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Mindfulness-Based Yoga during Pregnancy:

A Pilot Study Examining Relationships between Stress, Anxiety, Sleep, and

Pain

by

Amy E. Beddoe

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Nursing

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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by

Amy Eve Beddoe

Dedication

This work is dedicated to all pregnant women everywhere.

Acknowledgments

I am truly grateful for all the help, support, and encouragement that have been given to me which has allowed me to complete this dissertation. First, I want to thank the members of my committee. I am very grateful to Dr. Kathryn Lee who in her understated way has guided me as advisor, mentor, and dissertation chair. She has been unerring in her judgment. Many thanks to Dr. Holly Kennedy, Dr. Sandra Weiss, and Dr. Paul Yang, who participated in my committee, gave me their time, read my manuscripts, and offered sage advice. I appreciate their willingness to work with me and to help me develop this research. I am grateful to Dr. Steve Paul for his time, statistical advice, and good humor. I offer many thanks to Dr. Scott Anderson and Susan Pottish for their support, knowledge, many discussions, and belief in mind-body research. They helped me to see the value of my work and were instrumental in assisting in the funding received for the actual costs associated with conducting research. I also wish to acknowledge the wonderful Kofi Busia, senior Iyengar teacher, who has guided my knowledge in yoga all these years and has given me confidence to teach yoga to pregnant women in spite of the controversy on which poses are safe. I wish to thank Dr. Jon Kabat-Zinn for his continued confidence in and encouragement of my teaching Mindfulness-Based Stress Reduction over the years, and Nancy-Bardake, a nurse-midwife, for her discussions on mindfulness practices in the prenatal period. I also wish to thank Dr. Judith Lasater for our discussion on prenatal yoga and her donation of copies of her prenatal yoga book. Lastly, I thank my husband and daughter for their continued patience and support, and with great respect, Chögyal Namkhai Norbu for his kindness and wisdom.

Amy E. Beddoe May 22, 2007

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Mindfulness-Based Yoga during Pregnancy: A Pilot Study Examining Relationships Between Stress, Anxiety, Sleep, and Pain

Amy Eve Beddoe Doctorate of Philosophy University of California, San Francisco, 2006

The purpose of this study was to investigate the feasibility and effectiveness of a "mindful-yoga" intervention for healthy pregnant women that blended elements of Mindfulness-Based Stress Reduction and Iyengar style prenatal yoga, on stress, anxiety, sleep, and pain; to estimate statistical power and sample size for a larger study; and to establish whether the treatment is effective for second or third trimester women. The effects of variables on mindful-yoga were studied over time, comparing baseline (Time1) and post-intervention (Time2) data in a single treatment group of 19 English-speaking nulliparous women with healthy pregnancies, 17 of whom adhered to the intervention that met for seven weekly sessions.

Data were analyzed with descriptive statistics, correlations, parametric and nonparametric paired comparisons, and effect sizes. Participants were well-educated, middleclass, and planning vaginal birth. Although no one was currently being treated for psychiatric disorders, nearly 30% had a history of depression or anxiety.

The intervention resulted in higher scores for two facets of mindfulness (Observing and Nonreacting). From Time1 to Time2, third trimester participants demonstrated significant reductions in perceived stress and trait anxiety. Second trimester women demonstrated improvements in pain and sleep. In contrast, the third trimester group experienced worse pain and sleep as pregnancy progressed. To control for gestation, Time1 data for the 8 women who began mindful-yoga in the third trimester (26.5 weeks ± 2.3) were compared with Time2 data for the 9 women who began mindfulyoga in the second trimester (27.1 weeks ± 4.1). Second trimester women at Time2 experienced improved sleep (fewer night awakenings and less wake time during the night) as measured by wrist actigraphy compared to third trimester group baseline data.

This study demonstrated important clinical improvements in sleep and pain for women who began mindful-yoga in their second trimester. Mindful-yoga intervention merits further research for reducing perceived stress and anxiety and second trimester sleep enhancement and pain reduction. The mechanisms of mindful-yoga on stress appraisal, anxiety, sleep, and pain were not clearly linked to mindfulness, and further studies are required to develop theoretical linkages between mindful-yoga and symptom reduction during pregnancy.

Research Supported by NINR NRSA F31 NR009328; the Yoga Research Education Foundation; and the Graduate Student Research Award, University of California, San Francisco.

Approved:

Kathun a Lee

Kathryn A. Lee, RN, PhD, FAAN Dissertation Chairperson

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Chapter One

Introduction

CHAPTER 1:

INTRODUCTION

The Problem and its Significance

Evidence suggests that both perceived stress and anxiety during the prenatal period may contribute directly or indirectly to prematurity (gestational age < 37 weeks) and low birth weight (< 2500 grams). These two frequently studied indicators of neonatal outcome in the United States (U.S.) have incidence rates at 12.7% and 8.2%, respectively (Hamilton, Martin, & Ventura, 2007) and are associated with the majority of neonatal morbidity and mortality (Arias, MacDorman, Strobino, & Guyer, 2003). Neonatal outcomes have not improved in the U.S. despite medical and technological advances and a national effort to increase early access and number of prenatal care visits. Although racial and socioeconomic disparity in birth outcomes exists in the U.S., we do not fully understand its role in those outcomes. The infant mortality rate has increased for the first time in 40 years, from 6.8 infant deaths per 1,000 live births in 2001 to 7.0 in 2002. Most of the mortality increase occurred across all races and was equally distributed among mothers 20–34 years of age (MacDorman, Martin, Matthews, & Hoyert, 2005) signifying worsening neonatal outcomes generalized across all adult childbearing women.

Additionally, during pregnancy, psychological stress and negative mood such as anxiety are risk factors for postpartum depression (Beck, 2001) and cesarean birth now accounts for over 30% of all births (Bastani, Hidarnia, Montgomery, Aguilar-Vafaei, & Kazemnejad, 2006; Saunders, Lobel, Veloso, & Meyer, 2006). Research suggests that psychological stress and negative mood are also associated with greater physical

symptoms during pregnancy (Kelly, Russo, & Katon, 2001). Somatic symptoms such as pain and sleep disturbance occur for a majority of pregnant women (Lee, 1998; National Sleep Foundation, 1998; Ostgaard, Zetherstrom, & Roos-Hansson, 1997; Schweiger, 1972; To & Wong, 2003) and adequate interventions do not exist for these symptoms during pregnancy.

National health objectives for 2010 call for reductions in preterm birth (to 7.6%), low birth weight infants (to 5.0%), very low birthweight infants (VLBW) (to .09%), and cesarean birth among low-risk women (to 15%) (Department of Health and Human Services, 2000). Problems in the above areas remain despite intense work to provide adequate prenatal care and programs to promote abstinence from alcohol, cigarette smoking, and illicit drugs among pregnant women. For this reason, novel programs that promote stress reduction and relaxation may be beneficial and worth testing to improve maternal infant-health outcomes.

The causes of prematurity and other suboptimal birth outcomes are complex. However, psychological stress/distress during pregnancy, which appears to predispose a woman to preterm birth, low birth weight, and elective cesarean birth (Austin & Leader, 2000; Da Costa, Dritsa, Larouche, & Brender, 2000; Hobel & Culhane, 2003; Neggers, Goldenberg, Cliver, & Hauth, 2006; Rondo, Ferreira, Nogueira, Ribeiro, Lobert et al., 2003; Wadhwa, Sandman, Porto, Dunkel-Schetter, & Garite, 1993) is one modifiable risk factor. The linking of stress, and stress responses like anxiety, to a variety of pregnancy and birth outcomes suggests the potential for stress reduction as an appropriate intervention during pregnancy. The National Institute of Mental Health (NIMH; 1999) has endorsed group interventions as promising modalities for people who experience

stress and anxiety. Sparse data exist on interventions for stress reduction and relaxation among pregnant women. Mindfulness-Based Stress Reduction (MBSR), an intervention based on meditation and yoga, has been shown to diminish anxiety and other stress symptoms within a variety of populations and by varied self-report measures (Carlson, Speca, Patel, & Goodey, 2004; Kabat-Zinn, Massion, Kristeller, Peterson, Fletcher et al., 1992; Kristeller & Hallett, 1999; Miller, Fletcher, & Kabat-Zinn, 1995; Rosenzweig, Reibel, Greeson, Brainard, & Hojat, 2003). However, no published studies have evaluated MBSR in pregnant women even though it is currently taught to pregnant women with positive anecdotal results (N. Bardacke, personal communication, May 1, 2003; February 4, 2005). Likewise, although prenatal Hatha yoga has gained popularity, there are no published U.S. data to support its efficacy for pregnant women. In nonpregnant populations, recent studies suggest yoga practices are effective in treating symptoms associated with stress such as depression (Woolery, Myers, Sternlieb, & Zeltzer, 2004), anxiety (Michalsen, Grossman, Acil, Langhorst, Ludtke et al., 2005), back pain (Galantino, Bzdewka, Eissler-Russo, Holbrook, Mogck et al., 2004; Sherman, Cherkin, Erro, Miglioretti, & Deyo, 2005; Williams, Petronis, Smith, Goodrich, Wu et al., 2005), and insomnia (Khalsa, 2004). Therefore, one purpose of this dissertation research was to evaluate the acceptability and effectiveness of a mindfulness meditation and yoga intervention with pregnant women, and to examine the extent to which dimensions of mindfulness could be enhanced with this type of intervention.

Psychological stress and mood are not routinely considered by prenatal healthcare providers as a risk for poor perinatal outcomes. However, studies have shown that this domain of health is as robust a risk factor for poor birth outcomes as physical factors.

Effective group treatment for distress specific to pregnancy has not been examined in the U.S. No studies have evaluated a mindfulness and yoga intervention for its effects on stress, anxiety, sleep, and pain, common symptoms experienced during pregnancy. Therefore, another purpose of this dissertation research was to examine a mindful-yoga intervention during pregnancy on variables of perceived stress, anxiety, pain, and sleep. To date, no published studies have examined the effects of mindful-yoga on pregnant women's perceived stress and anxiety or somatic complaints.

