CHAPTER ONE

1.0 INTRODUCTION

This chapter will provide an overview of the study, including an introduction to the study, background information to the research problem, research purpose, research objectives and the significance of the study. There will be a clarification of key terms and theoretical assumptions. In addition, there is an overview of the research methods, design, trustworthiness of the study and ethical considerations.

Intensive Care Units commonly use physical restraints to reduce the risk of injury and ensure patient safety. However, there is still controversy regarding the practice of physical restraints in such units. Global research has shown that physically restrained patients encountered a prolonged hospital stay and developed complications resulting from their immobility. Severe adverse outcomes are also associated with the physical restraints, such as agitation, post-traumatic stress, physical injury and death.

Physical restraint use is an ethical dilemma for ICU nurses as there is a conflict of norms and values. Most importantly, it diminishes a patient's autonomy. Many nurses believe the restraining procedure is not ethically accepted; however, it is required in certain situations for the benefit of the patient. The moral conflict around the use of physical restraints has indicated there is a need for education and collaboration within the ICU with all healthcare providers, including the ICU patient and their family.

This study hopes to describe and explore the experiences of the ICU patient and their family members regarding the use of physical restraints in the ICU setting. The research findings may assist nurses later to reflect, ethically and critically, on what physical restraint means to the patient, and what effect it has on their family members, before physically restraining the patient.

1.1 BACKGROUND OF THE STUDY

Nurses use physical restraints on a daily basis, without realising that it is one of the major ethical arguments in a healthcare facility (Bader, 2014). Continuing with this practice without questioning its implications on the patients or making a thorough assessment of the situation before applying physical restraints means that evidenced-based practice is not followed and this could lead to allegations of professional misconduct and litigations from the patients and their families (Talson & Morley, 2013).

Nurses have the moral obligation to promote for the well-being of their patients through excellent nursing practice (Younis & Ahmed, 2017). Excellence in practice requires nurses to have an understanding of the significance of their conduct on the patients. According to Bader (2014), for nurses to provide best care when it comes to the use of physical restraints, they should understand its meaning to patients, and the patients understanding of the process.

The ethical dimension of care, ethical and critical reflection are further found by Bader (2014) to be an essential part of good nursing care as they enable nurses to have a thoughtful and balanced decision making process, especially in ethically charged situations such as those requiring physical restraints.

Physical restraints constitute the use of any material, devise or equipment on or near a person's body, which the person cannot control or easily remove (Meyer et al., 2009; Younis & Ahmed, 2017). This application is a deliberate intention to restrict a person's freedom of movement to a position of their choice or normal access to the body (Evans & Fitzgerald, 2002; Yam & Cheung, 2005; Meyer et al., 2009). It is also defined as the controlling of individuals by rendering them helpless or keeping them captive with the use of equipment or seclusion (Bader, 2014). By their very definition, restraints are incompatible with the principle of autonomy, as they involve restricting a patient or limiting a patients' freedom.

The main reason for using physical restraints in ICU is to ensure patients' safety, manage agitated patients and prevent removal of medical equipment connected to them (Talson & Morley, 2012; Langley et al., 2011; Taha & Ali, 2013; Freeman et al., 2016).

According to Talson (2012), a challenging behaviour does not justify the use of physical restraints. However, in situations where the patient may be a danger to himself or others if not physically restrained, Kalula and Petrose (2016) suggest that the decision to use physical restraints should outweigh the physical, psychological and ethical risks. This will help in avoidance of inherent dangers and adverse outcomes associated with the use of physical restraints, and help nurses to question the efficacy of physical restraints and to explore other suitable alternatives (Cheung & Yam, 2005).

Patients in ICU may undergo changes in behaviour due to their underlying illness and disease pathology, and as a result they become confused or delirious (Langley, Schmollgruber & Egan, 2011; Younis & Ahmed, 2017). The insertion of endotracheal tubes, arterial lines, and central venous lines might further leave patients in a state of irritability or aggression, which may cause them to remove these invasive devices inadvertently (Langley, Schmollgruber & Egan, 2011). Accidental removal of these devices could jeopardise a patient's treatment as well as their mental and physical well-being (Bray et al., 2004). Premature removal of an endotracheal tube could lead to severe respiratory distress and cardiopulmonary arrest (Hofsa & Coyer, 2007).

According to Kandeel and Attia (2013) and Younis and Ahmed (2017), physical restraints are seen as a simple solution in the prevention of risks such as falls or injuries to the patients, or in the maintenance of treatment and nursing care. The use of physical restraints is usually to restrain agitated patients exhibiting "abnormal" behaviours (Langley, Schmollgruber & Egan, 2011; Younis & Ahmed, 2017). Even though the use of physical restraints is to protect critically ill patients from harming themselves, several adverse outcomes are associated with such use in the ICU setting, including agitation, post-traumatic stress, physical injury and death (Kandeel & Attia, 2013; Lai et al., 2011).

The use of physical restraints on patients has undergone extensive investigation in developed countries, but less commonly in developing countries such as South Africa (Kalula & Petros, 2016). In the United States and Canada, their use in the acute hospital setting ranges between 5% and 26%, with a prevalence of 33% in the Intensive Care Unit (Talson & Morley, 2012). In a Johannesburg Hospital in South Africa, where 219 patients had been admitted into three ICUs, 106 (48.4%) were physically restrained (Langley, Schmollgruber & Egan, 2011). The results thus show that close to 50% of patients were

experiencing physical restraint. It appears to suggest that physical restraints have become an acceptable standard in managing patient’s safety and controlling their behaviour, even though it is evident that the use of such violates patients’ rights (Talson & Morley, 2012).

There has been extensive research done on the experiences and perceptions of healthcare providers with regard to the use of physical restraints, but there is very little regarding the experiences of patients or their family’s experiences and/or perceptions on the use physical restraints.

1.2 PROBLEM STATEMENT

In the ICU, it is a normal practice to use physical restraints in order to reduce the risk of injury, to ensure a patient’s safety and for behavioural control (Kandeel & Attia, 2013). However, Talson and Morley (2012) showed that the degree of use and application of physical restraints depends on the intensity of “disruptive behaviour." The latter authors made the assumptions that the more disruptive the behaviour, the more force is applied (Kandeel & Attia 2013; Talson & Morley, 2012). In this instance, restraints were as punishment for certain unacceptable behaviours (Talson & Morley, 2012). Regarding the use of physical restraints in an ICU, there is little knowledge about the experiences of patients who underwent restraint and their family’s perceptions. In the ICU, patients are in a state of confusion or are sedated when they are restrained, which does not allow them to consent to the use of restraints (Hofsa & Coyer, 2007). Physical restraints are also associated with physical and psychological adverse effects, which then causes an ethical dilemma as now the healthcare professionals are torn between their moral obligation to do no harm, to promote good, to ensure that patient’s dignity is respected, and their autonomy maintained (Mohr, 2010).

1.3 RESEARCH QUESTIONS

What are the experiences of physically restrained patients while admitted in the ICU setting?

What were the family member’s perceptions (experiences) of the use of physical restraints on their loved ones while admitted into Intensive Care Units?

1.4 PURPOSE OF THE STUDY

The purpose of this study is to describe and to explore patients' experiences of physical restraint and their family members' perceptions of this experience.

1.5 RESEARCH OBJECTIVES

- To describe the patients' experiences of physical restraint in an Intensive Care Unit
- To describe the family member's perceptions and or experiences regarding the use of physical restraints in ICU
- To formulate guidelines for the safe care of restraint ICU patients.

1.6 SIGNIFICANCE OF THE STUDY

The study has gathered and provided experiences regarding patients and family experiences of the use of physical restraints in ICU. The findings of this study will increase the understanding of the meanings this practice has on patients and/or their family members. The hope is this understanding will help nurses to reflect ethically and critically on these meanings so that their decisions to restrain patients is thoughtful and balanced.

1.7 RESEARCH ASSUMPTIONS

1.7.1 Meta-theoretical Assumptions

According to Poggenpoel (1996) and Schmollgruber (2015), meta-theoretical assumptions are a statement known to be obvious and not tested by the study, and are widely accepted to be true for the researcher.

Person, Environment, Health and Nursing are four meta-theoretical concepts that comprise nursing. The researcher's meta-theoretical assumptions regarding these concepts were as follows:

- **Person**

A person is a holistic individual characterised by physiological, psychological, socio-cultural, spiritual and developmental variables (Sadeghi & Ahmadi, 2017; Duman & Bademli, 2017). Furthermore, a person is an ever-changing open system that interacts with its internal and external environment to maintain a balance between disrupting factors known as stressors (Duman & Bademli, 2017; Spencer & Jukes, 2007). The person in the context of this study is a critically ill patient who is dependent on knowledgeable professionals for the safe implementation of all therapeutic interventions to meet his or her healthcare needs (Mitchell et al., 2016).

- **Environment**

The environment refers to all the internal and external forces surrounding and influencing the client system. These are stressors, and have the potential to alter system stability (Ahmadi & Sadeghi, 2017; Alligood & Tomey, 2010). The three relevant environments identified by Neuman are internal, external and a created environment. Internal environment is all the interactions contained within the boundaries of the client's system, meaning they are intrapersonal in nature. External environment includes all the forces that arise from outside the client system. The Created environment is an unconscious development used by the client to support protective coping by mobilising all system variables to create an insulated effect that helps the client cope with the threat of environmental stressors (Ahmadi & Sadeghi, 2017; Alligood & Tomey, 2010). In this context, environment refers to General and Trauma ICUs, which are high technological environments that require technical and clinical expertise provided by multidisciplinary teams working together in a fine choreographed manner to provide specialised care to critically ill patients (Langley, Schmollgruber & Egan, 201).

- **Nursing**

Nursing is a unique profession concerned with all the variables affecting an individual's response to stress (Ahmadi & Sadeghi, 2017; Alligood & Tomey, 2010). Ahmadi and Sadeghi (2017) further highlight that the main aim of nursing is to promote and maintain the stability of the client's system, which is achievable through nursing interventions that reduce the stressors. The conceptual framework for nursing uses the concept of the three levels of prevention, primary, secondary and tertiary prevention (Ahmadi & Sadeghi, 2017; Alligood & Tomey, 2010).

  - ***Primary prevention***

The primary concern of nursing is to help the client system to achieve, maintain or retain stability. To protect or reduce the possibility of the person from encountering a harmful stressor, and to strengthen the normal line of defence (Ahmadi & Sadeghi, 2017).

- ***Secondary prevention***

Secondary prevention takes place after the client system responds to a stressor. It relates to the manifestations that arise after a reaction to the stressors. It also includes the prioritisation of nursing interventions and treatment. The latter reduces the effects or possible effects of the stressor so that stability and balance is maintained (Ahmadi & Sadeghi, 2017)

- ***Tertiary prevention***

Tertiary prevention relates to the process of adaptation and adjustment of the client system so that the individual returns to stability (Almeida et al., 2018). According to (Alligood & Tomey, 2010), tertiary prevention attempts to reduce the residual stressor effects and returns the client to optimal wellness after treatment.

- **Health**

Health is a continuum of wellness to illness that is dynamic in nature and constantly changing. Optimal wellness exists when total system needs are met, and illness occurs at the opposite end of the continuum from wellness (Duman & Bademli, 2017; Alligood & Tomey, 2010; Ahmadi & Sadeghi, 2017). Health requires energy, and needs stability between physiological, psychological, socio-cultural, spiritual and developmental variables so that there is constant energy to keep the system in balance (Almeida et al., 2018; Duman & Bademli, 2017). The WHO deduced the same concept, which states that "health is the state of complete physical, mental, and social well-being, and it does not consist only in the absence of disease or infirmity (Almeida et al., 2018).

1.7.2 Theoretical Assumptions

Burns and Grove (2011) describe theory as "an integrated set of defined concepts and statements that present a view of a phenomenon and can be used to describe, explain, predict and control that phenomenon." Creswell (2009), conversely, defines a theory as "an interrelated set of constructs formed into proposition or hypothesis that specify the relationship among variables. In a research study, theory might appear as an argument, as a discussion or a rationale.

The main aim of theory is to explain the phenomena that occur in the world (Creswell, 2009). Assumptions are “statements taken for granted or considered true, even though they have not been scientifically tested” (Burns and Grove, 2007). Operational definitions are some of the theoretical assumptions used in this study.

1.7.2.1 Operational definitions

The researcher used the operational definitions in the study to give a detailed description on how variables are used; furthermore, the knowledge gained from such descriptions creates an understanding of the theoretical concept that the variables represent (Burns & Grove, 2007).

- **Experiences**

Wolf et al. (2014) describe experiences as the process of acquiring knowledge or skills during participation in a certain situation. For the purpose of this study, experiences refer to the sum of all the interactions shaped by an organisations culture that influence patients and or patients’ family members’ perceptions across the continuum of care (Wolf et al., 2014).

- **Perceptions**

Perception is the process of attaining awareness or understanding of sensory information (Mcdonald, 2011).

- **Patient**

Patient in ICU refers to a person in a life threatening or unstable condition, who needs skilled intervention to have their healthcare needs met. The ICU patient is usually dependent on knowledgeable professionals for the safe implementation of all therapeutic interventions (Mitchell et al., 2016).

- **Family**

Family is a team of individuals connected with bonds of marriage, blood and adoption, and interact with each other (Mitchell et al., 2016). For this study, a family member is recognised as a constant person in the patient’s life, who facilitates family professional interactions at all levels of healthcare (Mitchell et al., 2016).

- **Physical restraints**

Physical restraints are material, devices or equipment applied to or near a person's body, which he cannot control or easily remove. The deliberate intention of such applications is to restrict a person's freedom of movement to a position of his choice or normal access to his body (Maleho, 2018**).**

- **Intensive Care Unit**

An Intensive Care Unit is a specialist area for patients suffering from life-threatening illnesses or injuries. It is a high technological environment, which requires technical and clinical expertise provided by multidisciplinary teams working together in a fine choreographed manner (Langley, Schmollgruber & Egan, 2011).

1.7.3 Methodological Assumptions

Methodological assumptions help the researcher to lay out the strategy, plan of action, process or design behind the choice and use of particular methods. Furthermore, methodological assumptions link the choice and use of methods to the desired outcomes (Creswell, 2009).

1.8 Overview Research Methodology

According to Polit and Beck (2017), qualitative descriptive studies are naturalistic enquiries, which adapt methodological techniques from other qualitative research traditions, usually followed with interpretative descriptions. The qualitative descriptive design in this study used a semi-structured interview guide. This form of design allows the researcher to study the phenomena of social action, of which the researcher does not have an understanding (Brink, Van der Walt & Van Rensburg, 2012).

Furthermore, it allows the researcher to interact with the individuals or groups as the results enable the researcher to study their life experiences and to infer meaning from them (Burns and Groves, 2009). The setting where the study will take place is the general and trauma ICU of a tertiary hospital in Gauteng. The population will be ICU patients who experienced restraining in ICU, as well as their relatives who visited and witnessed them restrained. The study will use purposive sampling as it allows the researcher to choose the participants who have been through a certain lived experience and are knowledgeable

with the subject matter (Creswell, 2014; Polit & Beck 2014). Data collection will use a semi-structured guide through an in-depth interview. The raw data will be analysed using the five stages of thematic analysis by Braun and Clark (2006). There will also be the use of a Computer Assisted Qualitative Data Analysis software program NVIvo 12.

- **Ethical considerations**

Before the commencement of the study, the proposal was presented for peer review at the Department of Nursing Education, and the Post Graduate Research Committee of the University of the Witwatersrand for approval. The ethical clearance certificate was granted by Human Research Ethics Committee of the University of Witwatersrand. The Gauteng Department of Health, the Hospital CEO and Operational managers of the Intensive Care Units involved granted permission to conduct the research in the institution‘s Intensive Care Units.

