The effect conscious sedation used for an endoscopic procedure has on attention.

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Declaration page

A research project submitted in partial fulfilment of the requirements for the degree of MA (Research Psychology) by course work and research report in the faculty of Humanities, University of the Witwatersrand, Johannesburg, (December 2014)

I declare that this research project is my own, unaided work. It has not been submitted before for any other degree or examination at this or any other university.

Tasneem Hassem December 2014

Abstract

Past literature conducted on the effects of attention following conscious sedation highlight a significant decrease in attention. However, the sleep that occurs during sedation is associated with normal sleep and therefore there is a possibility that this sleep may repay sleep debt and could increase attention. As a result the following research explored the effects of conscious sedation on both the focus and encode elements of attention and the impact of propofol dosage on attention. The sample was formed by 31 outpatients from the Rosebank NetCare hospital undergoing an endoscopic procedure. Pre- and post-test measures of attention included the D-KEFS Color-Word Interference condition 1 and 2, Digit Span Forward subtest from the WAIS III as well as the Mental Control subtest from the WMS IV. Using a Matched Paired T-Test and a Wilcoxon Signed Ranked Test the following results were observed; significant results were found between the pre- and post-test scores on the D-KEFS Color Naming condition 1 number of corrected errors ($z = -1.93$ $p=0.05$), as well as on the Digit Span Forward subtest($z = -2.55$ $p=0.01$). For the remainder of the attention measures non-significant results were produced ($p>0.05$).When assessing the impact of the dosage of propofol using an Independent Samples t-test and a Mann-Whitney U-test, non-significant results ($p>0.05$) were produced for all the focus and encode elements of attention. The following results indicates the sleep that occurs during conscious sedation does not improve attention, therefore individuals' undergoing conscious sedation should adhere to post-sedation discharge guidelines.

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Research Disclaimer

The following study forms part of a larger study titled: "Is There a True Psychological (Cognitive Functioning and Mood) Effect of Conscious Sedation during Endoscopic Procedures?" which was conducted by four researchers including the principle researcher of this current study. The conceptualization as well as the data collection was conducted by all the researchers, however, data analysis was conducted independently by each researcher. The following are the names, titles of the research projects, as well as the contact details of the four principle researchers:

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Chapter one: Introduction

Attention is a complex cognitive function that is used in everyday life (Chun & Wolfe, 2005). There are numerous definitions of attention and therefore various theories of attention have been theorised based on these definitions. In accordance with Mirsky, Antony, Duncan, Ahearn, & Kellam (1991) attention is defined as a complex process of mental activities which can be dispersed among various information sources. Mirsky et al. (1991) describes attention of consisting of 4 elements namely: *focus, sustain, shift and encode.*

Conscious sedation has become a popular technique, which can be defined as a state in which an individual's consciousness is depressed through a drug-induced technique (American Society of Anesthesiology (ASA), 2004). Studies have been conducted to explore the relationship between the effects of conscious sedation on attention (Padamanabhan, Leslie, Eer, Maruff, & Silber, 2009; Girdler et al., 2002; Sarasin, Ghoneim, & Block, 1996). These studies revealed a significant decrease in attention following sedation. However, a study conducted by Tung, Bergmann, Herrera, Cao, & Mendelson (2004) showed that the sleep which occurred during sedation is similar to that of normal sleep and therefore may repay sleep debt. Therefore, the possibility of the sleep occurring due to sedation may increase attention, whereas the drugs used for the sedation decreases attention. Thus, the contradiction of these results formed the rationale for the current study.

The following manuscript will begin with a literature review. This section will consist of a critical analysis of the various definitions of attention, a description of Mirsky's model of attention, a discussion on the literature of the effects of sedation, and sleep on attention as well as the practical implications following conscious sedation discharge. Thereafter the rationale of the study will be presented followed by the research questions.

A methodology section will follow where the following topics will be discussed: the research design, variables and the sample employed in the study, the instruments used to measure attention will be discussed as well as the various ethical considerations acknowledged in order for the study to be conducted.

In the chapters to follow, the study's results will be presented and discussed in terms of the descriptive statistics, reliability and normality of the data as well as the two research questions explored by this research. Lastly, this manuscript will look at the observed results

in relation to past studies on the topic, highlight the various limitation and recommendations of this research and finally draw conclusions in relation to the research questions.

Chapter Two: Literature review

2.1. Overview

The following literature review will provide definitions on the concept of attention and will discuss Mirsky's model of attention. Thereafter, the effects of anaesthetic drugs on attention will be discussed with particular reference to midazolam and propofol. The impact of the sleep during anaesthesia will be discussed in relation to attention. Lastly, the practical implications following conscious sedation will be highlighted.

2.2. Attention model

Over the years research conducted on attention has highlighted the importance and vital role attention plays in an individual's life. In order for an individual to achieve his or her goals they have to sift out relevant stimuli from a world or environment that bombards him or her with a wide variety of stimuli (Johnson & Proctor, 2004). Attention is thus just one of the key cognitive abilities that makes every day functioning possible (Chun & Wolfe, 2005). Therefore, serving a supreme and gateway role to cognition (Taylor, 2008).According to the first definition of attention as defined by William James (2007), it is being in a clear and vivid possession of the mind when taking one object or train of thought out of several simultaneous options. Concepts like focalisation and concentration of the consciousness forms the core of this definition. This definition has been criticised for being too broad as well as using the terms consciousness and cognition synonymously (Styles, 2006).

In a more concise definition of attention, Shiffrin (1988) defines attention as being all those limited capacity/resources as well as methods of dealing with aspects of human cognition that can be controlled by an individual. This definition highlights that attention has many aspects ("all"), however is does refer to a particular important concept of limited capacity when defining attention (Styles, 2006).

Attention has also been defined as a complex process of mental activities or process sets (Friedenberg & Silverman, 2006; Mirsky, Pascualvaca, Duncan, & French, 1999). This activity can be dispersed among various information sources. Information sources represent the bombarded stimuli from one's environment, thoughts, as well as one's own mental content (Friedenberg & Silverman, 2006). From the above mentioned definitions of attention it is apparent that attention is a concept that has no clear cut or single definition, but rather serves as an umbrella term to define many psychological phenomena (Styles, 2006).

Due to the fact that no single definition can be assigned to attention there is no single theory or model for attention. Thus, there is no single cerebral region that can be assigned to attention and no single test that can be attributed to measuring or assessing an individual's attention (Zomeren & Brouwer, 1994). Thus, this research will adopt Mirsky's et al. (1991) neuropsychological model of attention for an in depth explanation of attention and as a basis for selecting tests of attention for the study. Mirsky's model of attention was selected on the basis that the model was derived from a sample of control subjects, neuropsychiatric patients as well as elementary school children where the identified elements of attention were consistent amongst these groups (Mirsky et al. 1991). In addition, Mirsky et al. (1991) relates the model to various neural substrates as well as neuropsychological tests

Mirsky et al. (1991) selected 8 attention and information processing tests commonly used in psychological experiments or in neuropsychological assessments, which seemed to assess his three postulated elements of attention (*focus, sustain and shift).* In order to test the various elements of attention postulated, the 8 tests were tested on both an adult and child sample. The adult sample was made up of normal subjects, subjects with affective disorders, eating disorders, as well as close head injuries, therefore a total sample of 203 participants was obtained. It should be noted that the sample was predominantly female.

The following 8 attention and information processing tests were used on the adult sample: The Stroop Colour Word Interference Test, Talland Letter Cancellation Test, Trail Making Test, Digit Symbol Substitution Test, Arithmetic Test, Digit Span Test, Continuous Performance Test, Wisconsin Card Sorting test as well as the Continuous Performance Test.

The child sample consisted of 435 children from Baltimore Public School. The attention test battery for the child sample was a modification or equivalent to the tests used on the adult sample. The following tests were used on the child sample: Digit Cancellation, Wisconsin Card Sorting Test, Coding Test, Arithmetic Test, Digit Span Test as well as the Continuous Performance Test.

For both the samples tested, a principle component analysis was conducted on the tests scores. For both the samples, scores loaded on the three postulated factors of attention: *focus, sustain and shift.* In addition, a fourth factor loading occurred in both the child and adult samples and this was termed *encode.* The factors loadings for the child sample were not in the same order as the adult sample and therefore two additional principle analyses were conducted. This grouped the parallel measures of attention of the adult and child sample

together. These analyses produced virtually the same ranking of the components, therefore the authors concluded that the tests used underlie the same components in both samples: *focus, sustain, shift and encode.*

The *focus* element of attention is representative of an individual's ability to draw on his or her attentional reserve to or for a specific task (Mirsky et al., 1999). It also encompasses the individual's ability to block out information or stimuli that is/are present in one's environment (Mirsky et al., 1991; Mirsky et. al., 1999). In order to obtain an accurate measure of an individual's focus, one has to acknowledge that for one to draw all their attention on a measure, one cannot rule out the possibility of a rapid response. Therefore one needs to treat focus in conjunction with execute (Mirsky et al., 1999). This component is also commonly referred to as being selective attention when assessed in the domains of visual and auditory perception (Zomeren & Brouwer, 1994). Zomeren and Brouwer (1994) also suggest that selection or focus of one's attention occurs for two main reasons. The first reason is attributed to the fact that majority of the information presented in an individual's environment is irrelevant for the specific task they have at hand and, secondly, every individual have a very limited processing capacity. Thus, one has to select information from various sources as well as select information from a particular category of one stimulus (Zomeren & Brouwer, 1994).

When assessing focused attention much research has used the visual and auditory domains (Zomeren & Brouwer, 1994). Mirsky et al. (1991) have suggested that the Stroop Colour Word Interferences test, Digit Symbol Span and Digit Symbol Substitution subtests from the Wechsler Adult Intelligence Scale (WAIS) effectively assesses focus attention. These tests require individuals to focus on the display and efficiently respond to the various selected targets. The focus element of attention can be assigned or mapped to the inferior parietal, superior temporal cortices as well as the various structures of the corpus striatum in the brain (Mirsky et al., 1991).

