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ROLE OF STRESS AND SOCIAL RESOURCES ON BIOMARKERS AND FATIGUE IN STAFF NURSES: A BIOBEHAVIORAL APPROACH

Mona Cockerham

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ROLE OF STRESS AND SOCIAL RESOURCES
ON BIOMARKERS AND FATIGUE IN STAFF NURSES:
A BIOBEHAVIORAL APPROACH

A DISSERTATION
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
SCHOOL OF NURSING

BY
MONA COCKERHAM, PHD, MSN, RN

AUGUST, 2016

Approval Form D3

The University of Texas Health Science Center at Houston
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Houston, Texas

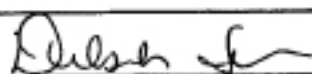
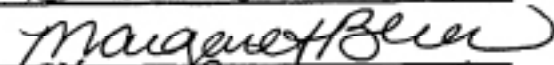
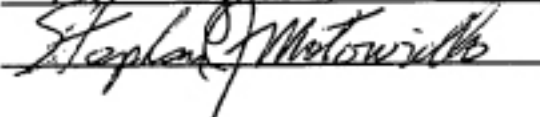
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To the Dean for the School of Nursing:

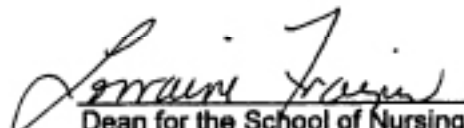
I am submitting a dissertation written by Mona Cockerham and entitled "Role of stress and social resources on biomarkers and fatigue in staff nurses: a biobehavioral approach." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.


Duck-Hee Kang, Committee Chair

We have read this dissertation
and recommend its acceptance:

Accepted


Dean for the School of Nursing

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Abstract
Mona Cockerham
August, 2016

Purpose

Consecutive 12-hr workdays can contribute to increased stress and fatigue and negative biological responses in nurses, potentially compromising quality of patient care and safety. The primary purpose of this study was to assess changes in stress, fatigue, and biological responses (salivary cortisol and alpha-amylase) over three consecutive 12-hr workdays in acute care nurses and how stress and social resources function in predicting fatigue and biological responses.

Methods

In a prospective study, 81 acute care nurses completed questionnaires and provided saliva samples four times: pre-shifts and post-shifts of day 1 and day 3.

Results

Although stress and biological responses did not change, fatigue increased significantly from pre-shift day 1 to post-shift day 3, particularly in night shift nurses. Stress measured with a visual analog scale significantly predicted fatigue at the end of day 1 and day 3. High social resources buffered negative impact of stress on fatigue of day 1.

Conclusion

Fatigue increased over consecutive workdays and stress can influence fatigue in acute care nurses. Social resources, on the other hand, may buffer the negative impact of stress on fatigue. Focused research is necessary to assess the effects of stress on fatigue and patient safety issues over consecutive workdays, incorporating biological responses in nurses at various settings.

Clinical Relevance

Because stress and fatigue may lead to compromised patient care and safety, additional research and interventions need to be tested in these topics.

Table of Contents

APPROVAL PAGE (FORM D-3).....	ii
ACKNOWLEDGMENTS	iii
ABSTRACT.....	iv
TABLE OF CONTENTS	v
SUMMARY OF STUDY	1
PROPOSAL	
Specific Aims.....	4
Significance	6
Conceptual Framework	8
Innovation and Preliminary Studies	13
Approach	14
Human Subjects Protection	24
References	27
DISSERTATION	37
APPENDIXES	
A. Salivary Collection Procedure.....	88
B.Houston Methodist IRB Notice of Approval.....	91
Houston Methodist IRB Change Request #1	93
Houston Methodist IRB Change Request #2	94
Houston Methodist IRB Change Request #3	95
Houston Methodist Continuing Review	96
C.UTHSC CPHS: Notice of Approval.....	99
UTHSC CPHS: Change Request #1.....	101
UTHSC CPHS: Change Request #2.....	103
UTHSC CPHS: Change Request #3.....	105

UTHSC CPHS: Change Request #4.....	107
UTHSC CPHS: Continuing Review	109
D. Research Funding Letter	112
E. Informed Consents.....	113
Houston Methodist	114
UT Health.....	119
F. Permission to Use Instruments	123
G. Study Instruments	128
H. Closing Questionnaire.....	138
CURRICULUM VITAE	140

Summary of Study

The specific aims of the study were: (1) to examine the changes in the levels of stress (personal, work-related and overall stress), biological responses (salivary cortisol and alpha amylase), and fatigue across three consecutive 12-hr workdays; (2) to examine the effect of perceived personal and work-related stress on biological responses and fatigue; (3) to test the moderating role of social resources in the relationship between stress and fatigue; and (4) to examine the correlation of salivary cortisol and alpha amylase with fatigue. It was hypothesized that:

- 1.1 Stress, biological responses, and fatigue will be significantly higher on day 3 than day 1.
- 1.2 Stress, biological responses, and fatigue will be significantly higher at post-shift than pre-shift on day 1 and day 3.
- 2.1 High levels of personal, work-related, and overall stress at pre-shift of day 1 will predict high levels of salivary cortisol and alpha-amylase at baseline, post-shift day 1 and day 3.
- 2.2 High levels of personal, work-related, and overall stress at pre-shift day 1 will predict high levels of fatigue at baseline, post-shift day 1 and day 3.
3. Social resources will moderate the effect of stress on fatigue.
4. Salivary cortisol and alpha amylase will be positively correlated with fatigue.

Eighty-one nurses including 43 day shift and 38 night shift nurses working three consecutive 12-hr shifts in acute care settings provided data and saliva at four different times, which were at the beginning and end of day 1 and day 3. Hypotheses 1.1 and 1.2 were tested using paired t-tests to examine changes in stress, biological responses, and fatigue over consecutive work days and within-day pre-to-post shift. Hypotheses 2.1 and 2.2 were tested using hierarchical regression models, controlling for covariates.

Hypothesis 3 was tested for stress x social resources interaction term on fatigue in a regression model. Hypothesis 4 was tested using Pearson's correlation coefficients. Prior to data analyses, biological responses were log transformed.

Day and night shift nurses were similar in demographic characteristics and in their baseline scores of stress, biological responses, and fatigue, except that night nurses reported significantly less social resources than day shift nurses. For changes over consecutive workdays, there were no significant changes in stress and alpha amylase responses in day or night shift nurses. Only significant changes were a significant decrease in pre-shift morning cortisol from day 1 to day 3 in day shift nurses and a significant increase in pre-shift fatigue from day 1 to day 3 in night shift nurses. For the effects of stress on biological responses and fatigue, baseline personal and work-related stress were not predictive of cortisol or alpha amylase at any time point in either group of nurses, but were predictive of baseline fatigue pre-shift on day 1. In comparison, a visual analog scale for overall stress explained 6% - 17% variance of fatigue which was significant on baseline and day 1 and 3 fatigue.

Social resources significantly moderated the effect of work-related stress on fatigue at baseline and post-shift day 3. Social resources also significantly moderated the effect overall stress (VAS) on fatigue at post-shift day 3. The moderating effect of stress on fatigue was easily visualized by the slope in the group of nurses reporting high social resources. The moderating effect was difficult to visualize for association between overall stress and fatigue.

Biological responses and fatigue were mostly not significantly correlated. Occasional significant correlations for day shift nurses included a negative correlation between am cortisol and fatigue on day 1, $r = -.33$, $p = .05$, and a negative correlation between day 1 am alpha amylase and day 3 am fatigue, $r = -.35$, $p = .05$.

More research is needed to understand the effects of nurses working consecutive 12-hour workdays, how these long shifts effect nurses' biological responses, stress, and

fatigue over time. This area of research is particularly of importance in ever-changing healthcare environment with the Affordable Care Act mandates for quality outcomes.

Specific Aims

High acuity, long hours, and complexity of patient care are significant contributors to nurses' stress, increasing the risk to patient safety. Nurses working multiple consecutive days of 12-hour shifts in an acute care hospital setting are highly vulnerable to stress. **Stress** has been associated with increased fatigue, burnout, and absenteeism. Patient and nurse injuries are also factors linked to stress, compensation of which is estimated to be over \$200 billion a year (Rice, 2011; Verhaeghe, Vlerick, Gemmel, Van Maele & De Backer, 2006). Nurses' stress may lead to poor patient outcomes, errors in care, and compromised patient safety (Texas Board of Nursing Bulletin, April, 2015). Because stress can activate the sympathetic nervous system and neuroendocrine system, it is important to understand biological responses in nurses working in acute care settings and how biological responses relate to stress and fatigue (Kang, Rice, Park, Turner-Henson, & Downs, 2010). **Fatigue** is a feeling of disinterest, sleepiness, and/or exhaustion (Barker & Nussbaum, 2011) and commonly occurs in response to stress. Prolonged work hours may increase fatigue and decrease job performance (Bae & Fabry, 2014; Carruso, 2012; Hazzard, Johnson, Dordunoo, Klein, Russell, & Walkowiak, 2013). Prolonged fatigue also is associated with other work-related injuries and errors that have been linked to major health and safety implications in patient care (Ahsberg, Kecklund, Akerstedt, & Gamberale, 2000; Page, 2004; Tourangeur, Cranley, & Jeffs, 2006). The central hypothesis of this study is that stress, biological responses, and fatigue will increase with time when nurses work three consecutive days of 12-hours worked.

In our preliminary study, stress and fatigue were significantly increased from the first 12-hr shift to the second day 12-hr shift in acute care nurses (Cockerham, Kang, & Howe, unpublished). Because nurses typically work more than two consecutive days of 12-hr shifts, additional studies are needed to assess biobehavioral responses in nurses working three or more consecutive days. **Social Resources** may moderate the relationship between stress and fatigue, suggesting the need for examining its moderating role. The

long-term goal of this study is to assess how stress, fatigue, and biological responses (cortisol and alpha amylase) affect nurses' cognitive functioning and decision making, and how nurses' job performance is affected by these factors. These findings may lead to developing tailored interventions and testing the efficacy of such interventions for nurses working in acute care settings. As the first step, the purpose of this study is to examine the relationships among stress, fatigue, and biological responses in acute care nurses working three consecutive days of 12-hr shifts.

The specific aims and hypotheses are as follows in nurses working 12-hr shifts in an acute care setting:

Aim 1: To examine the changes in the levels of stress (personal and work-related), biological responses, and fatigue across three consecutive 12-hr workdays.

Hypothesis 1.1: Stress, biological responses, and fatigue will be significantly higher on day 3 than day 1.

Aim 2: To examine the effect of perceived personal and work-related stress on biological responses and fatigue.

Hypothesis 2.1: High levels of personal and work-related stress on day 1 will predict high salivary cortisol and alpha-amylase at the end of day 1 and day 3.

Hypothesis 2.2: High levels of personal and work-related stress on day 1 will predict high levels of fatigue at the end of day 1 and day 3.

Aim 3: To test the moderating role of social resources in the relationship between stress and fatigue.

Hypothesis 3.1: Social resources will moderate the effect of stress on fatigue.

Aim 4: Examine the correlation of salivary cortisol and alpha amylase with fatigue.

Hypothesis 4.1: Salivary cortisol and alpha amylase will be positively correlated with fatigue.

Significance

Historically, shift work, working long hours, and accumulation of sleep debt negatively affects fatigue within health care providers (Bae & Fabry, 2014; Niu et al., 2011; Pisarski et al., 2008; Roger, Hwang, Scott, Aiken, & Dinges, 2004). The Institute of Medicine (IOM) study, “To Err is Human,” found hospital errors result in the deaths of nearly 100,000 Americans per year and further escalated the concern for errors that go unreported (Institute of Medicine [IOM], 2000). A second IOM report, “Crossing the Quality Chasm of Medicine,” called for the development of systems to identify hazards and errors by implementing safety principles (IOM, 2001). In 2004, “Keeping Patients Safe: Transforming the Work Environment of Nurses” reported nurses as essential to patient safety (IOM, 2004). Due to these reports, research has focused on the nurses’ ability to adapt to shift work in the hospital (Anderson, 2005; Blachowicz & Letizia, 2006; Carruso, 2012). Various study reported an inverse correlation of nurse fatigue on patient care outcomes (Needleman et al., 2011; Trinkoff et al., 2011). Given these studies, state and nursing professional organizations have moved in a positive direction toward developing staffing standards (Bae, 2013; Reed, 2013). Research supports that the frequency and severity of errors and injuries are repeatedly linked to shift work, long work hours, and fatigue (Pisarski et al., 2008; Roger et al., 2004). The extent of fatigue in nurses varies by hospital, state, and region of the United States. The Board of Nursing standards on mandatory overtime guidelines vary state to state (Bae, 2013; Bae & Fabry, 2014; Texas Nurses Association, 2009; ANA, 2014). Within the last year, nurse fatigue has received national media attention and interest from the American Nursing Association (ANA). The ANA issued an updated to their nurse fatigue position statement (ANA, 2014) calling for a reduction in long work hours, a collaboration with hospital leadership and staff nurses on developing staffing standards, and the creation of a culture of safety (ANA, 11.19.2014). This updated position statement supports the premise that fatigue has major health and safety implications on overall patient safety and nurse wellness.

The lack of a biobehavioral approach to nurses' response to stress is a gap in the current nursing research. Biological responses to stress and fatigue in nurses working consecutive days may offer important information in working to close this gap.

Various governmental agencies have established fatigue counter-measure restrictions, recognizing the impacts of long work hours on fatigue. Airline pilots and truck drivers are required to log hours worked and report those hours to company authorities. These industries do not allow their workers to work beyond an established number of hours and between off-hours. Nurses are not limited on the number of hours they can work. Nurses have reported working as long as 23 hours straight in an operating room setting when their on-call time and regular scheduled shift overlap (USA Today, February 2, 2015). In addition, nurses have worked as many as 14 days consecutively due to inadequate staffing (USA Today, February 2, 2015). Researchers have evaluated the effects of stress over consecutive work days; Chang et al. (2013) studied the effect of stress on cognitive functioning in nurses working in a hospital environment utilizing a fast-forward rotating 8-hour shifts common in Europe and Japan. Fast-forwarding shifts describes nurses working two 8-hr days, two 8-hr evening shifts, and two 8-hr night shifts. Chang et al. (2013) measured stress every two hours the day following a rapid-rotating work schedule at various times and found no increased stress. This did not support an earlier finding by Allan et al. (2009), who, in measuring stress over two consecutive 12-hr days, reported statistically significant increase in stress ($p < 0.01$) from day 1 to day 2. Later, Chang et al., (2014), measured stress the day after an off-day, after working two consecutive 8-hr night shifts (NS), and four consecutive 8-hr night shifts and found statistically higher stress after 2 night shifts ($p = 0.009$) only. These results show mixed results on the association of stress during (Allan et al., 2009) or after working days (Chang et al., 2014). Stress combined with the complexity of healthcare leads to fatigue causing increases in healthcare and workers' compensation, early disability, turnover costs, and legal fees related to patient injuries (Scott, Arslanian-Engoren & Engoren, 2014; Bae & Fabry,

2014; Smith-Miller, Shaw-Kokot, Curro & Jones, 2014).

The hospital environment has changed significantly since the enactment of the Affordable Care Act (ACA) of 2010 by establishing pay-for-performance initiatives and reduced reimbursements has added to the already extensive work hours of nurses. This financial pressure on hospital and nursing administrators to reduce costs to offset decreased reimbursements have greatly impacted nurses. Urgency to meet current initiatives related to patient care has risen as length of stay and the rate of readmission for patients has been reduced. Scrutiny and documentation has increased to support pay-for-performance requirements which have been linked to patient satisfaction and nurse-sensitive quality outcomes (US Department of Health and Human Services, 2015). Workforce reductions have left front-line nurses prone to longer shifts when a crisis occurs. The multifaceted and cumulative effect of these changes on stress in nurses is greatly underestimated, while the increased level of fatigue in nurses requires further research.

Using a biobehavioral approach will expand the knowledge and research on nurse fatigue by exploring mind-body interactions and quantifying biobehavioral interactions in nurses working consecutive days (Koh, & Koh, 2007). Kyungh, Starkweather, Sturgill, Kao, & Salyer (2014) reviewed the use of salivary biomarkers in stress research and found that only 5% of stress research was focused on the biological responses of stress. Biological markers could be used to measure an objective stress response and potentially predict fatigue. Salivary biomarkers are a non-invasive means of assessing biomarkers and have established scientific merit to better understand stress responses (Kyungh et al., 2014).

Biobehavioral Conceptual Framework

Proposed in this study is a modified biobehavioral conceptual framework based on Kang's Expanded Biobehavioral Interactions Model (Kang et al., 2010) to evaluate biobehavioral interactions among stress, social resources, fatigue, and salivary cortisol and alpha amylase. Briefly, the modified model of this study integrates how individual

appraisal of stress on personal and environment factors affects biological responses and fatigue, in interaction with social resources.

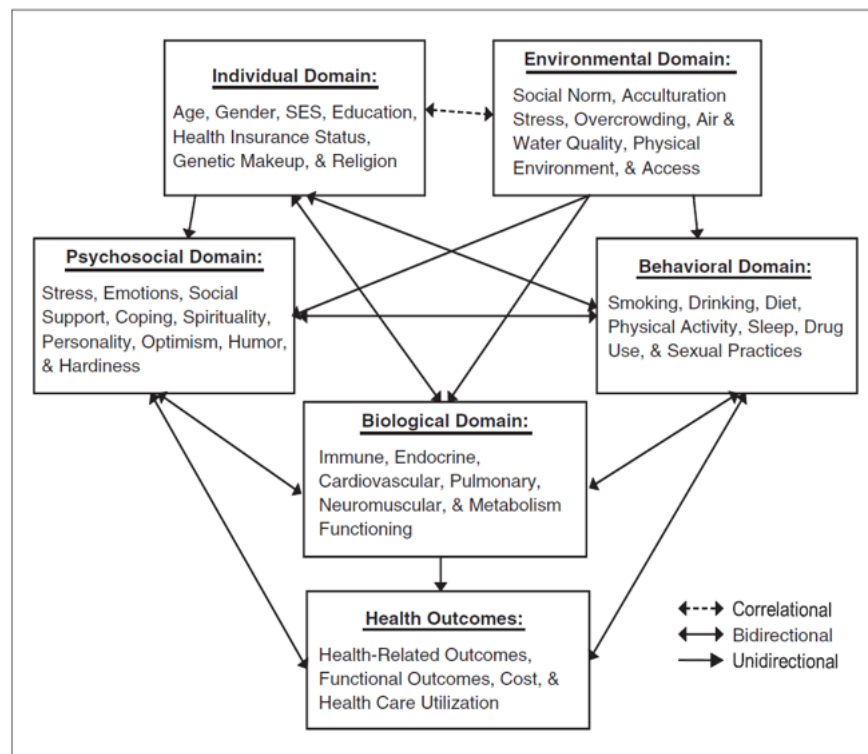


Figure 1. The expanded biobehavioral interaction model

Kang's Expanded Biobehavioral Interaction model represents a holistic view of addressing complex biobehavioral interactions in relation to health outcomes. Most typically, interactions among various factors in psychosocial, behavioral, individual, and environmental domains alter biological responses to influence health outcomes (Kang et al., 2010). However, the model also is flexible to allow biological responses acting as a moderator in certain inquiries. In this study, perceived personal stress and social resources represent factors in the psychosocial domain, work-related stress represent a factor in the environmental domain, cortisol and alpha amylase represent factors in the biological domain, and finally fatigue represents a health outcome (Figure 1). The modified version of conceptual framework for this study is presented below (Figure 2)

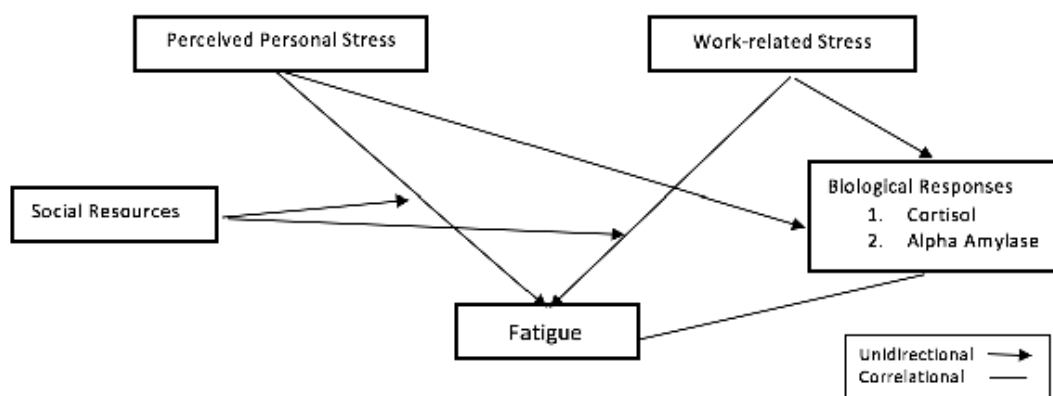


Figure 2. Modified version of Kang's Biobehavioral Model

Stress. Stress is a non-specific response of the body to any demand (Selye, 1974). Stress can be demands, people, or events that leave an individual feeling unable to meet actual or perceived expectations. A stress response is both physiological and psychological that elicits a mind-body interaction in response to a perceived threat (Klein & Corwin, 2007). Sources of stress are often more internal rather than external, relative to how humans think about what happens to them (Johnson, 2011). The stress response is the body's normal attempt to reestablish equilibrium and may cause wear and tear on the body, a condition known as the allostatic load (Korte, Koolhaas, Wingfield, & McEwen, 2005; McEwen & Winfield, 2010). Stress in nurses may come from both work-related and perceived personal stress.

