

# **Caring for the mind and body: Peri-operative Anxiety and Quality of recovery in Day Surgery patients**

By

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A dissertation submitted in partial fulfilment of the requirements for the Masters of  
Science (Mental Health Nursing)



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# ABSTRACT

**Background:** The amalgamation of mental health status into the peri-operative care of a surgical day case patient is seldom taken into consideration in practice, whilst the research undertaken on peri-operative anxiety relates to in-patients rather than ambulatory surgery patients.

**Objectives:** This study evaluated peri-operative anxiety and the quality of recovery including post-operative pain in patients undergoing day care surgery within a Maltese context.

**Design:** A quantitative non-experimental cross-sectional design.

**Participants:** One hundred and thirty six day surgery patients agreed to participate in the study, yielding a response rate of 90.7%.

**Settings:** Day care surgical unit at Mater Dei hospital.

**Methods:** Participants anonymously completed the Amsterdam pre-operative anxiety and information scale, the Quality of Recovery-40 scale and numerical pain scale. Systolic and diastolic blood pressure, heart rate and oxygen saturations were also measured.

**Results:** The prevalence of pre-operative anxiety was 71.3% where females and patients aged between 32-45 years experienced the highest levels of pre-operative anxiety. Inter-correlation revealed how patients who experienced high levels of pre-operative anxiety felt more anxious, experienced difficulty with falling asleep and experienced feelings of depression post-operatively. The majority of the patients (i.e., 45.6%), felt confused and lacked support post-operatively, where females expressed receiving less patient support. High levels of pre-operative anxiety were also associated with high levels of post-operative pain. Gender, pre-operative anxiety, pre-operative emotions and post-operative pain were identified as significant predictors of post-operative anxiety, while gender and post-operative pain were identified as predictors of post-operative comfort.

**Conclusions:** Consequently, providing knowledge about early identification and management of pre-operative anxiety and post-operative pain is significantly important as it aids in reducing post-operative anxiety while promoting post-operative comfort.

**Keywords:** Pre-operative Anxiety, Day surgery, Post-operative Anxiety, Post-operative Pain, Quality of recovery.

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# LIST OF ABBREVIATIONS

<b>ANOVA</b>	Analysis of variance
<b>APAIS</b>	Amsterdam Pre-operative anxiety and Information scale
<b>AS</b>	Ambulatory surgery
<b>AXIS</b>	Appraisal tool for Cross-Sectional Studies
<b>BMI</b>	Body Mass Index
<b>BP</b>	Blood pressure
<b>bpm</b>	Beats per minute
<b>CASP</b>	Critical Appraisal Skill Program
<b>CEO</b>	Chief executive officer
<b>CG</b>	Control group
<b>CinaHL</b>	Cumulative Index to Nursing and Allied Health Literature
<b>CI</b>	Confidence interval
<b>COSS</b>	Coping with Surgical Stress Scale
<b>DAS</b>	Corah's Dental Anxiety Scale
<b>df</b>	Degrees of freedom
<b>DBP</b>	Diastolic blood pressure
<b>FPS-R</b>	Faces Pain Scale-Revised
<b>GA</b>	General Anaesthesia
<b>HADS</b>	The Hospital Anxiety and Depression Scale
<b>HR</b>	Heart rate
<b>HyDi</b>	The Hydro Data Initiative
<b>ICC</b>	Intra-class correlation coefficient
<b>IG</b>	Intervention group
<b>ITT</b>	Intention to treat analysis
<b>KASA</b>	Cognitive-Autonomic-Somatic Anxiety Symptoms
<b>KMO</b>	Kaiser-Meyer-Olkin
<b>LA</b>	Local Anaesthesia
<b>M</b>	Mean
<b>MANOVA</b>	Multivariate analysis of variance test
<b>MDAS</b>	Modified Dental Anxiety Scale
<b>MDC</b>	Minimal detectable change
<b>MDH</b>	Mater dei Hospital

**mm Hg** Millimetres of mercury  
**n** Number of respondents  
**NRS** Numerical Rating Pain Scale  
***p*** Level of significance  
**PEO** Population exposure outcome  
**Ph.D.** Doctor of Philosophy  
**PRISMA** Preferred Reporting Items for Systematic Reviews and Meta Analyses  
**QOR** Quality of recovery  
**QoR-40** Quality of Recovery Score  
**RCT** Randomised controlled trial  
**SBP** Systolic blood pressure  
**SCL-9-K** The short form of the Symptom checklist  
**SD** Standard deviation  
**SEM** Standard error of measurement  
**SF-36** 36-Item Short Form Survey  
**SPSS** Statistical Product and Service Solution  
**STAI** State Trait Anxiety Inventory  
**STAI-S** State Trait Anxiety Inventory- Anxiety State  
**STAI-T** State Trait Anxiety Inventory- Anxiety Trait  
**STOA** State-Scale of the ‘State-Trait-Operation-Anxiety’  
**U** Test statistic for the Mann-Whitney test  
**UK** United Kingdom  
**UREC** University Research Ethics Committee  
**UOM** University of Malta  
**VAS** Visual analogue scale  
**VRS** Verbal rating scale  
**W** Wilcoxon signed-rank test  
**WHO** World Health Organisation  
 **$\chi^2$**  Chi-Square test statistic  
**z** z-approximation test  
 **$\alpha$**  Cronbach’s alpha

# **CHAPTER 1: INTRODUCTION**



## **1.1. Background information**

Globally, day surgery has been in place for more than forty years, with significant advances in the last two decades (Alacadag & Cilingir, 2018). Research has demonstrated that peri-operative anxiety is more common in ambulatory surgery (AS) patients than in-patients, and such anxiety has a huge psychological effect on the patient's emotional well-being (Cevik, 2018; Jiwanmall et al., 2020). Indeed, it was Janis (1958) who first explored the relationship between anxiety and surgical patients, where anxiety levels above the moderate level are considered as harmful and associated negatively with the patient's recovery (Janis, 1958). However, AS challenges the notion of keeping anxiety at a moderate level, as patients are expected to be 'street ready' briefly (Padmanabhan et al., 2005).

Over the years, peri-operative care has improved in terms of technological advancements; however, a common element that is often overlooked is the psychological status of the patients, and its effect on the quality of recovery (QOR) (Aspari & Lakshman, 2018). Although discussed in public forums, the amalgamation of mental health status into the peri-operative care of an AS patient is seldom taken into consideration in the clinical practice (Aspari & Lakshman, 2018). This is especially significant as the numbers of AS continue to increase, nurses may have less contact time with the patients, and hence, peri-operative anxiety may go unnoticed (Crockett et al., 2007).

Literature suggests that due to the increasing expansion of AS, healthcare professionals should be more knowledgeable about the patient's QOR, including post-operative emotional well-being and comfort (Sveinsdottir et al., 2016). The majority of AS patients presume uneventful recovery, nonetheless, complications may still arise (Lehmann et al., 2010). Such post-operative complications may result in the patient feeling anxious after surgery (Jaensson et al., 2017). Nonetheless, it is of utmost importance that patients are prepared for the surgery both mentally and physiologically (Levett & Grimmett, 2019).

## **1.2. Significance of the study**

The World Health Organisation (WHO) stated that AS for particular procedures are increasing significantly in Malta (Azzopardi-Muscat et al., 2017). In fact, during the months of January to November 2020, there were 19,058 day cases admissions in Mater Dei hospital (MDH) (Clinical Performance Unit, 2020). Although AS is convenient, attention still needs to be given to the psychological state of the patients (Bellani, 2008). Furthermore, Mitchell (2010) states that the effect of the modern AS environment has a significant role in pre-operative anxiety, but little research is available.

To date, patient's pre-operative anxiety and QOR in AS in Malta has not been evaluated. Consequently, this study seeks to answer the question: What is the relationship if any between pre-operative anxiety and post-operative anxiety and quality of recovery including pain in adults undergoing a day surgery? The present researcher evaluated pre-operative anxiety and need for pre-operative information, in relation to post-operative anxiety and QOR. Indeed, one of the main aims of this project was to identify the prevalence of peri-operative anxiety as the present researcher wanted to examine the prevalence of local peri-operative anxiety and possibly create awareness in order to highlight the scope of additional research.

Moreover, the QOR in AS was also evaluated, where domains included comfort, emotions, physical independence and patient support, which were evaluated both pre-operative and post-operative. Literature suggests that there is a lack of studies regarding QOR in AS (Mottram, 2011). Consequently, the present researcher included QOR so as this study contributes to this gap in literature, especially since this seems to be a weak link in the day surgery process (Berg et al., 2013). Furthermore, post-operative pain was also taken into account, as pain is a frequent distress for AS patients (Rosén et al., 2011; Shnaider & Chung, 2006). Moreover, literature suggests that physiological parameters can give a good insight of

the patient's level of anxiety (Fernandez-Aguilar et al., 2020). Indeed, physiological parameters were also taken into consideration, including blood pressure (BP), heart rate (HR) and oxygen levels in the present study.

Anxiety, being a subjective emotion is influenced by several aspects including, gender, age, education level, and type of surgery and former surgeries amongst others (Pritchard, 2009). Most of the international studies that evaluated such variables included in-patients and paediatric population not adults. Indeed, in the present study, such variables were taken into account, in addition to another variable, i.e., the presence of relatives, in order to evaluate if presence of relatives affect pre-operative anxiety and QOR after AS. Few studies have demonstrated the relatives' experience in AS, even though the present study has portrayed the importance of emotional support from relatives (Majholm et al., 2012; Rokach et al., 2014).

Moreover, there is also a dearth in both local and international literature regarding predictors of post-operative anxiety and post-operative comfort. In this study, post-operative comfort was evaluated in terms of nausea, vomiting, dry-retching, dizziness, feeling restless, shaking and coldness. As revealed in literature, such symptoms are all common in the recovery of AS (Lehmann et al., 2010). Indeed, the present study aims to target this lacuna, as such information could assist in targeting these outcomes. In view of the increasing number of AS, both locally and internationally, this study sought to assist policy makers to evaluate future initiatives to advance patient care by addressing peri-operative anxiety and QOR and hence, improve overall patient's well-being. For example, implementing an assessment tool to evaluate anxiety in the patient's care plan would assist the nurses in identifying anxiety and consequently implementing supportive measures. As a result, this would make certain that the patient is both physically and mentally well-prepared for AS (Caumo et al., 2001).

This is significantly important since literature revealed that ambulatory patients reported feelings of abandonment, highlighting the fact that nurses were not open to the patient's anxiety and concerns (Bailey, 2010; Gilmartin & Wright, 2008). Similarly, Mitchell (2010) in his study revealed that patients reported the lack of nurse's sympathetic presence. Such statements are preoccupying, especially since surgery affects the patient's psychological state (Wilson et al., 2016). The person-centred theory supports the shift from 'person-centred moments' to a person-centred culture, where feelings, satisfaction, and well-being of both the patients and nurses are taken into consideration (McCormack & McCance, 2006). As a result, the patient will feel understood, by being provided with the necessary psychological support (Pereira et al., 2016). Despite the proposal of such models, aspects of psychological care often become marginalised as bio-medical elements take dominance (Bundgaard et al., 2014).

Hence, one can conclude that as the complexity of AS continues to increase, nurses will have to take an active role in anxiety management and QOR (Mitchell, 2010). In the present study, several surgeries were included, such as endoscopy, general surgery, orthopaedic, gynaecology, urology, dental, hernia, vascular, endocrine and breast surgery. In addition, the increase in the volume and range of AS may have further increased pre-operative anxiety, due to lack of psychological care in restricted time and lack of specific nursing interventions according to the surgery being performed (Martin et al., 2010). As a result, nurses must be careful that this modern surgery approach does not constrain the nursing's ability to give the necessary care, including the psychological care (Fraczyk & Godfrey, 2010).

### **1.3. The Research design used**

Initially, several methodological designs were considered in order to determine which was the most suitable. AS patients wait for a long time until being called for surgery, however, they can be called anytime, so interviews were not deemed as efficient. Consequently, after taking into consideration the advantages and disadvantages of both quantitative and

qualitative research designs, the present author decided to utilise a quantitative method. The quantitative non-experimental cross-sectional approach was utilised to acquire statistical quantitative results by surveying a number of patients who attended MDH for an AS. Consequently, utilising this method of data collection, it was hoped that patient's peri-operative anxiety and QOR including post-operative pain, would be more recognised locally and hence, proper adjustments are made accordingly, such as the introduction of local anxiety assessment tool. In addition, the researcher also hopes that this study would contribute and add to the existing literature, by identifying significant predictors of post-operative anxiety and post-operative comfort.

#### **1.4. Structure of the Dissertation**

Written in the third person, this study is presented as follows:

**Chapter 2** offers a review of the available literature relevant to the topic.

**Chapter 3** presents a description of the methodology, sample population and research tools utilised, in addition to ethical issues.

Subsequently, **chapter 4** offers an account of the findings in addition to data analysis, which is followed by a weaved discussion of such findings, compared to available literature in **chapter 5**.

To conclude, **chapter 6** portrays a summary of the project in addition to future recommendations for research, education and management.

# **CHAPTER 2: LITERATURE REVIEW**

## **2.1. Introduction**

This chapter comprises a review of the strategy employed to identify contemporary research relevant to peri-operative anxiety and QOR, including pain levels in AS. Despite the continuous focus on person-centred care, the highly specialised day care setting might not be conducive for peri-operative nurses to deliver such care, even though these nurses frequently encounter patients with a wide range of mental disorders including anxiety. Corfee et al. (2013) state that a gap in literature exists regarding the care of surgical patients experiencing altered mental health status, such as anxiety. Since the day care setting is a specialised workplace, addressing peri-operative anxiety is of utmost importance since recommendations gathered from other settings might not be applicable to this specialised setting.

This gap in literature highlights the need to gather information regarding this topic in order to assist nurses to implement change that mitigates anxiety whilst augmenting their QOR. Traditionally, physical and mental health have been addressed as two different matters, hence, innovative methods to development are required to implement a workforce that amalgamates both mental and physical health (Das et al., 2016). Hence, this project contributed both to local and international literature by collating information on peri-operative anxiety and QOR in patients who underwent AS, in addition to providing information about the influence of several variables on such an experience. Moreover, there are no studies that identify specific predictors for post-operative anxiety and comfort in AS, hence, this study aims to target this issue.

## **2.2. Literature Search**

The following subsections include inclusion and exclusion criteria, a description of the search strategies and the process of screening of the articles.

### **2.2.1. Inclusion and Exclusion Criteria**

This study aims to recognise and evaluate peri-operative anxiety and QOR in patients undergoing an AS. Consequently, this chapter seeks to answer the question: What is the relationship if any between pre-operative anxiety and post-operative anxiety and quality of recovery including pain levels in adults undergoing a day case surgery? Indeed, the PEO (population, exposure, and outcome) model was utilised where the population included adults aged over 16 years undergoing AS, of any gender and ethnicity. The intervention is the AS while the main outcomes are peri-operative anxiety and QOR, including pain.

### **2.2.2. Search strategies and tools**

The University of Malta (UOM) online library was used to access databases, utilising HyDi (The Hydro Data Initiative). Different databases were included to generate the maximum amount of relevant data, while minimising literature bias while Google scholar was utilised when articles were not available as full text. Pappas and Williams (2011) highlight the emerging importance of grey literature, indeed, Google scholar was utilised to detect any grey literature including unpublished studies. Moreover, this was followed by scrutinizing of the reference lists of applicable studies to detect any additional relevant articles.

The literature search was restricted to English and to studies published between 2010 and 2020, to yield recent research. Hence, the researcher acknowledges language bias, as relevant data written in other languages had to be omitted. Another limitation is the fact that such rigorous process was conducted by one researcher, maximising the margin of error. The researcher made use of several databases, namely, the Cochrane Central Register of Controlled Trials, the Cumulative Index to Nursing and Allied Health Literature (CinaHL), Medline complete and PubMed.



Utilising the PEO model, keywords were generated from the main question, namely, ‘adults’, ‘pre-operative’, ‘anxiety’, ‘day case surgery’, ‘post-operative’, ‘quality of recovery’ and ‘pain’.

These keywords were additionally amended utilising Boolean Operators and truncations in order to generate different terms (Mishra et al., 2009). Table 2.1 demonstrates the keywords, their synonyms and truncated roots for each constituent of the PEO framework.

**Table 2.1**

*Keywords and Synonyms used in the search strategy*

Keywords	Adults	Pre-operative	Anxiety	Day-case surgery	Post-operative	Pain
Synonyms	Person, Man, Woman, Grownup, Mature	Pre-surgical, Pre-op	Worry, Tension, Concern, Unease, Doubt, Misery	Outpatient surgery, Ambulatory surgery, Same-day surgery, Day surgery	Post-surgical, Post-op	Physical suffering, Ache, discomfort
Truncated root	Adult*	Pre-op*	-	-	Post-op*	-

After identifying keywords, their synonyms and truncated roots, such terms were put together utilising the Boolean Operators “AND” and “OR”. Table 2.2 demonstrates the yield of the search strategies from different databases, including access date and MeSH terms for the PubMed database.

**Table 2.2***Search strategies for electronic databases*

Database	Access date	Search strategies	Articles found
Cochrane Central Register of Controlled Trials	October 10, 2020	<ul style="list-style-type: none"> <li>• <b>Search 1 Filters:</b> English, no time constraints. “pre-operative anxiety” AND “day case surgery”</li> <li>• <b>Search 2 Filters:</b> English, human subjects, Date: 2010-2020 and abstract available. “pre-operative anxiety” OR “worry” AND “day case surgery” OR “ambulatory surgery” OR “outpatient surgery” OR “day surgery” AND “post-operative pain” AND “quality of recovery”</li> </ul>	3 results  317 results
CinaHL via EBSCO Host	October 8, 2020	<ul style="list-style-type: none"> <li>• <b>Search 1 Filters:</b> English, date 2010-2020. “pre-operative anxiety” AND “day case surgery”</li> <li>• <b>Search 2 Filters:</b> English, date 2010-2020, keywords present in title. “pre-operative anxiety” OR “worry” AND “day case surgery” OR “ambulatory surgery” OR “outpatient surgery” OR “day surgery”</li> </ul>	6 results  22 results

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			AND	
			“post-operative pain”	
			AND	
			“quality of recovery”	
Medline Complete EBSCO Host	October 2020	14,	<ul style="list-style-type: none"> <li>• <b>Search 1 Filters:</b> English.</li> </ul>	3 results
			“pre-operative anxiety”	
			AND	
			“day case surgery”	
			<ul style="list-style-type: none"> <li>• <b>Search 2 Filters:</b> English, date 2010-2020, abstract and full text available.</li> </ul>	11 results
			“pre-operative anxiety”	
			AND	
			“day case surgery” OR “ambulatory surgery”	
			AND	
			“post-operative pain”	
			AND	
			“quality of recovery”	
PubMed	October 2020	17,	<ul style="list-style-type: none"> <li>• <b>Search 1 Filters:</b> English, free full text available.</li> </ul>	6 results
			“pre-operative anxiety”	
			AND	
			“day case surgery”	
			<ul style="list-style-type: none"> <li>• <b>Search 2 Filters:</b></li> </ul>	1 result
			English.	
			“pre-operative anxiety”	
			AND	
			“day case surgery”	
			AND	
			“post-operative pain”	
			AND	
			“quality of recovery”	

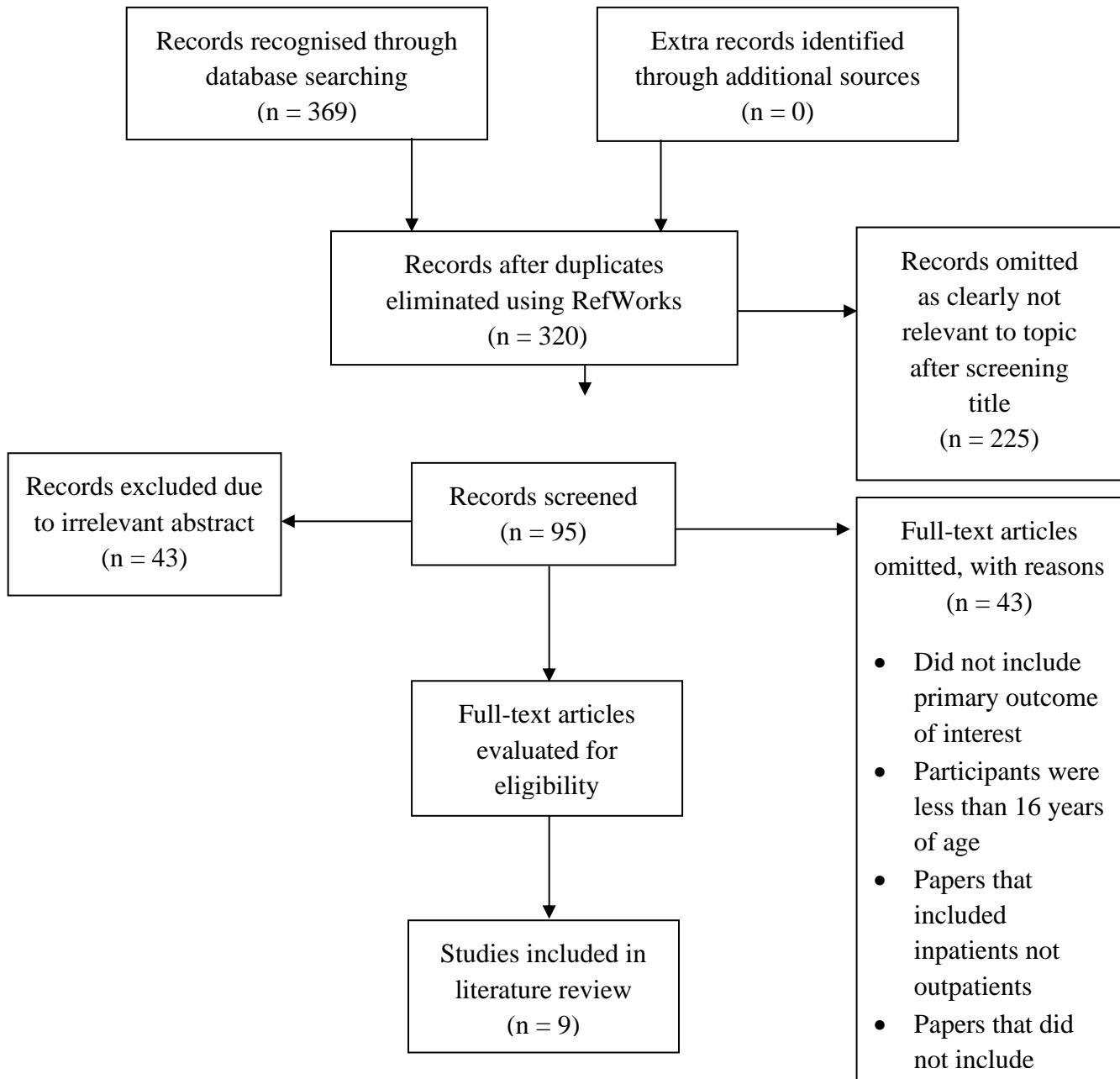
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### **2.2.3. Identification and Screening of Articles**

The search utilising electronic databases resulted in 369 potentially relevant results. Moher et al. (2009) suggested the PRISMA (The Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines when selecting papers for a review. Duplicates (n=49) were excluded using the duplicate remover via RefWorks, yielding 320 potentially relevant articles. Potentially relevant papers were identified depending on the relevance of the title. Articles with unclear titles or titles that did not seem relevant were eliminated. Consequently, 225 articles were excluded. Hence, the 95 remaining papers were examined for eligibility by reading the abstract, excluding irrelevant studies. 43 articles were excluded due to an irrelevant abstract, yielding 52 potentially relevant articles. Furthermore, the reference lists of these 52 potentially significant articles were scrutinized to classify studies that did not show up through the search, even though to no avail. Eventually this whole process yielded 9 relevant papers which were critically appraised for inclusion in this review. Figure 2.1 portrays this whole process with rationale for exclusion as recommended by Moher et al. (2009).

**Figure 2.1**

Flow diagram based on the PRISMA framework recommended by Moher et al. (2009)



### **2.3. Critical review of the selected research**

Stevens et al., (2014) highlight the importance of critical appraisal in nursing, due to its contribution to evidence-based practice, where the next sections demonstrate the steps taken to critically appraise the chosen articles.

#### **2.3.1. Organisation of the review**

Initially, the 9 retrieved articles for this review were organised in a table using the Microsoft Excel Spreadsheet, a simple yet a clear technique for presenting research (Tkeshelashvili & Klimenkov, 2019). The main aim of data extraction is to present the extracted results and eventually enable comparisons to be made between studies in a consistent manner. Moreover, extracting relevant data should ideally be done by more than one reviewer to minimise errors (Sargeant & O'Connor, 2014). Hence, the researcher acknowledges such limitation, as data extraction was done by the present researcher only.

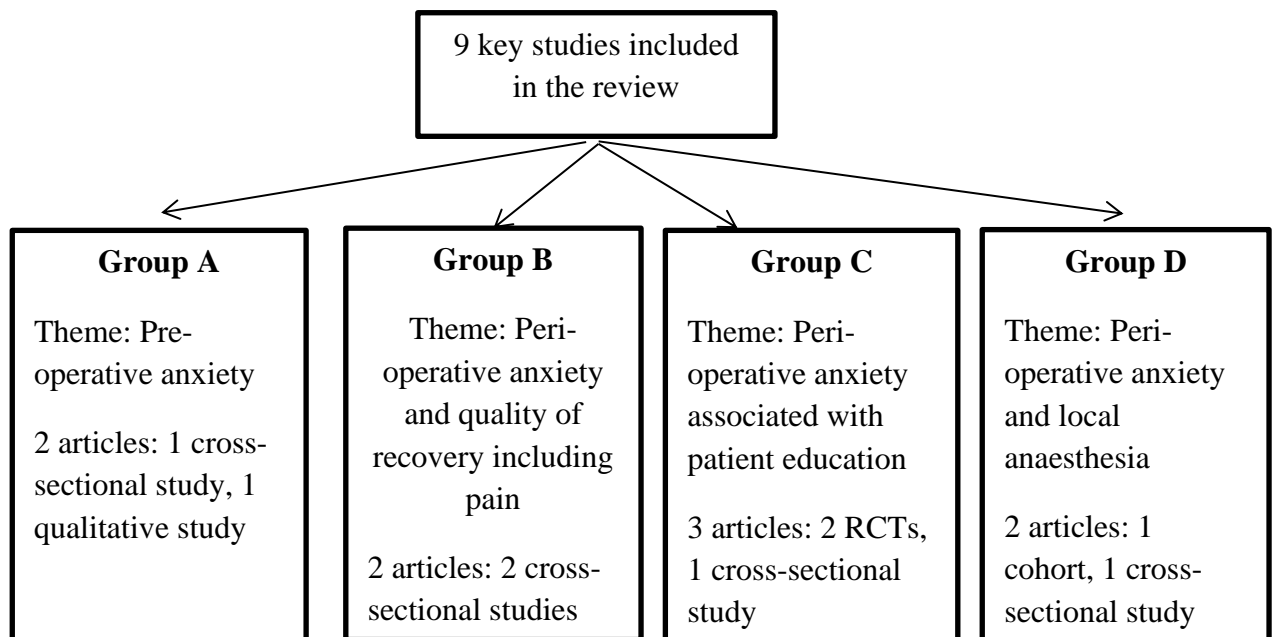
Although peri-operative anxiety has been a topic of interest for many years, few published articles have explored peri-operative anxiety in patients undergoing AS and its association with QOR including pain. Additionally, most of the studies are grounded on in-patients (Mitchell, 2010; Seers et al., 2008). Furthermore, QOR following AS is a significant measure and needs to be evaluated at several timeframes (Stessel et al., 2015). The majority of the studies have either assessed the first 24 to 48 hours following AS (Mitchell 2015; Viñoles et al., 2011) or have concentrated at a time-point between 1 week and 1 year following AS (Hoofwijk et al., 2015; Tran et al., 2014). Hence, the present project contributes to extant literature by focusing on the early in-hospital course. Moreover, there are no studies that identify specific predictors of post-operative emotions and post-operative comfort in AS, which however the present study addresses. This is especially significant as literature suggests that it is significant to be able to predict the recovery of an AS patient including post-operative emotions and post-operative comfort (Stessel et al., 2015). Moreover, it

enables one to target various predictors, thus ensuring a better hospital experience for AS patients.

Furthermore, the present researcher included another important variable (presence of relatives) in addition to the usual variables researched, such as gender and age. Indeed, few studies have demonstrated the relatives' experience in AS (Majholm et al., 2012). This is true, even though literature (Majholm et al., 2012; Rokach et al., 2014) and the present project have highlighted the importance of emotional support from relatives. Furthermore, this is the first local study of peri-operative anxiety and QOR in patients undergoing an AS within specifically the Maltese health care context. Figure 2.2 presents the organisation of the review, where although all studies include AS patients, the critique presented pertains to 4 different themes.

**Figure 2.2**

*Flow diagram depicting organisation of literature review*



### **2.3.2. Critical Appraisal tools**

Critical appraisal assists the researcher to identify strengths and weaknesses related to the study's validity, ethics and trustworthiness (Goldstein, 2017). The Critical Appraisal Skill Program (CASP) tools were used according to the research design being appraised (CASP, 2013). For the cross-sectional designs, the AXIS tool was utilised (Downes et al., 2016).

### **2.4. Critical appraisal of Studies exploring Pre-operative anxiety (Group A)**

Group A studies target pre-operative anxiety in persons undergoing AS where two studies were identified, namely a cross-sectional study (Mitchell, 2012) and qualitative study (Svensson et al., 2016). Details relating to these studies are summarised in Table 2.3 with the abbreviations listed, i.e., 'M' represents the mean and 'SD' the standard deviation.



**Table 2.3***Summary of the studies of Group A*

Author(s) & Place of study	Methodology, age, gender and sample size	Data collection tool, validity & reliability, Data analysis.	Main findings	Strengths & limitations
Mitchell (2012), Salford, UK	Cross-sectional 674 patients who did ambulatory surgery with anaesthesia; and returned by mail 24-48 hours post-operatively (n=672)  Age: 18-75years, average age 43 years.  Males=287 Females=385	Self-designed questionnaire compiled based on literature; general anaesthesia questionnaire 59 items and local anaesthesia 61 items; Likert-type Scale format. Content validity confirmed by experts in this field.  Descriptive statistics: a multivariate analysis of variance (MANOVA) test for all between group comparisons.	82.4% were anxious on the day of operation.  General anaesthesia patients (M:2.47, SD=1.05) were more anxious than local anaesthesia patients (M=2.18; SD=0.96). Females had higher anxiety scores on the day (M=2.57, SD=1.04) than males (M=2.10, SD=0.96).	A pilot study (for the first 10% of respondents) led to slight alterations to the surveys.  Ethically approved.  More female participants were surveyed however; this was compensated by the robust statistical test employed.  Low response rate (41.9%).
Svensson, Nilsson & Svantesson (2016), Orebro, Sweden	A qualitative descriptive design (n=20).  Age: ≥18 years, average 57 years.  Males= 12 Females= 8	Semi-structured face-to-face interviews (mean duration=27 mins) with 20 patients on the day before the surgery. Location selected the participants; home (n=16), the interviewers office (n=3), or place of work (n=1). Inductive content analysis. Use of the software program QRS NVivo10.	Various moods present on the day of the surgery, central category emerged: 'feeling hope about regaining health as a help to balance mood'.	A pilot study resulted in minor revision of the questions.  Patients suffering from cancer were excluded.  The researchers' personal biases were accounted for, but the risk of analyses being prejudiced by the researchers' subjective views can be a limitation.

*N.B: M=Mean; SD=Standard deviation.*

Both studies addressed a clearly focused question and recruited participants who underwent AS to assess pre-operative anxiety. The study of Svensson et al. (2016) included twenty adults where the main focus of this descriptive study was to assess the moods that patients waiting for AS experience. Mitchell (2012) additionally investigated the influence of sex and type of anaesthesia on pre-operative anxiety. A set of inclusion and exclusion criteria were applied in both studies to help minimise selection bias of subjects.

Choosing the most appropriate design to address a question is a significant point of the research process. Mitchell (2012) made use of a cross-sectional design to identify prevalence of pre-operative anxiety and its effect on patients undergoing AS. A cross-sectional design, which was utilised in the present study, is deemed suitable to identify peri-operative anxiety due to the relatively short duration of the patients at the hospital and their quick recovery. Such a design is very cost-effective and quick to conduct as data collection is conducted only once (Kesmodel, 2018). Consequently, such a design limits the researcher from differentiating cause and effect over time (Kesmodel, 2018).

As highlighted in the AXIS tool, sample size justification is important as it strongly affects the outcomes of the study (Downes et al., 2016). An incorrect sample size may lead to two types of errors acknowledged as Type I ( $\alpha$ ) and type II errors ( $\beta$ ) (Hazra & Gogtay, 2016). Type I errors lead to a false positive result, where the researcher claims that a variation exists between the groups, however, actually there isn't. Conversely, type II errors are associated with a false negative result, as the researcher rejects the null hypothesis when in reality it is true. The study of Mitchell (2012) initially distributed 1606 questionnaires; however, only 674 were returned, hence, a low response rate of 41.9%. However, the author acknowledged such limitation by applying robust statistical tests. Low response rates are common in postal questionnaires, especially in AS who resume to work quickly.

Conversely, qualitative designs such as that by Svensson et al. (2016) provide rich explanations of experiences through an open-ended approach, hence, suitable to evaluate the patient's pre-operative mood (Sandelowski, 2010). The study of Svensson et al. (2016) made use of content analyses and clearly stated the main objective of this study, i.e., to investigate patient's pre-operative moods in AS.

#### **2.4.1. Sampling**

Mitchell (2012) made use of non-probability sampling to recruit subjects, hence, some subjects had a higher chance than other subjects to be recruited (El-Masri, 2017). Consequently, this might have led to selection bias which restricts generalizability of results. In the study of Mitchell (2012), a convenience sample of participants awaiting AS were recruited from three AS units, hence, increasing generalizability of results. Convenience sampling is the most frequent type of sampling in quantitative research as subjects are recruited according to their convenience and willingness to take part (El-Masri, 2017).