The second element being *sustain* can be described as an individual's ability to maintain his or her focus and be alert on a particular task at hand for an appropriate or sufficient amount of time (Mirsky et al., 1991; Mirsky et al., 1999). Studies have shown that the most effective test that allows one to assess an individual sustained attention is the Continuous Performance Test (Mirsky et al., 1991; Mirsky et al., 1999; Zillmer, Spiers & Wadsworth, 2008). Sustained attention has been found to be mapped to the brain stem and thalamic structures of

the brain (Mirsky et al., 1991). In contrast to the ability of sustaining attention is the ability to shift one's attention. The *shift* element of attention deals with an individual's ability to be flexible in moving their attention from one aspect of a stimulus to another in an adaptive and efficient manner (Mirsky et al., 1991; Mirsky et al., 1999).

The final element of the attention system is *encode*. Encode is the ability of an individual to hold mnemonic information in his or her mind, while still able to effectively perform a cognitive operation or action on this particular information (Mirsky et al., 1999). Mirsky et al. (1991), found that the Digit Span subtest taps into the individual's ability to encode and retain information in memory by hearing a series of number and immediately repeating them (Mirsky, & Duncan, 2006). Both the Digit Span and the Arithmetic subtests from the WAIS were the most effective in measuring an individual's encoding attention (Mirsky et al., 1999). In addition, they found that the hippocampus and the amygdala can be attributed to the encode element.

In accordance with Mirsky's model of attention, the following study assessed both the *focus* and *encode* elements of attention. The focus element of attention was assessed through the following tests: Delis-Kaplan Executive Function System (D-KEFS) Color-Naming as well as the Word Reading conditions and the Mental Control subtest from the Wechsler Memory Scale. The Digit Span Forward from the Wechsler Adult Intelligence Scale III (WAIS III) was used to assess the encode element of attention.

2.3. The effect of anaesthesia drugs on attention

According to the American Society of Anesthesiologists (ASA) (2004) conscious sedation, also known as moderate sedation, is defined as state in which an individual's consciousness is depressed through a drug-induced technique. In addition, the individual under conscious sedation can respond purposefully to instructions either by themselves or with tactile simulation (ASA, 2004). The individual is also able to maintain their airways without any intervention, adequate ventilation is spontaneous, and the individual maintains cardiovascular functioning (ASA, 2004). Conscious sedation has become a popular technique worldwide (Bannert et al., 2012).

The popularity of this technique can be attributed to it being associated with a decreased risk than the risk associated with well monitored sedation techniques (Bannert et al., 2012). Conscious sedation is more advantageous than well monitored sedation techniques for the following reasons; recovery time is shorter, minimal side effects are experienced as well as

fewer complications (Odom-Forren, & Watson, 2005). In general, the drugs used either consist of both benzodiazepines and opiates combined or each used alone (Waring et al., 2003).

Midazolam is characterised as a short-acting benzodiazepine, which produces a muscle relaxant, amnestic as well as sedative effect (The South African Society of Anaesthesiologists (SASA, 2010). In addition, midazolam has no analgesic effect. Midazolam can be administered orally, intravenously, rectally and intranasally. The peak effect time of midazolam occurs between 3-30 minutes and the duration of its action lasts up to 20-60 minutes depending on the method of administration (SASA, 2010). Propofol on the other hand is a short-acting anaesthetic inducing agent, which is administered intravenously. Propofol has effective hypnotic and amnestic effects, and has a narrow safety margin with regards to deep sedation, apnoea as well as airway obstruction. Therefore, an experienced anaesthetist should administer propofol. Studies have assessed the impact propofol and midazolam used during conscious sedation has on one's cognitive function (Daneshmand, Bell & Logan, 1991).

A study conducted by Sarasin et al. (1996), randomly assigned a group of 28 healthy volunteers to either 0.1mg/kg midazolam or 0.1mg/kg propofol. Patients' attention was tested pre- and post- the sedation using the Digit Span Substitution and the Digit Symbol tests. The patients in the sedation group that were administered propofol were found to perform significantly lower than patients in the midazolam sedation group. Overall, the performances were lower for both sedation groups when compared to their baseline measures on each test. This study only considered the effect of each drug administered in isolation. However, the authors found that the effects of propofol had a shorter time span when compared to that of midazolam.

In another study conducted by Girdler et al. (2002), 18 patients undergoing a dental procedure were administered midazolam for conscious sedation and thereafter received an intravenous flumazenil to reverse the effects of midazolam. Pre- and post-testing for attention made use of Reaction Time, Simple Reaction Time, Choice Reaction Time, Combined Numeric and Word speed scores as well as combined Numeric and Word Accuracy scores. The post-test occurred in 6 hour intervals of the reversal procedure. The study showed that midazolam severely impaired cognitive functioning with an increase in reaction times and

decrease in attention. In addition, the flumazenil had no reversing effects on midazolam in terms of cognitive functioning.

The above-mentioned literature highlights the effects of midazolam and propofol in isolation, whereas a study conducted by Padmanabhan et al. (2009) combined midazolam and/or fentanyl to propofol for conscious sedation. This study was conducted on patients undergoing a colonoscopy, who were over the age of 18 years. The patients were randomly assigned to either the propofol alone group or the propofol combined with midazolam and/ or fentanyl group. The propofol dosage between the groups varied, with the propofol dosage in the midazolam group ranging from 60-600 mg and the midazolam constant at 2 mg.

This study made use of the CogStat brief computerized test battery to assess cognition. This test measured psychomotor function, attention, as well as visual memory. For the attention measure an identification task was used. When reporting the results the authors do not divide the results in terms of the propofol and midazolam or the propofol and fentanyl groups, but rather combine the two groups. The study highlighted a significant decline on the attention measure for this combined group in the post-operative tests, however there was no significant difference between the propofol alone group and the propofol combined group on the attention measure. Interesting to note that the authors did not consider the effect of the propofol dosage in the propofol combined with midazolam or fentanyl groups on the cognitive tests and rather highlighted this as a limitation of their study.

It should be highlighted that there is a lack of literature in the field of the combination of propofol and midazolam effects on attention, as well as the impact of the dosage of propofol on attention. This is highlighted through a literature search which was conducted in EBSCO host; MEDLINE, Psychology and Behavioural Sciences and PSYCHInfo as well as PUBMED on the 27th November 2014. The search made use of the following key phrases; "effects of midazolam combined with propofol on cognition/ attention", as well as "The impact of propofol dosage on attention". The search revealed that studies were mainly assessing the impact of sedation on memory, psychomotor function as well as the effect of the drugs on various physiological functions.

It should be noted that the studies mentioned above have not taken into account the possible effect the elimination half-life of these drugs could have on testing attention post conscious sedation. Elimination half-life is the time taken for the drug concentration to be decreased by 50% in the body (Gupta & Henthorn, 2009). The reason that elimination half-life is not

accounted for in these studies is due to fact that anaesthetics effects are decreased long before one elimination half-life has been completed, thus having a limited utility in anaesthesia (Gupta & Henthorn, 2009). It is for this reason that the study will not consider the factor of elimination half-life in the data analysis.

2.4 Sleep, anaesthesia and attention

Studies have shown that the physiological traits produced by anaesthesia are similar to that produced during natural sleep (Lydic & Helen, 2006). In addition, both anaesthesia and sleep have been associated with prefrontal cortex activity. To study the effect of sleep on attention, researchers have looked at the effects of sleep deprivation on attention. Studies on sleep deprivation indicated that attention, speed and memory are all adversely affected by sleep deprivation (Dorrian & Dinges, 2006; Jugovac & Covallero, 2012). In addition, Tung et al. (2004) have conducted a study on rats, which were deprived of 24 hours of sleep and then had undergone 6 hours of propofol anaesthesia or 6 hours of ad libitum sleep.

The results have indicated that recovery process of the anaesthesia was the same as that of natural sleep and therefore suggest that anaesthesia may repay sleep debt, increase sleep debt or have no effect on sleep debt. One wonders if the possibility of repayment of sleep debt will improve attention.

2.5 Practical considerations following conscious sedation discharge

Patients undergoing conscious sedation have to be discharged only when they have met the discharge criteria (Special Guidelines for Sedation and Analgesia by Non-Anesthesiologits, 2002). The discharge criteria entails the patient being alert, having stable vital signs, as well as being discharged in the presence of a responsible adult (Special Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002). In addition, the patients are not allowed to operate machinery, drive a vehicle as well as sign any legal documents for a 24 hour period following their discharge (SASA, 2010). An individual's attention can be seen to be implicated in the recommendations made above and therefore assessment of an individual's attention post sedation can be vital to their safety and well-being.

2.6 Rationale for the study

Past studies have shown that the drugs used for conscious sedation impairs attention, however literature suggests that conscious sedation induces the same traits as natural sleep and thus allowing for the possibility of improved attention (Lydic & Helen, 2006; Tung et al., 2004). As an attempt to elucidate this contradiction, this research set out to determine if conscious sedation using combination of midazolam and propofol has a negative, positive or no impact on an individual's attention This contradiction of possible results makes for an effective study and thus this research hopes to provide some insight into these contradictory results.

Past studies have failed to compare the effects of the propofol dosage given to patients on the various attention measures. Thus, the current study explored the propofol dosage effect on tests of attention. In addition, past research has failed to make use of an attention model as a guide to what test should be used when assessing attention. This study made use of Mirsky's model (Mirsky et al., 1991) of attention to select tests which measure the various components of attention as described by Mirsky. This research will also contribute to the large body of knowledge on the patient's fitness for discharge after conscious sedation by making reference to attentional ability post conscious sedation.

2.7 Research questions

- Does conscious sedation have an effect on both the focus and encode elements of attention on a group of individuals' scheduled for an endoscopic procedure?
- Does the propofol dosage of anaesthetic protocol used for conscious sedation have an effect on the focus and encode elements of attention for a group of individuals' scheduled for an endoscopic procedure?