Perceived personal stress is associated with global perception of stress related to perceived or actual stress. These include but are not limited to the ability of the nurses to maintain healthy and positive personal relationships, balance household and family responsibilities, and provide work/life balance in single-parent homes. Some nurses commit to furthering their education, handle moon-lighting a secondary job and/or a commitment to the practice of nursing outside of work-hours can produce perceived personal stress and contribute to fatigue (Ahsberg, et al., 2009).

Work-related stress is stress related to work settings. It may be associated with a lack of oversight of voluntary and mandatory overtime practices, the practice of calling

nonscheduled nurses to work to meet staffing needs reducing the time to rest between shifts (MacKusick & Minick, 2010; Trinkoff et al., 2007). In addition, rotating shifts lead to increases in stress and fatigue (Muecke, 2005). Work related stress is associated with errors and on-the-job injuries (Nolting, Berger, Schiffhorst, Genz, & Kordt, 2002; Windle, Mamaril, & Fossum, 2008), increased patient mortality rates (Aiken, Clarke, Sloane, Sochalski, & Silber, 2002) and compromises in the quality of patient care (Leveck & Jones, 1996; Scott, Rogers, Hwang, & Zhang, 2006). Stress with decreased cognitive function has been associated with attention lapses (Samaha, Lal, Samaha, & Wyndham, 2007; Van der Linden et al., 2005) difficulty with concentration (Maslach & Schaufeli, 2000), lack of attention to decision making (Keinan, 1987), decrease in reaction time (Harris, Hancock, & Harris, 2005), decrease vigilance (Meyer & Lavin, 2005; Scott et al., 2006); and lapses in judgment (Winwood et al., 2006). Work-related stresses include factors that influence physical and mental illness (Anderson, 2005). Stress contributes to work injuries, depression, anxiety, and obesity (Ahsberg, Nygren, Leopardi, Rylander, Peterson, & Wilczek, 2009; Kang et al, 2010; Winwood, Winefield & Lushington, 2006; Sundin, Hochwalder, Bildt, & Lisspers, 2007).

Stress, social resources, and fatigue. Social resources are potentially moderating variables which potentially decreases the effect of stress on fatigue. Social resources are defined as a support mechanism that assists in coping with internal and external stress (Barnes-Farrell et al., 2008). These resources can reduce an individual's response to stress and improve overall health (Samaha, Lal, Samaha, & Wyndham, 2007). Literature supports that being part of a family structure and having friendships positively minimize the effects of stress (Winwood et al., 2006). Furthermore, a supportive family provides a resource of emotional support, while providing for the needs of the family gives purpose to work. Companionship allows for sharing of work tension, individuals benefit from spousal intimacy, and physical contact (Winwood et al., 2006). In addition, being part of a supportive hospital culture of safety and a healthy work environment with resources for

nurses to help meet job expectations minimize the effects of work-related stress (Sarason, 1987). Maintaining a balance between stress and social support are associated with a healthy well-being; stability influences an appraisal of life events and the effectiveness of coping. Supportive hospital environments are recognized social resources. Magnet® recognized hospitals have a positive effect on stress and fatigue which are identified with the elements of Magnetism: management style, personnel policies and programs, quality of care outcomes, positive image of nursing, facilitate intraprofessional collegial relationships, and professional development facilitated through a shared governance structure (ANCC, 2015; Smith-Miller & Shaw-Kokot, 2014).

Stress and biobehavioral interactions. Acute stress can be triggered by factors within the personal and work environment, which can elicit biological responses of the sympathetic nervous system (SNS) (Funkud, Ichinose, Kusama, Yoshidome, Anndow, Akiyoski, & Shibamoto, 2008; Kang et al., 2010). The sympathetic nervous system leads to the release of epinephrine and norepinephrine which activates a fight-or-flight response (Klein & Corwin, 2007). Perceived threats causes an endocrine response mediated through the hypothalamus-pituitary-adrenal (HPA) axis and the sympathetic nervous system (SNS) (Selye, 1974). The HPA axis releases a corticotrophin-releasing hormone (CRH) to the pituitary by stimulating the adrenocorticotropin hormone (ACTH). This ACTH stimulates the adrenal cortex to release corticosteroids responsible for the release of hormones, such as cortisol. (Dickerson & Kemeny, 2004). Salivary cortisol release is a protective response that promotes adaptation and restores the body to a state of equilibrium (McEwen & Winefield, 2010). However, sustained and repeated stress over time may lead to hypercortisolism (Bae, 2013; Hellhammer, Wust, & Kudielka, 2009), which can diminish the healing power of sleep and leads to decreases in cognitive function associated with fatigue (Niu et al., 2011).

Fatigue and biobehavioral responses. Fatigue is a multidimensional concept that encompasses feelings of tiredness and a lack of motivation due to internal and

external stress (Barker & Nussbaum, 2011; Lambert, Lamber, & Ito, 2004). Biological responses of the sympathetic nervous system and endocrine response mediated through hypothalamus-pituitary adrenal (HPS) axis due to a stress response potentiate the effects on fatigue. This study desires to explore the correlation of biological responses of cortisol and alpha-amylase on fatigue.

Innovation

This study is innovative in that it uses a biobehavioral approach to explore the effects of perceived personal and work-related stress and the moderating influence of social resources on fatigue in nurses working consecutive days of 12-hour shifts. Few studies have used a repeated measure design to evaluate nurses' biological responses of stress on fatigue over consecutive work days in an acute care setting.

The results of this study will serve as a foundation for achieving the long-term goal of assessing how stress, biological responses (cortisol and alpha amylase), and fatigue affect nurses' cognitive functioning, decision making, and job performance. Also these results will support how nurses' stress-related biomarkers can predict fatigue and ultimately affect patient safety. The findings of this study will lead to the development and implementation of interventions and appraising the efficacy of the interventions for nurses working in acute care settings.

Preliminary Studies

In 2010, a quasi-experimental study was conducted to compare the association of stress and fatigue on, work satisfaction and job enjoyment using the National Database of Nursing Quality Indicator database (NDNQI). Acute care nurses (N=217) in a Houston suburban hospital units were randomized as a treatment group where they received fatigue countermeasure education related to the importance of scheduled work breaks in reducing fatigue. Group 1 received scheduled work breaks and the control group continued with non-scheduled work breaks. The findings of this study showed no statistical improvement in fatigue scores, work satisfaction or job enjoyment in treatment

group versus the control group. However, the study did increase awareness of the importance of a responsibility-free work break as reported by the participating nurses.

In 2014, an observational pilot study was conducted to examine the effects of perceived personal and work-related stress on fatigue in medical/surgical nurses (N=70) using a biobehavioral approach. The results of this pilot reported stress and fatigue statistically and clinically increased from day 1 to day 2. However, cortisol levels from shift 1 to shift 2 statistically significantly decreased from day 1 to day 2 for both a.m. and p.m. values.

Approach

Research Design/Method

The proposed study is an observational, within-subjects repeated measures design study of nurses working 12-hr shift on three consecutive days. Biobehavioral data will be collected over four time points capturing data pre-shift and post-shift on day 1 and day 3, using standardized questionnaires and saliva samples.

Population, Sample, and Sampling Procedures

Participants will be recruited from a community acute care hospital located in Houston, Texas. The target population consists of medical surgical nurses. The target population of acute care nurses within four hospital units (oncology, stroke, and surgical, and per diem nurses in float pool who float to these units during the study). If the sample of acute care nurses is not adequate, then sampling will be expanded to critical care and emergency room nurses.

Inclusion & Exclusion Criteria

Inclusion criteria are (1) full-time nurses who have worked two weeks prior to the study and (2) nurses who work a 12-hr day or night shift for three or more consecutive days in an acute care setting. If not enough nurses can be recruited, then the researcher will expand to include critical care services, then emergency services. Excluded are nurses (1) working less than 20-hrs per week, (2) on steroids or anti-inflammatory medications

within the last two weeks, and (3) with a current viral or bacterial infection.

Sample Size Estimate

Sample size was computed with G*Power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) for a paired t-test considering a null hypothesis that the difference between day 1 and day 3 values = 0, and the alternative hypothesis of a difference not equal to 0. Based on our primary interest of examining the changes in salivary cortisol and fatigue between day 1 and day 3, sample size was calculated using the cortisol and fatigue changes in the pilot data. The effect size of Cohen's $d = .45$ was estimated based on the pilot study mean change in salivary cortisol of .1 (SD = .22) between day 1 and day 2. At $\alpha = 0.05$ and Cohen's $d = .45$, a paired t-test will have 80% power when the sample size is 40.

For fatigue scores, the effect size of Cohen's $d = .34$ was estimated based on mean change in fatigue of .1 (SD 3.8) between day 1 am and day 2 pm. At $\alpha = 0.05$ and Cohen's $d = .34$, a paired t-test will have 80% power when the sample size is 71. Thus, based on a larger sample size of $N=71$, we anticipate a 20% attrition rate and will recruit $N = 85$ in this study.

Recruitment

Recruitment includes emails, personal letters, fliers, and informational sessions.

Information included in the flier will be inclusion criteria, a brief overview of the study, and the researcher's name and contact information. The process for enrolling nurses is as follows: (1) the potential participant who volunteers will contact the researcher in person or by email, (2) the researcher will explain the study and answer questions, and (3) nurses meeting the inclusion criteria will be asked to give their informed consent.

The informed consent process will disclose the purpose of the study, procedures, inclusion and exclusion criteria, start and end dates of the study, description of the procedures, explanation of potential benefits and risks, possibility of future use of salivary samples, and statement of confidentiality. A signed copy of the informed consent

will be maintained by the researcher and a copy will be provided for the participant.

The researcher will request permission in the informed consent to contact the participant about future studies, additional saliva samples, or to follow-up with participants to clarify the information provided during this study. Nurses selected for the study will be assigned a code number for questionnaire and cortisol specimen identification

Instruments

Stress. Two dimensions of stress will be measured at baseline (prior to 12-hr shift work on day 1): perceived personal stress and work-related stress. Because stress levels will be measured repeatedly prior to and after work on day 1 and day 3, a visual analog scale of stress will be used at repeated time points.

Perceived personal stress. Perceived personal stress will be measured using the Perceived Stress Scale (PSS). The PSS is a widely used instrument to assess the appraisal of stress during the past month on a Lickert scale of 0 to 4, 0=never and 4=very often (Cohen, Kamarck, & Mermelstein, 2007). The higher scores indicate higher perceived stress levels. The instrument is a 10-item tool with easy-to-understand questions tool psychometrically tested in various populations. The PSS is considered a reliable instrument with a Cronbach's alpha of .86 and test-retest reliability of .85 (Cohen et al., 2007).

Work-related stress. Work-related stress will be measured using the Nurse Stress Scale (NSS), a multidimensional, self-reported measure of the appraisal of sources of stress in the work environment in a hospital setting. The NSS has 11 subscales that are associated with general working conditions (Fukuda et al. 2008). The subscales evaluate perceived stress related to working conditions, workload, mental workload, support from supervisor, job control, problem in personal relationships, reward from the work, and support from colleagues (Bae, 2013; Montgomery, 2007). Subscales evaluate perceived stress specific to hospital nurses, such as caring for patients on life support, difficulties

with the nurse-patient relationships, dealing with death and dying, complications with patient care, and conflict with physicians. The tool provides self-reported scores on a 4-point Likert scale (with 1 representing no stress and 4 representing extreme stress). Cronbach's alpha coefficient ranged from .66 to .87, and the test-retest coefficient for the total scale was 0.81 (Gray-Toft & Anderson, 1981). The test-retest coefficient for the total scale is 0.81.

Visual analog scale for stress (VAS Stress). A 0-10 Visual Analog Scale-Stress (VAS-S) will be used to assess current levels of self-reported stress pre-shift and post-shift. Higher scores represent higher perceived stress. This will be used to measure perceived stress at the time of biomarker collection pre and post shift.

Biological response. Biological responses will be assessed with salivary cortisol to represent HPA activity and salivary alpha amylase to represent sympatho-medullary activity (Piazza, Almeida, Dmitrieva, & Klein, 2010; Klein & Corwin, 2007; Dickerson & Kemeny, 2004).

Salivary cortisol. Salivary cortisol is the biologically active form of cortisol and is thought to be a better measure of HPA function than serum cortisol (Hellhammer et al., 2009). Non-invasive saliva sampling also prevents venipuncture-related stress response. Increases in cortisol indicate increased levels of stress (Deane, Chummun, Prashad & Prashad, 2002). Cortisol sensitivity of the assay is $< 0.003 \mu\text{g/dL}$, and the coefficients of variation for intra-assay and inter-assay are 3.35 - 6.41% (Salimetrics, 2012).

Salivary alpha-amylase (sAA). Levels of sAA have a quick rise and fall as compared to cortisol as a measure of the sympathetic nervous system with sensitivity at $0.4 \mu\text{g/dL}$. This measures acute stress as a fight or flight response (Cicchetti, Rgosch, Hibel, Teisl, & Flores, 2007; Dickerson & Kemeny, 2004).

Procedure for saliva collection: The participant will abstain from eating, smoking, brushing teeth, and drinking sugar or caffeinated beverages 60 minutes prior to saliva

collection. Using a timed specimen collection schedule, saliva samples will be collected four times for each participant pre and post shift on day 1 and day 3. Before the sample is collected, the participant will be instructed to rinse his/her mouth with water and wait 5 minutes before collecting saliva. A passive drool method will be used. A swab collection method will be used only for those who cannot do a passive drool. The time of collection is recorded to recognize circadian variations. The collected specimens will be kept in a cold, portable, dry-ice box for transport to the UTHSC-H Center for Nursing Research Bioscience Laboratory in Houston, Texas. Samples will be stored in -80 degree C until batch assayed using Salimetrics Enzyme Immunoassay kits following the manufacturer's instruction.

Fatigue

Multidimensional fatigue inventory (MFI-20). MFI-20 is used to measure fatigue at baseline. This scale provides a multidimensional measurement of fatigue, as related to general fatigue, physical fatigue, mental fatigue, reduced activity, and reduced motivation (Dittner, Wessely & Brown, 2004). The tool uses a 5-point Likert scale, where (1) corresponds with agreement and (5) indicates disagreement. Internal consistency is high for all subscales in test-retest reliability, ranging for individual subscales from $r=.74-.87$ (p.165) and a reliability internal consistency of 0.85-0.96 (Dittner et al., 2004; Psychological Resource Assessments, 2014).

Visual analog scale fatigue (VAS-F). Fatigue will be measured at repeated time points using a Likert scale from 0-10. Higher scores represent higher perceived fatigue.

Social Resource

The multidimensional scale of perceived social support (MSPSS).

The MSPSS measures perceived social support of a significant other, family, and friends. The instrument includes a 7-point Likert scale with responses ranging from (1) Very Strongly Disagree to (7) Very Strongly Agree, with total score ranges from 12 to 84 and subscales scores range from 4 to 28. High scores indicate high-perceived social support.

The Cronbach's alpha for the total scale reliability is .88 and the test-retest two-to-three months after initial questionnaire completion was .85 (Zimet, Dahlem, Zimet, & Farler, 1988).

Closing questionnaire. The closing questionnaire explores various topics related to shift work, perceived personal and work-related stress, fatigue related to absenteeism,

Table 1
Instruments

Measures	Concept	Range	Reliability
Perceived Stress Scale (PSS)	Perceived personal stress	10 items (0-40) Higher—more stress	Cronbach's α — .86
Nurse Stress Scale (NSS)	Perceived work-related stress related to work	Likert scale 0-4 (0) representing no stress to (4) representing extreme stress 11 Subscales associated with perceived stress based on work conditions.	Cronbach's α — .66-.87
Multidimensional Fatigue Inventory (MFI)	Fatigue	0-5 Likert scale; (5) is highest fatigue with (0) not fatigued.	Cronbach's α — .85-.96
Multidimensional Scale of Perceived Social Support (MSPSS)	Social Resources	1-7 Likert scale (1)Very strongly disagree to (7) very strongly agree; total score range from 12 to 84 High scores=high social support	Cronbach's α — .88
Stress Visual Analog Scale (VAS-S)	Perceived stress	0-10cm; (8-10) high stress; 5-7 moderate stress; 1-4 low stress; 0 = no stress.	Test-retest .76-.82
Fatigue Visual Analog Scale (VAS-F)	Perceived fatigue	0-10 cm; (8-10) high fatigue; 5-7 moderate fatigue; 1-4 low fatigue; 0 = no fatigue.	Test-retest .79-.86
Salivary Cortisol (sCort)	Cortisol	Sensitivity ,0.003 ug/dl	Coefficients of variation for intra-assay are 3.35% - 3.61% and inter-assay are 3.75 - 6.4%.
Salivary Alpha Amylase (sAA)	Alpha-amylase	Sensitivity 0.4 U/ml	Intra-assay are 3.75 and mean inter-assay C.V , 6% using the Salimetrics kit

Data collection methods. At or near day 1 of shift work, participants will complete baseline questionnaires (MSPSS, PSS, NSS, VAS-S, VAS-F and MFI-20). In addition, VAS-S and VAS-F and saliva samples will be collected at various times as follows:

Table 2
Repeated Measures Data Collection

Sample Collection	Day 1 Pre-shift	Day 1 Post-shift	Day 2 Pre-shift	Day 2 Post-shift	Day 3 Pre-shift	Day 3 Post-shift
Demographics	X					
PSS (Personal stress)	X					
NSS (Work-related Stress)	X					
MFI (Fatigue)	X					
MSPSS (Social Resources)	X					
VAS-S (Stress)	X	X			X	X
VAS-F (Stress)	X	X			X	X
sCort (biological stress)	X	X			X	X
sAA (biological acute stress)	X	X			X	X

Each participant is given a study number and no identifying information will be used on any study documents or specimens except on the consents. The specimens will be coded by the study number and not contain any patient identifiers. Only study numbers will be used with saliva samples and levels obtained after analysis will be entered in a password-protected database. Research data is stored on a Methodist encrypted computer and backed up to a hospital-based server. The researcher will request permission in the consent to contact the participant about another study, additional saliva samples or follow-up with participants to clarify information provided during this study.

Salivary cortisol samples and VAS scores for stress and fatigue are collected between 6 a.m. and 7 a.m. pre-shift, and between 6 p.m. and 7 p.m. post a 12-hr shift for at least three consecutive days. The timing of the data collection aligns with starting and ending of shift work. The total time to complete study elements and salivary collection is approximately 3-6 minutes. At the time of saliva collection, Visual Analog Scale for Stress (VAS-S) and Fatigue (VAS-F) scores provide an assessment of the levels of stress and fatigue at each time point.

Data Analysis

Data will be entered into a secure, password-protected database with access only provided by those within the study team and statistical software, SPSS 20 will be used for statistical analysis. To maintain anonymity and confidentiality, data will be stored in a secure and locked area. Descriptive data will be used to analyze characteristics of study participants using age, educational level, years of experience, years on the present unit, marital status, children living at home, and secondary work status (yes or no). Descriptive statistics such as mean, standard deviation, frequency and percentage, as well as data validation will assess for missing values and duplications. A summary table will be generated with descriptive statistics and measures of central tendency. Data will be examined for normality and will be transformed if data is not normally distributed prior to conducting data analyses. Cortisol is a continuous measurement, and a simple linear regression will be used to predict a positive relationship to PSS, NSS, VAS, and MFI scores. All p values are two-sided and considered significant when less than 0.05. No adjustment for multiple hypothesis testing will be made.

Aim 1: To examine the changes in the levels of stress (personal and work-related), biological responses, and fatigue across three consecutive 12-hr workdays.

Hypothesis 1.1: Stress, biological responses, and fatigue will be significantly higher on day 3 than day 1.

A paired t-test comparing the first a.m. reading (day 1) with the last p.m. (day 3) reading will be used to examine the change over time for stress and fatigue. A second paired t-test comparing the first day 1 a.m. (day 1) reading with the last day 3 am (day 3) reading will be examined for the change over time in the a.m. cortisol readings. A third paired t-test comparing the first day pm (day 1) reading with the last day 3 pm (day 3) will be examined for the change over time in the p.m. cortisol readings. The following measures will be evaluated: salivary cortisol, alpha-amylase, VAS-S, and VAS-F.

Aim 2: To examine the effect of perceived personal and work-related stress on biological responses and fatigue.

Hypothesis 2.1: High levels of personal and work-related stress on day 1 will predict high salivary cortisol and alpha-amylase at the end of day 1 and day 3. Simple regression module will be used to assess the relationship between baseline stress as measured by PSS, NSS, VAS-S and cortisol and alpha amylase.

Hypothesis 2.2: High levels of personal and work-related stress on day 1 will predict high levels of fatigue at the end of day 1 and day 3.

