### A SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL COMPARING THE USE OF MULTIMEDIA INTERVENTION VERSUS ROUTINE CURRENT PRACTICE TO REDUCE PATIENTS' ANXIETY LEVELS PRIOR TO AN MRI STUDY AT A TERTIARY HOSPITAL IN TRINIDAD AND TOBAGO.

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# INTRODUCTION

- Anxiety as defined by the American Psychological Association is an emotion which results in the production of thoughts of worry which lead to feelings of tension and physical changes. There has been a plethora of research into the understanding of the mechanisms which result in the physical manifestations of anxiety.
- \* There are a multitude of stressors that elicit an anxiety response, especially within the field of medicine. The fear or phobia of hospitals or nosocomephobia and the fear of the unknown or xenophobia is frequently experienced by patients undergoing any type of medical investigation.
- \* Patients awaiting radiological procedures demonstrate significant levels of anxiety with one study describing 69% of patients experiencing high anxiety levels.

## **LITERATURE REVIEW**

\* A study performed in Germany by Eshed et al demonstrated a reported 37% incidence of anxiety issues related to MRI studies.

\* A review of the procedures over the period July 2017 to December 2017 demonstrated that 710 MRI studies were cancelled with 27 MRI studies due to claustrophobia, 28 MRI studies were the patient refused the procedure and the remainder of cancelled studies fell into category listed as "other" which consisted of various reasons including inability to located patients request, equipment malfunction, patients double registered and wrong planning.

## **THE PROBLEM**

- \* The duration of the imaging process which requires the patients to remain in a fixed position for a prolong period of time.
- Patients who reported experiencing increased anxiety states
  - the production of unwanted motion artefact from restlessness,
  - elevated respiration rates,
  - excessive swallowing, and
  - failure to comply with instructions which can result in the termination of the study or the acquisition of erroneous images which can mimic the presences of pathology in suboptimal studies.
  - \* A reduction in the pre procedural anxiety levels of a patient can be beneficial to both the patient and the physician as calmer patients would be more cooperative.

# **OBJECTIVES AND HYPOTHESIS**

- \* Objectives
  - To investigate the efficacy of an educational intervention in the anxiety levels of a cohort of patients presenting to the Department of Radiology at the Eric Williams Medical Sciences Complex.
  - \* To explore patient satisfaction post imaging after being educated about the imaging process.
- **\*** Hypothesis:
  - \* The use of educational video and pamphlet in the intervention group would not result in a reduction of pre procedural anxiety levels compared to the control group in patients who are presenting for their first MRI study.

## METHODOLOGY

This study was conducted at the radiology department of the Eric Williams Medical Sciences Complex utilizing a Siemens 1.5 tesla Symphony MRI scanner. It was conducted as a single blinded randomized control trial which compared the use of multimedia (a brief educational video and educational pamphlet) as opposed to the current routine practice to reduce the levels of anxiety that occur in patients presenting for their first MRI procedure.

#### **Control Group:**

These patients received the current standard routine appointment attached to their request form. These subjects, upon arrival into the MRI suite were asked to repeat the initial STAI form which was done prior to randomization.

#### **Test Group:**

There was one intervention in this group which defined the difference between the control and the test group. The test group was given a short 5min educational video prior to his or her scheduled MRI study. The video and was obtained from the Siemens vendor and was designed specifically as an educational video.

#### Sample Size:

A sample size of 120 patients was calculated which used an effect size of 0.3 as the assumed reduction in anxiety level would be 30%. In addition, the power was set at 90% and  $\alpha$  = 0.05. It is proposed that 150 of subjects be approached allowing for 20% non-willingness to participate

#### **Investigation Tools:**

The State and Trait Anxiety Inventory: All patients who consented to participate in this study were given a STAI form to fill out prior to randomization. The STAI is a psychometric forty item self-evaluation test and has been utilized in everyl studies to evaluate the anxiety levels in patients awaiting various medical procedures including MRI studies