Chapter three: Methodology

3.1 Research design

This study employed a quantitative one-group pre-test/post-test design without a control group (Williamson, 2002). Neuropsychological testing was conducted pre- and post- the endoscopic procedure. Participants received 1 mg madizolam and propofol dosage was given at the discretion of the anaesthetist. The assessors were blinded to the amount of propofol given to the participants.

3.2 Variables:

3.2.1. Independent variable.

Conscious sedation.

- Theoretical definition: administration of pharmacological agents that depresses the level of consciousness, while still retaining a patent airway of the individual. In addition, the patient is still able to appropriately respond to verbal and/or physical stimulation (Kost, 2004).
- Operational definition: a low dosage sedation which consisted of a single dose of midazolam of 1 mg combined with propofol. Propofol was administered at the discretion of the anaesthetist.

3.2.2 Dependent variable.

Attention.

- Theoretical definition: attention is a complex process of metal activities or process sets that can be dispersed among various informational sources (Freidenberg & Silverman, 2006). According to Mirsky's (1999) model of attention, attention has four components namely; *focus, sustain, shift and encode*. In particular, this study assessed the *focus* and encode elements of attention. The *focus* element of attention is representative of an individual's ability to draw on his or her attentional reserve to or for a specific task (Mirsky et al., 1999). The *encode* element is the ability of an individual to hold mnemonic information in his or her mind, while still able to effective perform a cognitive operation or action on this particular information (Mirsky et al., 1999).
- Operational definition: raw scores obtained on conditions 1 and 2 (total completion time) of the Color-Word Interferences Test subtest from the Delis-

Kapan Executive Function System (K-DEFS) and the Mental control subtest from the Wechsler Memory Scale IV (WMS IV) was used to assess the *focus* element of attention. Digit Span Forward from the Digit Span subtest of the WAIS III was used to assess the *encode* element of attention (Mirsky et al., 1991).

3.2.3 Extraneous variables.

Controlled variables.

1. Individuals' level of education: participants all had at least a Matric level of education
2. Post-operative symptoms: participants who experienced severe headaches, nausea and hypertension after the endoscopic procedure were not assessed on the post-operation battery.
3. Medication for neurological illnesses: participants who use medication for the above mentioned illnesses were excluded from the study, due to direct impact these types of medication and associated diagnosis have on an individual's cognitive performances (Medalia & Reheim, 2002).
4. Illegal drugs/substances and alcohol abuse: participants who are using illegal drugs/substances were excluded from the study, due to the effects of these substances on cognitive ability (Dregan & Gulliford, 2012).
5. Central nervous system injuries: participants who have a history of traumatic brain injury were excluded from the study, due to the neuropsychological correlates of these injuries (Griffen & Hanks, 2014).
6. Pre-morbid cognitive impairment: participants who have a diagnosed history of cognitive impairment, specifically in attention and memory functions were excluded from the study, due to the neuropsychological correlates of these impairments. This was identified by asking a cognitive impairment question in the demographic questionnaire (Appendix A).
7. Anxiety and depression: participants' anxiety and depression was assessed using the Hamilton Rating Scales for Depression (HAM-D), Hamilton Rating Scale for Anxiety (HAM-A) as well as the Profile of Mood States (POMS). Participants who were found to have high levels of anxiety or depression were excluded from the study, as anxiety and depression have been found to have a negative impact on attention, especially under testing conditions (Eysenck, Calvo, 1992; Landro, Stiles, & Sletvold, 2001).

Variables that were not controlled.

1. Participant's age: participant's age varied significantly from 18 to 78 years, as the participants were volunteers who were scheduled for an endoscopic procedure.
2. Individuals' socio-economic status: this was not measured in anyway by the researchers. However, assuming a minimum level of homogeneity a middle to upper class socio-economic status is presumed due the study being conducted in a private hospital (Lehohla, 2012).
3. Reason for undergoing an endoscopic procedure: the researchers could not control the reason for which the patients undergo the procedure as this was for a number of medical reasons.
4. Level of English proficiency: researchers could not control that all participants had English as their first or primary language. This could ultimately have an impact on the results due to being assessed in a second language. It should be noted that second language participant were included as a result of having at least five years of formal schooling. In order to determine the impact of language on the assessment results, the following linguistic information was obtained from participants; Number and name of languages spoken as well as participant home language (Appendix A).
5. Aspects of participant medical history: illnesses or disease that occurred prior to or during the research process that could directly or indirectly impact an individual's cognitive ability. Prior to the pre-assessment participants were required to state their previous reason for hospitalisation, as well as the type/types of medication they were taking. This information was used to exclude participants whose associated diagnosis or medication type would potentially impact on the cognitive functions assessed.
6. Participant motivation level: Participants, who have a higher motivation level to perform well on the test, will perform better than those participants who are less motivated (Chan, Schmitt, Deshon, Clause & Delbridge, 1997).
7. Previous exposure to neuropsychological testing: exposure to neuropsychological testing that occurred within six months prior to the research was controlled for by participants being excluded from the study. This could result in an increase on test performance due to practise effects and

individuals working on or developing strategies during the test taking process (McCaffrey, Ortega, Orsillo, Nelles, & Haase, 1992).

8. Assessor: due to this study being a part of a larger study, various researchers (4) were assessors. Assessor differences could have had an impact the administration scores. This was controlled for to a certain extent by using standardized methods of carrying out the assessments (Nell, 2000).
9. Assessment conditions: all assessments were conducted in the ward however, the ward was well lit, and had a sufficiently large desk.

3.3 Sample and sampling

This study used a convenience sampling method (Vanderstoep & Johnston, 2009) to obtain a sample from the Rosebank Netcare hospital. Out-patients that were scheduled for an elective endoscopy (colonoscopy, gastroscopy and /or gastroscopy & Colonoscopy) procedure were approached (ASA classification I, II and disease stable III). These patients were invited by the medical team over-seeing the endoscope procedure. Patients who volunteered to participate in the study were then briefed by the researchers. Participants were excluded based on the following criteria:

1. Any participant who was on neurological medication was excluded from the study, due to the fact that cognitive performance can be directly affected by these medications.
2. Any participant who was on any illegal drugs/ substances was excluded from the study, due to the possible effect on one's cognition.
3. Participants who have had the following injuries or pre-existing cognitive conditions was excluded; traumatic brain injury, dementia and/or nervous system injuries.
4. Participants who have serve headaches, hypertension and/or nausea post the endoscopic procedure was excluded from the study.
5. Participants who have not participated in both the pre- and post-neuropsychological tests.

A total of 44 participants' volunteered to participate in the study. Of the 44 participants, 1 participant was excluded due to being on anti-convulsion medication, 1 participant was excluded for being on medication for Attention Deficit Hyperactivity disorder (ADHD) and further 9 participants were excluded for not part-taking in both the pre and post-tests.

Therefore, the study had a final sample of 31 participants. Participants who were on anti-depressants were included in the study as when they were removed no significant difference occurred on any of the statistical tests.

Participants descriptive information is presented according to the demographic information, educational information, language information, medical history information as well as the experimental information (Tables 1, 2, 3, 4 & 5). Information is presented in relation to sample size and a percentage of the sample size per descriptor provided.

Table 1 *Sample Demographic Descriptors*

Descriptor	Descriptor level	Sample size	Percentage %
Age N = 31	29-39	4	12.9
	40-50	3	9.7
	51-61	17	58.4
	62-72	6	19.4
	72+	1	3.2
Gender N=31	Male	14	43.8
	Female	18	56.3
Alcohol N = 31	None	22	71
	1-5 glasses	5	16.1
	5-14 glasses	4	12.9

The participant's age ranged from 29-78 year olds, with the majority of the sample falling into the 51-61 age group. The female gender was predominant in the sample. Majority of the participants did not consume any alcohol.

Table 2 *Sample Education Descriptors*

Descriptor	Descriptor level	Sample size	Percentage %
Number of education years N= 30[a]	11	1	3.3
	12	10	33.3
	13	2	6.7
	14	2	6.7
	15	3	10
	16	3	10
	17	5	16.7
	18	2	6.7
	20	2	6.7
Level of education N = 30[a]	Matric	9	31
	Diploma	6	20.7
	Degree	6	20.7
	Post graduate	8	27.6

Note. [a] Missing education information for one participant

The study assumed that the participants level of education would have a negligible impact of test scores as the majority of the participants had at least having 12 years of formal education (Santos, Tudesco, Caboclo, & Yacubin, 2011).

Table 3 *Sample Language Descriptors*

Descriptor	Descriptor level	Sample size	Percentage %
Number of language spoken N = 30	1	6	20
	2	16	53.3
	3	5	16.7
	4	1	3.3
	5	1	3.3
	6	1	3.3

(Table continues)

Descriptor	Descriptor level	Sample Size	Percentage %
Name of spoken languages N = 31	English	31	96.9
	Afrikaans	21	67.7
	Zulu	2	6.7
	Sesotho	1	3.2
	Sepedi	1	3.2
	Other	14	45.2
Home language N = 31[a]	English	29	90.6
	Afrikaans	2	6.3
	Zulu	1	3.1
	Italian	1	3.1

Note. [a] two participants spoke more than one home language

From the above table it can be concluded that all the participants in the study were fluent as well as proficient in the English language. This conclusion was drawn based on the fact that all participants were able to participate in the study as it was only conducted in English (despite one participant not having stated language spoken) as well as the majority of the sample stating English as being their home language.