Purpose of the Study

The purpose of this pilot study was to investigate the feasibility and acceptability of a yoga and mindfulness meditation or "mindful-yoga" intervention during healthy, first time pregnancy. This feasibility study examined whether a 7-week mindful-yoga intervention would improve dimensions of mindfulness and thereby reduce self-report measures of: 1) stress, 2) anxiety, 3) pain, and 4) sleep disruption. The efficacy of the intervention was examined by evaluating pre-intervention and post-intervention selfreport scores of mindfulness, perceived stress, anxiety, pain, and sleep disruption. Salivary cortisol samples and wrist actigraphy for sleep-wake monitoring were also used. The process by which mothers incorporate the intervention into their lifestyle, and their satisfaction with the intervention at second and third assessments were also evaluated. Perinatal outcome data about their birth experiences were also collected by postpartum interview. To achieve the purpose of this feasibility pilot study, the following seven aims were addressed and four hypotheses were tested:

<u>Aim #1</u>: to determine whether the intervention would raise mindfulness scores.

Hypothesis: The group at 7 weeks post-intervention would self-report significantly higher mindfulness scores.

<u>Aim #2</u>: to determine whether the a seven-week mindful-yoga intervention would reduce prenatal distress by lowering intensity and frequency of pain and pain interference, lowering levels of anxiety and perceived stress, improving subjective sleep, and increasing levels of physical activity.

Hypothesis: The group at 7 weeks post-intervention would self-report significantly lower intensity and frequency of back pain, lower levels of anxiety and stress, and improved sleep, and greater levels of physical activity, compared to baseline scores.

<u>Aim #3</u>: to determine whether the intervention would improve objective sleep outcomes as estimated by wrist actigraphy.

Hypothesis: The participants would have significantly more total sleep time and less wake time during the night estimated by wrist actigraphy data, at post-intervention than at baseline.

<u>Aim #4</u>: to identify relationships between salivary cortisol levels, stress appraisal, anxiety, sleep disturbance by self-report and actigraph, pain, and mindfulness.

<u>Aim #5</u>: to determine whether pregnant second and third trimester women respond differently to mindful-yoga.

Hypothesis: Pregnant women beginning the intervention in the third trimester would respond differently than women beginning the intervention in the second trimester, with second trimester women demonstrating greater outcome response.

<u>Aim #6</u>: to evaluate the feasibility and desirability for pregnant women of mindful-yoga, a 7-week intervention that combines elements of Mindfulness-Based Stress Reduction and prenatal Iyengar yoga.

Hypothesis: Women who completed the 7-week intervention would report satisfaction with mindful-yoga, practice it at home, and recommend it to others.

<u>Aim #7</u>: to evaluate whether women who completed the 7-week session would use mindful coping skills during labor and birth.

Symptoms often progressively worsen as pregnancy advances. However, it was posited that a mindful-yoga intervention not only would halt the progression of pain and sleep disturbance, it might actually mitigate these symptoms. Likewise, because physical and psychological changes occur as pregnancy advances, it was supposed that women beginning the intervention in the third trimester may respond differently to the intervention than women beginning the intervention in the second trimester.

Advancement of Nursing Science and Practice

Nursing has had a history of focusing on assisting clients within vulnerable populations and during vulnerable time periods to their health. The current emphasis on education and prevention during prenatal care is rooted in this knowledge. The National Institute of Nursing Research has identified its priorities to include research for the special needs of women and biobehavioral aspects of disease prevention. This study combines a biobehavioral approach and utilizes biological markers of distress as well at self-reported symptoms of perceived stress, anxiety, pain, and sleep disturbance. The study was therefore aimed at increasing knowledge about stress during pregnancy, interactions between stress and symptom complaints, and the potential effects of an

intervention tailored for pregnancy that has shown promise for attenuation of psychological distress and cultivation of well-being in non-pregnant populations. The profession of nursing seeks to improve health and birth outcomes through judicial assessment and timely intervention. Several assumptions underpin the study. One assumption is the notion that there are critical periods of relatively greater health risk during pregnancy and birth, both for the mother and the baby. Another assumption is that each woman has a unique past which shapes her individual differences. A third assumption is that future potential adverse outcomes can be altered through judicious and timely intervention. A fourth is that stress can have negative health consequences for mother and infant..

Implicit in this approach is the assumption that an antenatal intervention may influence perinatal outcomes through interaction with critical periods, by altering trajectories of health and illness, and by diminishing stress reactivity. Novel treatments for pregnancy-specific distress and somatic complaints can easily be dovetailed into both childbirth education and nurse midwifery practice.

Theory of Psychological Stress and Coping

The transactional model of stress (Lazarus & Folkman, 1984) is offered as a framework for understanding how mindful-yoga potentially may alter stress appraisal and coping strategies during pregnancy, thereby attenuating the impact of perceived stress and stressful life events. Lazarus and Folkman define psychological stress as "a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering well-being" (p. 19, 1984). This model presents stress, not as an event, but rather a transaction between a person and the

environment. Stress belongs to neither the domain of person nor environment, but instead is a relational process that is dynamic and bidirectional. The theory of psychological stress helps to explain how imbalances between environment, perceived stress, and perceived coping lead to illness.

Appraisal refers to an individual's evaluation of the significance given to an event and her perceived capability to cope using personal resources. It is based on the assumption that the individual is perpetually appraising his or her relationship with the environment. Both individual perception and coping resources influence stress appraisal. Primary appraisals are judgments that an individual makes as to the significance of a specific transaction. They include decisions about relative harm, loss, threat, or challenge that the environment or an encounter poses. Commitments are an aspect of primary appraisals in which the individual weighs the stakes involved in a given situation. Primary appraisal is influenced by an individual's values, beliefs, and commitments (Folkman, 1984; Folkman & Greer, 2000).

Secondary appraisal refers to the individual's evaluation of his or her coping resources. Coping comprises the thoughts and behaviors an individual uses to "regulate distress (emotion-focused coping), manage the problem causing the distress (problemfocused coping), and maintain positive well-being (meaning-based coping) (Folkman & Greer, 2000, p. 12). Both appraisal and coping processes are influenced by attributes of both the individual and the environment/situation. Some person and environment variables are stable and less likely to change while others may be more changeable. Situational factors also influence how a person appraises threat. What happens during the

appraisal process will determine coping behavior and the emotions that arise (Lazarus & Folkman, 1984).

Both primary and secondary appraisals may be conscious or unconscious. Primary and secondary appraisals often occur simultaneously. They influence how a person reacts, behaves, and feels (Folkman, 1984). Folkman and Greer (2000) suggest that hardiness (Kobasa, 1979) and optimism (Scheier & Carver, 1985) are dispositional variables of primary appraisal while situational variables that influence secondary appraisal include hope (Snyder, Harris, Anderson, Holleran, Irving et al., 1991) and selfefficacy or an individual's belief in having the ability to cope with a situation to achieve a specific outcome (Bandura, 1982).

Personal behaviors and skills for coping are examples of secondary appraisals that can be altered. While secondary appraisal often is aimed at controlling perceived threat, primary appraisal processes have much to do with how a person perceives, greets the world, and relates with the environment. Appraisal is laden with assumptions about the world. However, assumptions about the environment and oneself are potentially changeable.

This model (Lazarus & Folkman, 1984) views thought processes as an antecedent that shapes emotion. In turn emotions influence thoughts. Anxiety and depression are considered human emotional responses that arise when stress appraisal is high and a mismatch exists between personal threat and resources. Offering tools to improve coping with the physical and emotional stress of pregnancy, and change threat appraisal could therefore also influence emotional responses to stress. Mindful-yoga is proposed as a way to alter primary and secondary appraisal by fostering coping skills to reduce feelings of

anxiety and perceived stress. Within this theoretical framework, mindful-yoga is suggested as a means of providing additional skills for meaning-based coping and altering the actual perception of stress.

Expanding upon Lazarus and Folkman's (1984) transactional theory of psychological stress and coping, it was hypothesized that the intervention would change aspects of mindfulness and provide skills for meaning-based coping, and by so doing, effect selected variables of stress, anxiety, pain, and sleep. These outcome variables were chosen to estimate the degree of psychological and physiologic distress. Figure 1 depicts the way in which mindfulness skills, proposed as a coping strategy, influence stress appraisal by fostering inner resources and thus altering behaviors and physiologic changes associated with the stress response. The practice of mindful-yoga, by leading to a capacity for being mindful, is proposed as a mediator of stress appraisal and selfregulation of physiological and behavioral outcomes.

The next chapters present three manuscripts that describe aspects of this research study. They have been prepared as manuscripts to be submitted to refereed journals for consideration for publication. Chapter two provides a review of literature that spans published studies from 1980 to the present and examines mind-body interventions during pregnancy and effects on stress, anxiety, and perinatal outcomes. Chapter three is a research manuscript that presents outcomes of this feasibility research specific to the effects of the mindful-yoga intervention during pregnancy. Dimensions of mindfulness as well as self-report data on perceived stress, anxiety, pain, and sleep disturbance for the baseline week before beginning the intervention and for the week following the final intervention session are examined. Chapter four is a manuscript that presents the

outcomes of this feasibility research specific to the objective data on sleep using actigraphy data over three days at baseline and three days at the end of the seven-week intervention sessions. The final chapter provides a synthesis of this research experience and suggestions for clinical practice and further research.