To ensure the study’s validity, the researcher will ensure an accurate presentation of all data obtained with the assistance of the supervisor, and there will be no manipulation of the data. The researcher, the sole collector of data, will further ensure that themes generated are on the experiences of the patients and the family members, not on the researcher’s assumptions. The coding process will use a coder as a way of checking the consistency and reliability of the information generated.

1.9 Outline of the study

The study will be divided into the following chapters:
Chapter One: Overview of the study
Chapter Two: Literature Review
Chapter Three: Research design & Methods
Chapter Four: Data analysis & Results
Chapter Five: Summary of the main Findings, Limitations, Recommendations

1.10 Summary

This chapter gave an overview of the study. The chapter firstly described the background, followed by the problem statement, the research questions, the purpose of the study, the objectives and operational definitions, and a discussion of the researcher's assumptions. Also outlined were the overview of the methodology, measures of trustworthiness, ethical considerations and finally, the plan of the research action.

The following chapter will focus on the literature review of the study in question

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

The previous chapter outlined the purpose of the research. This chapter reviews literature on issues surrounding the use of physical restraints in ICU. Topics covered include prevalence of the use of physical restraints, reasons for their use, nurse's perceptions, negative effects, family experiences of critical illness, ethical and legal issues, decision-making process, impact of training, and application of Neuman's theory in the care of ICU patients and nursing process in management of physical restraints in ICU.

2.2 Prevalence

During the early 1940s, the use of physical restraints became an acceptable standard of practice in the United States of America, Canada and some parts of Europe. This practice was frequent in clinical settings such as psychiatric, geriatric care and Intensive Care Units, where patients manifest with delirium and altered state of consciousness (Freeman et al., 2016; Martin & Marthisen, 2005; Langley et al., 2011).

Restraint prevalence ranges widely between and within countries, with different countries having varied perceptions on the acceptability of restraint use. Some countries, for instance the United States, consider restraint practice acceptable while others, including the United Kingdom and Norway, consider restraint practice unacceptable (De Jonghe et al., 2013). In the United Kingdom and Canada, the prevalence of physical restraint use in acute care settings ranges from 5 to 26%, with the prevalence of intensive care settings being 33%, while the United States showed a prevalence of 15 to 50% in Intensive Care Units (Talson & Morley, 2012; Taha & Ali, 2013). In South Africa, of the 219 patients admitted in the Intensive Care Unit in a Johannesburg hospital, 106 (48.6%) were physically restrained (Langley et al., 2011). Kalula and Petrose (2010), in their descriptive study of the use of physical restraints in South African hospitals, found a prevalence of 23%. The prevalence differs across ICU types, with surgical ICUs having the highest usage of 59 to 87% (Curry et al., 2008; Liu, Chou & Yen, 2009), while respiratory ICUs

usage range between 50 and 78% (Ismael et al., 2014) and in mixed ICUs, physical restraint use ranges from 31 to 78% (Mehta et al., 2015). This shows that across different countries and ICUs, the use of physical restraints has become an acceptable standard of practice in managing patients despite legislation and accredited standards, which recommend reduction of physical restraint use in the first world countries (Maleho, 2018).

2.3 Reasons for the use of physical restraints

The high prevalence of physical restraint use could be because their description is as protective devices. Also, the increasing technology in Intensive Care environment and the emphasis on patient safety, together with the recommendations by literature on the use of physical restraint as a safety measure, has given the manufactures power to market physical restraints as a method to keep patients safe (Martin & Marthisen, 2005).

Mitchell, Panchisin and Seckel (2018), on their quality improvement project on reducing physical restraint use in Intensive Care Units, found that the increased perceptions of nurses on the need for physical restraint use in prevention of self-extubation and consequences associated with this event have a positive influence on their decision to use physical restraints.

Previous studies examining restraining elderly patients (non ICU) pointed out that the predominant reasons for restraint was to maintain patient safety, manage agitation and aggression, exercise behavioural control, prevent patients from wandering and provide physical support (Cheung & Yam et al., 2003; Oduwde, 2016). There has been extensive research on this justification and, currently, it is no longer the main motivating factor underlying nursing decisions to initiate restraint (Oduwde, 2016). Facilitating work schedules and organisational goals, maintaining a comfortable social environment and preventing interference with therapeutic devises, were some reported staff-orientated reasons (Evans & Fitzgerald, 2002).

In ICU, the main justification for physical restraint use is to ensure patient safety by preventing agitated patients from accidental removal of invasive lines, such as endotracheal tubes, central and arterial lines, which could lead to serious harm and injuries (Talson & Morley, 2012; Langley et al., 2011; Taha & Ali, 2013; Freeman et al.,

2016). Premature removal of an endotracheal tube could lead to severe respiratory distress and cardiopulmonary arrest (Coyer & Hofsa, 2007) and further the need for re-intubation. According to seven clinical audits report undertaken between 1995 and 2005, in 22 general and surgical Intensive Care Units, re-intubation in critically ill patients was associated with severe morbidity and mortality (Coyer & Hofsa, 2007).

However, the claim that physical restraints prevent accidental removal of invasive devices is unjustified (Benbenbistity et al., 2010). The bicultural study by Martin and Marthisen (2005), comparing the restraint use between the U.S.A and Norway, U.S.A being a restraint permissible country while Norway is a restraint free country, found that seven incidents of unplanned removal of invasive devices that occurred in the U.S.A study group occurred with restrained patients. Da Silva and Fosenca (2012) support this in their systematic review on unplanned extubation in the Intensive Care Unit. The study found that 25 to 87% of patients who self-extubate were physically restrained at the time of incident.

Coyer and Hofsa (2007), in their study on chemical and physical restraints in management of ventilated patients in the ICU, found that patients have the ability to self-extubate even when they are restrained, and unplanned extubation was associated with physical restraint use.

Critically ill patients have life threatening illnesses or injuries that require continuous monitoring and intensive care. To achieve the required level of care, patients are connected to life support and monitoring equipment to ensure optimal functioning of vital organs (Kandel & Attia, 2013). Mechanical ventilation and presence of endotracheal tubes are some of the support measures used in Intensive Care Units. Maintaining patients' safety while on these devices is critical to Intensive Care nurses. In order to achieve this level of care, physical restraints are widely used (Taha & Ali, 2013).

Langley et al. (2011) and Martin and Marthisen (2005) further emphasised that treating patients in an Intensive Care Unit can be challenging, as most experience some form of agitation, confusion, or delirium during their stay as the result of pain, underlying illness, sleep deprivation, hypoxia, mechanical ventilation, alcohol withdrawal and altered cellular metabolism. Anxiety was due to the inability to speak, being in a strange environment,

loss of control, fear of the real or anticipated danger and noise (Coyer & Hofsa, 2013). Due to agitation, patients may attempt to remove invasive devices, thus causing harm to themselves. In this situation, the choice of physical restraint use becomes inevitable and the only readily available simple solution (Cheung & Yam, 2005).

Other factors that influence the use of physical restraints besides ensuring patient safety include environmental structures designed to enhance patients' privacy and dignity, which may interfere with nurses' ability to monitor patients continuously (Martin & Marthisen, 2005). The practice culture does not support keeping a nurse at the bedside of acutely or critically ill patients. In geriatric settings, patients' proximity to the nurse's station has been cited as a major factor for restraint use (Oduwde, 2016). Patients not visible from the nurse's station due to the size of the ward and the location of the patient, when nurses are sitting or standing, are more likely to be restrained (Moore and Haralambous, 2017).

Physical restraints also allow for the reduction of sedation. Prolonged use of sedation may result in delayed weaning and continued exposure to mechanical ventilation and its complications, such as ventilator-associated pneumonia (Luk et al., 2014; Benbenishty et al., 2010). Sedation is a form of chemical restraint, normally used in ICU in adjunct or as an alternative to physical restraints (Benbenishty et al., 2010).

Although studies show that sedation is used as an alternative to physical restraints, its use is associated with unfavourable adverse effects, such as depressed cardiovascular function, reduced gastrointestinal mobility, development of withdrawal symptoms (Hofso & Coyer, 2007), lack of memory about ICU and increased patient anxiety and post-traumatic stress disorders (Gu T. et al., 2019).

Maleho's (2018) study of describing nurse's attitudes and opinions of the use of physical restraints in ICU found that 74.3% of nurses agreed that use of physical restraints reduced sedation use in the ICU. However, the same study also indicated that 75.2% of nurses highlighted that physically restrained patients were sometimes re-sedated. Literature revealed there is a correlation between increased agitation and physical restraint use (Freeman et al., 2016; Coyer & Hofso, 2007), hence the need for re-sedation.

2.4 Nurses' perceptions of physical restraints

Dannette et al. (2018) identified the increase perception on the need for physical restraint use to have a positive influence on the decision to use physical restraints. Freeman and Mchugh (2016) support this claim, revealing that nurses have a favourable attitude towards physical restraint application. Even though Dannette et al. (2018) and Freeman and Mchugh (2016) showed that nurses have a positive attitude toward physical restraint use, Kalula and Petrose (2016) and Goethals et al. (2012) hold different views, with their studies pointing out that nurses' decision to use physical restraints leave them with the feeling of ambiguity, frustration, powerlessness and unease. Cheung and Yam (2005) further highlighted that caring for violent or potentially violent patients leaves nurses with a sense of fear, helplessness and hopelessness, and physical restraints become inevitable reality. However, after using physical restraints, nurses felt frustrated and guilty.

A systematic review and synthesis of qualitative and quantitative studies by Mohler and Meyer (2014) explored nurses' opinions on the use of physical materials to prevent geriatric patients from moving. This study observed that nurses had negative feelings towards physical restraint use; it left them with feelings of guilt, sadness, and pity for the patients. However, they also felt there was a need to use restraints in their clinical settings as it allowed them to be more in control of the patient's safety.

Kalula and Petrose (2016) agree there are situations where the patient may be a danger to himself or others if not physically restrained. Situations like these include when the patient changes mental status, causing inability to comprehend treatment and self-removal of invasive devices. Failure of medical teams to protect such patients could qualify as negligence; however, the decision to use physical restraints should outweigh the physical, psychological and ethical risks (Evans & Fitgerald, 2002, Iris nurse's organization 2003).

Cheung and Yam (2005) also emphasise that adequate justification for the decision to use physical restraints should be provided by the nurses as this will not only help in avoidance of inherent dangers and adverse outcomes associated with the use of physical restraints, but also help them to question the efficacy of physical restraints and explore other suitable alternatives.

2.5 Negative effects of physical restraints

Although regarded as a simple solution in controlling behavioural challenges, preventing life threatening consequences associated with discontinuation of invasive therapy (Kandeel & Attia 2013), literature revealed the detrimental physical and psychological effects of physical restraint use. The consequences caused by direct impact of restraint device on the patient are impaired circulation, ischaemic injury, lacerations, bruises, nerve damage, and oedema. The impaired mobility results in reduced functional ability, loss of muscle tone, urine and faecal incontinence, contractures (Kandeel & Attia, 2013).

A prospective point prevalence survey, conducted by Benbensishty et al. (2010) across ICU in European countries, found the psychological effects of physical restraints to range from feelings of denial and indifference to deterioration in cognitive function. Other psychological effects pointed out by Freeman et al. (2016), Kandeel and Attia (2013), Kalula and Petrose (2016) and Cheung and Yam (2005) include agitation, feeling of anger and fear, increased risk of developing post-traumatic stress disorder, demoralisation, humiliation, and depression. These negative consequences result in longer hospital stay and increased mortality (Smith et al., 2003).

In addition to that, literature further showed effectiveness of physical restraints in reduction of falls and injuries to lack scientific evidence, and their benefits questionable (Freeman et al., 2013). The study by Martin and Marthisen (2005) showed that a restrained patient could still fall and sustain injuries due to the attachment of part of their body to the bed, or they can climb over the bed rails and fall. This study further reported that incidences of death occur due to the suspension of patients from the beds or because they are trapped inside rails.

Observational studies reported that restrained patients exhibit the same amount or more agitated behaviours (Coyer & Hofso, 2007; Freeman et al., 2016). This means physical restraints have the potential to cause agitation to patients (Langley et al., 2011; Talson 2012; Kandeel & Attai, 2013; Benbenbishty & Endacott, 2010; Akansel, 2007). Physical restraints have caused catecholamine rush in the elderly (Oduwde 2016) due to escalating agitation. Catecholamines are neurotransmitters, such as adrenalin,

noradrenalin, dopamine, released during body's stress response (Urden, Stacy & Lough, 2010).

The definition of physical restraints is any material, devices or equipment attached to or near a person's body, which are not easily removed (Evans &Fitzgerald, 2002; Yam & Cheung, 2005; Meyer et al., 2009; Kopkel et al., 2012; Li & Fawcett 2014). The intention is to deliberately restrict a person's freedom of movement to a position of choice or normal access to the body. From this definition, physical restraints involve the use of force to restrict patient movement, which the patient could view as punishment.

Kandeal and Attia (2013), in their descriptive cross-sectional study to investigate practices of physical restraints among critical care nurses in Egypt, found the restraints materials used in ICUs were gauze bands, dressings, sheets and belts to tie the chest and one-glove fingers to tie the wrist (Demir 2007). Hospital management claim the restraining materials were expensive, which has resulted in nurses using the unstandardised materials (Kandeal and Attia, 2013). Reportedly, lack of policies and protocols to guide nurses on the use of restraints increase the use of these unstandardised materials (Kandeel & Attai, 2013). The use of protocol-based care has shown to improve both clinical practice and patient outcome. It also serves as an effective way of introducing evidence-based practice into the ICU (Talson & Morley, 2012).

Khaled (2016) showed that the intention of physical punishment is to reduce the behaviour by providing brief and non-injurious contact with an individual. However, when the physical punishment causes discomfort and damage, as in the case of physical restraints, that punishment triggers flight and fight responses, and the individual will try to avoid the punishment or fight the person providing the punishment. This explanation highlights the reasons for increased agitation in physically restrained patients.

2.6 Family experience of critical illness in ICU and physical restraints

Family is a team of individuals connected with bonds of marriage, blood, or adoption and who interact with each other (Mitchell, 2016). According to Gerritsen et al. (2017) family could also be an individual identified by the patient to be the family (not necessarily following a legal or genetic definition). Gerritsen et al. (2017) found critical illness of a loved family member to have an enormous impact on family members of the patient. The study identified that family members experienced acute stress, post-traumatic stress, generalised anxiety and depression, sense of shock, anger, guilt and frustration, both during and after critical illness.

Furthermore, role conflict, interruptions of normal routines and potential change in relationships are some of the family stressors identified by Mitchell (2016). Other potential stressors include exposure of family members to deterioration in the patient's condition, uncertainty of the patient's outcome, fear of death, pain and suffering the patient is going through and unfamiliar environment with high-tech equipment to which the patient is connected (Gerritsen et al., 2017; Mitchell, 2016).

Family members act as surrogate decision-makers for critically ill patients, and are an important source of information (Mitchell, 2016). However, this role is associated with high levels of distress (Gerritsen et al., 2017). Emotional distress hinders a family's ability to provide love and support for their patients and to make decisions about their care. This affects patient recovery processes and causes the family member to have difficulty in coping with their stress (Abdel-Aziz, Ahmed & Younis, 2017). The same study found family members used maladaptive coping strategies to deal with stress. Bademli (2017) found avoidance coping to be one of the maladaptive strategies used by family members.

Nurses provide critical care nursing. The study by Oduwole (2016) however, on relatives' perceptions on the use of physical restraints in the care of the elderly, clarifies that even though nurses are involved in the care of patients, it is crucial to note they cannot replace the functions of family members who wish to be involved in the physical and emotional care of their elderly patients.