Table 4 *Sample Medical History Descriptors*

Descriptor	Descriptor level	Sample size	Percentage %
Previous hospitalisation N = 31	Yes	20	61.3
	No	11	38.7
On medication N = 31	Yes	20	64.5
	No	11	35.5
Type of medication N = 32	Blood Pressure	6	16.2
	Cholesterol	6	16.2
	Heartburn	8	21.6
	Thyroid	4	10.8
	Sinus	2	5.4
	Osteoporosis	2	5.4
	Anti-Depressants	3	8.1
	Pain	1	2.7
	Menopause	2	5.4
	Cramps	1	2.7
	Asthma	2	5.4
Memory or attention problems N = 31	Yes	12	38.7
	No	19	61.3

Over half of the sample stated having had a previous history of hospitalization. Participants hospitalization history included; dental operations, previous endoscopic procedures, hormone related operations, appendix operations, operation exclusive to the female gender, limb related operations as well as heart operations. Majority of the participants were on some sort of medication, with the top three types of medication being for heartburn, blood pressure and cholesterol. In addition, less than half of the participants claimed to have some form of

memory or attention related difficulties. This included; forgetfulness, short-term memory problems, attention difficulties due to stress or being distracted.

Table 5 *Sample Experimental Descriptors*

Descriptor	Descriptor level	Sample size	Percentage %
Type of endoscopic procedure N = 31	Gastroscopy & Colonoscopy	15	48.4
	Colonoscopy	10	32.3
	Gastroscopy	6	19.4
Propofol dosage N = 31	≤ 250 mg	16	51.6
	> 250 mg	15	48.4
Procedure time N = 31	≤ 30 min	16	51.6
	>30 min	15	48.4

Sample experimental descriptors indicated that majority of the sample had undergone a colonoscopy & gastroscopy procedure, while the sample minority had either undergone a gastroscopy or an endoscopy. The majority of this split had undergone a colonoscopy. The sample majority were in the less than or equal to 250 mg propofol dosage group. Dosage of midazolam was constant across participants at 1 mg. The total time taken ranged from less than or equal to 30 minutes and above 30 minutes, with the majority being in the less than or equal to the 30 minutes group.

3.4. Instruments

3.4.1. The Demographic Questionnaire.

A brief questionnaire collecting demographic information was used to help as a screening tool to make an informed decision if the participant was suitable for the study. The questionnaire collected demographic data that included; age, home language and level of education. In addition, the participant's medical history was requested. This accounted for any neurological illnesses; the types of medication the patient was on, any cognitive complaints as well as the use of illegal substances (see Appendix A).

3.4.2. The Delis-Kaplan Executive Function System (D-KEFS) Color-Word Interference Test.

The D-KEFS Color-Word Interference Test (version of the Stroop Test) was used to assess the focus element of attention (Mirsky et al., 1991). This test took on average 10 minutes to complete. In particular, attention was measured using scores obtained from conditions 1 and 2. Condition 1 (Color Naming), the participant was required to name coloured rectangle blocks (red, blue and green) on a colour patch as quickly as possible without making mistakes. Condition 2 (Word Reading), participant was required to read the black inked printed colour words (red, blue and green) as quickly as possible without making mistakes (Delis, Kaplan, & Kramer, 2001).

Internal consistency reliability for all ages ranged between moderate to high (0.62-0.86) for both conditions. The test-retest reliability for the D-KEFS Color-Word Interference was conducted on a sample of 101 individuals, of which an improvement of test scores were observed during the post-test analysis and therefore highlights practise effects (Homack, Lee, & Riccio, 2005). The average time between the pre- and post-test administration was 25 days (Shunk, Davis, & Dean, 2006). The test-retest reliability ranged from 0.62-0.76 (Homack et al., 2005). The D-KEFS Color-Word Interference Test has been previously used in the South African context (Mattson et al., 2010).

For the D-KEFS, Color Naming condition 1 as well as the Word Reading condition 2, the total time to complete component is measured in seconds and is the raw score for this condition. The corrected, uncorrected and total errors represent the error analysis of the condition.

3.4.3. The Digit Span subtest from the Wechsler Adult Intelligence Scale III (WAIS III).

The Digit Span Forward subtest from the WAIS III was used to assess encode element of attention (Mirsky et al., 1991). The examinee read out a sequence of digits to the participant, the participant was required to repeat this sequence in the same order (forward) within a 120 seconds (Da Silva, 2008).

The WAIS III has been standardised in South Africa according to various stratifications. The first set of norms has been created for English-speaking South Africans characterised by age groups (Claassen, Krynauw, Paterson, & Mathe, 2001). In accordance with this norm set, the reliability computed for South Africans between the ages 20-34 was 0.81. The authors failed

to acknowledge the impact quality of education has on an individual's test score. In order to address this crucial variable, Shuttleworth-Edwards et al. (2004) created norms which accounted for the quality of education.

The norms created by Shuttleworth-Edwards et al. (2004) were stratified in accordance with language of origin, as well as the level and quality of education of the South African population. No psychometric properties were determined for this norm stratification groups.

For the Digit Span Forward subtest, the total item score was measured by adding the number of correct responses, which had a value of 1 point.

3.4.4. The Mental Control subtest from the Wechsler Memory Scale IV.

The Mental Control subtest from the WMS IV was used to assess the focus element of attention (Bigler & Clement, 1997). The participants were required to count from the number 20 to 1 backwards, as well as name the months of the year starting from December to January. The WMS IV reliability for the various subtests ranges from 0.74 to 0.97, while the internal consistency reliability ranges from 0.83 to 0.97 (Horne, & McDonald, 2012). Reliability values were obtained from a sample of 173 individuals with an average of 23 days interval between pre- and post-testing. On the Mental Control test the total completion time and the total errors are the weighted average of the raw scores obtained on the measure.

Both the Digits Span subtest from the WAIS III and the Mental Control subtest from the WMS IV took approximately 25 minutes to complete.

3.5. Procedure

3.5.1. Preparation.

Various documentations were prepared and processed to obtain ethical clearance and associated permissions from the Human Research Ethics Committee (HREC) (Medical) (Appendix D) of the University of the Witwatersrand and the Rosebank NetCare hospital (Appendix E).

3.5.2. Pre Testing.

Patients who were willing to volunteer to participate in the study were provided with an information sheet and were briefed by the researchers. Upon participation agreement participants were required to sign a consent form (see Appendix C). Due to this study being part of a larger study, participants were then required to undergo a battery of mood and

neuropsychological assessments (working memory and attention tests). Taking the briefing in consideration the pre-testing took approximately 60 minutes to complete.

The following tests were administered as part of the pre-test battery:

- Demographic Questionnaire
- Hamilton Rating Scale for Depression (HAM-D)
- Hamilton Rating Scale for Anxiety (HAM-A)
- Profile of Mood States (POMS)
- Stroop Color-Word Interference (D-KEFS)
- The Digit Span subtest (WAIS III)
- Letter Number Sequence subtest (WAIS III)
- Mental control subtest (WMS IV)

3.5.3. Sedation.

The anaesthetist explained to the patients as to what the sedation and endoscopic procedure entailed as well as obtained consent from the patients for the procedure. In addition, the anaesthetist assessed or evaluated the patient to confirm if the conscious sedation was appropriate for the procedure.

Each patient received a full ASA monitoring. The patient was then administered with supplemental oxygen in accordance with the patient's medical condition. An intravenous access was established. This was followed by the sedation. The sedation commenced with a bite block in place and the patient positioned onto their left side. A topical local anaesthetic (Lignocaine spray, 0.1ml, 1% solution) was sprayed in the back of the patient's throat. The sedation consisted of a single dose of midazolam of 1 mg combined with propofol which was administered at the discretion of the anaesthetist.

During the administration of the anaesthetic the patient's vitals were carefully and continuously monitored (ECG, pulse and saturations). In addition, the patient's non-invasive blood pressure was monitored every three minutes. The anaesthetist continuously monitored the anaesthesia level. This level was dependent on the anticipated level of painful stimulus that the patient experienced as well as the type of procedure that the patient had undergone. The anaesthetist aimed to achieve clinical procedural analgesia and amnesia throughout the procedure. The patient's changes in vitals were managed at the discretion of the anaesthetist.

After the procedure patients were placed in the Post Anaesthetic Care Unit (PACU), where the trained sister monitored the patients until they are deemed fit to be discharged. In addition, the Modified Aldrete Scoring System was administered by the staff. Post testing occurred thereafter. The results of the procedure were only available to the participant after they had undergone the post-testing, as thus could ultimately interfere with post testing results.

3.5.4. Post testing.

The following tests were administered as part of the battery of post- tests:

- Stroop Color-Word Interference (D-KEFS)
- Digit Span subtest (WAIS III)
- Letter Number Sequences subtest (WAIS III)
- Mental Control subtest (WMS IV)

The time after the procedure and the post-testing varied from across participants The post-testing took approximately 25 minutes to conclude.

3.6. Data Collection

Data collection occurred between June and August 2015 at the Rosebank Netcare Hospital. The principle researcher together with three fellow researchers was responsible for the administration of all the pre- and post-tests stipulated above. The principle researcher of this study conducted data analysis independently.

3.7. Ethical Considerations

According to the National Health Act (Act No. 61 of 2003) of South Africa, the following research is classified as being "health research", due to the nature of the research being both psychological and biological. According to this Act, this research needs to be approved be an accredited committee before the research can be carried out. Therefore the following research was submitted to the Human Research Ethics Committee (HREC) (Medical) of the University of The Witwatersrand and received approval (Ethics Clearance number M140302) (Appendix D). In addition, this study had received ethical clearance from the Rosebank Netcare Hospital ethics committee, as the study was conducted at this hospital (Appendix E).

The General Ethical Guidelines for Health Researcher (HPCSA, 2008), was used as a guideline to ensure that this study was conducted in a responsible manner. This also ensured that this research process was ethically, legally and scientifically valid. These guidelines also

helped to ensure that for the duration of the research process, participants rights were protected at all times.

3.7.1. Ethics with regards to the participants.

- Patients who volunteered to participate in the study were briefed about the research process by means of an information sheet (Appendix B). This sheet provided a clear explanation of what the study entailed and what was required of the participant.
- Participants were required to sign a consent form before participation in the study. This ensured that the participant was aware of and clearly understood what was required of him or her (Appendix C).
- Participants had the right to confidentiality and had the right to withdraw from the study at any given time, without any reason or prejudice.