This type of recruitment process is associated with selection bias, since subjects who volunteer to enrol in the study may differ from those who decline to participate (Sedgwick, 2013). Consequently, external validity is minimised when using convenience sampling (Frey, 2018). Despite such methodological shortcomings, Mitchell (2012) tried to minimise them by providing a thorough description of the sample through the use of a concise inclusion and exclusion criteria and also made an effort to include all possible participants, minimising response and self-selection bias. Additionally, the recruitment process was clearly described, and all subjects were theoretically relevant to the study, hence, selection wasn't entirely based on convenience.

Conversely, Svensson et al. (2016), recruited patients via stratified sampling according to age, gender and type of surgery. Stratified sampling is associated with greater precision and a

small sample; hence, it is less costly and more efficient. Since patients were recruited from only one hospital unlike that of Mitchell (2012), generalizability of the findings is limited. Although a small sample size is common in this design; investigators need to ensure that enough data is available to address the objectives of the study (Doyle et al., 2019). Furthermore, the sample of Svensson et al. (2016) consisted of twelve males and eight females; hence, gender bias was present. Moreover, most of the participants were of low education, mostly married and employed. Consequently, the conclusions of this study cannot be applied to subjects with different demographics. However, heterogeneity was kept at a minimum as only patients undergoing a general, hand, orthopaedic or urological surgery were recruited.

In the present study, gender bias was kept at a minimum (males=47%, females=53%) and although several surgeries were included, heterogeneity was kept at a minimum as surgeries were divided into sedation (endoscopy) and general anaesthesia (GA).

#### **2.4.2. Data collection and analysis**

A questionnaire is one of the most common tools utilised in quantitative data, hence, accuracy and consistency of a questionnaire are key characteristics, well-known as validity and reliability (Taherdoost, 2016). The study of Mitchell (2012) made use of a self-designed questionnaire based on literature (Leino-Kilpi et al., 2009; Lemos et al., 2009) where items were all concise to maximise return, that was of special importance as it made use of postal questionnaires which are associated with low response rates. The items on the questionnaire had clear content validity as they were all related to pre-operative anxiety which was confirmed by experts. Moreover, Mitchell (2012) conducted a pilot study that resulted in minor changes to the questionnaire, before continuation of study. However, nothing was mentioned concerning the reliability of the tool.

The study by Svensson et al. (2016) provided a clear description of the data collection and the semi-structured questions utilised. Consequently, such questions may be used to replicate the results in different populations. Face to face interviews are considered as the gold standard as the investigator can guide the participants whilst capturing non-verbal language (Irvine et al., 2013). However, the demographic characteristics of the investigator such as race, sex and class might influence the participant's response (Schröder, 2016). Furthermore, the interviews were audio recorded and transcribed by a professional transcriber.

Data collection followed by data analysis was clearly described in both studies. Such detailed analytical process intensifies the study's rigor (Neergaard et al., 2009). Inductive content analysis was appropriately used to address the main aims of the qualitative study, while Mitchell (2012) made use of descriptive statistics. In the study of Svensson (2016), data analysis was conducted by three authors, hence, minimising subjective and interpretation bias, while increasing consistency and reliability of the results. Moreover, a pilot study was conducted, which helped in revising some of the questions, further improving robustness.

Rigor is an important feature of a qualitative study where the more rigorous the study, the more trustworthy are the findings. Hence, the included qualitative study was assessed for rigor utilising both the CASP tool and Guba and Lincoln's four key criteria of rigor which include dependability, confirmability, transferability and credibility (Doyle et al., 2019). Several strategies were implemented to address these four criterions, such as, data analysis was primarily conducted by one author who then re-assessed the data and discussed it with two other authors, hence, increasing dependability. After analysis of data, which resulted in categories, data was validated by the authors who analysed six interviews for consistency. Interviews were conducted at a location according to the participants' choice; hence, participants were more at ease, increasing confirmability. Confirmability and dependability were also considered in the research process, as all contents of the interviews were then

reduced to one concept, ensuring confirmability. Additionally, several verbatim quotes from interviews were provided, along with a clear description of the process. This study also provided a clear explanation of the aims and participants that according to Hallberg (2013) allows the reader to appraise the transferability of the findings. Additionally, this study was peer reviewed. However, the recruitment of patients from one hospital limited credibility of this study.

### **2.4.3. Results and limitations**

Mitchell (2012) reported that 82.4% of the patients experienced pre-operative anxiety on the day of the surgery where 62.8% of the patients underwent GA while 31.8% underwent LA. Females (2.57+/-1.04) experienced higher anxiety levels on the day of surgery as they had higher means (SD) compared to males (2.10+/-0.96). Regarding anaesthesia type, patients undergoing GA (2.47+/-1.05) were statistically significant more anxious than patients undergoing LA (2.18+/-0.96). Additionally, 83% of the patients stated that they had undergone GA before and 58% LA, therefore, previous experience of anaesthesia did not lessen anxiety. Moreover, females significantly remarked that their waiting time would have been better if spent talking with a relative.

Similarly, Svensson et al. (2016) explored pre-operative anxiety, however, utilising a qualitative perspective. The most fundamental category was 'feeling hope about regaining health' which emerged from two subcategories: 'experiencing a harmonious mood' and 'experiencing a shifting mood.' The harmonious mood helped the patients to balance any negative thoughts, despite some pre-operative anxiety. Conversely, shifting mood was defined as shifting between suspense and anxiety, in addition to feelings of uncertainty during the waiting time for surgery. The findings of this study revealed that hope is very helpful pre-operatively in maintaining a positive mood, unlike the findings of former studies that reported anxiety pre AS (Bailey 2010; Jawaid et al. 2007).

Regarding limitations, both studies addressed different limitations. An important limitation of the study by Mitchell (2012), is the choice of the design, i.e., cross-sectional study as it does not ensure that the timing of data gathering can be truly representative of the general population. Consequently, it affects the validity of the study. Consequently, further studies should implement RCTs or longitudinal study designs. Furthermore, both studies made use of a non-random sampling method which introduces bias which might lead to underpowered results. However, Mitchell (2012) addressed this limitation by sending questionnaires to a large sample of the population (n=1606) even though, the response rate was 41.9%. Nonetheless, such low response rates might have led to sampling bias. High response rates endorse confidence in findings as such results are more representative of the population. Additionally, the sample population of Mitchell (2012) consisted of more females (n=385) compared to males (n=287), even though the researcher acknowledged this limitation by employing robust statistical tests.

A pilot study is a very important strength of the study by Svensson et al. (2016), as it resulted in minor changes to the questions, hence, increasing accuracy of results. Indeed, the present researcher conducted a pilot study with 12 participants to ensure feasibility of the study. However, in the study of Svensson et al. (2016) patients having a cognitive impairment were excluded; thus, moods experienced in such populations could not be evaluated. All of the audio-recorded interviews were transcribed by a professional transcriber and robust inductive analysis resulted in a concept that defined the research phenomenon. Another feature is the correct use of a number of direct quotes, as overuse can weaken data analysis, reducing accuracy. Moreover, although the authors stated that the researchers' personal bias and idiosyncrasies were accounted for; however, it could have still influenced results in terms of data analysis by the author's personal opinions. Despite such limitations, both studies were conducted according to ethical standards of research.

**2.5. Critical Appraisal of Studies that relate Peri-operative anxiety and Quality of recovery including Post-operative Pain (Group B)**

Group B consists of two cross-sectional studies which explored peri-operative anxiety, and its association with QOR, including post-operative pain. Table 2.4 provides a clear description of both studies.



**Table 2.4***Summary of the studies of Group B*

Author(s) & Place of study	Methodology, age, gender and sample size	Data collection tool, validity & reliability, Data analysis.	Main findings	Strengths & limitations
McIntosh & Adams, (2011), Peterborough, UK	<p>A non-experimental quantitative survey with 54 patients to identify the association between pre-operative anxiety and post-operative recovery (n=54).</p> <p>Age: 18-83, average age 44 years.</p> <p>Males=32 Females=22</p>	<p>The HADS and the QoR-40.</p> <p>HADS: Consists of 14 items measuring anxiety and depression.</p> <p>QoR-40: 40-item questionnaire; Part A: participants are asked how they have felt in the former 24 h; Part B: if they have experienced physical or emotional symptoms in the previous 24 h. 5-point Likert scale.</p> <p>Data analysis:</p> <ul style="list-style-type: none"> <li>• Categorical data: <math>\chi^2</math>test</li> <li>• Numerical data: t-test (level of significance P=0.05 or less)</li> </ul>	<p>54% of the participants had mild to severe anxiety (male=13, female=16). Moderate and severe pre-operative anxiety categories were most frequently recorded in women (female =32%; male 23%, respectively) compared to males (12.5% &amp; 16%, respectively).</p>	<p>Approved by the relevant ethics board.</p> <p>Confidentiality was ensured (no identifiable information).</p> <p>Small sample size.</p>

Mitchell (2014) Salford, UK	Cross-sectional postal questionnaires with 684 participants, to examine aspects of care possibly influencing recovery after ambulatory surgery (n=684). Questionnaires returned within 1 week post-surgery  Age: 18-108; average 55 years.	Self-designed 53-item questionnaire using a Likert scale format.  Main domains explored: <ul style="list-style-type: none"> <li>• Pre-assessment visit</li> <li>• Day of surgery</li> <li>• Journey home</li> <li>• Discharge information</li> <li>• Physical/social recovery (12 items)</li> <li>• Demographics</li> </ul> Data analysis: <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Multiple regression</li> </ul>	Peri-operative information has a significant positive association with patients' being fully prepared for home.  <u>Negative correlation (<math>R^2</math>) matrix:</u> Unsatisfactory pain management ( $R^2 = -0.328$ , $p < 0.0001$ ), increased anxiety ( $R^2 = -0.128$ , $p < 0.028$ ) and reduced help once home ( $R^2 = -0.259$ , $p < 0.0001$ ) had a statistically significant negative association with participants being ready for recovery.	Peer reviewed The survey was grounded on former relevant studies. A pilot study was conducted. Low response rate (29%).
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McIntosh and Adams (2011) recruited 54 participants while Mitchell (2014) recruited 684 participants, both from one AS unit, hence, reducing generalization. Despite the bias associated with convenience sampling, both studies tried to minimise selection bias by providing a description of the sample population. McIntosh and Adams (2011) also used an ethnic category code which revealed that most of the patients (96.3%) were coded as white British. Despite the efforts of the authors to minimise selection bias, in McIntosh and Adams's study (2011) the sample consisted of more males (n= 59.3%) than females (n=40.7%). This is a limitation due to an under representation of females. Conversely, Mitchell (2014) did not provide any information about the sex of the respondents.

Of the two studies, only that of McIntosh and Adams (2011) provided information about non-respondents (n=43), resulting in a small sample size of 54 patients, despite the fact that the authors provided addressed envelopes. Low response rates and non-respondents in a cross-sectional study are very problematic to address (Downes et al., 2016) and may affect the results, leading to a lack of proper representation of the general population. Conversely, Mitchell (2014) recruited a large sample size (n=684), even though no mention of any sample size justification was mentioned.

### **2.5.1. Validity and reliability of the measurement tools**

The study of McIntosh and Adams (2011) utilised 2 questionnaires, namely, the Hospital Anxiety and Depression Scale (HADS) and the Quality of Recovery (QoR-40) (APPENDIX B). The HADS has been widely utilised and validated in several studies (Al Aseri et al., 2015; Czerwiński et al., 2020) and despite its brevity, it is considered highly valid to measure peri-operative anxiety. Regarding the QoR-40, although no details were provided regarding its validity and reliability, it has been commonly used (Myles et al., 2000; Guimarães-Pereira et al., 2016). Details about the QoR-40 which was used in the present study are provided in Chapter 3.

Conversely, Mitchell (2014) did not make use of a published questionnaire, where a self-designed questionnaire was compiled on former studies by clinical experts. Items of this questionnaire were all concise with clear content validity, even though no reliability tests were mentioned.

### **2.5.2. Results and limitations**

Mild to severe pre-operative anxiety was reported in 54% of the respondents in the study of McIntosh and Adams (2011) while severe post-operative anxiety was recorded in 31% of the patients who underwent GA. Moreover, females had higher peri-operative anxiety, as conveyed in literature (Caumo et al., 2001). However, unlike previous studies (Caumo et al., 2001), this study revealed that former surgery does not necessarily decrease anxiety levels. Additionally, results revealed that a significant relationship exists between pre-operative and post-operative anxiety, but pre-operative anxiety and post-operative recovery (including pain) were not statistically significantly related.

Similarly, Mitchell (2014) explored several aspects of home recovery including anxiety on the day of surgery, and post-operative pain. Results revealed a positive correlation ( $R^2$ ) matrix between information provision both pre-operatively ( $R^2 = 0.188$ ,  $p < 0.001$ ) and post-operatively ( $R^2 = 0.412$ ,  $p < 0.0001$ ) and a better recovery once home ( $p < 0.001$ ). Contrary to the findings of McIntosh and Adams (2011), this study revealed a negative link between anxiety on the day of surgery ( $R^2 = -0.128$ ,  $p < 0.028$ ) in relation to full recovery at home ( $p < 0.050$ ). Lack of pain management at home was also statistically negatively associated with full recovery once discharged ( $R^2 = -0.328$ ,  $p < 0.0001$ ).

The main limitation of McIntosh and Adams (2011) is the small sample size ( $n=54$ ) while that of Mitchell (2014), although a large sample size, had a low response rate. Hence, this

might not reflect a diverse view. In the present study, participants had the choice to either fill in the English or Maltese version of the questionnaires, to maximise response rate.

Moreover, the vast range of surgeries in both studies and additional variables (such as social issues) not accounted for, might have influenced results. Moreover, the results of Mitchell (2014) should be construed with caution due to the age of the respondents as 70 participants were septuagenarians (70s), 18 octogenarians (80s) and one centenarian (108 years). QOR for a young person is not the same as that of an older adult.

## **2.6. Critical Appraisal of studies exploring Peri-operative anxiety and patient education (Group C)**

Group C consists of three studies, two RCTs and one cross-sectional study, which evaluated peri-operative anxiety and patient education. The RCTs consisted of 2 groups of participants who were randomly assigned to an intervention group (IG) or control group (CG) (Bothwell et al., 2016). Table 2.5 provides a description of the three studies.

**Table 2.5***Summary of the studies of Group C*

Author(s) & Place of study	Methodology, age, gender and sample size	Data collection tool, validity & reliability, Data analysis.	Main findings	Strengths & limitations
Pereira, Figueiredo -Braga & Carvalho (2016), Porto, Portugal	A RCT to evaluate how patient-centred approach affects pre-operative anxiety (n=104)  Age: $\geq 18$ years, average age: 43 years.  Males: n=69 Females: n=35	The STAI-Y tool (Portuguese form) to measure anxiety before and after the pre-operative interview and after the surgery. Good test–retest reliability coefficients for the Portuguese version (0.31- 0.86). Intervention group (IG): received personalised information via a 15mins interview while the control group (CG) received standardized information.  Data analysis: <ul style="list-style-type: none"> <li>• Predictive Analytics Software 18.0.</li> <li>• Chi-square</li> <li>• Independent-samples T-tests</li> <li>• Bonferroni correction (for multiple comparisons; <math>\alpha =</math> 0.013).</li> </ul>	Both groups were similar in terms of anxiety and demographic features. The IG group showed: <ul style="list-style-type: none"> <li>• Lesser levels of pre- operative anxiety (<math>p &lt;</math> 0.001) and pain (<math>p &lt;</math> 0.001)</li> <li>• Improved surgical recovery (<math>p &lt;</math>0.01)</li> <li>• Greater levels of daily activity (<math>p &lt;</math> 0.001) and better satisfaction regarding information (<math>p &lt;</math> 0.01) than the CG</li> </ul>	The STAI-Y is a reliable and valid tool for studying anxiety in research. Approved by an ethics committee. Randomisation reduces bias. However, no sample size calculation which led to a small sample size which might decrease statistical significance.
Wongkiet kachorn,W ongkietkac horn & Rhunsiri (2018), Bangkok, Thailand	A prospective, multi-center, single-blind, with 450 participants. RCT with a 1:1 allocation ratio. Day surgery patients were randomized into an intervention group, [IG] (n=225 needs- based education)	STAI and a 100-mm VAS for anxiety. Patients completed surveys to evaluate their anxiety before patient education, after patient education & after surgery. 30 interviews conducted to identify common educational topics required by patients. Needs-based patient education questionnaire	Findings revealed greater reduction in anxiety (IG: M=7.09, SD= 7.02 vs. CG: M= 5.33, SD=7.70; $p$ = 0.001) and greater increase in satisfaction (IG: M=21.1, SD=16.0 vs. CG: M=16.0, SD=21.6, $p <$ 0.001) in the	Peer reviewed Randomisation & blinding decreases bias. A pilot study was done in 30 patients. A structured script & video were utilised to guarantee the same amount of information was delivered to

	<p>or a control group [CG](n=225 traditional education).</p> <p>Age: <math>\geq 18</math> years, average 32 years.</p> <p>Males n= 198 Females n= 252</p>	<p>was piloted and validated with 20 patients.</p> <p>Data analysis:</p> <ul style="list-style-type: none"> <li>• STATA/SE version 12.1.</li> <li>• Mann–Whitney U tests</li> <li>• Pearson’s <math>\chi^2</math></li> <li>• Fisher’s exact tests</li> </ul>	<p>IG group compared to the CG.</p>	<p>patients. Questionnaires were submitted for data analysis anonymously. Sample size calculation was conducted. However, cultural difference between countries should be accounted for before generalization of findings. Subjective outcome measurement and used a standardized survey. Illiterate participants were excluded.</p>
<p>Alacadag &amp; Cilingir (2017), Amasya, Turkey</p>	<p>A descriptive and cross-sectional model (n=151).</p> <p>Age: <math>\geq 18</math> years, Mean age= 41.7, SD= 13.3 years.</p> <p>Males n=69 Females n=82</p>	<p>Face to face interviews pre-surgery using STAI questionnaire and Patient information form which includes 23 questions; 8 about demographic data and 15 questions about patient’s knowledge of the surgery.</p> <p>Data analysis:</p> <ul style="list-style-type: none"> <li>• Shapiro–Wilk tests</li> <li>• The post hoc Tukey test</li> <li>• Kruskal-Wallis Variance Analysis</li> <li>• Mann Whitney U test</li> </ul>	<p>Pre-op anxiety mean score for all participants: state anxiety M= 39.2 SD= 5.05; trait anxiety M= 45.3 SD=4.68.</p> <p>Statistically significant difference by gender in both state anxiety (males: M=40.2, SD=4.4; females: M=38.4, SD=5.4, p=.033) and trait anxiety (males: M= 44.3, SD= 4.7; females: M= 46.1, SD=4.6, p=.012).</p>	<p>95.5% response rate. Ethically approved. Included only orthopaedics &amp; trauma, urology, ophthalmology, general surgery, thoracic surgery, gynaecology, and obstetrics surgery. Small sample size from only a single university hospital.</p>

*N.B: IG=Intervention Group, CG=control group; M=Mean, SD=Standard deviation.*

### 2.6.1. Sample and setting

Randomisation in RCTs is utilised to circumvent systematic bias where in a well-designed RCT every respondent has an equivalent chance of being in either group (Ahuja, 2019). Wongkietkachorn et al. (2018) made use of simple randomisation by tossing a coin and assigning the patients in a 1:1 ratio. The main aim of this prospective multicentre RCT was to compare needs-based education with traditional education and its effect on pre-operative anxiety. A key strength of a multi-centre RCT is that it improves generalizability of results (Bhide et al., 2018). Indeed, the trial of Wongkietkachorn et al. (2018) was conducted in three hospitals, strengthening the credibility of the results.

Participants undergoing excision of benign mass were recruited in the trial of Wongkietkachorn et al. (2018) where through simple randomisation; the CG received traditional education while the IG received needs-based education. The needs-based patient education survey was established on prior literature, patient interviews and expertise in this field (King et al., 2014). Additionally, a pilot study was conducted and the questionnaire was validated before continuation of the study. The main outcome of this RCT was patient anxiety, which was assessed using the 'State-Trait Anxiety Inventory' (STAI) questionnaire (Spielberg, 1983) and the Visual Analogue Scale (VAS) (Kindler et al., 2000). The STAI measures anxiety-trait (STAI-T) and anxiety-state (STAI-S), where the STAI-T evaluates situations that the participant identifies as threatening while the STAI-S evaluates the transient emotional state.

Although the authors did not mention validity and reliability of both tools, such tools have been widely used. The STAI was previously tested for both validity and reliability, in various studies (Boker et al., 2002; Moerman et al., 1996; Spielberger, 1983). Similarly, VAS has also been validated (Kindler et al., 2000). Completed questionnaires were submitted anonymously for data analysis. Furthermore, the authors also highlighted anonymity and



confidentiality by allowing the participants to complete the questionnaires privately in a different room from the investigators. Baseline demographics (age, sex, trait anxiety) were similar in both groups. Moreover, the researchers also made use of a standardised script, to ensure that patients received same amount of information. Since all confounding factors were acknowledged, any variance in the outcome is expected to be due to the intervention.

Conversely, in the trial of Pereira et al. (2016), no information was provided regarding the randomisation. The main aim was to assess the effect of an empathic patient-centred approach including education on pre-operative anxiety, and other aspects of recovery, including satisfaction in AS. The authors just stated that the patients were randomly assigned into the IG, who received personalized information via interviews pre-operatively, and the CG, who received standard information. Similar to the other trial, anxiety was assessed using the Portuguese version of STAI, which has been widely validated (Andrade et al., 2001; Gorenstein & Andrade, 1996). This RCT made use of convenience sampling, which decreases external validity and leads to sampling bias. Furthermore, patients were only recruited from one hospital, limiting generalizability of the findings. Similar to the trial of Wongkietkachorn et al. (2018), both the CG and IG had similar baseline demographics. In both trials, the CG and IG received identical treatment, apart from the intervention being studied.

Regarding the cross-sectional study, Alacadag and Cilingir (2017) also made use of convenience sampling to recruit participants waiting for AS at one hospital. Similar to both RCTs, this study included a description of the demographics, identifying a baseline population. Moreover, alike to both RCTS, this study also made use of the STAI (Turkish version), and another tool, namely, 'The Patient Information Form.' Reliability tests and validity evaluation of the Turkish version of the STAI was performed by Öner & Compte (1985) where literature suggests that the internal consistency for the Turkish version of the

STAI is between 0.94-0.96 (Turan & Başbakkal, 2006). Conversely, the patient information form was self-designed by the author and nothing was mentioned about its validity and reliability, thus, further tests should be conducted.

### **2.6.2. Sample size**

A research study should have a sufficient sample size as this will in turn affect the power of the findings (Bell, 2018). Calculation of the sample size is a significant step, as this will determine the power to identify a pre-determined difference in the outcome variable, when the intervention is in fact real (Walters et al., 2019). The degree of difference between the IG and the CG is known as the effect size, while the statistical significant level is linked with type I error (Bhide et al., 2018). In the trial of Pereira et al. (2016), the significant level was kept at 1%, while that of Wongkietkachorn et al. (2018) the significant level was kept at 5%.

The trial of Wongkietkachorn et al. (2018) described the use of power calculation for approximating the sample size, as this will in turn influence the power of the trial. Indeed, with a 95% confidence interval (CI) and power of 80%, the designed sample size was 215 in every subgroup. However, the study in reality recruited 225 participants for both groups and a pilot study enabled the researchers to check for feasibility prior to continuation. Similarly, in the study of Alacadag and Cilingir (2017), sample size was calculated using the sampling formula, which resulted in 151 participants, a key strength of the study enabling the accurate determination of relevant differences (Faber & Fonseca, 2014). Moreover, this study also made use of two assistants, making the process of data analysis more efficient while minimising researcher bias. Conversely, the trial of Pereira et al. (2016) did not mention any sample size calculation, thus, prone to type II errors.

### **2.6.3. Blinding and Data Analysis in RCTs**

A key methodological feature of a RCT is the ability to eliminate bias and enhance external validity through the use of blinding (Bhide et al., 2018). In both trials, single blinding was utilised. In the trial of Wongkietkachorn et al. (2018), respondents were blinded to the nature of the intervention and were unaware that an extra questionnaire (needs-based) was being used for the IG. The investigators, however, were not blinded. Similarly, the other trial (Pereira et al., 2016), also made use of single blinding where only the patients were blinded. If both trials made use of double blinding, results would have been more accurate and any unconscious information bias would have been eliminated (Bhide et al., 2018).

In both RCTs, the statistical concept known as intention to treat analysis (ITT) was employed. ITT includes all randomised respondents for analysis, thus, minimising dropout bias (McCoy, 2017). ITT preserves both randomisation and sample size in a RCT, because if dropouts and non-compliant participants are omitted, it might considerably decrease the sample size (Gupta, 2011). As a result, this might lead to decreased statistical power.

### **2.6.4. Results and limitations**

In the trial of Pereira et al. (2016) both groups had similar demographics, however, after the interview, which included empathic patient-centred care and education, the IG had lower levels of anxiety ( $M=31.6$ ,  $SD=9.4$ ) compared to the CG ( $M=38.5$ ,  $SD=11.2$ ). Additionally, the IG had lower levels of postoperative pain ( $M=0.3$ ,  $SD=0.5$ ) compared to the CG ( $M=0.7$ ,  $SD=0.6$ ). This indicates that pre-operative empathic patient-centred approach reduces anxiety, and promotes a better QOR including pain levels. This highlights the significance of having nurses skilled in communication skills, specially, on empathic patient-centred methods. The results of this trial support other studies in promoting a feasible empathic patient-centred approach in AS (Oates et al., 2000; Soltner et al., 2011). This is particularly

vital as studies report that patients felt abandoned pre-operatively, with nurses not being open to their anxieties (Gardner et al., 2006; Marcolino et al., 2007; Mitchell, 2010).

In the trial of Wongkietkachorn et al. (2018), intraoperative anxiety was assessed and its relation with needs-based education, compared to the traditional education. Both groups had similar baseline mean anxiety levels, however, after receiving the personalised information, the IG had lower levels of anxiety (M=39.01, SD=10.26) compared to the CG (M=41.64, SD=9.78). Such results were also consistent post-operatively, with the needs-based education group having lower levels of anxiety (M=34.54, SD=9.99) compared to the traditional education group (M=37.02, SD=10.34). Such results highlight the significance of patient assessment of information needs, as it helps in reducing peri-operative anxiety and improves patient satisfaction.

Likewise, in the study of Alacadag and Cilingir (2017), pre-surgery anxiety and need for information were also explored where majority of the participants stated that they did not have any surgery and anaesthesia associated anxiety. This could be due to majority of the patients having LA (92.1%). However, the average scores of the STAI were high [state anxiety-M=39.2, SD=5.05; trait anxiety -M=45.3, SD=4.68]. In line with other studies, females (M=46.1, SD=4.6) significantly experienced higher levels of pre-operative anxiety (M=44.3, SD=4.7). Furthermore, patients who found pre-operative information inadequate had higher mean trait anxiety scores (M=47.5, SD=5.2) compared to those who found the pre-operative information adequate (M=45.0, SD=4.5), similar to the results of both RCTs. 87% of the participants stated that they expressed their anxiety with a relative, highlighting the support that a relative can provide. Such statement also revealed that patients preferred to share their worry with a relative or a doctor, as the rate of sharing worry with a nurse was quite low. Such findings suggest that nurses should assess more frequently pre-operative anxiety, as this can positively affect patient's post-operative morale.

Generalizability is a crucial criterion of research studies (Bhide et al., 2018). However, two of the studies (Alacadag & Cilingir, 2017; Pereira et al., 2016) were both conducted in one hospital, thus reducing the generalizability of their findings. Conversely, the other RCT (Wongkietkachorn et al., 2018) was performed in three hospitals. Hence, the population comprised in this RCT was more representative of the population. In both RCTs, a common limitation was the fact that minor ethnic groups were minimally represented. Moreover, even though the trial of Wongkietkachorn et al. (2018) was performed in three hospitals, the authors stated that cultural differences between countries should be accounted for before generalising their findings. In all studies, patients who were either illiterate or suffering from psychiatric conditions were excluded, hence further impacting the generalisability relating to peri-operative anxiety.

Another aspect that varied in these studies was the type of operations performed. In two of the studies (Alacadag & Cilingir, 2017; Wongkietkachorn et al., 2018), AS was only limited to basic procedures and LA, so the findings were limited to these type of procedures. The study of Alacadag and Cilingir (2017) was conducted amongst patients who underwent orthopaedics, urology, ophthalmology, general surgery, thoracic surgery, or a gynaecological procedure. This might have led to results with low levels of generalisation, even though this was done to limit confounding factors. Indeed, the present researcher included a vast range of surgeries, including both GA and mild sedation in order to increase generalisation of the findings. Nonetheless, the trial of Alacadag and Cilingir (2017) recruited a large sample size, unlike the other two studies. Thus for those studies with a small sample size, there was a bigger possibility of type II errors, and this indicates a need for larger sample sizes as computed from a power analysis computation. Despite the limitations, all of the studies were conducted in compliance with ethical standards.

## **2.7. Critical Appraisal of studies exploring Peri-operative anxiety and local anaesthesia**

### **(Group D)**

Group D consists of one cohort study (Reyes-Gilabert et al., 2017) and one cross-sectional study (Fernandez-Aguilar et al., 2020) which explored peri-operative anxiety in a dental setting. The included cohort is a prospective single cohort study i.e., participants that do not show the outcome of interest are referred to as internal controls, since no control groups were used.

An important advantage of cohort studies is the possibility of evaluating several outcome variables and they also provide key research unattainable from RCTs (Mann, 2003). Indeed, Reyes-Gilabert et al. (2017) examined several variables including age, sex, education and pain score. Both studies addressed a clear question, in terms of population and outcomes of the study, as depicted in the study descriptions presented in Table 2.6.

**Table 2.6***Summary of the studies of Group D*

Author(s) & Place of study	Methodology, age, gender and sample size	Data collection tool, validity & reliability, Data analysis.	Main findings	Strengths & limitations
Reyes-Gilabert et al. (2017) Seville, Spain	A longitudinal prospective & descriptive clinical study to assess peri-operative anxiety in 45 patients in a dental setting.  Male= 19 Female= 26  Age range: 18-65 years with a median age of 33.5+/- 9.6 years.	Pre & postoperative anxiety-state (STAI-S), anxiety-trait (STAI-T) and dental anxiety (MDAS) surveys.  Data analysis: <ul style="list-style-type: none"> <li>• Binary logistic regression analysis</li> <li>• Chi square test or Fisher's</li> <li>• Student t test</li> <li>• Shapiro-Wilk test.</li> </ul>	A statistically significant association between pre & post-operative anxiety.  <u>The Mean +/- Standard deviation:</u> <u>Pre-op STAI-S questionnaire:</u> 30 patients (66.7%) with anxiety scores (total score: M=23.9, SD=6); males: M=23.8, SD=5.2; females: M=24, SD=6.6 (p=0.93).  <u>Post-op anxiety with the STAI-S:</u> 33 patients (73.3%) with anxiety, with a mean of 25, SD=6.2, males: M= 24.7, SD=6.4; females: M=25.3, SD=6.1 (p=0.74).  <u>MDAS questionnaire:</u> 18 patients (40%) had severe postoperative anxiety	Approved by a bioethics committee. Small number of respondents and lack of CG.

Fernandez-Aguilar et al., (2020) Valencia, Spain.	<p>185 patients undergoing dental extraction were enrolled. To evaluate patient's anxiety vs. different parameters: pre and post-operative BP, and pre and post-operative HR and consequently, link the findings to the post-operative analgesic requirement.</p> <p>Age: 18-90, average 56 years.</p> <p>Males= 92 Females=93</p>	<p>Corah's Dental Anxiety Scale (DAS). DAS consists of four multiple choice questions for the participant with five possible answers. The numerical value acquired is utilised to classify the patient according to his/her level of anxiety.</p> <p>Patients filled a form about post-operative pain, the total of days the pain had lasted and which analgesia had been utilised i.e. (Paracetamol/Ibuprofen or other).</p> <p>Data analysis:</p> <ul style="list-style-type: none"> <li>• Inferential, descriptive and statistical analysis</li> <li>• Spearman's rho coefficient</li> <li>• Pearson's chi-squared test</li> </ul>	<p>DBP showed statistically significant differences between pre-operative and post-operative readings (<math>P = 0.001</math>). DAS was related with pre-operative DBP (<math>P = 0.001</math>) and post-operative DBP as well as pre-operative HR (<math>P = 0.027</math>) and post-operative HR (<math>P = 0.013</math>).</p> <p>Patients with high levels of DAS tend to use Ibuprofen 400 mg more frequently (<math>P = 0.038</math>).</p> <p>No significant differences between males and females.</p>	<p>Ethically approved. Patients voluntarily signed a consent form. The authors declared no competing interests.</p>
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### 2.7.1. Setting and sample size

Both studies (Fernandez-Aguilar et al., 2020; Reyes-Gilbert et al., 2017) recruited participants from a dental setting and restricted to having specific characteristics, a very powerful tool to try and minimise selection bias (Rochon et al., 2005). Indeed, both studies had a clear inclusion and exclusion criteria and included patients undergoing a dental extraction and excluded patients who were not capable to fill in questionnaires.

Although the sample size of a study is an aspect that has an effect on the power of the results of the study (Faber & Fonseca, 2014), in both studies, there was no mention of power



calculation to determine sample size. The authors stated that all possible participants were recruited in order to try and decrease dropout bias. However, one of the studies had a small sample size (n=45) which might have therefore evoked bias. When a sample size is too small, it might lead to vague results, while a large sample size requires extra resources (Sedgwick, 2014). Furthermore, in the study of Fernandez-Aguilar et al. (2020), all of the participants were Caucasian, hence, results do not present truly the entire population.

### **2.7.2. Measurement tools**

In the longitudinal study by Reyes-Gilabert et al. (2017), anxiety levels were measured using two instruments, including the STAI and the modified Corah dental anxiety scale (MDAS) (Coolidge et al., 2010). The study of Fernandez-Aguilar et al. (2020) made use of the Corah's Dental Anxiety Scale (DAS). Both the MDAS and DAS are specifically designed to assess anxiety related to dental procedures. Patients self-assess their anxiety levels using a Likert-type score from 5 (no anxiety) and 25 (severe anxiety).