There is extensive literature on physical restraints, but studies on family experience on the use of physical restraints in ICU are scarce. Oduwole (2016) looks at relative's perceptions on the use of physical restraints in the care of elderly patients. This study found that some relatives have accepted the use of physical restraints on patients as they regard them as a safety measures to prevent harm to their family member. They believe this is the best practice available, as they have no knowledge of alternatives to restraints.

Taha & Ali (2013) pointed out that family members are aware of emotional distress physical restraints might cause, such as feelings of embarrassment and anger; however, they felt that without physical restraints, serious physical injuries were likely to occur, and these were considered to be of greater concern than their emotional distress.

Despite this, Oduwole (2016) found that other relatives clearly showed their negative feelings about the use of physical restraints and these feelings were based on personal experience, observations, and perceived patients' feelings. These relatives believe use of physical restraints is undignified, a sad thing to do and horrifying. Oduwole (2016) further revealed that relatives support the patients' rights to participate in decision making regarding use of physical restraints, believe the patients have the right to refuse to be restrained, and the provider has no right to restrain the patients against their will. The patient's rights charter, which states that every person has the right to refuse treatment and to be free from an authorised force to restrain their movement, right to freedom and security of the person, including freedom from inhumane degrading treatment, endorses this statement (Langley Schmollgruber & Egan, 2011).

2.7 Ethical and legal issues surrounding physical restraint

The South African Nursing Counsel states under the SANC COMPETENCE OF CRITICAL CARE NURSES (Adults) "Applies the various patient restraints considering safety, prescriptive requirements, and the legal implications. SANC also states that the critical care nurse should states the critical care nurse should deliver care in the manner that preserves and protects the autonomy, dignity, rights, values, beliefs and preferences of the health care user and the family in the midst of dehumanising high technology

environment,(https://www.sanc.co.za/wpcontent/uploads/2020/06/SANC-Competencies-Critical-Care-Nurse-Specialist-Adult).

Healthcare practitioners have the moral obligation to do no harm, to promote good, to ensure the respect of patient dignity, and their autonomy maintained (Mohr, 2010); this is the code of ethics. Cheung (2005) defined code of ethics as public statements that set clear expectations to guide practice, speak to the core values of the profession and form the basis of the trusting relationship with the patients. There bases are four fundamental principles, autonomy, justice, beneficence and non-maleficence.

2.7.1 Autonomy

Respect to autonomy is one of the key moral values in Western society. In the caring environment, respect for autonomy and integrity plays a crucial role when dealing with the wellbeing of the patients (Mohr, 2010). Mohr (2010) found the two components of the principles of autonomy *were Liberty*, which is a right to self-determination without interference or control by others, and *Agency*, which is the ability to make decisions and act upon them. Martin and Mathisen (2005) describe it as a self-rule that is free from both control and limitations by others, which prevent one from making meaningful choices. Patients are able to make decisions without coercion or manipulation.

However, Mohr (2010) showed that such patients should be competent and capable to make such meaningful choices. Critically ill patients are considered to be incompetent and incapable of making their own autonomous decisions and therefore nurses may seem morally justified to select the best treatment options for the patients, based on their clinical experiences and available resources (Mohr, 2010). Martin and Mathisen (2005) pointed out that even the incompetent patients still have rights that continue after their capacity to make decisions has ended.

Literature shows that patients in ICU experience psychological changes due to critical illness, which can cause misunderstanding of the treatment. In these instances, the nurse is expected to communicate with the next of kin so that informed consent can be obtained (Mohr, 2010). However, a study by Moradimajd et al. (2015) found that obtaining written informed consent from patients and families was a standard not followed, even though literature pointed out that nurses need to obtain a written informed consent before

implementing any intervention to patients. Oduwde (2016) concluded that the reason for nurses overriding patient's autonomy could be due to nurse's paternalistic behaviour or the fact that a patient or the family may refuse such intervention.

The view of healthcare professionals is as experts in their field as they have sufficient and appropriate knowledge to judge what is in the best interest of the patients, to determine the best possible outcomes for patients, while the patients play the sick role and are cooperative recipients of that care (Murgic et al., 2015). Mohr (2010) found this idea to correspond with the notion of compliance, which suggests a disposition to yield to the wishes of others. He further clarifies that the idea of compliance as an expectation, as opposed to patient engagement in treatment, shows inequality and the use of coercive power to achieve compliance, such as in the use of physical restraints, further violating the principle of autonomy.

2.7.2 Beneficence and non-maleficence

The basis for the principle of beneficence is on the moral obligation to act for the benefit of the person. To prevent and protect a person from harm and discomfort, be it physical or psychological, to facilitate good or promote a person's welfare (Mohr, 2010; Brink et al., 2013). In the clinical setting, there is a likelihood of creating additional risks while acting for the benefit of the patients (Kalula & Petros, 2016). However, Mohr (2010) advised that healthcare professional must consider all available alternatives to facilitate maximum benefit for the patient; the benefits of the procedure must outweigh the risks. Mohr (2010) describes the principle of non-maleficence as simple, meaning not to harm, prevent harm, remove harm, and facilitate good.

Literature cites physical restraints as protective devices. In ICU, the main reason for the use of physical restraints is prevention of accidental removal of invasive lines, which could lead to serious harm (Yuk-yin & Lau, 2008; Martin & Marthisen, 2005; Cheung & Yam et al., 2003; Oduwde 2016). The use of physical restraints is to prevent patients from injury and protect them from harm. However, literature shows that physical restraints are unsuccessful in the prevention of treatment interference (Yuk-yin & Lau 2008; Coyer & Hofsa, 2007); in fact, they cause more harm than good (Kandeel & Attia, 2013; Yuk-yin & Lau, 2008).

2.7.3 Justice

Mohr (2010) summarised principle of justice as giving others their due, justice as fairness and equitable allocation or distribution of resources or scarce resources. To understand the principle of justice when it comes to the use of physical restraints, without looking into the state of the South African healthcare system, would be unfair.

According to Frenk et al. (2010), the healthcare system in South Africa is under massive pressure due to high staff shortages, high levels of de-motivation, inadequate skills, and unfriendly environment. Racial and gender discrimination, migrant labour system, the destruction of family life, vast income inequalities and extreme violence are some of the reasons found to affect the equal distribution of healthcare services (Frenk et al., 2010). Despite efforts to provide effective, equitable and affordable healthcare services, the health indices indicate that the healthcare system in Africa is stagnant, and in some cases, has deteriorated (Habte, 2004). Habte (2004) further showed that a major limiting factor to improve health outcomes is not financial resources, but lack of implementing capacity, which depends on the presence of a functional health system. The Lancet commission for the future of health in Sub-Saharan Africa further observed that poor leadership and stewardship and weak management were some of the factors that affected availability and accessibility of healthcare service (Agyepong et al., 2017).

Frenk et al. (2010) and Langely et al. (2010) pointed out that the state of the SA healthcare system has resulted in the drop in the nursing standards due to the inclusion of sub-professional categories of nurses and caregivers in the ICU in order to augment staff numbers and as a cost saving measure. The use of cheap and unskilled labour, lack of accountability and leadership are factors that result in unfair treatment to the vulnerable patients (Mohr, 2010).

2.8 Decision making process on physical restraints

Literature shows that nursing staff are the ones who make the decision to restrain and remove restraints from the patients (Benbenbishty et al., 2010; Langley, 2011; Kandel & Attin, 2012). This could relate to the fact that nurses are closely involved in the caring of the patients (Freeman et al., 2016). However, it found that majority of nurses and doctors

believe that the decision to use physical restraints is a joint decision (Kalula & Petrose, 2011).

Clinical decision-making is a complex issue especially in the care of critically ill patients; it requires nurse practitioners who are ethically sensitive and well equipped with the clinical decision-making skills (Mabona, 2018). Factors such as experiences, interpersonal relationships, working circumstances and specialty have an influence on nurse's clinical decision-making (Goethals, Casterle & Gastmans, 2012; Hoffman, Aitken & Duffield, 2009). However, Mabona (2018) found that the use of physical restraints on an Intensive Care patient is based on nurse's clinical decisions that is individualised for each patient, but Cheung & Yam (2005) regard such decisions as paternalist.

Freeman et al. (2016) and Kandeel and Attia (2012) found that even though nurses are the ones who initiate the use of physical restraints, they lack knowledge on risks associated with physical restraints, and how to apply and document their use. In a study by Akasel (2007) 93.7% of nurses reported they did not use any form of documentation before or after applying physical restraints. Those who claimed they frequently observed the restrained site, the analysis from the patient's records did not reflect the assessment as there was no reference to this activity. Lack of documentation could relate to the fact that physical restraint practice lacks scientific evidence, so it is hard for nurses to explain the reasons for physical restraint use and the kinds of results observed post restraining the patient (Akasel, 2007).

Ting and Gu. (2019), in their prospective, cross sectional, observational study of 312 patients in three ICU in a general hospital in China, revealed that even though lack of documentation can be related to lack of knowledge by nurses, it can also reflect the need for standard guidelines and policies to govern the use of physical restraints. The study by Moradimajd et al. (2015), on physical restraints in the ICU, emphasised that the mandatory documentation of the procedure can enhance the quality of restraint-related decisions and care services.

The effective nursing assessment and observation of patients is crucial to patient safety and outcomes, as Atkinson (2016) found this to be the first step in identifying signs of clinical concern. However, Kandeel (2013) reported that if nurses were to monitor the

physically restrained patient, assessment only occurs after eight hours and only related to peripheral circulation. Incomplete assessment of the restrained extremities reflects knowledge deficiency and training on caring for restrained patients by nurses (Moradimajd et al., 2015).

A study by Langely et al. (2011) on restraints in Intensive Care Units found that ties used to restrain patients were too loose, allowing patients to touch their face and neck. In other instances, there was only one hand restrained while the other remained free. A contributing factor to incidences of patient self-extubation could be the inappropriate application of physical restraints, which reflects nurses' lack of knowledge on the use of such (Ting & Gu, 2019).

2.9 Impact of training on the use of physical restraints

A quasi-experimental study with pre- and post-assessment on the impact of training programmes on nurses' knowledge, practice and patient outcomes, which was done on 38 nurses working in the ICU by Taha and Ali (2013), found that only eight out of 38 nurses reported having information about physical restraint use, while the rest reported practice as their source of reference. This means wrong practices or misconceptions would extend to nurses from previous generations, and this would be perpetual. The lack of knowledge by nurses on the use of physical restraints has a negative impact on the nursing care provided to the patients, and this may lead to complications among the patients, which will further lead to legal problems for the nurses providing the care (Taha & Ali, 2013). Langely et al (2011) shared the same sentiment and said it was concerning to find that the complex theoretical requirements in nursing was being ignored, but the practical skills not insightful application of knowledge appeared to be considered as sufficient for nursing practice by healthcare management.

Literature shows a lack of restraint education for nurses, and this highlights the need for educational programmes on the use of restraint for nurses. A systematic review conducted by Philabaum (2016) found that restraint educational interventions could be a useful way to increase safe restraint practices and decrease restraint use. Taha & Ali (2013) highlighted this in their study, which found that before the implementation of the standard guidelines on the use of physical restraints, patients suffered all types of

problems and complications related to physical restraining. However, post the implementation of the guidelines, there was a significant reduction in complications experienced by restrained patients. Credit was given to the educational guidelines, which improved nurses' knowledge and practice.

2.10 Application of Neuman system in the care of ICU patients

Education and training on the use of physical restraints has a tremendous impact on nurse's knowledge, as per the literature. Application of Betty Neuman's system model could assist nurses in caring for critically ill patients in ICU as it offers a system-based comprehensive conceptual framework and a dynamic structure that provides holistic viewpoints from primary, secondary, and tertiary levels of prevention (Sadeghi & Ahmadi, 2017; Duman & Bademli, 2017).

Patients in ICU have unmet needs (Ume-Nwagbo, Dewan & Lowry, 2006). The Neuman's system model reflects on the nature of these patients as an open system in constant interaction with each other and the environment. This open system has a central core of basic survival mechanisms, surrounded by lines of defence, namely flexible line of defence, normal line of defence and lines of resistance. These lines of defence protect the system from invasion by both external and internal stressors (Sadeghi & Ahmadi, 2017; Duman & Bademli, 2017).

Physical restraints, ICU environment, disease and illness are stressors with the potential to disrupt balance within the patient's system by penetrating the lines of defence (Duman & Bademli, 2017). When this occurs, disruptive behaviour, such as physical aggression, increased agitation, attempts to self-extubate, manifests as psychological response to these stressors (Taha & Ali, 2013; Langley et al., 2011).

Knowledge and understanding of the application of Neuman's model can assist nurses to design system guided, client-centred nursing care, as nursing practice demands effective implementation of nursing process in order improve the quality of care and to stimulate the construction of theoretical and scientific knowledge base (Pokorski et al., 2009).

Summary

This chapter presented a summary of the literature on the research topic and examined the results of previous research, including their results, which highlights recommendations made by previous authors. The chapter also presented an overview of prevalence, reasons for the use of physical restraints, nurses' perceptions of physical restraints, negative effects of physical restraints, family experience of critical illness in ICU and physical restraints, ethical and legal issues surrounding physical restraint, decision-making process on physical restraints, impact of training on the use of physical restraints, and application of Neuman's system in the care of ICU patients. The following chapter will outline the research methods and design used in the study.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

Grove, Burns and Gray (2013) describe research methodology as the process or plan for conducting the specific steps of the study. This chapter presents a broad overview of the research design, research settings, sampling process, data collection, data analysis, and discusses the ethical considerations.

3.2 Research Design

Research design is the systematic plan a researcher uses to address the research problem and specifications that enhance the integrity of the study (Polit & Beck, 2010; Burns & Grove, 2009). It involves the logic steps, which guide the research process (Burns & Grove, 2009). This study used a qualitative descriptive and explorative design.

3.2.1 Qualitative Research

A qualitative research approach refers to a broad range of research designs and methods used to study a phenomenon of social action of which the researcher does not have an understanding (Brink, Van der Walt & Van Rensburg, 2012). It allows the researcher to interact with the individuals or groups, as the results enable the researcher to study their life experiences and infer meaning from them (Burns and Groves, 2009). This study used a qualitative research approach study because it was a more appropriate and effective way to explore and to provide a descriptive summary of the patients and their families' experiences on using physical restraints in an Intensive Care Unit.

3.2.2 Descriptive Research

The purpose of a descriptive study design is to provide a picture of a situation as it naturally occurs (Grove, Burns & Gray, 2013) and involves observing and describing the behaviour of the subject without influencing it in anyway (Maleho, 2018). As indicated in the problem statement, the literature is scarce on how patients' experience of physical restraining and how their family members experienced it. This design was the most appropriate in addressing the problem under investigation in this study because the

design helps the researcher to gain more information about the characteristic of the phenomena under investigation as it naturally occurs (Polit & Beck, 2012). Methods that describe phenomena in qualitative studies include observation, semi-structured and unstructured interviews (Burns & Grove, 2011). This study used a semi-structured interview guide.

3.2.3 Explorative Research

According to De Vas et al. (2011) explorative research investigates a full nature of little understood phenomenon. The aim of this type of research is to gain an insight and familiarity into the phenomenon and people in order to identify a problem or develop a hypothesis. Commonly used methods in qualitative explorative study include focus groups and in-depth interviews. The researcher considered this approach because this study sought to understand the patients and their family member's experiences on using physical restraints in an Intensive Care Unit. This study conducted face-to-face interviews with the participants.

3.3 Research Setting

The specific location for data collection is the research setting (Brink et al., 2012). The selection of the setting is based on the nature of the problem under investigation and the type of data needed to solve the problem (Brink et al., 2012). Data collection in qualitative studies should occur in the natural setting of the lived experiences. The idea is to conduct the research in the real world, with as little intrusion as possible (Creswell, 2014).