3.7.2. Ethics with regards to data collected.

- Data collected was kept confidential and anonymous. This was ensured by the consent form of participants being kept separately from the rest of the data. The consent form is only made available to the University authorities should it be required for a random audit process. In addition, assessment protocols were assigned a number to ensure confidentiality and anonymity of results or data.
- Information obtained was strictly used for research purposes only.
- Due to participant name not being saved on assessment protocols, the researcher was unable to provide individual feedback.
- The overall results of the study are accessible to the participants.
- All researchers had undergone proper psychological assessment training by Ms Aline Ferreira-Correia, a registered clinical psychologist and supervisor on the project.

Chapter Four: Results

4.1. Overview

Data obtained for this study was analysed through the IBM SPSS Statistics software package version 22.

This section will begin with an overview of all the descriptive statistics for both the pre- and post- neuropsychological measures of the focus and encode elements of attention. This will be tabled in the form of means ($\bar{x}$), standard deviations (SD), medians as well as the range in relation to the dosage of propofol given to the participants. Means and medians obtained were raw scores for each neuropsychological test component, with the exception of the Mental Control, which is a scaled raw score.

In order to answer the research questions of this study, normality of the data was first established in terms of the nature of the data, the sample size, as well as data distribution. The data distribution was assessed using the Kolmogorov-Smirnoff test of normality (Howell, 2009). Thereafter, the test-retest reliability of the dependent measures was conducted using the Pearson correlation (Howell, 2009).

Once the above mention statistics were conducted, the study's two research questions were assessed using various statistical analyses. In order to answer research question 1 a Matched-Paired t-test was used on normally distributed data and Wilcoxon Signed Ranked test was conducted on non-parametric data (Howell, 2009). In addition, the various assumptions of the tests were discussed.

Research question 2 was answered using an Independent Samples t-test for normally distributed data and a Man-Whitney-U test for non-parametric data (Howell, 2009). However, before using the above mentioned test, the various assumptions for using the tests were discussed and tested.

4.2. Descriptive statistics

Table 6 *Descriptive Statistics for Pre- and Post-Neuropsychological Tests of Attention*

Attention Element	Neuropsychological test	Test component	Pre-VS Post-test	Descriptive Statistics				
				Mean ($\bar{x}$)	Median	Standard Deviation (SD)	Range	
							Minimum	Maximum
Focus Element	D-KEFS Condition 1: Colour Naming N=30	Total time to complete	Pre-Test	32.32	31.5	5.57	22	50.37
			Post-Test	33.7	32.87	7.02	15	47
		Corrected errors	Pre-Test	0.2	0	0.48	0	2
			Post-Test	0.57	0	0.82	0	3
		Uncorrected errors	Pre-Test	0.23	0	0.50	0	2
			Post-Test	0.13	0	0.35	0	1
		Total Errors	Pre-Test	0.43	0	0.68	0	2
			Post-Test	0.7	0.5	0.84	0	3

(Table continues)

Neuropsychological test	Test component	Pre-VS Post-test	Descriptive Statistics				
			Mean ($\bar{x}$)	Median	Standard Deviation (SD)	Range	
						Minimum	Maximum
D-KEFS: Condition 2: Word Reading N=30	Total time to complete	Pre-Test	23.36	21.85	5.45	17.3	46
		Post-Test	23.81	22	7.45	17	59
	Corrected errors	Pre-Test	0.3	0	0.47	0	1
		Post-Test	0.23	0	0.5	0	2
	Uncorrected errors	Pre-Test	0.07	0	0.25	0	1
		Post-Test	0.1	0	0.4	0	2
	Total Errors	Pre-Test	0.37	0	0.49	0	1
		Post-Test	0.33	0	0.76	0	3
Mental Control N=31	Total Completion Time	Pre-test	Constant x=4				
		Post-test	3.39	4	0.25	3	4
	Total Errors	Pre-test	7.2	8	1.86	2	8
		Post-test	7	8	2.08	2	8
Encode Element	Digit Span Forward N=31	Total Item Score	Pre-Test	11.7	11	2.18	8	16
			Post-Test	10.1	10	2.41	4	15

Due to the fact that conditions on the D-KEFS are interlinked, a participant was removed on all the D-KEFS conditions as a result of not completing the post-test condition 2, therefore resulting in a sample size of 30 instead of 31.

The means for the Color Naming condition 1 of the D-KEFS test components are larger in the post-tests, with the exceptions of the total number of uncorrected errors and the total errors, both having a smaller post-test mean when compared to the pre-test mean (Table 6).

The Word Reading condition 2 of the D-KEFS, post-test means for the total time to complete and uncorrected errors were slightly higher than that of the pre-test means. The pre-test means for corrected errors and total errors were slightly larger than that of the post-test means (Table 6).

For the total completion time on the Mental Control, the pre-test was constant, where as the mean of the post-test was slightly lower than the pre-test score (4). The post-test mean was slightly lower on the total errors when compared to the pre-test mean, however the range remained the same on both the pre- and post-test (Table 6).

For the Digit Span Forward, the mean of the pre-test was higher than that of the post-test, however the range of the post test was larger than that of the pre-test.

4.3. Data normality

In order to assess the normality of the dependent measures the following conditions will be looked at; the nature of the data, the sample size, as well as the normality of the data. The nature of the data is interval due to the scoring on the neuropsychological measures used. The sample size for the D-KEFS condition 1 and 2 is 30, whereas the sample size for the Digit Span Forward and the Mental control is 31.

Table 7 *Kolmogorov-Smirnoff Normality Test for the Neuropsychological Tests of Attention*

Attention Element	Neuropsychological test	Test component	Statistics			
			Pre-test		Post-test	
			Test Statistic	P-Value	Test Statistic	P-value
Focus Element	D-KEFS Colour Naming condition 1 N=30	Total time to complete	0.119	0.200*	0.074	0.200*
		Corrected errors	0.494	0.000	0.356	0.000
		Uncorrected errors	0.478	0.000	0.517	0.000
		Total errors	0.405	0.000	0.299	0.000
	D-KEFS Word reading condition 2 N=30	Total time to complete	0.160	0.050	0.234	0.000
		Corrected errors	0.440	0.000	0.478	0.000
		Uncorrected errors	0.537	0.000	0.531	0.000
		Total errors	0.406	0.000	0.470	0.000
	Mental control N=31	Total Completion Time	Constant x=4		0.537	0.000
		Total Errors	0.499	0.000	0.484	0.000
Encode Element	Digit Span Forward N=31	Total Item Score	0.164	0.039	0.125	0.200*

Note. *Lower bound of true significance

From the normality test observed in Table 7, both the dependent measures and their components have p-values of less than 0.05 (non-normally distributed), with the exception of the D-KEFS Color Naming condition1 total time to complete (pre and post p 0.200) on both the pre- and post-tests, and the Digit Span Forward post-test (p 0.200) (normally distributed).

Based on the above conditions, non-parametric tests was used for the dependent measures with the exception of the D-KEFS Color naming condition 1 total time taken, which a parametric test was conducted on the data. However, it should be noted that only on post-test statistical analysis of the Digit Span Forwards a parametric test was used.

4.4. Reliability of test measures

For the purpose of this study it was important to establish the test-retest reliability of both the focus and encode measures of attention, as little research has been conducted using some of these measures in the South African context. In addition, test-retest reliability was only conducted on the raw score measures of each test of attention, as the errors scores are solely based on the raw scores obtained for each test.

Table 8 *Pearson's Correlation Test-Reliability for Focus & Encode Measures of Attention*

Attention Element	Neuropsychological test	Test component	Pearson correlation (r)
Focus Element	D-KEFS Color Naming condition 1 N= 30	Total time to complete	0.766**
	D-KEFS Word reading condition 2 N= 30	Total time to complete	0.903**
	Mental Control N=31	Total Completion Time Total Errors	Constant pre-test 0.461*
Encode Element	Digit Span Forward N=31	Total Item Score	0.501*

Note. * Significant at 0.05 ** Significant at 0.01

From table 8 it can be seen that for the D-KEFS Colour Naming condition 1, the total time to complete, the test-retest reliability is fairly strong (r = 0.766) (Dattalo, 2008), and for the D-KEFS Word Reading condition 2, the total time to complete, very strong correlation can be seen (r = 0.903) (Dattalo, 2008) for the test retest reliability.

For the Mental Control subtest constant values in the pre-test was obtained for the data set therefore test-retest reliability could not be computed, however on the total errors scores a weak-moderate reliability is observed (r = 0.461) (Dattalo, 2008).

The Digit Span Forward subtest, a moderate test retest reliability (r = 0.501) (Dattalo, 2008) was observed.

4.5. Statistical tests for the study's research questions:

4.5.1. Research Question 1.

A Matched Paired t-test was only used for the D-KEFS Color Naming condition 1 total time to complete due to the fact that both the pre- and post-data was found to be normally distributed. Despite having post-test data for the Digit Span forward subtest being normally distributed, a Wilcoxon Signed Rank test was used as the pre-test data is non-normally distributed. For the balance of the attention measures a non-parametric Wilcoxon Signed Ranked test was used.

The Matched Paired t-test was used on the basis of the following assumptions; the dependent variable is interval, data is normally distributed and the samples are dependent due to the same participant being assessed in the pre- and post-test (Howell, 2009). A Wilcoxon Signed Rank test was used due to the data being skewed (non-normal), the dependent variable was interval and the samples are dependent due to the same participant being assessed in the pre- and post-test (Howell, 2009).