Although nothing was mentioned regarding the DAS's validity and reliability in the study of Fernandez-Aguilar et al. (2020), this tool has been widely validated (Bonafé et al., 2016; Leko et al., 2020). Likewise, the MDAS has been translated into numerous languages such as Spanish, which was used in the study by Reyes-Gilabert et al. (2017) and has good validity and cross-cultural reliability (Coolidge et al., 2010; Giri et al., 2017). Hence, through the utilisation of a validated questionnaire, information bias was kept at a minimum (Bookwala et al., 2011). Indeed, the present researcher made use of tools which have been widely validated and tested for both validity and reliability.

### **2.7.3. Data Analysis**

According to Bookwala et al. (2011), confounding variables in a cohort study may affect the outcome of the results; hence, they should be accounted for. Reyes-Gilabert et al. (2017)

proactively addressed several confounding variables such as age, sex, pain and anxiety-trait with STAI and MDAS. All of these confounding variables were adjusted for during analysis, hence, minimising information bias. Reyes-Gilabert et al. (2017) conducted data analysis using correlation and binary logistic regression where the values were expressed together with 95% CI where values of  $p < 0.05$  were considered significant.

Similarly, Fernandez-Aguilar et al. (2020) conducted data analysis using inferential and descriptive statistics where values of  $p < 0.05$  were considered significant. In addition to sex and age of the patients, different physiological variables such as BP and HR were also taken into consideration.

#### **2.7.4. Results and limitations**

Reyes-Gilabert et al. (2017) depicted that pre-operatively, 30 patients (66.7%) had severe anxiety, with mean anxiety scores of 23.8 (SD=5.2) for males and 24 (SD=6.6) for females. Regarding post-operative pain, patients did not express severe pain in relation to the procedure. Indeed, VAS revealed that 33.3% of patients experienced no pain, where the average score on the VAS was 1.6 (SD=1.8) (minimum=0; maximum=6). Additionally, a significant correlation was depicted between pre-operative and post-operative anxiety and pain score and post-operative anxiety. Indeed, data analysis utilising binary logistic regression for the confounding variables revealed that, post-operative anxiety was related to pre-operative anxiety (OR= 1.3, 95% CI=1.03-1.59) ( $p=0.03$ ). Furthermore, a correlation was found between pain score and postoperative anxiety ( $\rho = -0.035$ ,  $p=0.02$ ). Although statistically significant, results of both cohorts should be construed with caution owing to a small amount of respondents and the absence of a CG.

In the cross-sectional study of Fernandez-Aguilar et al. (2020), pre-operative anxiety was assessed in relation to different parameters where patient's analgesic need was also evaluated.

60% of the participants experienced moderate (20.5%), high (19.5%) or severe (20%) pre-operative anxiety as revealed from the DAS. Moreover, 55.7% of the patients required analgesia post-operatively. Cohen's  $f$  revealed a strong relationship between levels of anxiety and physiological parameters. The DBP and HR before and after the procedure were significantly correlated with levels of anxiety. Similar to Reyes-Gilabert et al. (2017), this study revealed no significance between gender and anxiety.

An important disadvantage of the study by Reyes-Gilabert et al. (2017) is the under representation of males (42.2%). Moreover, both studies made use of one setting, limiting the generalizability of the results. In the study of Reyes-Gilabert et al. (2017), follow-up period was too short and restricted to anxiety before and 1-week following oral surgery. Hence, no consideration was given to the possibility of alteration of the mid-term outcome due to possible complications. Nonetheless, the 1 week follow-up might help to decrease non-responders and memory bias due to the relatively short time.

Areas for improvement were taken into account in the study by Reyes-Gilabert et al. (2017), such as the use of CG to enhance the validity of the results. Furthermore, although all of the studies assessed anxiety through the use of a validated tool, results should be construed with caution as anxiety might be influenced by other factors (ex. anxiolytics). Moreover, the small sample population of Fernandez-Aguilar et al. (2020) was not truly a presentation of the general population as only Caucasian patients were enrolled. Nonetheless, similar to the present study, both studies were ethically approved.

## **2.8. Conclusion**

A detailed description of the literature search was delivered in this chapter, including the use of the PRISMA in locating relevant articles. 52 articles were identified after duplicates were excluded, where 9 key studies met the inclusion criteria. The majority of the articles exposed

that peri-operative anxiety significantly affects the QOR of a patient, including post-operative pain. Furthermore, peri-operative anxiety was more prevalent in females.

# **CHAPTER 3: THE METHOD**

### **3.1. Introduction**

This chapter presents the aims, the methodology, the research setting and research tools utilised in this project.

### **3.2. Aims and Objectives**

The present research study seeks to examine peri-operative anxiety and QOR, including pain levels in adults undergoing an AS. The QOR in terms of comfort, emotions, physical independence and patient support were explored both pre- and post-procedure. Although some international studies have explored peri-operative anxiety, most research is based on in-patients and does not take into account the QOR. Furthermore, there are no local studies to date; hence, this study identified the subsequent objectives:

1. To determine prevalence of anxiety before and after AS, and to determine whether it is associated with post-operative pain;
2. To determine if pre-operative anxiety varies significantly by gender, age, education, previous surgeries, presence of relatives and type of surgery;
3. To identify patients' satisfaction with the pre-operative information using the Amsterdam Pre-operative Anxiety and Information scale (APAIS);
4. To explore patients' QOR in terms of comfort, emotions, physical independence and patient support, before and after AS;
5. To compare the participant's BP, HR and oxygen saturations pre- and post-procedure;
6. To measure patients' subjective pain levels;
7. To identify predictors of post-operative emotions and post-operative comfort.

### **3.3. Rationale for design used**

The design employed in this study was a non-experimental cross-sectional study, as this study aims to examine perceptions of patients undergoing an AS and explores associations between

the various variables and the predictors of post-operative emotions and post-operative comfort. A quantitative design strives to minimise bias by adopting an objective perception (Bloomfield & Fisher, 2019) and although lack of in-depth views is a limitation, a quantitative study was more suitable, due to time limitations and the fact that patients spend only a few hours in the hospital.

As the data collected from a quantitative design can be evaluated using a Statistical Package for Social Science (SPSS), this enabled the researcher to evaluate outcome measures such as anxiety and QOR by various clinical (e.g., type of surgery) and demographic variables (e.g., age). Moreover, this design allows for a large recruitment of participants, enabling a generalisability of results, indeed, 150 participants were initially recruited. Furthermore, direct contact with the participants can be avoided since the data were collected anonymously, which is of importance considering that the researcher works at the day ward where data were collected. Hence, this guarantees the participant's confidentiality and anonymity (Queirós et al., 2017). Furthermore, literature suggests that participants feel more comfortable to express their views if they remain anonymous (Loomis & Paterson, 2018). In the present study, the survey method was utilised, that enabled a great amount of data collection in a relatively short period, increasing generalisability of results (Loomis, & Paterson, 2018).

### **3.4. Theoretical underpinnings**

Literature suggests that before implementing a study, an understanding of the paradigm is important, especially when drawing the research question (Kelly et al., 2018). Quantitative designs are principally dominated by the post-positivist paradigm, which is holistic and quantifies objective things, independent from the context (Davies & Fisher, 2018). Indeed, such paradigms guide a study to improve its value (Halcomb, 2018). Furthermore, paradigms

are crucial in bridging the nursing theory-practice gap and are defined by ontology, epistemology and methodology (Holloway & Galvin, 2016).

In terms of ontology, the post-positivist framework accepts that identifications of reality from the background of that reality can theoretically be imperfect (Welford et al., 2011). The ontology of this paradigm implements the critical realism theory as humans are not in a position to identify reality with their senses (Panhwar et al., 2017). Consequently, results are established from the interaction between the researcher and what is being researched. Regarding epistemology, this framework suggests that knowledge is hypothetical rather than absolute, therefore the centre of research is to make statements and reform or refine such statements, for other more strongly justified statements. As stated before, quantitative methods entail measuring observable phenomena, empirical testing or control, where the researcher and the researched are two separate entities (Weaver & Olson, 2006). An important advantage of this paradigm is that this knowledge is more definite and objective compared to knowledge developed from other paradigms (Scotland, 2012). Since the aims of the study are to appraise peri-operative anxiety and QOR in AS, post-positivism is a valuable underpinning paradigm.

### **3.5. Research setting**

This study was based in the Day ward at Mater Dei Hospital (MDH) where approximately hundred AS are conducted daily (ex. endoscopy, hernias & orthopaedic). All patients currently are requested to attend the day care unit at 7am and then wait until they are called for surgery. During this time, the potential participants were approached and handed an information letter by the intermediary. They were provided with sufficient time to read it and hence come to an informed decision. Those persons who were interested informed the intermediary, following which the intermediary provided them with an envelope containing three questionnaires. The intermediary also documented the values for the participant's BP,



HR and oxygen saturations both pre- and post-operatively on a separate paper where parameters were listed under a participant code to safeguard their confidentiality (APPENDIX E). Such parameters are routine investigations normally conducted within this setting. Moreover, demographic data for example gender, age, education, previous operations and type of surgery were also documented (APPENDIX D).

### **3.6. Target Population**

The target population is defined as the whole group of subjects in which the author is interested, and hence, to whom the results of the study can be applied (Martínez-Mesa et al., 2016). Consequently, a sample of patients undergoing an AS was selected from the target population over a specific time frame. A vigorous study should contain a sufficient number of subjects so that researchers can draw conclusions confidently (Martínez-Mesa et al., 2016). Hence, before calculating sample size for this study, a number of considerations were considered including statistical tests used for data analysis and time-frame. As a result, it was concluded that the target final sample should be between 140-150 patients. Furthermore, the use of software to compute sample size calculation was not possible as the number of operations varied according to the severity of the COVID-19 i.e., number of patients in intensive care.

#### **3.6.1. Inclusion Criteria**

The subsequent inclusion criteria were set for this study:

- Male and female patients who attend for an AS
- Above 18 years of age
- Free from any cognitive impairment that would influence their ability to complete the questionnaires
- Having a good understanding of either Maltese or English

### 3.6.2. Exclusion Criteria

The exclusion criteria include:

- Under 18 years of age
- Patients who did not understand Maltese or English
- Had a cognitive impairment
- Patients who were not going to be discharged on the same day

### 3.7. Research tools

As revealed in literature, there are several advantages associated with self-administered questionnaires. Firstly, they are cheap as no need to hire trained interviewers, consequently minimising interviewer bias. Additionally, they are less energy and time consuming (Hamel, 2011). Hence, such questionnaires can be disseminated in large numbers at one point in time, minimising administrative work and can also ensure anonymity, considering the stigma associated with mental health (Puhan et al., 2011). Moreover, self-administered questionnaires may be less threatening to participants than interviews.

After conducting a literature review on several research instruments available, in addition to consultation with my supervisor, it was decided to utilise two questionnaires and a numerical pain scale. Namely, the tools utilised were:

- The APAIS (Moerman et al., 1996) (APPENDIX A)
- The QoR-40 (Myles et al., 2000) (APPENDIX B)
- The Numerical Rating Pain Scale (NRS) (APPENDIX C)

All of the above tools have been utilised in a selection of studies including AS patients and provide measures for peri-operative anxiety (APAIS), QOR (QoR-40) and post-operative pain (NRS). They are available in the public domain and hence there was no need to obtain permission to utilise. To ensure an accurate translation of the questionnaires, they were first

translated by a qualified language translator into Maltese, in which the translated Maltese versions were then translated back into English by a linguistic professional, to ensure that the translated version was a true reflection of the original version.

### 3.7.1. The Amsterdam Preoperative Anxiety and Information Scale (APAIS)

Literature reveals that several tools are available to compute scores for anxiety including the General Well-Being Questionnaire (Bradley & Gamsu, 1994); the State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1983); and the HADS (Zigmond & Snaith, 1983). Although effective in recognising pre-operative anxiety, such tools are too long, complex and time consuming (Pritchard, 2009). Consequently, Moerman et al. (1996) established the Dutch version of the APAIS, to reveal pre-operative anxiety and the amount of pre-operative information required. The APAIS consists of six statements and measures two domains i.e. pre-operative anxiety and need for information about anaesthesia and surgery. Boker et al. (2002) further developed this tool by translating it into English and splitting question 1 and 2 (Sum A) by being related to anaesthesia and question 4 and 5 (Sum S) by being related to surgical anxiety. The combined sum (Sum A + Sum S) is the total combined anxiety score (Sum C). However, the information element stayed unchanged, that is, a combination of question 3 and question 6. Indeed, Boker et al. (2002) established that the APAIS is a tool that enables the identification of the anxiety component of APAIS (Sum C).

**Table 3.1**

*APAIS subscales [as reported in Boker et al. 2002]*

Subscales	Sum
Anaesthesia-related anxiety	Sum A = question 1 + question 2
Surgery-related anxiety	Sum S = question 4 + question 5
Information desire component	Question 3 + question 6
Combined anxiety component	Sum C = Sum A + Sum S (1+2+4+5)

Participants utilise a 5-point Likert scale ranging from 1 (not at all) to 5 (severely), which is quite straightforward. Then, scores from questions 1, 2, 4 and 5 are combined to identify the participant's level of anxiety, while a combination of questions 3 and 6 reveal the participant's need for information, as revealed in table 3.1. Several advantages are associated with this tool, including its brevity and the wide application in several clinical areas. Being simple, it takes only five minutes to complete, thus ideal in a busy pre-operative setting (Pritchard, 2009).

Moerman et al. (1996) compared the APAIS with the STAI (Spielberger, 1983) in order to develop a cut-off point for sensitivity, specificity and predictive value, by analysing the content and criterion validity. Such analysis concluded that a participant with a sum of 11 or above is suffering from anxiety. This was deemed as a satisfactory equilibrium between false-positive and false-negative results (Pritchard, 2009). Regarding information needs, participants with a score of 2 to 4 are categorised as having little or no information needs, between 5 to 7 as having moderate information needs, while a score of 8-10 is deemed as having high information needs (Moerman et al., 1996).

Several studies highlighted the efficiency of the APAIS, which has been utilised in several pre-operative settings, including in Japan (Nishimori et al., 2002) and in Germany (Berth et al., 2007). This highlights the fact that such a tool can be easily used in different languages, and most importantly that the findings are consistent when related with other anxiety tools (Pritchard, 2009).

### **3.7.2. Quality of Recovery (QoR-40)**

This tool was developed by Myles et al. (2000) to analyse recovery of patients undergoing different surgeries. It is deemed very useful in peri-operative studies, like the present study, in order to assess quality of care (including emotional well-being) after anaesthesia. Initially,

Myles et al. (1999) developed a 61 item questionnaire that evaluated QoR in surgical patients. By time, the most highly ranked dimensions of this questionnaire were incorporated in a final 9 item index score, known as the 'QoR Score.' Although the QoR-Score was valid and reliable, it was concluded that the QoR-40 had superior reliability and validity (Myles et al., 2000). In the study by Myles et al. (2000) most of the participants completed the questionnaire within ten minutes and without any assistance. Hence, this research instrument is deemed suitable for the present study, in order to evaluate patient's post-operative anxiety and pain levels, in a busy setting.

The QoR-40 consists of 40 items with the following domains and the number of corresponding items indicated in brackets: emotional state (n=9), physical comfort (n=12), psychological support (n=7), physical independence (n=5) and pain (n=7) (Myles et al., 2000) (APPENDIX B). In part A of the tool, participants selected from a Likert-scale of 1-5 (1=none of the time, 5=all of the time). For part B of the QoR-40, the scale is reversed (1=all of the time, 5=none of the time).

### **3.7.3. Numerical Pain Scale**

In this study, respondents were additionally requested to rate their post-operative pain using a NRS. Since literature suggests that there is a potential risk of over-rating pain if the NRS is used solely, this tool was used in addition to the QoR-40 (that also has a pain subscale). Indeed, participants were asked to circle the number between zero and ten that best defines their subjective pain, where 0=no pain and 10=severe pain. Several studies have demonstrated the high correlations between the NRS and other pain evaluation tools (Haefeli & Elfering, 2006; Jensen et al., 1986). Furthermore, several studies have additionally proven its feasibility and good compliance (Closs et al., 2004).

### **3.8. Validity and Reliability of the Research tools**

In quantitative studies, an excellent study provides a clear appraisal of the validity and reliability of the tools used, as this will determine the rigour of the study (Heale & Twycross, 2015). Consequently, it was of utmost importance to evaluate validity and reliability of all the tools utilised in this study. All of the tools are well established and have been meticulously assessed for both validity and reliability. Validity (content, construct & criterion) in quantitative research is defined as the degree to which a notion is precisely measured (Heale & Twycross, 2015).

Content validity relates to how accurate the research tool measures completely all the aspects of a concept, while construct validity relates to the degree to which the tool measures the intended concept. On the other hand, criterion validity relates to how much the tool is related to other tools that calculate the same concepts (Heale & Twycross, 2015). Furthermore, criterion validity is defined by convergent, divergent and predictive validity (Korb, 2012). Convergent validity as the name implicates, reveals the extent to which the tool is correlated with other tools calculating the same variables. Conversely, divergent validity reveals that the tool is poorly correlated to other tools that calculate dissimilar variables. Predictive validity indicates that the tool should have good association with prospect variables (Korb, 2012). Additionally, all of the tools were initially discussed with the supervisor for face validity, despite not being the strongest form of validity (Frantz & Holmgren, 2019).

Moreover, reliability of a tool defines how consistent the tool is to measure a specific variable (Heale & Twycross, 2015). An estimation of reliability can be attained through three concepts, i.e. homogeneity, stability and equivalence. Stability is evaluated utilising the test-retest and parallel or alternate-form testing, where during the test-retest the tool is provided to the same participants, in similar conditions, repetitively. On the other hand, homogeneity is also known as internal consistency, and it defines the degree to which all the items on the

research tool calculate one concept while stability refers to the uniformity of results after repetitive testing. Furthermore, equivalence refers to uniformity amongst responses of different users of a research tool. Cronbach's  $\alpha$  is the test most frequently utilised to define the homogeneity of a tool, amongst others, such as Kuder-Richardson coefficient (Shuttleworth, 2015). Cronbach's  $\alpha$  calculates the mean of all correlations in all possible combination of split halves, and the result should be between 0 and 1, with a result of 0.7 or above deemed the most reliable (Shuttleworth, 2015). Indeed, in the present study, the Cronbach alpha values were all above 0.7, demonstrating good internal reliability for all the subscales. Table 3.2 provides details regarding the Cronbach alpha values obtained in the present study.

**Table 3.2**

*Cronbach alpha values of the subscales*

Subscale	Cronbach $\alpha$
APAIS- Anxiety subscale	.94
APAIS- Information subscale	.90
Pre-operative comfort	.87
Pre-operative emotions	.93
Pre-operative physical independence	.89
Pre-operative patient support	.91
Post-operative comfort	.84
Post-operative emotions	.90
Post-operative pain	.79

### 3.8.1. Validity of the APAIS

Regarding validity, the authors of APAIS performed several tests including construct validity and criterion validity (Moerman et al., 1996). Moerman et al. (1996) conducted analyses of the APAIS by comparing it with the STAI, which is used to calculate state and trait anxiety. STAI-STATE measures the participant's tension, calmness and security, which all are rated on a 4-point scale where the larger the number, the higher the anxiety (Spielberger et al., 1983). Utilising STAI-STATE at a score of 46 as a reference point, the specificity, sensitivity and predictive value were also calculated on the anxiety scale, at a cut-off point of 11, which led to a good balance. At a cut-off point of 11, 37 participants are misclassified that is, 18 false-positives and 19 false-negatives with a good predictive value of 71%, as depicted in table 3.3.

**Table 3.3**

*Characteristics of the APAIS at different cut-off points with a score of 46 on the STAI as a reference point (n=200) [as reported by Moerman et al. 1996]*

	Cut-off point at 10	Cut-off point at 11	Cut-off point at 12	Cut-off point at 13
Sensitivity	75.0%	70.3%	59.4%	53.1%
Specificity	78.7%	86.8%	90.4%	97.1%
Positive predictive value	62.3%	71.4%	74.5%	89.5%
Patients, n (%)				
True-positive	48 (24)	45 (22.5)	38 (19)	34 (17)
False-positive	29 (14.5)	18 (9)	13 (6.5)	4 (2)
False-negative	16 (8)	19 (9.5)	26 (13)	30 (15)
True-negative	107 (53.5)	118 (59)	123 (61.5)	132 (66)



Moerman et al. (1996) analysed construct validity of the APAIS utilising factor analysis, which determines the relationship between several factors. As shown in Table 3.4, factor analysis with oblique rotation exposed two factors, anxiety and the need for information, where the correlation between them was 0.31, and this accounted for the 72% of the variance.

**Table 3.4**

*Factor loadings in a two-factor solution [data reported from the study by Moerman et al. 1996]*

	Factor	
	1	2
<b>Anaesthesia</b>		
1. Worried about	0.83	0.03
2. Thinks about it continually	0.86	-0.04
3. Wishes to know as much as possible	0.01	0.87
<b>Surgery</b>		
4. Worried about	0.81	0.03
5. Thinks about it continually	0.85	-0.02
6. Wishes to know as much as possible	-0.01	0.87
Eigenvalue	3.07	1.25
% of variance	51.1	20.8

Additionally, in the study of Moerman et al. (1996) concurrent validity was confirmed by correlation with the STAI, where the correlation between anxiety subscale of APAIS and STAI-STATE was high (0.74), while the correlation between the need for information and STAI-STATE was low (0.16). Furthermore, Boker et al. (2002) evaluated the validity of the English form of the APAIS, where three anxiety tools were compared, namely, the VAS, APAIS and STAI-STATE. Concurrent validity was tested using the Pearson's correlation. Internal validity results for the domains in the study of Boker et al. (2002) were compared to those of Moerman et al. (1996), where a correlation coefficient ( $r$ ) > 0.6 was deemed significant and statistical significance was presumed at the  $p < 0.05$  level. The study of Boker et al. (2002) revealed a positive correlation between total APAIS and VAS and no correlation

between total APAIS and STAI. Furthermore, analysis of the APAIS subscales revealed a positive correlation between total anxiety score of the APAIS and STAI ( $r=0.63$ ), and between total anxiety score of the APAIS and VAS ( $r=0.61$ ). Table 3.5 depicts the correlation coefficients between subscales of APAIS, STAI and VAS.

The findings of the study by Boker et al. (2002) support the former correlation identified between anxiety score on the APAIS and STAI, as conveyed in various studies (Millar et al., 1995; Miller et al., 1999). Consequently, it can be concluded that the APAIS has a good validity with the STAI as depicted in the correlations obtained in several studies [Boker et al., (2002) with  $r=0.64$ ; Moerman et al. (1996) with  $r=0.74$ , and Nishimori et al. (2002) with  $r=0.67$ ]. Additionally, the original Dutch APAIS was translated into several languages, including Spanish (Vergara-Romero et al., 2017), Chinese (Wu et al., 2020) and Japanese (Nishimori et al., 2002).

**Table 3.5**

*Correlation coefficients between the subcomponent of APAIS, STAI, and VAS [as reported in the study of Boker et al. 2002]*

	Sum A	Sum S	Sum C
STAI	0.51	<b>0.60*</b>	<b>0.63*</b>
VAS	0.5	0.56	<b>0.61*</b>
Sum A	/	0.55	<b>0.85*</b>

*N.B: Items in bold demonstrate significance at  $p \leq 0.001$ ; Sum A= Anaesthesia related anxiety, Sum S= surgery-related anxiety, Sum C= combined anxiety component.*

Another study by Berth et al. (2007) revealed how the two original subscales of the APAIS could accurately be replicated by factor analysis, hence, demonstrating construct validity. This study, conducted in 68 pre-operative orthopaedic patients, revealed how the APAIS was correlated with another five questionnaires, namely, the HADS, the short form of the

Symptom checklist (SCL-9-K), the Coping with Surgical Stress Scale (COSS), the State-Anxiety-Questionnaire ‘Cognitive-Autonomic-Somatic Anxiety Symptoms’ (KASA) and the State-Scale of the ‘State-Trait-Operation-Anxiety’ questionnaire (STOA).

Factor analysis of the total APAIS produced 2 factors that explain 83.5% variance (varimax rotation, principal component analysis, eigenvalue >1). Question 1, 2, 4 and 5 of the APAIS loaded between 0.80-0.91 on the anxiety factor and <0.40 on the need for information factor. On the other hand, questions 3 and 6 loaded with 0.88 and 0.93 on the need for information factor and 0.30 and 0.18 on the anxiety factor (Berth et al., 2007). Furthermore, the Spearman coefficient at  $p < 0.01$  of the two subscales (anxiety and need for information) was  $r = 0.59$ . Table 3.6 depicts the Spearman-Rank-correlation coefficients.

**Table 3.6**

*Spearman-Rank-correlation coefficient of the scale anxiety (rho A) and need-for-information (rho I) of the APAIS with the scales of the COSS, SCL-9-K, KASA, STOA and HADS [as reported in the study of Berth et al. 2007]*

Scale (questionnaire)	rho A	rho I	Scale (questionnaire)	rho A	rho I
Information seeking (COSS)	<b>.37**</b>	<b>.55**</b>	Cognitive Anxiety symptoms (KASA)	<b>.78**</b>	<b>.36**</b>
Rumination (COSS)	<b>.67**</b>	<b>.47**</b>	Autonomic Anxiety Symptoms (KASA)	<b>.70**</b>	<b>.36**</b>
Optimism (COSS)	<b>.24*</b>	<b>.28*</b>	Somatic Anxiety Symptoms (KASA)	<b>.41**</b>	.11
Comparison downwards (COSS)	.23	.18	Trait-Anxiety (STOA)	<b>.68**</b>	<b>.36*</b>
Advance one's resources (COSS)	.20	.01	Cognitive State-Anxiety (STOA)	<b>.78**</b>	<b>.33**</b>
Religion (COSS)	.12	.17	Affective State- Anxiety (STOA)	<b>.80**</b>	<b>.32*</b>
Deflection (COSS)	.06	.16	Total Value of State-Anxiety (STOA)	<b>.83**</b>	<b>.36**</b>
Distress (SCL-9-K)	<b>.65**</b>	<b>.28*</b>	Anxiety (HADS)	<b>.64**</b>	<b>.27*</b>

*N.B: Items in bold demonstrate significance at \* $p < 0.05$ ; \*\* $p < 0.01$*

As depicted in table 3.6, the anxiety subscale of the APAIS had a low to average correlation with the coping scale (COSS). Conversely, it had a high correlation with KASA, STOA, HADS and SCL-9-K (Berth et al., 2007). The anxiety scale of the APAIS showed the highest correlation with the State-Anxiety scale of the STOA which examines pre-operative anxiety, where  $\rho=0.83$ . The other subscale (information seeking) had an average correlation with the information scale of COSS ( $\rho=0.55$ ), and a lesser correlation with other anxiety tools including the global psychological distress (SCL-9-K). Additionally, known-groups validity of the APAIS was verified in a study by Bakalaki et al. (2017), where such scale discriminated well between different subgroups of pre-operative surgical patients, depending on the severity of the surgery.

### **3.8.2. Reliability of APAIS**

In a study by Moerman et al. (1996) Cronbach's  $\alpha$  was utilised to calculate internal consistency of the APAIS subscales, where results revealed that the APAIS is a reliable tool despite its brevity. Indeed, Cronbach's  $\alpha$  for the anxiety component was 0.86 while Cronbach's  $\alpha$  for the need for information items was 0.68. Likewise, a study by Bakalaki et al. (2017) revealed excellent internal consistency reliability of the APAIS, as demonstrated by the Cronbach's  $\alpha$ -values: APAIS-anaesthesia ( $\alpha = 0.84$ ), APAIS-surgery ( $\alpha= 0.85$ ).

### **3.8.3. Validity of the QoR-40**

To evaluate the validity of the QoR-40, Myles et al. (2000) performed an analytic study in 160 patients undergoing GA. As there were not any tools to measure QOR prior to the QoR-40, analysis was carried out by comparing it with a 100mm Visual Analogue Scale (VAS). In order to analyse convergent validity, the QoR-40 was compared with the VAS including inter-item correlations. Content validity has been validated in previous studies by Myles et al. (1999). Furthermore, to analyse known-groups validity, the QoR-40 was compared between males and females, as literature suggests that females have a worse QOR (Myles et al., 1997).

Furthermore, the authors calculated the relationship between the QoR-40 and length of stay in the recovery area and the time to complete the questionnaire.

Results in the study of Myles et al. (2000) revealed good convergent validity between the QoR-40 and VAS ( $r = 0.68$ ,  $p < 0.001$ ), and this correlation was stable for all patients after an AS ( $r = 0.76$ ,  $p < 0.0005$ ); major procedure ( $r = 0.72$ ,  $p < 0.0005$ ) and minor procedure ( $r = 0.66$ ,  $p < 0.0005$ ). Additionally, construct validity was also highlighted by a negative correlation between QoR-40 and the length of hospital stay ( $\rho = -0.24$ ,  $p < 0.001$ ). Moreover, results also depicted a negative correlation between the QoR-40 and time to finish the survey ( $\rho = -0.22$ ,  $p < 0.001$ ). Results confirmed the known groups validity of the tool with different QoR-40 mean scores between males and females, where males had higher QoR-40 score (better recovery) (Myles et al., 2000). Furthermore, a systematic review by Gornall et al. (2013) revealed how the QoR-40 demonstrated good validity when translated into different languages such as Arabic (Terkawi et al., 2017), Japanese (Tanaka et al., 2011) and Turkish (Karaman et al., 2014). This meta-analysis included 17 studies where results confirmed the convergent, content and construct validity of the QoR-40 (pooled  $r = 0.58$ , 95% CI: 0.51-0.65) (Gornall et al., 2013).

#### **3.8.4. Reliability of the QoR-40**

Regarding reliability of the QoR-40, in a study by Myles et al. (2000), 160 participants were asked to complete the questionnaire twice, one being later on the same day, to assess for test-retest reliability. Internal consistency was assessed using the median correlation between items within each element and item-to-own element correlation. Additionally, split-half reliability was utilised to assess the correlation between split sections of the QoR-40. Results indicated that test-retest reliability ( $r = 0.92$ ,  $p < 0.0005$ ) and internal consistency ( $\alpha = 0.93$ ) for this tool were excellent. Moreover, the value for the split-half coefficient was 0.83 ( $p < 0.0005$ ). Furthermore, the median element-to-own coefficients and Cronbach's  $\alpha$ -value for every

domain making up the scale were: emotional state ( $r=0.66$ ,  $\alpha=0.82$ ), patient comfort ( $r=0.63$ ,  $\alpha=0.83$ ), psychological support ( $r=0.67$ ,  $\alpha=0.80$ ), physical independence ( $r=0.74$ ,  $\alpha=0.80$ ) and pain ( $r=0.63$ ,  $\alpha=0.77$ ). Every dimension mentioned was internally consistent and had a good correlation with the total QoR-40.

Such results confirm the reliability of this tool as the values of the reliability coefficients surpassed those recommended in publication, which is 0.70 to 0.80 (Kirshner & Guyatt, 1985) highlighting the fact that this tool is reliable for both groups and individual measurements. Similarly, in a study of 114 adult patients (not day case), the QoR-40 was completed pre-operatively, 1 day after surgery and 12 weeks later, where findings revealed that the QoR-40 proved to be a reliable tool with a significant correlation with the SF-36 questionnaire (Guimarães-Pereira et al., 2014). Similarly, Kluivers et al. (2008) have demonstrated the excellent reliability, construct and content validity, with no negative ratings of the QoR-40. Correspondingly, a meta-analysis led by Gornall et al. (2013) confirmed the reliability of this tool, by excellent intra-class correlation (pooled  $\alpha=0.91$ , 95% CI: 0.88–0.93), test-retest reliability (pooled  $r=0.90$ , 95% CI: 0.86–0.92), and inter-rater reliability (intra-class correlation=0.86).

### **3.8.5. Validity of the NRS**

Regarding the NRS, validity was also confirmed in several studies, such as that by Alghadir et al. (2018), which assessed pain management in osteoarthritis of the knee. Validity was assessed using Pearson's correlation between NRS, VAS, verbal rating scale (VRS) and demographic details for instance age, gender, pain and body mass index. Results depicted an excellent correlation between the VAS and NRS ( $r=0.941$ ) and NRS and VRS ( $r=0.925$ ) (Alghadir et al., 2018). Additionally, demographic data were all correlated with the three tools of pain, as shown in table 3.7.

**Table 3.7**

*Correlation of VAS, NRS and VRS with demographic variables [as reported in the study by Alghadir et al. 2018]*

	VAS	NRS	VRS
Age	<b>0.262*</b>	<b>0.224*</b>	<b>0.261*</b>
BMI	<b>0.379**</b>	<b>0.359**</b>	<b>0.399**</b>
Gender	0.071	0.056	0.048
NRS	<b>0.941**</b>	-	
VRS	<b>0.878**</b>	<b>0.925**</b>	-

*N.B: Items in bold demonstrate significance at \*  $p < 0.05$ ; \*\*  $p < 0.001$ ; VAS= visual analogue scale, NRS= numerical rating scale, VRS= verbal rating scale.*

Similarly, in another study conducted by Pathak et al. (2018), 200 adults with muscular pain graded pain utilising four scales, namely, the Faces Pain Scale-Revised (FPS-R), NRS, VRS and VAS. Regarding construct validity, the NRS revealed the highest factor loading, both for maximum pain (0.84) and average pain (0.88) as shown in table 3.8, which depicts results of the principal axis factor for all the scales. Pathak et al. (2018) remarked that the NRS allows the participant to accurately grade pain precisely, hence, the result of the highest factor loading. Through factor analysis, construct validity was confirmed though a confirmation of the domains making up the tool.

**Table 3.8**

*Factor loadings on the first factor of the principal axis factor analyses [as reported in the study of Pathak, Sharma & Jensen. 2018]*

	Maximum pain (n=86)	Average pain (n=68)
VAS	0.78	0.69
NRS	0.84	0.88
VRS	0.83	0.71
FPS-R	0.75	0.74

*NB: VAS= visual analogue scale, NRS= numerical rating scale, VRS= verbal rating scale, FPS-R= Faces Pain Scale-Revised.*



Literature suggests that the NRS has a good validity compared to other pain scales, as revealed in a number of studies (Chanques et al., 2010; Hjermland et al., 2011). Indeed, in a study by Thong et al. (2018), a hundred participants with chronic pain graded pain utilising various tools (i.e., NRS, VAS, VRS and the FPS-R) where the strongest correlation was between the NRS and VAS ( $r= 0.93$ ), which suggests that these two scales measure pain in the same way (table 3.9).