The conducting of this study was in a tertiary hospital in Gauteng. This hospital is a tertiary research and training institution for health professionals, providing specialised services, accredited as a centre of excellence for intensive care, internal medicine, obstetrics, and gynaecology. The hospital serves as the referral centre for several hospitals in Gauteng. This study used one ICU with two divisions, trauma and general. According to Maleho (2018), the SASA 2013 guidelines describe ICUs according to the levels. Multi-disciplinary (General) and Trauma ICUs are level three ICUs as they admit patients with multi-organ dysfunctions. These two divisions have a total bed capacity of 18 beds. The patients admitted in the ICU have the following diagnoses: acute respiratory distress syndrome, acute kidney injury on dialysis, eclampsia, organophosphate poisoning, head

injuries, and laparotomy secondary to gunshot and stab wounds. Patients admitted with these conditions are at risk of becoming confused and may inadvertently remove their endotracheal or tracheostomy tubes (Langley et al., 2011). Premature removal of the endotracheal tube could lead to severe respiratory distress and cardiopulmonary arrest (Coyer & Hofsa, 2007), and further the need for re-intubation.

3.4 The Research Methods

Brink et al. (2012) define research methods as an approach used by the researcher to choose, in an appropriate manner, the optimal objects, persons and events from which to draw research answers.

3.4.1 Population

Population refers to the entire group of persons or objects, which meet the criteria that the researcher is interested in studying (Grove, Burns, & Gray, 2013; Brink et al., 2012). The population for this study consisted of the patients admitted into the Intensive Care Unit of a tertiary hospital in Gauteng. The population of this study consists of physically restrained patients while admitted in ICU, as well as the patients' family who visited the patient while restrained. The total population initially was sixteen participants: ten family members and six patients but four family members and two patients didn't want to participant in this study. Therefore, the total population that participated in this study was only six family members and four patients. The assumption was that one family member visited the patient while admitted in the ICU.

The target population, which is the entire set of persons, or elements the researcher would like to make generalisations about (Brink et al., 2012). The target population for this study were all patients or family that were aged eighteen years of age, who had either been physically restrained in the ICU setting, or who had witness the uses of physical restraints on the patient (their family member) in the ICU setting.

3.4.2 Sampling and Sample Size

The selection of a group of people, or events and behaviours with which to conduct the study is sampling (Groove, Burns & Gray, 2013). In qualitative research, the sampling process continues until the reaching of data saturation, because the total number of participants is unknown in advance (Brink et al, 2012).

This study used a non-probability purposive sampling method to select participants who met the inclusion criteria. This sampling technique allows the researcher to select participants or objects that are typical or representative of the study phenomenon (Brink et al., 2012). The researcher used her own judgement in the selection process. Non-probability sampling method further allows the researcher to choose the participants who have been through a certain lived experience and are knowledgeable with the subject matter (Creswell, 2014; Polit et al., 2014). The aim was to include a variety of participants according to factors such as age, gender and various ethnic backgrounds and different family members.

With qualitative studies, the sample size is adequate when the meanings are clear, and data fully explored (Brink et al., 2012). This is data saturation, the definition of which is the point where any additional information, ideas and views gathered from the participants does not yield any new information (Polit & Beck, 2010; Grove, Burns, & Gray, 2013).

In this study, interviews took place with four patients and six family members. The sample size was determined by data saturation; to determine if obtained, the open-ended questions were repeatedly asked and checked with some probing for more information from participants until a sense of closure was achieved.

3.4.3 Inclusion Criteria

Polit and Beck (2010) and Brink et al. (2012) pointed out that it is crucial for the researcher to clearly define and describe the population and specifically stipulate criteria for inclusion in the study.

These criteria are the basis for the decision of whether an individual is included or not as a member of the population.

The inclusion criteria in this study were:

- Patients physically restrained while in the Intensive Care Unit and >18 years' age
- Family members who visited and witnessed the physical restraining of the patientin the Intensive Care Unit
- Patients and family members able to speak and understand English, Sotho, Setswana and IsiZulu

3.5 Data Collection

Grove, Burns, and Gray, (2013) describe data collection as a systematic collection of information, which meets the research objectives and answers the research questions.

3.5.1 Data Collection method

In this study, semi-structured, in-depth, face-to-face interviews collected the data, as they enabled the researcher to gather information about the experiences and allowed the interviewees a degree of freedom to explain their thoughts. (Harrell & Bradley, 2009). This type of interview also enables the preparation of topics and questions to cover during the interview process (Polit & Beck, 2017). According to Polit and Beck (2017), the use of this type interview allows an early preparation of topics and questions to be covered during the interview process.

In this study, the interviews were supposed to take place once the patients were transferred from the Intensive Care Unit into the ward; this was to ensure the patients privacy was maintained and allowed them freedom to express their experiences without being fearful of their treatment been affected by their participation in the study (Drabble et al., 2016). However, the interviews occurred after discharge from the hospital, in the comfort of their own homes, because there was no visitation allowed in the hospitals at the beginning of the Covid 19 global pandemic. Drabble et al. (2016) state that the environment plays a pivotal role when interviews collect sensitive data. The researcher did the interviews at the homes of the participants as this was a safe space and their privacy maintained. The safe space allowed the participants to share their experiences freely.

This study used an interview guide because it allowed the researcher to focus on interview specific objectives of the study and guide the participants, as well as encourage them to give detailed information freely. The interview guide consisted of the following semi-structured questions: (**See Appendix E**)

Patient interview guide

- How was being physically restrained for you when you were in Intensive Care Unit?
- In your opinion, what could change your experiences of being physically restrained?

Family Interview guide

- How did you feel when you visited the patient and was physically restrained in the Intensive Care Unit?

3.5.2 The process of data collections

Data collection process

The head of the ICU departments was asked to grant permission to conduct the study (**See Appendix I),** and once approved, the researcher met with the operational managers and briefly presented an overview of the study. The operational managers helped with identifying the patients who underwent physical restraint before their transfer to the ward. The patients and next of kin's details were taken from the patient's hospital file. Before going to the participant's homes, the researcher phoned them, ten family members and six patients to introduce herself and to invite them to be part of the study. However, six family members and four patients agreed to be part of the study. Both family members and patients who declined the invitation cited their lack of readiness to talk about their ICU experience. Only once the participants accepted to be part of the study, the researcher obtained verbal consent and made an appointment date. As data collection took place during the peak of Covid-19 levels 5 and 4, the researcher reassured the participants that their safety was important and to ensure that, they would adhere to the World Health Organization's global safety precautionary measures: wearing of masks, hand sanitising and keeping a social distance during the interview. The researcher re-introduced herself and further explained the purpose of the study when she arrived at the participant's home.

Before the interviews started, an informal conversational exchange took place in the form of small talk in order to place both the researcher and participants at ease. The participants received a consent form to sign in writing as an indication that they consented

to participate in the study and permitted digital recording in order to capture an accurate description of the discussions (**See Appendices B & C**). The duration of the interviews varied amongst the participants, with the range of 30 minutes and 35 minutes. During the interviews, questions were refined according to the information shared from the first interview, and the order of questioning determined by the answers provided by the participants (Harrell & Bradley, 2009). Probing questions gained more insight into the participant's experiences and further allowed them an opportunity to express themselves. This continued until no new information arose, known as data saturation (Creswell, 2014; Polit et al., 2014). After the interview, the participants had the opportunity to ask questions, and the researcher responded to the best of her ability until the participants were satisfied. Once there were no more questions asked and the participants were happy with the information the researcher gave, the researcher thanked them for their voluntary participation in the study.

3.6 Data analysis process

Analysis of collected data aids the researcher to draw conclusions and obtain answers pertaining to the research objectives and questions (Polit and Beck, 2012). A qualitative thematic analysis method, as described by Braun and Clark, analysed the data in this study. Thematic analysis is known as an inductive and detailed process intended to examine and categorise themes from written data in a manner that is distinct and dependable (Guest MacQueen & Namey, 2011). Alternatively, thematic analysis takes several 'chunks' of texts and categorises them into codes, then further groups similar codes into different categories and finally themes.

Six stages of Thematic Analysis by Braun and Clarke (2006) explained.

3.6.1 Data familiarisation

Reading and re-reading of contextual data and listening to audio recordings is the first step in qualitative analysis (Maguire & Delahunt, 2017) as it allows the researcher to be involved deeply with the data and to be more familiar with the entire body of data (Braun & Clarke, 2012). During the process, reading and listening to the audios, the researcher made and jotted down notes actively, analytically and critically (Braun & Clarke, 2012). As a result, the researcher was able to draw the meaning out of the data. After each

interview, the researcher personally transcribed the audio-digital recording into verbatim accounts and created word documents (**See Appendix J**). To avoid transcription error and to ensure accurate reflection of recordings, there were comparisons made between the written and audio tape versions of each interview.

3.6.2 Generating initial codes

In this phase, data is organised in a systematic and meaningful way using codes (Braun & Clarke, 2012). Coding enables the researcher to identify the concepts of interest within the data, in a more meaningful way, concerning the research problem and/or research question (Maguire & Delahunt, 2017). During the opening reading, the researcher emphasised the important and relevant sections of the text and attached labels to mark them; this was to make the data analysis process effortless (Creswell, 2013:205; Creswell, 2015; King, 2004; Nowell et al., 2017). Using NVivo 12 Plus, in the preliminary stage, the examination of the transcripts was through lexical queries, such as word frequency and text search queries, as a way of gathering and exploring subcategories of the data provided. The lexical queries augment the data analysis process, where the generation of a word cloud is to summarise the meaning of the study.

3.6.3 Search for Themes

A theme is a pattern that captures something significant or interesting about the data and or the research question (Maguire & Delahunt, 2017). The reviewing and analysing of the coded data, was to identify areas of similarity and overlap between codes. The codes that reflected and described coherent and meaningful patterns from the data were clustered and presented in a table, which outlined the candidate themes (Braun & Clarke, 2012). The collating of data relevant to each candidate theme was to enable the researcher to work with the data and review the viability of each candidate theme (Maguire & Delahunt, 2017) See (**Appendix K**).

3.6.4 Reviewing potential themes

This phase reviews developing themes in relation to the coded data and the entire data set to verify if candidate themes were coherent with coded data (Braun & Clarke, 2012). In this study, repeated reading of the emergent findings and transcripts was to understand its meaning and to review categories for possible rearrangement or combination to establish rich description of coherent themes for the phenomenon. Themes were refined until the data became specific to the research question, but broad enough to incorporate a set of related ideas meaningful to the phenomena under study. The researcher was satisfied that the emergent themes represented the objectives of the study and used them for argument in the discussion.

3.6.5 Defining and Naming the Themes

This phase is theme refinement. The aim is to identify the essence of what each theme is all about in relation to the data provided by the participants and to provide the comprehensive description of the data content and the scope (Braun & Clarke, 2012). To achieve this process, the researcher and supervisor reviewed and evaluated collated data extracts against the analysis drawn. Throughout the whole process, the work was refined and the relevance of the themes to the data context made.

3.6.6 Report writing

This final phase involves bringing together the analytic narrative and data extracts, and contextualising the analysis in relation to existing literature (Braun & Clarkes 2012). After completing an analytic review, the researcher presented the study findings, which included capturing data extracts to corroborate the credentials of the themes.

3.7 MEASURES OF TRUSTWORTHINESS

The terms in qualitative literature that address validity are trustworthiness, authenticity and credibility (Creswell, 2014), but this study used Lincoln and Guba’s Framework for Establishing Trustworthiness, which is an approach suggested for a study that is explorative and descriptive in nature (Polit & Beck, 2012: 584). Trustworthiness has four evaluative criteria, which are credibility, dependability, conformability and transferability.

- **Credibility**

Achieving this is by ensuring confidence in the truth and interpretations of the data (Polit & Beck, 2010) and done to enhance believability of the findings to ensure congruency of results with reality. This occurred by using research methods that are well established for this kind of study, such as semi-structured interviews to collect data. Frequent debriefing with the supervisor ensured the use of correct methods and the data collection was in a way that was relevant for this kind of a study.

Information gathered from the patients, as well as their families, was to ensure the credibility of the study (Moon et al. 2016), so that different viewpoints could be verified against others and ultimately the construction of a rich picture of their experiences based on the contributions of a range of people. The use of the coder in the coding process was to check the consistency and reliability of the information generated. Furthermore, the coder helped the researcher to discuss the coding frame, before reaching a consensus as a way of refining the coding system, thus adding accuracy and validity to the propositions extracted from the codes, categories and themes created (Bazeley & Jackson, 2013).

- **Dependability**

According to Moon et al. (2016), to address dependability, a detailed reporting of the process within the study is necessary to enable a future researcher to repeat the work and gain the same results. The provision of the full description of the processes and methods were to enable other researchers, who may be interested in using the same processes, to have a clear understanding of the data collection and analysis methods to reach the conclusions presented in the study.

Supervisor checks related to the acceptability of processes and procedures used by the researchers in the study was also another principle used to ensure dependability. The supervisor provided guidance and ensured the researcher adhered to the research plan, and evaluated the content of interviews for quality and adequacy.

- **Confirmability**

Confirmability is concerned with establishing that data represents the information that the participants provided and that the researcher's own beliefs and attitudes do not influence the interpretations (Polit & Beck, 2010). The participants who showed interest in voluntarily participating in the study, and to being audiotaped, received a consent form to sign after they read and understood the information sheet issued to them. Participants' anonymity and confidentiality was maintained throughout the study. The audios and word documents used for transcription were filed on password-protected computer and only accessible to the researcher and the supervisor. Data identifiable to participants received a code to avoid bridging their confidentiality and anonymity. Accurate and consistent representation of data findings were ensured for the reliability of the study. As stipulated by the University of Witwatersrand Research Policy, the obtained data would remain filed for five years to serve as an audit trail.

- **Transferability**

The generalisability of the research findings in other setting (Brink et al., 2012). This study used two Intensive Care Units to describe and explore patients and their families' experiences. Achieving transferability was by describing the methodology and context of the study in as much detail as relevant to ensure that the findings of the study could be transferred or applicable to other similar Intensive Care Units (Polit & Beck, 2012).

3.8 Ethical Consideration

Ethical issues should take priority during the research process, especially with research that involves human and animals (Polit & Beck, 2010). The generation of new knowledge was the purpose of research; however, this did not take priority over the participant's rights and interest. The Nuremberg code of 1945 was the guideline to ensure the protection of the participant's rights. The code showed it is mandatory for the participants to voluntarily consent to participate in the study, that the risk and benefits be well balanced, and that participants be protected from risk and harm, and be given freedom to withdraw from the study anytime (Brink et al., 2012).

3.8.1 Permission to conduct the study

The Gauteng Department of Health (**Appendix F**), the Head of the ICUs at Barangwanath Hospital (**Appendix G**) and nursing managers of the units involved granted permission to conduct the study. The Department of Nursing Education and the Post Graduate Research Committee of the University of the Witwatersrand received the proposal for peer review for approval. The Human Research Ethics Committee of the University of Witwatersrand granted ethical clearance (**Appendix H**).

3.8.2 Informed consent

Informed consent means the participants have adequate information regarding the research, are capable of comprehending the information and have the power of free choice, enabling them to consent voluntarily to participate in the research or decline participation (Brink et al., 2012).

An information sheet, containing the purpose of the study, potential benefits and risks associated with participating in the study, and how anonymity and confidentiality would be ensured, was communicated to prospective participants to understand. The information sheet clearly emphasised that participation in the study was voluntary, and that individuals could withdraw anytime and their withdrawal would not jeopardise the kind of treatment they were receiving. Participants were given time to ask questions and to get clarity on any concerns relating to the study process.