At baseline high levels of stress (personal perceived and work-related) on day 1 as measured by PSS, NSS, VAS-S will predict high levels of fatigue as measured by MFI and VAS-F in acute care nurses. For baseline measures, using simple regression models will be used to assess the relationship between the baseline fatigue and baseline stress scores (both perceived and work-related). One model will examine the relationship between MFI and baseline stress as measured by PSS and NSS. An additional model will examine the relationship between VAS-F and baseline stress as measured by PSS and NSS. The third model will examine the relationship between VAS-F and baseline stress as measured by VAS-S.

Aim 3: To test the moderating role of social resources in the relationship between stress and fatigue.

Hypothesis 3.1: Social resources will moderate the effect of stress on fatigue

The social resources measure MSPSS will be added to the two models in Aim 2 using a linear regression to examine the moderating effect of social resources on the relationship between stress and fatigue. The interaction term of Stress x social resources (modifier) will be added to the regression model and tested for statistical significance with the Wald test. Because both types of stress (perceived personal and work-related) are highly correlated, two models will be run with each type of stress.

Aim 4: Examine the correlation of salivary cortisol and alpha amylase with fatigue.

Hypothesis 4.1: Salivary cortisol and alpha amylase will be positively correlated with fatigue.

Two approaches will be used. In approach 1, for each of the four time periods, the relationship between VAS-F and cortisol will be assessed using a linear mixed model for the specific time period. In approach 2, one model will assess the relationship between alpha amylase and VAS-F which includes a variable indicating the time period the data was collected. These two models will be repeated to examine the relationship between VAS-F and alpha-amylase levels. The two corresponding beginning and ending values will be compared for each measure.

Table 3
Proposed research timeline.

	Oct. 2015	Nov. 2015	Dec. 2016	Jan. 2016	Feb. 2016	Mar. 2016	Apr. 2016
IRB approval	X						
Collection of Data		X	X				
Data Analysis				X	X		
Writing Results				X	X	X	X

Limitations and strengths. There are various limitations to this study such as a convenience sampling using non-probability sampling methods based on the design. There is potential for the biomarker results to show limited variability. There may be a difficulty in the collection of specimens due to emergencies during change of shift and unreported use of caffeine prior to the salivary collection. The researcher will attempt to minimize the obstacle of missing data by checking all instruments following completion. Strengths of the study include: (a) repeated measures design for the measurement of visual analog scale for stress and fatigue, along with salivary cortisol and alpha amylase

pre-shift and post-shift; (b) different types of stress will be assessed to better understand the specific area of future stress intervention(s) to improve fatigue; and (c) perceived personal stress, perceived stress, social resources, and multidimensional fatigue and all measurement tools are well accepted forms of measurement for stress and fatigue and are given prior at the start of the study as baseline measurements.

Summary. The purpose of this study is to examine the relationships among stress, fatigue, and biological responses in acute care nurses working three consecutive days of 12-hr shifts in an acute care setting. Nurses and other healthcare professionals should be aware of safety implications of regarding the effects of fatigue and its relationship to consecutive workdays. Nurses often voice their concerns about the increase in the potential errors when working consecutive 3 days. Job performance is reduced after long work hours and without adequate sleep (Barker, & Nussbaum, 2011). These above issues directly affect patient safety as well as the health and well-being of nurses. There are still many unknowns concerning how biological responses interact to predict future health risks (Cohen, Janicki-Deverts, & Miller, 2007). Limited studies have measured stress, biological responses, and fatigue in nurses over consecutive worked days.

Human Subjects Protection

Risk of Subjects

Human subjects involvement and characteristics. Acute care nurses (medical/surgical) who work at least three consecutive days will be approached by the researcher to participate in the study. Flyers, email, informational session, and posted advertisement will advertise the study. The researcher will review the consent form with each participant, answer any questions, and explain that participation is voluntary and that they may refuse to participate at any time. The purpose, procedures, time requirements, risks, benefits, and study withdrawal will be discussed as part of the consenting process. The researcher will keep the signed consent and a copy provided to the nurse. If a nurse

is found to be extremely stressed or fatigued, the researcher will discuss risks related to high stress and fatigue with the nurse and encourage him or her to seek assistance from employee health.

Sources of materials. Demographic and other psychosocial information will be collected using standardized questionnaires by self-reports. Two stress-related biomarkers will be assessed from saliva samples. No medical records or personal records are accessed, except for the staffing database to determine consecutive days worked to determine eligibility of nurses to participate.

Potential risks. Potential risks of participation in this study are minimal. A potential risk may include a breach of confidentiality due to salivary samples being collected from each unit in the conference room prior to the start and end of each shift, or at key entrances and exits to the facility.

Protection against risk. This investigator of the University of Texas Health Science Center, School of Nursing and Houston Methodist Willowbrook Hospital will obtain the informed consent. The investigator and research assistants received training in informed consent and protection of human subjects. All personal and identifying information including names and identification numbers will not be used in the study. Each nurse is assigned a number for questionnaires and salivary samples. Study data will be stored in password-protected database. Research assistants and faculty will have access to stored data. To maintain confidentiality, the storage of data and collection Methodist will be maintained in a secure and locked office. Salivary samples will be stored in a laboratory freezer at the University of Texas Center for Nursing Biological Sciences until analyzed. Only study numbers will identify saliva samples and levels obtained for analysis and entered into a database with restricted access.

Potential benefits of the research to the subjects and importance of the knowledge to be gained. The potential short-term benefits of this study is the nurses will

receive the results of their questionnaires and biological samples, if requested and the results of this study. The long-term benefits will be to develop and implement fatigue countermeasure interventions to support a healthy work-life balance.

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In a large survey, 60% of nurses reported working through their breaks, coming in early, or working late to complete their work, while one-third perceived workloads to be high, and 82% identified work-related stress as the top work health and safety risk (American Nursing Association [ANA], 2015). Stress is associated with fatigue and may lead to poor patient outcomes, increased errors in care, and compromised patient safety (Montgomery, 2007; Trinkoff, Johantgen, Storr, Gurses, Liang, & Han, 2011). Fatigue is a feeling of disinterest, sleepiness, and/or exhaustion (Barker & Nussbaum, 2011) and prolonged work hours may potentiate fatigue and decrease job performance (Bae & Fabry, 2014; Carruso, 2012; Hazzard, Johnson, Dordunoo, Klein, Russell, & Walkowiak, 2013).

Stress can alter an individual's biological responses and circadian rhythmicity (Klein, & Corwin, 2007). Most typically, stress activates the neuroendocrine system, releasing hormones and neuropeptides, such as cortisol, epinephrine, and nor-epinephrine, which influence the body's immune and other regulatory systems. Chronic stress may lead to the dysregulation of the body's defense mechanisms, increasing the susceptibility to negative health outcomes (McEwen & Winfield, 2010). Biobehavioral approaches would facilitate the understanding of mind-body interactions on health (Kang, Rice, Park, Turner-Henson, & Downs, 2010). Furthermore, potential moderators of stress, such as social resources, need to be studied to determine their roles in reducing stress and fatigue among nurses. Despite the fact that nurses are working long hours across several consecutive days under highly stressful conditions, studies on nurses' stress and fatigue, particularly those studies using a biobehavioral marker is extremely limited. The central purpose of this study is to examine the relationships among stress, social resources, biological responses and fatigue in acute care nurses working three consecutive days of 12-hr shifts.

Stress

Stress is a demand or an event that a person feels unable to meet actual or

perceived expectations (McEwen & Winfield, 2010). A stress response can be both physiological and psychological that elicits a mind-body interaction in response to a perceived threat (Klein & Corwin, 2007). The body's natural stress response is to reestablish equilibrium and minimize the wear and tear on the body from chronic stress (McEwen & Winfield, 2010). The stress that nurses experience comes from two common sources, personal and work-related. Personal stress is experienced in relation to managing interpersonal relationships, balancing household and family responsibilities, personal environment, and other life-style factors outside work= (Ahsberg, et al., 2009). Work-related stress is related to antecedents around the hospital setting. Antecedents effecting stress in the work environment are voluntary and mandatory overtime practices, nonscheduled work time to meet staffing needs, workload, staffing deficiencies, confounding patient care initiatives, and reduced time to rest between shifts due to extended work hours (Bae, & Fabry, 2014; MacKusick & Minick, 2010; Barker, & Nussbaum, 2011). Though not often seen in the US hospital setting, rotating shifts lead to increases in stress and fatigue (Chang, Chen, Wu, Hsu, Liu, & Hsu, 2014; Muecke, 2005). In two studies conducted in Taiwan, consecutive rotating 8-hour shifts had a positive relationship with stress as measured by cortisol and heart rate (Chang, et al., 2013; Chang, et al., 2014). Nurses who worked consecutive two or four 8-hr night shifts reported higher stress than off-duty nurses (Chang et al. (2014). Lin et al. (2015) reported that nurses working consecutive 8-hour rotating shifts and night shifts reported significantly higher stress than nurses working day shifts. Work related stress is associated with errors and on-the-job injuries (Windle, Mamaril, & Fossum, 2008), increased patient mortality rates (Needleman, Buerhaus, Pankratz, Leibson, Stevens, & Harris, M: 2011), and compromised quality of patient care (Scott, Arslanian-Engoren, & Engorenn, 2014). Stress with decreased cognitive function has been associated with attention lapses (Chang, Chen, Hsu, Su, Liu, & Hsu, 2013; Samaha, Lal, Samaha, & Wyndham, 2007).

Stress and Biological Responses

Stress elicits neuroendocrine responses via activation of the hypothalamus-pituitary-adrenal (HPA) axis (Piazza, et al., 2010). The activated hypothalamus releases corticotrophin-releasing hormone (CRH), which acts on the pituitary gland to release adrenocorticotropin hormone (ACTH). ACTH, in turn, stimulates the adrenal cortex to release corticosteroids, such as cortisol (Piazza, et al., 2010). While most cortisol stays in circulation in a bound form to corticosteroid-binding globulin, a small fraction of unbound cortisol is transported to saliva. While cortisol is necessary to release stored energy during times of stress (Piazza, et al., 2010), sustained and repeated stress may lead to hypercortisolism, which can disrupt sleep and cognitive function (Niu et al., 2011).

Acute stress also activates the sympathetic nervous system (SNS), leading to the release of epinephrine and norepinephrine (Funkud, Ichinose, Kusama, Yoshidome, Anndow, Akiyoski, & Shibamoto, 2008; Klein & Corwin, 2007). Alpha amylase (AA) in saliva has been found to be a surrogate marker for SNS activity (Nater, & Rohleder, 2009). Levels of salivary AA have shown a quick rise and fall, compared with cortisol (Dickerson & Kemeny, 2004). No studies have evaluated the effects of stress, cortisol and alpha amylase over three consecutive workdays of 12-hour shifts in nurses.

Social Resources

Extensive research has reported the benefits of social resources as a moderator of stress (Underwood, 2012). High social support has allowed nurses to manage stress and remain effective in their roles as caregivers (Chana, 2015; Rezaee & Ghajeh, 2009), but in contrast, low levels of support may be a threat to nurses' personal health and indirectly affect patient care (Stewart, & Tilden, 1995). Being part of a family structure and having friendships reduces the effects of stress, and a supportive family provides emotional support (Sarason, 1987). Similarly, social resources such as companionship and intimacy allow for reducing work tension and stress (Winwood et al., 2006). In addition, a supportive hospital culture of safety and a healthy work environment help

nurses to meet job expectations and reduce work-related stress in nurses (Smith-Miller & Shaw-Kokot, 2014). Among healthcare providers, including nurses, social resources were reported to moderate the effects of mind-body interactions when coping with internal and external stress (Barnes-Farrell et al., 2008). Nurses working shiftwork found the relationships among stress and fatigue to be influenced by the presence of various coping behaviors that reduced nurses' response to stress and improved health (Samaha, Lal, Samaha, & Wyndham, 2007). Supportive hospital environments are significant social resources. Magnet® recognized hospitals, for example, might have a positive effect on stress and fatigue via positive management style, personnel policies and programs, quality of care outcomes, and positive collegial relationships (ANCC, 2015; Smith-Miller & Shaw-Kokot, 2014). The term social resources and social support mean the same for this study.

Fatigue and Biobehavioral Responses

Fatigue is a multidimensional concept that encompasses feelings of tiredness and a lack of motivation from stress (Barker & Nussbaum, 2011). Fatigue includes acute psychological and physiological symptoms and behaviors ranging from general malaise to exhaustion that can lead to decreased performance (Barker & Nussbaum, 2011). Cortisol production from stress increases energy metabolism (Powell, Lioffi, Moss-Morris & Schlotz, 2013) and glucocorticoid treatments have shown to alleviate short-term fatigue (Khani and Tayek, 2001). Although cortisol has been studied in relation to fatigue, most research has been on the relationship between chronic fatigue syndrome and symptom response to disease but not in the nursing population. (Powell et al., 2013).

Fatigue in nurses is an important safety concern for nurse and patient safety. Fatigue has been associated with decreased cognitive functions and increased physical injuries and practice errors (Geiger-Brown et al., 2012; Johnson, Jung, Brown, Weaver, & Richards, 2014). Antecedents of fatigue in nurses has been associated with strenuous patient care, shiftwork, length of a working shift, recovery time between shifts, and

irregular work hours (Chen et al., 2014; Oyane, Pallensen, Moen, Akerstedt, & Bjorvatn, 2013). There is a lack of research in the study of the effects of fatigue over consecutive shifts and biological response in the United States. Geiger-Brown et al. (2012) reported that nurses accumulate a significant sleep debt while working three-consecutive 12-hour shifts, and 36% of nurses reported a high level of fatigue even between shifts. In an integrative review of nurses working in hospital settings, working shifts longer than 12-hours significantly contributed to increased fatigue (Smith-Miller, Shaw-Kokot, Curro & Jones, 2014). Neither of these studies evaluated biological response and fatigue

Conceptual Framework

Conceptual framework of this study is based on the Expanded Biobehavioral Interactions Model (Kang et al., 2010). In the base model, ~~briefly~~, various factors in six domains (individual, environmental, psychosocial, behavioral, biological, and health outcomes) are conceptualized to interact to affect health outcomes. Although bidirectional relationships between domains are included, most typically, factors in the first four domains are believed to influence biological responses, which, in turn, can change health outcomes. This framework represents a multidimensional and holistic view of factors influencing biological responses' and health outcomes (see Figure 1).

In this study, a nurse's personal and work-related stress (psychosocial domain) is conceptualized to impact biological responses (biologic domain) and fatigue (health outcome domain). Biological responses may mediate fatigue but, because of the limited sample size, such mediation is not tested. Instead, social resources (psychosocial domain) are conceptualized to moderate the relationship between stress and fatigue in this study. Biological responses included salivary cortisol and alpha amylase and correlations between biological responses and fatigue were examined (see figure 2).

Objectives

The primary objective of this study was to assess the changes in perceived stress, fatigue,

and biological responses in acute care nurses working three consecutive 12-hour shift workdays.

Aims

1. To examine the changes in stress, biological responses, and fatigue across three consecutive 12-hour workdays in acute care nurses.
2. To examine the effect of perceived personal and work-related stress on biological responses and fatigue.
3. To test the moderating role of social resources in the relationship between stress and fatigue.
4. To examine the correlation of salivary cortisol and alpha amylase with fatigue.

Hypothesis

- 1.1. Stress, biological responses, and fatigue will be significantly higher on day 3 than day 1.
- 1.2. Stress, biological responses, and fatigue will be significantly higher at post-shift than pre-shift on day 1 and day 3.
- 2.1. High levels of personal, work-related, and overall stress at pre-shift of day 1 will predict high levels of salivary cortisol and alpha-amylase at baseline, post-shift day 1 and day 3.
- 2.2. High levels of personal, work-related, and overall stress at pre-shift day 1 will predict high levels of fatigue at baseline, post-shift day 1 and day 3.
3. Social resources will moderate the effect of stress on fatigue.
4. Salivary cortisol and alpha amylase will be positively correlated with fatigue

Methodology

Sample/Setting

Of the 85 subjects recruited, one subject dropped from the study for unknown reasons, two failed to work three consecutive shifts during the study period, and one moved before saliva samples could be collected. Responses of 81 subjects, 43 were full-time, dayshift nurses and 38 were full-time, night shift nurses at a Magnet-designated suburban hospital were included in the analysis. Power analysis indicated a sample size of 70 to meet the power level of 80% and alpha level set at .05, assuming moderate correlation between stress and cortisol. Participation was voluntary and uncompensated

Recruitment

Invitation letters were sent to over 300 nurses in Medical/Surgical acute care settings and Critical Care and Emergency Care settings throughout the hospital. Interested participants were screened by the researcher for inclusion and exclusion criteria and signed a consent form. Inclusion criteria were: (1) full-time nurses who had worked within the two weeks prior to the study to control for the potential effects of vacation in lowering stress and fatigue levels prior to the beginning of the study; and (2) nurses who were scheduled to work a 12-hr day or night shift for three or more consecutive days in an acute care setting. Excluded were nurses: (1) working less than 36-hrs per week, (2) using steroids or anti-inflammatory medications within the last two weeks, and/or (3) with a current viral or bacterial infection. The university and hospital Institutional Review Boards approved the study.

Instruments and Saliva Collection

Stress. Three dimensions of stress, perceived personal stress, work-related, and overall stress were measured within 24 hours of the start of a 12-hr shift on day 1. Because stress levels were measured repeatedly prior to and after work on day 1 and day 3, long forms of personal and work-related stress were used only for baseline measure (pre-shift of day 1). A visual analog scale of stress (VAS-S) was used to measure stress at repeated time points corresponding with saliva collection.

Perceived personal stress. Perceived personal stress was measured using the Perceived Stress Scale (PSS) (Cohen, Kamarak, & Mermelstein, R., 1983). The PSS is a widely used instrument to assess the appraisal of stress during the past month on a Likert scale of 0 to 4, 0 = never and 4 = very often. The higher scores indicate higher perceived stress levels. The instrument is a 10-item tool with easy-to-understand questions that have been psychometrically tested in various populations. The Cronbach's alpha for the PSS total scale reliability was .81 for this study.

Work-related stress. Work-related stress was measured using the Nurse Stress Scale (NSS), a multidimensional, self-reported measure of the appraisal of sources of stress in the work environment in a hospital setting (Gray-Toft & Anderson, 1981). The NSS has 11 subscales that are associated with general working conditions (Fukuda et al. 2008). Subscales evaluated perceived stress specific to hospital nurses, such as caring for patients, difficulties with the nurse-patient relationships, dealing with death and dying, workload, and conflict with physicians. The tool provides self-reported scores on a 4-point Likert scale (with 1 representing no stress and 4 representing extreme stress). The Cronbach's alpha NSS for the total scale reliability was .91 for this study.

Overall stress. A Visual Analog Scale-Stress (VAS-S) scale was used to assess current levels of self-reported stress, on a 0 – 10 scale. Higher scores represent higher perceived stress.

Biological responses. Biological responses were assessed with salivary cortisol to represent HPA activity and salivary alpha amylase to represent sympatho-medullary activity (Piazza, Almeida, Dmitrieva, & Klein, 2010; Klein & Corwin, 2007; Dickerson & Kemeny, 2004).

Salivary cortisol. Natural circadian rhythm peaks in early morning on and shortly after awake and steadily declines throughout the day until the middle of the night (Almadi, Cathers, & Chow, 2013). Finding a significant change in the levels of cortisol

over a 12-hour shift in day shift nurses would be expected results because of the circadian rhythm. Increases in stress cause increased levels of cortisol (Deane, Chummun, Prashad & Prashad, 2002). Prolonged high levels of cortisol can lead to a flattened or lack of variability in the circadian diurnal pattern and is associated with a decrease in the release of cortisol by the adrenal cortex (Almadi, et al., 2013).

Salivary alpha-amylase (sAA). Levels of sAA is a surrogate measure of the sympathetic nervous system with sensitivity at 0.4 ug/dl. sAA reflects the response to acute stress and its response typically is faster than cortisol responses. Stress activates the amygdala, which activates the locus coeruleus which activates the sympathetic nervous system leading to a neural impulse which activates the smooth muscles and glands leading to an increase in the secretion of alpha amylase into the saliva.

Procedure for saliva collection. The participants were instructed to abstain from eating, smoking, brushing teeth, and drinking sugar or caffeinated beverages 60 minutes prior to saliva collection. Saliva samples were collected at four times for each nurse, pre- and post-shift on day 1 and day 3 of consecutive workdays. Saliva collection was by passive drool method on the hospital unit between pre-shift and post- shift. Optimally, 2ml of saliva was collected at each collection point and approximately at the same time of the day for each collection. The time of saliva collection was recorded by the nurse to recognize circadian variations and verified by the researcher (see Appendix A for more procedure details). The researcher was present at every data collection time to verify that all elements were completed. The collected specimens were kept in a cold, portable, ice box and then stored in a freezer at the hospital until transported to the UTHSC-H Center for Nursing Research Bioscience Laboratory in Houston, Texas. Samples were stored in -80-degree C until batch assayed using Salimetrics Enzyme Immunoassay kits following the manufacturer's instructions (Salimetrics, LLC. State Park, PA). The intra-assay coefficient of variation (CV) was calculated in duplicates and inter-assay (CV) was calculated from controls on different plates per the manufactures specifications. Intra-

assay and inter assay CVs were <10% and < 15% for cortisol.