**Table 3.9**

*Pearson's correlation between the tools targeting NRS, VAS and VRS [as reported in the study of Thong et al. 2018]*

	NRS	VAS	VRS
VAS	<b>0.93*</b>	/	/
VRS	<b>0.77*</b>	<b>0.73*</b>	/
FPS-R	<b>0.75*</b>	<b>0.72*</b>	<b>0.69*</b>

*N.B: Items in bold demonstrate significance at  $p < 0.05$ ; NRS= numerical rating scale, VAS=visual analogue scale, VRS= verbal rating scale, FPS-R= faces pain scale-revised.*

Such results are consistent with other studies that state that the association between NRS and VAS is stronger than any correlations with other scales, namely, VRS and FPS-R (Hjermland et al., 2011). Moreover, Thong et al. (2018) state the NRS and VAS are the least affected by non-pain intensity elements compared to VRS and FPS-R.

### **3.8.6. Reliability of the NRS**

Several studies confirmed the reliability of the NRS (Breivik et al., 2000; DeLoach et al., 1998; Good et al., 2001). Alghadir et al. (2018) assessed the reliability of the NRS, in addition to that of the VAS and VRS, during 2 succeeding visits. This was done calculating the intra-class correlation coefficient (ICC) of all the pain assessment tools. ICC results were as indicated in the following brackets: VAS (0.97), NRS (0.95) and VRS (0.93). Also, all of the tools were significantly correlated to age, gender and BMI. This study also revealed the

preference of the elderly population towards NRS over VAS, since it is easier to understand, hence, it was suitable to include in the present study. Similarly, Gallasch and Alexandre (2007) state that the NRS has a better reliability than VRS in the elderly population and less educated participants, even though it correlated highly with the VRS.

### **3.9. Pilot Study**

In the present study, a pilot study was established utilising the same inclusion and exclusion criteria of the main study, to identify any issues that could be improved. Vogel and Draper-Rodi (2017) state that the sample sizes of the pilot study should be 10% of the whole sample; thus, 12 participants were engaged.

During the pilot study, the intermediaries asked the participants questions about the questionnaires, such as, the layout, time to complete them and regarding the coherency of the questions. The majority of the participants stated that the APAIS was pretty straightforward and that the QoR-40 was somewhat longer to complete but the questions were easily understood too. On the whole, most of the patients stated that instructions were clear on the information letter and that they had no difficulty in completing the questionnaires. Since no special concern was shown, the questionnaires were distributed as originally planned.

### **3.10. Ethics**

The WHO (2020) states that every study must be approved by an ethics board to guarantee that ethical principles are adhered to. Indeed, a proposal was submitted to the Ethics committee of the Faculty of Health Science, which provided ethical clearance whilst data protection approval was granted by the Data Protection Officer of MDH. Furthermore, consent from the chief executive officer, nursing officer of day ward, and head of surgery of MDH was also sought. The intermediaries, who were nurses working in Day care, were also contacted, provided with information letter, and requested to indicate their approval to act as

intermediaries. The intermediaries were informed that their participation was entirely voluntary.

Several nursing boards have published ethical guidelines to ensure participants' ethical rights are guaranteed which highlight the four principles: Beneficence, Non-maleficence, Justice and Autonomy (Council for Nurses and Midwives Malta, 2020; Nursing and Midwifery Board of Ireland, 2015). Beneficence aims to do good to the human subjects, including making the society better through research (Wertheimer, 2013). Moreover, non-maleficence aims not to pose any emotional, psychological or physical harm to the participants (Doody & Noonan, 2016). Additionally, a morally justified study ensures that each individual is treated fairly and equitably (Pratt & Loff, 2011). The fourth ethical principle is autonomy, which allows the patients to take their own decisions independently (Doody & Noonan, 2016).

In this study, eligible participants were identified by the intermediaries, and were supplied with an information letter by the intermediaries and not by the present researcher, to avoid any feelings of coercion, thus ensuring that patients could take an autonomous decision. The information letter stated clearly the objectives and the possible benefits of this study (beneficence). This letter explained that participation is entirely voluntarily and that they can withdraw from the project at any time, without any explanation, hence, ensuring autonomy of the subjects (WHO, 2020). Moreover, it was emphasised that should they decide to withdraw, quality of care will not be affected. Furthermore, contact particulars of both the present author and the supervisor were supplied if they required more detailed information.

Furthermore, there was the possibility of psychological distress, hence; participants were informed that the provision of a psychologist was accessible at no financial cost. If patients experienced any distress, they were to inform the researcher who would then make the

necessary arrangements for referral to the psychological support unit. However, none of the participants requested psychological support.

In this study, a written consent form was not necessary since patients answered the questionnaires anonymously where participants were informed that completion of the questionnaires implied automatic consent. Moreover, the researcher had the responsibility to ensure that data collection must not lead to any type of identification, hence, respecting patient's confidentiality (Doody & Noonan, 2016). This was ensured as no personal identifying details were collected and instead participants were assigned a code. Patients were also informed that a hard copy would be available at the UOM.

### **3.11. Data Analysis**

The first step in data analysis was the tabulation of quantitative data into Excel, which was further analysed using the SPSS. Computations included categorical data such as pre-operative anxiety by gender and age amongst others. Furthermore, Cramer's V was utilised to measure the strength of the association between two categorical variables or more, while the Shapiro-Wilk test was utilised to evaluate the distribution of the data (skewed), therefore, non-parametric tests were utilised. Subsequently, the Spearman's correlation test was utilised to analyse inter-correlations between the different subscales of the questionnaires while the Mann-Whitney test was utilised to scrutinise by gender and type of surgery. Conversely, the Kruskal-Wallis test was utilised to analyse data by age and education. Subsequently, the Post hoc Mann Whitney test was used to identify any significant relationships resulting from these analyses. A regression analysis was conducted to predict post-operative emotions and post-operative comfort utilising the ANCOVA regression model since the predictors consisted of both of covariates and categorical variables and the distribution of the dependent variables was skewed. Consequently, the parsimonious model was utilised.

### **3.12. Conclusion**

The objective of this chapter was to give an insight of the methodology used to assess anxiety and QOR in AS patients in relation to several variables, such as demographics and physiological parameters. Consequently, two questionnaires and a pain assessment tool were utilised for data collection.

## **CHAPTER 4: FINDINGS**

## **4.1. Introduction**

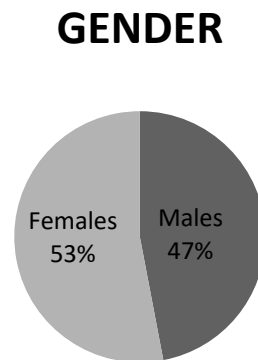
Chapter 4 presents analyses of the findings where subsequently data processing was done using the SPSS. Section 4.2 provides an account of the demographic features of the participants while section 4.3 presents participant's responses on the pre-and post-operative surveys. Consequently, sections 4.5 and 4.6 present an analysis of such findings by gender, age, education, previous operations, presence of relatives and type of surgery. Additionally, section 4.7 presents the physiological parameters while section 4.8 evaluates any inter correlations between different subscales of the questionnaires. Finally, section 4.9 presents regression analyses for two outcome measures.

## **4.2. Response rate and Demographic data**

150 questionnaires were distributed amongst AS patients between the months of July 2020 till October 2020, where 136 questionnaires were returned, yielding a response rate of 90.7%. Participants had the choice to either fill in the English (n=64) or Maltese version (n=72), to maximise response rate. The succeeding subsections present information regarding the demographic features of the sample by gender, age, education, previous operations, presence of relatives and type of surgery.

### **4.2.1. Gender of participants**

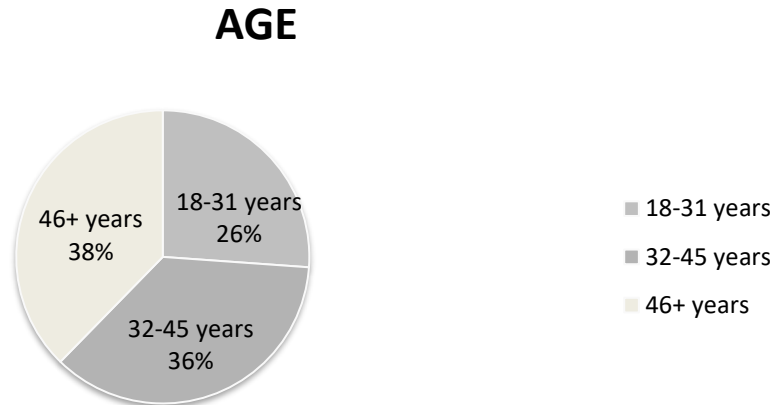
The majority of participants in this study were females (n=72, 53%), as portrayed in the following pie chart (Figure 4.1).

**Figure 4.1***Percentage of participants by gender*

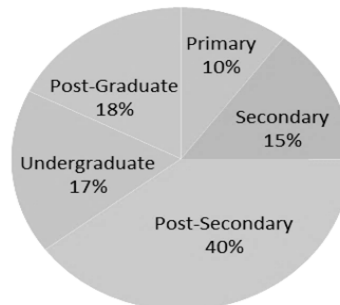
#### 4.2.2. Age of participants

Respondents were provided with the following seven age categories i.e.; 18-24 years, 25-31, 32-38, 39-45, 46-52, 53-59 and above 60 years. However, since the number of respondents in the first two categories (aged between 18-31 years) and the last three categories (aged between 46+ years) were small, the researcher decided to amalgamate various sections together for data analysis purposes, yielding 3 categories (i.e., 18-31 years; 32-45 years and 46+ years). This decision enabled the researcher to conduct various statistical tests by age due to a sufficient amount of respondents in every group. The modal group for age category was that of 46+ years, with 51 respondents (37.5%). Subsequently, there were 49 participants in the 32-45 (36%) age bracket and 36 participants in the 18-31 age bracket (26%). The least number of respondents was in the youngest age range i.e., 18-31 years as depicted in figure 4.2.

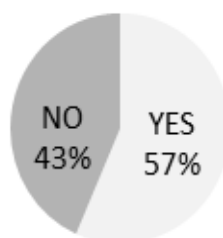


**Figure 4.2***Percentage of respondents by age category***4.2.3. Educational level of participants**

Initially, eight educational levels were included, i.e., primary, secondary, post-secondary, diploma, bachelors, masters, Ph.D. and others. To facilitate data analysis, these were reduced to the following five: primary, secondary, post-secondary (including diploma), undergraduate (bachelors) and post-graduate (e.g., masters, Ph.D). The modal group was that of a post-secondary education (n=54, 40%) followed by the following categories: undergraduate (n=24, 17%), post-graduate (n=24, 18%), secondary (n=20, 15%) and primary (n=14, 10%). as depicted in figure 4.3.

**Figure 4.3***Percentage of respondents by education***EDUCATIONAL LEVEL****4.2.4. Previous history of surgical operations**

Participants were additionally asked whether they did a previous surgery, to evaluate the link between levels of peri-operative anxiety and previous operations. The majority of the participants (n=73, 54%) had undergone surgery, while 41% (n=56) of the respondents did not. Seven participants did not answer this question. Figure 4.4 presents the proportion of respondents who had undergone surgery compared to those who did not.

**Figure 4.4***Percentage of respondents with or without a surgical history [responses relate to the number who responded to this question]***SURGICAL HISTORY**

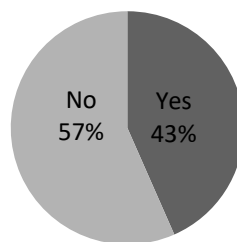
#### 4.2.5. Presence of relatives

Respondents in this study were also asked whether some relatives accompanied them to the hospital to analyse any relationship between presence of relatives and levels of anxiety. The majority of the participants (56.6%) were not accompanied by any relatives (n=77). However, this should be interpreted with caution as due to COVID restrictions, during the months of September and October, no relatives were allowed in MDH. 43.4% of the respondents were accompanied by relatives (n=59) as presented in figure 4.5.

**Figure 4.5**

*Percentage of participants either accompanied or not accompanied by relatives*

#### ACCOMPANIED BY RELATIVES



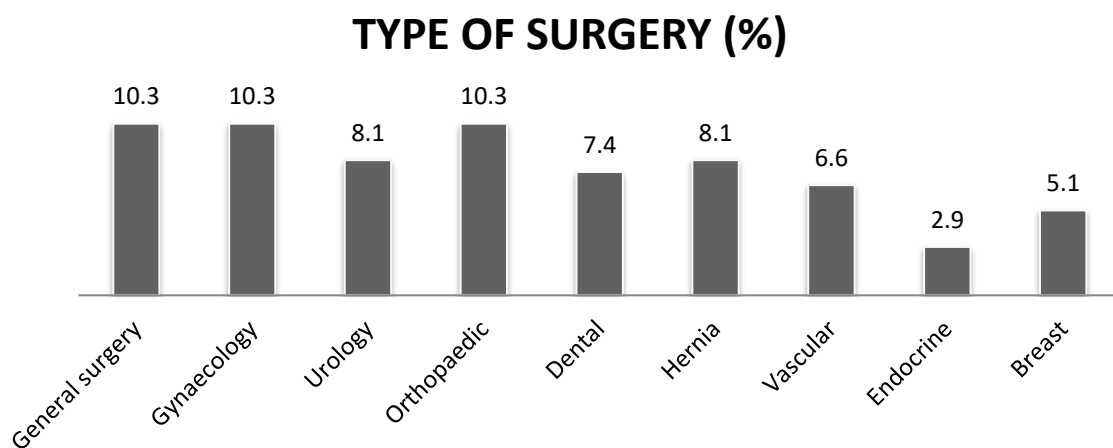
#### 4.2.6. Type of Surgery

Participants were furthermore requested to specify the type of surgery for which they attended the day clinic. Initially, ten different categories were included: endoscopy, general surgery (ex. appendectomy and haemorrhoidectomy), gynaecology, urology, orthopaedic, dental, hernia, vascular, endocrine and breast. Due to the vast range, such categories were ultimately divided into two, depending on the type of sedation provided namely: mild sedation (e.g., endoscopy) and GA (e.g., general surgery, gynaecology, urology, orthopaedic, dental, hernia, vascular, endocrine and breast). The majority of the respondents had GA (n=94, 69%) while 31% of the participants had a mild sedation procedure (n= 42). Such a

question was included to examine any link between type of surgery/anaesthesia and levels of peri-operative anxiety and QOR, including pain. Figure 4.6 reveals the percentage of different type of surgeries, while figure 4.7 presents the percentage of respondents who had mild sedation compared to GA.

**Figure 4.6**

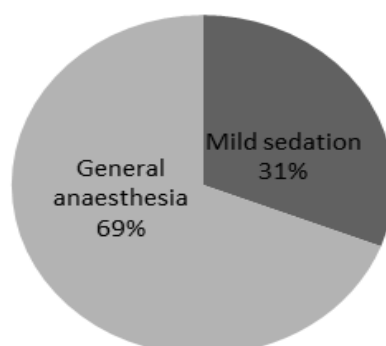
*Different types of surgeries (%)*



**Figure 4.7**

*Percentage of participants requiring Mild sedation vs. General Anaesthesia*

**TYPE OF ANAESTHESIA**



The subsequent section depicts information about participant responses on the APAIS, QoR-40 and NRS.

### 4.3. Participant responses on the Pre-and Post-Operative Surveys

Respondents were requested to fill the APAIS and part A of the QoR-40 pre-operatively, using a 5-point Likert-scale, 1 being the minimum and 5 being the maximum score. These pre-operative statements (n=24) and the percentages responses, are presented in table 4.1. Subsequently, part B of the QoR-40 and the NRS were filled post-operatively, as shown in table 4.2 (n=23 statements). For part B of the QoR-40, the number scale is reversed, hence, 1 is the maximum and 5 is the minimum score.

The APAIS assessed the participant's anxiety levels and information needs pre-operatively, while part A of the QoR-40 assessed the comfort, emotions, physical independence and patient support pre-operatively. Similarly, part B assessed the patient's level of comfort, emotions, patient support and pain levels post-operatively. Tables 4.1 and 4.2 present the participant's responses on the pre-operative and post-operative survey respectively, while table 4.3 presents the post-operative participant's responses on the NRS.

Pre-operatively, as depicted in table 4.1, the majority of the patients (25%) scored 5 on the 5 point-Likert scale, expressing severe levels of anxiety in relation to the anaesthetic, while in relation to surgery-anxiety, the majority of the participants (29.4%) also scored 5 on the Likert-scale (maximum score). Regarding pre-operative information needs, about both the anaesthetic and surgery, most of the patients did not desire a lot of information, with the majority scoring 2 on the 5 point-Likert scale (28.7%). Additionally, regarding pre-operative comfort measured by the QoR-40, for all the statements of this domain, the participants rated the maximum score (5), expressing good pre-operative comfort. In terms of general well-being, the majority of the respondents (35.3%) felt emotionally stable for all of the time. Moreover, regarding sense of control, the majority (30.1%) scored 4 on the Likert-scale, expressing good sense of control for most of the time. Regarding physical independence, for all the domains, the majority scored the maximum score, expressing good physical

independence. Also, the majority of the respondents (59%) felt they were able to communicate with the staff for all of the time before surgery, expressing most support for all of the time from doctors (49%), followed by nurses (42%) and least by family (40%). Lastly, the majority of the participants (36%) stated that they were able to understand instructions for all of the time before surgery.

**Table 4.1***Participants' responses on the pre-operative surveys*

Pre-operative Statement	Mean (SD)	None of the time 1 (%)	Some of the time 2 (%)	Usually 3 (%)	Most of the time 4 (%)	All of the time 5 (%)
<b>Amsterdam scale</b>						
I am worried about the anaesthetic	3.26(1.34)	10.3	22.8	22.1	19.9	25
The anaesthetic is on my mind continually	2.96(1.37)	16.9	24.3	24.3	14.7	19.9
I would like to know as much as possible about the anaesthetic	2.88(1.40)	19.1	28.7	16.2	17.6	18.4
I am worried about the procedure	3.50 (1.25)	3.7	25	18.4	23.5	29.4
The procedure is on my mind continually	3.34 (1.36)	11	21.3	16.9	24.3	26.5
I would like to know as much as possible about the procedure	2.88 (1.39)	18.4	28.7	17.6	16.9	18.4
<b>QoR-40</b>						
<b>Comfort:</b> Able to breathe easy	4.62 (.67)	0.7	1	5.9	23.5	68.9
Had a good sleep	4.23 (.89)	0.7	5.1	11	36.8	46.3
Been able to enjoy food	4.29 (1.06)	4.4	3.7	8.1	25.7	58.1
Feel rested	4.03 (.95)	0.7	5.1	23.5	31.6	39
<b>Emotions:</b> Having a feeling of general well-being	3.90 (1.03)	0.7	10.3	22.1	31.6	35.3
Feeling in control	3.74 (1.03)	0.7	11.8	28.7	30.1	28.7
Feeling comfortable	3.77 (.99)	0.7	9.6	30.1	30.9	28.7

<b>Physical Independence:</b> Have a normal speech	4.88 (.53)	1.5	0	0	5.9	92.6
Able to wash, brush teeth or shave	4.82 (.65)	1.5	1.5	0	15.4	81.6
Able to look after own appearance	4.76 (.63)	1.5	0	1.5	15.4	81.6
Able to write	4.77 (.68)	1.5	0	5.1	6.6	86.8
Able to return to work or usual activities	4.57 (.79)	1.5	0.7	7.4	20.6	69.9
<b>Patient support:</b> Able to communicate with hospital staff	4.37 (.88)	0.7	2.9	13.2	24.3	58.8
Able to communicate with family or friends	4.18 (1.02)	2.2	5.1	15.4	26.5	50.7
Getting support from hospital doctors	4.30 (.82)	0.7	2.2	11.8	36.8	48.5
Getting support from hospital nurses	4.21 (.83)	0.7	2.9	12.5	41.9	41.9
Having support from family or friends	3.94 (1.13)	3.7	9.6	16.2	30.1	40.4
Able to understand instructions or advice	3.83 (1.07)	0.7	11	28.7	23.5	36

*N.B: Minimum score =1; maximum score =5; scale midpoint=3.*



Post-operatively, as demonstrated in table 4.2, most of the patients did not suffer from nausea (46%), vomiting (57%) and dry-retching (73%) in terms of comfort. Similarly, most of the patients did not suffer from post-operative restlessness (63%) or twitching (85%). However, the majority of the participants (38%) suffered from post-operative anxiety for some of the time, followed by 27% of the participants that usually felt anxious. Moreover, 14% of the participants suffered from severe anxiety, scoring either 1 or 2 on the Likert-scale. The majority of the participants (63%) did not feel alone post-operatively, however, 25% of the participants felt alone for some of the time. Indeed, 28% of the participants had bad dreams for some of the time after surgery. Furthermore, the majority of the participants (46%) felt confused for some of the time after surgery. Regarding post-operative pain according to the QoR-40, the majority of the patients (57%) suffered from moderate pain for some of the time. Additionally, most of the participants (70%) did not suffer from sore throat or sore mouth post-operatively.

**Table 4.2***Participants' responses on the post-operative survey*

Post-operative Statement	Mean (SD)	All of the time	Most of the time	Usually	Some of the time	None of the time
		1 (%)	2 (%)	3 (%)	4 (%)	5 (%)
<b>QoR-40</b>						
<b>Comfort:</b> Nausea	4.18(.93)	0	7.4	14	32.4	46.3
Vomiting	4.35(.90)	0	6.6	8.8	27.2	57.4
Dry-retching	4.60(.75)	0	3.7	5.1	18.4	72.8
Feeling restless	4.46(.83)	0.7	2.9	8.8	25	62.5
Shaking or twitching	4.80(.50)	0	0	4.4	11	84.6
Shivering	4.74(.53)	0	0	4.4	17.6	77.9
Feeling too cold	4.47(.66)	0	0	8.8	35.3	55.9
Feeling dizzy	4.49(.62)	0	0	6.6	38.2	55.1
<b>Emotions:</b> Had bad dreams	4.18(.94)	0	6.6	16.9	27.9	48.5
Feeling anxious	3.65(1.03)	2.9	11	26.5	37.5	22.1
Feeling angry	4.37(.82)	0	3.7	10.3	30.9	55.1
Feeling depressed	4.31(.92)	0.7	5.9	8.8	30.9	53.7
Feeling alone	4.46(.83)	0.7	2.9	8.8	25	62.5
Had difficulty with sleeping	4.19(.94)	0	8.1	11.8	33.1	47.1
<b>Patient support:</b> Feeling confused	4.15(.80)	0.7	1.5	16.2	45.6	36

<b>QoR-40 Pain:</b> Moderate pain	4.24(.63)	0	0.7	8.1	57.4	33.8
Severe pain	4.51(.59)	0	0	4.4	40.4	55.1
Headache	4.56(.59)	0	0	5.1	33.8	61
Muscle pains	4.74(.58)	0	0	6.6	13.2	80.1
Backache	4.60(.77)	0.7	1.5	8.8	15.4	73.5
Sore throat	4.60(.72)	0.7	1.5	5.1	22.8	69.9
Sore mouth	4.64(.62)	0	1.5	2.9	25.7	69.9

*N.B: Minimum score =5; maximum score =1; scale midpoint=3*

Additionally, on the NRS (Table 4.3), most of the patients (31%) rated their post-operative pain as 6, where 0 was the least and 10 was the worst possible pain. None of the participants rated their pain as a 9 or 10.

**Table 4.3**

*Participants' responses on the numerical pain scale*

Numerical pain scale	Mean (SD)	0 (%)	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	6 (%)	7 (%)	8 (%)	9 (%)	10 (%)
	4.71 (1.94)	6.6	1.5	5.1	8.1	16.9	19.1	30.9	8.1	3.7	0	0

*N.B: Minimum score=0, maximum score=10.*

#### 4.4. Normality testing

To decide whether to utilise parametric or non-parametric tests for data analysis, normality tests were conducted. The Shapiro-Wilk test was utilised to determine if data is either skewed or of normal distribution. Such a test was preferred to the Kolmogorov-Smirnov test, as it is more powerful (González-Estrada & Cosmes, 2019). Since the data obtained from the questionnaires varied significantly from a normal distribution and was skewed, non-parametric tests were used, for instance the Mann Whitney test and Spearman's rho for inferential and correlational analysis respectively. The following tables present the results of normality testing for both the pre-operative (Table 4.4) and post-operative surveys (Table 4.5).

**Table 4.4***Test of Normality for pre-operative statements*

Statements in the Pre-operative survey	Statistic	Significance
<b>Amsterdam score</b>		
I am worried about the anaesthetic	.891	<.001
The anaesthetic is on my mind continually	.893	<.001
I would like to know as much as possible about the anaesthetic	.882	<.001
I am worried about the procedure	.868	<.001
The procedure is on my mind continually	.881	<.001
I would like to know as much as possible about the procedure	.885	<.001
<b>QoR-40: Comfort</b>		
Able to breathe easily	.609	<.001
Have had a good sleep	.781	<.001
Been able to enjoy food	.690	<.001
Feel rested	.837	<.001
<b>QoR-40: Emotions</b>		
Having a feeling of general well-being	.853	<.001
Feeling in control	.876	<.001
Feeling comfortable	.874	<.001
<b>QoR-40: Physical independence</b>		
Have normal speech	.228	<.001
Able to wash, brush teeth or shave	.313	<.001
Able to look after own appearance	.428	<.001
Able to write	.384	<.001
Able to return to work or usual home activities	.604	<.001
<b>QoR-40: Patient support</b>		
Able to communicate with hospital staff	.722	<.001
Able to communicate with family or friends	.773	<.001
Getting support from hospital doctors (when in hospital)	.771	<.001
Getting support from hospital nurses (when in hospital)	.796	<.001
Getting support from family or friends	.826	<.001
Able to understand instructions and advice	.852	<.001

**Table 4.5***Test of Normality for post-operative statements*

Statements in the post-operative survey	Statistic	Significance
<b>QoR-40: Comfort</b>		
Nausea	.791	<.001
Vomiting	.717	<.001
Dry-retching	.582	<.001
Feeling restless	.684	<.001
Shaking or twitching	.443	<.001
Shivering	.537	<.001
Feeling too cold	.723	<.001
Feeling dizzy	.719	<.001
<b>QoR-40: Emotions</b>		
Had bad dreams	.787	<.001
Feeling anxious	.888	<.001
Feeling angry	.738	<.001
Feeling depressed	.740	<.001
Feeling alone	.684	<.001
Had difficulty falling asleep	.780	<.001
<b>QoR-40: Patient support</b>		
Feeling confused	.815	<.001
<b>QoR-40: Pain</b>		
Moderate pain	.766	<.001
Severe pain	.707	<.001
Headache	.685	<.001
Muscle pains	.507	<.001
Backache	.585	<.001
Sore throat	.606	<.001
Sore mouth	.609	<.001
<b>Numerical pain score 0-10</b>	.904	<.001

Table 4.6 presents the normality test results for data relating to physiological parameters, namely, the BP, HR and oxygen saturations which were taken both before and after surgery.

**Table 4.6***Test of Normality for physiological parameters*

Physiological parameters	Statistic	Significance
Pre- operative systole	.974	.011
Pre-operative diastole	.980	.042
Post-operative systole	.962	.001
Post-operative diastole	.969	.004
Pre-operative heart rate	.962	.001
Post-operative heart rate	.975	.014
Pre-operative oxygen saturations	.846	.000
Post- operative oxygen saturations	.757	<.001

The following section, i.e. section 4.5 presents the participants' responses to the pre-operative survey.

#### **4.5. Participant responses by demographic features on the Pre-operative survey**

In the next subsections, participant's answers on the pre-operative survey are analysed by gender, age, education, previous operations, presence of relatives and type of surgery. The patient's responses were assembled from participant responses on the Pre-operative survey, which consisted of the APAIS and part A of the QoR-40.

##### **4.5.1. Participant responses on the Pre-operative survey by gender**

Table 4.6 depicts the participant's responses on the pre-operative survey which were subsequently evaluated utilising the Mann Whitney test to identify if significant differences exist by gender. Indeed, several significant differences were acknowledged. A significant difference was obtained on the APAIS, where females experienced higher pre-operative anxiety compared to males ( $U=1613$ ,  $z=-3.02$ ,  $p<.001$ ). Additionally, for the emotions and comfort subscales, males scored significantly higher scores. Hence, males were more comfortable before the surgery ( $U=1715.5$ ,  $z=-2.62$ ,  $p=.01$ ) and had a better general well-

being and feelings of control ( $U=1445$ ,  $z=-3.79$ ,  $p<.001$ ) compared to females. Moreover, males also scored significantly higher than females for the physical independence subscale ( $U=1863$ ,  $z=-2.20$ ,  $p=.03$ ). As depicted in table 4.7, no statistical significance was identified by gender for the QOR subscale i.e. patient support.

**Table 4.7**

*Participants' responses on the Pre-operative survey by gender*

Questionnaire domains	Gender	Mean Rank	Mann Whitney U	W	Z	p
<b>Amsterdam score</b>	<b>Male</b>	<b>57.10</b>	<b>1613.000</b>	<b>3693.000</b>	<b>-3.02</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>78.10</b>				
<b>Comfort (QoR-40)</b>	<b>Male</b>	<b>77.70</b>	<b>1715.500</b>	<b>4343.500</b>	<b>-2.62</b>	<b>.01</b>
	<b>Female</b>	<b>60.33</b>				
<b>Emotions (QoR-40)</b>	<b>Male</b>	<b>81.92</b>	<b>1445.000</b>	<b>4073.000</b>	<b>-3.79</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>56.57</b>				
<b>Physical independence (QoR-40)</b>	<b>Male</b>	<b>75.39</b>	<b>1863.000</b>	<b>4491.000</b>	<b>-2.20</b>	<b>.03</b>
	<b>Female</b>	<b>62.38</b>				
Patient support (QoR-40)	Male	73.39	1991.000	4619.000	-1.36	.17
	Female	64.15				

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .*

#### 4.5.2. Participant responses on the Pre-operative survey by age range

Table 4.8 depicts the results for participant's responses on the pre-operative survey by age range. As described before, age ranges were amalgamated into three age brackets i.e., 18-31 years (presented as '1' in Table 4.8), 32-45 years (presented as '2' in Table 4.8) and 46+ years (presented as '3' in Table 4.8). As shown in table 4.8, statistical significance was depicted in APAIS and physical independence subscales through the use of the Kruskal-



Wallis test. The Kruskal-Wallis test was utilised as two or more groups of an independent variable on an ordinal dependent variable was used (Fan & Zhang, 2012).

Patients aged between 32-45 years experienced the highest levels of anxiety and the highest levels of need for information according to the Amsterdam scale ( $H=7.19$ ,  $p=.03$ ). Post hoc analysis indicated a significant difference on the APAIS between participants aged 32-45 years and those aged 46+ ( $p=.03$ ), with the latter having the lowest levels of anxiety and information needs pre-operatively. Hence, older patients experienced lower levels of pre-operative anxiety and required less information pre-operatively, compared to younger patients. Moreover, patients aged 18-31 years had higher level of pre-operative physical independence ( $H=7.23$ ,  $p=.02$ ) unlike those aged 46 years and above, where post hoc analysis revealed a statistic significance for this domain between participants aged between 18-31 years and those aged 46+ years ( $p=.006$ ).

**Table 4.8**

*Participants' responses on the Pre-operative survey by age range*

Questionnaire domains	Age range	Mean rank	Chi-square	df	P
<b>Amsterdam score</b>	<b>1</b>	<b>72.90</b>	<b>7.190</b>	<b>2</b>	<b>.03</b>
	<b>2</b>	<b>76.67</b>			
	<b>3</b>	<b>57.54</b>			
Comfort (QoR-40)	1	71.18	1.272	2	.53
	2	68.00			
	3	67.09			
Emotions (QoR-40)	1	67.76	0.332	2	.85
	2	67.56			
	3	69.92			
<b>Physical independence (QoR-40)</b>	<b>1</b>	<b>78.96</b>	<b>7.230</b>	<b>2</b>	<b>.02</b>
	<b>2</b>	<b>71.15</b>			
	<b>3</b>	<b>58.57</b>			
Patient Support (QoR-40)	1	70.56	1.258	2	.53
	2	63.81			
	3	71.56			

*N.B: Age range: 1 =18-31 years; 2=32-45 years, 3= 46+ years and older; Items in bold demonstrate significance at  $p\leq .05$ .*

### 4.5.3 Participant responses on the Pre-operative survey by educational level

Table 4.9 portrays the results obtained from the participants' responses on the pre-operative survey by education where the Kruskal-Wallis test was utilised to determine significance. As depicted in table 4.9, no significant differences were detected on participant's responses by educational level on the pre-operative survey.

**Table 4.9**

*Participants' responses on the Pre-operative survey by education*

Questionnaire domains	Education Collated	N	Mean rank	Chi-square	p
Amsterdam Score	Primary	14	48.57	5.35	.24
	Secondary	20	66.08		
	Post-secondary	54	72.17		
	Undergraduate	24	76.79		
	Post-graduate	24	65.60		
Comfort (QoR-40)	Primary	14	69.14	6.58	.16
	Secondary	20	71.78		
	Post-secondary	54	73.49		
	Undergraduate	24	50.35		
	Post-graduate	24	72.31		
Emotions (QoR-40)	Primary	14	66.57	5.23	.27
	Secondary	20	72.68		
	Post-secondary	54	64.37		
	Undergraduate	24	60.75		
	Post-graduate	24	83.19		
Physical independence (QoR-40)	Primary	14	74.21	8.18	.09
	Secondary	20	53.75		
	Post-secondary	54	64.93		
	Undergraduate	24	80.81		
	Post-graduate	24	73.19		
Patient support (QoR-40)	Primary	14	63.50	3.67	.45
	Secondary	20	71.45		
	Post-secondary	54	65.30		
	Undergraduate	24	63.40		
	Post-graduate	24	81.27		

#### 4.5.4. Participant responses on the Pre-operative survey by surgical history

Table 4.10 portrays the participant's responses on the pre-operative survey compared to surgical history with the '1' in Table 4.10 representing a 'yes' response, indicating that they had previously undergone an operation and '2' is no, indicating no previous surgery. As stated previously, seven participants did not respond to this question, hence, the number of responses to this statement amount to 129 participants. As depicted in Table 4.10, there is no statistical significance between the participant's responses on the pre-operative questionnaire by surgical history.