3.8.3 The principle of beneficence

The researcher needs to secure the wellbeing of participants, who have the right to protection from the discomfort and harm (Brink et al., 2012). This is achievable by providing confidentiality and anonymity for research study participants. Furthermore, an arrangement was made to refer the participants to the social worker in the Hospital for counselling and emotional support if the need arise.

Confidentiality and Anonymity were maintained to safeguard the respondent's rights by clearly and specifying the intended use of obtained data to participants during the process of obtaining consent. The information shared by participants was not accessible

to parties other than those involved in the research. After the audios where translated verbatim by the researcher, word documents were created for all 10 participants. Pseudonyms such as “P 1” for patient 1 and “F5” for family member 5 were given to the participants as a way of preserving and protecting their original identity whilst allowing the participants to provide information that address the research objectives of the study. Secure filing of the audios and word documents occurred in a password-protected computer. Any other raw data, e.g. research notes, remained in a secure locker. All obtained data had to be retained for a period of 5 years, as stipulated by the university of Witwatersrand Research Policy. Even though qualitative studies are non-invasive in nature, the researcher enters people’s lives and the nature of qualitative enquiry risks exploring unresolved issues, which may upset the participants (Brink et al., 2012); to address this issue the researcher carefully structured the interview questions and monitored for any signs of distress from the participants during the interview.

3.9 Conclusion

This chapter described the research design and methods used by the researcher to achieve the research objectives. The chapter discussed the research objectives, setting, population and sample, as well as data collection procedure, data analysis and ethical considerations. The next chapter will discuss the findings of the study.

CHAPTER FOUR
DATA ANALYSIS AND RESULTS

4.1 INTRODUCTION

The study intended to explore and describe the experiences of ICU patients and their family members regarding the use of physical restraints in the ICU setting of a central hospital in Gauteng. The qualitative analysis results were from the description of the experiences of patients and family members of the use of physical restraints in an Intensive Care Unit. A qualitative thematic analysis method, as described by Braun and Clark, analysed the data. The Braun and Clark thematic analysis consists of the following steps: data familiarisation, generating initial codes, search for themes, reviewing potential themes, defining and naming the themes, report writing. In this study, there were four themes deduced during this process:

1. Patients' experiences of restraints.
   Negative experience
2. Family experiences towards restraints.
   - Positive experience towards restraints.
   - Negative experience towards restraints.
3. Mixed experiences towards restraints.
4. Recommendations
   - More care and social responsibility.
   - More improved communication channels.
   - More skilled and competent healthcare professionals

Eleven sub-themes emerged from the four themes (Table 4.1). The themes will be presented and discussed in detail, substantiated by verbatim quotations from the interview transcripts, in the context they were expressed, to support observations or conclusions drawn by the researcher and give them meaning.

THEMES	SUB-THEMES
1. Patient experience of restraints. Negative experience	1.1 Form of imprisonment 1.2 Causes physical injuries 1.3 Traumatic experience 1.4 No memory at all 1.5 Not a good practice
2. Family experience towards restraints Positive experience	2.1 Safety and control measure 2.2 Alternative to sedatives
Negative experience	2.3 No informed consent issued
3. Mixed family experience towards restraints	3.1 Rejection and Acceptance
4. Recommendations	4.1 More care and social responsibility. 4.2 More improved communication channels. 4.3 More skilled and competent healthcare professionals

Table 4.1 Themes and Sub-themes.

DESCRIPTION OF EMERGENT THEMES

4.2 Patient experience of restraints

Through the data analysis process, patients indicated that the experience of restraint in the ICU had never been a ‘bed of roses.’ They all suggested that physical restraint in ICU was characterised by negative experiences as they all indicated discomfort, lack of freedom, psychological trauma and physical injuries due to restraint. Despite most of the participants mentioning the negative experiences they encountered during their time in ICU while being restrained, some indicated they had no memory of such.

4.2.1 Form of Imprisonment

Participants viewed the restraining of patients in ICU as a form of imprisonment, as some highlighted the lack of freedom when one is restrained and the form of discomfort that comes with this. Some of the participants mentioned that restraining patients puts them in a claustrophobic environment where they feel trapped

P3 shared that, *“I still remembered at that time that I was gunshot, but now I am restrained, it was like I was held captive, or imprisonment… it was like I am held captive or in prison and at that time I was helpless…. all I saw was like I am in prison, or I couldn’t do anything and I was wondering what is that I have done*…”

P2 explained that*, “Yes but what came in to my mind is I felt like I am in prison, I was deprived of my freedom and was so uncomfortable…though I was aware that I am in the Hospital…*”

P1 reinforced the above and *explained, “Hmm sometimes you can restrain the person…. you know… have you heard…like the situation I was in… when I slept on one side, there is no one to turn me and change my position… I felt like… I was always sleeping facing up… with no one to turn me and change my position… for 4 days, the whole week sleeping on one side, it’s painful and uncomfortable*. *You feel you are trapped.*”

4.2.2 Causes physical injuries

Information provided by the participants who took part in the study indicated that restraining patients in an Intensive Care Unit causes physical injuries. For most of these patients, the physical scars left on them due to the restraints reminded them of their

throbbing journey experiences in the ICU. For one participant, the memory of physical restraint has gone, but when the patient gets a glimpse of the picture taken whilst in the ICU, his heart bleeds. The following quotations support the notion above that restraining patients may cause physical injuries:

P1 stated that, "*Like the situation I was in… when I slept on one site, there is no one to turn me and change my position… I felt like…even today at the back of my head I don't have hair, it doesn't grow at all, I have marks, no hair… is because I was restrained and was always sleeping facing up… with no one to turn me and change my position….*

Echoing the above experience is **P2,** who expressed the similar idea that, "*Even now I have a picture showing that I was tied to the bed with a bandage, my arm swollen. And right now, I can see the marks.*"

P4 reinforced this shared information, "*Yahhhh… my hands were big, and painful. the bandages caused my hands to raise. And I was not able to tell the nurses that the bandages were causing pain*

4.2.3 Traumatic experience

Participants in this study claimed they had a traumatic restraining experience in the ICU. Most of the participants indicated that the environment was unfriendly; there was a lack of care from the health professionals. The participants described the ICU as if it was a prison and sometimes felt they were treat like dogs. The following excerpts from the participants support the above-mentioned argument:

P1, in supporting that restraining patients contributed to their experience as being traumatic, said, "…… *yes, so that these can be corrected… I was tied like a dog, and above all just dumping this animal without even caring, the only thing you do just come give it water, food and then leave you will come again when you need to bath it, still been tied but not thinking about how this animal you have tied feel about what you have done…. even SPCA can put you in Jail if they find that the chain used is too tied, it doesn't give the dog the space to move and do what it wants. This was exactly I feel was been done to us…."*

P1 continued to say*…" yes that the way I feel; it was like this person is an animal, how do you tie a person both the hands and legs, but that person it's a patient, how do you tie*

*both the hands and legs, go to ward 38, you see how these patients are restrained... this patient I am talking about, I was saying to myself this patient is very sick, he is suffering mentally but he is being restrained both legs and hands, he can't move or do anything…. really sad, disturbed my mind especially when I was told that I was restrained like this, I was very sad even though I didn't feel or understand why…. but I am wondering why I was restrained…it was really painful, patient ended up passing away still restrained***..."**

P2 reinforcing the above said, *"What I remember is that they were tie-ing me while I was crying saying they shouldn't, tie me, I don't know if it was in High care or ICU but I could see on the photo that my hands are tied in the Hospital bed with a bandage and no one ever listened to me..*."

From the data provided, remembering the entire ordeal hurt some of the participants.

P3 said, *"I was tied? Yes, it hurts me when I think about it, I normally cry when I look at the picture seeing how swollen my arm, I wonder why I was tied because I don't remember any one fighting when admitted.*"

P4 also explained that the treatment was bad*, "You see I didn't know what was happening and what was the purpose of being restrained, I didn't know the ultimate results or what nurses wanted to achieve… I felt I was being treated badly by being tied on the bed and as that time I didn't do anything which deserves this punishment but I didn't realise that if they didn't tie me I could take out the pipes that were assisting me live, or which were bring life to me."*

4.2.4 No memory at all

Some participants showed lack of memory on the experience of physical restraints. They pointed out that they had actually forgotten what their experience was like.

P1 said, *"Eish…I don't remember anything, all I remember is just eating, and the urinary catheter, there is a lot of things I dreamed about happening… I don't know how to put it or position it, eish I don't know because I don't remember being restrained, I was only told but if I remember I could be in the right position to tell you how I feel about it but I don't know because I was told..…. maybe I was doing things I can't remember now because when they tell me, they said I sometimes had fits or became so restless as a result I could injure someone next to me or the other patients so that's why they had restrained me."*

P2 expressed the similar experience, "*Hmmmm what I remember is…Someone told me I was busy pulling things hence they decided to tie my hands on the bed even when I don't remember that I was doing that or agreeing with that, I don't know but it's like I remember nurses hold me with the arms, tie me on the bed side, like I don't know what I did, but I remember crying…. I wonder why I was tied because I don't remember any one fighting when admitted".*

P3 echoed this statement, *"… I was not aware of what was happening or what was going on around me…"*

4.2.5 Not a good practice

Some of the participants who took part in the study stated that restraining patients is not a good practice despite the fact that it prevents patients from causing harm to themselves or other patients in the ICU.

P1 said, *"I don't think it's a right thing for people to be physically restrained because sometimes it's against their rights and they feel much discomfort that no one listens to them" …… "like when they are going to bathe him they will untie him and then restrained him again, it's not a right thing…it's not right at all, I saw it happening to other people…"*

P1 reinforced the above information, *"…and the next nurse coming to shift does not know why this patient is being physically restrained… this nurse when she comes in she does her own things that she is supposed to do, she doesn't care about this restrained patient to find out why the patient is restrained, and maybe the patient is hurting but the nurses doesn't care so it's not a good thing."*

P4 further explained this experience, "*…. But when you are not on your senses you don't see it that way… you just see that this people are treating you badly on top of that these people have inserted you pipes in the mouth, nose…"*

From the data presented by participants, restraining patients is a violation of patients' rights, as the patients remain captive and restraints cause discomfort.

4.3 Family experiences towards restraints

4.3.1 Safety and control measure

The Family members in this study highlighted the importance of restraining patients in ICU. They pointed out that after putting the patients on drips they became delirious, irritated and aggressive. The latter behaviour change caused them to remove the intravenous therapy unintentionally, thus endangering their lives. they explained that restraining patients was a form of safety measure used to protect the patients from jeopardising their lives during treatment.

F5 Showed that, *"…. like when he is asleep, he was much safer but when he was awake sometimes, he could fall, so I think it's safe procedure."*

F7 shared similar sentiments, "…. *saw that really they have to tie him because what he was doing was not right because it was difficult to feed him and give him medication through those pipes, finally I understand that nurses were right in restraining him."*

F6 had an understanding that patient was restrained to provide immediate treatment and to prevent falls. He said, "*He was restrained, that they truly wanted to give him an immediate treatment as he might hurt himself further……. yes… yes, it means if he is not restrained at the time when is restless he will fall and he has machines, also he can hurt himself further so he can cause further injuries."*

To emphasis further on safety component of the use of physical restraints, **F8** said, "*The reason he went to ICU was due to Gunshot, so when memory returns he could fall because he was so restless so he was restrained for his safety so that he could not fall from the bed and hurt himself… I did understand the way they explained it to us."*

F9 explained that when the patient wakes up he pulls the drips out, thus endangering his lif*e.* He said*, "…that when he wakes up or sometimes when he experienced some fits… he holds to…apparently he had some tubes and connected to the machines…he had another for feeding that was inside his nose, he was pulling it and when he pulled it injured him because it goes straight from the stomach from the nose… so I did understand that ok why they restrained him, it was for protecting him… if this is the only measure they*

have to use…” “*When they have restrained him they are preventing him from causing more harm to himself…. So if I said they should untie him… it means I am saying he should hurt himself even more*…”

F10 reinforced this information*, “…...being tied on the bed…. remember there are professionals there who had to do that, unfortunately we cannot question why did you do this in this way while been assisted because they will be talking about safety measures.”*

4.3.2 Alternatives to sedatives

The participants in this study regarded the use of physical restraints as an alternative to sedation. Participants understood that the use of sedation had some negative adverse effects on the patients. The following information taken from the participants supports the above argument.

F6 emphasised*, “Hmmm… Sister I think, you know sometimes patients are giving the pills to make patient feel better and sleep, so I think even if you have given those medication, I think you still have to restrain him to support him so that when he wakes up he has another support of been restrained because he is not lying properly on the bed, because when he felt…. he had power he wanted to wake up.”*

F5 reinforced this information, *“If this is the only measure they have to use … because also I did ask why are you not at least give him something to calm him down, an injection or something…. they said already they are given him injections and a lot of drugs so they don’t want him to sleep too much, so restraining is used as an alternative…”*

F9 commented, *“Yes, I think sometimes they should restrain to make the patient sleep than giving them too much medication because it is not good for them.”*

F9 further highlighted the side effects of sedation and how using physical restraints as an alternative could prevent such… “*Yes they don’t want him to sleep too much…because sometimes when he sleeps too much it becomes a problem as he might not respond to some of the medications he is getting, also they cannot be able to assess his heart rate if he is not restrained…”*

A similar statement was echoed by **F6** who said, “*Like I said, I did ask about the injection that is normally used apparently they inject to people who refuse to calm down…I don’t know what they call it but it make one to numb…. I thought about it… ok instead of*

restraining him like this, why are they not giving it to him but they did explain to me that they can't give him too many drugs as they could not be able to assess which one make him to respond like this or which one makes his heart rate to be irregular…"

4.3.4 No Informed consent issued

From the information presented through the analysis, the participants stated there was no informed consent issued to the patient or relatives with regard to physically restraining. Some of the participants indicated they were shocked when they visited their loved ones in ICU and found them restrained. This lead to a heated discussion between the healthcare professionals and the relatives because most wanted to understand why there was restraining. The following information supports the idea discussed above:

F6 indicated that there was no informed consent issued*. "We were not told why he was restrained and even us as people we not did understand why he was restrained."*
F8 shared the same sentiment, "*Yes one day when I got into ICU I found a chaos, people or relatives coming out of ICU unhappy because their patient was restrained without their knowledge … you understand things like that…."*

F9 shared his frustrations by saying, "…. *to be honest I was frustrated and I was hurting inside (my heart was so sore) …. Ok but why a person can be restrained like this, I couldn't understand why the person can be restrained like especially in his situation when we are not asked or told about it…. according to me… when I arrived he was not fitting or doing all those things the nurses said he was doing but at night I am not there so at some point I had to make peace with that…"*

4.4 THEME 3 MIXED FAMILY EXPERIENCES TOWARDS RESTRAINTS.

4.4.1 Rejection and Acceptance

Through the analysis process, some family members indicated mixed perceptions towards their lived experiences when visiting restrained patients in ICU. Some family members initially rejected the process of restraining patients for they believed it was a depressing process for both patients and family. However, somehow they felt the restraints might be necessary for patient safety despite some concerns over their health

upkeep and personal freedom. The discussion of this ambivalence of experiences is with the aid of quotations extracted from the participants who took part in the research study.