Table 9 *Wilcoxon Signed Ranked Test for Focus & Encode Elements of Attention*

Attention Element	Pre- & Post- Neuropsychological test	Test component	Mean rank		z-Statistic	p-value
			Negative	Positive		
Focus element	D-KEFS Colour Naming condition1 N=30	Number of corrected errors	7.76	8.60	-1.93[b]	0.05*
		Number of uncorrected errors	3.75	3.00	-1.00[a]	0.32
		Total errors	9.42	9.54	-1.36[b]	0.17
	D-KEFS Word Reading condition 2 N=30	Total time taken	12.62	14.38	-0.29[b]	0.77
		Number of corrected errors	6.50	7.80	-0.50[a]	0.62
		Number of uncorrected errors	2.00	3.00	-0.38[b]	0.70
		Total errors	6.00	10.20	-0.10[a]	0.92
	Mental Control subtest N=31	Total completion time	1.50	0.00	-1.41[a]	0.16
		Total errors	3.60	5.00	-0.69[a]	0.49
Encode element	Digit Span Forward subtest N=31	Total Item Score	11.75	8.60	-2.55[a]	0.01*

Note. *Significant $p \leq 0.05$

[a] based on positive rank [b] based on negative ranks

Table 10 *Matched Paired t-test for the Focus Element of Attention*

Attention Element	Pre- & Post Neuropsychological Test	Test Component	Degrees of Freedom	t-Statistic	P-value	Confidence Interval	
						Lower	Upper
Focus Element	D-KEFS Colour Naming condition1 N=30	Total Time Taken	29	-1.675	0.105	-3.07	0.30

When using the Wilcoxon Signed Rank Test to assess the difference between pre- and post-sedation scores it can be seen that the D-KEFS Color Naming condition 1 number of corrected errors (z= -1.93 p=0.05) and the Digit Span Forward subtest (z = -2.55 p=0.01) produced statistically significant results (Table 9). The remainder of the test components on the D-KEFS Color Naming condition 1, the Word Reading condition 2 as well as the components on the Mental Control subtest were all non-significant (p>0.05) (Table 9).

For the D-KEFS Color Naming condition 1 number of corrected errors, the pre-test score (32.32) is significantly lower than that of the post-test score (33.7), therefore participants did not self-correct as many errors as they had done in the pre-test (Table 6). In addition, when assessing the effect size for this significant difference ($r = {}^{z}/_{\sqrt{2N}}$) (Li, 2014), a small effect size (Dattalo, 2008) was observed (r = -0.25).

The Digit Span Forward subtest, the pre-test score (11.7) is significantly higher than that of the post-test score (10.1), therefore participants produced a shorter string of numbers in the post-test (Table 6). In addition, when assessing the effect size of this significant difference, a medium effect size (Dattalo, 2008) was observed (r = -0.32).

From Table 10, it can be observed through the computation of a Matched Paired t-test, there is a non-significant difference between pre- and post-test scores on the D-KEFS Color Naming condition 1 for the total time taken(t_{29}= -.675 p= 0.105).

Based on the above mentioned results the null hypothesis for the research question 1 was rejected.

4.5.2. Research Question 2.

In order to answer this question one needs to first establish that there is no significant difference between the two propofol dosage groups on the pre-test measures of the dependent variables. For data that were not normally distributed a Mann-Whitney U-test was used and an Independent Samples t-test was used to assess normally distributed data namely: D-KEFS Color Naming condition 1 total time taken pre- and post-test as well as the Digit Span Forward subtest post-test only.

For an Independent Sample t-test to be conducted on the D-KEFS Color Naming condition1 total time taken, the following assumptions needed to be met; nature of the data (as discussed above), normality of the data (discussed above), independent samples in each groups

(assumed as different participants received either propofol dosage), as well as the homogeneity of variance (Howell, 2009). Homogeneity of variance was assessed by using Levene's test for homogeneity.

Table 11 *Levene's Test for Homogeneity of Variance of the Pre-Test D-KEFS Color Naming Condition 1 Total Time Taken*

Attention element	Neuropsychological test	Test component	F-statistic	p-value
Focus element	D-KEFS Color Naming condition 1	Total time taken	0.196	0.662

As shown in Table 11, a non-significant result was obtained for the D-KEFS Color Naming Condition1 total time taken ($F = 0.196$, $p>0.05$), therefore when computing an Independent Samples t-test, the values for equality of variance not assumed was used.

When conducting a Mann-Whitney U-test, the data has to be non-normally distributed and Homogeneity of variance does not need be established (Howell, 2009). In addition, the data needs to be interval (as discussed above).

Table 12 *Independent Samples t-test for the Pre-Test D-KEFS Color Naming condition 1 Total Time Taken*

Attention element	Neuropsychological test	Test component	Propofol dosage	Mean	Degrees of freedom (df)	Mean difference	t-statistic	p-value	Confidence intervals	
									Lower	Upper
Focus element	D-KEFS Color Naming condition 1	Total time taken	<250 mg (n=15)	33.10	26.28	-1.21	-0.467	0.644	-6.55	4.13
			>250 mg (n=15)	34.31						

Table 13 *Mann-Whitney U-test for Pre-Test Measures for the Focus & Encode Elements of Attention*

Attention element	Neuropsychological test	Test component	Propofol dosage	Mean Rank	z-statistic	p-value
Focus element	D-KEFS Color Naming condition 1	Number of corrected errors	1 (n=15)	15.19	-0.38	0.70
			2 (n=15)	15.10		
		Number of uncorrected errors	1 (n=15)	16.57	-0.95	0.34
			2 (n=15)	14.43		
		Total errors	1 (n=15)	16.57	-0.80	0.42
			2 (n=15)	14.43		
	D-KEFS Word Reading condition 2	Total time taken	1 (n=15)	14.87	-0.39	0.69
			2 (n=15)	16.13		
		Number of corrected errors	1 (n=15)	14.00	-1.17	0.24
			2 (n=15)	17.00		
		Number of uncorrected errors	1 (n=15)	14.50	-1.44	0.15
			2 (n=15)	16.50		
		Total errors	1 (n=15)	13.00	-1.86	0.06
			2 (n=15)	18.00		

(Table Continues)

	Neuropsychological test	Test component	Propofol dosage	Mean Rank	z-statistic	p-value
	Mental Control	Total completion time	1 (n=16)	16.00	0.00	1.00
			2 (n=15)	16.00		
		Total errors	1 (n=16)	16.53	-0.52	0.60
			2 (n=15)	15.43		
Encode element	Digit Span Forward	Total item score	1 (n=16)	16.28	-0.18	0.86
			2 (n=15)	15.70		

Notes. Propofol dosage 1: <250 mg

2: >250 mg

As described in Tables 12 & 13, the propofol groups of <250 mg and >250 mg are found to be non-significant ($p>0.05$) for all the focus as well as encode measures of attention.

Therefore, the two propofol dosage groups (<250 mg & >250 mg) were the same initially. On the premise of these results both a Mann-Whitney U-test and an Independent Samples t-test was conducted on the post-test measures of the focus and encode elements of attention.

Test assumptions for both the Mann-Whitney U-test as well as the Independent Samples t-test have been discussed above. However, in order to conduct the Independent Samples t-test, homogeneity of variance needs to first be established for both the D-KEFS Color Naming condition 1 total time taken as well as the Digit Span Forward as normality for these post-test data has been established (Table 7).

Table 14 *Levene's Test for Homogeneity of Variance for the Post-Test D-KEFS Color Naming Condition 1 Total Time Taken and the Digit Span Forward Subtest*

Attention element	Neuropsychological test	Test component	F-statistic	p-value
Focus element	D-KEFS Color Naming condition 1	Total time taken	0.20	0.66
Encode element	Digit Span Forward subtest	Total item score	0.49	0.49

From Table 14 it can be observed that the criteria for homogeneity of variance has not been met ($p>0.05$) for both the D-KEFS Color Naming condition 1 total time taken as well as the Digit Span Forward subtest, therefore when conducting an Independent Samples t-test values for unequal variance not assumed was used.

Table 15 *Independent Samples t-test for the Post-Test D-KEFS Color Naming Condition 1 Total Time Taken and Digits Span Forward Subtest*

Attention element	Neuropsychological test	Test component	Propofol dosage	Mean	Degrees of freedom (df)	Mean difference	t-statistic	p-value	Confidence intervals	
									Lower	Upper
Focus element	D-KEFS Color Naming condition 1	Total time taken	<250 mg (n=15)	33.1	26.28	-1.21	-0.47	0.64	-6.55	4.13
			>250 mg (n=15)	34.31						
Encode element	Digits Span Forward	Total item score	<250 mg (n=16)	10.69	27.01	1.09	1.27	0.22	-0.67	2.85
			>250 mg (n=15)	9.6						

Table 16 *Mann-Whitney U-Test for Post-Test Measures for the Focus Element of Attention*

Attention element	Neuropsychological test	Test component	Propofol dosage	Mean Rank	z-statistic	p-value
Focus element	D-KEFS Color Naming condition 1	Number of corrected errors	1 (n=15)	15.93	-0.31	0.76
			2 (n=15)	15.07		
		Number of uncorrected errors	1 (n=15)	15.50	0.00	1.00
			2 (n=15)	15.50		
		Total errors	1 (n=15)	15.97	-0.32	0.75
			2 (n=15)	15.03		
	D-KEFS Word Reading condition 2	Total time taken	1 (n=15)	13.93	-0.98	0.33
			2 (n=15)	17.07		
		Number of corrected errors	1 (n=15)	16.57	-0.95	0.34
			2 (n=15)	14.43		
		Number of uncorrected errors	1 (n=15)	15.47	-0.05	0.96
			2 (n=15)	15.53		
		Total errors	1 (n=15)	16.43	-0.83	0.40
			2 (n=15)	14.57		
	Mental Control	Total completion time	1 (n=16)	16.03	-0.05	0.96
			2 (n=15)	15.97		
		Total errors	1 (n=16)	14.69	-1.14	0.26
			2 (n=15)	17.40		

Notes. Propofol dosage 1: <250 mg

2: >250 mg

From the computation of an Independent Samples t-test (Table 15), non-significant results between the two propofol dosage groups were observed on both the D-KEFS Color Naming condition 1 total time taken ($t_{26.28}$=-0.47, p=0.64) and the Digit Span Forward subtest (t=1.27, p=0.64).

From Table 16, non-significant results have been observed between the two propofol dosage groups based on the computation of a Mann-Whitney U-test for the remainder of the D-KEFS Color Naming condition 1 test components (p>0.05), D-KEFS Word Reading condition 2 test components (p>0.05) and on both the test components of the Mental Control subtest (p>0.05).