For alpha amylase, the above procedures were followed for transport and storage. Alpha amylase was run in singular samples following the manufacturer's instruction, and optical density (OD) readings were taken at 1 and 3 minutes. The concentrations were calculated by subtracting the 1-min OD values from the 3-min OD valued multiplied by the conversion factor provided by the manufacturer. The results were expressed in U/ml. The sensitivity of the assay is <0.01 change in absorbance, and the coefficients of variation for intra-assay and inter-assay precision are 2.5 – 7.2% (Salimetrics, LLC. State Park, PA). Inter- assay CV was 6.15% in this study.

Fatigue. Multidimensional fatigue were assessed at baseline using a long form Multidisciplinary Fatigue Inventory and a single item, Visual Analog Scale for Fatigue scale from 0 - 10 for repeated measure of fatigue.

Multidimensional Fatigue Inventory (MFI-20). This scale provides a multidimensional measurement of fatigue, as related to general fatigue, physical fatigue, mental fatigue, reduced activity, and reduced motivation (Dittner, Wessely & Brown, 2004). The tool uses a 5-point Likert scale, where 1= agreement and 5= disagreement. The Cronbach's alpha for the MFI -20 was total scale reliability .80.

Visual analog scale fatigue (VAS-F). Fatigue was measured at baseline and as a repeated measure coinciding with the collection of saliva using a Likert scale from 0 - 10. Higher scores represent higher perceived fatigue.

Social Resources. The Multidimensional Scale of Perceived Social Support (MSPSS). The MSPSS 12 item survey measures perceived social support of a significant other, family, and friends. The instrument includes a 7-point Likert scale with responses ranging from 1 = Very Strongly Disagree to 7 = Very Strongly Agree, with total score ranges from 12 to 84 and subscales score ranges from 4 to 28. High scores indicate high-perceived social support. The Cronbach's alpha for the MSPSS total scale reliability was

.95 for this study.

Data Collection Methods

Using Qualtrics software questionnaires were sent via a link to the email provided by the nurse 24-hours prior to the start of a series consecutive workdays. The researcher was able to inform the nurses via telephone that a link was sent for them to complete prior to the start of day 1 of the study. Once the questionnaires were completed, the researcher received a notification via email from Qualtrics. If 6-12 hours prior to the start of day 1 the questionnaires were not completed another contact was made by the nurse. The nurse would be rescheduled if questionnaires were not completed.

At or near the first day of consecutive workdays, participants completed baseline demographic and baseline questionnaires. In addition, repeated collections using Visual Analog Scales for stress and fatigue and saliva samples were collected between 6 – 7 pre-shift/post-shift coinciding with the beginning and end of a 12-hour shift for day and night shift nurses (See Table 1). Each participant was assigned to a study code number and no identifying information was used on study documents or specimens except on the consents. Research data was then stored on an encrypted computer and backed up to a hospital-based server.

Data Analysis

Descriptive data were examined to describe the characteristics of study participants using SPSS 24 (IBM, 2016) and STATA version 13.1 (STATA, 2015). Descriptive statistics included mean, standard deviation, frequency and percentage. Data were examined for missing values and normality in data distribution using scatterplots and histograms. Because biomarker data of salivary cortisol and alpha amylase were not normally distributed, biomarker data were log transformed prior to conducting data analyses. Group differences between day and night shift nurses were assessed using chi-square for categorical variables and independent *t*-test tests for continuous variables.

For Aim 1, a paired *t*-test was used to compare the differences between day 1 pre-shift and post-shift day 3 for stress, and fatigue. For biomarkers, comparisons between two time points were adjusted to account for natural circadian variations so that pre-shift values of day 1 were compared with pre-shift values of day 3, as post-shift values of day 1 were compared with post-shift values of day 3. To evaluate within shift changes, a comparison of stress, biological responses, and fatigue between pre- and post-shift on each shift were performed separately for day and night shift nurses because work shifts start and end at different time points of the day when considering circadian rhythmicity of the biological responses.

For Aim 2, hierarchical regression was used to examine the effect of stress on biological responses and fatigue, after controlling for demographic covariates. Significant covariates were identified using *t*-test or ANOVA for categorical variables (e.g., race) or Pearson's correlation coefficients for continuous variables on dependent variables. Significant covariates ($p < .05$) were entered in step 1 for each regression model, followed by entering stress variables in step 2. Baseline stress measures included both perceived personal and work-related stress as predictors with biological responses and fatigue as the dependent variables. Each regression model explained how much of the variance can be explained by both the baseline stress scales individually and together in the model for each dependent variable: cortisol, alpha amylase and fatigue post-shift day 1 and day 3.

For Aim 3, social resources (MSPSS) were divided into 2 groups using the histogram to delineate the high (>55) vs, low group (≥ 55) because social resources data were severely skewed into a pattern of high or low. Moderation was tested by a significant change in R^2 of an interaction terms of stress x social resources in the regression models.

For Aim 4, a Pearson's correlation was used to assess the association between

cortisol and alpha amylase and fatigue at each biomarker assessment time points (pre- and post-shift day 1 and day 3). Separate correlations for day and night shift nurses were run to account for different patterns of circadian rhythmicity in relation to their work shift, day or night. For statistical significance, *p* values, two-sided, less than 0.05 were considered significant.

Results

Characteristics of Participants

The sample consisted of 81 nurses, 43 day shift nurses and 38 night shift nurses, and included 22% male nurses. The ages of the nurses were mostly in two group ranges: 30-39 (25%), and 40-49 (43%). The most common race was Asians (38%) and Caucasians (32%), followed by African Americans (16%) and Hispanics (10%). The majority were BSN graduates (85%) with approximately years' of experience groups evenly distributed from 0-5 years (25%), 6-10 years (25%), and 11-15 years (30%). These nurses reported working an average of 12.5 hours per shift ($SD \pm 0.5$). The majority (78%) of the nurses were married and reported that spouses helped with household management (77%). There was no significant difference on any demographic variable between the day and night shift nurses (see Table 2). When levels of stress, fatigue, and social resources were compared between day and night shift nurses at baseline, only social resources (MSPSS) were significantly lower in night shift nurses than day shift nurses ($p = .05$). The Cronbach's alphas for the study instruments ranged from .81 to .95 (see Tables 3 and 4).

Comparison of Stress, Fatigue, Cortisol, and Alpha Amylase between Day 1 and Day 3

Hypothesis 1.1: Stress, biological responses, and fatigue will be significantly higher on day 3 than day 1. There was not a significant increase in overall stress as measured by the VAS-S scale for either day or night shift nurses. For biological responses, changes were compared between pre-shift of day 1 and pre-shift of day 3, as

well as between post-shifts of day 1 and day 3 for day and night shift nurses separately to control for circadian variability. The only significant findings was a significant decrease in cortisol from pre-shift day 1 to pre-shift day 3 for day shift nurses, ($p=.007$). Alpha amylase levels were not significantly different for pre-shift or post-shift changes for either shift nurses. Fatigue measured by VAS-F was increased in both groups of nurses but the increase was significant only for night shift nurses, $p = .001$ (see Table 5).

Hypothesis 1.2. Stress, biological responses, and fatigue will be significantly higher at post-shift than pre-shift on day 1 and day 3. This hypothesis tests acute changes within a 12-hour shift work. There were no significant changes in stress (VAS) from pre- to post-shift in both groups of nurses. For biological responses, cortisol decreased significantly within the shift ($p=.005$) for both days for day shift nurses, though not for night shift. Alpha amylase significantly increased within shift day 1 ($p=.005$) and day 3 ($p=.003$) in day shift nurses, but decreased significantly within day 1 ($p=.001$) and day 3 ($p=.007$) for night shift nurses. Fatigue levels were not significantly higher within the shift for day shift nurses but there was a significant increase in fatigue from day1 pre-shift to day 1 post-shift, ($p=.005$) for night shift nurses (see Table 6).

Effect of the Baseline Stress on Cortisol and Alpha Amylase

Hypothesis 2.1. High levels of personal, work-related, and overall stress at pre-shift of day 1 will predict high levels of salivary cortisol and alpha-amylase at baseline, post-shift day 1 and day 3. A hierarchical regression was run for day and night nurses separately, controlling for covariates. Significant covariates were race, hours of sleep per night between shifts, and number of children. There were no significant predictive power of stress on cortisol and alpha amylase at any time point for both shifts nurses (see Table 7).

Hypothesis 2.2. High levels of perceived personal, work-related, and overall stress at pre-shift day 1 will predict high levels of fatigue at baseline, post-shift day 1 and

day 3. A hierarchical regression was run for all nurse groups combined to determine if perceived personal and work-related stress predicted baseline fatigue and fatigue post-shift of day 1 and day 3 controlling for covariates (race, marital status, care for extended family, years in nursing, and type of shift). The change in R^2 indicated that personal and work-related stress statistically significantly contributed to baseline fatigue, $\Delta R^2 = .09$, ($p = .03$), but not for day 1 or day 3 fatigue (see Table 8). For overall stress (VAS-S), it significantly predicted baseline fatigue, $R^2 = .06$, $p = .031$, fatigue on day 1, R^2 of .17, ($p = .000$), and post-shift fatigue on day 3, $R^2 = .08$, $p = .008$. (see Table 9).

Moderation of Social Resources in the Relationship Between Stress and Fatigue

Hypothesis 3: Social resources will moderate the effect of stress on fatigue. The effect of moderation was evaluated by the significance of interactions between stress and social resources on fatigue, after accounting for covariates. Social resource (MSPSS) and stress variables were centered to reduce potential collinearity problems. Social resources total score results showed a negative skew (skewness = -1.77 and Kurtosis = 3.33) with the majority of nurses reporting very high social resources. Therefore a visualization for a cut-off point using a histogram was used to determine high and low social resources for this study. The cut-off point was determined to be a total score of 55. Nurses with <55 were in the low social resource group, and those with score ≥ 55 were considered to be in the high social resource group. Three models were identified as showing significant moderation: the model with baseline fatigue as the dependent variable (DV), and interaction between work-related stress (NSS) and social resources category (MSPSS) ($p = .03$, $\beta = -.26$); the next model with fatigue post-shift day 3 as DV, and the interaction of NSS by MSPSS ($p = .04$; $\beta = .28$); and the model with Fatigue post-shift day 3 as DV, and the interaction of overall stress VAS by MSPSS ($p = .03$; $\beta = .74$) (see Table 10 & 11). These models are explained below in more detail in relation to nurses in the high and low social support groups. There was a strong association between work-related stress (NSS) and baseline fatigue (MFI) in those with a MSPSS <55 (slope

= .61, $p = .01$) than in nurses with a MSPSS ≥ 55 (slope = .11, $p = .06$) (see Figure 3). We are not looking for p value to be significant, moderation effect would be seen in the p value $\geq .05$ as illustrated by figures 3-5. There was a negative association between work-related stress (NSS) and fatigue post-shift day 3 in nurses with MSPSS < 55 (slope = -.11, $p = .04$), while those with a MSPSS ≥ 55 basically showed no association (slope = .01, $p = .62$) (see Figure 4). There was a negative association between overall stress and post-shift day 3 fatigue in those with a MSPSS < 55 (slope = -.36, $p = .22$), while those with a MSPSS ≥ 55 showed a positive association (slope = .33, $p = .003$) (See Figure 5). In Figure 3 and 4 the moderating effect was noted in the group of nurses reported a MSPSS total score ≥ 55 . This was the moderating effect we expected to see, however in the last model the opposite association was reported for overall stress and post-shift day 3 fatigue. The low social resources group reported the moderating effect though this association is hard visualize, both group slopes look similar.

Association between Biological Responses and Fatigue at Salivary Collection

Hypothesis 4: Salivary cortisol and alpha amylase will be positively correlated with fatigue. A Pearson correlation was used to evaluate the relationships between biological responses and fatigue (VAS-F) over 4 time points. In day and night shift nurses, the correlations between cortisol and alpha amylase and fatigue have limited statistical significance, and there was no consistent pattern in the associations (see Tables 12 & 13).

Discussion

The primary purpose of this study was to assess changes in perceived stress, and biological responses using salivary cortisol, alpha-amylase and fatigue in acute care nurses working three consecutive workdays of 12-hour shifts in a Magnet-designated hospital. Additionally, the role of social resources in buffering the effects of the stress on fatigue was examined. Findings of this study partially fill a gap in understanding how working consecutive 12-hour shifts affects nurses in current healthcare environment in

the US. There have been many changes introduced into the hospital work environment in the last five years in the US such as pay-for-performance and readmission penalties and decreased length-of-stays for certain patient populations in an effort to minimize the cost of health care (Anderson, 2014; Graham, 2014). This leads to a philosophy of do more with less resources for nurses at the forefront of meeting these initiatives (Graham, 2014). These initiatives undertaken by the US healthcare system have added to the nurses' workload (Anderson, 2014; Graham, 2014).

Stress

The findings of the study did not support the hypothesis that stress would increase over consecutive shifts from day 1 to day 3, or within shifts (pre-shift to post-shift). Stress was measured in three different ways to represent personal perceived stress, work-related stress, and overall stress for repeated measures using a visual analog scale in which case nurses reported personal stress levels to be relatively low to moderate 18.8 (± 5.2). Work-related stress was moderately high with an average score of 112.8 (± 28.3) and the levels of overall stress were low to moderate at 3.5 (± 2.8). Stress scores did not differ significantly between day and night shift nurses. For work-related stress, nurses reported the highest stress for the previously mentioned subscales, followed by the stress of dealing with death and dying, and conflicts with physicians which was consistent with a recent survey by the American Nursing Association (ANA, 2015). This group of nurses reported low to moderate scores for stress scales. This lack of variability potentially influenced the ability to detect the interactions between biological responses and fatigue.

The hypothesis that baseline stress using the perceived stress scale (PSS) and nurse stress scale (NSS) would predict increases in salivary cortisol, alpha amylase and fatigue levels at the end of shift of day 1 and day 3 was not supported in any of the models. Potentially these questionnaires (PSS/NSS) were not sensitive in predicting changes in biological responses. In contrast, the hypothesis that baseline overall stress using a visual analog scale for stress (VAS-S) significantly predicted fatigue at baseline,

post-shift day 1 and at post-shift day 3 was supported. Single item (VAS-S) was chosen for repeated measures of stress to reduce subject burden, and our findings indicate that (VAS) could be a sensitive and useful tool for examining stress to predict fatigue at later time points. These findings suggest the visual analog scale for stress (VAS-S) using a 0 - 10 scale is a superior predictor of fatigue in the future. To our knowledge, a single item visual analog scale for stress has not been used to predict fatigue at future time points in other studies.

Other studies have reported higher levels of stress in nurses working shiftwork, than our study. Allan et al. (2009) reported that nurses' stress increased significantly from day 1 to day 2 in a nurse call-center. Lin et al. (2015) reported that consecutive 8-hour rotating night shift nurses had significantly higher stress than day shift nurses. Similar to this study, Chang, et al. (2013) did not find any significant differences in perceived stress between day and night shift nurses, similar to our findings. Overall findings on stress over consecutive workdays seem to be mixed which is possibly related to the differences between nursing practice across countries, types of nursing, and length of shiftwork. The majority of the studies on nurses' stress over consecutive workdays were done outside the US where nurses work 8-hour or rotating shifts, whereas nurses in the US typically work a 12-hr shift. There is a need for more studies evaluating stress using biological responses in US nurses working consecutive workdays of 12-hour shifts to provide an objective measure of stress.

Biological Responses

The hypothesis that cortisol and alpha amylase levels would increase significantly on day 3 than day 1 was partially supported. There was a significant decrease in cortisol from pre-shift day 1 to post-shift day 3 in day shift nurses, but not for night shift nurses. Alpha amylase did not show any significant change for either day or night shift nurses. In contrast, for within shift changes, pre-shift to post-shift levels were significant reduction for cortisol in the day shift nurses, but not in night shift nurses. Most likely

these changes were related to cortisol diurnal rhythmicity and not stress due to the low reported perceived stress scores. For alpha amylase, significant pre-to-post shift increases in day shift vs. significant pre-to-post shift decreases in night shift nurses indicate lower am values but higher pm values. It is unclear if these changes reflect the effects of stress. Instead, it appears these are changes based on circadian rhythmicity.

The hypothesis that high levels of personal, work-related, overall stress day 1 would predict high salivary cortisol and alpha-amylase at post-shift day 1 and day 3 was not supported. Cortisol and alpha amylase manifest different stress responses. Cortisol has a distinctive diurnal rhythm showing a high peak early in the morning on awake and decreases throughout the day to reach the lowest point after midnight. Cortisol and alpha amylase typically increase in response to psychosocial stress, but alpha amylase responds faster than cortisol indicating a sympathetic nervous system (SNS) response. Cortisol, on the other hand, is slower to react than the SNS response, indicating a neuroendocrine response (HPA). The SNS may be more sensitive to stress than HPA however both coordinate to ameliorate stress using different mechanisms in their response to stress (Hellhammer, Wust, & Kudielka, 2009; Nater, & Rohleder, 2009). Other studies have shown a lower waking cortisol concentration as a result of life-long exposure to stress in normal adults (Van Cauter, Leproult, Kupfer, 1989). Carlsson, Hansen, Garde, & Orbaek, (2006) reported morning shift workers had a significantly lower mean cortisol concentration across the workday than late waking evening shift workers.

One of the earliest studies comparing nurses' perceived level of stress and biological responses was in the Yang, Koh, Ng, Lee, Chan, Dong & Chia, (2001) study which reported that general ward nurses had higher levels of morning salivary cortisol than did emergency room nurses, and reported a negative correlation between perceived stress and cortisol levels, similar to some of our correlation findings. Fujimaru et al. (2011) reported cortisol levels were not different between different types of neonatal intensive care nurses (NICU) and medical-surgical nurses, but NICU nurses reported

higher perceived stress. Chang, et al. (2013) reported no differences in cortisol levels in night shift nurses working two consecutive 8-hour shifts and off-duty nurses. In the rapidly changing healthcare settings, mixed findings indicate the need for additional studies using more biobehavioral approaches. Nurses working in different work settings and hours as well as their impact on nurses' performance may need to be included.

Social Resources as a Moderator

A hypothesis that social resources would moderate the effect of stress on fatigue was partially supported in certain regression models. When we divided the nurses into high (MSPSS ≥ 55) and low social resource group (< 55), work-related (NSS) and overall stress (VAS-S) were reported a significant buffering of stress on fatigue at baseline and at post-shift day 3. In addition using the MSPSS scale reported high social support in the majority of nurses, showing a relative ceiling effect. In addition, social resources showed a buffering effect on the association of stress on fatigue in the group of nurses reporting high social resources. However in the final model, the low resource group reported a buffering effect between stress on fatigue thought not easily visualized by the slopes. The relationship between overall stress and fatigue were inconsistent with what we expected. For overall stress we speculate there could be another factor buffering the effect of stress in this group of nurses with low social resources, such as resilience or vigilance. Also there could be a difference in how work-related stress (NSS) and overall stress (VAS) effect the association on fatigue. Work-related stress instrument is a more comprehensive measure of work stress, while overall stress was a single item questionnaire and perhaps not as sensitive to changes in stress. Other studies have reported a potential coping factor associated with night shift workers, the environment, or family support. Lim, Hepworth, and Bogossian, (2010) suggest that social resources such as strong family support have a beneficial effect on psychological well-being of nurses in their interactions between their personal and professional life. In addition, Uchino (2006) reported in a review that high social resources may positively influence disease outcomes and overall wellbeing

Potential reasons for nurses reporting high social resources may be from several factors. One reason is that the study was conducted in a Magnet Accredited hospital. It is known that Magnet designated organizations report the highest patient outcomes and nurse satisfaction compared with non-magnet facilities (Petit, Dit, Dariel & Regnaud, 2015). Similarly, other researchers report social resources to be high in Magnet designated facilities (Smith-Miller, & Shaw-Kokot, 2014). Chen, Davis, Daraiseh, Pan and Davis (2011) reported Magnet hospitals provided longer breaks on average than did non-Magnet hospitals. High social resources collectively support a healthy work and home environment where nursing is supported and valued.

Biological Responses and Fatigue

The hypothesis that fatigue will be significantly higher on day 3 than day 1 was partially supported, with a statistically significant increase of fatigue in night shift nurses. This suggests that night shift nurses are at a higher risk of experiencing fatigue with each consecutive shift than day shift nurses. Although fatigue increase was not statistically significant ($p = .06$), fatigue also was clearly increased over consecutive shifts in day shift nurses. An increase in fatigue has been shown in other studies. Prolonged work hours may contribute to increases in fatigue and decreases in job performance (Bae & Fabry, 2014; Carruso, 2012; Hazzard, Johnson, Dordunoo, Klein, Russell, & Walkowiak, 2013). Prolonged fatigue also has been associated with other work-related injuries and errors that have been linked to major health and safety implications in patient care (Ahsberg, Kecklund, Akerstedt, & Gamberale, 2000; Page, 2004; Tourangeur, Cranley, & Jeffs, 2006). Future interventions to reduce fatigue should be tested on nurses, particularly those working night shifts, using recommendation from the ANA fatigue countermeasures toolkit (ANA, 2014).