F6 "*hmk…hmk (shaking his head) it was my first time to see that with him, again I was scared and wondering why because there were patients who were not restrained……. Eishhh… (sign of frustration), you know what…. I was frustrated, I didn't understand or had an answer why or what happened for him to be restrained…., I couldn't even take a lot of time standing next to him, I will just see him and leave…. but while still frustrated and asking ourselves all these questions, the Dr told us why he was restrained and we understood…… the Drs know their Job and what they were doing more than us, we listened and trusted that* …. Hmmm*… Sister I think, you know sometimes patients are giving the pills to make patient feel better and sleep, so I think even if you have given those medication, I think you still have to restrain him to support him."*

To relate these mixed perceptions further, **F8** said*, "Hmmm… eeeerrrr…. I was not right…not happy but what was more important was that at least I found him… the Drs and nurses on duty on that day told us the reason why we found him restrained…. After their explanation, I did understand that it was necessary for him to be restrained…."*

F7 shared the same sentiment, …." *Eish…it was really hurting, I was not happy, asking myself why is he like that, what is it that he did but as time goes, I saw that really they have to tie him because what he was doing was not right because it was difficult to feed him and give him medication through those pipes, finally I understand that nurses were right in restraining him… yes I was not OK, I was not happy at all until the full explanation was given to me and we understood…"*

These feelings of ambivalence were also echoed by **F9**, who was frustrated but somehow after receiving the information from health professionals he understood, "*To be honest I was frustrated and I was hurting inside (my heart was so sore) …. Ok but why a person can be restrained like this, I couldn't understand why the person can be restrained like especially in his situation… I asked why they restrained him …. why are you not at least give him something to calm him down, an injection or something…?... they did explain to me… apparently he had some tubes and connected to the machines…he had another for feeding that was inside his nose, he was pulling it and when he pulled it injured him*

because it goes straight from the stomach from the nose… so I did understand that ok… if this is the only measure they have to use…."

F5 said, " *I think it was a good idea because it was to safe him. yah… it was a good idea, not a bad thing……. yhaaaaa… because I think if it was not a good idea they can sometimes inject him so that he falls asleep*…"

The use of physical restraints frustrated the participants of this study, but they were concerned about patient's safety over their feelings. They believed and trusted the healthcare professionals, and the good communication and professionalism from them had an influence on feelings of acceptance and rejection by the participants.

F6 said, " *I was frustrated, I didn't understand or had an answer why or what happened for him to be restrained…., …. but while still frustrated and asking ourselves all these questions, the Dr told us why he was restrained and we understood…… the Drs know their Job and what they were doing more than us, we listened and trusted that…".* **F7** highlighted the same feeling when he said, *"Yes I was not OK, I was not happy at all until the full explanation was given to me and we understood."*

F10 further stated that, "…. *remember there are professionals there who had to do that…. but to the fact that he came out alive we really appreciate what ever that was done…."*

4.5 THEME 4 RECOMMENDATIONS

Through the data analysis process, there surfaced some important findings or codes. In this analysis, recommendations mentioned by some of the participants for restrained patients in the ICU to more bearable and acceptable.

4.5.1 More care and social responsibility

Data taken from the participants highlighted more care and social responsibility as one of the recommendations that might make life bearable for patients. They cited that if there is more care, patients will never have physical scars. For example, **F8** said, *"yes they should work professionally… like what I mean by that is… ICU where my brother was they tried to work professionally towards us, this is what is the most important and what is needed…more care and love to the patients*".

This was supported through **P1** who said, "*you know what I am saying is that, patients can be restrained due to certain circumstances or situations, let's say you are inside the*

office and doing some paper work and you see that his situation is not alright, maybe he is restless, not complying, waking up but unaware that he is waking up, walking, climbing or anything (confused) so if you have to restrain that person, know that it's your responsibility to check on him now and then… not to just restrained a person knowing that at 19hrs you are knocking off and you don't care. Hence, we are calling for more social responsibility from health professionals".

4.5.2 More good communication channels

From the analysis, one participant mentioned that more communication channels should be improved when it comes to patient restraints. Participant indicated that communication is important is knowing the daily routine or updates on the patients. **F5** said, "*understanding that people are different… those are only things that need to be address, nurses should be professional and should come to people and explain to them what is happening with the patient, what is the patient problem, why we have restrained him…*

like they were explaining to us as a family when we got in ICU… this is what is needed and it is important… so that even us when we leave our patients at least we want to be clued up on what is going on, have courage that at least that they are trying to help him".

4.5.3 More skilled and competent workers

Data shows that more skilled and competent health workers were mentioned as another suggestive recommendation. Participants cited that patients in ICU need extra hand from competent workers and they are normally a handful to deal with hence more skilled nurses will be able to understand. **F6** said, "more *skilled nurses must be hired because sometimes these nurses they seem not to care about the patient*". Supporting the quotation is **P3** who said, "…*people who really understands me and my situation will be the best candidate."*

4.6 Participants Demographical data

The participant's demographic data of this study comprised of participants, gender, age, and ethnicity. (**See the appendix H**). Ten (n-10) participants comprising six (n-6) relatives and four (n-4) participated in this study.

Table 4.1 below summarises the characteristics of the Ten (n-10) participants for discussion.

Items	Demographic Data	Frequency (n)	Percentage (%)
1.	**Gender:** Male	7	70%
	Female	3	30%
2.	**Age Range**		
	18-33	3	30%
	34-49	6	60%
	50-65	1	10%
	66+	0	0%
3.	**Participants**		
	Patients	4	40%
	Family Members	6	60%
4.	**Ethnicity**		
	African	10	100%

The majority of participants 60% (n-6) in this study were relatives who experienced their patients being physically restrained while in intensive care units) Most of the participants were males with the percentage of 70% (n-7). The entire population of the study were African people with 100% (n-10) coverage. A well represented age group was the age between 34-49 with 60% (n-6) representation.

4.7 SUMMARY OF THE FINDINGS

This chapter presented the findings of this study under four themes and eleven sub-themes that emerged from the use of a thematic approach to data analysis developed by Braun and Clark (2013).

The patients' experiences towards restraints was the first theme to address the first objective mentioned in Chapter 1. There were five sub-themes deduced from the first theme, elaborated on to explain the theme in more detail. The patients explained that restraint in ICU was characterised by negative experiences. It caused physical injuries and deprived them of their personal freedom. It was a form of imprisonment. Others indicated that they had no memory of being physically restrained. The family experience toward restraints was the second that surfaced from the study findings. The restraints were perceived positively and again negatively by participants. The positive experience was that physical restraints was viewed as a safety measure to protect patients from accidental harm and also as an alternative to sedation. While the negative experience was that the practice was not well regulated as no informed consent was issued to either the patient and or the family. This resulted in a lack of understanding on restraint procedure.

In the third theme family had mixed experience. The negative effects of restraints were observed, however, patient safety took precedence over the concerns of personal freedom as the results participants accepted the practice even though they were hurting inside.

The participants recommended that more care and social responsibility be showed to restrained patients in the fourth theme.

Quotes from participants supported all the sub-themes, with substantial evidence from literature. The data served to address the study purpose, which was mainly to describe and to explore patients' experiences of physical restraint and their family members' perceptions of this experience.

The detailed discussion of the findings continues in the next chapter.

CHAPTER FIVE

DISCUSSION OF MAIN FINDINGS, RECOMMENDATIONS, LIMITATIONS AND CONCLUSION

5.1 Introduction

This chapter provides a discussion of the findings of the study, presents the justifications together with limitations, and concludes with recommendations for nursing practice, education, management and future research, and a final conclusion for the study.

5.2 Discussion of main findings

This study provided evidence that physical restraints in Intensive Care Units caused physical injuries, such as skin abrasions, wounds, swelling of hands. Similar findings were revealed by Freeman et al. (2016), Kandeel and Attia (2013) and Kalula and Petrose (2016) who showed that the use of physical restraints had detrimental physical effects caused by the direct impact of the restraint device on the patient causing impaired circulation, ischaemic injury, lacerations, bruises, nerve damage, and oedema. The most cited reason in literature for restraining patients is to maintain safety (Oduwde, 2016; Talson & Morley, 2012; Langley et al., 2011; Taha & Ali 2013; Freeman et al., 2016), however the results of this study showed that the use of physical restraints could still cause harm to the patients. The principle of beneficence states that nurses have a moral obligation to prevent and protect a person from harm and discomfort, be it physical or psychological, to facilitate good or promote a person's welfare (Mohr 2010; Brink et al., 2013). In the clinical setting, according to Kalula and Petros (2016), there is a likelihood of creating additional risks while acting for the benefit of the patients.

According to Younis and Ahmed (2017) and Al-Khaled, Zahran and El-Soussi (2011), if the following nursing interventions are implemented they can significantly reduce consequences associated with the use of physical restraints**:** use of proper restraining material, which is commercially evidenced based and adheres to the national guidelines; bony prominences be cushioned to prevent friction, which can cause pressure sores and the restraint should be accurately secured; assessing the skin colour, capillary refill, movement and sensation and pulse of the restrained extremity every 2 hours if the patient

is calm, if agitated every 30 minutes; giving the patient a break of 30 minutes from the restraints every 2 hours, frequent position change and skin care.

This study showed that for some participants the restrained experience had totally varnished from their memory. The findings of this study corroborate with the results of Perez de Griza Amatriain et al. (2012) who showed that 41.6% of physically restrained patients did not remember the incidence. Loss of memory in ICU could be due to prolonged use of sedation, increased length of stay, and increase in severity of illness (Hofso & Coyer 2007; Gu et al., 2019). Studies by Younis and Ahmed (2017) and Al-Khaled, Zahran and El-Soussi (2011) showed that reducing sedation to allow the patient periods of awakening, frequent re-orientation of patient to time and place, and allowing patients period of rest, to be some of the nursing interventions to prevent memory loss in ICU.

From the data analysis process, the results of this study showed participants viewed physical restraints as a form of safety and control measure. These results are supported by the majority of studies in literature, which showed that physical restraints in ICU ensures patient safety by preventing agitated patients from accidental removal of invasive lines, such as endotracheal tubes, central and arterial lines, which could lead to serious harm and injuries (Talson & Morley, 2012; Langley et al., 2011; Taha & Ali, 2013; Freeman et al., 2016). However, this claim was found unjustified by other studies. The systematic review by Da Silva and Fosenca (2012), on unplanned extubation in the Intensive Care Unit, found that 25-87% of patients who self-extubated had restraints at the time of the incident. Even though literature showed that the use of physical restraints is unjustified, the results of this study illustrated that patients and family members accepted the practice. A similar study conducted by Perez de Griza Amatriain et al. (2012) found that most of their participants accepted the use of physical restraints because of the information received from the nurses about their safety in preventing accidental harm to the patient.

In the clinical environment, the healthcare professionals are in a powerful position, which can create an imbalance with regard to communication (Bowman, 2000). The aim of communication between the nurses, patients and relatives, according to Potter and Perry (2009), is to establish a positive relationship, to give factual information, to determine

needs and to optimise the use of resources; however, if it happens that communication focuses on one aspect, which in this case is the safety measure of physical restraints, this could lead to the acceptance of the practice as a safety measure even though studies by Benbenbistity et al. (2010) and Da Silva and Fosenca (2012) showed this claim is unjustified.

To further support the safety provided by physical restraints, this study found that family members perceive the use of physical restraints to be an alternative to sedatives, which could indirectly jeopardise the safety of the patients. Freeman, Hallett and McHugh (2016), Maleho (2018), Luk et al. (2014) and Benbenishty et al. (2010) supported this finding and showed that physical restraints reduced sedation use in ICU. Sedation is a form of chemical restraint used in the ICU to restrict patient's movement and to avoid treatment interference (Freeman, Hallett, & McHugh, 2016). The use of sedation is associated with unfavourable adverse effects such as depressed cardiovascular function, reduced gastrointestinal mobility, development of withdrawal symptoms (Hofso & Coyer, 2007), lack of memory about ICU and increased patient anxiety and post-traumatic stress disorders (Gu et al., 2019). This sentiment was shared by one of the relatives in this study who said, *"…because sometimes when he sleeps too much it becomes a problem as he might not respond to some of the medications he is getting, also they cannot be able to assess his heart rate."*

In contrast to these findings, a survey by Egyptian nurses showed that 75% of nurses use sedatives as an alternative to restraint use, resulting in one-third of patients (27.3%) being sedated (Kandeel, 2013). To support this notion, Maleho's (2018) study showed that even though there were stated adverse effects of sedation, the majority (83.9%) of participants indicated they preferred sedation for the management of agitated patients if they could not use physical restraint.

The negative perception found in the results of this study was that the participants perceived the use of physical restraints as a form of imprisonment, as they deprived a patient of freedom. Participants felt they were in prison or in captivity. The description of prison is as a place where an individual stay as a punishment for a crime, or while he is waiting to go to court (Duckett, 2006). Physical restraints are any material, devices or equipment attached to or near a person's body, which cannot be easily removed (Evans

& Fitzgerald, 200’, Yam & Cheung, 2005; Meyer et al., 2009; Li & Fawcett, 2014). The intention is to use force to restrict a person’s freedom of movement deliberately to a position of choice or normal access to the body.

Previous studies examining restraining elderly patients (non ICU) showed that some of the predominant reasons for restraining patients was to exercise behavioural control, to enforce treatment compliance, (Cheung & Yam et al., 2003; Oduwde, 2016). To support this statement, Talson and Morley (2012) further showed that the degree of use and application of physical restraints depended on the intensity of “disruptive behaviour, or failure to comply with treatment;" the assumption was that the more disruptive the behaviour or failure to comply with treatment, the more force was applied. In this instance, the view of the restraints was as a punishment for certain behaviours (Talson & Morley, 2012) and could explain the findings of this study.

According to Khaled (2016), the intention of physical punishment is to reduce the behaviour by providing brief and non-injurious contact with an individual. However, when the physical punishment causes discomfort and damage, as in the case of physical restraints, that punishment triggers flight and fight responses and the individual undergoing punishment would try to avoid it or fight the person providing the punishment. This result is increased agitation in the patient who is physically restrained.

This state of imprisonment was painful and depressing for the participants. It evoked feelings of anger, embarrassment as the participants clearly stated that they were treated like dogs. This finding is in accordance with the studies of Taha and Ali (2013) and Oduwde (2016), where family members’ experienced emotional distress seeing their patients physically restrained: feelings of embarrassment, depression, anger.

To make the experience of physical restraints more bearable and acceptable, Younis and Ahmed (2017), Al-Khaled, Zahran and El-Soussi (2011) and Bell, Roche & Mueller et al. (2018), suggested the following interventions: nurses should inform the patient and the family member of the need for physical restraints. Information should clearly state the purpose of the procedure and possible risks. This will enable the nurse to get an informed consent and allow the patients and the family to be involved in the decision-making processes, application of physical restraint in such a way that it upholds patients’ rights and dignity, use a proper restraining material, which is commercially evidence based and

adheres to the national guidelines, patient should not be restrained while lying flat, and reassure the patient, and support and provide therapeutic touch to allay anxiety and stress.

Regarding the family members' views about physical restraints, the results of this study showed that the family members had mixed perceptions towards their lived experiences when visiting restrained patients in ICU. Participants indicated negative perceptions towards the process of restraining patients for they believed it is a depressing process for both patients and family but at the same time also indicated positive perceptions towards their experience and the experience of the patients, despite some concerns over their health upkeep and personal freedom.

The mixed feelings on the use of physical restraints from the results of this study were also cited by Taha and Ali (2013) and Oduwde (2016) in their studies, where they showed that family members were aware of the emotional distress physical restraints might cause and thus showed feelings of embarrassment and anger. However, they felt that without physical restraints, serious physical injuries were likely to occur, and these were of greater concern than their emotional distress.

The study findings showed that the experience of restraints in ICU was not a good one, as the results the recommendations were made by the participants for the restrained patients stay in ICU to be more bearable and acceptable. The participants suggested more care and social responsibility as one of the recommendations. From this recommendation conclusion could be drawn that participants were not satisfied with the care that was provided, even though the aim of physical restraints was to provide patients safety. Almaze and De Beer (2017) found different factors, such as professionalism towards patients and relatives, good communication or information sharing, to increase patients and relative's satisfactions. According to Popa, Drugus and Rogozea (2017), customer satisfaction is an attitude based on the perception of service quality, measured by understanding the received information, the necessary procedures, institutional structure, the management process and the results of the medical care provided.

