Proposal Title: Intra-Intensive Care Unit vs Post-Hospitalization Psychological Intervention to Reduce Medical PTSD in Patients Hospitalized for Sepsis

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Intra-Intensive Care Unit vs Post-Hospitalization Psychological Intervention in Patients Hospitalized for Sepsis

ABSTRACT

INTRODUCTION: Medical trauma or medical PTSD can develop following prolonged hospitalization for critical illness and can lead to long-term health outcomes that impact daily functioning. Efforts have been made to investigate risk factors for the development of medical PTSD and to implement an effective intervention in reducing its prevalence, but more research is necessary. This study aims to determine whether an intra-hospital or post-discharge approach to psychological support services is more effective in reducing symptoms of PTSD following an admission for sepsis in a population of patients ages 18-25.

METHODS: A 3-month randomized, single-blind, experimental design will be used to compare the effectiveness of intra-intensive care unit psychological intervention (IIC) to post-hospitalization psychological intervention (PHI) in patients aged 18-25 admitted to a HCA affiliated ICU with an APACHE-II score of 10-15. Criteria meeting patients will be asked to complete the IES-R assessment at admission, discharge, 2-weeks post-discharge, and 3-months post-discharge. Patients will also be asked to complete the IPF assessment 3-months post-discharge. The p-value will be used to assess the significance of the findings between the groups of interest and the r-value will be assessed to determine the extent of correlation between the groups.

HYPOTHESIS: We hypothesize that both the IIC and PHI will experience a decrease in IES-R assessment scores at 3-months post-discharge, while the IIC group will show a greater reduction in IES-R score.

FUTURE IMPLICATIONS: This study will implicate where resources should be focused when developing interventions to prevent and treat symptoms of medical PTSD.

Keywords: medical trauma; PTSD; severe sepsis; cognitive therapy; intensive care unit

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INTRODUCTION

Post-hospital syndrome can develop following admission to intensive care units for a critical illness, and may affect both the physical and mental wellbeing of patients long after discharge. This syndrome has also been labeled medical trauma, medical PTSD, acute stress disorder, and is characterized by a variety of symptoms that impact daily functioning including flashbacks, insomnia, increased susceptibility to repeated admission, and cognitive impairments[1]. Prior research has demonstrated the prevalence of medical PTSD in patients with prolonged stays in ICUs. In a meta-analysis conducted in 2007, prevalence rates of PTSD in ICU patients post discharge ranged from 5%-63% of patients[2]. Many factors may contribute to the risk of developing medical PTSD depending on the cause of hospitalization, length of stay, treatment during stay, and pre-existing mental disorders. Several studies have suggested that the strongest predictor of developing PTSD symptoms is the association of the ICU stay with traumatic memories and experiences[3]. This may suggest that the most effective interventions would target behaviors =during the ICU stay. It has also been proven that there is a significant link between the development of PTSD and physical health conditions, confirming the necessity of interventions to reduce likelihood of medical PTSD[4].

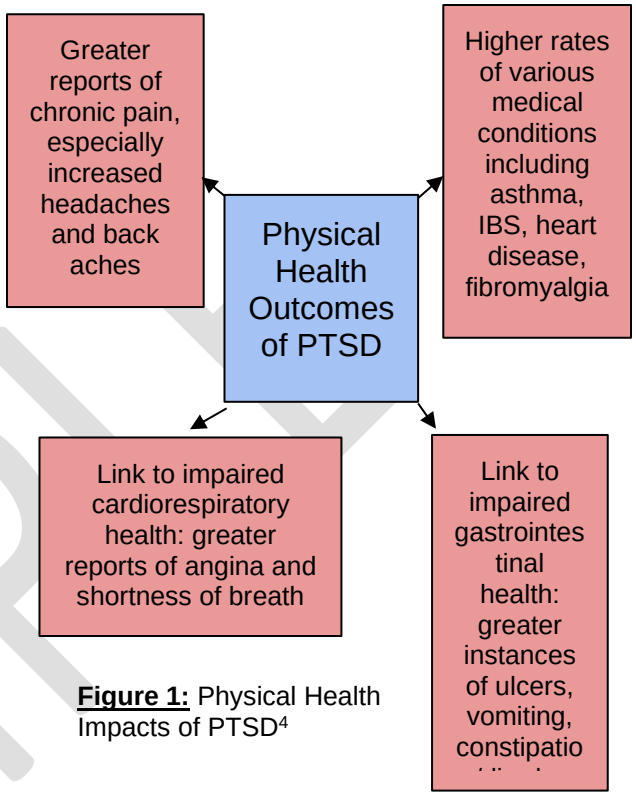

Figure 1: Physical Health Impacts of PTSD[4]