The hypothesis that salivary cortisol and alpha amylase are positively correlated with fatigue was not supported. There were limited numbers of statistically significant correlations between cortisol and fatigue and between alpha amylase and fatigue, but

the pattern was not consistent and directions of correlations were mixed, making the interpretation difficult. Other studies have evaluated cortisol as measured by the cortisol awakening response (CAR), circadian profile (CP), or diurnal slope (DS) across multiple time points throughout a 24-hour period (Powell et al., 2013). A systematic review indicates that CAR and CP did not predict fatigue because within-day measures of cortisol changes may be more predictive of fatigue (Powell et al., 2013). In future studies, when collecting saliva samples collect CAR levels, and at multiple time points will help to explore a diurnal slope, rather than relying on only pre-and post-shift samples.

Factors affecting fatigue in other studies included shift rotation. Disruptions in circadian rhythms affected the quality of sleep leading to increased fatigue which was attributed to increased cortisol secretion (Niu et al., 2011). Other factors included the length of a working shift, recovery time between shifts, and irregular work times (Oyane, Pallensen, Moen, Akerstedt, & Bjorvatn, 2013). Also workload has been shown to significantly correlate with acute and chronic fatigue (Han, Trinkoff, & Geiger-Brown, 2014). Han et al. (2014) also reported that after working two consecutive 12-hour shifts, nurses reported that direct patient care contributed the most to acute fatigue. Lack of adequate sleep is an antecedent to fatigue and their ability to be attentive to details at work. Geiger-Brown et al. (2012) reported wide variations in fatigue levels between day and night nurses over three consecutive shifts. The physical demands of patient care related to patient handling, and actual physical patient care at the bedside measured by heart rate contributed to acute fatigue in nurses working two 12-hour shifts (Chen et al., 2014). There is evidence that consecutive shifts, the strenuous nature of patient care, stress of conflict in relationships at work, and the management of household responsibility are related to increased fatigue in nurses. Our findings support the findings that nurses' fatigue increases over consecutively worked shifts in every hospital even in a Magnet hospital environment in the US though perhaps to a lesser degree. Fatigue cannot be eradicated in the health care industry, but recognizing its potential impact

on human errors and patient safety brings needed attention to the effect of fatigue on nurses, especially night shift nurses. Continued research and development for effective interventions to reduce fatigue may significantly improve health outcomes for nurses and patients.

Strengths and Limitations

The strengths of the study include a repeated-measures prospective design, biobehavioral approach, and the use of reliable and valid tools for data collection in addition to following strict saliva collection protocols. Furthermore, different types of stress were examined to assess the potential for differential sensitivity and impact on outcomes of this research. Social resource was added as a potential buffer to stress. Out of the 85 nurses that agreed to participate in the study, 81 completed the study showing a very high retention rate. Findings of the study provide the valuable insight to future studies in this important topical area.

Limitations include a limited generalizability of study results. The study was conducted at a Magnet-designated hospital, representing only the top 10% of high performing acute care hospitals nationally (American Nurses Credentialing Center [ANCC], 2016). The population was homogenous and the majority of the nurses reported working more than 10 years with high levels of social resources. Finally, biological responses were limited to salivary cortisol, alpha amylase, and their circadian rhythmicity which made the interpretation of the data challenging. Despite these limitations, study strengths were noted which aptly contribute to the knowledge base within this important research field.

Conclusion

Overall, the findings of this study indicate that nurses working consecutive 12-hour shifts in acute care settings have a significant increase in fatigue at the end of three 12-hr shift work days, particularly in night shift nurses. Stress levels using a visual analog 10-point scale can significantly predict fatigue levels at the end of day 1 and day 3. Social

resources can buffer the negative impact of stress on fatigue. Continued research is needed to understand the relationship between the biobehavioral response of stress and fatigue in nurses working extended hours beyond 12-work hours per shift and over more than three consecutive workdays, controlling for the confounding effects of circadian rhythmicity.

Clinical Resources

The ANA endorses best practices in the management of fatigue and recommends specific interventions to reduce the risks to nurses and their patients (ANA, 2014a). Most importantly, nurses need to inspire and encourage self-care within their practice. Hospital leadership should focus on the adaptation of ANA interventions which can decrease fatigue and potentially reduce the risk of patient safety errors and fosters a healthy work environment. According to ANA recommendations, leaders should minimize long-hour days in their schedules, limit consecutive shifts, and support a healthy lifestyle that includes exercise, healthy eating, and time off between shifts to foster adequate sleep (ANA, 2014b). Resources are available to assist nurses at risk for sleep disorders and excessive fatigue through the federally mandated Employee Assistance Programs. Resources are available to help nursing leaders provide support to nurses to reduce stress and implement fatigue countermeasure interventions (ANA, 2014b).

The ANA's Healthy Nurse program provides information on sleep, weight control, fatigue interventions, and other health-related topics to help nurses adjust to shiftwork. Although nurses are generally aware of the attitudes and practices to maintain a healthy work environment, often these practices are not applied toward self-care (Nahm, Warren, Zhu, An, & Brown, 2012). In addition, researchers have recommended work hour regulations within the hospital to minimize the effects of fatigue. Bae et al. (2013) and Hazzard et al. (2013) recommended limiting a workweek to no more than three consecutive 12-hour shifts.

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Table 1

Repeated Measures Data Collection

	Baseline	Day 1 Preshift	Day 1 Postshift	Day 2 Preshift	Day 2 Postshift	Day 3 Preshift	Day 3 Postshift
Demographics	X						
Personal stress (PSS)	X						
Work Stress (NSS)	X						
Fatigue (MFI)	X						
Social Resources (MSPSS)	X						
Stress (VAS-S)	X	X	X			X	X
Fatigue (VAS- F)	X	X	X			X	X
Saliva Cortisol/Alpha Amylase		X	X			X	X

Table 2

Characteristics of the Study Population

Variables	All Nurses (N = 81)	Day Shift Nurses (n = 43)	Night Shift Nurses (n = 38)	Comparison
	Mean (SD) or Frequency (%)	Mean (SD) or Frequency (%)	Mean (SD) or Frequency (%)	p
Age				
20-29	13 (16)	7 (9)	6 (7)	.66
30-39	21 (25)	10 (11)	11 (14)	
40-49	35 (44)	19 (23)	16 (20)	
50-59	9 (11)	5 (6)	4 (5)	
60+	3 (4)	2 (3)	1 (1)	
Gender				
Male	18 (22)	10 (12)	8 (10)	.51
Female	63 (78)	33 (41)	30 (37)	
Ethnicity				
Asian	31 (38)	13 (16)	17 (22)	.26
Caucasian	26 (32)	15 (19)	11 (14)	
Hispanic	8 (10)	5 (6)	3 (4)	
Afr. Am.	13 (16)	7 (8)	7 (8)	
Other	3 (4)	3 (4)	0	
Education				
ADN	6 (7.5)	2 (2)	4 (5)	
BSN	69 (85)	37 (46)	32 (39)	
Graduate	6 (7.5)	4 (5)	2 (2)	
Years in Nursing				
0-5	20 (25)	12 (15)	8 (10)	.93
6-10	20 (25)	9 (11)	11 (14)	
11-15	24 (30)	11 (14)	13 (16)	
16-20	14 (17)	9 (11)	5 (6)	
21-30	3 (3)	2 (2)	1 (1)	
Hours worked/ week				
36-40	53 (65)	27 (33)	26 (32)	.86
40-50	24 (30)	15 (19)	9 (11)	
50-60	4 (5)	1 (1)	3 (4)	
Hours worked/day	12.53 (± 0.5)			
12	41 (51)	22 (27)	19 (24)	.90
13	38 (47)	20 (25)	18 (22)	
14	2 (2)	1 (1)	1 (1)	
Hours	6.1 (± 0.5)			
4 or less	12 (15)	5 (6)	7 (9)	.06
6	58 (72)	29 (36)	29 (36)	
8 or more	11 (14)	9 (11)	2 (3)	
Married				
Yes	63 (78)	34 (42)	29 (36)	.67
No	18 (22)	9 (11)	9 (11)	
Children in home	2.5 (± 1.3)			
0	1 (1)	16 (20)	14 (16)	.68
1	28 (34)	7 (9)	7 (9)	
2	14 (17)	11 (14)	8 (10)	
3	19 (24)	7 (9)	8 (10)	
4 or more	19 (24)	2 (3)	2 (3)	
Care for extended family in home				
Yes	21 (26)	13 (16)	8 (10)	.35
No	60 (74)	30 (37)	30 (37)	
Spouse helps w/household management				
Yes	62 (77)	33 (41)	29 (36)	.96
No	19 (24)	10 (12)	9 (11)	

Table 3

Descriptive and Reliability Analysis for Baseline Stress, Social Resources, and Fatigue Instruments (N=81)

	Ranges		Mean	SD	Cronbach	α
	Possible	Actual				
Personal Stress	0 - 49	6 - 30	18.7	5.2	.81	
Work-Related Stress	0 - 165	45 - 165	112.8	28.3	.91	
Stress VAS	0 - 10	0 - 10	3.51	2.8		
Cortisol AM	ND - 1.515	.029 - .706	0.275	0.172		
Cortisol PM		.005 - .789	0.135	0.174		
Alpha Amylase AM	3.1 - 423	5.2 - 259.9	97.1	68.4		
Alpha Amylase PM		4.19 - 415.5	57.1	94.0		
Multidimensional Fat.	20 - 100	20 - 82	45.1	14.1	.92	
Fatigue VAS	0 - 10	0 - 10	3.54	3.1		
Social Resources	0 - 84	0 - 84	68.4	17.2	.95	

Note. PSS=Perceived Stress Scale for Perceived Personal Stress; NSS=Nurse Stress Scale for work-related stress; VAS-S==Visual Analog Scale for Ovcml Stress Baseline; VAS-F; Visual Analog Scale Fatigue for General Fatigue Baselines; MFI=Multidimensional Fatigue Inventory for baseline general fatigue; MSPSS=Multidimensional Scale of Perceived Social Support for social resources.

Raw cortisol values reported in ug/dL and alpha amylase in u/mL

ND= not detected.

Table 4

Comparison of Baseline Descriptive Data for Stress, Fatigue, and Social Support between Day and Night Shift Nurses

Variable	All Nurses (N=81)	Day Shift Nurses (N=41)	Night Shift Nurses (n=38)	Comparison
	Mean (SD)	Mean (SD)	Mean (SD)	<i>p</i>
Personal Stress (PSS)	18.7 (5.2)	18.0 (5.6)	19.5 (4.6)	.21
Work-related Stress (NSS)	112.8 (28.3)	113.1 (29.4)	113.0 (27.4)	.94
Overall Stress (VAS)	3.51 (2.8)	3.5 (2.8)	3.4 (3.0)	.92
Multidimensional Fatigue (MFI)	45.1 (14.1)	45.5 (13.6)	45.5 (13.7)	.80
Overall Fatigue VAS	3.54 (3.1)	3.7 (3.3)	3.4 (3.0)	.74
Social Resources MSPSS	68.36 (17.26)	72.1 (11.9)	64.2 (21.2)	.05

Table 5

Changes in Stress, Fatigue, Cortisol and Alpha Amylase over Three Consecutive 12- hour Workdays

Day Nurses				Night Nurses			
Variables	Mean (SD)	Mean Diff	P	Variables	Mean (SD)	Mean diff	p
Stress VAS							
Day 3 Post-shift	4.2 (2.5)	0.2	.68	Day 3 Post-shift	3.1 (2.5)	0.1	.87
Day 1 Pre-shift	4.0 (2.8)			Day 1 Pre-shift	3.2 (2.1)		
Cortisol							
Day 3 Pre-shift	-1.65 (.93)	- 0.45	.007	Day 3 Pre-shift	-1.79 (.81)	0.18	.19
Day 1 Pre-shift	-1.20 (.79)			Day 1 Pre-shift	-1.97(1.02)		
Day 3 Post-shift	-2.95 (1.01)	0.16	.30	Day 3 Post-shift	-2.31(1.37)	-0.33	.12
Day 1 Post-shift	-3.11 (0.96)			Day 1 Post-shift	-1.96 (.83)		
Alpha Amylase							
Day 3 Pre-shift	4.22 (.93)	0.06	.59	Day 3 Pre-shift	4.76 (.79)	-.06	.54
Day 1 Pre-shift	4.16 (.90)			Day 1 Pre-shift	4.82 (.92)		
Day 3 Post-shift	4.61 (.80)	-0.10	.43	Day 3 Post-shift	4.43 (.89)	0.19	.17
Day 1 Post-shift	4.71 (.81)			Day 1 Post-shift	4.24 (.90)		
Fatigue VAS							
Day 3 Post-shift	4.8 (2.8)	1.2	.06	Day 3 Post-shift	4.5 (2.5)	2.0	.001
Day 1 Pre-shift	3.6 (3.2)			Day 1 Pre-shift	2.5 (2.2)		

Note. Salivary samples were collected between 6am-7am and evening samples between 6pm-7pm with pre-shift as start of a shift, and post-shift as end of the shift.

Table 6

Changes in stress, Cortisol, Alpha Amylase, and fatigue within each work Day 1 and Day 3

Variables	Day Shift Nurses (n = 43)		Night Shift Nurses (n=38)	
	Mean/(SD) Log Trans	<i>p</i>	Mean (SD) Log Trans	<i>p</i>
Visual Analog Scale				
Stress				
Pre-shift Day 1	4.0 (2.8)	.14	3.3 (2.5)	.90
Post-shift Day 1	4.8 (2.5)		3.4 (2.3)	
Pre-shift Day 3	4.0 (2.7)	.66	2.7 (2.4)	.28
Post-shift Day 3	4.2 (2.5)		3.2 (2.5)	
Cortisol				
Pre-shift Day 1	-1.33(0.85)	.005	-2.14 (1.1)	.71
Post-shift Day 1	-3.04 (1.0)		-2.03 (0.77)	
Pre-shift Day 3	-1.69(0.94)	.005	-1.88 (0.86)	.15
Post-shift Day 3	-2.97 (1.0)		-2.33 (1.43)	
Alpha Amylase				
Pre-shift Day 1	4.24 (0.92)	.005	4.83 (0.91)	.001
Post-shift Day 1	4.75 (0.85)		4.29 (0.89)	
Pre-shift Day 3	4.24 (0.91)	.003	4.78 (0.81)	.007
Post-shift Day 3	4.58 (0.78)		4.43 (1.02)	
Fatigue VAS				
Pre-shift Day 1	3.5 (3.2)	.39	2.4 (2.1)	.005
Post-shift Day 1	4.1 (2.9)		4.2 (2.6)	
Pre-shift Day 3	4.1 (2.8)	.18	3.9 (2.3)	.18
Post-shift Day 3	4.8 (2.8)		4.6 (2.5)	

Table 7

Hierarchical Multiple Regression Predicting Cortisol and Alpha Amylase from Baseline Personal and Work-related Stress

Predictor	Post-Shift Cortisol Day 1			Post-Shift Cortisol Day 3			Post-Shift Alpha Amylase Day 1			Post-Shift Alpha Amylase Day 3		
	Day Shift		Night Shift	Day Shift		Night Shift	Day Shift		Night Shift	Day Shift		Night Shift
	ΔR^2	β	ΔR^2	β	ΔR^2	β	ΔR^2	β	ΔR^2	β	ΔR^2	β
Step 1	.03		.05		.01		.20*		.01		.06	
Covariates												
Step 2	.04		.14		.06		.07		.02		.02	
Personal stress		-.06			-.25			.17		.04		-.08
Work stress		-.17		-.36		-.01		-.29		-.13		.17
												.11
Total R ²	.07		.19		.07		.27		.03		.08	
												.04

Note. Covariates were race, hours of sleep between shifts, and number of children in the home. Personal stress=PSS; Work Stress=NSS; General stress=VAS-S; Cortisol and alpha amylase are log-transformed.

* $p=.05$; ** $p=.01$, however none of the models were significant. Standardized beta used.

Tolerance levels for all regression models were checked for collinearity.

Table 8

Hierarchical Regression Predicting Fatigue from Baseline Personal and Work-related Stress

Predictor	Baseline Fatigue (MFI)		Post-Shift Fatigue Day 1		Post-Shift Fatigue Day 3	
	ΔR^2	β	ΔR^2	β	ΔR^2	B
Step 1						
Covariates	.05		.10		.17*	
Step 2						
Perceived stress (PSS)	.09*	.13	.07	-.13	.02	.12
Work stress (NSS)		.26*		.26*		.08
Total R	.14*		.17		.19	

Note. Covariates were race, shift, marital status, care for extended family, years in nursing, baseline fatigue (VAS-F) for cortisol. PSS=Perceived Stress Scale for Personal Stress; NSS= Work-related stress; VAS-F= Visual Analog Scale Fatigue for General Fatigue at baseline; MFI (Multidimensional Fatigue Inventory for baseline general fatigue; MSPSS=Multidimensional Scale of Perceived Social Support for social resources.

* $p=.05$; ** $p=.01$.

Table 9

Hierarchical Regression Predicting Fatigue from Baseline Stress Using Visual Analog Scale

Predictor	Baseline Fatigue (MFI)		Post-Shift Fatigue Day 1		Post-Shift Fatigue Day 3	
	ΔR^2	β	ΔR^2	B	ΔR^2	β
Step 1	.10		.16		.19*	
Covariates						
Step 2	.06*		.17**		.08**	
Overall stress (VAS)		.25*		.44**		.30**
Total R^2	.15*		.33**		.27**	

Note: Covariates were VAS-F, race, marital status, cares for extended family, shift, and years of experience.

VAS-S=Visual Analog Scale for Overall Stress at baseline; Post-Shift Fatigue=Visual Analog Scale Fatigue for Overall Fatigue at baseline.

* $p=.05$; ** $p=.01$.

Table 10

Moderation of Social Resources in the Relationship between Baseline Stress and Fatigue

Predictor	Baseline Fatigue (MFI)		Post-Shift Fatigue Day 1		Post-Shift Fatigue Day 3	
	ΔR^2	B	ΔR^2	B	ΔR^2	β
Step 1 Covariates	.12		.13		.27*	
Step 2 General stress (PSS)	.09*	.10	.07	.12	.02	.15
Work stress (NSS)		.29*		.26*		.02
Step 3 Social Resources	.01	.11	.14**	-.42**	.03	-.11
Step 4 PSS x Social Resources	.08*	.17	.01	.06	.06	.11
NSS x Social Resources		.61*		.07		.005
Total R	.29*		.35		.38	

Note: Covariates (race, marital status, care of extended family, care for extended family, years of experience, and VAS fatigue.

NSS= Work-related stress; VAS-S=Visual Analog Scale for Overall Stress at baseline; VAS-F= Visual Analog Scale Fatigue for Overall Fatigue at baseline; MFI (Multidimensional Fatigue Inventory for baseline Overall Fatigue; MSPSS=Multidimensional Scale of Perceived Social Support for social resources. NSS and MSPSS were centered to avoid multicollinearity.

* $p=.05$; ** $p=.01$.

Table 11

Moderation of Social Resources in the Relationship between Overall Stress and Fatigue

Predictor	Baseline Fatigue (MFI)		Post-Shift Fatigue Day 1 (VAS)		Post-Shift Fatigue Day 3 (VAS)	
	ΔR^2	β	ΔR^2	β	ΔR^2	β
Step 1 Covariates	.12		.13		.28*	
Step 2 Overall stress (VAS)	.08*	.29*	.22**	.50**	.07*	.28*
Step 3 Social Resources	.01	-.08	.11**	-.37**	.03	-.18
Step 4 VAS x Social Resources	.001	-.10	.00	.03	.05*	.74*
Total R^2	.20		.45		.42*	

Note: Covariates (race, marital status, care of extended family, years of experience, and VAS-fatigue.

Visual Analog Scale for Overall Stress at baseline=VAS-S; Visual Analog Scale Fatigue for Overall Fatigue at baseline=VAS-F.

Baseline fatigue=Multidimensional Fatigue Inventory (MFI); Social resources = Multidimensional Scale of Perceived Social Support for social resources.

* $p=.05$; ** $p=.01$.

Table 12

Correlations of Biomarkers and Fatigue for Day Shift Nurses

Measure	1	2	3	4	5	6	7	8	9	10	11	12
1. Cortisol Day 1 AM	-	-.030	.15	.29	.27	.17	.24	.06	-.33*	-.13	-.18	.20
2. Cortisol Day 1 PM		-	-.20	.58*	.23	.39	.11	.26	.28	-.29	.20	-.07
3. Cortisol Day 3 AM			-	-.33*	-.08	-.34*	-.22	-.25	-.01	.25	.13	.18
4. Cortisol Day 3 PM				-	-.13	.005	-.01	-.01	.39*	-.23	.15	-.16
5. Alpha Amylase Day 1 AM					-	.64*	.70*	.56*	.03	-.35*	-.06	.07
6. Alpha Amylase Day 1 PM						-	.68*	.54*	-.19	-.14	-.32*	-.06
7. Alpha Amylase Day 3 AM							-	.71*	-.08	-.12	-.09	.12
8. Alpha Amylase Day 3 PM								-	.23	-.04	.20	.12
9. Fatigue Day 1 AM									-	.00	.61**	.17
10. Fatigue Day 1 PM										-	.17	.34*
11. Fatigue Day 3 AM											-	.40*
12. Fatigue Day 3 PM												-

Note. VAS-F= Visual Analog Scale Fatigue for Overall Fatigue at baseline.

* $p < .05$; ** $p < .01$.