### DEMOGRAPHICS



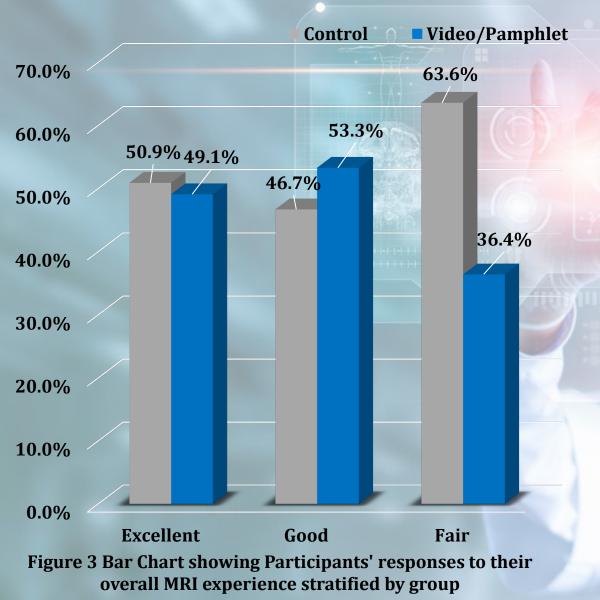
Figure 1 Bar Chart demonstrating Age group stratified by gender

# RESULTS

Characteristic	Pre -Intervention STAI	Post-Intervention STAI	Correlation	Difference	t	P value
	Mean	Mean				
Control	79.45	77.75	0.975**	-1.71	-2.84	0.006
Intervention	72.54	65.44	0.860**	-7.09	-6.00	<0.001
** p <0.01						

- > The two groups were analysed for pre-post changes in the STAI scores.
- There was a meaningful change in both the control and intervention groups in the pre- and postintervention STAI scores. In the control group, there was a difference in the scores of only 1.71 (t=-2.84, p<0.006), while in the intervention group, there was a greater difference in the pre-post scores of 7.09 (t=-6.00, p<0.001).</p>
- The pre- and post-interventions STAI scores were strongly and positively correlated in the control and intervention groups (0.975 and 0.860 respectively)

# RESULTS



- There were noteworthy differences in the responses between the control and intervention groups.
- Of all the participants who responded that their experience was fair, 63.6% (N=7) were in the control group, while only 36.4% (N=4) were from the intervention group
- There was a higher proportion of individuals who selected that their experience was "good" in the intervention group than the control group (53.3% vs 46.7% respectively).
- Noteworthy is the fact that in the intervention group, 48.1% (N=26) and 44.4% (N=24) indicated that their MRI experience was "excellent" or "good" respectively; compared to the 49.1% (N=27) and 38.2% (N=21) in the control group.

### CONCLUSION

The results obtained in this study were comparable to previous international studies which showed that the use of patient education methods such as the use of the extended written information, digital video and telephone conversations resulted in reduced MRI anxiety levels. Specifically, the use of digital video was shown to reduce movement within the MRI scanner (16) as well as increasing patients' knowledge base and preparedness.

The post procedure patient satisfaction survey provided some interesting insights. The results revealed the following

- 1. The control group showed a lower percentage (45.5%) of anxious patients than the intervention group (51.9%) with an overall population of 48.6% being anxious
- 2. The video and pamphlet provided in the intervention group contained information which was meant to prepare the patient for their MRI study and by extension alleviate to some extent their anxiety levels which led to a reduction in the pre and post STAI scores for both the control and intervention groups.
- 3. Overall, both groups were provided with information to patients that helped in the alleviation of the pre procedural anxiety levels and also relaxed the patient for the duration of the MRI study. However there was a greater degree in the reduction of in the pre procedural anxiety levels in the intervention group when compared to the control group.

#### Limitations

There were a few limitations that were encountered during this study:

- 1. Older patients despite their educational background had difficulty completing the form. This resulted in partially completed or incomplete invalid forms.
- 2. This study was conducted by obtaining a sample population from patients that present at a single centre. Therefore, this limits the generalizability of the results obtained from this study to the population of Trinidad and Tobago.
- 3. During this study a note of the region that was scanned was made and correlated with the patient's anxiety levels, however no review of the pricent's request form was performed. This is an important limitation because the indication for the scan may have been a major contributing factor to the patient's anxiety levels particularly in oncological cases.