**Table 4.10**

*Participants' responses on the Pre-operative survey by surgical history*

Questionnaire domains	Previous operations	Mean rank	Mann-Whitney U	W	Z	p
Amsterdam score	1	65.25	2026.000	3622.000	-0.02	.16
	2	64.68				
Comfort (QoR-40)	1	63.34	1923.000	4624.000	-0.15	.14
	2	67.16				
Emotions (QoR-40)	1	64.74	2025.000	4726.000	-0.03	.31
	2	65.34				
Physical independence (QoR-40)	1	65.68	1994.500	3590.500	-0.05	.16
	2	64.12				
Patient support	1	63.59	1941.000	4642.000	-0.08	.10
	2	66.84				

#### 4.5.5. Participant's responses on the Pre-operative survey by presence of relatives

Study participants were also asked whether they were accompanied by relatives. Table 4.11 presents the results of the participant's responses in relation to presence of relatives where '1'

is a yes and '2' is a no. As depicted in the table, a statistical significance ( $p=.01$ ) was identified between emotions of the patients before the operation and presence of relatives. Such finding suggests that pre-operatively patients have a better general well-being when accompanied by a relative.

**Table 4.11**

*The participants' responses on the Pre-operative survey by presence of relatives*

Questionnaire domains	Presence of relatives	Mean rank	Mann-Whitney U	W	z	p
Amsterdam score	1	62.81	1936.000	3706.000	-1.36	.17
	2	72.03				
Comfort (QoR-40)	1	65.71	2018.000	4077.000	-1.29	.38
	2	69.78				
<b>Emotions (QoR-40)</b>	<b>1</b>	<b>77.63</b>	<b>1673.670</b>	<b>4599.670</b>	<b>-2.63</b>	<b>.01</b>
	<b>2</b>	<b>60.52</b>				
Physical independence (QoR-40)	1	66.51	2096.900	4329.100	-1.04	.35
	2	69.15				
Patient support	1	75.85	1778.92	4704.92	-2.22	.13
	2	62				

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .*

#### **4.5.6. Participant's responses on the Pre-operative survey and type of surgery**

Different types of surgeries were collated into two categories i.e., mild sedation (endoscopy) which is presented as '1' in table 4.11, and GA (listed as '2' in the table). Table 4.12 presents the participants responses on the pre-operative survey in relation to different type of surgeries, namely, sedation or GA, which reveals no statistical significance.

**Table 4.12***The participants' responses on the Pre-operative survey by type of surgery*

Questionnaire domains	Type of surgery	Mean rank	Mann Whitney U	W	z	p
Amsterdam score	1	60.88	1654.000	2557.000	-1.51	.13
	2	71.90				
Comfort (QoR-40)	1	69.00	1953.000	6418.000	-0.10	.92
	2	68.28				
Emotions (QoR-40)	1	67.82	1945.500	2848.500	-0.14	.89
	2	68.80				
Physical independence (QoR-40)	1	68.10	1957.000	2860.000	-0.09	.93
	2	68.68				
Patient support	1	69.55	1930.000	6395.000	-0.21	.84
	2	68.03				

The next subsection presents a summary of the statistical significance identified on the pre-operative survey in relation to various variables.

#### **4.5.7. Summary of the participant's responses on the Pre-operative survey**

Statistical significance was identified on the pre-operative survey in terms of gender, age and presence of relatives. Females suffered from higher levels of pre-operative anxiety and information needs, while males had a better emotional well-being, levels of comfort and feeling of control pre-operatively. In terms of age, patients aged between 32-45 years experienced the highest levels of pre-operative anxiety and the highest levels of need for information according to the APAIS. Additionally, patients who were accompanied by a relative pre-operatively had a better general well-being and sense of control in comparison to those not accompanied. Conversely, no statistical significance was identified for participant responses by the pre-operative survey in terms of education, previous surgical history or type of surgery.

The subsequent sections present the participant's responses on the post-operative survey.

#### 4.6. Participant responses by demographic variables on the Post-operative survey

In the subsequent subsections, participant answers on the post-operative survey were analysed by gender, age, education, previous operations, presence of relatives and type of surgery. The participant responses were amalgamated from the post-operative questionnaire which was completed after surgery, while waiting for discharge.

##### 4.6.1. Participant responses on the Post-operative survey by gender

Table 4.13 presents the participant's responses on the post-operative survey in relation to the gender of the respondents. Statistically significant differences by gender on all the subscales of the post-operative survey were identified. Post-operatively, males were more comfortable ( $U=1248.500$ ,  $z=-4.66$ ,  $p<.001$ ), had a better general well-being ( $U=1083.000$ ,  $z=-5.36$ ,  $p<.001$ ) better patient support ( $U=1450.500$ ,  $z=-4.03$ ,  $p<.001$ ) and experienced less pain compared to females. Indeed, on the NRS, females scored significantly higher ( $U=1630.500$ ,  $z=-3.0$ ,  $p<.001$ ) compared to males and consequently scored lower on the pain subscale of the QoR-40 ( $U=1522$ ,  $z=-3.45$ ,  $p<.001$ ). A low rating on the pain subscale of the QoR-40 signifies higher levels of pain.

**Table 4.13**

*The responses of participants on the Post-operative survey by gender*

Questionnaire domains	Gender	Mean Rank	Mann Whitney U	W	Z	p
Comfort	<b>Male</b>	<b>84.99</b>	<b>1248.500</b>	<b>3876.500</b>	<b>-4.66</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>53.84</b>				
Emotions	<b>Male</b>	<b>87.58</b>	<b>1083.000</b>	<b>3711.000</b>	<b>-5.36</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>51.54</b>				
Patient support	<b>Male</b>	<b>81.84</b>	<b>1450.500</b>	<b>4078.500</b>	<b>-4.03</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>56.65</b>				
Pain (QoR-40)	<b>Male</b>	<b>80.72</b>	<b>1522.000</b>	<b>4150.000</b>	<b>-3.45</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>57.64</b>				
Numerical pain scale	<b>Male</b>	<b>57.98</b>	<b>1630.500</b>	<b>3710.500</b>	<b>-3.00</b>	<b>&lt;.001</b>
	<b>Female</b>	<b>77.85</b>				

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .*

#### 4.6.2. Participant responses on the Post-operative survey by age range

Table 4.14 demonstrates the participant's responses on the post-operative survey by age category. As shown in table 4.14, patients aged 46+ had a statistically significant better emotional well-being post-operatively ( $H=6.69$ ,  $p=.04$ ) compared to other younger participants. Post hoc analysis revealed a statistical significance between participants aged between 18-31 years and those above 46 years ( $p=.017$ ) and between those aged between 32-45 years and participants above 46 years ( $p=.028$ ). Furthermore, this finding was not a consequence of the type of operation i.e., whether GA or sedation undertaken by age group ( $\chi^2=.902$ ,  $p=.64$ , Cramer's  $V=.08$ ). Cramer's  $V$  was used as a statistical test to measure the connotation between two nominal definite variables (Kvålseth, 2018). Conversely, no statistical significance was identified regarding the other subscales.

**Table 4.14**

*Participants' responses on the Post-operative survey by age*

Questionnaire domains	Age range	Mean rank	Chi-square	df	p
Comfort	1	60.19	3.62	2	.16
	2	66.80			
	3	76.00			
<b>Emotions</b>	<b>1</b>	<b>61.47</b>	<b>6.69</b>	<b>2</b>	<b>.04</b>
	<b>2</b>	<b>61.99</b>			
	<b>3</b>	<b>79.72</b>			
Patient support	1	63.42	1.11	2	.57
	2	68.87			
	3	71.74			
Pain scale (QoR-40)	1	70.40	.32	2	.85
	2	69.59			
	3	66.11			
Numerical pain scale	1	65.97	.25	2	.88
	2	68.64			
	3	70.15			

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .*

### 4.6.3. Participant responses on the Post-operative survey by educational level

Table 4.15 demonstrates the participant's responses on the post-operative survey by education where indeed, no statistical significance was identified.

**Table 4.15**

*Participants' responses on the Post-operative survey by education*

Questionnaire domains	Education Collated	N	Mean rank	Chi-square	df	p
Comfort	Primary	14	70.89	2.41	4	.66
	Secondary	20	76.10			
	Post-secondary	54	66.88			
	Undergraduate	24	59.88			
	Post-graduate	24	73.04			
Emotions	Primary	14	66.68	3.66	4	.45
	Secondary	20	73.00			
	Post-secondary	54	68.96			
	Undergraduate	24	56.44			
	Post-graduate	24	76.83			
Patient Support	Primary	14	66.46	6.16	4	.19
	Secondary	20	70.30			
	Post-secondary	54	61.61			
	Undergraduate	24	68.56			
	Post-graduate	24	83.63			
Pain (QoR-40)	Primary	14	61.68	2.55	4	.64
	Secondary	20	76.65			
	Post-secondary	54	71.25			
	Undergraduate	24	60.79			
	Post-graduate	24	67.21			
Numerical pain scale	Primary	14	58.00	9.14	4	.06
	Secondary	20	54.65			
	Post-secondary	54	75.40			
	Undergraduate	24	80.35			
	Post-graduate	24	58.79			



#### 4.6.4. Participant responses on the Post-operative survey by surgical history

Table 4.16 depicts the participant's responses on the post-operative survey by previous operations with '1' indicating that the participant has experienced surgery while a '2' represents not having experienced surgery. No statistical significance was found in relation to surgical history and patient's responses on the post-operative survey.

**Table 4.16**

*Participants's responses on the Post-operative survey by surgical history*

Questionnaire domains	Previous operations	Mean rank	Mann-Whitney U	W	Z	p
Comfort	1	63.36	1924.000	4625.000	-0.58	.57
	2	67.14				
Emotions	1	63.73	1951.000	4652.000	-0.44	.66
	2	66.66				
Patient support	1	67.10	1890.500	3486.500	-0.79	.43
	2	62.26				
Pain Scale (QoR-40)	1	62.39	1853.500	4554.500	-0.92	.36
	2	68.40				
Numerical pain scale	1	68.94	1756.500	3352.500	-1.40	.16
	2	59.87				

#### 4.6.5. Participant responses on the Post-operative survey by presence of relatives

Table 4.17 presents a description of the participant's responses on the post-operative survey in relation to presence of relatives. Presence of relatives before the operation is represented by a '1' on the table. Those patients who were accompanied by relatives expressed experiencing higher levels of pain, both on the QoR-40 and on the NRS. Furthermore this was not influenced by the type of operation (i.e., whether mild or general) received by their relative ( $\chi(1)= 2.87$ ,  $p=.09$ ,  $\Phi=.15$ ). However, as discussed before, this should be construed with caution due to restriction of relatives during the course of this project, as part of the COVID regulations. In terms of other subscales, no statistical significance was identified.

**Table 4.17***Participants' responses on the Post-operative survey by presence of relatives*

Questionnaire domains	Presence of relatives	Mean rank	Mann-Whitney U	Wilcoxon W	Z	p
Comfort	1	65.60	2100.500	3870.500	-0.64	.53
	2	69.86				
Emotions	1	67.54	2215.000	3985.000	-0.12	.90
	2	68.36				
Patient support	1	62.75	1932.000	3702.000	-1.49	.14
	2	72.08				
<b>Pain Scale (QoR-40)</b>	<b>1</b>	<b>60.01</b>	<b>1770.500</b>	<b>3540.500</b>	<b>-2.12</b>	<b>.03</b>
	<b>2</b>	<b>74.20</b>				
<b>Numerical pain scale</b>	<b>1</b>	<b>75.61</b>	<b>1793.000</b>	<b>4719.000</b>	<b>-2.04</b>	<b>.04</b>
	<b>2</b>	<b>62.09</b>				

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .***4.6.6. Participant responses on the Post-operative survey by type of surgery**

Table 4.18 provides a description of the responses on the post-operative survey by type of surgery. Endoscopy procedures are represented by a '1' on the table while GA is represented by a '2'. As depicted in table 4.18, patients who underwent an endoscopy procedure expressed receiving more post-operative patient support ( $U=1578$ ,  $z=-2.02$ ,  $p=.04$ ) when compared to patients who underwent GA. Additionally, in terms of post-operative pain, patients who underwent GA had higher levels of pain, both on the QoR-40 ( $U=1505$ ,  $z=-2.24$ ,  $p=.03$ ) and on the NRS ( $U=897.500$ ,  $z=-5.18$ ,  $p<.0001$ ).

**Table 4.18***Participants' responses on the Post-operative survey by type of surgery*

Questionnaire domains	Type of surgery	Mean rank	Mann Whitney U	W	z	p
Comfort	1	70.43	1893.000	6358.000	-0.39	.70
	2	67.64				
Emotions	1	72.93	1788.000	6253.000	-0.88	.38
	2	66.52				
<b>Patient support</b>	<b>1</b>	<b>77.93</b>	<b>1578.000</b>	<b>6043.000</b>	<b>-2.02</b>	<b>.04</b>
	<b>2</b>	<b>64.29</b>				
<b>Pain scale (QoR-40)</b>	<b>1</b>	<b>79.67</b>	<b>1505.000</b>	<b>5970.000</b>	<b>-2.24</b>	<b>.03</b>
	<b>2</b>	<b>63.51</b>				
<b>Numerical pain scale</b>	<b>1</b>	<b>42.87</b>	<b>897.500</b>	<b>1800.500</b>	<b>-5.18</b>	<b>.00</b>
	<b>2</b>	<b>79.95</b>				

*N.B: Items in bold demonstrate significance at  $p \leq .05$ .***4.6.7. Summary of the participant's responses on the Post-operative survey**

Statistical significance was identified on the post-operative survey in terms of gender, age, presence of relatives and type of surgery. Post operatively, males were more comfortable, had a better general well-being and better patient support compared to females. Furthermore, females suffered from higher levels of post-operative pain compared to males. In terms of age, patients aged 46+ years had a statistically significant better emotional well-being post-operatively compared to younger participants. Moreover, patients who were accompanied by relatives had higher levels of post-operative pain. However, this should be interpreted with caution due to the imposition of restricted attendance of relatives as part of the COVID regulations. Statistical significance was also revealed in relation to the type of surgery with patients who underwent an endoscopy, perceiving having a significantly greater amount of post-operative patient support compared to GA. Additionally, in terms of post-operative pain, patients who underwent GA had higher levels of pain. Finally, no statistical significance was identified on the post-operative survey in terms of education and former surgery.

The subsequent section i.e., 4.7 presents data in relation to the physiological parameters gathered during this project.

#### 4.7. Pre-operative and post-operative physiological parameters

The Wilcoxon test was utilised to detect any relationship between the pre-operative and post-operative parameters, namely SBP and DBP, HR and oxygen saturation, as depicted in Table 4.19. Statistically significant differences were identified in pre-operative and post-operative SBP, HR and oxygen saturation. This indicates that post-surgery, no statistical significance was identified between pre-operative and post-operative diastole readings.

**Table 4.19**

*Pre-operative and post-operative physiological parameters*

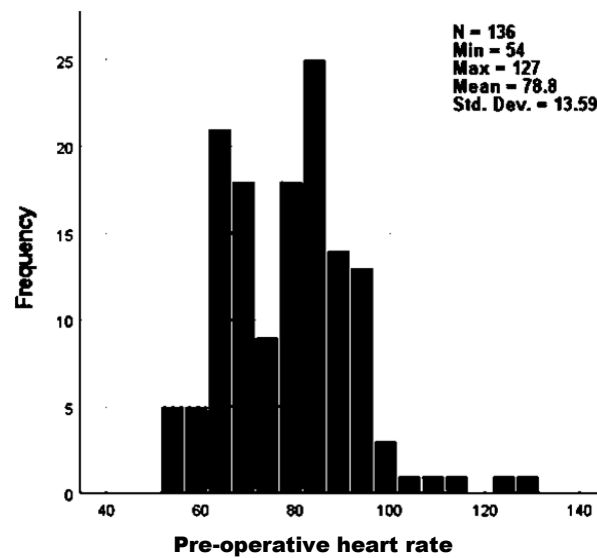
Physiological parameter	Mean rank	z	W	p
<b>Pre-operative heart rate</b>	<b>57.50</b>	<b>-3.17</b>	<b>3047.500</b>	<b>&lt;.001</b>
<b>Post-operative heart rate</b>	<b>73.29</b>			
<b>Pre-operative systole</b>	<b>55.56</b>	<b>-4.59</b>	<b>2500.000</b>	<b>&lt;.001</b>
<b>Post-operative systole</b>	<b>74.22</b>			
Pre-operative diastole	70.20	-1.60	3861.000	.11
Post-operative diastole	66.49			
<b>Pre-operative oxygen saturation</b>	<b>31.46</b>	<b>-5.03</b>	<b>1573.000</b>	<b>&lt;.001</b>
<b>Post-operative oxygen saturation</b>	<b>25.70</b>			

*N.B: Items in bold demonstrate significance at  $p \leq .05$ ; W=Wilcoxon test*

The Wilcoxon test revealed the positive and negative differences between pre-operative and post-operative HR, where the majority were negative differences i.e. a decrease in HR post-operatively. Graphs relating to the Wilcoxon test for pre-operative and post-operative HR are presented in Appendix K. Subsequently, figure 4.8 depicts the minimum pre-operative HR (54bpm), the maximum pre-operative HR (127bpm) and the average pre-operative HR (78.8bpm).

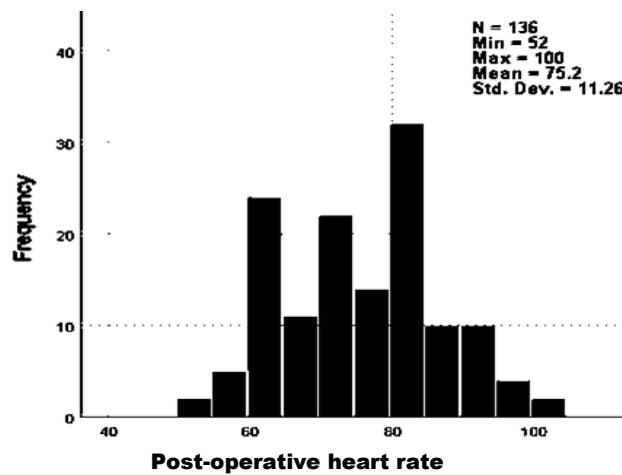
**Figure 4.8**

*Pre-operative heart rate*



**Figure 4.9**

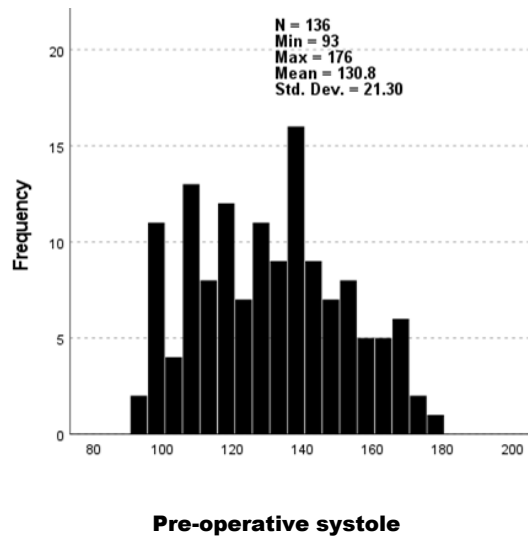
*Post-operative heart rate*



As depicted in table 4.19, there was a statistical significance between the pre-operative and post-operative systole unlike the diastole reading which revealed no significance. Graphs relating to the Wilcoxon test for pre-operative and post-operative SBP are presented in Appendix L. Additionally, figure 4.10 reveals the minimum (93mm Hg), mean (130mm Hg) and maximum (176mm Hg) pre-operative systole while figure 4.11 presents the post-operative systole readings, which were less than the pre-operative readings.

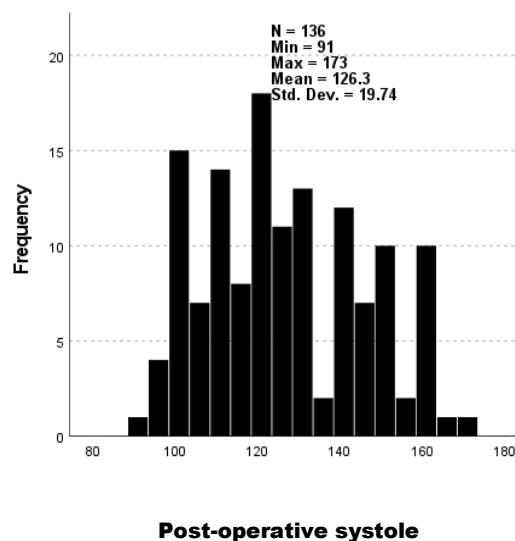
**Figure 4.10**

*Pre-operative systole*



**Figure 4.11**

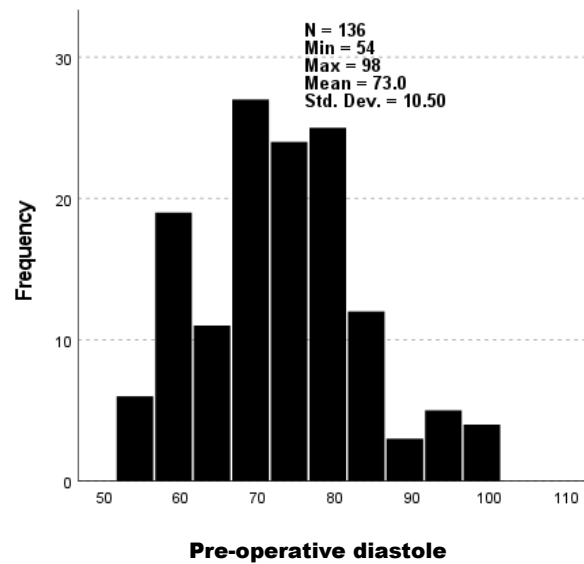
*Post-operative systole*



As described before, there was no statistical significance between pre-operative and post-operative diastole readings as depicted in appendix M. Figures 4.12 and 4.13 below present the diastole readings for the pre-operative and post-operative phase respectively.

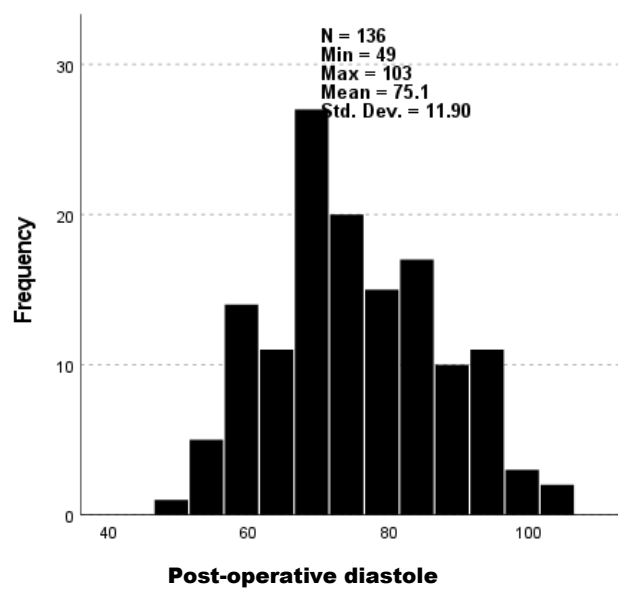
**Figure 4.12**

*Pre-operative diastole*



**Figure 4.13**

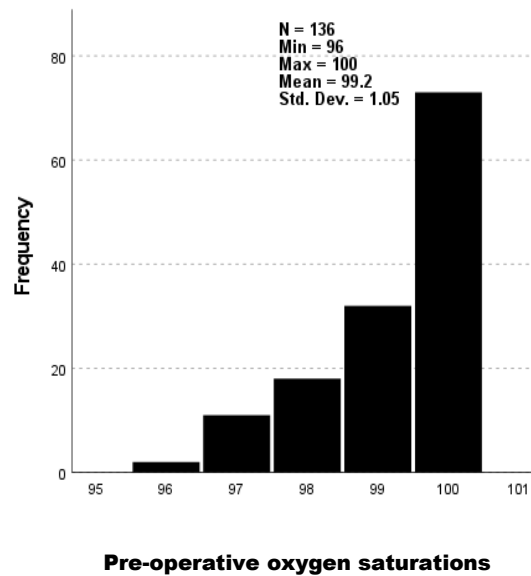
*Post-operative diastole*



Regarding oxygen saturations, there was a statistical significance ( $p < .001$ ) between pre-operative and post-operative readings, as depicted by the Wilcoxon test (APPENDIX N). Additionally, figures 4.14 and 4.15 present the pre-operative and post-operative oxygen saturations levels respectively. For both the pre-operative and post-operative phase, the minimum oxygen saturation was 96% while the maximum was 100%.

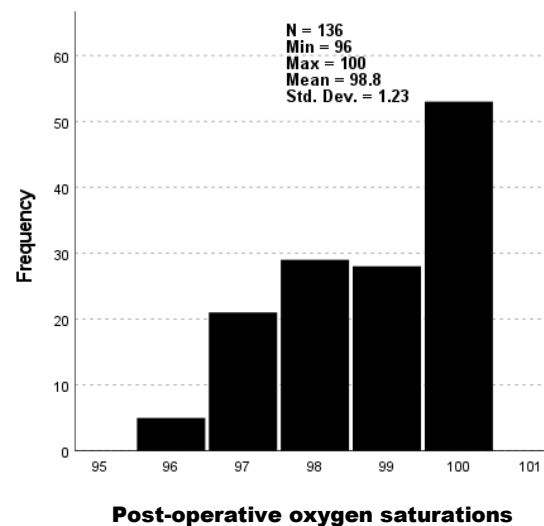
**Figure 4.14**

*Pre-operative oxygen saturations*



**Figure 4.15**

*Post-operative oxygen saturations*





#### 4.8. Inter correlation between the subscales dimensions

The following data gathered from the pre-operative and post-operative questionnaires were inter-correlated namely:

1. Gender
2. Age
3. Education
4. Type of surgery
5. Presence of relatives
6. Amsterdam score (patient's pre-operative anxiety and information needs)
7. Pre-operative comfort (i.e., patient's pre-operative ability to breathe easily, have a good sleep, and feel rested)
8. Pre-operative emotions (patient's pre-operative general well-being and comfort)
9. Pre-operative physical independence (patient's pre-operative ability to write, wash and look after own appearance)
10. Pre-operative patient support (patient's pre-operative support from hospital staff including nurses, family and friends)
11. Post-operative comfort (post-operative nausea, vomiting, dizziness)
12. Post-operative emotions (post-operative anxiety, difficulty with falling asleep)
13. Post-operative patient support (patient's support post-surgery)

Since the data collected from the pre-operative and post-operative survey subscales were, skewed, the present researcher made use of a non-parametric test, i.e., Spearman's rho for data analysis. The Spearman's rho non-parametric test was utilised to compute the inter-correlations between the eight subscales. As shown in table 4.20, gender was positively correlated with the APAIS. Indeed, females demonstrated higher pre-operative anxiety. Conversely, gender was negatively correlated with pre-operative emotions and pre-operative physical independence. In fact, males had better pre-operative well-being and were more physically independent than their female's counterparts. Likewise, post-operatively, gender was negatively correlated with post-operative comfort, emotions and patient support where males felt more comfortable and supported.

**Table 4.20***Inter-correlations between the subscales dimensions*

	1	2	3	4	5	6	7	8	9	10	11	12	13
Gender	1.000	-.127	-.009	.008	-.044	<b>.260**</b>	<b>-.225**</b>	<b>-.326**</b>	<b>-.190*</b>	-.118	<b>-.401**</b>	<b>-.461**</b>	<b>-.347**</b>
Age	.042	1.000	<b>-.244**</b>	.029	-.152	<b>-.177*</b>	-.040	.024	<b>-.241**</b>	.024	.164	<b>.201*</b>	.088
Education	-.009	<b>-.244**</b>	1.000	.062	-.052	.101	-.072	.067	.144	.081	-.043	-.003	.124
Type of surgery	.008	.029	.062	1.000	-.128	.130	-.009	.012	.008	-.018	-.033	-.076	<b>-.174*</b>
Presence of relatives	-.044	-.152	-.052	-.128	1.000	.106	.111	<b>-.227**</b>	.091	<b>-.204*</b>	.065	-.002	.121
Amsterdam scale	<b>.260**</b>	<b>-.177*</b>	.101	.130	.106	1.000	-.080	<b>-.292**</b>	-.077	-.108	-.116	<b>-.440**</b>	<b>-.264**</b>
Pre-op comfort	<b>-.225**</b>	-.040	-.072	-.009	.111	-.080	1.000	<b>.449**</b>	<b>.289**</b>	.054	<b>.316**</b>	<b>.269**</b>	<b>.262**</b>
Pre-op emotions	<b>-.326**</b>	.024	.067	.012	<b>-.227**</b>	<b>-.292**</b>	<b>.449**</b>	1.000	<b>.271**</b>	<b>.357**</b>	<b>.268**</b>	<b>.484**</b>	<b>.426**</b>
Pre-op physical independence	<b>-.190*</b>	<b>-.241**</b>	.144	.008	.091	-.077	<b>.289**</b>	<b>.271**</b>	1.000	.156	.135	.188	<b>.275**</b>
Pre-op patient support	-.118	.024	.081	-.018	<b>-.204*</b>	-.108	.054	<b>.357**</b>	.156	1.000	<b>.184*</b>	<b>.303**</b>	<b>.343**</b>
Post-op comfort	<b>-.401**</b>	.164	-.043	-.033	.065	-.116	<b>.316**</b>	<b>.268**</b>	.135	.184	1.000	<b>.492**</b>	<b>.389**</b>
Post-op emotions	<b>-.461**</b>	<b>.201*</b>	-.003	-.076	-.002	<b>-.440**</b>	<b>.269**</b>	<b>.484**</b>	<b>.188*</b>	<b>.303**</b>	<b>.492**</b>	1.000	<b>.588**</b>
Post-op patient support	<b>-.347**</b>	.088	.124	<b>-.174*</b>	.121	<b>-.264**</b>	<b>.262**</b>	<b>.426**</b>	<b>.275**</b>	<b>.343**</b>	<b>.389**</b>	<b>.588**</b>	1.000

*N.B: 1=gender; 2=age; 3=education; 4=type of surgery; 5=presence of relatives; 6=pre-operative anxiety and information needs; 7=pre-operative comfort; 8= pre-operative general well-being; 9=pre-operative physical independence; 10=pre-operative patient's support; 11= post-operative comfort; 12=post-operative emotions; 13=post-operative patient support. \*Correlation is significant at the  $\leq 0.05$  level (2-tailed); \*\*Correlation is significant at the  $\leq 0.01$  level (2-tailed)*

Regarding age of the participants, this was negatively correlated with education, the APAIS and pre-operative physical independence. Therefore, being older was associated with lower levels of education, lower levels of pre-operative anxiety and being less physically independent. However, age was positively correlated with post-operative emotions which include post-operative anxiety. Hence, the elder participants were emotionally better in terms of anxiety, depression, and with falling asleep post-operatively.

Regarding type of surgery, this was negatively correlated with post-operative patient support. Indeed, patients who underwent an endoscopy procedure perceived having better levels of post-operative support in comparison to patients who underwent GA. Furthermore, presence of relatives did not seem to improve patient's pre-operative emotions and pre-operative patient support, as depicted by the negative correlation. However, this should be interpreted with caution as due to COVID, relatives were not able to stay with some of the participants who participated.

As depicted in table 4.20, pre-operative anxiety (Amsterdam score) was negatively associated with pre-operative emotions. Hence, having high levels of pre-operative anxiety on the APAIS was associated with having a low general well-being, being less comfortable and having a low sense of control. Similarly, the APAIS was also negatively associated with the post-operative emotions domain, which included statements regarding post-operative anxiety, bad dreams, and difficulty with falling asleep, feelings of anger and feelings of depression. Hence, patients who experienced high levels of pre-operative anxiety felt more anxious, experienced difficulty with falling asleep and experienced feelings of depression post-operatively.

Additionally, patients who had high levels of pre-operative anxiety perceived that they had less patient support post-operatively, denoted by the negative correlation. As regards to pre-

operative comfort (i.e., in terms of ability to breathe, have a good sleep, able to enjoy food and feel rested), this was positively associated with gender, pre-operative emotions and pre-operative physical independence. As discussed previously, males expressed higher levels of pre-operative comfort compared to females. In addition, expressing greater comfort before the procedure was associated with better general well-being in terms of emotions, post-operatively. Moreover, such patients also felt that they were highly supported in the post-operative period, as highlighted by the positive correlation.

In terms of pre-operative emotions, this was negatively correlated with presence of relatives and pre-operative anxiety (Amsterdam scale), as described before. Moreover, patients who were emotionally better pre-operatively, had a better post-operative experience in terms of comfort, emotions and patient support (positive correlation). Patients who rated themselves as less physically independent, in terms of ability to look after own appearance, had low levels of comfort and emotions before the procedure, as shown in table 4.20. Furthermore, correlation analysis revealed that patients, who had high levels of support before the procedure, were emotionally better both before and after surgery.

Inter-correlational analysis was also conducted between the various subscales and the two measures of pain, namely, the QoR-40 and the NRS as depicted in table 4.21. On the QoR-40, patients had to rate their pain on a Likert-like scale, with the highest number being 5 and the lowest number being 1, where the higher the number, the lower the levels of post-operative pain. This subscale of the QoR-40 evaluated whether patients suffered from headaches, muscle pains, backaches, sore throat or sore mouth after the surgery. Furthermore, patients also rated their post-operative pain on the NRS from 0 (no pain) to 10 (worst possible pain).

**Table 4.21***Inter-correlations between subscale dimensions of pain*

	Post-operative pain (QoR-40)	Numerical rating pain scale
1	<b>-.297**</b>	<b>.258**</b>
2	-0.046	0.042
3	-0.051	0.074
4	<b>-.193*</b>	<b>.446**</b>
5	<b>.188*</b>	<b>-.175*</b>
6	<b>-.249**</b>	<b>.352**</b>
7	<b>.451**</b>	<b>-.183*</b>
8	<b>.331**</b>	<b>-.194*</b>
9	<b>.232**</b>	-0.085
10	0.142	-0.095
11	<b>.419**</b>	<b>-.299**</b>
12	<b>.461**</b>	<b>-.310**</b>
13	<b>.401**</b>	<b>-.352**</b>

*N.B: 1=gender; 2=age; 3=education; 4=type of surgery; 5=presence of relatives; 6=pre-operative anxiety and information needs; 7=pre-operative comfort; 8= pre-operative general well-being; 9=pre-operative physical independence; 10=pre-operative patient's support; 11= post-operative comfort; 12=post-operative emotions; 13=post-operative patient support. \*Correlation is significant at the  $\leq 0.05$  level (2-tailed); \*\*Correlation is significant at the  $\leq 0.01$  level (2-tailed).*

Females described experiencing higher levels of post-operative pain highlighted by the negative correlation with the pain scale of the QoR-40 and the positive correlation with the NRS. Additionally, post-operative pain was also significantly correlated with type of surgery as described in section 4.6.6. Furthermore, patients who were accompanied by relatives experienced higher levels of post-operative pain. However, this should be interpreted with caution due to restriction of relatives as part of the COVID policies.