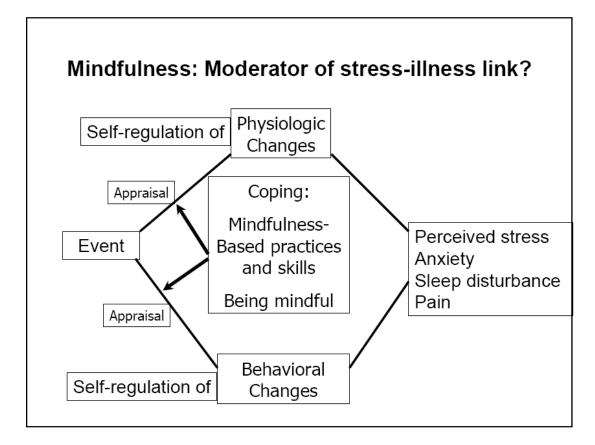


Figure 1. Mindfulness-Based Practices and Skills as the Moderator of Stress Appraisal

References

- Arias, E., MacDorman, M. F., Strobino, D. M., & Guyer, B. (2003). Annual summary of vital statistics--2002. *Pediatrics*, 112, 1215-1230.
- Austin, M. P., & Leader, L. (2000). Maternal stress and obstetric and infant outcomes: Epidemiological findings and neuroendocrine mechanisms. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 40, 331-337.
- Bandura, A. (1982). Self efficacy mechanisms in human agency. *American Psychologist,* 37, 122-147.
- Bastani, F., Hidarnia, A., Montgomery, K. S., Aguilar-Vafaei, M. E., & Kazemnejad, A.
 (2006). Does relaxation education in anxious primigravid Iranian women influence adverse pregnancy outcomes? A randomized controlled trial. *Journal of Perinatal and Neonatal Nursing*, 20, 138-146.
- Beck, C. T. (2001). Predictors of postpartum depression: An update. *Nursing Research*, 50, 275-285.
- Carlson, L. E., Speca, M., Patel, K. D., & Goodey, E. (2004). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress and levels of cortisol, dehydroepiandrosterone sulfate (DHEAS) and melatonin in breast and prostate cancer outpatients. *Psychoneuroendocrinology*, 29, 448-474.
- Da Costa, D., Dritsa, M., Larouche, J., & Brender, W. (2000). Psychosocial predictors of labor/delivery complications and infant birth weight: A prospective multivariate study. *Journal of Psychosomatic Obstetrics and Gynaecology*, *21*, 137-148.
- Folkman, S. (1984). Personal control and stress and coping processes: A theoretical analysis. *Journal of Personal and Social Psychology*, *46*, 839-852.

- Folkman, S., & Greer, S. (2000). Promoting psychological well-being in the face of serious illness: When theory, research and practice inform each other. *Psycho-Oncology*, 9, 11-19.
- Galantino, M. L., Bzdewka, T. M., Eissler-Russo, J. L., Holbrook, M. L., Mogck, E. P.,Geigle, P., et al. (2004). The impact of modified Hatha yoga on chronic low backpain: A pilot study. *Alternative Therapies in Health and Medicine*, *10*, 56-59.
- Hamilton, B. E., Martin, J. A., & Ventura, S. J. (2007, January 11, 2007). *Births: Preliminary data for 2005*. Retrieved February 3, 2007, from
 http://www.cdc.gov/nchs/products/pubs/pubd/hestats/prelimbirths05/prelimbirths
 05.htm
- Hobel, C., & Culhane, J. (2003). Role of psychosocial and nutritional stress on poor pregnancy outcome. *Journal of Nutrition*, 133, 1709S-1717S.
- Kabat-Zinn, J., Massion, A. O., Kristeller, J., Peterson, L. G., Fletcher, K. E., Pbert, L., et al. (1992). Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. *American Journal of Psychiatry*, 149, 936-943.
- Kelly, R. H., Russo, J., & Katon, W. (2001). Somatic complaints among pregnant women cared for in obstetrics: Normal pregnancy or depressive and anxiety symptom amplification revisited? *General Hospital Psychiatry*, 23, 107-113.
- Khalsa, S. B. (2004). Treatment of chronic insomnia with yoga: A preliminary study with sleep-wake diaries. *Applied Psychophysiology and Biofeedback, 29*, 269-278.
- Kobasa, S. C. (1979). Stressful life events, personality, and health: An inquiry into hardiness. Social Psychology, 37, 1-11.

- Kristeller, J. L., & Hallett, B. (1999). Effects of a Meditation-Based Intervention in the Treatment of Binge Eating. *Journal of Health Psychology*, *4*, 357-363.
- Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York: Springer.
- Lee, K. A. (1998). Alterations in sleep during pregnancy and postpartum: A review of 30 years of research. *Sleep Medicine Reviews, 2*, 231-242.
- MacDorman, M. F., Martin, J. A., Matthews, T. J., & Hoyert, D. L. (2005). Explaining the 2001-2002 infant mortality increase: Data from the linked birth/infant death data set. Hyattsville, Maryland: National Center for Health Statistics.
- Michalsen, A., Grossman, P., Acil, A., Langhorst, J., Ludtke, R., Esch, T., et al. (2005).
 Rapid stress reduction and anxiolysis among distressed women as a consequence of a three-month intensive yoga program. *Medical Science Monitor*, *11*, CR555-561.
- Miller, J. J., Fletcher, K., & Kabat-Zinn, J. (1995). Three-year follow-up and clinical implications of a mindfulness meditation-based stress reduction intervention in the treatment of anxiety disorders. *General Hospital Psychiatry*, 17, 192-200.
- National Institute of Mental Health. (1999). Anxiety Disorders (No. NIH Publication OM-99 4152). Bethesda, MD: National Institute of Mental Health, National Institutes of Health, U.S. Department of Health and Human Services.
- National Sleep Foundation. (1998). *Women and Sleep Poll*. Retrieved October 4, 2005, from http://www.sleepfoundation.org/sleeplibrary/index.php?secid=&id=54

- Neggers, Y., Goldenberg, R., Cliver, S., & Hauth, J. (2006). The relationship between psychosocial profile, health practices, and pregnancy outcomes. *Acta Obstetricia et Gynecologica Scandinavica*, *85*, 277-285.
- Ostgaard, H. C., Zetherstrom, G., & Roos-Hansson, E. (1997). Back pain in relation to pregnancy: A 6-year follow-up. *Spine*, *22*, 2945-2950.
- Rondo, P. H., Ferreira, R. F., Nogueira, F., Ribeiro, M. C., Lobert, H., & Artes, R. (2003). Maternal psychological stress and distress as predictors of low birth weight, prematurity and intrauterine growth retardation. *European Journal of Clinical Nutrition*, 57, 266-272.
- Rosenzweig, S., Reibel, D. K., Greeson, J. M., Brainard, G. C., & Hojat, M. (2003). Mindfulness-based stress reduction lowers psychological distress in medical students. *Teaching and Learning in Medicine*, 15, 88-92.
- Saunders, T. A., Lobel, M., Veloso, C., & Meyer, B. A. (2006). Prenatal maternal stress is associated with delivery analgesia and unplanned cesareans. *Journal of Psychosomatic Obstetrics and Gynaecology*, 27, 141-146.
- Scheier, M. F., & Carver, C. S. (1985). Optimism, coping, and health: Assessment and implications of generalized outcome expectancies. *Health Psychology*, *4*, 219-247.
- Schweiger, M. S. (1972). Sleep disturbance in pregnancy. A subjective survey. American Journal of Obstetrics and Gynecology, 114, 879-882.
- Sherman, K. J., Cherkin, D. C., Erro, J., Miglioretti, D. L., & Deyo, R. A. (2005). Comparing yoga, exercise, and a self-care book for chronic low back pain: A randomized, controlled trial. *Annals of Internal Medicine*, 143, 849-856.

- Snyder, C. R., Harris, C., Anderson, J. R., Holleran, S. A., Irving, L. M., Sigmon, S. T., et al. (1991). The will and the ways: Development and validation of an individualdifferences measure of hope. *Journal of Personal and Social Psychology*, 60, 570-585.
- To, W. W., & Wong, M. W. (2003). Factors associated with back pain symptoms in pregnancy and the persistence of pain 2 years after pregnancy. *Acta Obstetricia et Gynecologica Scandinavica*, 82, 1086-1091.
- U.S. Department of Health and Human Services. (2000). *Healthy people 2010: Understanding and improving health* (2nd ed.). Washington, DC: United States
 Government Printing Office.
- Wadhwa, P. D., Sandman, C. A., Porto, M., Dunkel-Schetter, C., & Garite, T. J. (1993).
 The association between prenatal stress and infant birth weight and gestational age at birth: A prospective investigation. *American Journal of Obstetrics and Gynecology*, 169, 858-865.
- Williams, K. A., Petronis, J., Smith, D., Goodrich, D., Wu, J., Ravi, N., et al. (2005).Effect of Iyengar yoga therapy for chronic low back pain. *Pain*, *115*, 107-117.
- Woolery, A., Myers, H., Sternlieb, B., & Zeltzer, L. (2004). A yoga intervention for young adults with elevated symptoms of depression. *Alternative Therapies in Health and Medicine*, 10, 60-63.

Chapter Two

Paper 1

Mind-Body Interventions during Pregnancy:

A Review of the Literature

Chapter Two:

Mind-Body Interventions during Pregnancy: A Review of the Literature

ABSTRACT: Background: Mind-body therapies during pregnancy enjoy increasing popularity yet little is known about their effects. This review examined published evidence on the effectiveness of mind-body interventions during pregnancy, including relaxation, yoga, meditation, and psychoeducation on perceived stress, mood, and perinatal outcomes. Methods: PubMed, Cinahl, PsycINFO, and the Cochrane Library were searched for intervention studies that took place during pregnancy among healthy, adult women during from 1980 to February 2007. Studies were categorized by type of mind-body modality used. **Results:** Of the twelve published studies that met criteria for review, progressive muscle relaxation was the most common intervention. Other studies used a multimodal psychoeducation approach or a yoga and meditation intervention. The research contained methodological problems, primarily absence of a randomized control group or failure to adequately control confounding variables. Nonetheless, there was modest evidence for the efficacy of mind-body modalities during pregnancy. Treatment group outcomes included higher birth weight, shorter length of labor, fewer instrumentassisted births, and reduced perceived stress and anxiety. Further research is necessary to replicate and build on these studies in order to predict characteristics of subgroups that might benefit from mind-body interventions, and to examine cost effectiveness of perinatal outcomes associated with mind-body practices during pregnancy. **Conclusions:** There is evidence that pregnant women have health benefits from mind-body therapies used in conjunction with conventional prenatal care.

Keywords: mind-body intervention, pregnancy, stress-reduction, review

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Research is increasingly suggesting that stress during pregnancy, in animals and humans, affects perinatal outcomes. During the prenatal period both mother and fetus are vulnerable to physical and psychological stress. Although abundant research draws associations between stressors in pregnancy, fetal development, birth outcomes, and health indicators in offspring, few published studies have evaluated the efficacy of interventions provided during pregnancy designed to diminish stress and anxiety or to increase relaxation. The purpose of this review is to critically evaluate the literature on prospective mind-body intervention studies for pregnant women in which stress or relaxation treatment was linked to perinatal outcomes.