Propofol dosage does not have any effect on both the focus and encode elements of element of attention. Therefore, the null hypothesis for research question 2 has been failed to be rejected.

Chapter Five: Discussion

This study determined if conscious sedation had an effect on both the focus and encode elements of attention. In addition, the study also assessed if the propofol dosage influenced test scores of both the focus and encode elements of attention.

Before conducting any analysis on the research questions of the current study, test-retest reliability was first established. For the D-KEFS Color-Word Interference condition 1 Color Naming a test-retest reliability of 0.766 and on the condition 2 Word Reading a test-retest reliability of 0.903 was observed. The condition 1 Color Naming condition is in line with the results stated by Homack et al. (2005), as it falls within the stipulated upper bound range of the Color-Word Interference test of 0.62-0.76. However, the test-retest reliability for condition 2 Word Reading does not fall within the stipulated range (0.62-0.76), but is rather much higher than the upper bound stated by Homack et al. (2005). It should be noted that the time period of the pre- and post-testing of these two conditions where within a range of hours and not days, whereas the reliability coefficients reported by Homack et al. (2005) was calculated within an average of 25 days between the pre- and post-administration. This difference in pre- and post-test time-period could have account for the increase in reliability observed on condition 2 Word Reading in the current study.

The test-retest reliability for the Digit Span Forward subtest for the current study was 0.501, which was much lower than that reported by Claassen et al. (2001) (0.81). The decrease in the reliability for the current study could be attributed to the participants' age as well as the test component. Concerning the participants' age, majority of the participants of the current study were aged between 51-61 years, whereas the reliability computed by Claassen et al. (2001) was conducted on individuals between the ages of 20-34 years. The current study only ran a reliability test for the Forward component of the Digit Span subtest, whereas the Claassen et al. (2001) conducted the reliability on both the Backwards and Forwards components of the Digit Span subtest.

The test-retest reliability for the Mental Control subtest of the current (0.461) study fell below the lower bound range of that computed by Horne & McDonald (2012). This could be attributed to the sample size (31) of the study as well as the time interval (matter of hours) between pre- and post-testing of the current study when compared to the sample reported by Horne & McDonald (2012) (sample = 173, average time interval = 23 days). In addition, test-retest reliability for the total completion time of the Mental Control could not be computed

for the current study and therefore the reliability is based on only one component of the Mental Control, whereas Horne & McDonald (2012) report test-retest reliability on both the test components of the Mental Control.

When exploring the impact conscious sedation has on the focus and encode elements of attention following an endoscopic procedure, the current study produced significant results on D-KEFS Color-Word Interference condition 1 Color Naming total number of corrected errors (z=-1.93 p=0.05) (focus element) and on the Digit Span Forward subtest (z=-2.55 p=0.01) (encode element). However, non-significant results we obtained on all the other measures of the D-KEFS and the Mental Control subtest (focus elements). Therefore, participants were less likely to self-correct their errors made on naming the colours on the D-KEFS Color-Word condition 1 Color Naming in the post-test when compared to the pre-test and produced a shorted string of numbers in the post-test when compared to the pre-test on the Digit Span Forward.

From these results, it can be observed that these findings are not consistent for the focus element of attention as the D-KEFS Color-Word Interference condition 1 Color Naming total number of corrected errors (focus element), is just one of three of the error analysis components of this condition. Out of the three measures of the focus element of attention, only one test component from one of the three measures has been found to be significant. In addition, the effect size obtained for the D-KEFS Color-Word Interference condition 1 Color Naming total number of corrected errors was small (-0.25) (Dattalo, 2008). Thus, these results do not allow one to conclude that conscious sedation does change the focus element of attention following conscious sedation, but rather remains the same.

For the encode element of attention, only one measure was used to assess this element (Digit Span Forward subtest) and significant results were produced, which can possibly be attributed to practise effects.

Upon comparing the results of research question one of the current study with that of past studies both contradictory as well as complimentary results have been obtained. In a study conducted by Sarasin et al. (1996), an overall significantly lower post-test performance in comparison to baseline performance was produced in relation to attention. This result partially correlates with that of the current study, as described pre-test scores on both the D-KEFS Color Word Interference condition 1 number of corrected errors (z = -1.93 p=0.05) (focus element) and the Digit Span Forward subtest (z = -2.55 p=0.01) (encode element),

were significantly lower than post-test scores. In addition, it should be noted that the D-KEFS Color Word Interference condition 1 number of corrected errors is just one of four test components of this particular condition. For the majority of the test components and attention measures non-significant results have been observed ($p>0.05$), between the pre- and post-test results and therefore is contradictory to the above-mentioned study's results.

The various methodological differences between the two studies could possibly account for the contrast in results. The study conducted by Sarasin et al. (1996) divided participants into receiving either midazolam or propofol, whereas participants of the current study received propofol combined with midazolam. Thus, the impact of the combination of these drugs could have affected the results obtained. The results for Sarasin et al. were obtained 10 minutes after the treatment and not post-surgery, whereas the results of the current study was only obtained post-surgery.

Contradictory results are produced when contrasting the results of the current study with that of Girdler et al. (2002). Girdler et al. (2002) report a severe decrease in attention following the administration of midazolam and flumazenil (reverse the effects of midazolam) to participants undergoing dental procedures. However, for the current study the significant results produced the D-KEFS Color Word Interference condition 1 number of corrected errors ($r= -0.25$) and Digit Span Forward subtest ($r = -0.32$) ranged between being small-medium effects, therefore slightly moderate effects were produced. These contradictory results could be the result of the various methodological differences in these studies.

Girdler et al. (2002) administered a computerised battery telephonically, which could have eliminated the possible impact of assessor differences in the current study. In addition, test-wiseness (telephonic based testing) could have been attributed to the results obtained by Girdler et al. (2002). The current study was conducted on participants who had undergone an endoscopic procedure, whereas Girdler et al. (2002) conducted the study on participants who had undergone dental surgery. The impact of the various anxiety and post-pain associated with these different types of surgical procedures could possibly account for the differences in results observed. Lastly, in the current study midazolam was combined with propofol and no reversing agents were used when compared with that of Girdler et al. (2002).

Partial correlation between the current study's results and that of Padamanabhan et al. (2009) is observed. The authors showed a significant decline from baseline to post-test scores on the

attention task. However, only two of the attention measures of the current study were significant result obtained, highlight lower results on both the post-test measures.

The discrepancy in these results can possibly be attributed to the various methodological differences between the studies. Firstly, the administration of the attention assessments differed; computerised assessment of attention only occurred in the study conducted by Padamanabhan et al. (2009). The use of computerised assessments eliminated the possibility of the impact of the assessor on test scores, whereas the assessor differences in the current study could have impacted the results despite having a standardised method of conducting the assessments. Secondly the current studied used a constant 1 mg dosage of midazolam, whereas the study conducted by Padamanabhan et al. (2009), the midazolam dosage was 2 mg. Results of Padamanabhan et al. (2009) where not isolated results of the propofol and midazolam groups but rather combined with that of the midazolam and fentanyl group. Lastly, the participants of the current study had undergone any type of endoscopic procedure, whereas in Padamanbhan et al. (2009) only conducted their study on individuals undergoing a colonoscopy.

From the above-mentioned studies, the complexity of contrasting the results of the current study with previous literature in the field can be seen and the lack of literature on this particular topic in the field is highlighted. In addition, above-mentioned findings are not consistent and thus, results cannot necessarily be taken as a proof of changes in the construct due to the anaesthetics. Consequently, alternative explanations should be considered, such as those related to test administration, participants' age, medical history, assessor differences as well as the surgical procedures undergone by participants in the study.

The results for the second research question of this study indicated that there were no significant ($p>0.05$) differences between the propofol dosage groups of less than 250mg and greater than 250 mg on both the focus and encode element of attention. The lack of research in this field has been highlighted in the literature review. Based on this there is a need for more literature in this particular field to explore the current results. In addition, the current study could be used as a stepping-stone for future research surrounding this topic.

With regards to the possibility of the repayment of sleep debt during anaesthesia as suggest by Tung et al. (2004), the current study suggests that sleep debt may not be repaid due to the significant results obtained on the Digit Span Forward subtest as well as the D-KEFS Color-Word Interference condition 1 number of corrected errors. Participants respectively made less

self-correction and produced a shorter string of numbers. However, with regards to the non-significant results obtained on the majority of test components and attention measures, it could be suggestive that the anaesthesia has no effect on the repayment of sleep debt. It should be noted that the study by Tung et al. (2002) was conducted on rats and they had undergone duration of 6 hours of propofol anaesthesia, whereas the anaesthesia given to participants in the current study lasted for approximately 1-2 hours. The possibility of these results allows for further probe into the short and long-term duration of anaesthesia.

The above findings have practical implications and highlight the importance of the patient adhering to the discharge criteria as recommended by SASA (2010). As the cognitive function of attention is implicated in the activities (driving, operating machinery, and signing legal documentations for a 24 hour period post-surgery) patients are recommended to refrain from post-sedation (Banich & Compton, 2010).

Limitations and Recommendations

The sample used in this study was very small (n=31), therefore the statistical power of the tests used decreases and the results of this study cannot be generalised due to the sample not being representative of the South African population (Dattalo, 2008). In order to overcome the sample size and the highly specific nature of the sample future research of this nature needs to be conducted for longer periods (6-12 months), as well as being conducted in more than one public and private hospital were the control of the drug used and dosage can be controlled to the same degree.

The post assessments battery was relatively long for patients who had just undergone an endoscopic procedure and this could have accounted for the attrition during the post-test. In addition, the same tests were used in the pre- and post-testing, which could have resulted in practise effects. Future researcher need to design an assessment battery for attention that is relatively short but still assesses the various elements of attention. In order to account for the possible practise effects future researchers could use parallel or alternative tests when conducting the post-tests.