As depicted in table 4.21, post-operative pain on the QoR-40 was negatively associated with the Amsterdam score, hence high levels of pre-operative anxiety was associated with high levels of post-operative pain (represented by a low score on the QoR-40). Indeed, the NRS was positively associated with the Amsterdam score. In addition, post-operative pain on the

QoR-40 was positively associated with both pre and post-operative comfort and emotions. Therefore, having a general good well-being and feeling comfortable pre-operatively was associated with low levels of post-operative pain. Similarly, patients who rated their pain as high on the NRS had a lower general well-being of emotions and were less comfortable, both pre-operatively and post-operatively. Moreover, post-operative pain was also positively correlated with post-operative patient support on the QoR-40 and negatively correlated on the NRS. Hence, one can conclude that patients, who suffered from high levels of post-operative pain, perceived having lower levels of post-operative patient support.

#### **4.9. Regression Analysis**

Regression analysis can be used to find or confirm a relationship between a dependent variable and several predictors (independent variables) (Vetter & Schober, 2018). Since the predictors consisted of both of covariates and categorical variables, and distribution of the dependent variables was skewed, an ANCOVA regression model was utilised. The identified predictor covariates that correlated significantly with post-operative emotions and post-operative comfort, were incorporated in an ANCOVA regression model in addition to categorical demographic variables, as fixed factors. The parsimonious model was consequently utilised using a backward elimination method.

Table 4.22 presents data for the outcome measure of post-operative emotions. This model contained four significant predictors, which explained 44.7% of the total variance in the post-operative emotions, as shown in table 4.22. The regression coefficients indicated that males were scoring on average 2.10 scale points more than females in terms of post-operative emotions. Additionally, high levels of pre-operative anxiety result in lack of good emotional well-being post-operatively. Conversely, a good well-being and good control of post-operative pain pre-operatively, result in good emotional well-being post-surgery.

**Table 4.22***Regression analysis with post-operative emotions as the dependant variable*

Parameter	Regression Coefficient, B	Standard error	t value	p value
Intercept	6.805	3.561	1.911	.058
Gender = Male	2.096	.642	3.265	.001
Gender= Female	0 <sup>a</sup>	.	.	.
Pre-operative anxiety	-.184	.064	-2.885	.005
Pre-operative emotions	.450	.116	3.897	.000
Post-operative pain	.459	.107	4.303	.000

*N.B: Dependent variable= post-operative emotions, Adjusted R<sup>2</sup>=44.7%, 0<sup>a</sup>= parameter set to 0.*

The final model of post-operative comfort proved significant as shown in table 4.23. Indeed, two important predictors, namely, gender and post-operative pain explained 22.5% of the total variance regarding post-operative comfort. Since all the regression coefficients have a positive value, one can conclude that a positive relationship exists between the predictors and the outcome. Indeed, males were scoring on average 2.50 scale points more than females in terms of post-operative comfort. Additionally, similar to post-operative comfort, good control of post-operative pain is a predictor for good post-operative comfort of the patients. Therefore, one can conclude that an important key factor of both well-being and post-operative comfort is the good control of post-operative pain.

**Table 4.23***Regression analysis with post-operative comfort as the dependant variable*

Parameter	Regression Coefficient, B	Standard error	t value	p value
Intercept	22.287	3.291	6.773	.000
Gender= Male	2.499	.632	3.952	.000
Gender= Female	0 <sup>a</sup>	.	.	.
Post-operative pain	.396	.105	3.771	.000

*N.B: Dependent variable= post-operative comfort, Adjusted R<sup>2</sup>=22.5%, 0<sup>a</sup>= parameter set to 0.*

#### **4.10. Conclusion**

This chapter demonstrated the findings of this project, which was gathered using both pre-operative and post-operative surveys. Subsequently, the results and implications of such findings will be additionally elaborated in the next chapter.



# **CHAPTER 5: DISCUSSION**

### **5.1. Introduction**

The aim of this study is to evaluate peri-operative anxiety and QOR including post-operative pain in adults undergoing AS. Although peri-operative anxiety has been researched for years, the amalgamation of mental health status into the peri-operative care of a surgical day case patient is seldom taken into consideration in practice (Aspari & Lakshman, 2018). Additionally, no local research has evaluated such relationship, in addition to gaps in international literature i.e. predictors of post-operative emotions and post-operative comfort. Consequently, the objective of this study is to address this literature gap where such findings are of utmost importance as they shed light on important aspects of local peri-operative nursing that may need to be acknowledged to ensure a positive experience for the AS patient.

### **5.2. The Demographic Characteristics of the Participants in this study**

In this section, the author portrays a discussion about the demographics of the participants and subsequently compares them to corresponding literature. Such a comparison enables the present researcher to present a framework about the general demographic features of AS patients.

Out of 150 questionnaires, 136 questionnaires were returned, yielding a response rate of 90.7%. This high response rate can be endorsed to the fact that data collection was conducted during the time participants were awaiting surgery (pre-operative) and during the time they were awaiting discharge (post-operative). To encourage participation in the study, questionnaires were available in English (n=64) or Maltese (n=72) with the number of participants using each version in brackets. They were also instructed to complete the questionnaire while in hospital rather than posting it by mail, due to COVID precautions.

The response rate achieved in the present study is comparable to that attained in various other studies. For instance, the following studies using the QoR-40 [Gower et al., 2006 (100%);

Karaman et al., 2014 (85%); Tanaka et al., 2011 (pre-surgery 97% and post-surgery 96%)] obtained similar response rates (as indicated in the brackets) to the present study. However, there is one exception with a study conducted by McIntosh and Adams (2011), where the response rate was 50%, due to postal surveys. Regarding the APAIS similar response rates were also identified: [Jiwanmall et al., 2020 (100%); Kumar et al., 2019 (100%); Pokharel et al., 2011(89.5%); Wu et al., 2020 (91%)].

Regarding the age of the participants, the modal group for age category in the current study was that of 46+ years (37.5%), with an additional 36% of participants in the 32-45 age bracket. This data is also in congruence with other studies (McIntosh & Adams, 2011; Mitchell, 2012; Svensson et al., 2016), where the median age of AS patients was 44 years, 43 years and 57 years respectively. Furthermore, in the current study the majority of respondents (53%) were females. This gender constitution is also in line with other studies evaluating AS patients, as demonstrated by the percentage of females indicated in brackets for the following studies: [Alacadag & Cilingir., 2017 (54%); Reyes-Gilabert et al., 2017 (58%); Wongkietkachorn et al., 2018 (56%)].

The modal group for the education in the present study was that of a post-secondary education (39.7%), followed by the following categories: undergraduate (17.6%), post-graduate (17.6%), secondary (14.8%) and primary (10.3%). This data also concurs with the percentage of participants having a post-secondary education in the following retrieved studies: (Reyes-Gilabert et al., 2017; Svensson et al., 2016) where 31.1% and 25% of the AS participants had post-secondary education respectively.

Additionally, the majority of the participants in the current study (53.7%) had undergone a former surgery. This finding is consistent with some available studies, including that of McIntosh and Adams (2011), where 70.4% of AS patients had undergone surgery. Moreover,

a study conducted by Jiwanmall et al. (2020), evaluating pre-operative anxiety in AS patients revealed how 59.4% of the patients had a previous surgical experience. Contrarily, in two of the retrieved articles (Pereira et al., 2016; Reyes-Gilabert et al., 2017), most of the patients 77.9% and 51.1% respectively, did not undergo surgery before.

The current study has also demonstrated that the majority of the participants (56.6%) were not accompanied by relatives. As previously highlighted, this should be interpreted with caution, as due to COVID policies, no relatives were allowed during the months of September and October 2020. In the study of Mitchell (2012) that evaluated gender and type of anaesthesia on AS anxiety, 57% of the females stated they would prefer to spend their waiting time with a relative.

In this study, the majority of the respondents (69.1%) had GA while 30.9% of the participants had mild sedation. The most common surgeries in this study were general surgery, gynaecology and orthopaedic surgery with 10.3% of the participants in each category. This was followed by urology surgery and hernias procedures, with a percentage of 8.1% each. Such findings conform to some retrieved studies such as that of Mitchell (2012), where 28% of the patients underwent general surgery followed by orthopaedic (26%), gynaecology (18%) and urology (11%). In another study of Mitchell (2014), 63% of the participants were given GA, while 30% were given LA. In another study by Pereira et al. (2016), 71.2% of AS patients were given GA; where 30.8% had a hernia operation and 10.6% of the participants had a haemorrhoidectomy.

### **5.3. Prevalence of local and international Pre-operative anxiety**

Various authors (Gangadhar et al., 2012; Harsoor, 2010) highlight that pre-operative anxiety is a real issue for patients undergoing AS. Pre-operative anxiety is a multifactorial issue where nurses have the ultimate responsibility to prepare the surgical patient both physically

and psychologically (Matthias & Samarasekera, 2012); however this is quite a challenge, due to limited timeframe (Gangadharan et al., 2014). Hence, one of the main aims of this study was to evaluate prevalence of local pre-operative anxiety to try and implement change by incorporating information relating to the patients' physical health and mental well-being.

Although anxiety is a subjective phenomenon, and not easy to evaluate (Shafer et al., 1996), it was decided to specifically use the APAIS as a measure of pre-operative anxiety on the day of the surgery, since it has been established principally for the pre-operative patient and evaluates both anxiety and information needs about both anaesthesia and surgery (Moerman et al., 1996).

The APAIS has been translated into numerous languages, such as Spanish and Japanese, where different cultural differences have been highlighted in the evaluation of anxiety, suggesting that this phenomenon is worldwide (Wu et al., 2020). Indeed, this study also contributes to a gap in international literature, since to date, no local study has assessed pre-operative anxiety in AS. Furthermore, there is a variation in literature in the prevalence of pre-operative anxiety worldwide, which ranges from 60% to 92% (Maranets & Kain, 1999; Perks et al., 2009; Pokharel et al., 2011).

In the current study, 18.4% experienced moderate pre-operative anxiety, while 52.9% of the participants experienced moderately high or extreme pre-operative anxiety. Hence, this study shows that the prevalence of local pre-operative anxiety was 71.3%. A contemporary study by Jiwanmall et al. (2020) which made use of the APAIS, revealed a prevalence of pre-operative anxiety in AS of 58.1%, while another Mexican study highlighted a higher prevalence of 76% (Lichter et al., 1987). Another study by Gangadharan et al. (2014) identified 60% prevalence and further highlighted several important related aspects to pre-operative anxiety, including former surgery, type of surgery and gender. However, two Sri

Lankan studies (i.e., Kiyohara et al., 2004; Matthias & Samarasekera, 2012) respectively reported a lower prevalence of pre-operative anxiety, specifically, 23.4% and 42.2%, which might be due to cultural differences. Similarly, Wetsch et al. (2010) identified a 38.3% prevalence of pre-operative anxiety in AS. Another contemporary study presented by Wu et al. (2020) highlighted the variation in the prevalence of pre-operative anxiety, where the prevalence was higher in China compared to both UK and Switzerland. However, it displayed no significant differences in comparison to both Indonesia and Japan.

As conveyed by these different studies and the present study, the influence of cultural differences on pre-operative anxiety is still not clear (Stein, 2009). Additionally, an important aspect cited in the literature, is the fact that over the years the patient's mental well-being has been given more importance in the developing countries (Wu et al., 2020). Hence, this study demonstrates that further studies should be implemented to evaluate the effect of cultural variances on pre-operative anxiety and why such a variation in prevalence exists.

As described before, the APAIS takes into consideration both pre-operative anxiety and the need for information. In the current study, the majority of the participants (47.8%), stated that they either did not wish to know anything or they wanted to know a little bit more about the anaesthetic. Indeed, only 36% of the participants required either a moderately high or extremely high need for information about the anaesthetic. Regarding the need for information about surgery, the majority of the participants (47.1%) stated that they did not wish to know anything or just a little about the surgery. In fact, only 35.3% of the participants required extensive or moderately high information about the surgery.

Similar to the present study, Oldman et al. (2004) indicated that 65% of the participants did not portray a need for detailed information about the anaesthetic. The findings in the present study differ from some studies (Jiwanmall et al., 2020; Kakande et al., 2005; Kindler et al.,

2000; Nigussie et al., 2014; Pokharel et al., 2011) which portrayed how patients with severe anxiety required more detailed information. The prevalence of pre-operative anxiety in the present study was 71.3%, which is quite high; however the need for information was low (36% anaesthetic related, 35.3% surgery-related). Literature suggests that such a difference in need for information exists due to patients either being classified as ‘monitors’ or as ‘blunters’, depending on their capability to deal with anxiety (Miller, 1987). Monitors are defined as seekers of information, while blunters (as most of the participants in the present study) have a tendency to avoid information, and become highly anxious when supplied with it (Stoddard et al., 2005).

This present study may contribute to literature by suggesting that, rather than adopting a standard protocol of information, the first important step is to pro-actively identify whether patients are monitors or blunters, and then adjusting the level of information accordingly. Kumar et al. (2019) propose that being pro-active towards patients’ pre-operative anxiety, is significantly important in achieving better physical and mental care, even though identifying patients susceptible to anxiety might be a challenge. Based on the inconsistent findings of several studies, including this present study, further studies should evaluate individualised pre-operative information.

#### **5.4. Theories and models related to this study**

One of the main aims of this project was to identify the prevalence of local peri-operative anxiety in AS so as to create awareness about the prevalence of pre-operative anxiety, to highlight the scope of additional research to alleviate anxiety. Alleviating anxiety in an intraoperative setting is especially relevant, as usually anxiolytic medication is commonly omitted (Jiwanmall et al., 2020).

Hence, the present study provides support for the patient-centred model of communication, which incorporates the empathic approach, which addresses the patient's well-being and emotions in clinical practice (Pereira et al., 2016; Stepien & Baernstein, 2006). Such a model of communication suggests that an empathic patient-centred approach, including tailor-made information, should be applied in the pre-operative care of AS, as it improves patients' mental well-being by decreasing anxiety and improved QOR. This is especially significant, since some studies, portrayed that AS patients felt abandoned pre-operatively as some nurses were not open to their worries (Bailey, 2010; Bellani, 2008).

The high prevalence of local pre-operative anxiety identified in the current study highlights the importance of applying Parse's theory in local practice (Mitchell & Copplestone, 1990). Parse's theory is an alternative belief system that challenges the traditional perioperative nursing, especially since there is an increasing drift in nursing practice to move towards a more humanistic approach with patients. Traditional perioperative nursing, views the physical problem from the perspective of a healthcare professional. Contrarily, Parse's paradigm focuses on the view that the patient is a human being who assembles meaning in life in a unique particular approach through the nurse-patient relationship (Mitchell & Copplestone, 1990). Back in 1990, Mitchell and Copplestone (1990) demonstrated the importance of perioperative nurses in guiding the patients to talk about their feelings and consequently, responding to their psychological needs, facts which exemplify Parse's first practice dimension in clinical practice.

The other two dimensions of the theory are going along with the patient's thoughts and feelings (synchronizing) and mobilizing wholeness through moving beyond, by for example, assisting the patient in imaging how things are going to be post-operatively. In line with Parse's theory, encouraging the patients to talk about their feelings might help in alleviating pre-operative anxiety. Indeed, literature reveals how patients emphasised the significance of



having the opportunity to discuss and be attended to, before AS (Rosen et al., 2008; Svensson et al., 2016).

Similarly, McCormack and McCance (2006) developed the person-centred nursing theory, which consists of four fundamental notions, namely, prerequisites, the care setting, person-centred processes and projected outcomes. The characteristics and features of the nurse refer to the prerequisites, while the hospital environment (e.g., cleanliness and lights) refers to the care environment. Characteristics of nurses that can promote person-centred care are the development of interpersonal skills and the development of self-awareness in relation to their views about pre-operative anxiety in patients. Such views can have an impact on the nursing care that is provided. Person-centred processes however refer to the activities which focus on person-centred care and hence, expected outcomes such as satisfaction with care (McCormack & McCance, 2006). An example of such person-centred processes is the importance of working with patient's beliefs and values relating to the surgical procedure and the impact on them. Hence, there is a need to explore and examine such beliefs, with the present study contributing by providing information on patient beliefs relating to undergoing surgery. Nonetheless supplementary qualitative studies are vital to explore in-depth the lived experiences of patients undergoing an AS locally.

This theory also further contributes by emphasising the importance of shifting from 'person-centred moments' to a person-centred culture, where feelings, satisfaction, and well-being of both the patients and nurses are taken into consideration (Dewing, 2008). The promotion of such a culture requires an extensive systematic approach to education, policy and practice developments, incorporated with evidence-based research (McCormack et al., 2009).

## **5.5. Factors associated with Pre-operative anxiety**

Several factors are linked with pre-operative anxiety, such as gender, age, education, former surgery and type of anaesthesia (Matthias & Samarasekera, 2012; Mulugeta et al., 2018). The subsequent subsections explore the association between such factors and pre-operative anxiety.

### **5.5.1. Gender**

In the present study, females experienced higher pre-operative anxiety levels as demonstrated by the APAIS. This finding is in line with the literature which reports that women experience higher levels of pre-operative anxiety (Mitchell, 2012; Nigussie et al., 2014; Nilsson et al., 2019). Comparable findings were demonstrated in several other studies, where females portrayed higher levels of pre-operative anxiety (Ai et al., 2005; Pokharel et al., 2011; Wu et al., 2020).

Literature suggests that such high anxiety levels have been linked with the fluctuating levels of certain hormones, namely, oestrogen and progesterone in females (Weinstock, 1999). Moreover, others suggest that such a difference exists due to the fact that males tend to admit and report anxiety less frequently than females (Kumar et al., 2019). A univariate analysis performed by Pokharel et al. (2011) not only portrayed higher anxiety levels in females on the operating table but also with the type of anaesthesia, namely, GA. Despite the fact that most of the literature depicts that woman suffer from higher pre-operative anxiety, a recent paper by Jiwanmall et al. (2020) revealed discordant results, with males depicting higher levels of anxiety. However, such a finding must be interpreted with caution, as 72.2% of the participants were middle-aged men, hence, a low representation of the female gender.

### **5.5.2. Age**

In the present study, patients aged between 32-45 years experienced the highest levels of anxiety and the highest levels of need for information according to the APAIS. Post hoc analysis indicated a significant difference on the APAIS between participants aged 32-45 years and those aged 46+ years, with the latter having the lowest levels of anxiety and information needs pre-operatively. Hence, elder patients experienced lower levels of pre-operative anxiety and required less pre-operative information compared to younger patients. Similarly, in a Nepalese study led by Pokharel et al. (2011) participants aged less than 30 years were identified as the most that required pre-operative information.

Conversely, other studies did not identify any difference in pre-operative anxiety and information needs between different age groups (Kumar et al., 2019; Moerman et al., 1996; Wu et al., 2020). Such differences might be due to different demographics of the participants, such as cultural differences and type of surgery. Indeed, in the study by Wu et al. (2020), the sample population consisted of Chinese participants who only underwent orthopaedic, otolaryngology and general surgeries, unlike the present study which also included several surgeries. Additionally, the Indian study of Kumar et al. (2019) did not include AS patients. Consequently, since the findings in the local study differ from the international literature, the present researcher recommends future local studies analysing pre-operative anxiety in the younger population, and different age groups, as this was significant in the present study.

### **5.5.3. Educational level**

As described in chapter 4, different educational levels were collated into five main categories (primary, secondary, post-secondary, undergraduate and postgraduate) to facilitate data analysis. The present researcher did not identify any significant differences on participants' responses by educational level and pre-operative anxiety. These results are in line with the outcomes of the recent studies conducted by Jiwanmall et al. (2020) and Wu et al. (2020),

both of whom made use of the APAIS tool in AS patients, similar to the present study. The study of Wu et al. (2020) made use of 204 questionnaires, which were collected a day before the surgery, unlike the present researcher who collected the data on the same day of the surgery. Although the findings in the study of Jiwanmall et al. (2020) concurs with the present study, such a result must be interpreted with caution, as 86.5% of the respondents were literate, as compared to 100% in the present study. Hence, future studies in patients who are illiterate must be conducted, as only 13.5% of the sample population in this study were of low education, which might have influenced the generalisability of the findings.

Conversely, a prospective study revealed that education was significantly associated with pre-operative anxiety (Kumar et al., 2019). This research study demonstrated how illiterate patients experienced higher pre-operative anxiety on the day of the surgery, in the holding area and on the operating table. Nonetheless, one must keep in mind that the respondents in the study of Kumar et al. (2019) were admitted one day before the procedure and were given anxiolytic treatment. Additionally, most of the patients (80%) were from rural areas and were assisted to fill up the APAIS. All of these factors might have affected the reported levels of pre-operative anxiety, and hence, the reliability of the results. This is in concordance with the findings achieved in two studies (i.e., Ai et al., 2005; Pinar et al., 2011) that demonstrated higher pre-operative anxiety levels in patients with low education. Other studies (e.g., Caumo et al., 2001) have demonstrated opposite findings, as authors argue that a better educated patient can understand the risks and consequently, express his anxieties in a better way. Similarly, Pokharel et al. (2011) also revealed a positive correlation between high education status and an increased need for more information in elective surgical patients (not day cases).

#### **5.5.4. Surgical history**

The majority of the participants, (i.e. 53.7%) in the present study had undergone former surgery, while seven participants did not respond to this question. Findings of the present study revealed no statistical significance between pre-operative anxiety and surgical history. This is in concordance with the current results obtained by Wu et al. (2020), as APAIS scores did not differ in relation to surgical history, where 44.1% of the patients had undergone surgery. However, contradictory results have been published in other studies, either associated with higher anxiety (Jiwanmall et al., 2020; Kumar et al., 2019; Pinar et al., 2011) or lower anxiety scores (Carr et al., 2006; Caumo et al., 2001; Nigussie et al., 2014) in relation to surgical history.

Previous exposure to surgery resulted in higher anxiety in the study of Kumar et al. (2019), which might be attributed to a former unpleasant experience. Additionally, patients with surgical history required more detailed need for information in the ward and on the operating table (Kumar et al., 2019). Conversely, a prospective study by Pokharel et al. (2011) demonstrated how elective patients with no surgical history, portrayed more need for information. Nonetheless, such results must be interpreted with caution, as patients were given diazepam. Such contradictory results might be attributed to the fact that a previous experience might either worsen or alleviate pre-operative anxiety, depending on the former experience (Kumar et al., 2019).

#### **5.5.5. Presence of Relatives**

Study participants in this study were also asked whether they were accompanied by relatives; the majority of the participants (56.6%), were not accompanied by any relatives. During the time of data collection, COVID policies inhibited the presence of relatives, which might have affected the findings. Although no statistical significance was identified between pre-operative anxiety and the presence of relatives, a statistical significance ( $U=1673.7$ ,  $z=-2.63$ ,

$p=.01$ ) was identified between the pre-operative emotions and the presence of relatives. Such a finding suggests that pre-operatively, patients have a better general well-being and sense of comfort when accompanied by a relative. In all studies included in the literature review, only Alacadag and Cilingir (2017) provided an insight into the involvement of the relatives during AS, where 74.8% of the relatives stated that they were not involved in the patients' care.

Since the current study demonstrated a positive correlation between the presence of relatives and pre-operative emotions, further studies should be implemented exploring such a relationship, especially due to the continuous expansion of AS which involves a meticulous discharge plan, including the involvement of the relatives. This is especially important as according to Mitchell (2012), 57% of the females indicated they would prefer to spend their waiting time with a relative. Indeed, few studies have demonstrated the relatives' experience in AS (Majholm et al., 2012). This is true, even though literature and the present study have portrayed the key importance of emotional support from relatives (Majholm et al., 2012; Rokach et al., 2014).

#### **5.5.6. Type of Surgery**

In this local study, different types of surgeries were collated into two main categories i.e., mild sedation and GA. In terms of pre-operative anxiety and type of surgery, no statistical significance was identified. This line of thought is in agreement with the cross-sectional study conducted by Jiwanmall et al. (2020) who recruited 399 AS participants. However, although not statistically significant, patients who underwent GA experienced higher levels of pre-operative anxiety in comparison to LA, a finding similar to the present study. Similar results were portrayed in two studies (i.e., Wetsch et al., 2009; Wu et al., 2020) which however identified a statistically significant correlation between GA and higher anxiety scores.

Nonetheless, the results of Wu et al. (2020) should be construed with caution, as only 33 participants underwent GA. Consequently, further future evidence-based studies are required to confirm such findings. Additionally, this contemporary study included a relatively narrow range of surgeries (orthopaedic, otolaryngology & general procedures), unlike the present study, which included several surgeries. The results in the current study, in addition to that conveyed in the general literature (Wu et al., 2020), highlight the need for further research with representative samples on the different types of anaesthesia and anxiety scores.

### **5.6. Pre-operative comfort, emotions and patient support**

Even though modern AS facilities tend to provide high quality care, hospitalisation tends to exert a great deal of psychological distress on patients, affecting their mental and emotional well-being (Rokach et al., 2014). Part A of the QoR-40 in the current study evaluated the level of comfort, emotions and patient support in the day care setting pre-operatively. In terms of pre-operative comfort, the majority of the patients (68.9%) stated that they felt comfortable and rested. Furthermore, in terms of emotions and general well-being, the majority of the participants (35.3%) stated that they felt generally well all of the time, followed by 31.6% of the participants feeling well for most of the time. Interestingly enough, for both the comfort and emotions subscales, males scored significantly higher scores. Therefore, males were more comfortable pre-operatively and had a better general well-being and feeling of control. Literature explains such a variance due to the fluctuating levels of certain hormones in females (Weinstock, 1999). Moreover, others suggest that such a difference exists due to the fact that males tend to report less frequently than females, in terms of emotions (Kumar et al., 2019).

Regarding pre-operative patient support, in the current study, most of the patients felt supported, mostly by hospital doctors (48.5%) followed by nurses (41.9%) and the least by relatives (40.4%). Although not statistically significant, males felt more supported pre-

operatively in this study. However, a recent study conducted by Rafiq and Safdar (2021) revealed how men, pre-operatively, scored lower on support which might be endorsed to the fact that men are less likely to talk about their stressors. In the study of Rafiq and Safdar (2021), a negative correlation was identified between pre-operative social support and mental health issues. Hence, patients who are provided with pre-operative support through counselling are less likely to experience mental health challenges, for example anxiety.

In the present study, less than half of the patients (41.9%) felt supported pre-operatively by the nurses. The present researcher hopes that such findings may create awareness amongst nurses about the importance of person-centred theory in practice, where feelings and well-being of the patients are taken into consideration, which also exemplifies Parse's first practice dimension. Consequently, this will enable nurses to be in a better position to provide all the necessary psychological help (Rafiq & Safdar, 2021).

### **5.7. Prevalence of local and international post-operative anxiety**

In the current project, the prevalence of post-operative anxiety was 40.4% (n=55). With regard to post-operative anxiety, 26.5% (n=36) of the participants experienced moderate post-operative anxiety while 11% (n=15) of the patients experienced severe post-operative anxiety. Furthermore, females experienced higher levels of post-operative anxiety. Such findings are in concordance with the study conducted by McIntosh and Adams (2011), which reported a 31% prevalence of post-operative anxiety in AS, where similar to the present study, females experienced higher levels of anxiety. A prospective study by Reyes-Gilabert et al. (2017) reported a higher prevalence of post-operative anxiety in AS, specifically, 73.3%. However, the study setting was different, as this was conducted in a primary dental setting and included patients who underwent LA only. Nonetheless, this study, similar to the present study, indicated that females experienced higher post-operative anxiety, where literature suggests that females are more truthful when completing surveys regarding anxiety (Shafer et



al., 1996). Another study led by Akinsulore et al. (2015) conveyed a lower prevalence of post-operative anxiety (15.7%) where such a variance might be due to a different health setting (i.e. tertiary hospital in Nigeria).

### **5.7.1. Pre-operative and post-operative anxiety**

Few studies assess the quality of life of an AS patient (Suhonen et al., 2007). In the current study, anxiety was reduced from 71.3% (pre-operative) to 40.4% (post-operative). In fact, pre-operative anxiety was negatively statistically significantly associated with the post-operative emotions domain, which included statements regarding post-operative anxiety, bad dreams and difficulty with falling asleep, feelings of anger and feelings of depression. Hence, patients who experienced high levels of pre-operative anxiety felt more anxious, experienced difficulty with falling asleep and experienced feelings of depression post-operatively.

Such trends also concur with the results obtained by McIntosh and Adams (2011), where anxiety decreased from 54% to 31% in a convenience sample of AS participants, where pre-operative and post-operative anxiety were also correlated. Such a reduction in anxiety has also been recognised in emergency surgical patients, as demonstrated in the study of Young et al. (2000). Several other studies also demonstrated that pre-operative and post-operative anxieties are inter-correlated (Caumo et al., 2001; Suhonen et al., 2007). By means of binary logistic regression analysis for several factors (e.g., gender, education, etc.), Reyes-Gilabert et al. (2017) reported that the statistical likelihood of having post-operative anxiety was related to pre-operative anxiety, in ambulatory oral surgery. The present study contributes to literature by exploring predictors, however, in patients undergoing both mild sedation and several surgeries under GA. In an additional study by Akinsulore et al. (2015), levels of pre and post-operative anxiety were similar to the present study, where mean anxiety scores pre-operatively ( $42.72 \pm 9.84$ ) were significantly higher than the post-operative readings ( $37.73 \pm 8.44$ ;  $p = .001$ ). Such findings are consistent with two other studies (Nijkamp et al., 2004;

López-Jornet et al., 2013), which both demonstrated lower levels of post-operative anxiety. Such a reduction in anxiety levels might be attributed to the reduction of presenting symptoms, in addition to the fact that, most patients are worried about the outcome of the procedure (Akinsulore et al., 2015).

### **5.8. Post-operative recovery**

The awareness that person-centred care should target providing a good care experience and involving patients in their care (McCormack & McCance, 2017) is often cited, yet literature suggests that a lack of support exists regarding QOR (Mottram, 2011). Indeed, Mottram (2011) argues that there is an increasing need for knowledge about the QOR in AS. The present researcher included QOR as a key outcome so this study contributes to this gap in literature, especially since this post-operative stage seems to be a weak point in the AS process (Berg et al., 2013). In the current project, findings revealed that males had a better QOR, in terms of comfort, emotions, patient support and they experienced less levels of post-operative pain. Additionally, patients aged 46+ years, had a statistically significant better emotional well-being post-operatively, compared to other younger participants. This line of thought is in agreement with the RCT conducted by Nilsson et al. (2019) where post-operatively, poor mental health was linked with younger patients, even though the exact reason is still unknown (Nilsson et al., 2019). Indeed, Jaensson et al. (2017) state that the role of age and QOR in AS requires further exploration.

A phenomenographic study by Berg et al. (2013) revealed the emotional impact of surgery, as patients felt that they wanted comfort and to be cuddled once home. Additionally, Berg et al. (2013) conducted interviews with patients who only underwent orthopaedic, general or urologic day surgery and indicated that when QOR did not go as projected, this triggered anxiety. Similar to the findings of the current study, several studies portrayed that women have a poorer QOR (Buchanan et al., 2011; Myles et al., 2001; Nilsson et al., 2019; Teunkens

et al., 2017). Such results might be attributed to the fact that men tend to portray less emotion, due to gender stereotypes (Koenig, 2018). Additionally, Jaensson et al. (2018) argue that few studies have evaluated this gender dissimilarity in QOR, an important aspect for future recommendation. Indeed, to contribute to this literature gap, in the current study, gender was included as a predictor of QOR in terms of emotions and comfort. This is especially significant, since the stereotype that women are the emotional ones and that there are great gender dissimilarities in feelings, still exist (Hyde, 2014). Although most authors agree that men tend to have a better QOR, Jaensson et al. (2018) conveyed no significant difference between the sexes in their study.

Aspari and Lakshman (2018) point out that the patient's pre-operative psychological and mental status is often overlooked, consequently, impacting QOR. Since QOR is largely influenced by the pre-operative phase, routine pre-operative assessment should take into consideration the mental status of the client (Nilsson et al., 2019). Despite such an important issue, few studies examine QOR of AS patients and its significant relationship with poor pre-operative mental health status (Nilsson et al., 2019). Hence, the present study contributes to this literature gap.

To date, no local intra-operative assessment has been done in relation to the patient's mental health, even though literature depicts that a poor pre-operative mental health status is related with an augmented risk of complications (O'Connell et al., 2018); mortality (Takagi et al., 2017); overuse of opioids (O'Connell et al., 2018); adverse events (Baker et al., 2015) and increased pain (Ali et al., 2014; Raichle et al., 2015).

### 5.8.1 Post-operative patient support and follow-up

Pre-operative anxiety is a significant predictor of QOR, including patient support and dissatisfaction (Adogwa et al., 2014; Ali et al., 2007). Findings in the current study revealed how the majority of the patients (45.6%) felt confused and lacked support for some time post-operatively. Furthermore, a statistical significance was identified in terms of gender, with females experiencing less patient support. Moreover, patients who underwent an endoscopy procedure expressed receiving more post-operative patient support when compared to GA. Consequently, intra-operative nurses should ensure that effective support should be provided to patients who undergo GA, especially since AS burdens the patients in terms of self-management at home (Dahlberg et al., 2018; Odom-Forren et al., 2017). As posited by the person-centred care model, this incorporates working with the patient's beliefs and engaging sympathetically by recognising the uniqueness of each patient and also responding to cues to help maximise coping in patients (McCormack & McCance, 2017).

QOR, including patient support, could be further improved by considering the patients' mental health status; not only their physical statuses, including the pre-operative psychological status, as these all influence the recovery (Jaensson et al., 2019). Similarly, Aspari and Lakshman (2018) indicated that poor mental health is associated with a negative QOR, being one of the most overlooked aspects in practice.