A thorough review of the literature suggested that there may be a specific risk for medical PTSD associated with admission for severe sepsis[5]. Therefore, our study targets patients admitted for sepsis with a stay of at least 12 days. While extensive research has been done into the prevalence and risk factors for medical PTSD, we aimed to define a clearer approach to interventions to reduce its development and impact on daily functioning. Previous studies have proposed interventions altering the structure of the hospital protocol and actions of hospital personnel[6-7]. While these interventions did show some effectiveness in reducing PTSD, our study aimed to find a less burdensome and more cost-effective approach to intervention. Other studies of note included the addition of an ICU diary with significant decrease in the symptoms of PTSD and the implementation of a nurse-led follow up program for ICU survivors that showed no evidence of improvement of PTSD[8-9]. These studies explored a variety of different avenues in attempts to prevent or manage the impact of PTSD, with some focusing on intra-hospital interventions and others focused on post-hospital care. In an effort to maximize use of resources and develop a clear picture of where interventions should be focused, our study aimed to compare the effectiveness of psychological support provided in hospital versus psychological support provided after discharge. In one study's model of identification, prevention, and management of PTSD among ICU survivors, the authors emphasized that while early identification and intra-hospital services may be beneficial, also important is efforts after discharge for patients to continue to recall their experiences in the ICU to better process and understand these events[10]. For this reason, we chose to design a study with three groups: a control group, a group receiving intra-hospital psychological support services, and a group receiving post-hospitalization support services. The intention is to determine whether intra-hospital services or post-hospital services are more effective in decreasing the severity of PTSD symptoms following critical illness. The content of our psychological intervention was broadly modeled off of one study that focused on early intervention for symptoms of PTSD, depression, and anxiety in which patients in the ICU were assigned a clinical psychologist who provided education, stress management

approaches, coping methods, and counseling to patients and their families during the course of their ICU stay[11]. However, our study implemented these techniques both intra-hospital and post-discharge. Additionally, the group receiving services post-discharge had an additional element to their therapy - the psychologists also focused on assisting the patient in recalling the entirety of their ICU experience and identifying memories and events that may be contributing to symptoms of PTSD such as painful procedures, hallucinations that may have been induced by their treatment, and feelings of helplessness. Identifying and understanding these memories may be essential in decreasing the severity of PTSD symptoms.

Our study will follow an experimental design with participants recruited based on certain inclusion criteria and randomly assorted into the three groups described above and receive their assigned intervention. Symptoms of PTSD will be measured at 4 specific time points: upon recruitment, at discharge from ICU, 2 weeks following discharge, and 3 months following discharge. At 3 months, the impact of PTSD symptoms of daily functioning will also be measured. The change between each time period will be plotted and visualized. Additionally, the mean difference in severity of symptoms between the discharge time point and 3 month follow up will be calculated for each group and a t-test will be performed to determine if significant improvement was noted.

METHODS

Design:

A 3-month randomized, single-blind sided, experimental design will be used to compare the effectiveness of intra-intensive care unit psychological intervention (IIC) to post-hospitalization psychological intervention (PHI). Measurements will be taken at discharge, 2-weeks post-discharge, and 3-months post-discharge.

Subjects:

The proposed study aims to study a sample of 90 patients aged 18-25 admitted to the ICU of a HCA affiliated hospital in Florida for sepsis. Patients will be excluded from the study if they are ventilated at any point during their hospital stay, have a hospital stay >15 days, or if they do not have an APACHE-II score between 10-15. Sepsis patients were chosen because previous studies indicate that sepsis is a significant predictor of PTSD[5].

Protocol:

Recruitment:

1. All medical staff at HCA affiliated hospitals in Florida will be briefed on the aim and purpose of the proposed research study.
2. Clinical psychologists at HCA affiliated hospitals in Florida will be educated on how to administer IES-R, Inventory of Psychosocial Functioning (IPF), and how to conduct psychological intervention sessions. Physicians will be trained on how to administer APACHE-II.
3. All patients who fit the criteria for the proposed study will be asked about interest in participating in the proposed research project.
4. If consent is given, the patients' names, emails, and phone numbers will be collected.
5. Patients will be randomly sorted into three different groups.

Admission-Discharge:

1. At 8:00 a.m. the morning after admission, patients from all groups (IIC, PHI, control) will be asked to complete IES-R.
2. The IIC group will receive 6 psychological intervention sessions administered by a clinical psychologist every other day throughout the duration of their hospital stay.
3. The PHI and control groups will not receive any psychological intervention sessions throughout the duration of their hospital stay.
4. At discharge all groups will be asked to complete the IES-R at discharge.