Background

Nationwide there has been worsening birth outcomes despite medical and technological advances and efforts to increase early access to prenatal care (1). Evidence suggests that both psychological stress and anxiety during the prenatal period contribute directly or indirectly to prematurity and low birth weight associated with the majority of neonatal morbidity and mortality (2; 3, 4). Higher psychological stress and anxiety during pregnancy have also been associated with unplanned cesareans (5), prolonged sick leave during pregnancy, more frequent visits to prenatal providers (6), analgesia in childbirth (5; 7), postpartum depression (8), alcohol consumption (9), and smoking (10). Ample evidence in animal models links prenatal maternal psychological stress to offspring outcomes that include changes in behavior and learning (11). Psychological distress and

anxiety during pregnancy are at least as significant as other risk factors in predicting adverse perinatal outcomes and therefore require testing interventions that may potentially reduce perceived stress and anxiety.

The prevalence of anxiety in the general population is estimated to be 16.4% and affects twice as many women as men (12). Anxiety is characterized by marked negative affect, bodily tension, and apprehension about the future (13). Prevalence does not diminish during pregnancy which can be a time when psychological problems are common (14). Anxiety is characterized as a disorder, yet it need not always be viewed as a psychopathologic condition. In some cases it is a normal, even healthy reaction to life events. Childbirth qualifies as such an event.

Conceptual Framework

In Lazarus and Folkman's (15) transactional model of stress, anxiety is seen as an emotion that accompanies stress and can arise as a result of a mismatching of person and environment. When an individual's appraisal of threat is not in balance with her resources or capacities for coping, anxiety is a common reaction. Anxiety may be triggered by an important life event such as pregnancy (12) and may prompt learning new tools for coping.

In non-pregnant women mind-body modalities such as yoga and meditation are being increasingly evaluated as nonpharmacologic approaches to reduce anxiety (16-20) and minimize symptoms related to stress such as depression (21), low back pain (22), and insomnia (23). Sparse data exist on interventions for stress among pregnant women who are in particular need of non-pharmacologic types of therapies that do not harm the fetus.

The linking of stress and anxiety to a variety of pregnancy and birth outcomes suggests the potential for mind-body interventions as an appropriate intervention during pregnancy. The National Institute of Mental Health (24) has endorsed group interventions as promising modalities for people who experience stress and anxiety. Data suggest that pregnant women in the U.S. are already using various mind-body therapies to enhance well-being and diminish distress, and that prenatal providers are referring their pregnant patients to yoga, massage, and other modalities (25).

Mind-body "medicine" emphasizes how interactions between the mind, the body, and behavior influence health by way of emotional, mental, social, spiritual, and behavioral factors. Its interventions use techniques that facilitate the mind's capacity to affect bodily function, improve symptoms, and foster health. Guiding this approach is an emphasis on the enhancement of each person's capacity for self-knowledge and self-care. Common mind-body strategies are relaxation, hypnosis, visual imagery, meditation, yoga, biofeedback, tai chi, qi gong, cognitive-behavioral therapies, group support, autogenic training, and spirituality, all of which are thought to foster mind-body processes (26). Mind-body interventions constitute a major portion of the overall use of complementary and alternative medicine (CAM) by the public. In 2002, several relaxation and imagery techniques, biofeedback, and hypnosis, taken together, were used by more than 30% of adults in the United States (US) population (27).

This review evaluates the evidence for relaxation, stress-reduction, and mindbody interventions in reducing prenatal stress and anxiety and maximizing healthy birth outcomes. Evaluation of current literature will identify gaps in knowledge and potential

areas for research to provide evidence-based guidelines to help women who experience maternal stress.

Methods

Studies included in this literature review have the following design elements: they investigated a mind-body modality with adult pregnant women, were prospective in design, original research, contained quantitative data, were published in English in peer reviewed journals, and contained a variable related to psychological stress. Excluded were interventions designed specifically for use in labor, interventions specifically for depressed women, case reports, studies that failed to provide an intervention, and studies about CAM that did not fit into the definition of mind-body medicine (e.g., acupuncture, aromatherapy, and massage) (26; 28).

This review does not evaluate other forms of CAM, such as chiropractic and massage; energy medicine including sound or subtle energy fields; biological based practices such as dietary supplements; or whole medical systems such as Traditional Chinese Medicine and Ayurveda. These four fields are not included within the framework of Mind-Body Therapies as defined by National Center for Complementary and Alternative Medicine (26). Also not covered in this review is biofeedback for specific conditions like headache or urinary incontinence, or hypnosis for management of labor where several reviews are currently available.

Studies of cognitive behavioral therapy were also excluded. Although considered by psychologists as a mind-body therapeutic (28), it is classified as psychotherapy and studies evaluating its efficacy in pregnancy typically focus on psychopathology. Because the effects of social support are well documented in perinatal literature (29; 30),

psychoeducational interventions were not included in this review if they relied solely on social support, education, problem-solving skills or coping strategies that did not explicate a relaxation, imagery or psychosomatic component. As education is a main component of perinatal health care, psychoeducational studies were excluded unless they specified attention to relax or distress.

Literature searches were conducted in three major electronic databases: PubMed, PsychINFO, and CINHAL, and the Cochrane Library between 1980 and February 2007, using a combination of key words: prenatal stress, perceived stress, anxiety, relaxation, stress-reduction, stress-management, pregnancy anxiety, and various mind-body therapy terms (e.g., yoga, meditation, guided imagery, relaxation, biofeedback, psychoeducation, hypnosis, tai chi, and qi gong) and combinations of terms (e.g., "pregnancy AND anxiety AND prenatal AND stress" and "pregnancy AND yoga"). Hand searches were also conducted on references from each study's citations. Studies meeting criteria for inclusion were abstracted into a table to evaluate design elements: (1) aim of study, (2) sampling, (3) variables, (4) intervention protocol (5) data collection, (6) analyses, and (7) findings. Table 1 describes evaluated and included articles.

Results

Several categories of mind-body interventions emerged that investigated efficacy for stress reduction and relaxation in pregnant women. The results are organized by type of mind-body approach. The three approaches were categorized as psychoeducational, relaxation, and yoga or meditation. There were no relevant studies on Tai Chi or Qi Gong. After reviewing biofeedback and hypnosis studies, they were excluded, as the

focus was on labor management, and Smith (31) recently reviewed CAM for pain management in labor.

Psychoeducational Approaches

Psychoeducational approaches often combine psychological strategies for greater personal understanding with group education to help change client attitudes and behaviors. Several studies focused on psychoeducational approaches to deal with fear of childbirth. In one randomized clinical trial (RCT) ten group sessions were provided to 176 low-risk healthy women to test whether fear of giving birth vaginally would decrease (32). Although anxiety did not diminish in the treatment group compared to controls, two specific anxiety items, fear of labor pain (p = .04), and fear of the obstetrician's unfriendly demeanor (p = .05) differed between groups at post-intervention. Treatment group worries about birth also decreased (p = .02) and mean labor time shortened (p=.04).

A second intervention study conducted by the same authors evaluated the effects of five weekly group sessions that discussed fears and feelings about birth, taught positive birth imagery, and included relaxation exercises (33). Subjects were 187 primiparae with severe fear of childbirth. More women in the intervention group chose vaginal birth (82%) compared to controls (67%) (p = 0.02), and mean length of labor was 45 minutes shorter for the intervention group compared to controls. This sample was not randomized, but results suggest that psychoeducation is a promising way to diminish fear of childbirth.

Affonso and colleagues (34) evaluated a psychoeducational approach in 223 nulliparous women. The treatment group received a psychosocial package conducted by

public health nurses in individual sessions to promote adaptation to childbearing. The cognitive adaptation consisted of managing distress, instruction on childbearing topics, mobilizing social support, and integrating cultural beliefs and ethnic healers into pregnant women's lives. By third trimester, the intervention group had significantly lower scores for stressful events and Global Severity than controls receiving standard care. These changes also held at postpartum assessments when the treatment group also scored significantly higher on purpose of life, mastery, and self-esteem.

Relaxation

Relaxation techniques include practices to elicit a state of psychological and physiological relaxation. In some practices, the aim might be to reduce muscular tension (as in progressive muscle relaxation). In others, the primary goal is to achieve a state of reduced sympathetic arousal (28; 35). Urizar and colleagues (36) examined whether cortisol and mood could be altered by a simple reminder during a prenatal care visit to avoid stress. The sample was predominantly low-income and Latina (n=41) and they were instructed to: "Eliminate things that are stressful and/or participate in things that increase your level of relaxation." Women participated in a baseline period during which time data collection occurred but no intervention was provided. This was followed by a wash-out period, a treatment period, and another wash-out period. When given reminders to relax, they reported lower levels of depression and better mood. In addition, morning cortisol levels were lower during the stress-reduction phase. This study lacked a control group and data were collected only once during the non-stress-reduction condition and only once during the stress-reduction.

Teixeira and colleagues (37) conducted a RCT in which 58 pregnant women in the United Kingdom between 28-32 weeks gestation were evaluated before and after a 45-minute period of active-and-passive-relaxation. Active relaxation involved a guided hypnotherapy imagery script while passive relaxation meant sitting quietly, feet up, looking at a fashion magazine. Self-reported state and trait anxiety, maternal heart rate, and serum cortisol concentrations were significantly lowered in both groups from pre- to post-treatment. At post-treatment, state anxiety and maternal heart rate were significantly lower in the active group compared to the passive group. The passive-relaxation group demonstrated significant reductions in norepinephrine compared to the active group and greater drops in cortisol, suggesting that participants in the active-relaxation group were responding to novelty and concentration. Limitations include failure to control for social bias and motivation, and the active group having received support from a "trainer" in learning a new skill.

Bastani and colleagues (38) conducted a RCT to investigate the effect of Ost's (39) progressive relaxation training on anxiety and perceived stress in 110 primiparae. Post-intervention anxiety and perceived stress scores decreased in the intervention group (n=55) compared to controls (p < .001) and perceived stress significantly increased from pre- to post-intervention in the control group. In a separate article, Bastani and colleagues (40) analyzed the sample's birth outcomes. Mean birth weight for infants born to relaxation group mothers averaged 285 grams higher (p < .01). The control group experienced a significantly greater rate of cesarean births (40%) than the relaxation group (15%, p = .001). Prematurity rate differed by group (.02% for controls and .002% for the relaxation group; p = .10). Bastani and colleagues (38; 40) were the first to bring together

a mind-body approach specifically aimed at stress-reduction during pregnancy and to correlate this reduction with perinatal outcomes. Validity of the findings was threatened by a design in which the control group was passive and did not receive an alternate intervention. Anxiety and stress were only measured once at pre- and post-intervention and stress and anxiety data were not normally distributed. The design did not control for mental illness, nor were exclusion criteria disclosed. Some women may have had undiagnosed psychiatric or medical conditions that could contribute to high anxiety scores.