Table 13

Correlations of Biomarkers and Fatigue for Night Shift Nurses

Measure	1	2	3	4	5	6	7	8	9	10	11	12
1.Cortisol Day 1 AM	.	-.28	.56**	-.32	.03	-.20	-.12	-.03	-.01	-.006	-.20	-.12
2.Cortisol Day 1 PM		.	.02	.57**	-.14	-.02	.13	.11	-.04	.04	-.05	-.09
3.Cortisol Day 3 AM			.	.04	.04	-.03	.12	.17	-.06	-.15	-.16	-.37*
4.Cortisol Day 3 PM				.	.08	.13	.45*	.10	-.09	.21	.22	.08
5.Alpha Amylase Day 1 AM					.	.58**	.67**	.62**	-.03	-.40*	-.02	-.07
6.Alpha Amylase Day 1 PM						.	.73**	.83	.11	-.29	-.05	-.14
7.Alpha Amylase Day 3 AM							.	.75**	.07	-.14	.15	.06
8.Alpha Amylase Day 3 PM								.	.19	-.29	-.15	-.07
9. Fatigue Day 1 AM									.	.35*	.29	.40*
10. Fatigue Day 1 PM										.	.18	.38*
11. Fatigue Day 3 AM											.	.48*
12. Fatigue Day 3 PM												.

Note. VAS-F= Visual Analog Scale Fatigue for Overall Fatigue at baseline.

* $p=.05$; ** $p=.01$.

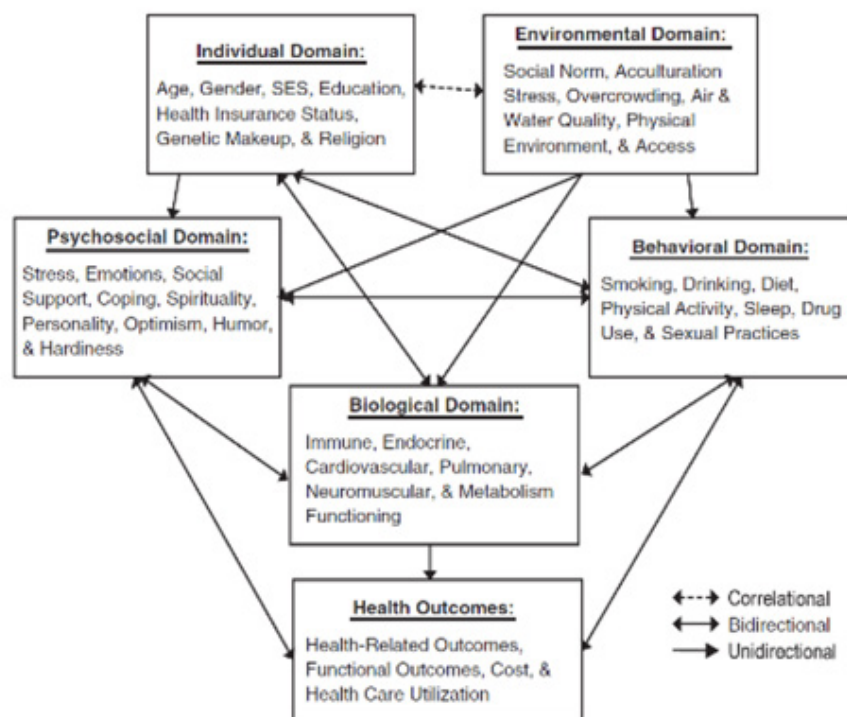


Figure 1. Kang's Biobehavioral Interaction Model

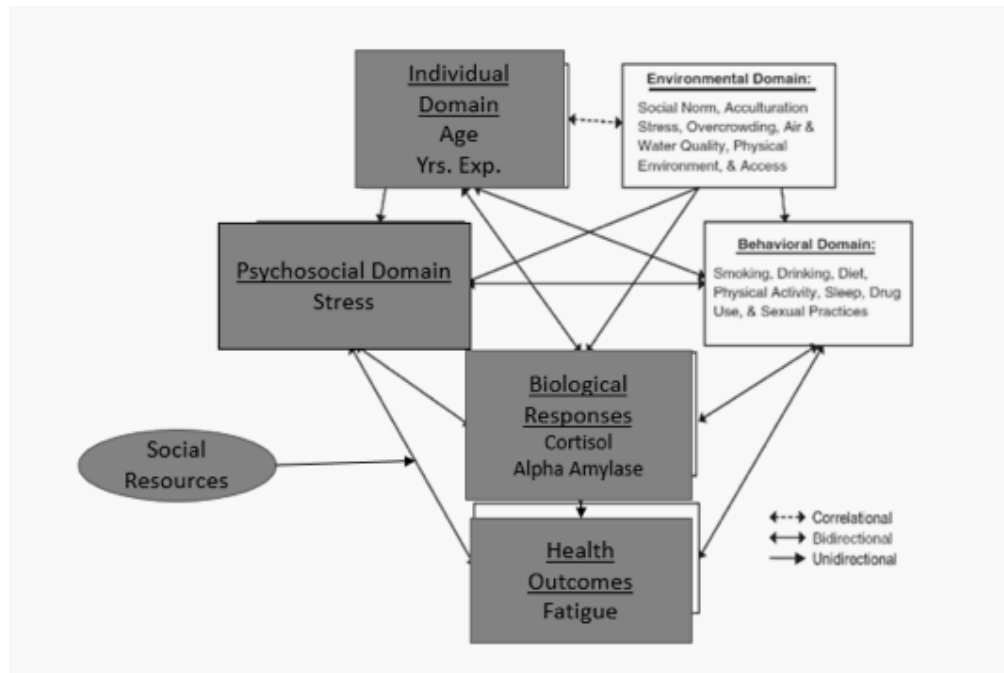


Figure 2. Modified Kang's Behavioral Interaction Theory. Adapted from "Stress and inflammation: A behavioral approach for nursing research by Kang, D., Rice, M., Park, N., Turner-Henson, A. & Downs, C. (2010). *Western Journal of Nursing Research*, 32, 730-760.

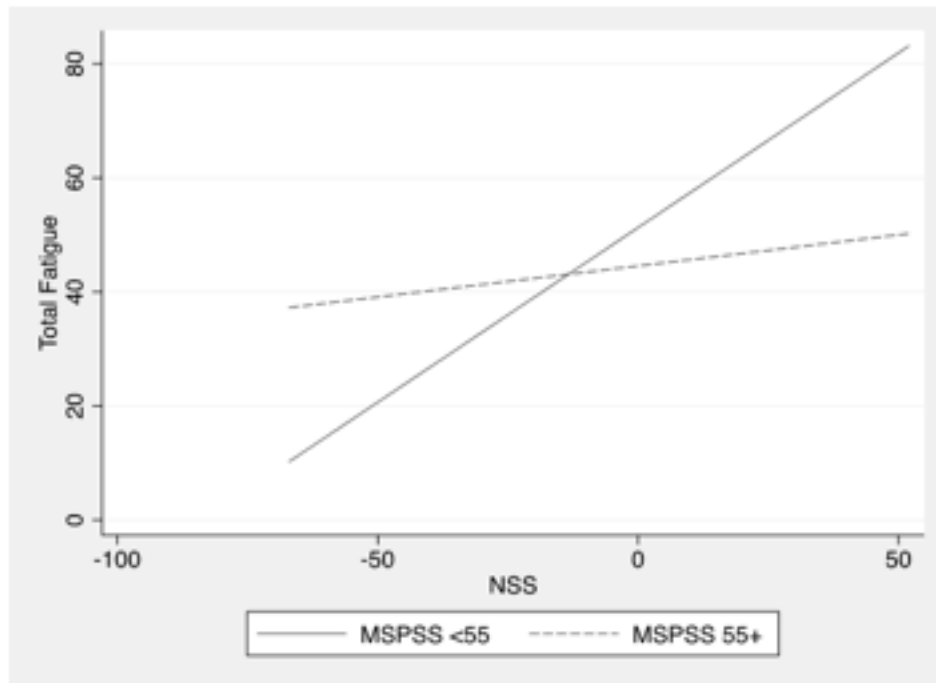


Figure 3. The relationship between NSS and Total fatigue is positive and significant (slope=.61, $p=.01$) for nurses with low social resources (MSPSS<55). This relationship is represented by blue line in the graph below. However, for nurses in the group with high social resources (MSPSS ≥ 55) this relationship is no longer significant (slope=.109, $p=.06$). This is represented by the red discontinuous line in the graph. In other words, social resources moderate the effect of stress (NSS) in baseline fatigue (MFI) by attenuating the effect that stress has in increasing fatigue.

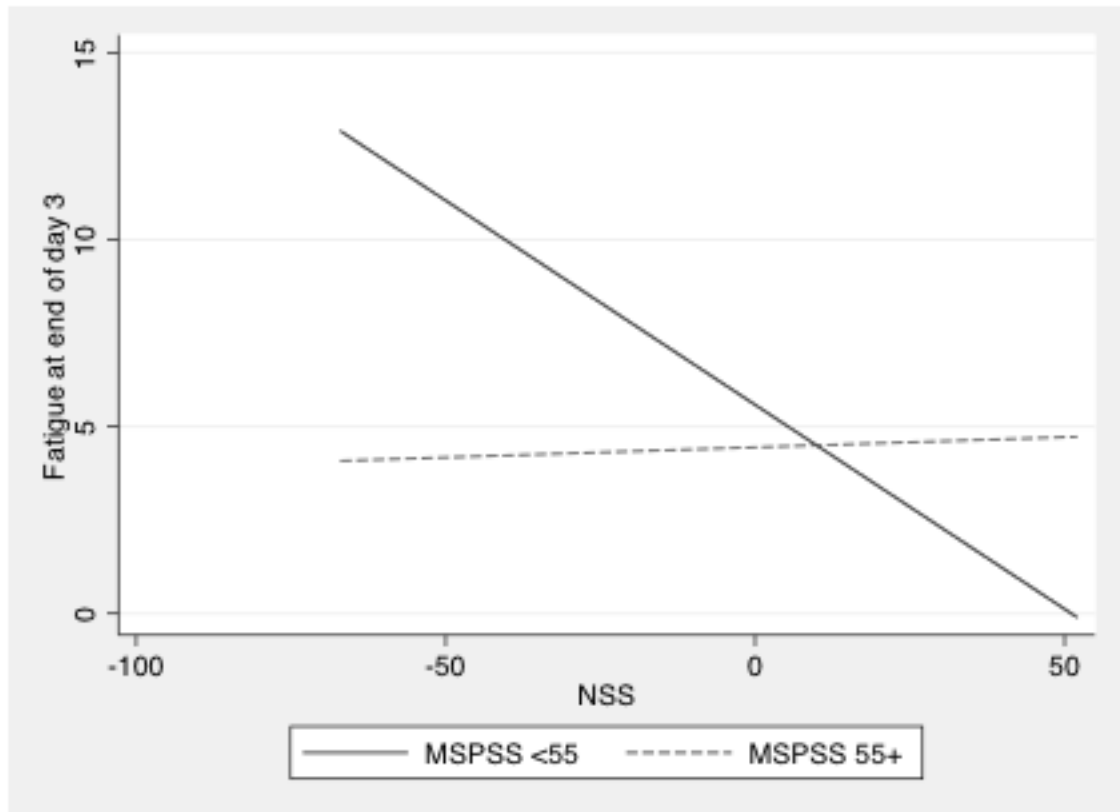


Figure 4. The relationship between NSS and post-shift day 3 fatigue is negative and significant (slope=-.11, $p=.04$) for nurses with low social resources (MSPSS<55). This relationship is represented by blue line in the graph below. However, for nurses in the group with high social resources (MSPSS ≥ 55) the relationship between NSS and post-shift day 3 fatigue is not significant (slope=.01, $p=.62$). This is represented by the red discontinuous line in the graph.

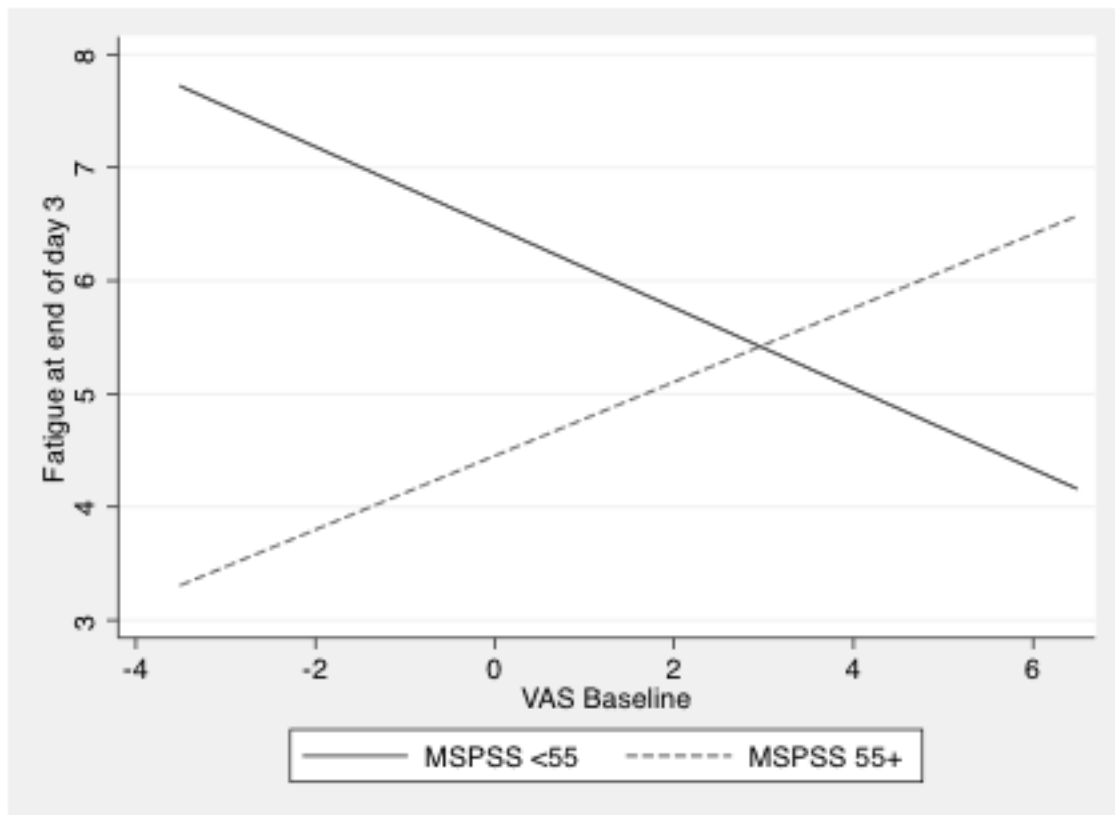


Figure 5. The relationship between VAS-S and post-shift fatigue day 3 is negative and although not significant (slope=-.36, $p=.22$) for nurses with low social resources (MSPSS<55). This relationship is represented by blue line in the graph below. However, for nurses in the group with high social resources (MSPSS ≥ 55) the relationship between VAS-S and post-shift fatigue day 3 is positive and significant (slope=.33, $p=.003$). This is represented by the red discontinuous line in the graph.

Appendix A
Salivary Collection Procedure

Salivary Collection Procedure:

1. Saliva collection occurs between 6am-7am and 6pm-7pm to control for circadian rhythmicity. The participant is reminded to refrain from drinking caffeine at least 2hrs prior to specimen collection.
2. Participants receive a text message 2 hours prior to when saliva collection is required (4 am and 4pm)
3. Before the sample is collected, the participant will be instructed to rinse his/her mouth with water and wait 5 minutes before collecting saliva.
4. Participant will go to a private area to bend the head forward and let the saliva run naturally to the front of the mouth.
5. Open blue top tube, passive drool saliva into tube till reach black marked 2ml line.
6. Participant applies the appropriately labeled specimen label either am or pm.
7. Write the start time on the top of the Visual Analog Scale and end time after 2ml is completed.
8. Alternative method to passive drool is a swab collection method will be used only for those who cannot do a passive drool.
9. Saliva collection specimens are logged in black specimen log prior to placing in portable ice chest for transport to researcher's freezer.
10. AM collection is transported to freezer and batched to take to UTHSC Biolaboratory.
11. PM collection is transported to freezer and batched to take to UTHSC Biolaboratory.
12. Saliva collection, visual analog scale results, and saliva rate are logged in study spreadsheet.

13. The collected specimens will be kept in a cold, portable, dry-ice box for transport to the UTHSC-H Center for Nursing Research Bioscience Laboratory in Houston, Texas. Samples will be stored in -80 degree C until batch assayed using Salimetrics Enzyme Immunoassay kits following the manufacture's instruction.

Appendix B

HMRI IRB



NOTIFICATION OF INITIAL APPROVAL

DATE: 07/09/2014

FROM:

Susan Miller

Chair, HMRI IRB 1

To: Mona Cockerham

Re: IRB0614-0126

Title: Role of Stress and Social Resources on Cortisol and Fatigue in Nurses and Nurse Managers

The Institutional Review Board reviewed your Request for Expedited Review and the above numbered protocol has been FULLY APPROVED. The study is approved from 7/1/2014 through 6/30/2015. Your approved documents are listed below.

- Protocol titled, "Role of Stress (Interpersonal versus Work-Related) and Social Resources and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting"
- Informed Consent Version 1 dated
- HIPAA Authorization Document
- Closing Questionnaire following end of study Document
- Demographic Information Document
- Life Stressors and Social Resources Scale Document
- Multidimensional Fatigue Scale Document
- Nurse Stress Scale Document
- Perceived Stress Scale Document
- Stress and Fatigue Visual Analog Scale Document

Revision. 1. Role of Stress and Fatigue in Nurses and Nurse Managers (0.02) Document
Role of stress in Nurse and Nurse Leaders Flyer Document

Please note that prior to starting any experiments, it is your responsibility to give a copy of this document to all research personnel involved in the project and to discuss the project with each employee. Please ensure that only the most current IRB approved consent may be used during the study. Any changes to the protocol or consent must be approved by the IRB before the changes can take place.

To post information on this clinical trial to the HMRI web site, the study must be listed on ClinicalTrials.gov. Please enter the ClinicalTrials.gov Identifier (i.e., the NCT number) and the Brief Summary from that listing for this trial by clicking on the Submit Web Info activity button in the left navigation list on the study page in the MORTI IRB Module.

If you have any questions or comments, please contact the Office of Research Protection at 713-441-9908 or 713-441-5837 or come to MGJ6-014.

Sincerely,

Susan Miller, MD, MPH

**HMRI IRB 1****NOTIFICATION OF AMENDMENT (EXPEDITED) APPROVAL**

Date: 07/23/2014

From:

Susan Miller

Chair, HMRI IRB 1

To:

Mona Cockerham

CC:

RE: Ame1_Pro00011191 of MS1_Pro00011191 (IRB0614-0126)

Title: Role of Stress and Social Resources on Cortisol and Fatigue in Nurses and Nurse Managers

AMENDMENT APPROVAL DATE: 07/22/2014

The Institutional Review Board has reviewed your amendment submission dated 7/21/2014, to the above numbered protocol and the following changes have been **FULLY APPROVED**.

- Modification to the Protocol Document: Cockerham Summer Proposal revision 4-Kang7.21.2014 Clean.doc
- Modification to the Consent Document: 0614-0126 Consent v2 072214 Amd 1.docx

Please note that prior to starting any experiments, it is your responsibility to give a copy of this document to all research personnel involved in the project and to discuss the project with each employee. Please ensure that only the most current IRB approved consent is being used during the study.

If you have any questions or comments, please contact the Office of Research Protection at 713-441-9908 or 713-441-5837 or come to MGJ6-014.

Sincerely,

Susan Miller, MD, MPH

HMRI IRB 2**Cockerham, Mona G.**

From: IRB
Sent: Tuesday, May 19, 2015 5:01 AM
To: Cockerham, Mona G.
Subject: Your amendment request is approved



ID: [Ame2 Pro00011191](#) / IRB0614-0126

Title: Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

Description: The amendment listed above has been approved by the IRB and an approval letter being is issued for your record. To navigate to the project workspace, click on the above ID.

If you are logging into MORTI from outside the Houston Methodist system, the above link may not work. Please log into MORTI directly at <http://morti.tmhhs.org> and then navigate to the above referenced project.

This e-mail is the property of Houston Methodist and/or its relevant affiliates and may contain confidential and privileged material for the sole use of the intended recipient(s). Any review, use, distribution or disclosure by others is strictly prohibited. If you are not the intended recipient (or authorized to receive for the recipient), please contact the sender and delete all copies of the message. Thank you.

Houston Methodist Research Institute
6670 Bertner
Houston, TX 77030
713-441-1261

**HMRI IRB 3**

To: Cockerham, Mona G.

Reply-To: IRB@houstonmethodist.org

Date: October 22, 2015

Title: Your amendment request is approved

ID: Ame3_Pro00011191 / IRB0614-0126

Title: Role of Stress (Interpersonal versus Work-Related) and Social Resources on
Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

Description: The amendment listed above has been approved by the IRB and an approval
letter being is issued for your record. To navigate to the project workspace, click on the
above ID.