Although no precise consensus exists about follow-up after AS (Discharge process & criteria, 2016), there is a developing body of research supporting electronic follow-up tools (Armstrong et al., 2017; Williams et al., 2018). Literature supports digital follow-up tools, such as smartphone applications that patients find easy to utilise (Debono et al., 2016; Jaensson et al., 2015) and that have a positive outcome on QOR (Jaensson et al., 2017). Such tools will help the patients to feel safer after AS, hence, minimising post-operative anxiety (Dahlberg et al., 2018). To date, no local digital follow-up tools exist in terms of AS, even

though such tools might help in the QOR by addressing certain discomforts that can happen post-operatively (Jaensson et al., 2017).

### **5.8.2. Post-operative pain after day surgery**

In spite of on-going advances in pain management, the incidence of pain after AS remains high (Dewar et al., 2003). In the present study, females experienced higher levels of pain. Most of the participants (30.9%) rated their pain as 6 on the NRS (0=minimum pain, 10=maximum pain), followed by 19.1% of the patients rating their pain as 5. None of the participants in this study rated their pain as 9 or 10, while 6.6% of the participants did not experience post-operative pain. This is in line with literature, which reveals that a significant amount of patients experience different severe levels of pain from different surgeries, following AS (Coll et al., 2004; Coll & Ameen, 2006).

Although pain is a common symptom following AS, there is a variation in the reported levels (Suhonen et al., 2007). Post-operative pain is experienced by the majority of the AS patients, however literature depicts that it depends on the type of surgery (Rosén et al., 2011). Indeed, in the present study, patients who underwent GA had higher levels of pain. Similarly, Shnaider and Chung (2006) report that patients who underwent orthopaedic or general surgery, reported higher levels of post-operative pain. This is in concordance with the study of Coley et al. (2002) who reported that orthopaedic patients suffered the most post-operative pain. Such disparity in the reported pain levels in literature might be attributed to the lack of knowledge about post-operative pain management (Coll et al., 2004). Hence, this points toward future studies about evaluating and improving new methods of pain assessment (Barthelsson et al., 2003).

The present study also showed how post-operative pain was negatively correlated with post-operative patient support. Hence, one can conclude that patients, who suffered from high

levels of post-operative pain, perceived having lower levels of post-operative patient support. Such a finding highlights the importance of providing a strong support system to the patients, by monitoring and discussing patient's subjective pain experience and consequently supporting them. Hence, this exemplifies Parse's second dimension (i.e. synchronizing with the patient's thoughts).

The findings in the present study, in addition to literature, depict that post-operative pain needs to be assessed and documented regularly in the QOR of AS patients, utilising a proper assessment tool (Rae, 2016). Moreover, nurses have a crucial role in managing post-operative pain, in addition to educating the patients and their relatives about good pain management at home (Suhonen et al., 2007). This is particularly important, as findings in this study revealed that both pre and post-operative comfort and emotions were positively associated with post-operative pain. Hence, good pain management in AS contributes to a better general well-being and comfort of the patients.

### **5.8.3. Pre-operative anxiety and post-operative pain**

One of the main aims of this study was to identify any possible association between peri-operative anxieties in relation to post-operative pain. Post-operative pain on the QoR-40 was negatively associated with the APAIS; hence this study shows that high levels of pre-operative anxiety are associated with high levels of post-operative pain. Consequently, such findings highlight the importance of identifying anxiety in AS, as it is associated with increased pain levels. This is especially important since studies show that acute hospital nurses frequently lack the essential skills in identifying common mental health problems for instance anxiety, which subsequently influence hospital care (Royal College of Psychiatrists, 2013).

Furthermore, this study revealed that post-operative pain was positively associated with both pre and post-operative comfort and emotions. Therefore, having a general good well-being and feeling comfortable pre-operatively were associated with low levels of post-operative pain. Similarly, patients who rated their pain as high on the NRS had a lower general well-being of emotions and were less comfortable, both pre-operatively and post-operatively, as revealed through inter-correlation. Pereira et al. (2016) conducted a RCT that evaluated the power of an empathic patient-centred approach on pre-operative anxiety and QOR, including pain, in AS. This study revealed that personalised pre-operative information reduced pre-operative anxiety, which in turn, helped to minimise post-operative pain. Hence, this study shows that future studies should be evaluate the power of an empathic patient-centred approach in practice.

Similarly, the cross-sectional study by Fernandez-Aguilar et al. (2020) revealed how patients who suffered from high levels of pre-operative dental anxiety required more analgesia post procedure. Moreover, literature also reveals that patients who experience severe pre-operative anxieties tend to have higher expectations of post-operative pain, resulting in an increased amount of analgesia (Perković et al., 2014). Such findings concur with other studies, such as those published by Torres-Lagares et al. (2014); Kazancioglu et al. (2017) and Wang et al. (2017). These studies consequently highlight the significance of the present study, i.e., addressing anxiety, as it might also help to minimise the use of unnecessary analgesia.

Conversely, McIntosh and Adams (2011) revealed no association between pre-operative anxiety and post-operative pain in AS. Nonetheless, such a study highlighted the importance of implementing a peri-operative anxiety assessment tool, even though this might be a challenge due to the restricted timeframe (McIntosh & Adams, 2011). This is significantly important, as to date; no local anxiety assessment tool is implemented during the peri-operative care of a day surgery patient. In fact, two recent studies implemented by Jaensson

et al. (2019) and Nilsson et al. (2019) both argue that valid tools should be utilised during the pre-operative period to monitor the patients' mental health status. Both authors claim that the standard assessment should incorporate the patients' pre-operative mental health status to identify patients who require further psychological preparation for surgery (Jaensson et al., 2019; Nilsson et al., 2019). Consequently, according to this mental status, counselling might be provided in the pre-operative assessment clinic, to prepare the patients both physically and mentally for the surgery, as this will eventually enhance QOR, as demonstrated in the present study. Additionally, mental health assessment, utilising a validated tool, should also be conducted in the post-operative period, so as to assess the whole spectrum of symptoms (Nilsson et al., 2019). Indeed, Wetsch et al. (2009) recommend that in practice, a short screening method should be utilised to analyse anxiety as this will aid nurses to provide holistic care.

This line of thought is in agreement with the study of Aspari and Lakshman (2018), which highlights that, a patient's mental preparation for AS is as equally central as the physical preparation. In addition to an assessment tool, an empathic approach including the use of personalised information can support the patient's mental well-being (Pereira et al., 2016). Consequently, healthcare professionals in AS, especially nurses, play a significant role in identifying factors that can lead to a negative QOR, such as pre and post-operative anxiety and uncontrolled pain. Hence, such personnel should ideally be trained in identifying such factors, as this will support the patients mentally and psychologically. Furthermore, further evidence-based research can be implemented to evaluate the outcome of this suggested pre-operative screening and possibly detect further elements that influence QOR in AS (Jaensson et al., 2019). Additionally, future studies should also assess the relation between peri-operative anxiety and QOR in patients with various mental health challenges, such as patients



who are diagnosed with bipolar disorder (Jaensson et al., 2019). The present researcher acknowledges such a limitation, as cognitively impaired patients had to be excluded.

### **5.9. Physiological Parameters**

In the current study, the Wilcoxon test was utilised to identify any relationship between the pre-operative and post-operative BP, HR and oxygen saturation where statistically significant differences in pre-operative and post-operative SBP, HR and oxygen saturation were identified. Conversely, no statistical significance was identified between pre-operative and post-operative DBP. Indeed, the average pre-operative heart rate was 78.8bpm, while the average post-operative heart rate was 75.2bpm, i.e., a decrease in heart rate post-operatively. This indicates that in the present study, participants felt calmer after the procedure. Similarly, the mean pre-operative SBP was 130mm Hg, while the post-operative systole was 126.3mmHg, indicating a decrease in SBP post-operatively. Conversely, the mean DBP was 75.1mm Hg, while post-operatively 73mmHg; hence, no statistical significance was identified. Mean oxygen saturations pre-operatively were 98.8%, while post-operatively the reading increased to 99.2%, indicating better oxygen levels in the patients' bloodstream post-procedure.

In a study by Fernandez-Aguilar et al. (2020), 185 patients undergoing a dental extraction were recruited to assess dental anxiety where BP and HR were measured before and after the dental extraction. Similar to the trend of the present study, although not statistically significant, the SBP decreased from 100mmHg before the procedure to 97mmHg after the procedure. However, the pre-operative DBP increased from 52mmHg to 55mmHg post-procedure. Furthermore, similar to the trend of the present study, the HR decreased from 53bpm to 45bpm, although not statistically significant. In the study of Fernandez-Aguilar et al. (2020), a statistical significant difference was observed for different levels of anxiety (low,

moderate, high, severe) and both pre and post-operative BP and HR. The most significant differences were identified for persons with moderate and severe levels of anxiety, where comparable findings were conveyed in the study of Sharma et al. (2019). Indeed, results depicted that post anaesthesia, the HR increased in the moderate and severe categorical levels of anxiety. However, the present study contributes to extant literature as the parameters measured were not identified as significant predictors for post-operative emotions and post-operative comfort in the regression analyses.

### **5.10. Conclusion**

This study showed that a significant amount of patients suffer from pre-operative (71.3%) and post-operative anxiety (40.4%); pre-operative anxiety is significantly associated with post-operative pain. Additionally, such findings were analysed in relation to several variables where the next chapter provides further recommendations for education, research and practice.

# **CHAPTER 6: CONCLUSION & RECOMMENDATIONS**

### **6.1. Introduction**

This chapter provides a review of the study, which was conducted amongst AS patients. Subsequently, this review is followed by critique of the study and recommendations which emerged from the findings.

### **6.2. Summary of the study**

The person-centred theory highlights the importance of shifting from ‘person-centred moments’ to a person-centred culture, where feelings and well-being of the patients are taken into consideration (McCormack & McCance, 2006). Nurses play a significant role in minimising patient’s anxiety and enhancing QOR, hence; need to be equipped to deliver person-centred care. Consequently, the patient will feel understood, by providing the necessary psychological support (Pereira et al., 2016).

Subsequently, the purpose of this study was to evaluate peri-operative anxiety in relation to QOR, including post-operative pain, in AS. Several demographic variables were taken into account, including gender, age, education, previous operations, presence of relatives and type of surgery. Additionally, predictor variables were identified for both post-operative comfort and post-operative emotions. To the knowledge of the researcher, no local research has been done to evaluate peri-operative anxiety and its effect on QOR, including pain. Moreover, both local and international studies did not evaluate predictors of post-operative emotions and post-operative comfort in AS. Consequently, a cross-sectional design was utilised to gather data from patients undergoing AS, through the use of 3 tools, i.e. APAIS, QoR-40 and NRS. Out of 150 questionnaires distributed, 136 were returned (response rate= 90.7%), where the majority of the participants were females (53%) and aged 46+ years (37.5%).

The prevalence of pre-operative anxiety was quite high (71.3%), highlighting the importance of applying Parse's theory in practice, i.e. guiding the patients to talk about their feelings and consequently, responding to their psychological needs. There is a variation in the prevalence of pre-operative anxiety worldwide, with values ranging from 60% to 92% (Perks et al., 2009). As conveyed by several studies and the present study, the influence of cultural differences on pre-operative anxiety is still not clear (Stein, 2009).

Regarding information needs, 47.8% of the participants did not wish to know either at all or somewhat more about the anaesthetic while 47.1% stated that they did not wish to know either at all or somewhat about surgery. The findings in the present study differ from some studies (Jiwanmall et al., 2020; Nigussie et al., 2014) which demonstrated how patients with high anxiety scores required more detailed information. In the current study, most of the participants did not desire a lot of information i.e. classified as 'blunters.' Hence, an important recommendation is to pro-actively identify whether patients are monitors or blunters, and then adjusting level of information provision accordingly.

Significant differences were identified in participant's pre-operative anxiety by gender and age, where females experienced higher anxiety. Furthermore, patients aged between 32-45 years experienced the highest levels of anxiety and the highest levels of need for information. Regarding pre-operative comfort, the majority of the patients (68.9%) stated that they felt comfortable while the majority of the participants (35.3%) stated that they felt generally well in terms of emotions. For both the comfort and emotions subscale, males scored significantly higher scores.

Furthermore, the prevalence of post-operative anxiety was 40.4%, where inter-correlational analysis revealed that pre-operative anxiety was statistically significant with post-operative anxiety. Moreover, males had a better QOR and experienced less post-operative pain. Additionally, patients aged 46+ had a statistically significant better well-being post-operatively, compared to younger participants. Regarding post-operative support, the majority of the patients (45.6%) lacked support for some of the time post-operatively where females perceived experiencing less patient support and patients who underwent an endoscopy expressed receiving more support than GA. Consequently, as posited by the person-centred care model, this incorporates working with the patient's beliefs and engaging sympathetically by recognising the uniqueness of each patient and hence responding to cues to help maximise coping in patients (McCormack & McCance, 2017).

Regarding pain, females experienced higher levels of post-operative pain where the majority of the participants (30.9%), rated their pain as 6 on the NRS. Additionally, post-operative pain was positively correlated with post-operative patient support. Such a finding highlights the importance of providing a strong support system to the patients, which exemplifies Parse's second dimension (i.e. synchronizing with the patient's thoughts). The findings in this study, in addition to literature depict that post-operative pain needs to be assessed regularly in the QOR of AS patients, utilising an assessment tool (Rae, 2016). Moreover, post-operative pain was negatively associated with the APAIS where such finding highlights the importance of identifying anxiety as it is associated with increased pain. This is especially important since studies show that acute nurses frequently lack the essential skills in handling common mental health issues such as anxiety (Royal College of Psychiatrists, 2013).

Finally, important predictors of post-operative anxiety and post-operative comfort were identified. Gender, pre-operative anxiety, pre-operative emotions and post-operative pain were acknowledged as significant predictors of post-operative emotions, while gender and post-operative pain were identified as predictors of post-operative comfort. Hence, early identification and management of pre-operative anxiety and post-operative pain aid in reducing post-operative anxiety, while promoting QOR.

### **6.3. Strengths and limitations**

This study examined the perceptions of patients who made use of a day surgery unit in Malta and shed some light on their experience, especially their mental well-being, before and after surgery. Therefore, this project contributed both to local and international literature by collating information on peri-operative anxiety and QOR in patients who underwent AS, in addition to providing information about the influence of several variables on such an experience. Moreover, important predictors of post-operative emotions and post-operative comfort were identified. Furthermore, the Cronbach alpha values for all the subscales of the surveys were all above 0.7, demonstrating good internal reliability. Consequently, this study may help to address the lacuna in both local and international research about peri-operative anxiety and its effect on the hospital experience.

Nevertheless, despite the efforts to keep limitations at a minimum, the researcher acknowledges a series of methodological drawbacks, for example, the number of participants, which could have affected the findings.

#### **6.3.1. The Research Design**

The response rate was high (90.7%), therefore, increasing validity of this study, as this minimises potential differences between respondents and non-respondents (Brtnikova et

al., 2018). Consequently, the results in this study can be generalised to the general population and hence decreasing response bias (Johnson & Wislar, 2012). Additionally, to increase response rate, participants had the opportunity to either fill in the English or Maltese version of the questionnaires and were advised that it should not take longer than 10 minutes. Indeed, a qualified translator translated the English questionnaires into Maltese, in order to increase accuracy. The majority of the participants in this research study were females (53%) and mainly aged above 46+ years (38%). Such demographics represent the current cohort characteristics for AS patients in Malta. Furthermore, participants completed the questionnaires anonymously and thus may have felt more at ease to express their actual viewpoint.

Due to time constraints and COVID, a cross-sectional design was utilised which provides valuable numerical data; however, it restricts the collection of in-depth information (Queirós et al., 2017). Nonetheless, within a limited framework, this study has gathered important aspects which could be further evaluated, for instance, through phenomenological studies, which assess the lived experiences of participants. There is a need of further studies, possibly a mixed method design, which evaluates quantitative data followed by in-depth interviews.

### **6.3.2. The Research Method**

The current study utilised three measurements tools, (i.e., APAIS, QoR-40 and NRS), as these were deemed as the most suitable. The APAIS assessed pre-operative anxiety and information needs while the QoR-40 was utilised to assess QOR including post-operative pain. Anxiety, being a subjective phenomenon is not easy to evaluate (Shafer et al., 1996); however, after extensive research of the available tools; the APAIS, which was psychometrically tested, was deemed as the most efficient to be used in a busy setting. All of the tools utilised demonstrated good validity and reliability.



Additionally, since the present author made use of three established tools, comparability with other studies could be adopted. Furthermore, several advantages are related with the use of questionnaires, including the possibility of a large recruitment of participants, in a relatively constrained framework. If focus groups or interviews were used instead, this could have presented difficulties and would have been almost impossible to conduct, due to the busy setting and the fact that patients are called in for surgery at any time. Moreover, since the questionnaires were completed by the same participant, this enabled the researcher to evaluate the anxiety, comfort, emotions and patient support before and after surgery. Most of the retrieved studies included in the literature review, either assessed pre-operative anxiety or post-operative anxiety separately, not utilising the same participants. Nonetheless, the researcher acknowledges the fact that patients filled the post-operative survey while still in hospital, so this limited the span of QOR to a few hours after surgery (4-5 hours).

### **6.3.3. The Research Setting and Data Collection**

An important aspect of this project is the fact that two intermediaries approached potential participants and not the present author to avoid feelings of coercion. During the waiting time before the surgery, potential participants were approached and handed an information letter by an intermediary. One cannot rule out the possibility of some copying responses among the participants, whilst waiting in the same area. Nonetheless, this arrangement of setting was crucial in promoting a high response rate, whilst minimising contamination of responses. However, the researcher acknowledges the fact that the sample population was heterogeneous in terms of age, education and type of surgery and that such diversity could be examined through the application of statistical analyses such as the ANOVA. Furthermore, a pilot study was implemented amongst 12 respondents to test the actual time to complete the questionnaires. Although no

significant changes were made, it is still considered as important to identify any problems that could be improved for the main study (Blatch-Jones et al., 2018).

#### **6.3.4. Data Analysis**

Since the researcher had not conducted quantitative data analysis before, this was deemed as both as a strength and a limitation. Such a hectic process proved to be a learning experience for the researcher as this entailed attending online SPSS courses offered by the UOM. This helped in guiding the researcher to make use of appropriate data analytic techniques. Nonetheless, in order to address such a limitation, a qualified statistician was consulted online via ZOOM to ensure that data analyses were conducted appropriately. Such a process minimised the possibility of subjective and/or incorrect interpretations, which could have led to research bias. Furthermore, data was checked for normal distribution in order to utilise appropriate test statistics. Additionally, regression analyses were also conducted, which is deemed as an important strength of this study, as it enabled the identification of significant predictors of both post-operative emotions and post-operative comfort and has not been performed in the extant literature available.

#### **6.3.5. Ethical standards**

The present author acknowledged several ethical responsibilities especially since it involved human beings (Doody & Noonan, 2016). The information letter explained that participation was entirely voluntarily and that they could withdraw from the study anytime, hence, ensuring autonomy of the subjects (WHO, 2020). Moreover, it was emphasised that should they decide to withdraw, quality of care would not be affected. Additionally, the researcher made sure that the anonymous data did not lead to any type of identification, hence, respecting the patients' confidentiality (Doody & Noonan, 2016). Several permissions to conduct the study were sought as described in chapter 3

and ethical clearance was also given by UREC. Finally, participants were also informed that the service of a psychologist would be available at no financial cost in case of distress.

#### **6.4. Recommendations and Interventions**

The collated findings in this study provide the groundwork for recommendations in relation to education, clinical practice and future research, as presented in the subsequent concluding sections.

##### **6.4.1. Recommendations for Educational Policy**

- Lectures and conferences should focus on the psycho-emotional aspect of the surgical patient as nurses would be sensitised to incorporating mental health with physical health and hence, would be able to provide person-centred care, targeting the patient's unique needs.
- Nurses must recognise that patient support is required both pre-and post-operatively with focus on certain features (gender, type of anaesthesia) that make the patient more vulnerable to lack of support, as demonstrated in this study. Subsequently, how to make a referral to appropriate services (counselling, psychological, spiritual support) when needed.
- Inclusion of Parse's theory and person-centred models in the curriculum as this would provide nurses with the necessary knowledge to assist the patients to have better emotional well-being by taking a 'whole person' perspective.
- Gender, pre-operative anxiety, pre-operative emotions and post-operative pain were identified as predictors of post-operative emotions, while gender and post-operative pain were identified as predictors of post-operative comfort. Hence, providing knowledge and increasing awareness amongst staff and students about

early identification of pre-operative anxiety and post-operative pain is important as it aids in reducing post-operative anxiety while promoting comfort.

#### **6.4.2. Recommendations for Clinical Practice**

- Introduction of person-centred approach through the use of personalised information, in the pre-operative assessment clinic. This should include face to face instructions, where patients can ask questions, rather than standard telephone-based education.
- This study demonstrated that pre-operative anxiety and pre-operative emotions are predictors of post-operative emotions, hence, a pre-operative anxiety tool is significant for early identification of anxiety, such as the Short Form 36 Health Survey, which takes into account both the physical and mental component, and literature reveals that it is effective in AS (Nilsson, Dahlberg & Jaensson, 2019). Based on the SF-36, counselling can be introduced to prepare the patient, both mentally and physically for AS and hence, improve QOR.
- Encouraging nurses to include relatives in their care as this study revealed how pre-operatively, patients had a better general well-being and sense of comfort when accompanied by a relative.
- Introduction of electronic follow-up tools, such as the Recovery Assessment by Phone Points (RAPP) mobile app. The RAPP evaluates QOR utilising the QoR-40, where literature reveals its effectiveness in improving QOR in AS (Nilsson, Dahlberg & Jaensson, 2019). Through daily assessments, patients can enhance QOR through positive feedback from the RAPP.
- Educating the patients and their relatives about pain management, especially, since this study revealed that both pre and post-operative comfort and emotions were positively associated with pain.

- The International Association for AS (2021) suggests that a follow-up call is done by nurses 24 hours after AS, especially in those prone for poor recovery. The present study endorses such recommendation as the majority of the patients (45.6%) lacked post-operative support for some of the time.

#### **6.4.3. Recommendations for Further Research**

- A longitudinal study which evaluates peri-operative anxiety in AS over time, for example, over a year, to understand the impact of AS over a longer duration as this was not explored in the present study.
- More local qualitative research, as this would enable the researcher to acquire in-depth data about the lived experiences of the AS patients.
- Consequently, such findings might create room to new studies that examine the use of apps (ex. RAPP) on anxiety and QOR in AS.
- Further research in people who are cognitively impaired or illiterate as these were excluded in the present study.

#### **6.5. Conclusion**

The present study was the first study addressing peri-operative anxiety and QOR in a local setting where despite the limitations; it revealed significant findings, such as a high prevalence of pre-operative anxiety (71.3%) and post-operative anxiety (40.4%). Furthermore, high levels of pre-operative anxiety were associated with high levels of post-operative pain. QOR including patient support could be further improved by considering the patients' mental health status; not only their physical statuses, including the pre-operative psychological status. Additionally, significant predictors of post-operative comfort and post-operative emotions were also revealed. To conclude, it is

hoped that the current study will spur interest in other researchers to further explore peri-operative anxiety and QOR in AS patients.

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**Appendix A: English and Maltese version:  
The Amsterdam Pre-Operative Anxiety and  
Information Scale**



### English version

Questions	The Amsterdam preoperative anxiety and information scale				
	1	2	3	4	5
1. I am worried about the anesthetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The anesthetic is on my mind continually	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I would like to know as much as possible about the anesthetic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am worried about the procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The procedure is on my mind continually	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I would like to know as much as possible about the procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1: Not at all, 2: Somewhat, 3: Moderate, 4: Moderately high, 5: Extremely

### Maltese version

Mistoqsijiet	The Amsterdam preoperative anxiety and information scale				
	1	2	3	4	5
1. Inkwetat/a dwar il-loppju	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Il-loppju l-ħin kollu fuq moħħi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Irrid inkun infurmat/a kemm jista' jkun dwar il-loppju	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Inkwetat/a dwar il-proċedura	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Il-proċedura l-ħin kollu fuq moħħi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Irrid inkun infurmat/a kemm jista' jkun fuq il-proċedura	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1: Lanqas xejn, 2: Xi ftit, 3: Moderatament, 4: Pjuttost, 5: Ħafna

**Appendix B: English and Maltese version:  
The Quality of Recovery Scale (QoR-40)**

# English version

Date: \_\_/\_\_/\_\_

## Patient Survey (QoR – 40)

Name: \_\_\_\_\_ study #: \_\_\_\_\_ Hospital UR #: \_\_\_\_\_

### PART A

**How have you been feeling in the last 24 hours?**

(1 to 5, where : 1 = very poor and 5 = excellent)

**For example:** If you have been able to breathe easily all of the time, you should indicate this by circling the response 5 = *all of the time* as shown below:

	None of the time	Some of the time	Usually	Most of the time	All of the time
Able to breathe easily	1	2	3	4	5

	None of the time	Some of the time	Usually	Most of the time	All of the time
<b>Comfort</b>					
Able to breathe easily	1	2	3	4	5
Have had a good sleep	1	2	3	4	5
Been able to enjoy food	1	2	3	4	5
Feel rested	1	2	3	4	5
<b>Emotions</b>					
Having a feeling of general well-being	1	2	3	4	5
Feeling in control	1	2	3	4	5
Feeling comfortable	1	2	3	4	5

**How have you been feeling in the last 24 hours?**

(1 to 5, where : 1 = very poor and 5 = excellent)

	None of the time	Some of the time	Usually	Most of the time	All of the time
<b>Physical Independence</b>					
Have normal speech	1	2	3	4	5
Able to wash, brush teeth or shave	1	2	3	4	5
Able to look after your own appearance	1	2	3	4	5
Able to write	1	2	3	4	5
Able to return to work or usual home activities	1	2	3	4	5
<b>Patient Support</b>					
Able to communicate with hospital staff (when in hospital)	1	2	3	4	5
Able to communicate with family or friends	1	2	3	4	5
Getting support from hospital doctors (when in hospital)	1	2	3	4	5
Getting support from hospital nurses (when in hospital)	1	2	3	4	5
Having support from family or friends	1	2	3	4	5
Able to understand instructions and advice	1	2	3	4	5

## PART B

*Have you had any of the following in the last 24 hours?*

(5 to 1, where: 5 = excellent and 1 = very poor)

	None of the time	Some of the time	Usually	Most of the time	All of the time
<b>Comfort</b>					
Nausea	5	4	3	2	1
Vomiting	5	4	3	2	1
Dry-retching	5	4	3	2	1
Feeling restless	5	4	3	2	1
Shaking or twitching	5	4	3	2	1
Shivering	5	4	3	2	1
Feeling too cold	5	4	3	2	1
Feeling dizzy	5	4	3	2	1
<b>Emotions</b>					
Had bad dreams	5	4	3	2	1
Feeling anxious	5	4	3	2	1
Feeling angry	5	4	3	2	1
Feeling depressed	5	4	3	2	1
Feeling alone	5	4	3	2	1
Had difficulty falling asleep	5	4	3	2	1

***Have you had any of the following in the last 24 hours?***

**(5 to 1, where: 5 = excellent and 1 = very poor)**

	<b>None of the time</b>	<b>Some of the time</b>	<b>Usually</b>	<b>Most of the time</b>	<b>All of the time</b>
<b>Patient Support</b>					
Feeling confused	5	4	3	2	1
<b>Pain</b>					
Moderate pain	5	4	3	2	1
Severe pain	5	4	3	2	1
Headache	5	4	3	2	1
Muscle pains	5	4	3	2	1
Backache	5	4	3	2	1
Sore throat	5	4	3	2	1
Sore mouth	5	4	3	2	1

Thank you for your assistance.

**Please check that all questions have been answered.**

If you have any questions, please contact: Jenny Hunt or Helen Fletcher through the hospital's switchboard (03) 9276 2000.

# Maltese version

Data: \_\_/ \_\_/ \_\_

## Sondagg tal-Pazjent (QoR – 40)

### PARTI A

#### *Kif kont qed tħossok fl-aħħar 24 siegħa?*

(minn 1 sa 5, fejn : 1 = ħażin ħafna u 5 = eċċellenti)

**Pereżempju:** Jekk kien qed jirnexxilek tiegħu nifs faċilment, indika dan billi timmarka risposta numru 5 = *il-ħin kollu* kif muri hawn:

	Qatt	Xi drabi	Normalment	Ħafna mid-drabi	Il-ħin kollu
Kapaċi niegħu nifs faċilment	1	2	3	4	5

Qatt	Xi drabi	Normalment	Ħafna mid-drabi	Il-ħin kollu
1	2	3	4	5

#### **Kumdità**

Kapaċi niegħu nifs faċilment					
Irqadt raqda tajba					
Stajt niegħu gost niekol					
Inħossni mistrieħ/a					

#### **Emozzjonijiet**

Inħossni b'saħħti b'mod ġenerali					
Inħossni f'kontroll tiegħi nnifsi					
Inħossni komdu/a					

**Kif kont qed thossok fl-aħħar 24 siegħa?**

(minn 1 sa 5, fejn : 1 = hażin ħafna u 5 = eċċellenti)

	Qatt	Xi drabi	Normalment	Ħafna mid-drabi	Il-ħin kollu
<b>Indipendenza fiżika</b>	1	2	3	4	5

Nitkellem normali					
Kapaċità li ninhasel, naħsel snieni u nqaxxar					
Kapaċità li nieħu ħsieb l-apparenza tiegħi					
Kapaċità nikteb					
Kapaċità nmur lura għax-xogħol jew għall-attivitajiet normali tad-dar					

**Sapport tal-pazjent**

Kapaċità nikkomunika mal-impjegati tal-isptar					
Kapaċità nikkomunika mal-familja jew ħbieb					
Nikseb is-sapport mit-tobba tal-isptar (meta nkun l-isptar)					
Nikseb is-sapport mill-infermiera tal-isptar (meta nkun l-isptar)					
Nikseb is-sapport tal-familja jew ħbieb					
Kapaċi nifhem struzzjonijiet jew pariri					



## PARTI B

***Kellek xi waħda minn dawn fl-aħħar 24 siegħa?***

(minn 1 sa 5, fejn : 1 = ħażin ħafna u 5 = eċċellenti)

	Qatt	Xi drabi	Normalment	Ħafna mid-drabi	Il-ħin kollu
Kumdità	1	2	3	4	5
Dardir					
Remettar					
Tqalligh					
Thossok bla kwiet					
Tirtogħod					
Itterter					
Thoss wisq bard					
Tistordi					

### Emozzjonijiet

Ħlomt ikrah					
Thossok anzjuż/a					
Thossok irrabjat/a					
Thossok imdejjaq/imdejqa					
Thossok wahdek					
Ikollok diffikultà biex torqod					

**Kellek xi waħda minn dawn fl-aħħar 24 siegħa?**

(minn 1 sa 5, fejn : 1 = ħazin ħafna u 5 = eċċellenti)

	Qatt	Xi drabi	Normalment	Ħafna mid-drabi	Il-ħin kollu
<b>Sapport tal-pazjent</b>	1	2	3	4	5

Thossok konfuż/a

**Ugħiħ**

Ugħiħ moderat

Ugħiħ sever

Ugħiħ ta' ras

Ugħiħ fil-muskoli

Ugħiħ fid-dahar

Griżmejn misluħin

Ħalq misluħ

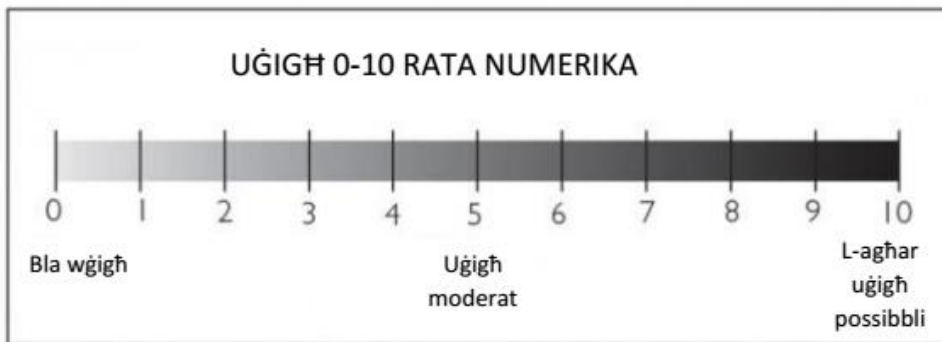
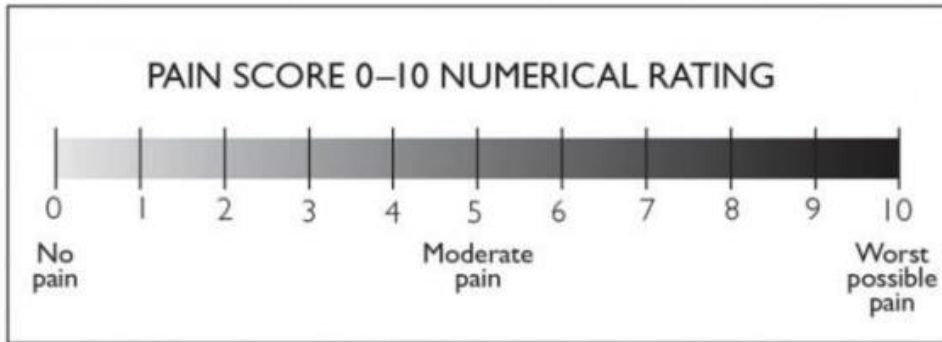

Grazzi tal-assistenza tiegħek.

**Jekk jogħġbok ara li weġibt il-mistoqsijiet kollha.**

Jekk ikollok xi mistoqsija, jekk jogħġbok ikkuntattja lil: Jenny Hunt jew Helen Fletcher permezz tal-iswitchboard tal-isptar: (03) 9276 2000.

## **Appendix C: English and Maltese version:**

### **Numerical Rating Pain Scale**



# **Appendix D: Demographic questions**

## **English and Maltese version**

Demographics

**Put a circle around the correct response.**

Please indicate your gender

- a. Male
- b. Female

Please select in which range your age falls

- a. 18-24
- b. 25-31
- c. 32-38
- d. 39-45
- e. 46-52
- f. 53-59
- g. 60+

Please select your educational level

- a. Primary school
- b. Secondary school
- c. Post secondary (sixth form/MCAST)
- d. Diploma
- e. Bachelors
- f. Masters Degree
- g. Ph.D
- h. Others \_\_\_\_\_

Did you undergo any previous surgical operations?