Nickel and colleagues (41) conducted a prospective RCT to evaluate the efficacy of progressive muscle relaxation for pregnant women with asthma. The treatment group (n = 32) underwent a progressive muscle relaxation program that consisted of sequential tensing and relaxing of muscles for 30 minutes three times each week for eight weeks and were instructed to practice at home for 15 minutes twice a day. Controls (n=32) received a placebo of extremity movement for the same time periods. The groups were compared weekly on physiological parameters as well as the SF-36 health survey (42). Analyses showed a significant reduction in systolic blood pressure in the progressive muscle relaxation group at the end of 8-week intervention compared to controls. Treatment group participants reported reduction in anger and improvements in pain, mental health, and role limitations due to emotional problems, all of which can affect perceived stress and anxiety during pregnancy. This study was well designed but had a small sample and needs to be replicated in the US and include birth outcome measures.

Janke (43) compared women with preterm labor who adhered to a daily progressive relaxation exercise with women receiving standard care in a non-randomized

design. A total of 107 women with singleton pregnancies (at 28 ± 2.9 weeks gestation) participated. Inclusion criteria were uterine contractions with cervical change and intact membranes. Three groups were evaluated: the treatment group (n=44), a group receiving standard care (n=40), and a group originally assigned to treatment but unable to adhere to the regimen (n=23). The treatment group was instructed in progressive relaxation and asked to follow daily guided audiotapes at home. They had longer gestation (p < .001) and higher birth weight (p < .001) compared to standard care and non-adherent groups. Confounding these results, however, was the significantly greater preterm labor risk in the nonadherent group compared to treatment and control groups. Lack of randomization and poor adherence limit the external validity of the findings.

To test whether a combined biofeedback and relaxation training would reduce blood pressure and prevent hospital admissions during pregnancy among women with high blood pressure, Little (44) randomized a convenience sample into three groups. One group attended six weekly sessions of relaxation instructions and was asked to listen to a guided relaxation audiotape at home at least once daily. A second group was given the same treatment with the addition of skin-conductance audio-feedback (reflecting sweat gland activity). A third group acted as controls receiving standard care. Fewer women in the relaxation intervention were admitted to hospital than controls (p = .02) and the mean number of days of hospitalization was higher in controls (6.5 days) than either treatment group (2.1 days; p < .03). Systolic blood pressure was significantly lower in relaxationonly treatment group than controls. Proteinuria was more prevalent in controls than both treatment groups (p < .005). Anxiety was assessed but data were not provided, Relaxation

had limited efficacy for women with high blood pressure, and biofeedback did not add to effects achieved by relaxation.

Yoga and Meditation

Although health effects of meditation and yoga for pregnant women are largely unexamined, meditation has been increasingly integrated into healthcare practice over the last two decades as a way to treat or prevent many stress-related illnesses (45; 46). Meditation has been defined as the "intentional self-regulation of attention, a systematic mental focus on particular aspects of inner or outer experience" (28). Two forms of meditation extensively studied in health care settings are transcendental meditation in which the participant repeats a silent word or phrase with the goal of quieting the ordinary stream of internal mental dialogue (47), and mindfulness meditation in which the participant observes, without judgment, any thoughts, emotions, sensations, and perceptions, as they arise in the moment (48). The word "yoga" comes from a Sanskrit root "yuj" meaning to yoke, to join, and thus to direct and concentrate one's attention. The aim of yoga is to calm and unify the mind, body and spirit to promote positive health, self-awareness and spirituality (49). Although yoga originates from Indian philosophy, the practice of yoga does not require spiritual beliefs or religious ritual.

Two Indian studies evaluated the efficacy of a combined program of transcendental-style meditation, yogic breathing, and yoga postures during pregnancy. Narendran and colleagues (50) conducted a prospective study with 335 pregnant women (between 18 and 20 weeks gestation) that evaluated the efficacy of yoga for improving birth outcomes. Women in control and treatment groups were matched for age, parity,

body weight, and Doppler velocimetry scores of umbilical and uterine arteries. Group assignment was based on the distance that each woman lived from the hospital, with those living closer comprising the treatment group. The treatment group practiced yoga, the control group walked twice daily. There were 19% born small for gestational age (<2500) in the yoga group compared to 31% in the control group (p = .01); 21% were born with IUGR in the yoga group compared to 36% in the control group (p = .003); and 14% born prior to 37 weeks gestation in the yoga group compared to 29% in the control group (p = .0006). There were significantly fewer women with PIH accompanied by IUGR in the treatment group (p < .003). The emergency cesarean birth rate for the yoga group was 23% compared to 33% for controls. This difference is clinically important regardless of not attaining statistical significance.

Narendran and colleagues (51) also evaluated the effects of the yoga intervention in a subsample of 121 women with Doppler abnormalities. Sixty-eight women from the yoga group were matched with 53 controls on age, gravida and Doppler velocimetry scores from umbilical and uterine arteries. Mean birth weight of babies in the yoga group was significantly higher (2.8 ± 0.52 kg) than controls (2.6 ± 0.52 kg, p < .02). Complications (including PIH, IUGR, prematurity, emergency cesarean birth, and fetal demise) all showed lower trends in the yoga group. The decreased perinatal mortality and morbidity in this small sample indicate that yoga does no harm and could have potential benefits that outweigh any risks.

Validity of findings in Narendran and colleagues' (50; 51) two Indian studies is weakened by selection bias. Their sample did not have risk factors for poor pregnancy outcomes that are common in developing countries, such as low income, being

unpartnered, living in environments of excessive physical stress, maternal illness, malnutrition, or substance abuse and smoking. Women at risk for preterm birth may demonstrate an even greater benefit from a yoga intervention than was demonstrated by Narendran and colleagues. However, women with higher risk pregnancy may have more difficulty adhering to the intervention, as was found in the Janke study (43). It would be important to replicate these findings in samples from cultures and ethnic groups within the U.S.

Discussion

Data on mind-body interventions for stress and anxiety or for any perinatal outcomes are limited. The reviewed studies have multiple methodological limitations, particularly failure to utilize a random design with adequate placebo. Another limitation is that most of the studies used an inactive control group. Across these studies, variables were measured at different time points, and conceptualization of the interventions differed. When stress and anxiety were measured, these variables were operationalized in various ways. Studies were hampered by small sample sizes and too few data collection points without rationale for the selected time intervals. Most studies relied on convenience samples and thus did not adequately represent the population of pregnant women. These design issues seriously limit the conclusions that can be drawn.

Not only did each researcher envision and deliver the mind-body modality differently, treatments differed by delivery techniques. Interventions were presented in groups, one-on-one in a therapist-client model, by audiotape for self-administration, or in a combination of several methods. Using a guided audiotape at home will yield different effects than an interactive group presentation. These different delivery methods are

predicted to influence effects. Some participants may feel more comfortable than others in a study situation and some relaxation techniques may increase anxiety in some women (52).

These studies ranged across various countries but results are not necessarily generalizable to all pregnant women. The therapist for mind-body modalities cannot be blinded to the treatment and the nature of the intervention may make it difficult to blind women to group assignment. Variables such as social support, the group facilitator's attention, spousal attention, social desirability, and positive expectancy may be partially responsible for results. Since these factors are difficult to identify and cannot be accounted for, RCT studies are essential.

Although intervention research was evaluated, a challenge in appraising these studies was the limited information for the specific intervention. Length of treatment is a quantitative variable in which a linear dose-response is assumed, and mind-body modalities themselves are quite qualitative in nature. Given the various components of an intervention, a comparison between two modalities may be difficult without providing more detail. It is difficult to establish standardized procedures to introduce mind-body modalities, even if instructions are standardized. Professional licensing tells us little about the expertise, abilities, experience, and personal qualities of a therapist and provides no information about overt and covert messages transmitted to pregnant women. Studies have not evaluated the pedagogical element of role modeling, a major feature of Bandura's (53) Social Cognitive Learning Theory which posits that people learn by watching and replicating behaviors. Primiparous women may learn how to be pregnant

and prepare to give birth from watching and imitating role models. Yet, mind-body studies have not yet included this facet of learning theory in their frameworks.

Two decades of research on prenatal stress and anxiety have demonstrated the deleterious effects of stress for pregnant women and their infants. Research that links maternal stress to perinatal outcomes, coupled with data that demonstrate recent deterioration in key outcomes argues for expediency in finding successful strategies to reduce stress and anxiety in the antenatal period. This review of literature would suggest that clinical evidence for improved perinatal outcomes can result from mind-body interventions during pregnancy, and merit further well designed clinical trials. Stress-reduction and relaxation interventions for pregnant women may modify psychoneuroendocrine processes and therefore have both short term effects on the pregnancy as well as long term maternal-child health benefits.

Future studies should include testing culturally relevant interventions. Racial and socioeconomic discrepancies in birth outcomes are well known and may be linked to stress. Further research should include measures of stress by both self-report and biomarkers to examine relationships between perceived stress and physiological reactivity, with attention on timing, as it is not known when maternal stress and anxiety exert their greatest influence and data suggest that stress appraisal is altered by pregnancy (54; 55)

It is well documented that prenatal anxiety predicts postpartum depression but it is not known whether interventions for anxiety during pregnancy would protect against postpartum depression. Well-designed RCTs should follow women throughout pregnancy, provide an intervention for everyday stress, and evaluate for postpartum

depression. There is also limited information on interactions between stress and the potentially buffering effects of mind-body modalities. Positive traits during pregnancy are inversely related to anxiety and stress. Some authors suggest that these qualities can be taught and may buffer against stress (56-58).

Conclusions

There are limited data to support the efficacy of mind-body interventions for stress-reduction during pregnancy. Studies that included progressive muscle relaxation, yoga, and meditation need to be replicated. Research on this phenomenon could contribute to our understanding of stress and anxiety during pregnancy, address how mind-body modalities influence perinatal outcomes, or even evaluate relief from common symptoms of pregnancy such as insomnia or back pain. Results from these types of investigations will add to current knowledge of potentially feasible clinical interventions to improve obstetric and neonatal outcomes.