2-weeks Post Discharge:

1. Patients in the PHI group will receive 6 psychological intervention sessions administered by a clinical psychologist every other day throughout the duration of the 2-week post discharge period.
2. Patients in the IIC and control groups will not receive any psychological intervention sessions throughout the duration of the 2-week post discharge period.
3. Patients from all groups will be asked to complete the IES-R at 2-weeks post discharge.

2- weeks to 3-months Post Discharge:

1. Patients from all groups will be asked to complete the IES-R and IPF at 3-months post discharge.

Conditions/Groups:

The 90 criteria meeting patients recruited for the study will be randomly assigned into three groups of 30 patients (IIC, PHI, control). Two of the three groups will receive psychological intervention sessions at varying time points. The IIC group will receive a total of 6 psychological intervention sessions administered by a trained clinical psychologist every other day throughout the duration of their hospital stay. The PHI will receive a total of 6 psychological intervention sessions administered by a trained clinical psychologist every other day throughout the 2-week post discharge period. The control group will not receive psychological intervention at any point. The psychological intervention will be 1 hour in duration and administered at a HCA affiliated hospital by a clinical psychologist. The psychological intervention sessions will include counseling, education, stress management techniques, and coping methods for psychological distress. The purpose of the psychological intervention sessions is to ease feelings of anxiety, depression, and helplessness.

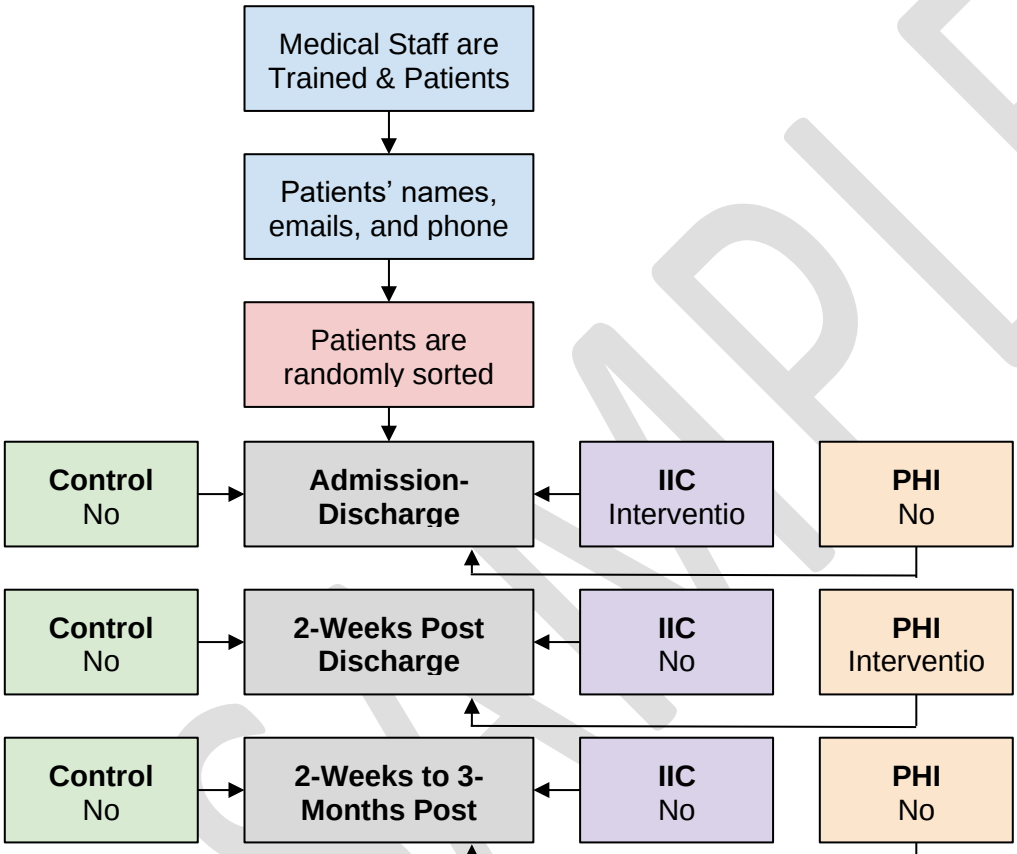

Figure 2:
Protocol.

Measures/Instruments:

APACHE-II: APACHE-II is a system that measures the likelihood of ICU mortality based on patient age and hospital lab values[12]. The APACHE-II system is based on a scale of 0-71 and will be used to determine whether patients meet the criteria for participating in the proposed research study. To be considered for the proposed study, patients must have an APACHE-II score between 10-15. APACHE-II will be administered to prospective participants at a HCA affiliated hospital at admission by the admitting physician.

