of the community without prescription. The NIN device has been designed to self-adjust to any changes in resistance in the skin, so the voltage output will always adjust to a safe level. On occasion NIN users may feel a stronger or more uncomfortable prickly stimulation, but if this occurs the device can be easily turned down and this sensation does not cause any damage. A small number of people such as pregnant women or those with demand-type pacemakers should not use the NIN device. The investigator will have screened for these conditions before asking you to participate in the study.

Possible benefits
Participation in this study may have no direct benefit for you, or potentially may help with better management of pain during your dressings changes and while you recover from your injury. The NIN device has been used in studies not related to burn injuries, and has been shown to provide a beneficial effect in the management of pain following knee, ankle and hip surgeries. In these studies, patients also experienced improvements in range of movement and swelling which would be considered beneficial following a burn injury. If you would like further information regarding these studies prior to consenting to participate, this can be provided to you by the researcher.

Privacy and confidentiality
The information gathered about you by the investigator or obtained during this study will be held by the investigator in strict confidence and all the people who handle your information will comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients.

What if something goes wrong?
In the event that you suffer an expected or unexpected side effect or medical accident during this study that arises from your participation, you will be offered all full and necessary treatment by Royal Perth Hospital. The Ethics Committee has approved this study on the basis (amongst others) that the reported risk of such an event is either small or acceptable in terms of the risk you face as a result of your current illness.

Costs to participation
There will be no costs incurred as a result of participation in this study. You will not be paid for participation.

Voluntary participation and withdrawal
Participation in this study is entirely voluntary. You do not have to participate if you do not want to and your decision to participate or not will in no way affect your current or future care at RPH. You are also free to withdraw from the study at any time without reason or justification.

Contact Information
If you have questions about this study, please contact Katrina Liddiard on 0401 147 442, or Dr Janet Richmond on (08)6304 3575.

This study has been approved by the Royal Perth Hospital Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Prof Frank van Bockxmeer, Chairman of the RPH Ethics Committee, via (08) 9224 2292 or rph.hrec@health.wa.gov.au and quote the ethics approval number (REG 14-108).
The feasibility of using non-invasive interactive neurostimulation (NIN) in acute distal upper limb burns.

Principal Investigator: Katrina Liddiard, Bachelor of Health Science Honours student, ECU
RPH Investigator: Prof Fiona Wood, Director Burns Service WA, Royal Perth Hospital

I, ............................................. agree to participate in the above study. I have been provided with a copy of the Participant Information Sheet explaining the study which I have read and understood. I have been given the opportunity to ask questions about the study by the Investigator and any questions have been answered to my satisfaction. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study. I am aware that all research data collected will only be used for the purpose of this study and will be kept confidential and that my participation will not be disclosed without my consent.

Signed .................................................. Date ............................

Signature .................................................. Date ............................

of Investigator
Appendix E: Instructions for Application and Use of NIN:

1) Position electrode strap against arm & anchor briefly against body
2) Wrap strap around arm
3) Fasten strap using Velcro attachment
4) Connect cable to NIN device
5) Operate NIN simply:
   a. Press and hold POWER BUTTON.
   b. SELECT SETTING to A1 or A2 as instructed.
   c. ADJUST INTENSITY to a strong comfortable level. The NIN device can be turned up or down for comfort at any stage. If the sensation becomes prickly or unpleasant simply turn the intensity down. This sensation is not causing any damage but does not offer any benefit over a strong comfortable tingling sensation.
Appendix F: Infection Control Report

A meeting was held with the Infection Control Manager, Royal Perth Hospital, 22/4/14, to address overall risks for using the NIN device, and to determine whether to use the plastic, wipeable single-patient electrode array, or the disposable, self-adhesive electrode array.

The overarching consideration was that the benefits of using any piece of equipment in patient care must outweigh the potential risks.