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| Modality | No. Evaluated | No. Included |
|--------------------------|---------------|--------------|
| Acupuncture | 9 | 0 |
| Exercise | 6 | 0 |
| Hypnosis | 14 | 0 |
| Massage | 9 | 0 |
| Psychoeducation | 7 | 3 |
| Qi Gong | 0 | 0 |
| Relaxation | 7 | 7 |
| Tai Chi | 0 | 0 |
| Yoga and Meditation | 2 | 2 |
| Other CAM | 6 | 0 |
| Individual psychotherapy | 2 | 0 |

Table 1. Evaluation and inclusion of CAM articles

References

- Braveman P, Marchi K, Sarnoff R et al. *Promoting access to prenatal care: Lessons from the California experience*.Menlo Park: The Henry J. Kaiser Family Foundation. Spring 2003.
- Wadhwa PD, Sandman CA, Porto M et al. The association between prenatal stress and infant birth weight and gestational age at birth: A prospective investigation. *Am J Obstet Gynecol* 1993;169:858-865.
- 3. Dole N, Savitz DA, Hertz-Picciotto I et al. Maternal stress and preterm birth. *Am J Epidemiol* 2003;157:14-24.
- Arias E, MacDorman MF, Strobino DM, Guyer B. Annual summary of vital statistics--2002. *Pediatrics* 2003;112:1215-1230.
- Saunders TA, Lobel M, Veloso C, Meyer BA. Prenatal maternal stress is associated with delivery analgesia and unplanned cesareans. *J Psychosom Obstet Gynaecol* 2006;27:141-146.
- 6. Andersson L, Sundstrom-Poromaa I, Wulff M et al. Implications of antenatal depression and anxiety for obstetric outcome. *Obstet Gynecol* 2004;104:467-476.
- Andersson L, Sundstrom-Poromaa I, Wulff M et al. Neonatal outcome following maternal antenatal depression and anxiety: A population-based study. *Am J Epidemiol* 2004;159:872-881.
- Heron J, O'Connor TG, Evans J et al. The course of anxiety and depression through pregnancy and the postpartum in a community sample. *J Affect Disord* 2004;80:65-73.

- Albrecht SA, Rankin M. Anxiety levels, health behaviors, and support systems of pregnant women. *Matern. Child Nurs. J.* 1989;18:49-60.
- McCormick MC, Brooks-Gunn J, Shorter T et al. Factors associated with smoking in low-income pregnant women: Relationship to birth weight, stressful life events, social support, health behaviors and mental distress. *J. Clin. Epidemiol.* 1990;43:441-448.
- Weinstock M. The potential influence of maternal stress hormones on development and mental health of the offspring. *Brain. Behav. Immun.* 2005;19:296-308.
- U.S. Department of Health and Human Services. *Mental health: A report of the surgeon general*. Rockville, MD: U.S. Department of Health and Human Services 1999; www.surgeongeneral.gov/library/mentalhealth/home.html.
- American Psychiatric Association. Anxiety disorders. In. *Diagnostic and* Statistical Manual of Mental Disorders. 4th edn. Washington, DC: The American Psychiatric Association, 1994.
- Altshuler LL, Hendrick V, Cohen LS. An update on mood and anxiety disorders during pregnancy and the postpartum period. *Prim Care Companion J Clin Psychiatry* 2000;2:217-222.
- Lazarus RS, Folkman S. *Stress, appraisal, and coping*. New York: Springer, 1984.
- 16. Beddoe AE, Murphy SO. Does mindfulness decrease stress and foster empathy among nursing students? *J Nurs Educ* 2004;43:305-312.

- 17. Gupta N, Khera S, Vempati RP et al. Effect of yoga based lifestyle intervention on state and trait anxiety. *Indian J Physiol Pharmacol* 2006;50:41-47.
- Rosenzweig S, Reibel DK, Greeson JM et al. Mindfulness-based stress reduction lowers psychological distress in medical students. *Teach Learn Med* 2003;15:88-92.
- Williams KA, Kolar MM, Reger BE, Pearson JC. Evaluation of a wellness-based mindfulness stress reduction intervention: A controlled trial. *Am J Health Promot* 2001;15:422-432.
- 20. Michalsen A, Grossman P, Acil A et al. Rapid stress reduction and anxiolysis among distressed women as a consequence of a three-month intensive yoga program. *Med Sci Monit* 2005;11:CR555-561.
- Woolery A, Myers H, Sternlieb B, Zeltzer L. A yoga intervention for young adults with elevated symptoms of depression. *Altern Ther Health Med* 2004;10:60-63.
- 22. Williams KA, Petronis J, Smith D et al. Effect of Iyengar yoga therapy for chronic low back pain. *Pain* 2005;115:107-117.
- 23. Khalsa SB. Treatment of chronic insomnia with yoga: A preliminary study with sleep-wake diaries. *Appl Psychophysiol Biofeedback* 2004;29:269-278.
- 24. National Institute of Mental Health. *Anxiety Disorders*. NIH Publication OM-99 4152.Bethesda, MD: National Institute of Mental Health, National Institutes of Health, US Department of Health and Human Services 1999; http://www.nimh.nih.gov/publicat/adfacts.cfm.

- Wang SM, Zinno PD, Fermo L et al. Complementary and alternative medicine for low-back pain in pregnancy: A cross-sectional survey. *J Altern Complement Med* 2005;11:459-464.
- National Center for Complementary and Alternative Medicine. Understanding CAM: NCAAM, National Institutes of Health, 2007; http://nccam.nih.gov/health/backgrounds/mindbody.htm.
- Wolsko PM, Eisenberg DM, Davis RB, Phillips RS. Use of mind-body medical therapies. *J Gen Intern Med* 2004;19:43-50.
- Astin JA, Shapiro SL, Eisenberg DM, Forys KL. Mind-body medicine: State of the science, implications for practice. *J Am Board Fam Pract* 2003;16:131-147.
- Hoffman S, Hatch MC. Stress, social support and pregnancy outcome: A reassessment based on recent research. *Paediatr. Perinat. Epidemiol.* 1996;10:380-405.
- Orr ST. Social support and pregnancy outcome: A review of the literature. *Clin Obstet Gynecol* 2004;47:842-855; discussion 881-842.
- Smith CA, Collins CT, Cyna AM, Crowther CA. Complementary and alternative therapies for pain management in labour. *Cochrane Database Syst Rev* 2007:CD003521.
- Saisto T, Salmela-Aro K, Nurmi JE et al. A randomized controlled trial of intervention in fear of childbirth. *Obstet Gynecol* 2001;98:820-826.
- Saisto T, Toivanen R, Salmela-Aro K, Halmesmaki E. Therapeutic group psychoeducation and relaxation in treating fear of childbirth. *Acta Obstet Gynecol Scand* 2006;85:1315-1319.

- Affonso DD, De AK, Korenbrot CC, Mayberry LJ. Cognitive adaptation: A women's health perspective for reducing stress during childbearing. *J Womens Health Gend Based Med* 1999;8:1285-1294.
- Benson H, Greenwood MM, Klemchuk H. The relaxation response: Psychophysiologic aspects and clinical applications. *Int J Psychiatry Med* 1975;6:87-98.
- 36. Urizar GG, Milazzo M, Le HN et al. Impact of stress reduction instructions on stress and cortisol levels during pregnancy. *Biol Psychol* 2004;67:275-282.
- 37. Teixeira J, Martin D, Prendiville O, Glover V. The effects of acute relaxation on indices of anxiety during pregnancy. *J Psychosom Obstet Gynaecol* 2005;26:271-276.
- 38. Bastani F, Hidarnia A, Kazemnejad A et al. A randomized controlled trial of the effects of applied relaxation training on reducing anxiety and perceived stress in pregnant women. *J Midwifery Womens Health* 2005;50:e36-40.
- Ost LG. Applied relaxation: Description of a coping technique and review of controlled studies. *Behav Res Ther.* 1987;25:397-409.
- 40. Bastani F, Hidarnia A, Montgomery KS et al. Does relaxation education in anxious primigravid Iranian women influence adverse pregnancy outcomes? A randomized controlled trial. *J. Perinat. Neonatal Nurs.* 2006;20:138-146.
- 41. Nickel C, Lahmann C, Muehlbacher M et al. Pregnant women with bronchial asthma benefit from progressive muscle relaxation: A randomized, prospective, controlled trial. *Psychother Psychosom* 2006;75:237-243.

- 42. Stewart AL, Ware JE, eds. *Measuring functioning and well-being: The Medical Outcomes Study approach*. Raleigh-Durham (NC): Duke University Press, 1992.
- Janke J. The effect of relaxation therapy on preterm labor outcomes. J. Obstet.
 Gynecol. Neonatal Nurs. 1999;28:255-263.
- 44. Little BC, Hayworth J, Benson P et al. Treatment of hypertension in pregnancy by relaxation and biofeedback. *Lancet* 1984;1:865-867.
- 45. Eisenberg DM, Davis RB, Ettner SL et al. Trends in alternative medicine use in the United States, 1990-1997: Results of a follow-up national survey. *Jama* 1998;280:1569-1575.
- Everly GS, Jr., Benson H. Disorders of arousal and the relaxation response:
 Speculations on the nature and treatment of stress-related diseases. *Int J Psychosom* 1989;36:15-21.
- Canter PH, Ernst E. The cumulative effects of Transcendental Meditation on cognitive function--a systematic review of randomised controlled trials. *Wien. Klin. Wochenschr.* 2003;115:758-766.
- 48. Kabat-Zinn J. Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness. New York: Dell Publishing, 1990.
- 49. Iyengar BKS. *Light on Yoga*, 2nd edn. New York: Schocken Books, 1979.
- 50. Narendran S, Nagarathna R, Narendran V et al. Efficacy of yoga on pregnancy outcome. *J Altern Complement Med* 2005;11:237-244.
- 51. Narendran S, Nagarathna R, Gunasheela S, Nagendra HR. Efficacy of yoga in pregnant women with abnormal Doppler study of umbilical and uterine arteries. J. Indian Med. Assoc. 2005;103:12-14, 16-17.