Impact of Event Scale–Revised (IES-R): IES-R is a subjective assessment of distress caused by traumatic events[13]. This assessment consists of 22 items, with scores ranging from 0 to 88. Higher scores indicate more severe PTSD symptoms. The assessment will be administered at admission, discharge, 2-weeks post-discharge, and 3-months post-discharge at a HCA affiliated hospital by a trained clinical psychologist.

Inventory of Psychosocial Functioning (IPF): IPF is a subjective assessment of PTSD related functional impairment experienced by a patient in the last 30 days[14]. The assessment will be administered at a HCA affiliated hospital by a trained clinical psychologist 3-months post-discharge.

Data Handling and Cleaning:

The main outcome of interest in this study is improved scores on the Impact of Event Scale (IES-R) after intervention implementation. The outcome variables are the IES-R scores that will be analyzed and compared at each stage of data collection (admission, 2-weeks post discharge and 3-months post discharge). For data

cleansing, we will identify incorrect, irrelevant, and incomplete values in the dataset. Data cleansing will also include correcting spelling and syntax errors.

Data Analysis:

A code book was created prior to data collection identifying each group, outcome measures and intervention received. This analytic plan will describe and summarize the characteristics of the group of data collected, specifically the change in IES-R scores at each stage of clinical assessments between the IIC, PHI and control groups. The results of this assessment will be entered into a Microsoft Excel Spreadsheet. The independent is the timing of the psychological therapy intervention that will be implemented for both IIC and PHI treatment groups with no covariates. The dependent variable is the change in the IES-R score with an emphasis on scores collected at the 3-month post discharge follow up to determine long term effectiveness. The IES-R includes three subscales: avoidance, intrusion and hyperarousal. The IES-R has a maximum mean score on each of the three subscales of '4', therefore the maximum 'total mean' IES-R score is 12. Subjects with a change in IES-R score of 5 will be considered as demonstrating "improved scores" while those with a change in scores of 5< will be considered insignificant. Outcome will be measured based on IES-R scores and change between each time period will be calculated as slope on a linear diagram. An independent t-test will be performed for each group to determine if there is a significant difference in the mean of IES-R scores at 3 months. The data values collected will be analyzed as an intent-to-treat design.

DISCUSSION

Expected Results:

Of the three groups (IIC, PHI, and control), it is predicted that the IIC group will be the most effective in reducing the severity of PTSD in patients hospitalized for sepsis. Psychological intervention during hospitalization has the potential to prevent the onset of PTSD symptoms by allowing patients to form coping mechanisms early, rather than treating the symptoms after they manifest[10]. Therefore, the IIC group is more likely than the PHI group to minimize the severity of PTSD experienced by patients hospitalized for sepsis.

Study Limitations:

There are a couple of possible limitations to be considered with this study, most notably is the generalizability of the findings given the very specific population being targeted. The results may also be affected by the subjective nature of the self-reporting trauma measurements.

Ethical Principles:

This study will obtain written informed consent, in which patients will have the right to accept or decline participation in the study. Coercion in patient participation will be prohibited, and patients maintain the right to withdraw from the study at any time. All researchers and staff will be trained in HIPAA compliant protocols and confidentiality of health information will be maintained. All data from the study will be stored on a password protected computer and compiled in a password protected spreadsheet. Data from the study will be assigned a unique identification number for each participant, and names and contact information will be stored separate from the data. In order to encourage retention, clients will be offered a $50 VISA gift card at completion of the intervention, and a $75 VISA gift card upon completion of the 3-month follow up visit.

Future Implications:

The proposed study aims to utilize early treatment in reducing the long-term effect and severity of PTSD that patients develop as a result of hospitalization. With the ability to detect/intervene at an early stage, the severity of PTSD can possibly be reduced. More severe cases of PTSD will cause a greater disruption of patients' day-to-day activities and physical health[4]. This study will help to determine which time period in a patient's treatment and recovery is the most critical for intervention in an effort to reduce medical PTSD. Ideally, a patient could be offered psychological support throughout treatment and post-discharge, however this may not be feasible for the healthcare system or the patient themselves, and therefore this study may shed light on if resources for psychological support should be focused on early intervention during a hospital stay, or if there is greater benefit

in post-discharge therapy. A future study could focus on identifying the events and actions by hospital staff that may be contributing factors to the development of PTSD and to design an intervention to minimize these factors. This may also help to prevent the onset of PTSD rather than treating its symptoms.

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Name	**Percent Effort**	**Signature**
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[redacted]	20%	[redacted]
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TOTAL PERCENT EFFORT	100%	