---

---

Are you accompanied by any relatives/friends?

- a. Yes
- b. No

Please select type of surgery that you will be undergoing

- |                                         |                              |
|-----------------------------------------|------------------------------|
| a. Endoscopy                            | f. Dental                    |
| b. General surgery                      | g. Hernia                    |
| c. Gynaecology                          | h. Vascular (varicose veins) |
| d. Urology (kidneys, bladder, prostate) | i. Endocrine                 |
| e. Orthopaedic                          | j. Breast                    |

## Demografija

### Penġi ċirku mar-risposta t-tajba.

Indika s-sess tiegħek:

- a. Raġel
- b. Mara

Età:

- a. 18-24
- b. 25-31
- c. 32-38
- d. 39-45
- e. 46-52
- f. 53-59
- g. 60+

Livell ta' Edukazzjoni:

- a. Primarja
- b. Sekondarja
- c. Post Sekondarja (sixth form, MCAST)
- d. Diploma
- e. Baċċelerat
- f. Masters
- g. Dottorat
- h. Ohrajn \_\_\_\_\_

Ghamilt xi operazzjonijiet kirurġiċi qabel?

---

---

Ghandek xi qrafa jew hbieb li qed jakkumpanjawk?

- a. Iva
- b. Le

Indika l-operazzjoni li se tagħmel:

- |                                                   |                         |
|---------------------------------------------------|-------------------------|
| a. Endoscopy (l-istrument)                        | f. Dentali              |
| b. Operazzjoni ġenerali                           | g. Tal-Ftuq             |
| c. Ġinekologika                                   | h. Vaskulari (tal-vini) |
| d. Uroloġika (kliwi, buzzieqa tal-pipi, prostita) | i. Endokrinali          |
| e. Ortopedika                                     | j. Fis-sider            |

## **Appendix E: Parameters charting**



Parameters Charting

Code (listed on questionnaire)	Blood pressure	Heart Rate	Oxygen Saturation
e.g. 001			

## **Appendix F: Ethical Approval**

4/22/2021

University of Malta Mail - UREC FORM V\_11022020 4647 Marija Abela



Marija Abela <marija.abela.14@um.edu.mt>

---

### UREC FORM V\_11022020 4647 Marija Abela

**Research Ethics HEALTHSCI** <research-ethics.healthsci@um.edu.mt>

30 May 2020 at 17:27

To: Marija Abela <marija.abela.14@um.edu.mt>

Cc: Josianne Scerri <josianne.scerri@um.edu.mt>, Rosienne Farrugia <rosienne.farrugia@um.edu.mt>

Dear Marija,

In view of the below, FREC's approval has been granted and you may commence with your study. Good Luck.

Sincere Regards,  
Christabel

Christabel Vella  
FREC Secretary

**Faculty of Health Sciences**  
Room 117,  
Dun Mikiel Xerri Lecture Centre  
University of Malta

 <https://www.um.edu.mt/healthsciences/students/researchethics>



[Quoted text hidden]

## **Appendix G: Permission from hospital administration**

## Chief Executive Officer of Mater Dei Hospital

4/30/2020

University of Malta Mail - RE: [EXTERNAL] - Fwd: Masters Thesis Permission

**From:** Marija Abela <[marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt)>  
**Sent:** Tuesday, 28 April 2020 21:55  
**To:** CEO at Health-MDH <[ceo.mdh@gov.mt](mailto:ceo.mdh@gov.mt)>  
**Subject:** [EXTERNAL] - Fwd: Masters Thesis Permission

Dear Ms Falzon

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As a partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled '**Assessment of anxiety and post-operative pain in adults undergoing a day case surgery**'. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the Faculty of Health Sciences at the University of Malta.

Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. Participants will be approached by an intermediary (i.e., a nurse working at day care) pre-operatively, whilst waiting in the day care unit. All patients are requested to attend the day care unit at 7am and then wait in the unit till they are called in for their procedure. During this time the potential participants are approached and handed an information letter outlining details of the study by the intermediary. They are also provided with sufficient time to read it and hence come to an informed decision. Following that those persons who are interested to participate can inform the intermediary, who is a nurse working in this unit. Once the participant indicates their willingness to partake in the study, the intermediary will provide them with an envelope containing 3 questionnaires all having a similar code e.g. 001. The questionnaires are filled in anonymously by the participants. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, participants can select whether to complete an English or Maltese version.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and would all have been provided with a unique code by myself as the researcher. Should the patient agree to participate the nurse will note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine

<https://mail.google.com/mail/u/0/?ik=2499ab89a1&view=pt&search=all&permthid=thread-f%3A1665300293352000752&simpl=msg-f%3A1665300293352000752>

2/14

4/30/2020

University of Malta Mail - RE: [EXTERNAL] - Fwd: Masters Thesis Permission

investigations normally conducted within this ward setting and participants' consent will be obtained for these coded measures to eventually be provided to the researcher.

Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope to the researcher. Participation will be entirely voluntary and no coercion will be exerted. Participants will be informed that they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

I am duly asking for your permission as the CEO at Mater dei hospital to grant approval for me to proceed with this study. If you require any further information please do not hesitate to contact me on 99652426 or [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) or my supervisor Dr Josianne Scerri, on 23401175 or by email [josianne.scerri@um.edu.mt](mailto:josianne.scerri@um.edu.mt). Thank you for your time and consideration in this matter.

Kind regards,

Marija Abela

----- Forwarded message -----

**From:** Data Protection at MDH <[dataprotection.mdh@gov.mt](mailto:dataprotection.mdh@gov.mt)>  
**Date:** Tue, 28 Apr 2020 at 18:54  
**Subject:** RE: Masters Thesis Permission  
**To:** [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) <[marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt)>  
**Cc:** Young Sharon at Health-MDH <[sharon.young@gov.mt](mailto:sharon.young@gov.mt)>, Data Protection Approval Form at Health-MDH <[dpaform.mdh@gov.mt](mailto:dpaform.mdh@gov.mt)>, Abela Marija at Health-MDH <[marija.abela@gov.mt](mailto:marija.abela@gov.mt)>

Dear Ms Abela

On the basis of the documentation you submitted, from the MDH data protection point of view you have been cleared to proceed with your study "**Assessment of anxiety and post-operative pain in adults undergoing a day case surgery**" provided that you obtain approval from MDH CEO ([ceo.mdh@gov.mt](mailto:ceo.mdh@gov.mt)) - please provide the necessary

<https://mail.google.com/mail/u/0/?ik=2499ab89a1&view=pt&search=all&permthid=thread-f%3A1665300293352000752&simpl=msg-f%3A1665300293352000752>

3/14



Marija Abela <marija.abela.14@um.edu.mt>

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**RE: [EXTERNAL] - Fwd: Masters Thesis Permission**

1 message

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CEO at Health-MDH <ceo.mdh@gov.mt>  
To: Marija Abela <marija.abela.14@um.edu.mt>

29 April 2020 at 11:55

Dear Ms Abela,

Please note that Ms Celia Falzon has granted approval for you to conduct this study in line with applicable hospital protocols.

Regards

Carmen Farrugia  
Personal Assistant to the CEO



T +356 +356 25454102

E [carmen.farrugia@gov.mt](mailto:carmen.farrugia@gov.mt)

Mater Dei Hospital, Triq Id-Donaturi Tad-Demm, Msida, Malta MSD 2090 | Tel +356 2545 0000 | <https://careandcure.gov.mt/>

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1/14

# Data Protection officer of Mater Dei Hospital

29/04/2020

RE: Masters Thesis Permission

 Reply all |  Delete Junk | 



## RE: Masters Thesis Permission



Caruana Simon at Health-MDH on behalf of Data Protection at MDH

 Reply all | 

Yesterday, 18:54

'marija.abela.14@um.edu.mt'; Young Sharon at Health-MDH; Data Protection / 

Inbox

You forwarded this message on 28/04/2020 19:15

 Action Items 

Dear Ms Abela

On the basis of the documentation you submitted, from the MDH data protection point of view you have been cleared to proceed with your study *"Assessment of anxiety and post-operative pain in adults undergoing a day case surgery"* provided that you obtain approval from MDH CEO ([ceo.mdh@gov.mt](mailto:ceo.mdh@gov.mt) - please provide the necessary documents including the Chair's approval and this letter).

**All data will be provided to you anonymised because information will be collected through a self-administered questionnaire.**

**NB: This clearance does not cover ethical approval.**

**This clearance does not allow viewing of medical records nor access to Health Information Systems.**

**Please communicate with the Charge Nurse before you start your data collection. You must also present this clearance letter.**

**This clearance does not allow participants to be reached by postal services.**

**If any participant erroneously encloses his / her personal details with the answered questionnaires, you are bound to destroy these immediately. Destruction should be carried out properly and you must ensure that no one finds parts or parts of such information intact.**

**This clearance does not permit you to communicate with participants as these will be approached by your intermediaries Ms Christine Farrugia and Ms Paradise Melit to hand the questionnaires.**

**The questionnaires and information letters are to be distributed in blank envelopes which are then sealed by the participant on completion and posted in a specially appropriated mailbox outside the Charge Nurse's office within the Day Care Unit or sent to you through a self-addressed envelope which you will leave with the intermediaries. It is your responsibility to ensure that this is arranged so that envelopes are not left accessible to others since no individual is allowed to open the sealed envelopes, not even the head of the unit, in view of confidentiality.**

**UOM's logo is to be included in all documents (information letters and questionnaires) that are presented to the participants.**

<https://webmail.gov.mt/owa/projection.aspx>

1/6

## **Charge nurse of Day Care Unit at Mater Dei hospital**

Dear Mr Schembri

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled 'Assessment of anxiety and post-operative pain in adults undergoing a day case surgery. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the Faculty of Health Sciences at the University of Malta.

Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. Participants will be approached by an intermediary (i.e., a nurse working at day care) pre-operatively, whilst waiting in the day care unit. All patients are requested to attend the day care unit at 7am and then wait in the unit till they are called in for their procedure. During this time the potential participants are approached and handed an information letter outlining details of the study by the intermediary. They are also provided with sufficient time to read it and hence come to an informed decision. Following that those persons who are interested to participate can inform the intermediary, who is a nurse working in this unit. Once the participant indicates their willingness to partake in the study, the intermediary will provide them with an envelope containing 3 questionnaires all having a similar code e.g. 001. The questionnaires are filled in anonymously by the participants. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, participants can select whether to complete an English or Maltese version.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and will be provided a unique code by the present researcher. Should the patient agree to participate the nurse will note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations normally conducted within this ward setting and participants consent will be obtained for these coded measures to eventually be provided to the researcher.

Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. I am hereby asking your permission for setting up a small box for the questionnaires inside Day Care Surgical. Participation will be entirely voluntary and no coercion will be exerted. Participants will be informed that they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

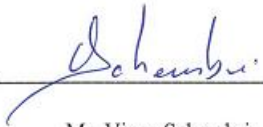


**Charge nurse of Day Care Unit at  
Mater Dei hospital**

I am duly asking for your permission as the charge nurse of Day Care Surgical. Your approval to conduct this study is highly appreciated. If you require any further information please do not hesitate to contact me on 99652426 or marija.abela.14@um.edu.mt or my supervisor on 23401175 or by email josianne.scerri@um.edu.mt. Thank you for your time and consideration in this matter. If you grant me permission kindly provide signature below.

Kind regards,

Marija Abela



Mr. Vince Schembri  
Charge Nurse Day Care



Dr. Josianne Scerri  
Research Supervisor

## Head of Surgery of Mater Dei hospital

Dear Mr Caruana Dingli

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled '**Assessment of anxiety and post-operative pain in adults undergoing a day case surgery**'. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the Faculty of Health Sciences at the University of Malta.

Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. These participants will be approached by the intermediary (i.e., a nurse) pre-operatively, whilst waiting in the day care unit. The intermediary will provide the potential participants with an envelope containing an information letter outlining details of the study. After reading the information letter, should they wish to participate; the intermediary will provide them with an envelope containing three questionnaires. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, participants can select whether to complete an English or Maltese version.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and will be provided a unique code by the ~~present~~ researcher. Should the patient agree to participate the nurse will note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations normally conducted within this ward setting and participants consent will be obtained for these coded measures to eventually be provided to the researcher.

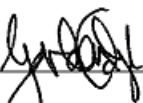
Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. Participation will be entirely voluntary and no coercion will be exerted. Participants will be informed that they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

## Head of Surgery of Mater Dei hospital

Do not hesitate to contact me on 99652426 or marija.abela.14@um.edu.mt or my supervisor Dr Josianne Scerri, on 23401175 or by email josianne.scerri@um.edu.mt. Thank you for your time and consideration in this matter. If you grant me permission kindly provide signature below.

Kind regards,

Marija Abela



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Mr Gordon Caruana Dingli

Head of Surgery

*Subject to ethical approval*



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Dr. Josianne Scerri

Research Supervisor

## **Appendix H: Invitation letter**

Dear Ms Melit

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled 'Assessment of anxiety and post-operative pain in adults undergoing a day case surgery'. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the Faculty of Health Sciences at the University of Malta. Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. Participants should be above 18 years of age, both males and females, undergoing general anaesthesia and who under normal circumstances would be discharged on the same day. Participants who are illiterate are to be excluded from the study. The rationale for this decision is that they would require assistance to fill the questionnaires which may be difficult to provide in a day care setting.

I would like to kindly ask for your help as an intermediary to identify such patients. These participants will be approached pre-operatively by you, whilst waiting in the day care unit and provided with an information letter with details about the study. These participants should be allowed to take their time to take an informed decision on whether to participate or not. Should any person indicate their willingness to participate, I am requesting that you then provide them with a self-addressed envelope containing questionnaires on my behalf. It is important that you do not provide me with details of any persons who decline to participate. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, participants can select whether to complete an English or Maltese version. In addition, participants are to be informed which questionnaires are to be filled pre-operatively and which to be filled post-operatively by yourself, even though this is indicated on the questionnaires.

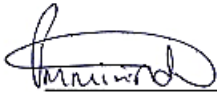
The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, and support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and a unique code will be provided to each questionnaire by the present researcher. Should the patient agree to participate you will kindly note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations conducted in this ward.

Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. It is important to explain to the participants, that participation will be entirely voluntary and no coercion will be exerted. Moreover, they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

I am kindly asking for your help as an intermediary in this study. If you require any further information please do not hesitate to contact me on 99652426 or [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) or my supervisor Dr Josianne Scerri, on 23401175 or by email [josianne.scerri@um.edu.mt](mailto:josianne.scerri@um.edu.mt). I wish to thank you for your help and co-operation. If you grant me permission kindly provide signature below.

Kind regards,

Marija Abela



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Ms Paradise Melit  
Staff Nurse



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Dr. Josianne Scerri  
Research Supervisor

Dear Ms Farrugia

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled '**Assessment of anxiety and post-operative pain in adults undergoing a day case surgery**'. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the Faculty of Health Sciences at the University of Malta. Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. Participants should be above 18 years of age, both males and females, undergoing general anaesthesia and who under normal circumstances would be discharged on the same day. Participants who are illiterate are to be excluded from the study. The rationale for this decision is that they would require assistance to fill the questionnaires which may be difficult to provide in a day care setting.

I would like to kindly ask for your help as an intermediary to identify such patients. These participants will be approached pre-operatively by you, whilst waiting in the day care unit and provided with an information letter with details about the study. These participants should be allowed to take their time to take an informed decision on whether to participate or not. Should any person indicate their willingness to participate, I am requesting that you then provide them with a self-addressed envelope containing questionnaires on my behalf. It is important that you do not provide me with details of any persons who decline to participate. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, participants can select whether to complete an English or Maltese version. In addition, participants are to be informed which questionnaires are to be filled pre-operatively and which to be filled post-operatively by yourself, even though this is indicated on the questionnaires.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, and support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and a unique code will be provided to each questionnaire by the present researcher. Should the patient agree to participate you will kindly note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations conducted in this ward.

Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. It is important to explain to the participants, that participation will be entirely voluntary and no coercion will be exerted. Moreover, they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

I am kindly asking for your help as an intermediary in this study. If you require any further information please do not hesitate to contact me on 99652426 or [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) or my supervisor Dr Josianne Scerri, on 23401175 or by email [josianne.scerri@um.edu.mt](mailto:josianne.scerri@um.edu.mt). I wish to thank you for your help and co-operation. If you grant me permission kindly provide signature below.

Kind regards,

Marija Abela



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Ms Christine Farrugia  
Staff Nurse



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Dr. Josianne Scerri  
Research Supervisor



# **Appendix I: Participant's Information letter**

**English and Maltese version**

### Participants` Information Sheet

Dear Participant,

My name is Marija Abela and I am currently reading for a Master's Degree in Mental Health Nursing at the University of Malta. As part of my course requirements I am conducting a research study entitled **"Assessment of anxiety and post-operative pain in adults undergoing a day case surgery"**. The aim of this study is to investigate the levels of anxiety pre and post-operatively and possible link with post-operative pain. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently your participation would help us examine the perceptions of persons undergoing such a service. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

You are being invited to participate in a study which will investigate anxiety levels before and after the operation and level of pain after the operation. You will be approached by an intermediary (i.e., a nurse working at day care) pre-operatively, whilst waiting in the day care unit and handed an information letter outlining details of the study. As a potential participants please take your time to read the information letter and hence come to an informed decision. Following that, if you are interested in participating please inform the intermediary, who is a nurse working in this unit and she will provide you with an envelope containing 3 questionnaires all having a similar code e.g. 001. The questionnaires are to be filled in anonymously. Moreover, filling in the questionnaire indicates that you consent to participate. All questionnaires are user-friendly and should be completed within 10 minutes. Moreover, you can request an English or Maltese version of the questionnaires from the intermediary to fill in.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess your comfort, emotions, physical independence and support within the last 24 hours while part B will assess your comfort, emotions, and support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves rating the discomfort that you may feel using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst waiting to be discharged. The questionnaires are to be filled in anonymously and this will also imply that you consent to participate in this study. The nurse will also document on a separate sheet of paper your blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations normally conducted within this ward setting.

You are not obliged to participate in this study or to answer all the questions and you may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and any data collected will be stored anonymously. You will be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. I can assure you that confidentiality will be maintained throughout the study. This coded data may only be accessed by the researcher, supervisor and examiners. Coded data files will be stored on the researcher's personal computer that is password protected. Any material in hard-copy form will be placed in a locked cupboard. In the event that you feel distressed due to participation in this study, the service of a psychologist will be available at no financial cost on your part. Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 99652426 or by e-mail [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) or my supervisor Dr. Josianne Scerri on **23401175 or by email [josianne.scerri@um.edu.mt](mailto:josianne.scerri@um.edu.mt)**.

If you are willing to participate could you please inform the nurse who provided you with this information letter and she will provide you with an envelope containing the required questionnaires.

Yours Sincerely,



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Marija Abela  
Researcher



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Dr. Josianne Scerri  
Research Supervisor

### Ittra ta' informazzjoni lill-partecipant/a

Għażiż/a Partecipant/a,

Jiena Marija Abela u qed nagħmel kors fuq livell ta' Masters fis-saħha mentali fl-Università ta' Malta. Bħala parti mill-kors, jien qed nagħmel riċerka: "Assessment of anxiety and post-operative pain in adults undergoing a day case surgery." L-għan ta' din ir-riċerka hi li ninvestiga l-livell ta' anzjetà qabel u wara l-operazzjoni u possibbilment norbot din l-anzjetà mal-uġiġh ta' wara l-operazzjoni. L-istudju tiegħi hu sinifikattiv hafna f'dan ir-rigward minhabba l-fatt li l-operazzjonijiet lokali li jsiru matul il-ġurnata żdiedu b'mod konsiderevoli f'dawn l-aħhar snin. Għaldaqstant, nixtieq il-partecipazzjoni tiegħek biex neżamina dawn il-perċezzjonijiet fil-persuni li jkun se jiġu bżonn dan is-servizz. Kull informazzjoni miġbura minn din ir-riċerka se tinzamm kunfidenzjali, użata għal dan il-kors biss.

Qed nistiednek biex tipparteċipa f'dan l-istudju li se jinvestiga l-livelli ta' anzjetà qabel u wara l-operazzjoni u l-livell ta' wġiġh marbut mal-operazzjoni. Se tkun qed tiġi infurmat minn intermedjarja kkonċernata, jiġifieri infermiera fid-dar care, qabel l-operazzjoni, waqt li tkun qed tistenna fid-day care unit u se tkun qed tinghata din l-ittra ta' informazzjoni bid-dettalji tal-istudju. Il-partecipanti se jinghataw hin biżżejjed biex jaqraw l-ittra ta' informazzjoni u jiehdu d-deċiżjoni jekk jipparteċipawx jew le. Wara dan, dawn il-persuni li jkunu interessati jipparteċipaw jistgħu jinfurmaw lill-infermiera kkonċernata f'dan il-unit. Meta turi x-xewqa li tipparteċipa f'dan l-istudju, l-intermedjarja se tagħtik envelop bi tliet kwestjonarji bl-istess kodiċi eż. 001. Il-kwestjonarji għandhom jiġu mimlija b'mod anonimu. Jekk ha timla l-kwestjonarji tindika li qed ittina l-kunsens tiegħek biex tipparteċipa. Il-kwestjonarji kollha m'għandhomx ikunu tqal għalik u għandhom johdulek madwar 10 minuti biex tlestihom. Tista' twieġeb kemm bl-Ingliż kif ukoll bil-Malti.

L-ewwel kwestjonarju jittratta dwar l-*Amsterdam preoperative anxiety and information scale*. It-tieni wieħed jittratta l-*Quality of recovery-40* u hu maqsum f'parti A u parti B. Parti A se timlieha qabel l-operazzjoni u parti B wara l-operazzjoni. Parti A se tkun qed tassessjak dwar is-saħha, il-mistrieħ, l-emozzjonijiet, u s-support u l-indipendenza fiżika fl-aħhar 24 siegħa mill-operazzjoni, waqt li f'Parti B se tiġi assessjat dwar is-saħha, l-emozzjonijiet, u l-livelli ta' support u wġiġh wara l-operazzjoni. Iż-żewġ kwestjonarji jużaw l-iskala Likert. It-tielet kwestjonarju huwa dwar xi skumdità li tista' thoss u għalhekk se tiġi użata l-iskala *VAS numeric pain distress*. Din l-iskala se tkun qed tużaha wara l-operazzjoni waqt li tkun qed tistenna li jillieċenzjawk. Il-kwestjonarji li se tkun qed timliehom b'mod anonimu, jindikaw il-kunsens tiegħek biex tipparteċipa f'dan l-istudju. L-infermiera se tkun qed tieħu nota wkoll tal-persjoni fid-demm, it-tahbit tal-qalb u l-ammont tal-ossiġnu fid-demm fuq karta separata qabel u wara l-operazzjoni. Dawn il-miżuri fiżjoloġiċi huma testijiet li jsiru regolari f'dan il-ward.

M'intix obligat tipparteċipa f'dan l-istudju jew li twieġeb kull mistoqsija. Tista' tagħzel li tieqaf mill-istudju xhin trid. Apparti minn hekk, jekk tiddeċiedi li tieqaf mill-istudju nassigurak li mhux se jkun hemm riperkussjonijiet negattivi u l-informazzjoni li tkun diġà tajjni tkun maħżuna

b'mod anonimu. Se tkun qed tinghata wkoll għażla biex tpoġġi l-kwestjonarji lesti f'kaxxa fid-Day Care Surgical inkella tista' timpustahom lura f'envelop *self-addressed*. Nassigurak li se tinżamm kunfidenzjalità massima f'dan l-istudju. Id-data kkodifikata se tkun aċċessata biss mir-riċerkatur, superviżur u l-eżaminaturi. L-informazzjoni se tkun qed tinżamm fil-kompjuter personali tar-riċerkatur b'password protett. Kull materjal hard-copy se jkun qed jinżamm f'kabinett magħluq. Jekk waqt li tkun qed tipparteċipa thossok anzjuż, tista' tuża s-servizz tal-psikologu mingħajr hlas. Il-partecipazzjoni tiegħek f'dan l-istudju hi volontarja u int hieles li taċċetta jew tirrifjuta mingħajr ma tagħti raġuni.

Grazzi tal-hin u l-konsiderazzjoni tiegħek. Jekk tkun trid tistaqsi xi mistoqsijiet jew ikollok xi diffikultajiet tiddejjaq xejn iċċempilli fuq 99652426 jew ibgħatli ittra elettronika fuq l-indirizz [marija.abela.14@um.edu.mt](mailto:marija.abela.14@um.edu.mt) jew lis-superviżur Dr. Josianne Scerri fuq 23401175 inkella fuq l-indirizz elettroniku [josianne.scerri@um.edu.mt](mailto:josianne.scerri@um.edu.mt).

F'każ li tkun tixtieq tipparteċipa tista' tinforma lill-infermiera li tkun tatek l-ittra ta' informazzjoni u hi tkun tista' tipprovdi lek envelop bil-kwestjonarji kkonċernati.

Dejjem tiegħek,



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Marija Abela  
Riċerkatriċi



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Dr. Josianne Scerri  
Superviżur

## **Appendix J: Psychological assistance**

Dear Mr Sciberras

I am Marija Abela, a staff nurse working at Day Care Surgical and I am currently reading for a Master of Science in Mental Health Nursing at the University of Malta. As partial fulfilment of requirements relating to this degree, I intend to conduct a quantitative research study entitled 'Assessment of anxiety and post-operative pain in adults undergoing a day case surgery'. The significance of my study relates to the fact that day surgery rates locally have continued to rise steadily over the past years and consequently it is important to examine the perceptions of persons undergoing such a service. This study will be undertaken under the supervision of Dr. Josianne Scerri, who heads the department of Mental Health within the faculty of Health Sciences at the University of Malta. Participants will be asked to answer three questionnaires, two pre-operatively and one post-operatively after they have fully recovered from anaesthesia.

Due to the nature of the study, I aim to recruit adult patients who attend the Day Care Surgical for a procedure. Participants will be approached by an intermediary (i.e., a nurse working at day care) pre-operatively, whilst waiting in the day care unit. During waiting time the potential participants are approached and handed an information letter outlining details of the study by the intermediary. They are also provided with sufficient time to read it and hence come to an informed decision. Following that, those persons who are interested to participate can inform the intermediary, who is a nurse working in this unit. Once the participant indicates their willingness to partake in the study, the intermediary will provide them with an envelope containing 3 questionnaires all having a similar code e.g. 001. The questionnaires are filled in anonymously by the participants. All questionnaires are user-friendly and should be completed within 10 minutes.

The first questionnaire is the 6 item 'Amsterdam preoperative anxiety and information scale'. The second questionnaire is the 40 item 'Quality of recovery-40' which is divided into part A and part B. Part A will be filled in pre-operatively while part B will be filled in post-operatively. Part A will assess participant's comfort, emotions, physical independence and patient support within the last 24 hours while part B will assess participant's comfort, emotions, support and pain levels post-operatively. Both questionnaires utilise a five point Likert scale. The third questionnaire involves the participants rating their pain using the VAS numeric pain distress scale. This scale will be completed post-operatively whilst the participant will be waiting to be discharged. The questionnaires will be filled in anonymously and will be provided a unique code by the present researcher. Should the patient agree to participate the nurse will note the participants unique code number (as listed on the questionnaires) and will also document on a separate sheet of paper the values for the participant's blood pressure, heart rate and oxygen saturations both pre- and post-operatively. These physiological measures are routine investigations normally conducted within this ward setting.

Participants will also be given the choice to either place the completed questionnaires in a box at Day Care Surgical or to mail the questionnaires back in a self-addressed envelope. Participation will be entirely voluntary and no coercion will be exerted. Participants will be


informed that they have the right to withdraw from the study at any time and that the quality of care provided will not be affected, should they decline to participate in the study.

I assure you that all participants will have confidentiality and anonymity guaranteed, and that approval will be sought from University Ethics committee before commencement of the study. As participants answering questionnaires may show signs of distress or discomfort, I am kindly requesting that they can avail themselves of the psychological services at Mater Dei if need be.

Whilst thanking you in advance for your co-operation and support, please do not hesitate to contact me if any queries arise on 99652426 or marija.abela.14@um.edu.mt or my supervisor on 23401175 or by email josianne.scerri@um.edu.mt.

Kind regards,

Marija Abela



Marija Abela  
Researcher



Dr. Josianne Scerri  
Research Supervisor

Approved  
28.04.2020



Mr. Paul Sciberras  
Managing Psychologist

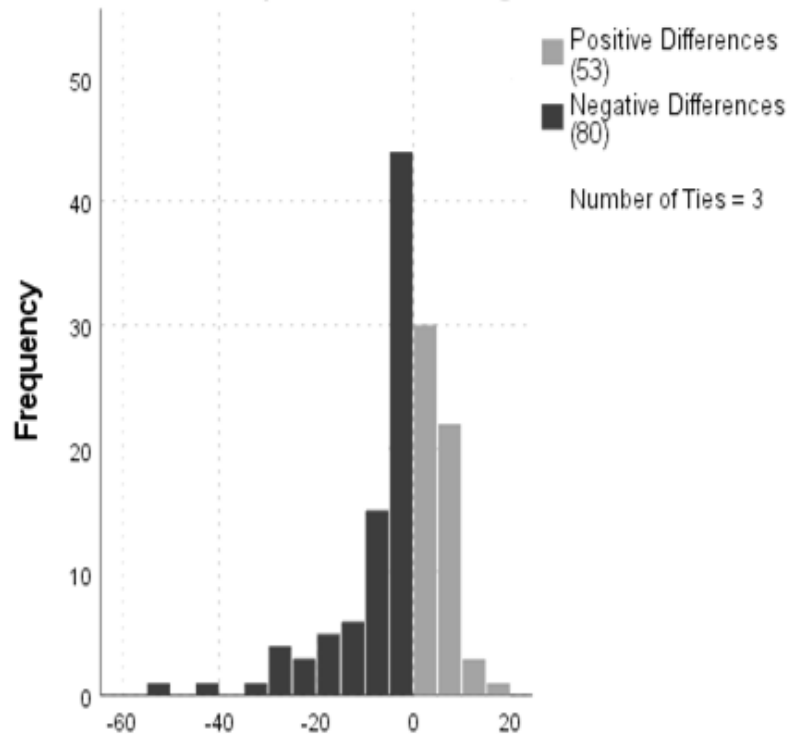
Paul Sciberras M.Sc.  
Registered Clinical Psychologist  
Managing Psychologist  
Mater Dei Hospital

CLINICAL PSYCHOLOGY DEPARTMENT  
MATER DEI HOSPITAL MSD2090



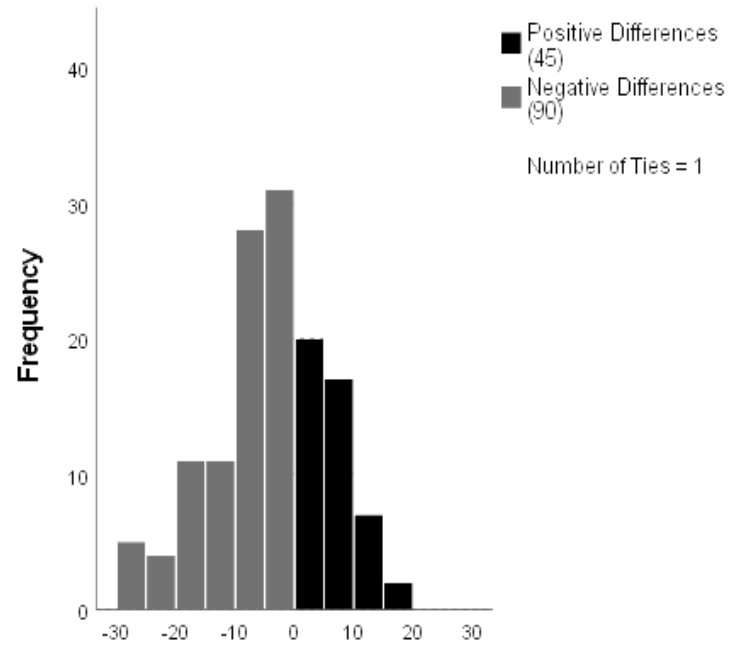
## **Appendix K: Wilcoxon Rank test for pre-operative and post-operative heart rate**

### Related-Samples Wilcoxon Signed Rank Test



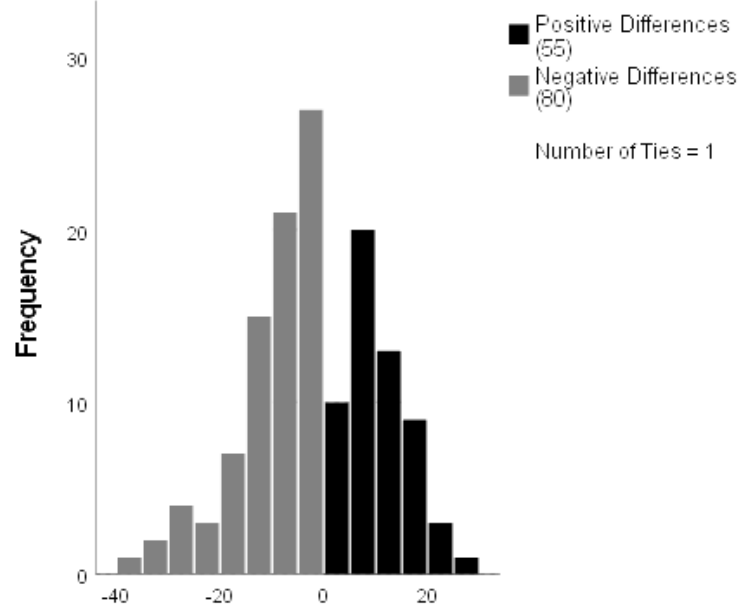
# **Appendix L: Wilcoxon Rank test for pre-operative and post-operative systole blood pressure**

### Related-Samples Wilcoxon Signed Rank Test



# **Appendix M: Wilcoxon Rank test for pre-operative and post-operative diastole blood pressure**

### Related-Samples Wilcoxon Signed Rank Test



## **Appendix N: Wilcoxon Rank test for pre-operative and post-operative oxygen levels**