- Braith JA, McCullough JP, Bush JP. Relaxation-induced anxiety in a subclinical sample of chronically anxious subjects. *J. Behav. Ther. Exp. Psychiatry* 1988;19:193-198.
- Bandura A. Self-efficacy: Toward a unifying theory of behavioral change.
 Psychol. Rev. 1977;84:191-215.
- 54. Glynn LM, Schetter CD, Wadhwa PD, Sandman CA. Pregnancy affects appraisal of negative life events. *J Psychosom Res* 2004;56:47-52.
- 55. Glynn LM, Wadhwa PD, Dunkel-Schetter C et al. When stress happens matters: Effects of earthquake timing on stress responsivity in pregnancy. *Am J Obstet Gynecol* 2001;184:637-642.
- 56. Lobel M, DeVincent CJ, Kaminer A, Meyer BA. The impact of prenatal maternal stress and optimistic disposition on birth outcomes in medically high-risk women. *Health Psychol* 2000;19:544-553.
- 57. Park CL, Moore PJ, Turner RA, Adler NE. The roles of constructive thinking and optimism in psychological and behavioral adjustment during pregnancy. *J Pers Soc Psychol* 1997;73:584-592.
- 58. Seligman MEP. Learned optimism. New York: Knopf, 1990.

Chapter Three

Paper 2

A Feasibility Study of Yoga and Mindfulness Meditation during Pregnancy: Effects on Prenatal Distress and Behavioral Changes

A Feasibility Study of Yoga and Mindfulness Meditation during Pregnancy:

Effects on Prenatal Distress and Behavioral Changes

Abstract

Background: Yoga and stress reduction programs are popular among pregnant women yet there is little evidence of their efficacy.

Objective: The aim of this study was to examine the feasibility and the level of acceptability of a mindful-yoga intervention administered during pregnancy. This pilot study was also intended to gather preliminary data on the efficacy of the intervention in reducing distress and fostering behavioral change.

Design: The study had a single treatment group. Data collection occurred at baseline and post-intervention. Outcomes were evaluated from pre- to post-intervention and between second and third trimesters with Repeated Measures Analysis of Variance and post-hoc nonparametric tests.

Participants: Participants were 16 healthy pregnant nulliparous women with singleton pregnancies between 12 and 32 weeks' gestation at the time of enrollment.

Intervention: The 7-week mindfulness-based yoga intervention combined elements of Iyengar yoga and Mindfulness-Based Stress Reduction.

Outcome Measures: Baseline and posttreatment measures included state and trait anxiety, perceived stress, sleep disturbance, pain, mindfulness, and physical activity. Post-intervention data collection also included participant evaluation of the intervention. Results: Women practicing mindful-yoga in their second trimester had significant reductions in physical pain and sleep disturbance from baseline to post-intervention in contrast to third trimester women whose pain increased. The entire treatment group showed reductions in perceived stress and trait anxiety.

Chapter Three:

A Feasibility Study of Yoga and Mindfulness Meditation during Pregnancy: Effects on Prenatal Distress and Behavioral Changes

There is considerable evidence that psychological distress during pregnancy is associated with adverse perinatal outcomes. The characteristics of psychological stress include anxiety, impaired concentration, depressed immune function, poor coping, muscle tension, and somatic complaints. During pregnancy stress has been associated with alcohol consumption,¹ smoking,² prolonged sick leave, and increased number of visits to care providers.³ It places a woman at risk for obstetric and neonatal complications including unplanned cesarean birth,⁴ lower birth weight,⁵ increased incidence of prematurity,^{6, 7} and postpartum depression.⁸ Additionally, maternal anxiety in the third trimester of pregnancy has been positively correlated with difficult temperament in infancy⁹ and behavioral and emotional problems in children.¹⁰

Physical pain and sleep disturbance reflect components of physical distress during pregnancy. These symptoms are frequently linked to psychological distress and often overlooked in stress research.¹¹ For example, daily stressors and lack of control in the workplace places a pregnant woman at greater risk for developing pain.¹²⁻¹⁴ Pregnant women often report pain as the cause of sleep disturbance,^{15, 16} and psychological distress is also associated with sleep disturbance during pregnancy.^{13, 17} Approximately 70% of pregnant women experience low back pain (LBP) and it may start as early as the first trimester.^{15, 16} Peak onset of LBP occurs between the fifth and seventh month of gestation and pain intensity worsens with advancing gestation.^{18, 19} LBP has been closely linked to

disability, functional impairment,¹⁶ and work absenteeism.^{15, 20} Alterations in sleep also begin in early pregnancy and include frequent awakenings.²¹⁻²³

Psychological and physical distress during pregnancy are at least as significant as other risk factors in predicting adverse perinatal outcomes and therefore requires further study. Yet stress is not routinely assessed during prenatal care. From epidemiological studies, the prevalence of anxiety is estimated in the general population at 16.4%. As the most common stress disorder, anxiety affects twice as many women as men.²⁴ Its prevalence does not diminish during pregnancy when psychological and physical distress are commonly expected.²⁵ The National Institute of Mental Health²⁴ has endorsed group interventions as promising modalities for people who experience stressful life events. Yet few studies using group interventions have evaluated the potential to reduce psychological or physical distress associated with pregnancy.

Group Yoga and Meditation Interventions

Research demonstrates that yoga and meditation can effectively reduce psychological and physical distress in both clinical and non-clinical populations ²⁶⁻²⁸ including depression,^{29, 30} low back pain,³¹ and insomnia.³² Higher stress or anxiety is linked to a variety of pregnancy outcomes, and somatic complaints and sleep disturbance often occur with mood disorder in pregnant women.³³ This link suggests the potential for yoga and meditation as an appropriate intervention during pregnancy.

Women are increasingly using mind/body modalities during pregnancy to enhance well-being. A large survey found that 34% of pregnant women reported using complementary and alternative modalities (CAM) during pregnancy and 62% would consider using CAM as treatment for LBP.³⁴ Prenatal yoga is popular, yet no published studies have evaluated its effectiveness for reducing perceived stress and anxiety, or somatic complaints such as pain and sleep disturbance during pregnancy.

Several researchers have considered the effects of psychological and physiological relaxation on pregnancy. During a prenatal care visit, a simple reminder to avoid stress and participate in things that increase relaxation actually lowered salivary cortisol levels, reduced depression scores, and improved affective mood in a sample of low-income Latina women.³⁵ A randomized trial evaluated self-reported anxiety, maternal heart rate, and serum cortisol concentrations before and after 45-minute periods of active and passive relaxation in 58 pregnant women, and outcomes in both groups significantly improved from pre- to post-treatment.³⁶ Bastani et al.^{37, 38} conducted a randomized clinical trial of 110 healthy Persian primiparae to investigate the effects of a 7-week training program of progressive relaxation on anxiety, perceived stress, and perinatal outcomes. Anxiety and perceived stress scores significantly decreased in the relaxation group compared with controls. Mean birth weight of infants born to mothers in the relaxation group was significantly higher (p = .009) than control infants and cesarean birth rate in the relaxation group was significantly reduced.

Narendran et al.³⁹ tested the effects of a yoga and meditation intervention on perinatal outcomes in a study of 335 healthy pregnant women in India. Significantly fewer treatment group infants were small for gestational age or preterm compared with infants born to control mothers. They also evaluated the effects within a subsample of 121 women with Doppler abnormalities during pregnancy.⁴⁰ In the yoga subgroup, infant birth weight was significantly higher (2.78 ± 0.52 kg.) compared to controls (2.55 ± 0.52 kg, p < .02).

In Lazarus and Folkman's transactional model of psychological stress, anxiety is an emotion that accompanies stress and can result from a mismatching of person and environment.⁴¹ Sleep disturbance and pain are physical symptoms often associated with psychological distress and may be appraised as threatening. When an individual's appraisal of threat is not balanced with her resources or capacities for coping, anxiety and sleep disturbance are common responses. Anxiety may be triggered by an important life event or by transition and change.²⁴ Childbirth qualifies as such a life-changing event. Processes of pregnancy include changes outside a woman's control and require accommodation, particularly when it is the first pregnancy. A mind/body program provided during pregnancy may alter stress appraisal, offer new ways of coping with psychological and physical distress, and form the basis of personal resources needed to weather the storms of stressful life events during pregnancy and the childbirth experience.

Aims and Hypotheses

The primary purpose of this study was to examine the feasibility, acceptability, and potential efficacy of a yoga and mindfulness meditation or "mindful-yoga" intervention during pregnancy. To date, no published studies have examined the effects of mindful-yoga on pregnant women's perceived stress and anxiety or somatic complaints. In this pilot feasibility study, we tested the hypotheses that a 7-week mindfulyoga intervention would reduce self-reports of distress operationalized as: 1) perceived stress, 2) anxiety, 3) pain, and 4) poor sleep. We also hypothesized that pregnant women in their third trimester would respond differently to the intervention than women in their second trimester. A secondary aim was to evaluate whether self-reports of behavioral

change in the form of mindfulness and physical activity improved as a result of the intervention. A third aim of this pilot study was to examine pregnant women's acceptability and satisfaction with the mindful-yoga intervention.

METHODS

Research Design and Procedures

The pilot study was intended to gather data to estimate the effect size required for a larger cohort of subjects and evaluate the feasibility of the intervention. The study used a one group pre-post-intervention design. Baseline and posttreatment assessments included self-report measures of psychological distress (perceived stress and anxiety), physical distress (sleep disturbance and pain), and behavioral change (mindfulness and physical activity). Acceptance of the intervention by participants was also examined after its completion. Data were collected by self-report prior to the first day of the group intervention (Time 1) and immediately after completion of the seven weekly intervention sessions (Time 2).

Subjects

A community sample in central California was recruited from posting approved recruitment flyers throughout the community, including prenatal care provider offices and county-sponsored perinatal programs. Childbirth education programs in two hospitals hand-delivered or mailed out flyers; and 5-minute presentations were made about the study at childbirth education classes. The flyers, emails, and mini presentations explained that the study was to see whether weekly mindful-yoga classes might reduce stress and increase relaxation and that women would be paid up to \$100 for participating.

Women meeting eligibility criteria and interested in participating were enrolled in the study. Eligible women were at least 18 years old, able to read and write English, expecting a first baby, carrying a singleton pregnancy, planning a hospital birth, and between 12 and 32 weeks' gestation when the intervention began. Women were excluded from the study if they reported current psychiatric illness; currently used medications for pain, sleep, depression, or anxiety; worked nightshift; or had diabetes, hypertension, HIV infection or history of back surgery. We screened 42 pregnant women for eligibility, enrolled 23 women, and 19 were able to meet on the day and time of the mindful-yoga group. Two women left the study due to pregnancy complications (one on bed rest for preterm labor without preterm birth after the third class, and the other with preeclampsia and preterm birth after the second class). The final group at Time 2 was comprised of 17 subjects. However, one had incomplete baseline data and was excluded from the analysis.