Houston Methodist Research Institute
6670 Bertner
Houston, TX 77030
713-441-1261



Continuing Review

NOTIFICATION OF CONTINUING REVIEW APPROVAL (EXPEDITED)

TO: Dr. Mona Cockerham

From: Dr. Susan Miller

Chair, HMRI IRB 1

Date: June 2, 2016

RE: Pro00011191

Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol
and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

Dear Dr. Mona Cockerham,

The Institutional Review Board has received your Continuing Review application and the above numbered protocol has been renewed for the following period:

APPROVED Date: 6/1/2016

EXPIRATION: 5/31/2017

The Continuing Review was approved by Expedited Review for minimal risk research, or research with only minimal risk procedures remaining.

****PLEASE NOTE:** The Informed Consent has not been updated since the study status is Data Analysis Only (Data collection has been completed)**

If you have any questions or comments, please contact the Office of Research Protection at 713-441-5848 or 713-441-5837 or come to MGJ6-014. 1130 John Reeman Blvd, Houston, TX 77030.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States

Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HMRI Federal Wide Assurance No. FWA 00000438, as well as those of hospitals and institutions affiliated with the Institute.

Appendix C

CPHS


Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

Mona Cockerham
UT-H - SN - Department of Family Health

NOTICE OF APPROVAL TO BEGIN RESEARCH
July 09, 2014

HSC-SN-14-0513 - Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

Number of Subjects Approved: 70 Target: /Screen: 70

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: July 9, 2014

APPROVAL DATE: 07/09/2014

EXPIRATION DATE: 06/30/2015

CHAIRPERSON: John C. Ribble, MD

Subject to any provisions noted above, you may now begin this research.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT DETERMINATION:

Signed Informed Consent Required

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Exempt from HIPAA

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent and HIPAA documents if required, in a manner that ensures subject confidentiality.



Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES

July 29, 2014

HSC-SN-14-0513 - Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting
PI: Mona Cockerham, Nursing

Reference Number: 111860

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Amendment to Protocol Version 1.1 (dated 7/21/2014)
Consent Version 1.2 (dated 7/29/2014)

REVIEW DATE: July 29, 2014

APPROVAL DATE: July 24, 2014

CHAIRPERSON: Rebecca Lunstroth, JD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please**

note that if revisions to the informed consent form were made and approved, then old blank copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.


Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

Dr. Mona Cockerham, Nursing
UT-H - SN - Department of Family Health

NOTICE OF CONTINUING REVIEW APPROVAL

April 08, 2015

HSC-SN-14-0513 - *Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting*

PI: Mona Cockerham, Nursing

PROVISOS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

NOTE: If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at www.clinicaltrials.gov in order to publish results in any of the key peer-reviewed journals. For further information write to clinicaltrials@uth.tmc.edu or call 713-500-7909.

APPROVED: By Expedited Review and Approval

REVIEW DATE: April 07, 2015

APPROVAL DATE: April 08, 2015

EXPIRATION DATE: 03/31/2016

CHAIRPERSON: Rita Swinford, MD

Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

CHANGES: The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in

the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.



Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES

November 02, 2015

HSC-SN-14-0513 - Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

PI: Mona Cockerham, Nursing

Reference Number: 129681

PROVISIONS; Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Revised Protocol Version 2.0 (dated 11/2/2015)
Multidimensional Questionnaire Version 1.1
Revised Consent Document Version 1.1
Closing Questionnaire Version 1.2
Increased Enrollment to 170

REVIEW DATE: November 2, 2015

APPROVAL DATE: November 2, 2015

CHAIRPERSON: Rita Swinford, MD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that if**

revisions to the informed consent form were made and approved, then old blank copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.



Committee for the Protection of Human Subjects

6410 Fannin Street, Suite 1100
Houston, Texas 77030

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES

December 01, 2015

HSC-SN-14-0513 - Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

PI: Dr. Mona Cockerham, Nursing

Reference Number: 130895

PROVISIONS; Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Revisions to Role of Stress and Social Resources on Biomarkers and Fatigue Version 1.1 (Dated 12/1/15)
Increase enrollment to 155.

REVIEW DATE: November 30, 2015

APPROVAL DATE: December 1, 2015

CHAIRPERSON: Rita Swinford, MD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that if revisions to the informed consent form were made and approved, then old blank**

copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.



Committee for the Protection of Human Subjects

6410 Fehsenlin Street, Suite 1100
Houston, Texas 77030

Dr. Mona Cockerham, Nursing
UT-H - SN - Department of Family Health

NOTICE OF CONTINUING REVIEW APPROVAL

February 18, 2016

HSC-SN-14-0513 - *Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting*

PI: Mona Cockerham, Nursing

PROVISOS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

NOTE: If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at www.clinicaltrials.gov in order to publish results in any of the key peer-reviewed journals. For further information write to clinicaltrials@uth.tmc.edu or call 713-500-7909.

APPROVED: By Expedited Review and Approval

REVIEW DATE: February 18, 2016

APPROVAL DATE: February 18, 2016

EXPIRATION DATE: 01/31/2017

CHAIRPERSON: Rita Swinford, MD

Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

CHANGES: The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in

the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.

Appendix D
Research Funding Letter

Research Funding Letter



Administration
18220 Tomball Parkway, Suite 365
Houston, Texas 77070
281-477-1003
Fax: 281-477-1361
www.methodistwillowbrook.com

January 26, 2016

Dear University of Texas Health Science Center Houston - School of Nursing,

As the Vice President and Chief Nursing Officer for Houston Methodist Willowbrook Hospital, I am proud to continue the support of nursing research. This letter confirms my support of \$6750.00 to Mona Cockerham, and the study of "ROLE OF STRESS AND SOCIAL RESOURCES ON BIOMARKERS AND FATIGUE IN STAFF NURSES."

Please bill expenses to:

Houston Methodist Willowbrook Hospital
18220 State Highway 249,
Houston Texas, 77070

The Center for Professional Excellence and Education
Account Number 10204201
Attn: Denise McNulty

If you have billing questions, please contact Charlotte Davis, 281-737-1568.

Sincerely,

A handwritten signature in cursive script that reads "Nancy Keenan".

Nancy Keenan, RN, MSN, MBA, NE-BC
Vice President Operations & Chief Nursing Officer
Office: 281-737-1010
E-mail: nkeenan@houstonmethodist.org

NK/bl

Appendix E
Informed Consents



Informed Consent for Experimental, Observational/Non-Interventional Research

Participant's Name:

Subject ID Number:

Principal Investigator: Mona Cockerham

Study Title: Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting

Funding Source (if applicable): Houston Methodist Willowbrook Hospital

Study Purpose: The purpose of this study is to assess your interpersonal and work-related stress, social resources, salivary cortisol, and fatigue using questionnaires and saliva sampling. This is an experimental, observational study with four-time data collection or more (at the beginning and end of 12-hour shift for at least three consecutive shifts). The findings of this study will help to narrow down the specific focus of future interventions to decrease stress and fatigue in nurses and nurse leaders in an acute care setting to improve health of the nurses, the culture of the work place and patient safety.

Why me: You are a registered nurse or manager working in an acute care setting. This study desires to understand your feelings, observations and experiences of stress and fatigue. You are being asked to take part in this study because you are an acute care nurse working at least 20 hours a week or a nurse leader with 24-hour responsibility over a patient care unit and have not been on vacation in the last two weeks prior to the study.

Study Purpose/Executive Summary:

Stress leads to a positive biobehavioral interaction on the endocrine system and produces a fatigue response. If the fatigue response is not minimized with sleep, rest or exercise could further develop into chronic fatigue. The purpose of this study is assess the effect of stress (interpersonal stress versus work-related stress) on fatigue; (2) Compare the effect of interpersonal stress with the effect of work-related stress on fatigue; (3) Assess the correlation between social resources and stress; (4) Examine the effect of stress on cortisol; (5) Compare the levels of cortisol, stress and fatigue over three consecutive 12-hour shifts; (6) Compare the responses of stress, social resources, cortisol and fatigue between acute care nurses and nurse leaders.

Design: The study is an experimental, observational study with a within-subject repeated measures design.

Procedures: Nurses and Nurse Leaders complete demographic information, 4 questionnaires measuring stress, fatigue, and social resources. Salivary cortisol samples and visual analog scales for stress and fatigue are collected between 6am-7am before and at the end of the 12-hour shift for three or more consecutive shifts. A brief follow-up questionnaire will be provided at the end of the study following the last cortisol sample.

FOR IRB OFFICE USE ONLY

IRB No. 0614-0126 Page 1 of 5
 Consent Approval Date: 05/14/2015 Expiration Date: 06/03/2016
 Consent Version: 3
 HMRI non-interventional ICF template v. 10/16/2013

Patient Label

Data Collection Methods

Prior to Day 1 shift work, all participants will complete the Modified LISRES-A (Interpersonal Stress & Social Resources), Perceived Stress Scale, Nurse Stress Index (work-related stress), and Multidimensional fatigue scale (MFI-20). Visual analog tool scale and saliva samples will be collected as follows:

Day 1	Pre-shift VAS/Salivary cortisol	0 hours worked
	Post-shift VAS/Salivary cortisol	12 hours worked
Day 2	No salivary samples or questionnaires	0 hours worked 12 hours worked
Day 3	Pre-shift VAS/Salivary cortisol	0 hours worked
	Post-shift VAS/Salivary cortisol	12 hours worked
	Follow-up/closing questionnaire	

At the time of saliva collection, a simple visual analogue scale will be offered to assess the levels of stress and fatigue at each time point. All these requirements for questionnaire completion and data collection will take 1 hour to complete.

Protection against Risk: All personal and identifying information including names and identification numbers will not be used in the study. Each participant will be assigned a number for that is used for questionnaires and cortisol samples. The potential loss of confidentiality is the only known risk of being in this study.

The investigators may end the study at any time for administrative reasons, or if data collection is no longer needed.

Your participation in this study is purely voluntary. You can choose to participate at any time without any penalty or loss of benefits to which you are entitled.

What risk will I face by taking part in the study and how will Researchers protect me from these risks?

- Your saliva could be used in research you would find personally objectionable. It is impossible to predict what kinds of research could be performed in the future. Some research may be controversial or sensitive and you will not be able to select in which research your saliva might be used. When you agree to donate saliva, you agree to allow Houston Methodist, its researchers and collaborators to use the saliva in any research that the hospital IRB committee approves.

As with any research study, there may be additional risks that are unknown or unexpected, and very unlikely in this study. If these become known, the study team will notify you in a timely manner of any changes that may change your willingness to participate. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

Research Related Injury: Not applicable in this study. This study will not cause any injury because there is not an intervention.

How could I and others benefit if I take part in this study?

FOR IRB OFFICE USE ONLY

IRB No. 0614-0126

Page 2 of 5

Consent Approval Date: 05/14/2015 Expiration Date: 06/03/2016

Consent Version: 3

HMRI non-interventional ICF template v. 10/16/2013

Patient Label

This study is unlikely to help you. This study may help us learn information about stress and fatigue in nurses and its physiological effect on the body.

You will not learn the results of your testing, unless you request the results in writing.

Potential Benefits of this research: Development of interventions to reduce stress and fatigue in acute care nurses and leaders to improve nurses health, work environment, patient safety and quality outcomes.

There is no cost in participating in this study.

You will not be paid for taking part in the study.

The investigator, Houston Methodist Willowbrook Hospital and Houston Methodist Research Institute does not have any financial interest in the outcome of the study.

If commercial products or other valuable discoveries result from this research project, these products and discoveries could be patented, licensed, or otherwise developed for commercial sale by Houston Methodist Research Institute or the study Sponsor or their respective designees. If this should occur, there are no plans to provide financial compensation to you. There are no plans for you to share in the patent rights, other ownership rights, or rights to control the commercial products and discoveries that may result from this research project.

If I want to stop participating in the study, what should I do?

If you wish to stop your participation in this research study for any reason you should let the principal investigator/study coordinator know as soon as possible so that you can stop safely. You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information".

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights. For questions about your rights as a research participant, or if you have complaints, concerns, or questions about the research, please contact Susan M. Miller, M.D., M.P.H., Chair, Houston Methodist Research Institute Institutional Review Board for the Protection of Human Subjects, at 713-441-2750 or Ethan Natelson, MD, Chair, Houston Methodist Research Institute Institutional Review Board for the Protection of Human Subjects, at 713-441-5154. You may also contact the Director, HMRI Office of Research Protections at HMRI Office of Research Protections, 1130 John Freeman, MGJ6-016, Houston, Texas 77030. Ph: 713-441-7548

The research team will take proper precautions to ensure that any information regarding your identity obtained in connection with this research will remain confidential. A separate form will need to be signed by you to give authorization for the disclosure and use of your private health information.

Where can I get more information?

If you have any questions regarding your participation in this study, please ask us. If you have any additional questions later, please contact the researchers listed below to:

FOR IRB OFFICE USE ONLY

IRB No. 0614-0126

Page 3 of 5

Consent Approval Date: 05/14/2015 Expiration Date: 06/03/2016

Consent Version: 3

HMRI non-interventional ICF template v. 10/16/2013

Patient Label

Principal Investigator: Mona Cockerham
 Mailing Address: 18220 Hwy 249, Houston Texas 77070
 Telephone: 281-731-4475
 Email: mcockerham@houstonmethodist.org

Study Coordinator: same as above

Optional Participation:

USE OF DATA AND / OR SAMPLES

The researchers would like to use your excess saliva samples and data for future research. Your samples may be kept by an external third party Sponsor, HMRI, or a collaborative organization designated by HMRI (such as another research organization, university, or a private company). Once you contribute data and samples, they may no longer be in an identified form that would allow them to be located and destroyed, or there may be other reasons why the samples need to be retained for further study and validation of results. Therefore, when you contribute data or samples, you should assume that it will not be possible for you ever to get them back.

Please ✓ check one:

☐ Yes ☐ No

RECONTACTING PARTICIPANTS

It is possible that, in studying saliva samples and data from you and others, researchers may discover information that would be potentially relevant to your future health. In the event that this occurs, there are no plans to make this information available to you. This is because the tissue samples may have been coded or de-identified in a way that makes it difficult to trace the result back to a specific person, and because the results of research often are too uncertain to be used as specific medical information. Your signature below indicates that you understand this to be true.

Please ✓ check one:

☐ Yes ☐ No

FUTURE CONTACT

Please indicate whether you would or would not be willing to let our researchers get in touch with you in the future, to ask whether you would be willing to contribute more saliva samples or data or participate in another study at that time:

Please ✓ check one:

☐ Yes ☐ No

I have read this consent form. I have discussed it with the research investigator and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I checked 'yes'*.

Signature of Study Participant: _____ Date: _____

FOR IRB OFFICE USE ONLY

IRB No. 0614-0126

Page 4 of 5

Consent Approval Date: 05/14/2015 Expiration Date: 06/03/2016

Consent Version: 3

HMRI non-interventional ICF template v. 10/16/2013

Patient Label

Name (Print Legal Name): _____

Person Obtaining Consent:

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____

FOR IRB OFFICE USE ONLY

IRB No. 0614-0126 Page 5 of 5
Consent Approval Date: 05/14/2015 Expiration Date: 06/03/2016
Consent Version: 3
HMRI non-interventional ICF template v. 10/16/2013

Patient Label

**HOUSTON METHODIST WILLOWBROOK HOSPITAL
AND
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER – HOUSTON**

**“Role of Stress (Interpersonal versus Work-Related) and Social Resources
on Cortisol and Fatigue in
Staff Nurses and Nurse Leaders in an Acute Care Setting”**

INFORMED CONSENT TO JOIN A RESEARCH STUDY

INVITATION TO TAKE PART

You are invited to take part in a research project called, **“Role of Stress (Interpersonal versus Work-Related) and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting”** conducted by Mona Cockerham, RN MSN, Accelerated PhD student and by Dr. Duck-Hee Kang of the University of Texas Health Science Center at Houston School of Nursing. The Principal Investigators (PI) are Mona Cockerham and Dr. Kang. You have been invited to join this research study because you are an acute care nurse working at least 20 hours a week. Your decision to take part is voluntary and you may refuse to take part or choose to stop taking part at any time during the study. A decision not to take part or stop being part of the research project will not affect your work status in any way. You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as IRB number.

DESCRIPTION OF RESEARCH

PURPOSE:

The purpose of this study is to assess your interpersonal and work-related stress, social resources, cortisol, alpha amylase, and fatigue using questionnaires, and how these factors are associated with immune responses in your saliva. In addition, we will assess your current level of stress and fatigue prior and at the end of each shift. This is an observational study with four-time data collection (at the beginning and end of 12-hour shift for three consecutive days) in Houston, Texas. We plan to enroll at least 70 nurses from a Houston community hospital.

PROCEDURE:

If you agree to join this study, you will be asked to do the following activities:

- ☐ You will be asked to complete a basic demographic information form.
- ☐ You will be asked to complete a set of standardized questionnaires regarding the following topics:
 - Interpersonal stress
 - Work-related stress
 - Social Resources
 - Fatigue
- Quick assessment of fatigue and stress – four times at beginning and end of shift on three consecutive days

IRB NUMBER



IRB NUMBER: HSC-SN-14-0513

IRB APPROVAL DATE: 11/02/2015

☐ You will be asked to provide a small saliva sample (2 – 3 ml) each time. The procedure will involve rinsing your mouth, letting saliva collected in the mouth for a few minutes, and passive drool method into a test tube via a small straw. This is a completely non-invasive procedure. The saliva will be transported to the Bioscience Laboratory within the UT School of Nursing for biomarker assessment. Primary interest is in cortisol and alpha amylase (a biomarker) that is responsive to stress.

COLLECTION AND STORAGE OF SALIVA SAMPLES:

If there is a left-over of saliva sample, we hope to keep the sample for additional biomarker analyses. For example, there are several inflammatory and hormonal markers that can provide valuable information to better understand the potential effects of stress and moods on biological responses. Your samples will not be used to test any other condition or tests not related to inflammatory and stress biomarkers. Your samples will not be shared with other researchers. Please circle your response below to allow us to save the samples for additional analyses.

☐ YES NO I agree to allow the left-over saliva sample to be stored for additional biomarker analyses by PI

TIME COMMITMENT:

Your time commitment in this study is about 45 minutes (about 30 minutes to complete the questionnaires and about 15 minutes to provide a saliva samples each time). Your saliva samples will be stored by the PI up to 10 years.

BENEFITS:

You may receive no direct benefit from being in this study. The new information the PI will find by doing this research may help us learn how better to help nurses who are stressed in the future.

RISKS AND/OR DISCOMFORTS:

If you agree to take part in the study, the risks would include potential for others to know you are participating in a study or for your personal information to be inadvertently disclosed although the likelihood for the latter is very low. You may feel uncomfortable to complete questions about stress, social resources, and fatigue and get tired of completing questionnaires. You do not have to answer any questions you do not want to answer. By sharing your sample with the study investigators, there is a risk of the possible loss of your information. Although no identifiable (name, gender, etc.) information will be shared with others outside of this research project, the possibility exists that your information may be taken and used for reasons outside of this project.

ALTERNATIVES:

The only alternative is not to take part in this study.

STUDY WITHDRAWAL:

Your decision to take part is voluntary. You may decide to stop taking part in this research at any time. You will be withdrawn from the study if you are unable to independently complete the questionnaires or saliva sample collection. During and after the study, you will have the right to have your sample destroyed at any time. If you decide to have your sample destroyed, any data or analysis that were done before the request cannot be removed, but no further testing will be done and all remaining samples will be destroyed. This means that if you decide to withdraw from this research, your data collected prior to withdrawal may still be used up to the point of withdrawal.

COSTS, REIMBURSEMENT, AND COMPENSATION:

It will cost nothing to join this study. You will not be paid to be in this study. If you decide to allow your samples to be stored, you are providing your sample to be used by UTHHealth. UTHHealth owns any use of the results, treatments or inventions that can be made from the research. You will not be paid for any use of your samples or results.

CONFIDENTIALITY:

Please understand that representatives of the Committee for the Protection of Human Subjects may review your research for the purposes of verifying research data, and will see personal identifiers. However, identifying information will not appear on records retained by the investigators. You will not be personally identified in any reports or publications that may result from this study. A special number will be used to identify you in the research project. Only the principal investigator will know your name.

The left-over saliva samples will be stored in -80oC freezer in the Bioscience Laboratory of the UT School of Nursing Center for Nursing Research for up to 10 years for additional analysis as needed. At the end of this storage period, samples will be discarded following the university biosafety guidelines. The sample bank is administered by the University of Texas Health Science Center Houston (UTHSC-H) and will remain with UTHSC-H unless the UTHSC-H agrees to release and/or transfer the samples. Please be aware that if the PI leaves the University, the samples within the sample bank will remain the property of UTHSC. The University's ownership includes the right to transfer ownership to other parties, including commercial sponsors.

QUESTIONS:

The PI, Mona Cockerham or Dr. Duck-Hee Kang, will be glad to answer any further questions you may have at any time. You can contact her to discuss problems, voice concerns, obtain information, and offer input in addition to asking questions about the research. Mona Cockerham, 281-731-4475 or Dr. Kang can be reached at 713-500-2052.

SIGNATURES:

IRB NUMBER: HSC-SN-14-0513

IRB APPROVAL DATE: 11/02/2015

Sign below if you understand the information given to you about the research and choose to take part. Make sure that your questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at 713-500-7943. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research, and offer input about current or past participation in a research study. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of the Participant

Signature of the Participant Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

CPHS STATEMENT:

This study has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at 713-500-7943.