A decision was made that overall, the potential benefit in terms of pain relief could be significant: the potential risk of infection is relatively low. Both types of electrodes carry potential risks for different reasons described below. The decision was made to use the wipeable electrode arrays for this study, however, the self-adhesive electrode arrays may be more cost-effective, and therefore should be considered for larger studies or ongoing use.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Potential solution</th>
</tr>
</thead>
</table>
| **InterX 900:**  
• Difficult to wipe over effectively with alcohol swabs | Use larger Isowipes to ensure more thorough cleaning |
| **Single Patient Dual Array Electrodes:**  
• Crevices present breeding ground for microorganisms  
• Foam or Velcro wraps may become dirty | Ensure adequate patient education regarding cleanliness:  
• hand washing prior to use,  
• regular cleaning of equipment,  
• visual inspection of equipment and replacement of electrodes or straps if visibly soiled  
Replace foam straps as required |
| **Single Patient Self-adhesive Electrodes:**  
• Self-adhesive surface may present breeding ground for microorganisms  
• Foam or Velcro wraps likely to become dirty easily | Ensure adequate patient education regarding cleanliness:  
• hand washing prior to use,  
• regular cleaning of equipment,  
• visual inspection of equipment and replacement of electrodes if visibly soiled or breaking down  
Suggest replacing electrodes as required |
Appendix G: Participant Questionnaire – Pre and Post-Wound Care Procedures

On the following scales please rate your experience. Please mark along the scale according to your current feelings:

1. What level of pain do you currently have?

   NO PAIN ———— WORST PAIN IMAGINABLE

Comments:
________________________________________________________________________
________________________________________________________________________

2. How anxious are you about the dressings procedure you are about to undergo?

   NO ANXIETY ———— WORST ANXIETY IMAGINABLE

Comments:
________________________________________________________________________
________________________________________________________________________

3. How confident are you that you can manage your own pain effectively?

   COMPLETELY CONFIDENT ———— NOT AT ALL CONFIDENT

Comments:
________________________________________________________________________
________________________________________________________________________

4. Do you think it will be easy to use the NIN device during this dressings procedure?

   EXTREMELY EASY ———— EXTREMELY DIFFICULT

Comments:
________________________________________________________________________
________________________________________________________________________

5. Are you motivated to use the NIN device during this dressings procedure?

   EXTREMELY MOTIVATED ———— NOT AT ALL MOTIVATED

Comments:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Additional space for comments over page
Appendix H: Nursing Staff Questionnaire

On the following scales please rate your perception of the patient’s experience based on the average throughout the dressings procedure:

1. During the dressings procedure, what level of pain did the patient have on average?

   NO PAIN ———— WORST PAIN IMAGINABLE

2. During the dressings procedure, how anxious was the patient on average?

   NO ANXIETY ———— WORST ANXIETY IMAGINABLE

3. How confident are you that the patient could manage their own pain in the future?

   COMPLETELY CONFIDENT ———— NOT AT ALL CONFIDENT

4. How easy was it for the patient to use the NIN device during the dressings procedure?

   EXTREMELY EASY ———— EXTREMELY DIFFICULT

5. How motivated was the patient to use the NIN device for the dressings procedure?

   EXTREMELY MOTIVATED ———— NOT AT ALL MOTIVATED

6. How much did the NIN device interfere with your treatment?

   NO INTERFERENCE ———— INTERFERED EXTREMELY

7. Would YOU be motivated for the patient to use the NIN device for future procedures?

   EXTREMELY MOTIVATED ———— NOT AT ALL MOTIVATED

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Appendix I: Sample from Volitional Questionnaire

The Volitional Questionnaire (Chern et al., 1996), allows for observation of an individual in an occupational context to determine level of motivation for a task. Behaviours are rated according to the level of spontaneous behaviour observed.

Environmental context is taken into consideration:
Appendix J: Participant Diary Sample Page

1. On average what level of **pain** have you experienced today?

   ![Pain Scale]

2. On average what level of **anxiety** have you experienced today?

   ![Anxiety Scale]

3. On average how confident have you been today that you can **manage your own pain** effectively?

   ![Confidence Scale]

4. How easy has it been to use the NIN device today?

   ![Ease Scale]

5. How **motivated to use the NIN device** have you been today?

   ![Motivation Scale]

Comments:

____________________________________________________

____________________________________________________

____________________________________________________

____________________________________________________

____________________________________________________

Additional space for comments over page

<table>
<thead>
<tr>
<th>Substance consumed</th>
<th>Units (no.)</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeinated drinks</td>
<td>(cup/mug/glass) (tea/coffee/caffeinated soft drink)</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>(standard drinks)</td>
<td></td>
</tr>
<tr>
<td>Tobacco</td>
<td>(cigarette/cigar/pipe) (nicotine weight)</td>
<td></td>
</tr>
<tr>
<td>Prescribed medications:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix K: Recruitment Notice

Recruitment Notice

NIN in Burns Research Project

Study: The feasibility of non-invasive interactive neurostimulation (NIN) in burns.

Purpose: This study will determine the feasibility of using InterX as a self-applied form of transcutaneous electrical nerve stimulation (TENS) in hand burns.