Professionalism of healthcare professionals, their kindness and willingness to help, inspired hope strategies for relatives in the critical care environment. Also the provision

of timely, honest and factual information to family members enables them to comprehend and deal with patient's critical illness (Almaze & De Beer, 2017).

Literature shows that nurses lack knowledge of the use of physical restraints, restraint reduction or alternatives; their practice was based on factors such as experiences, interpersonal relationships, working circumstances and specialties (Goethals, Casterle & Gastmans, 2012; Hoffman, Aitken & Duffield, 2009. Taha and Ali, 2013. Philabaum 2016). The lack of knowledge regarding nurses on the use of physical restraints, has a negative impact on the nursing care of patients and also on the information provided to relatives, (Taha and Ali, 2013 and Philabaum, 2016).

Knowledge about the phenomenon affects one feelings so poor understanding and knowledge of physical restraints could have an impact on how patients and family members perceive this practice (Bell et al. (2020).

According to (Loghmani, Borhani and Abbaszadeh, 2014), communication in ICU is challenging due to the dynamic nature of the environment and increased workload, as the result of this has caused a public outcry about the behaviour of nurses during communication with the patient's family in ICU. To support this statement, Moradimajd et al. (2015) found that obtaining the written informed consent, which requires good and effective communication from the nurses to the patients and families, was a standard not followed in their study.

The maintenance of high quality good communication is the core of nursing as it has a significant impact on patients' well-being, as well as the quality outcomes of nursing care and the overall patient's family satisfaction with the care (Loghmani, Borhani & Abbaszadeh, 2014).

The results of this study also revealed the issue of lack of informed consent, as the participants indicated that the patients or family did not receive informed consent concerning patient restrainment. Family members showed they were shocked to find their loved ones restrained. Obtaining an informed consent is one of the moral and ethical standards expected from the healthcare professional when caring for the patients (Mohr, 2010). The belief is that patients in ICU are incompetent and incapable of making

informed decisions therefore the expectation is that nurses should communicate with the next of kin to obtain informed consent (Mohr 2010).

According to Geyer et al. (2013), accountability and responsibility are challenging concepts for nurses and they depend on professional levels. Responsibility is accepting liability for your acts and omissions, and it requires the nurse to act in the reliable, trustworthy and incredible manner (Geyer et al. 2013).

Furthermore, responsibility forms the basis of accountability. Conditions of professional accountability, as stated by Geyer et al. (2013), included the ability of the nurse to perform nursing task and duties. It requires a nurse to have necessary knowledge, skills, judgement, experience and attitude to address the demands of professional responsibilities (competence) adequately.

The nursing education and training programmes were found to provide this basic framework for the knowledge and skills required for the provision of nursing care (Geyer et al. 2013), however the study by Al-Khaled, El-Soussi and Zahran (2011) on nurses' related factors influencing the use of physical restraints in critical care, found that nurses who graduated from a technical institute of nursing only received brief training while those who graduated from secondary nursing schools did not receive any training on physical restraining. To support this, a quasi-experimental study with pre- and post-assessment on the impact of training programmes on nurses' knowledge, practice and patient outcomes, conducted with 38 nurses working in ICU by Taha and Ali (2013), found that only eight out of 38 nurses reported having information about physical restraint use, while the rest reported practice as their source of reference.

Another issue of professional responsibilities, as set out in the nurse's scope of practice, requires that nurses should maintain the patients' health status through assessment, planning, administration, evaluation and recording of the care provisions contributing to the maintenance (Geyer et al. 2013). The effective nursing assessment and observation of patients is crucial to patient safety and outcomes, as Potter & Perry (2009) found this to be the first step in identifying signs of clinical concern. However, Kandeel (2013) reported that if nurses happened to monitor the physically restrained patient, assessment was only after eight hours and only related to peripheral circulation. Incomplete assessment of the restrained extremities reflected knowledge deficiency and training on

caring for restrained patients by nurses (Moradimajd et al., 2015). Furthermore, Freeman et al. (2016) and Kandeel and Attia (2012) discovered that nurses lacked knowledge on risks associated with physical restraint and, how to apply and document their use. In a study by Akasel (2007), 93.7% of nurses reported they did not use any form of documentation before or after applying physical restraints. Those who claimed they frequently observed the restrained site, the analysis from the patient's records did not reflect the assessment as there was no reference to this activity.

This research took place in South Africa, where, according to Frenk et al. (2010), the healthcare system is under massive pressure due to high staff shortages, high levels of de-motivation, inadequate skills, and unfriendly environments, and this has resulted in the drop of nursing standards due to the inclusion of sub-professional categories of nurses and caregivers in the ICU in order to augment staff numbers and as a cost saving measure. The use of the pool of cheap and unskilled labour, lack of accountability and leadership were factors that resulted in unfair treatment to vulnerable patients (Mohr, 2010). As cited in different studies, nurses lack knowledge on the use of physical restraints and viewed as the initiators of this controversial practice (Frenk et al., 2010 and Langely et al. 2010). However, Bell et al. (2018) showed that nurses are also the victims of this practice and the healthcare system that is too bureaucratic and non-functional, putting more emphasis on the prevention of falls in fear of litigation. This highlights the need for educational programmes on the use of restraint and support from management to equip nurses with necessary skills and knowledge so that they can provide more care and social responsibility in a competent way, as suggested by the participants of this study.

5.3 Limitations of the study

The following limitations need noting in this study:

- The use of a single public institution
- The small sample size

Generalisation of findings were restricted as the conducting of this study was at one public institution. The study used a qualitative research design, where meanings could have more than one interpretation of narratives; however, replication of the study in other

general and trauma ICUs of other public sector hospitals is necessary to support or oppose these findings.

There is insufficient literature on the experience and perceptions of patients and family members on the use of physical restraints in an Intensive Care Unit from a South African perspective. Literature, however, indicates there are studies that have focused on the use of physical restraints in an Intensive Care Unit as a safety measure to prevent accidental extubation (Talson & Morley, 2012; Langley et al., 2011; Taha & Ali, 2013).

5.4 RECOMMENDATIONS

5.4.1 Recommendations for Clinical Practice

The findings of this study showed that the use of physical restraints has a physical and psychological impact on both the relatives and the family members. Furthermore, the findings revealed that there is no regulation on the use of physical restraints, as this study showed that the patients or relatives did not receive informed consent concerning the restraining of the patient.

These findings therefore serve as empirical evidence on the need to develop a written policy and procedures that will serve as a decision-making tool for the healthcare professionals on the use of physical restraints. Once such a policy is developed, it needs to be accessible to every staff member. The finalised policy will need to be evaluated for its effectiveness and efficiency. A collaboration between healthcare professionals, patients, and family members is necessary throughout the policy development and review.

5.4.2 Recommendations for Nursing Education

Findings of this study showed that nurses lack social responsibility and accountability. Competency is one of the conditions of social accountability (Geyer et al. 2013). There is a need for educational programmes to empower nurses both in the basic or postgraduate levels, as well as in the form of in-service training. The Curriculum should be designed which incorporates the use of physical restraints in ICU. The module should emphasise the indications, management, use of alternatives, complications and the ethical and legal issues surrounding the use of physical restraints. Patients and relatives need education about the purpose of the procedure, benefits and risks and alternatives. The sharing of this information can in the form of pamphlets.

5.4.3 Recommendations for further Research

There is insufficient literature on the experience and perceptions of patients and family members on the use of physical restraints in an Intensive Care Unit from a South African perspective. The recommendation is that a replication of the study take place in other institutions in South Africa in order to support or dispute the findings and to get diverse experiences of patients and family members. Also recommended is a qualitative study to explore nurse's perceptions with regard to their role in the use of physical restraints.

5.5 Conclusion

The purpose of this study was to describe patients' experiences of physical restraint and their family members' perceptions of this experience in the ICU of a tertiary academic institution in South Africa. The aim was to explore the meanings of these experiences on patients and family members. The use of physical restraints is the common practice in ICU. In this study, restraining patients left participants with mixed feelings. Some regarded this practice as a form of safety and control measure to prevent serious harms and injuries, while others perceived the practice as a form of imprisonment, as it deprived patients of their freedom.

The participants suggested interesting recommendations to make patients' lives bearable in ICU. Participants pointed out the need for more care and social responsibility, good communication channels and more competently skilled nurses, but these recommendations seemed to be normal requirements in the nursing practice. The researcher thought that participants would recommend some sort of alternative to the use of physical restraints, but this was not the case in this study. Therefore, there is a need to understand nurses, patients and family member's knowledge of the alternatives to physical restraints.

This chapter was a summary of the study. It included the discussion of the main findings, the recommendations, limitations and the conclusion.

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APPENDIX A:

INFORMATION SHEET FOR PARTICIPANTS: THE EXPERIENCES OF PATIENTS AND FAMILY MEMBERS OF THE USE OF PHYSICAL RESTRAINTS IN AN INTENSIVE CARE UNIT

Good day,

My name is Liepollo Anacletta Makhetha, and I am from the University of the Witwatersrand, School of Nursing Education. I am doing research on the patients and family members' experiences of the use of physical restraints for my Master's Degree in Nursing Education.

The purpose of the study is to describe how patients experienced physical restraint or how their family members experienced the patient being physically restrained while in the Intensive Care Unit. The results of this study will suggest best practices for nurses on the use of physical restraints.

The information will be collected using semi-structured interviews, where I will engage in a discussion with the participant for a period of 20-30 minutes. The interviews will be audio recorded with the permission of the participant. The destroying of the audiotapes will take place two years after the publication or after six years if there is no publication.

The information collected will remain confidential and not used for anything else other than for the research purposes. There will be no names used in the reporting of the findings of the research and any identifying information changed. The answers given during interview will undergo transcription and analysis to find common themes and experiences. The writing up of the information will be in the form of a report.

The University of the Witwatersrand's Research Ethics Committee granted permission to carry out this research. Informed consent will be obtained from participants to conduct semi-structured interviews and to audio tape the interviews; where a participant does not consent for audio taping the interview, written notes will be taken to record the interview. If audio recording is consented and conducted, its use will be for the purpose of this study only and destroyed after two years of the publication of the findings.

There will be no negative consequences for not consenting to participate in the study. for participating in the study. Participation in the study is voluntary, with no remuneration, and you have the right to withdraw from the study at any time.

I will be happy to answer any questions you may have about the study.

APPENDIX B

CONSENT FORMS FOR SEMI-STRUCTURED INTERVIEWS WITH PARTICIPANTS

I have received the information sheet on the research project entitled: *The experiences of patients and family members of the use of physical restraints of patients in an Intensive Care Unit.* I have read and understood the information sheet and had all my questions answered satisfactorily.

I understand that it is up to me whether or not I would like to participate in the semi-structured interview and that there will be no negative consequences if I decide not to do so. I also understand that I do not have to answer questions that I am uncomfortable with and that I can stop the interview at any time.

I understand that the researcher will make every effort to ensure confidentiality, that my name will not appear in the study reports, and that comments I make will not be reported to anybody else. I consent voluntarily to participate in the interview for this study. I have received telephone numbers that I may call if I have any questions or concerns about the study.

Participant's Signature: ________________ Date: __________________

Interviewer's Signature: ________________ Date: __________________

APPENDX C

Consent form for recording with an Audiotape

Dear participant,

Thank you for agreeing to participate in this study titled:

THE EXPERIENCES OF PATIENTS AND FAMILY MEMBERS OF THE USE OF PHYSICAL RESTRAINTS IN AN INTENSIVE CARE UNIT

As discussed, one-on-one interviews will take place regarding your experiences of being physically restrained while being treated in an Intensive Care Unit. If you have any questions or concerns whatsoever, you can contact me via the email address and telephone number provided on the information sheet.

You can ask questions or raise concerns at any time about the nature of the study at the email address and telephone numbers provided below.

Our discussion will be audio taped to help me accurately capture your insights in your own words. I will be the only person to listen the tapes for the purpose of this study. If you feel uncomfortable with the recorder, you may ask for it be turned off at any time.

You also have the right to withdraw from the study at any time. In the event you choose to withdraw from the study, all information provided by you (including tapes) will be destroyed, and omitted from the final paper.

Insights gathered by you and other participants will assist in the writing of a qualitative research report, which my supervisor will read before presenting it to the Hospital Group. Although there will be direct quotes from you used in the paper, your name and other identifying information will remain anonymous.

By signing this consent form, I certify that I agree to the terms of this agreement.

Signature of participant ___________________________________

Date of signature ___________________________________

APPENDIX D

2781 Mark Square Street,
Protea North 1818,
Soweto,

20th March 2017

Chris Hani Baragwaneth Hospital
26 Chris Hani Road,
Johannesburg, 1860

Dear Sir/Madam

Re: PERMISSION TO CONDUCT RESEARCH FOR MSc (NURSING):

THE EXPERIENCES OF PATIENTS AND FAMILY MEMBERS OF THE USE OF PHYSICAL RESTRAINTS OF PATIENTS IN AN INTENSIVE CARE UNIT

I am Liepollo Makhetha, currently registered as a student with the University of Witwatersrand for the degree of Master of Science in Nursing (Course work). I would like to request permission to conduct a research study at Chris Hani Baragwaneth Academic Hospital in an Intensive Care Unit.

This study pertains to the patients and family's experiences of the use of physical restraints in Trauma and General Intensive Care Units. I have attached the research proposal for your perusal.

Should you grant permission to do the research in this hospital the results will be used to suggest best practices for nurses and continuing education towards quality patient care.

Yours sincerely,

Liepollo Makhetha
Mobile: 0736029456
Email address: liepolloma@gmail.com

APPENDIX E

PATIENT INTERVIEW GUIDE

1) How was being physically restrained for you when you were in the Intensive Care Unit?
2) In your opinion, what could change your experience of being physically restrained?

FAMILY INTERVIEW GUIDE

1) How did you feel when you visited the patient and was physically restrained in the Intensive Care Unit?

APPENDIX F.

Statement by the researcher: Liepollo Anacletta Makhetha.

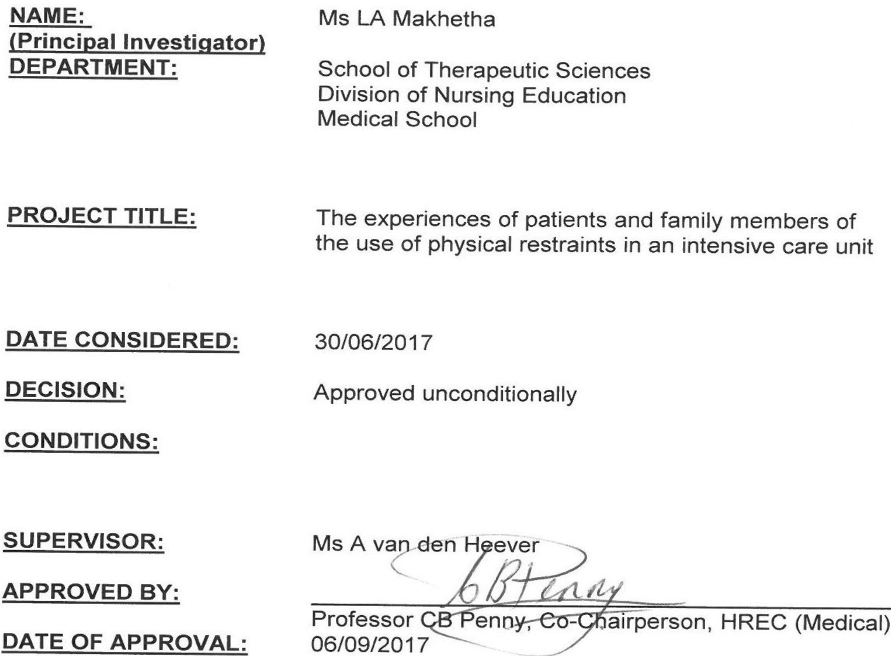
I have accurately explained the details of this research study to the participating patients and their families and have offered an opportunity to these participants to ask questions. I have answered any questions to the best of my ability. I confirm there was no coercion of participants into participating in this study, and consent was voluntarily and freely given.