The assessments was conducted in the ward, which was associated with multiple challenges or limitations, such as; the testing environment was not ideal for testing, due to the noise levels in the ward, doctors and nurses entering the room to talk to the patient as well as the patients' relatives entering the room. In order to achieve an ideal testing environment, future

researchers conducting research of this nature would need to assess patients in a room that is close to the ward but isolated where interference is minimal.

Lastly, the time between post-procedure and the post-assessment varied amongst participants. Therefore, results of the study could have been attributed to this variation in time. In order to address this limitation future studies should standardise the time between the post-procedure and post-assessment.

Through the discussion of the current study with that of past studies various methodological differences have been highlighted between studies approaching a similar aim to the current study, therefore making it difficult to understand the relationship between variables, thus, replication studies with larger samples should be conducted in this field of research.

Conclusion

The following conclusions can be drawn from the current study: both the encode and focus elements of attention appear to be affected by sedation. For the focus element of attention participants produce a significantly shorter string of numbers on the Digit Span Forward subtest post-sedation. For the focus element of attention, the D-KEFS condition1 number of corrected errors, participants self-corrected a significantly lower amount of errors in the post-test. Furthermore, the dosage of propofol administered to patients does not appear to have a significant impact on an individual's attention post sedation.

The current study highlights the importance of patients adhering to the discharge recommendations made by medical staff post their endoscopic procedures, as one's attention is decreased post the conscious sedation. The lack of research in this field has been highlighted and this study can serve as a stepping-stone for future research on the effects of anaesthesia drug combinations, the various dosages of propofol on the attention elements as well as research on the impact of anaesthesia duration on sleep debt repayment.

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Appendix A. Demographic Questionnaire

TO BE COMPLETED BY MEDCAL TEAM ONLY:

PARTICIPANT NUMBER: _____

TO BE COMPLETED BY PARTICIPANT:

Demographic information:

- How old are you? _____
- How many languages do you speak (please specify the languages)?
  _____
- Which one is your home language? _____
- How many years of formal education do you have? _____
- What is your highest level of education? _____

Health history:

- Are you taking any medication? Yes No
  - If you answered 'yes' to the previous question, please specify the type of and reason for medication:
    _____
- Do you have any history of hospitalisation? Yes No
  - If you answered 'yes' to the previous question please specify for the reason and duration of your stay:
    _____
  - Please indicate if you have any history of neurological –including TBI- and/ or psychiatric illnesses:
    _____
- Do many glasses of alcohol do you consume per day?
  _____
- Have you experienced any problems with attention and/ or memory in the past 6 months? (e.g. feeling distracted, forgetfulness, getting lost)

  Yes No
  - If you answered 'yes' to the previous question please specify your experience(s):

    _____

Appendix B: Participant Information Sheet

Psychology

School of Human & Community Development

Private Bag 3, Wits 2050, South Africa. Telephone: +27 11-717-4500/2/3/4. Fax: +27-11-717-4559

2014

Dear Participant

Our names are Sharlene Richard, Tasneem Hassem, Melissa Vrachionidis and Rivkie Hadar. We are Psychology students (Masters by Coursework and Research in Psychology and Honours) in the School of Human and Community Development, at the University of the Witwatersrand.

As part of our degree requirements, we need to complete a research study. The aim of our research is to find out the cognitive and emotional implications of sedation associated to endoscope procedures. These possible implications are known to be transitory. As a patient about to undergo an endoscope procedure, you are invited to take part in this research study titled: *The psychological effect of conscious sedation administered for endoscopic procedures*. To date, there is very little known about this area. Your participation will thus enable us to contribute to the knowledge of such cognitive effects.

Participation will require completing the following psychological assessment batteries both before and after your endoscope procedure:

- Questionnaire (only pre-test section): A brief questionnaire will be used to collect demographic data (age, level of education, and home language) and health history (presence of any neurological or psychiatric illness, current medication, cognitive complaints, and use of illegal substances);
- Profile of Mood States (POMS): A self-rating scale consisting of adjectives describing your feelings of the last week as well as feelings you experience when filling out the questionnaire;
- Hamilton Rating Scale for Depression and for Anxiety (HAM-D & and HAM-A) (only pre-test section): two 17 and 14 item self-rating scales respectively, designed to assess symptoms associated with depression and anxiety in adults;
- Neuropsychological tests (Digit Span, Stroop Colour Word Interference, Letter Number Sequence Subtest, Mental Control) will be used to assess attention and working memory. These tests will require you to remember information and solve mind-puzzle like problems.

The pre-test battery should take about 60 minutes to complete and the post-test about 25 minutes. The pre-test will take place before you go for sedation and the post-test will take place once you are discharged from the PACU unit.

Participation on this research study requires the completion of the entire assessment process as outlined above. The assessment process will take place in a private room at the Rosebank Netcare Hospital, in two sessions (pre- and post-testing). These sessions will be scheduled in accordance with your endoscope procedure. Should you agree to participate in this research study, you will be asked to sign the attached consent form. This form will be kept separately from the rest of the data for the purpose of anonymity and confidentiality. The consent form will only be made available to the University authorities should it be required for a random audit process.

Please note that participation will not be compensated for, monetary or otherwise. Results of the assessments will be saved anonymously and therefore, the researchers will not be able to provide any feedback regarding assessment results. As the researchers of this study, we do not foresee any obvious risks in participating. However, the assessment process might reveal difficulties with certain activities and elicit sensitive personal information. We would therefore like to stress that your participation in this study is completely voluntary and you may withdraw from it at any point until results are saved. Because results will be saved anonymously, we will not be able to retract your results after this stage. You may also refrain from answering any particular questions with no negative consequences. If you experience any distress associated with the assessment process, please refer to the following free counselling services: The South African Depression and Anxiety Group at 011 262 6396/ 0800 20 50 26; and/ or Life Line at 011 728 1347.

Your identity as a participant will only be known to the medical team involved in the endoscope procedure and the four assessors/ researchers. All the assessment results will be saved anonymously and will be locked in a secured office for 5 years. The entire research process will be dealt with confidentially. The assessment results will not be published or used for purposes other than the research aim stated in the beginning.

The thesis resulting from this research will be available in the library of the University of the Witwatersrand, which offers access to material on the world-wide web. The findings will also potentially be published in scientific journals. If you wish to have access to the results, you may request so by contacting us.

This project has been approved by the Human Research Ethics Committee of the University of The Witwatersrand, Johannesburg. If you have any questions please do not hesitate to contact the committee.

Should any matters require further clarification please do not hesitate to contact:

- Sharlene Richard (082 328 2704 – richard.sharlene@gmail.com),
- Tasneem Hassem (082 494 9725- 361406@students.wits.ac.za),
- Melissa Vrachionidis (071 371 3327 - melissav86@me.com);
- Rivkie Hadar (072 988 2008 -Rivkiehadar@gmail.com).

You may also contact our supervisor, Ms Aline Ferreira Correia (011 717 4527- Aline.FerreiraCorreia@wits.ac.za.).

Many thanks for considering participating.

Kind regards,

Sharlene Richard, Tasneem Hassem, Melissa Vrachionidis and Rivkie Hadar

Appendix C: Participant Consent Form

Psychology

School of Human & Community Development

Private Bag 3, Wits 2050, South Africa. Telephone: +27 11-717-4500/2/3/4. Fax: +27-11-717-4559

Consent for research participation

I am an adult person above the age of 18 years and I confirm that I have read and understand the information provided in the information sheet in relation to the participation in *The psychological effect of conscious sedation administered during endoscopy procedures*. I have been informed about what the psychological assessments entail and what is required of me. I also understand that:

- My participation is completely voluntary;
- I may withdraw from the assessment at any time with no negative consequences for me;
- All the information I provide and my participation will be kept confidential;
- No rewards will be offered or provided for my participation;
- No feedback on the results will be provided to me;
- I have received the contact details of the researchers Sharlene Richard, Tasneem Hassem, Melissa Vrachionidis, Rivkie Hadar; and the supervisor Aline Ferreira Correia;
- I have received contact details for free counselling services in case I experience any distress regarding the assessment activities.

Therefore, I agree to undergo the psychological assessment administered by the researchers.

Researcher's Name: _____

Researcher's signature: _____

Participant's name: _____

Participant's signature: _____

Date: _____

Appendix D: Human Research Ethic Committee (Medical) Clearance Certificate

R14/49 Ms Sharlene Richard et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140302

NAME: (Principal Investigator)	Ms Sharlene Richard et al
DEPARTMENT:	Psychology Netcare Rosebank
PROJECT TITLE:	Is there a True Psychological (Cognitve Functioning and Mood) Effect of Consious Sedation during the Endoscopic Procedure?
DATE CONSIDERED:	28/03/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ms Aline Ferreira Correia
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	09/05/2014

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date 16 MAY 2014

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix E: Netcare Ethics Committee Clearance Certificate

Netcare Rosebank Hospital

Tel: +27 (0) 11 328 0500
Fax: +27 (0) 11 328 0509
14 Sturdee Avenue, Rosebank, South Africa
PO Box 52230, Saxonwold, 2132, South Africa
www.netcare.co.za

Date: 1/4/2014

To: University of WITS Ethics Committee

RESEARCH TO BE CONDUCTED IN NETCARE FACILITY

The Management of Netcare Rosebank Hospital has taken note of the application for ethical approval by WITS Ethical Committee for the following research study to be conducted

IS THERE A TRUE PSYCHOLOGICAL EFFECT OF CONSCIOUS SEDATION DURING ENDOSCOPIC PROCEDURE ? (Title of research)

In principle the Netcare Hospital Management does not have any reservations for the abovementioned research to be conducted on its premises subject to unconditional ethics approval being granted.

We furthermore confirm that application will then be made to the Netcare Research Committee and that the research may not commence prior to receipt of FINAL APPROVAL from the Academic Board of Netcare (Research Committee).

Yours faithfully

Signed by Hospital Management — **Date** 01/04/2014

General manager.
(Specify designation)