Appendix F

Permissions

Request Permission to Use Multidimensional Fatigue Scale-20

From: Cockerham, Mona C

Sent: Friday, February 12, 2016 10:43 AM

To: j.w.boot@amc.nl

Subject: Request permission to use MFI-20

Dr. Smets,

I am a PhD student and I am writing for permission to use the MFI-20 in a nurse stress study. Please provide information also on scoring.

Many thanks

Mona Cockerham, PhDc MSN, RN

Accelerated PhD Student, Vivian Smith Foundation Scholar

UTHSC School of Nursing

Houston Texas 77070

Cell (281) 731-4475

Mona.C.Cockerham@uth.tmc.edu

MFI Query Letter Response

From: E.M.A. Smets [e.m.smets@amc.uva.nl]

Sent: Thursday, February 18, 2016 5:07 AM

To: Cockerham, Mona C

Subject: MFI

Dear Mona,

Thank you for your interest in the MFI. Please find the questionnaire, scoring instructions and a bibliography attached.

Kind regards,

Ellen smets

Ellen M.A. Smets, PhD

professor Medical Communication | Medical Psychology J3-220

Academic Medical Center | University of Amsterdam

P.O.box 22660 | 1100 DD Amsterdam | The Netherlands

Permission to Use Nurse Stress Scale

From: Cockerham, Mona C
Sent: Friday, February 12, 2016 11:08 AM
To: andersonj@purdue.edu
Subject: Permission to use Nurse Stress Scale

Dr. Anderson,

I am a PhD student, I have attempted to reach your colleague Dr. Pamela Gray-Toft. I am writing to request permission to use the Nurse Stress Scale for my dissertation study. I am also interested in the scoring guidelines for the scale.

Can you please grant me permission to use the Nurse Stress Scale?

Thanks

Mona Cockerham, MSN, RN
Accelerated PhD Student, Vivian Smith Foundation Scholar
UTHSC School of Nursing
Cell (281) 731-4475
Mona.C.Cockerham@uth.tmc.edu

Nurse Stress Scale Query Letter Response



COLLEGE OF LIBERAL ARTS

Department of Sociology

January 2015

RE: Nursing Stress Scale

I have enclosed a copy of the Nursing Stress Scale. You have our permission to use the Nursing Stress Scale in your research. Please cite the original source in the Journal of Behavioral Assessment, Vol. 3, No. 1, 1981, pp. 11-23. Please note that six of the items were dropped on the basis of the factor analysis. I have checked the final 34 items that were included on the enclosed copy of the NSS.

Good luck. I would be most interested in receiving a copy of any of the publications that result from the research. Please call me at (765) 494-4703 or send me an email if you have any questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James G. Anderson".

James G. Anderson, Ph.D.
Professor of Medical Sociology
Professor of Health Communication
(765) 494-4668
FAX: (765) 496-1476
e-mail: andersonj@purdue.edu
web.ics.purdue.edu/janders1

DISTINGUISH *yourself*

Appendix G

Study Instruments

Demographic Information

1. Age
 - a. 20-26 b. 30-36 c. 40-49 d. 50-59 e. 60 or older
2. Level of education
 - a. Diploma b. Associate c. BSN d. Masters e. Certified in specialty
3. Years of experience as an RN
 - a. < 5 years b. 5-9 years c. 10-19 years d. 20-29 years e. 30 or more
4. Years in management
 - a. 1-5 years b. 5-10 years c. 10-15 years d. 15 to 20 years e. 20-30 years
5. Normal hours of work a week
 - a. 20-30 hours b. 30-40 hours c. 40-50 hours d. 50 or more
6. Average hours worked per day
 - a. 12 hours b. 13 hours c. 14 hours d. 15 hours e. 16 hours
7. Hours of sleep per night between shifts
 - a. 4 hours or less b. 6 hours c. 8 hours d. 10 plus hours
8. Are you married? Yes or No
9. How many children do you have living in your home?
 - a. One b. Two c. Three d. Four or more
10. Do you care for extended family members in your home?
 - a. Yes b. No
11. Does your spouse help with home responsibilities?
 - a. Yes b. No
12. Please describe the percentage weight you carry managing home/family responsibilities?
 - a. 30 b. 50 c. 75 d. 100



MFI® MULTIDIMENSIONAL FATIGUE INVENTORY

© E. Smets, B. Garssen, B. Bonke (2013) .

Instructions:

By means of the following statements we would like to get an idea of how you have been feeling **lately**.
There is, for example, the statement:

"I FEEL RELAXED"

If you think that this is **entirely true**, that indeed you have been feeling relaxed lately, please, place an **X** in the extreme left box; like this:

yes, that is true ☒1 ☐2 ☐3 ☐4 ☐5 no, that is not true

The more you **disagree** with the statement, the more you can place an **X** in the direction of "no, that is not true". Please do not miss out a statement and place only one **X** in a box for each statement.

1	I feel fit.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
2	Physically, I feel only able to do a little.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
3	I feel very active.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
4	I feel like doing all sorts of nice things.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
5	I feel tired.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
6	I think I do a lot in a day.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
7	When I am doing something, I can keep my thoughts on it.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
8	Physically I can take on a lot.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
9	I dread having to do things.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
10	I think I do very little in a day.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
11	I can concentrate well.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
12	I am rested.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
13	It takes a lot of effort to concentrate on things.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
14	Physically I feel I am in a bad condition.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
15	I have a lot of plans.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
16	I tire easily.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
17	I get little done.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
18	I don't feel like doing anything.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
19	My thoughts easily wander.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true
20	Physically I feel I am in an excellent condition.	yes, that is true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	no, that is not true

Thank you very much for your cooperation

Nurse Stress Scale

(Gray-Toft & Anderson)

Below is a list of situations that commonly occur on a hospital unit. For each item indicate by means of circling how "often" on your present unit you have found the situation to be stressful. Your responses are strictly confidential as a participant in this study.

- | | | | | |
|--|-------|--------------|------------|-----------------|
| 1. Breakdown of computer | Never | Occasionally | Frequently | Very Frequently |
| 2. Criticism by physician | Never | Occasionally | Frequently | Very Frequently |
| 3. Performing procedures that patient experience pain. | Never | Occasionally | Frequently | Very Frequently |
| 4. Feeling helpless in the case of a patient who fails to improve. | Never | Occasionally | Frequently | Very Frequently |
| 5. Conflict with supervisor | Never | Occasionally | Frequently | Very Frequently |
| 6. Listening or talking to a patient about approaching death. | Never | Occasionally | Frequently | Very Frequently |
| 7. Lack of an opportunity to talk openly with other unit personnel about problems on the unit. | Never | Occasionally | Frequently | Very Frequently |
| 8. The death of a patient | Never | Occasionally | Frequently | Very Frequently |
| 9. Conflict with a physician | Never | Occasionally | Frequently | Very Frequently |
| 10. Fear of making a mistake in treating a patient | Never | Occasionally | Frequently | Very Frequently |
| 11. Lack of an opportunity to share experiences and feelings with other personnel on the unit | Never | Occasionally | Frequently | Very Frequently |
| 12. The death of a patient with whom you developed a close relationship | Never | Occasionally | Frequently | Very Frequently |
| 13. Physicians not being present when a patient dies | Never | Occasionally | Frequently | Very Frequently |
| 14. Disagreement concerning the treatment of a patient. | Never | Occasionally | Frequently | Very Frequently |
| 15. Feeling inadequately prepared to help with the emotional needs of a patient's family. | Never | Occasionally | Frequently | Very Frequently |

16. Lack of an opportunity to express to other personnel on the unit my negative feelings toward patients	Never	Occasionally	Frequently	Very Frequently
17. Inadequate information from a physician regarding the medical condition of a patient.	Never	Occasionally	Frequently	Very Frequently
18. Being asked a question by a patient for which I do not have a satisfactory answer.	Never	Occasionally	Frequently	Very Frequently
19. Making a decision concerning a patient when the physician is unavailable.	Never	Occasionally	Frequently	Very Frequently
20. Floating to other units that are short-staffed.	Never	Occasionally	Frequently	Very Frequently
21. Watching a patient suffer.	Never	Occasionally	Frequently	Very Frequently
22. Difficulty in working with a particular nurse (or nurses) outside the unit.	Never	Occasionally	Frequently	Very Frequently
23. Feeling inadequately prepared to help with emotional needs of a patient.	Never	Occasionally	Frequently	Very Frequently
24. Criticism by a supervisor	Never	Occasionally	Frequently	Very Frequently
25. Unpredictable staffing and scheduling	Never	Occasionally	Frequently	Very Frequently
26. A physician ordering what appears to be inappropriate treatment for a patient.	Never	Occasionally	Frequently	Very Frequently
27. Too many nonnursing tasks required, such as clerical work.	Never	Occasionally	Frequently	Very Frequently
28. Not enough time to provide emotional support to a patient	Never	Occasionally	Frequently	Very Frequently
29. Difficulty in working with a particular nurse or nurses on the unit.	Never	Occasionally	Frequently	Very Frequently

30. Not enough time to complete all of my nursing tasks.

Never Occasionally Frequently Very Frequently

31. A physician not being present in a medical emergency.

Never Occasionally Frequently Very Frequently

32. Not knowing what a patient or a patient's family ought to be told about the patient's condition and its treatment.

Never Occasionally Frequently Very Frequently

33. Uncertainty regarding the operations and functioning of specialized equipment.

Never Occasionally Frequently Very Frequently

34. Not enough staff to adequately cover the unit.

Never Occasionally Frequently Very Frequently

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts <i>during the last month</i> . In each case, you will be asked to indicate by circling <i>how often</i> you felt or thought a certain way.									
0 = Never		1 = Almost Never		2 = Sometimes		3 = Fairly Often		4 = Very Often	
1. In the last month, how often have you been upset because of something that happened unexpectedly?						0 1 2 3 4			
2. In the last month, how often have you felt that you were unable to control the important things in your life?						0 1 2 3 4			
3. In the last month, how often have you felt nervous and "stressed"?						0 1 2 3 4			
4. In the last month, how often have you felt confident about your ability to handle your personal problems?						0 1 2 3 4			
5. In the last month, how often have you felt that things were going your way?						0 1 2 3 4			
6. In the last month, how often have you found that you could not cope with all the things you had to do?						0 1 2 3 4			
7. In the last month, how often have you been able to control irritations in your life?						0 1 2 3 4			
8. In the last month, how often have you felt that you were on top of things?						0 1 2 3 4			
9. In the last month, how often have you been angered because of things that were outside of your control?						0 1 2 3 4			
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?						0 1 2 3 4			

Mark "X" at the point along the line that best represents the overall level of stress you have felt over the last month.



Multidimensional Scale of Perceived Social Support Assessment

PERCEIVED SOCIAL SUPPORT ASSESSMENT



afterdeployment.org

MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT ASSESSMENT

Source: The items come from the 12-item Multidimensional Scale of Perceived Social Support. Used with permission

Reference: Zimet, G.D., Powell, S.S., Farley, G.K., Werkman, S. & Berkoff, K.A. (1990). Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment*, 55, 610-17.

Zimet, G.D., Dahlem, N.W., Zimet, S.G. & Farley, G.K. (1988). The Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment*, 52, 30-41.

Scale Description: A 12-item scale of perceived social support from family and friends. Does not refer to deployment.

Scoring and Algorithm

Note: For each assessment, there is an algorithm leading to one of three acuity ranges. The logic for the user receiving specific feedback is included in the algorithms below.

Scoring, Algorithm and Feedback notes

Each item is scored 1-7 as indicated below. Total is sum of all 12 items, possible range for total is 7-84.

All items are scored:

Very Strongly Disagree = 1
 Strongly Disagree = 2
 Mildly Disagree = 3
 Neutral = 4
 Mildly Agree = 5
 Strongly Agree = 6
 Very Strongly Agree = 7

Algorithm

Total = 69-84 High Acuity
 Total = 49-68 Moderate Acuity
 Total = 12-48 Low Acuity

PERCEIVED SOCIAL SUPPORT ASSESSMENT



afterdeployment.org

SOCIAL SUPPORT ASSESSMENT

Instructions: We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

Very Strongly Disagree 1	Strongly Disagree 2	Mildly Disagree 3	Neutral 4	Mildly Agree 5	Strongly Agree 6	Very Strongly Agree 7
1.						1 2 3 4 5 6 7
2.						1 2 3 4 5 6 7
3.						1 2 3 4 5 6 7
4.						1 2 3 4 5 6 7
5.						1 2 3 4 5 6 7
6.						1 2 3 4 5 6 7
7.						1 2 3 4 5 6 7
8.						1 2 3 4 5 6 7
9.						1 2 3 4 5 6 7
10.						1 2 3 4 5 6 7
11.						1 2 3 4 5 6 7
12.						1 2 3 4 5 6 7



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Visual Analog Scale for Stress and Fatigue



Visual Analog Scale for Stress and Fatigue

Visual Analog for Stress & Fatigue - Please place an "X" to best describe where you feel right now.

I feel stressed.

0 (not stressed)  _____  10) Extremely stressed

I feel fatigued.

0 (not fatigued)  _____  10) Extremely fatigued

Appendix H

Questionnaire

Managing Stress and Fatigue

1. Hours of worked last week? _____
2. Hours of overtime on average per week? _____
3. How do you manage life- stress?
 - a. Eating
 - b. Hobbies
 - c. Personal relationships with other nurses
 - d. Personal relationships outside of work
 - e. Faith/Pray
 - f. _____
4. How do you manage work-related stress?
 - a. Break away from the unit
 - b. Participating in unit decision-making
 - c. Strong relationship with leader
 - d. Believe what I do makes a difference
 - e. _____
5. How do you manage fatigue?
 - a. Strategic caffeine usage
 - b. Sleep
 - c. Medication/alcohol
 - d. Work-breaks
 - e. _____
6. If you could give advice to a “new nurse” about how to manage stress and/or fatigue related to work and home, what would you recommend?

7. If you could change one process on “your unit” to make it a better work environment, what would it be?

8. If you could change one process “ at home” to help reduce your stress, what would it be?

9. How many shifts do you miss on average per year due to fatigue? _____
10. How many work related injuries have experienced over the last year (reported or unreported)? _____

Comments:

Thank you for your participation in the study.

Curriculum Vitae

Mona Colvin Cockerham, PhD, MSN, RN

Education:

<u>Institution</u>	<u>Dates</u>	<u>Degree</u>	<u>Major/Minor</u>
The University of Texas Health Science Center. Houston, TX.	2013-2016	PhD	Nursing
The University of Texas Health Science Center. Houston, TX.	2015-2016	Post Master's Certificate	Education
The University of Texas Health Science Center. Houston, TX.	2007-2009	MSN	Nursing Leadership & Administration of Complex Health Systems
Louisiana College, Pineville, LA	1985-1990	BSN	Nursing
Southwood High School, Shreveport, LA	1981-1985	Diploma	

Professional and academic career:

<u>Institution</u>	<u>Position/Title</u>	<u>Date</u>
Rapides Regional Medical Center, Alexandria, LA	Staff Nurse	1990-1991
Louisiana State University Hospital and Medical School Shreveport, LA	Staff Nurse/Bone Marrow Transplant Coordinator	1991-1996
St. Francis Hospital, Tulsa, OK	Administrative Coordinator/ Nursing Supervisor	1996-2001
Conroe Regional Medical Center, Conroe, Texas	Nursing Supervisor	2002-2014
Houston Methodist Willowbrook Hospital, Houston, TX.	Nursing Quality Specialist/ Nursing Supervisor	2005-Present

Scholarly society:

<u>Society</u>	<u>Date</u>
Sigma Theta Tau	2007-present
American Nurses Association	2009- present

Publications:

In process of submission

***Cockerham, M.**, Kang, D.H., Motowildo, S., Beiers, M. & Jones, D.M. The Role of Stress and Social Resources on Biological Responses and Fatigue in Acute Care Nurses (Dissertation manuscript- two publications).

Cockerham, M., Kang, D.H., Howe, R., & Weimer, S. Role of Stress and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting. *American Academy of Medical Surgical Nurses*.

***Cockerham, M.**, Kang, D.H., Bergstrom, N., & Jones, D.M. What is Known about Stress, Cognitive Functioning, and Biomarkers in Nurses and Other Healthcare Providers: A Systematic Review.

Presentations

National

Cockerham, M. Kang, D.H., & Howe, R. Stress and Social Resources on Cortisol and Fatigue in Staff Nurses and Nurse Leaders in an Acute Care Setting presented a poster at the 2015 Magnet Conference in Atlanta, Georgia.

Local

Santebanez, L., **Cockerham, M.**, & Chudi Ekwemalor. Risk Factors Associated with Malpractice Catastrophic Payout among Advance Practice Nurses. Poster session presented at the annual conference of University of Texas Health Science Center, Research Day, Houston, TX.

Cockerham, M. & Howe, R. We Brake for Breaks.

Impact of a Responsibility-Free Breaks on Nurse Fatigue and Job Satisfaction.

- Podium presentation, 2015 Nursing Management Conference, Orlando, Florida
- Poster presentation 2014 ANA National Quality Forum, Las Vegas, Nevada
- Poster presentation 2013 Houston Methodist and New York Presbyterian Research Symposium, Houston Texas.

Cockerham, M., Howe, R., & Branson, S. Magnesium Sulfate Safety: Taking Preeclampsia Out of the Emergency Department. Originally identified as part of a class assignment, this project became an institutional quality patient safety project utilizing a rapid cycle change process. The project crossed organizational boundaries and sponsored through the collaborative efforts of nursing supervisor, staff development, and labor and delivery staff. Podium presentation The Methodist Health System Quality Board of Directors, May 2009.

Professional awards and special recognitions:

<u>Award</u>	<u>Date</u>
PhD Student Award of the Year, 2015. Sigma Theta Tau Chapter, Houston, Texas	2015
Nursing Excellence Award. The Good Samaritan Foundation of Houston, Texas	2014
Vivian L. Smith Foundation Scholar, Accelerated PhD Student Award.	2013-2016
Lapin/Landa Scholarship, Master in Nursing Scholarship.	2008-2009

Certifications:

ISO 9001 Lead Auditor, 12/2017

ACLS, expires 02/2017

BLS, expires 02/2017

Professional organizations and participation:

<u>Professional Organization</u>	<u>Office Held and/or Committee Assignment</u>	<u>Date</u>
Texas Nurses Association District #9	Member	2007-present
Sigma Theta Tau	Member	2009- present

Teaching responsibilities:

<u>Course Number</u>	<u>Course Name</u>	<u>Dates: Semester/ Year</u>
The University of Texas Health Science Center at Houston. Houston, TX		
N4527	Professional Practice and Leadership	Spring 2016
N6702B	Nursing Leadership and Administration Practice 1	Spring 2016

Areas of research interest (list):

- Nursing stress, fatigue and workforce issues
- Quality measures, indicators, and outcomes
- Biobehavioral research approach

1. Research Support

Research: Present—Currently Active

Approved Project Period: 1/2016-present

PI: Cockerham, Mona

Co-PI: Kang, D.H.

Source: Houston Methodist Willowbrook

Annual Direct Costs: \$7,600

Title of Project: **ROLE OF STRESS AND SOCIAL RESOURCES ON BIOMARKERS AND FATIGUE IN STAFF NURSES (Dissertation)**

Project Goal: The purpose of this study is to assess how stress, fatigue, and biological responses (cortisol and alpha amylase) affect nurses' cognitive functioning and decision making, and how nurses' job performance is affected by these factors

Approved Project Period: 10/2015-present

PI: Motowidlo, S.

Co-I: Cockerham, M., Beier, M., Kang, D.H., Howe, R.

Annual Direct Costs: Time donated

Title of Project: **NURSES' RESPONSES TO STRESSFUL EVENTS.**

Project Goal: The purpose of the study is to develop a measure to assess the extent to which nurses use prosocial responses to stressful situations. The research will be conducted in two phases: Phase 1 comprises interviews with 50 nurses from whom we will derive content for a measure of nurses' knowledge about the utility of prosocial responses to stressful situations. After a measure is developed, an additional 50 nurses will rate each of the items for the extent to which it expresses prosocial behavior (in Phase 2).

Approved Project Period: 5/2014-8/2014

PI: Cockerham, M.

Co-PI: Kang, D.H., Howe, R.

Source: Houston Methodist Willowbrook Hospital

Annual Direct Costs: \$1,400

Title of Project: **WORK-RELATED AND INTERPERSONAL STRESS ON FATIGUE IN MEDICAL/SURGICAL NURSES AND NURSE LEADERS.**

Project Goal: To assess the effect of stress on salivary cortisol and fatigue between staff nurses and nurse leaders over two consecutive 12-hour workdays.

Period: 6/2010-6/2011

PI: Cockerham, M

Co-PI: Howe, R.

Source: Houston Methodist Willowbrook Hospital

Annual Direct Costs: \$3,500

Title of Project: **WE BRAKE FOR BREAKS.**

Project Goal: Assess the impact of a responsibility-free break on nurse fatigue and job satisfaction.

Participation in academic and administrative activities:**Houston Methodist Willowbrook Hospital:**

National Database for Nursing Quality Indicators (NDNQI)
data team 11/12 - present

Nursing Peer Review Committee 9/13 - present

Community Activities:

National Charity League 9/2011 - present

Camp Nurse 6/2013 - present