Suitable participants: Patients with bilateral hand/forearm burns.

Inclusion criteria:

- Bilateral distal upper extremity partial-thickness burns of no greater than 4% total body surface area per upper limb.
- Requiring active wound management without surgical intervention.
- Able to give informed consent to participation in the study.
- Willing to record ratings and comments in a diary for two weeks.
- Not greater than seven days since burn injury.

Exclusion Criteria:

- Cognitive or language impairment that would impact on the participant’s ability to understand the instructions or apply the NIN SPS.
- Presence of contraindications to the use of NIN including history of epilepsy or seizures; demand-type pacemaker; pregnancy; or malignant tumour within the treatment field (Nigam et al., 2011).
- History of self-immolation or illicit substance abuse due to possible confounding factors in the measurement of anxiety and pain.

Principal Investigator contact details:

I am happy to review all patients, please contact me at any time on my mobile if you are unsure whether a patient may be suitable, or for further queries or concerns please contact Prof Fiona Wood.

Katrina Liddiard, 0401 147 442

Bachelor of Health Science Honours student

Edith Cowan University
### Appendix L: Volitional Questionnaire Behavioural Observations

<table>
<thead>
<tr>
<th>Continuum of Change Level</th>
<th>Behavioural category</th>
<th>Examples of observed behaviours seen among participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exploration</td>
<td>Shows curiosity</td>
<td>Trying out buttons without prompting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asking questions to confirm correct use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Voluntarily testing out how high device can go while still tolerable</td>
</tr>
<tr>
<td></td>
<td>Initiates actions/tasks</td>
<td>Turned on NIN device and commenced use without being asked</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Turned up device when prompted but not spontaneously</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positioned NIN device in pocket to allow hands to be free</td>
</tr>
<tr>
<td></td>
<td>Tries new things</td>
<td>Immediate/eager uptake of NIN at first offer</td>
</tr>
<tr>
<td></td>
<td>Shows preferences</td>
<td>Chose to restart the NIN device after accidentally pressing wrong button and turning off and also when 10 min cut out was reached</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requested NIN at beginning of dressing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removes and reappliies strap for firmer fit</td>
</tr>
<tr>
<td></td>
<td>Shows that an activity is special or significant</td>
<td>Asking questions about how NIN operates and potential use for partner</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: &quot;I'd rather do something like that [NIN] and not use drugs at all.&quot;</td>
</tr>
<tr>
<td>Competency</td>
<td>Shows pride</td>
<td>Showed pleasure when researcher observed competent use of NIN</td>
</tr>
<tr>
<td></td>
<td>Stays engaged</td>
<td>Retained thumb on control throughout use, adjusted intensity multiple times during wound care procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not always aware of NIN but returns to adjust intensity on occasion</td>
</tr>
<tr>
<td></td>
<td>Tries to solve problems</td>
<td>Repositioned electrode strap after asking whether it was safe to do so</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adjusts position and anchors strap against body when fitting unsuccessful</td>
</tr>
<tr>
<td></td>
<td>Tries to correct mistakes/failures</td>
<td>Swapped from minus to plus button when incorrectly selected</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restarted NIN device without prompting after accidentally switching off</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Notices not plugged in and asks how to do this</td>
</tr>
<tr>
<td></td>
<td></td>
<td>When prompted, turns strap opposite direction for better fit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>When researcher pointed out NIN on chair, picked up and repositioned</td>
</tr>
<tr>
<td></td>
<td>Indicates goals</td>
<td>Spontaneously planning/discussing timing of return to work and ADL tasks (showering) while using NIN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Planning how to use when dropping hand to dependent position</td>
</tr>
<tr>
<td>Achievement</td>
<td>Seeks challenges</td>
<td>Flexing and extending fingers and attempting to make fist while adjusting NIN device</td>
</tr>
<tr>
<td></td>
<td>Pursues an activity to completion/accomplishment</td>
<td>Restarted NIN after 10 min cut-out without prompting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Continued to use to end of wound care procedure</td>
</tr>
<tr>
<td></td>
<td>Seeks additional responsibilities</td>
<td>Removed NIN without prompting for washing at basin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repositioned hand/NIN to assist with dressing application</td>
</tr>
<tr>
<td></td>
<td>Invests additional energy/emotion/attention</td>
<td>Adjusted intensity of NIN up without prompting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most attention drawn to discussion with partner about financial/work issues</td>
</tr>
</tbody>
</table>