Signature of researcher ____________________________

Date ____________________________

APPENDIX G

R14/49 Ms LA Makhetha



HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170636

NAME: (Principal Investigator)	Ms LA Makhetha
DEPARTMENT:	School of Therapeutic Sciences Division of Nursing Education Medical School
PROJECT TITLE:	The experiences of patients and family members of the use of physical restraints in an intensive care unit
DATE CONSIDERED:	30/06/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ms A van den Heever
APPROVED BY:	Professor CB Penny, Co-Chairperson, HREC (Medical)
DATE OF APPROVAL:	06/09/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature ____________ Date ____________

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 1 June 2017

TITLE OF PROJECT: The experiences of patients and family members of the use of physical restraints of patients in an Intensive Care Unit

UNIVERSITY: Witwatersrand

Principal Investigator: L Makhetha

Department: Nursing Education

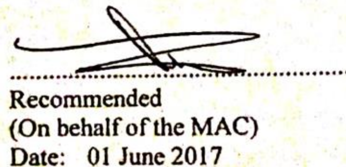
Supervisor (If relevant): A van den Heever

Permission Head Department (where research conducted): Yes

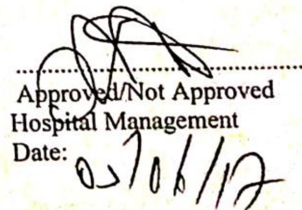
Date of start of proposed study: June 2017
Date of completion of data collection: Dec 2020

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.



Recommended
(On behalf of the MAC)
Date: 01 June 2017



Approved/Not Approved
Hospital Management
Date: 02/06/17

APPENDIX I

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Intensive Care unit

Dr JM Brown
Jacqui.Brown@wits.ac.za
Tel: 0119381596
Fax.0119381595

30th May 2017

To whom it may concern

Re: Permission to collect patient data in Chris Hani Baragwanath Hospital Intensive Care unit

Title of research project: The Experiences of patients and family members of the use of physical restraints of patients in an Intensive Care Unit.

Investigator: Liepollo Makhetha

Permission is hereby granted for Liepollo Makhetha conduct interviews with patients and family in ICU for the purpose of her study. The data collected will be used for her MSc Nursing research report. Permission is subject to ethics approval.

Regards

[signature]

Dr JM Brown
Deputy Head: Intensive Care Unit
Chris Hani Baragwanath Hospital
Soweto
Affiliated to University of the Witwatersrand

APPENDIX J

An extract from an interview with the participant:

Thank you so much Mr. (patient name), what I want us to talk about is whether you remember that you were physically restrained while in ICU?

"*No I don't remember that but I was told…* **hmmm**… "yes."

Ok you don't remember at all..." *yesses"*…

Ok who told you that you were restrained? "*Its (wife name)"* ... **Ohkk, totally you don't remember anything, but is there anything you remember while you were at Bara?** **"***Eish…I don't remember anything, all I remember is just eating, and the urinary catheter, there is a lot of things I dreamed about happening….*"

Hmm...Hmm (in agreement) ... ok you mean which you dreamed about?

"*I mean which I was thinking about happening, like having the urinary catheter, and have to drive with it, I didn't understand, even other patients when I see them in machines what they were doing, it's what I was thinking, what my mind was telling me at that time in ICU*."

Ohhk… those things were what you were thinking about? "*yesses*." **Ok but after (wife name) spoke to you and told you that you were restrained in ICU, how do you feel about that?**

"*I don't know how to put it or position it, eish I don't know because I don't remember being restrained, I was only told but if I remember I could be in the right position to tell you how I feel about it but I don't know because I was told*."

Hmm...Hmm… what I thought, and I do understand when you said you totally forgot about this, the reason why you totally forgot also needs to be explored to find out why totally you don't remember what was happening with you in ICU, but I want to understand, for example now that you are at home and when you sitting down with your wife discussing this experience you had in ICU, mentioning that you were physically restrained, what comes in your mind, is there any negative impact, or feeling about that?

"*No I don't feel any impact because I wasn't aware of it while it was happening but I saw it happening to someone in ward 38, when they were physically restraining the other patients…"* **Hmm…Hmmm… "***I don't think it's a right thing for people to be physically restrained but there could be a reason why they are restrained, the situation allowed the need to restrain. I don't know maybe even in my situation what was happening to this people happened to me because in the wards I saw people been restrained and I asked myself why are people been physically restrained like that… even the patient that was next to me was restrained and I wondered why are people been restrained like this, only to find that the possible reason he was restrained he could injurie other patients… even me I didn't know I was restrained and I was surprised when I was told I was restrained like these other patients…"*

Iyoooooo.. oohhk (a sign of been surprised or feeling sorry for what happened**) but when your memory recovered and saw other patients been restrained, how did you feel about that practice, did you like it or totally you didn't like it? (sign of a patient taking a deep breath heard)**

"... but I don't see it as right practice because what I saw, a patient will be restrained from the morning and stay 3 days or more been physically restrained…" **Hmmm…Hmmm…** "…*like when they are going to bathe him they will untie him and then restrained him again, it's not a right thing…it's not right at all, I saw it happening to other people… sometimes a person can do things unaware, even me maybe… I don't know the reason why I was physically restrained… maybe I was doing things I can't remember now because when they tell me, they said I sometimes had fits or became so restless as a result I could injury someone next to me or the other patients so that's why they had restrained me… what I can say what they do is wrong but also I can say somehow is right but after you have restrained someone you need to continuously check on him all the time…"* ***yes… yes*** *…*

" But what I see in the ward patient will be restrained and got freed only when he is been bathed, or been freed when he is supposed to eat…like a someone needs to be untie now and then and all the time try to guard him and continuously keep on checking on him to see if still doing what he was doing before or he is better now… this is what is supposed to happen, not to tied someone and totally forgot about him it's not right, … as if that

person it's not your responsibility… it's your responsibility because you are at work, and you came to look after him, it's your responsibility, you need to continuously look after him..”

Thank you so much…. what you just shared has brought and insight even though on your site you were unaware of what was happening in ICU… thank you so much because we really need to understand how our patients felt so that we can be able to improve our practice. What you have just shared bring me to another question… what do you think we should do instead of restraining patients… what do you think is an alternative?

“*… you know what I am saying is that, patients can be restrained due to certain circumstances or situations, let's say you are insight the office and doing some paper work and you see that his situation is not alright, maybe he is restless, not complying, waking up but unaware that he is waking up, walking, climbing or anything (confused) so if you have to restrain that person, know that it's your responsibility to check on him now and then… not to just restrained a person knowing that at 19hrs you are knocking off and you don't care… and the next nurse coming to shift does not know why this patient is been physically restrained… this nurse when she comes in she does her own things that she is supposed to do, she doesn't care about this restrained patient to find out why the patient is restrained, maybe at that time the patient is right, is no longer doing what he was doing, those things that the sister who restrained him saw him doing, now is right… because I remember the patient who passed on, this patient was next to me, since I arrived into the ward I found this patient restrained, he was always restrained, I wondered why this patient was restrained like this, even his relatives were fighting asking why their patient is restrained like this, even when the Drs are there he is still restrained,,, Whyyy… I was so disturbed, it was so painful and I was so surprised when they told me I was restrained also but in my case it was like I was restrained for the short period not the long period like this patient*.”

Hmmm…Hmmm Ok… you were restrained for the short time…”

“*Hmm… yes… when I was in ICU. So what can be corrected is when you have restrained someone, know that you are just restraining that person for only that period when he is*

not well…hmmmm sometimes you can restrain the person…. you know… have you heard…like the situation I was in… when I slept on one site, there is no one to turn me and change my position… I felt like…even today at the back of my head I don't have hair, it doesn't grow at all, I have marks, no hair… is because I was always sleeping facing up… with no one to turn me and change my position… for 4 days, the whole week sleeping on one site, no one changes my position or caring for me…what is that…like if you have to tie a person be responsible for what you have done, know how the person you have restrained feels about the way you have tied him, if you have done something be conscious on how that person will feel about what you have done the moments he recovers or be well… how will he feels because there was no one to turn him or even care about… the person who restrained him left and now there Is another person who don't even care because she doesn't know why the person is restrained."

Iyooooo *(sign of distress about what happened)* **Ntate (Thapelo) eishh thank you so much for the information you have shared, this research is meant to address these kind of issues** …

"*Yes so that these can be corrected… not to tie a person as if you tied a dog, and above just dumping this animal without even caring, the only thing you do just come give it water, food and then leave you will come again when you need to bath it, still been tied but not thinking about who this animal you have tied feel about what you have done….even SPCA can put you in Jail if the find that the chain used is too tied, it doesn't give the dog the space to move and do what it wants… but what is happening at Bara I really don't understand, it's like when someone is doing his job is doing someone a favour, it's like she got irritated by her job.. this is what I saw happening at Bara*…"

Ohk thank you…. Hmmm…you have just mentioned something very important, you said *when someone was restrained it appeared as if we have tied an animal, is the way you feel?*

"*Yes that the way I feel; it was like this person is an animal, how do you tie a person both the hands and legs, but that person it's a patient, how do you tie both the hands and legs, go to ward 38, you see how these patients are restrained... this patient I am talking about, I was saying to myself this patient is very sick, he is suffering mentally but he is been*

restrained both legs and hands, he can't move or do anything… it's really sad, disturbed my mind especially when I was told that I was restrained like this, I was very sad even though I didn't feel or understand why….. but I am wondering why I was restrained…it was really painful, patient ended up passing away still restrained, since I came into that ward these patients was still restrained, even the Drs when they come to do the rounds they don't say anything, who are complaining patient's relatives who are the ones when they arrive will untie him, do you see that this person is regarded as animal?"

Iyoooo (sign of being shocked) Thank you so much for the information you have shared, and this will be taken back to management so that this can be addressed, like you said the nurse after restraining the patient needs to go back and assess

"…. *she has to continuously assess how is this patient, if he is still the way he was before, still having fits… is the condition changing or what…it happens like myself I was not aware what I was doing which caused me to be restrained but there is something I have experience…ICU is different from the wards, ICU the care was great, it was like I was in the private hospital but in the wards is very worse… I was unable to walk, turn or do anything, and someone just came and give you the basin to bath yourself at that time you can't do anything for yourself, you can't even lift your leg, but this person it's her Job to wash you and turn you but they can't …. They will only come at 11hrs to change you, at night you will stay the whole night the way you are, if you are unable to go to the toilet… Dr when he comes will tell you if you are unable to go to the toilet and you fell you want to relieve yourself and you are wearing a pampers just relieve yourself in that… they (nurses) will come and change you… but they don't do that, they will just come at 11hrs to change you… at night no sister will come to change you, you will be left like that…even if you want a urinal it's really a problem, sister will tell you that you are annoying her or disturbing her…"*

Eishh I am sorry to hear what you went through but this report will educate nurses on what measures to take if there are left with no choice but to physically restrained a patient… thank you so much…

"*You know what I was not nice, it was painful when I was in the wards but when I was in ICU I was treated very well, I managed to recover quickly…. But in the wards they don't*

treat us well, someone will just come and shift you and at that time you are sick and people who are helping you are sisters and it's their job, why should they just throw you into the toilet, it's their job, why should the sister when she is supposed to wash becomes angry yet is her job, and just throw you with cold water at 4 o'clock in the morning, this saddened me the sister throwing cold water to me and knowing very well that she is going to be off duty, also pouring me with this liquid, the one that burns the skin, at that time I can't even move my hands but pour it to my body and then tell me why am I not able to wash myself…"

I am again so sorry to hear what you went through and I can feel this conversation bring back these memories but like I said this study is not going to help you directly as you have already went through the experience but if you need help, I can arrange a professional to talk to you*.*

"I am fine my sister thank as long as your study can help other patients its fine… thank you.'

APPENDIX K

Examples of significant statements, codes, categories, and themes:

Themes	**Sub-themes**	**Frequency**	**codes**
Patient's experience of restraints	Causes physical injuries	5	Sometimes you can restrain the person…. you know… have you heard…like the situation I was in… when I slept on one site, there is no one to turn me and change my position… I felt like…even today at the back of my head I do not have hair, it does not grow at all, I have marks, no hair… is because I was always sleeping facing up… with no one to turn me and change my position… for 4 days, the whole week sleeping on one site, no one changes my position or caring for me…

	Deprives personal freedom	3	Yes, I still remember I was tied on the bed, but I just saw myself restrained; I do not know what happened. I just felt trapped, and I was not free
	Traumatic experience	4	The person who restrained him left and now there is another person who does not even care because she doesn't know why the person is restrained.
	No memory at all	1	Eish…I don't remember anything, all I remember is just eating, and the urinary catheter, there is a lot of things I dreamed about happening…
	Alternative to sedatives	4	Yes, I think sometimes they should restrain them to make the patient sleep because sometimes they cannot put them to sleep.
	Safety and control measure	10	But also, I can say somehow is right but after you have

Positive perception towards restraints			restrained someone you need to continuously check on him all the time and this help him not to harm others
Negative perception towards restraints	Form of imprisonment	6	All I saw was like I am in prison, or held captive and I was wondering what is that I have done…
	No informed consent issued:	4	Wondered why this patient was restrained like this, even his relatives were fighting asking why their patient is restrained like that, even when the Drs are there he was still restrained, why… I was so disturbed, because there was no consent to do in the first place from the patient or relatives.
	Not a good practice to restrain patients	5	But I do not see it as a right practice because what I saw, a patient will be restrained from the morning and stay 3 days

			or more been physically restrained…
Mixed Perceptions			
	Depressing and painful experience	6	“Eish…it was really hurting, I was not happy, asking myself why is he like that, what is it that he did to be restrained like this, but as time goes…
	Rejecting and accepting	8	Not a good practice, I was frustrated and hurting….but at the same time He was pulling the tubes, they explained and we understood…

APPENDIX L

Gill Smithies

Proofreading & Language Editing Services

59, Lewis Drive, Amanzimtoti, 4126, Kwazulu Natal

Cell: 071 352 5410 E-mail: moramist@vodamail.co.za

Work Certificate

To	Ms. V Herbert
Address	Dept. of Nursing Research, University of Witwatersrand.
Date	24/03/2021
Subject	Research Report: THE EXPERIENCES OF PATIENTS AND FAMILY MEMBERS OF THE USE OF PHYSICAL RESTRAINTS IN AN INTENSIVE CARE UNIT
Ref	GS/VH/04

I, Gill Smithies, certify that I have proofed the following for language, grammar and style,

Research Report: The experiences of patients and family members of the use of physical restraints in an Intensive Care Unit, by L. A. Makheta,

to the standard as required by Wits Dept. of Nursing Education.

Gill Smithies

APPENDIX H

Items	Demographic Data	Frequency (n)	Percentage (%)
1.	**Gender:**		
	Male	7	70%
	Female	3	30%
2.	**Age Range**		
	18-33	3	30%
	34-49	6	60%
	50-65	1	10%
	66+	0	0%
3.	**Participants**		
	Patients	4	40%
	Family Members	6	60%
4.	**Ethnicity**		
	African	10	100%