Participant protection.

The Committee on Human Research at the University of California, San Francisco approved this study. The research was conducted according to the principles outlined in the Declaration of Helsinki. Participation was voluntary; each subject was assured confidentiality and freedom to withdraw from the study at any time.

Measures

Psychological Distress

Perceived stress. The 10-item Perceived Stress Scale $(PSS)^{42}$ was used to estimate the degree to which a person perceives life situations as unpredictable, uncontrollable, or taxing. Responses are rated on a 5-level scale (1= "never true" to 5=

"almost always"). It has good internal consistency (alpha = .84) and test-retest stability (.85). The Cronbach alpha coefficient in this sample was .91.

Pregnancy stress. The Prenatal Psychosocial Profile (PPP) stressor subscale⁴³ asks women to indicate, on a 4-level scale (1 = "no stress" to 4 = "severe stress"), the extent to which each of 11 items (e.g., financial worries and feeling "generally overloaded") is a current stressor or hassle. Average PPP scores have been between 18 and 20 (range = 11-44) in studies of culturally diverse pregnant women. It has fair internal consistency (alpha = .73-.78) and test-retest stability (.82).⁴⁴ The Cronbach alpha coefficient in this sample was .78.

State and trait anxiety. The Trait Anxiety subscale of the State-Trait Anxiety Inventory $(STAI)^{45}$ consists of 20 statements in which respondents are asked to describe how they generally feel on a 4-level scale (1= "not at all"; 4= "very much so"). It has good internal consistency (alpha = .65 to .86) and test-retest stability (.87-.92). The internal consistency reliability in this sample was .94.

The 6-item state STAI (S-STAI-6)⁴⁶ is a short-form version of the State STAI that also uses a 4-level scale (1= "not at all"; 4= "very much"), adjusted to yield a similar range of scores to those obtained with the full 20-item version. It has been validated with several populations. It has good internal consistency (alpha =.82). The Cronbach alpha for this sample was .85.

Physical Distress

Pain. Pain was assessed using a modified version of the Brief Pain Inventory
 (BPI)⁴⁷ with two dimensions: pain intensity and pain interference with daily activities.
 The BPI asks subjects to rate the frequency of current pain intensity from 0 ("no pain") to

10 ("worst pain imaginable"). Pain Interference is composed of seven items that assess the degree to which pain interferes with daily activities. Subjects are asked to rate the extent to which pain interfered with activities during the last week from 0 ("does not interfere") to 10 ("completely interferes"). The scale has good internal consistency reliability (Cronbach alpha coefficient = .88)⁴⁸ and an alpha of .91 in the present study. Total hours of pain was calculated by multiplying hours per day of pain by number of days that pain interfered with mood or activities during the past week.

Sleep disturbance. Subjective sleep disturbance was measured with the General Sleep Disturbance Scale (GSDS).⁴⁹ The GSDS asks about frequency in the past week of various poor sleep experiences (such as difficulty getting to sleep, waking during sleep, and sleeping poorly) on a numerical rating frequency scale of 0 ("never") to 7 ("every day"). It has good internal consistency (alpha = .88). The Cronbach alpha in this sample was .81. The scale yields a mean score ranging between 0 and 7 with higher scores indicating greater frequency of sleep disturbance during the past week. A mean score of 3 or higher distinguishes poor sleep from good sleep.

Behavior Change

Mindfulness. Mindfulness was measured with the Five Factor Mindfulness Questionnaire $(FFMQ)^{50}$ a 39-item measure of mindfulness skills operationalized as a multidimensional 5-subscale construct. Respondents are asked to rate what they notice on a 5-level scale (1= "never or very rarely true" to 5 = "almost always or always true"). The Cronbach alpha coefficients in this sample were adequate: Observing (.83); Describing (.91); Acting with Awareness (.87); Nonreactivity (.75); and Nonjudging (.87).

Physical activity. Physical activity was measured by the 10-item Rapid Assessment of Physical Activity (RAPA) modified to include an additional item that queried the frequency of stretching activities.⁵¹ It is an item checklist with 10 possible yes/no options. It asks subjects to record by category the duration, frequency, and intensity in which they participate in physical activities, stretching, and strength building. In older adults the RAPA has shown high correlation with the Community Health Activities Model Program validated instrument. RAPA has good sensitivity (81%), a 77% positive predictive value and a 75% negative predictive value.⁵² A score between 7 and 11 is considered optimal for nonpregnant adults. There are no recommendations RAPA scores for pregnant women.

Acceptability

Acceptability was measured at Time 2 with a questionnaire asking respondents to rate their experience and satisfaction with the intervention. The instrument was modified from an intervention evaluation tool used in a prior sleep study and from a follow-up questionnaire from the Stress Reduction Program at the University of Massachusetts Medical School. After the birth of their infant, women were contacted by telephone at home to ask them to comment retrospectively about their experience with the intervention classes and determine how many of them continued to practice the intervention, and how often they did mindful-yoga, after the seven weeks were completed.

Intervention

The 7-week, mindfulness-based yoga intervention combined elements of two methods. It was patterned after the yoga methods of Iyengar⁵³ and the curriculum of Mindfulness-Based Stress Reduction (MBSR), a relaxation and stress management

program developed by Kabat-Zinn.⁵⁴ Although shortened to 14 hours in length, an aim of the intervention was to maintain fidelity with MBSR's emphasis on mindfulness. Mindfulness is a purposive process of learning how to pay attention from moment-tomoment to one's present experience while noticing and learning to let go of judgments and reactivity.⁵⁴ Aspects of mindfulness practice include self-reflection, acceptance, and being open to difficulties without avoidance.²⁶

The intervention in this study differed from MBSR in its focus on principles of Iyengar, a form of Hatha yoga that emphasizes props to tailor poses, careful anatomical alignment, and correct muscular actions. In weekly sessions conducted by the first author, mindfulness was taught sequentially so participants could discover relationships between mindful practice and ability to cope more effectively with stress. Mindfulness was presented using the following techniques: 1) Body scan, a progressive relaxation in which participants direct attention and observe sensations; 2) Sitting meditation, involving observation of one's breathing, sensations, emotions, sound and thoughts; 3) Hatha yoga, involving gentle physical poses integrated with breathing to develop strength, flexibility and balance that is no more strenuous than a 30-minute walk on flat ground; and 4) Walking meditation, involving slow and observant walking. The sessions also explored use of mindfulness in daily life, the psychological and physiological effects of stress, and the possibilities of using mindfulness during birth.

Asana is a Sanskrit word that literally means "seat" but in the practice of Hatha yoga it means a pose or posture. Asana is the third stage of the eight-limbed yoga system.⁵³ The yoga *asanas* in this study were designed for women late in pregnancy. Each session lasted approximately 75 minutes with guided instruction throughout each

pose, safe ways to get in and out of the positions, pose modification, and use of props to suit needs and limitations of each woman. For instance the seated twist can be done on a chair rather than on the ground. Blankets, cushions, belts, and other props were used to maintain body alignment, structural support, and comfort. Emphasis was placed on building length along the spine while maintaining neutrality of spinal position, keeping awareness of the breath, and using breath and sensations within the body to anchor attention to the present moment. The emphasis was not on flexibility per se.

Data Analyses

Data from all instruments were evaluated for completeness. Frequency distributions were checked for extreme or inconsistent values. Descriptive statistics were used to characterize the sample. Repeated measures analysis of variance (RMANOVA) was used to examine change from pre- to post-intervention as the within-subjects factor and group (second versus third trimester) as the between-subjects factor. Due to small sample, differences between baseline and post-intervention scores were analyzed post hoc using nonparametric Wilcoxon signed ranks tests to compare groups and Mann-Whitney U tests to ascertain significant change over time. These analyses were done using SPSS version 14 for Windows. Level of significance was set at .10 for this pilot study.

RESULTS

Baseline Characteristics

Of the 19 women eligible to participate, 16 participated in the mindful-yoga intervention and completed the study. They were college-educated, married women averaging 30.4 years of age with middle-class combined household income (see Table 1).

None reported currently smoking cigarettes, taking prescription drugs, illicit drugs, or having medical problems. All women were having their first baby, planned on attending childbirth education class, intended to breastfeed, and wanted a vaginal birth. A baseline demographic comparison of the 8 women who received prenatal care from physicians and the 8 women who received care from nurse midwives revealed that those who received midwifery care did not differ from those who received obstetric care with respect to marital status, age, income, education, and ethnicity. As seen in Table 2, eight women were in their second trimester (13-26 weeks). Most were planning to work after the baby was born (n=13, 81%). Although none of the women had current mental health problems, nearly one third (n = 5) reported a history of depression or anxiety in the past.

Psychological distress

At baseline, participants reported moderate levels of perceived stress on the PSS (14.8 ± 8.0) . There was no significant time-by-group interaction for change in perceived stress by trimester group (Table 3). There was a significant decrease in perceived stress (p = .04) from baseline to post-intervention. The third trimester group had more of a decrease in perceived stress than the second trimester group (p = .06)

Stressors and hassles unique to pregnancy were measured with the PPP-stressor subscale. At baseline, participants reported low levels of stressors (18.1 ± 4.6). The within-subject decrease from baseline to post-intervention was significant (p = .10), and there was no group-by-time interaction (Table 3). Stressors and hassles decreased primarily for women in the third trimester group.

As seen in Table 3, women reported moderate trait anxiety (36.3 ± 13.6) and state anxiety (28.8 ± 9.7) at baseline. Trait anxiety decreased post-intervention (p = .03). This reduction in trait anxiety was due to lower scores for third trimester women compared to second trimester women (p = .02). There was no change in state anxiety for either group. *Physical distress*

At baseline, second trimester women had mean sleep disturbance (GSDS) scores of 2.9 ± 1.0 while third trimester women had scores of 1.8 ± 0.5 . At post-intervention, mean GSDS scores were 2.4 ± 1.0 for both second- and third-trimester groups. There was a significant group-by-time interaction on the GSDS (p = .09) and for the number of nights of poor sleep (p = .006): second trimester women reported fewer nights of poor sleep in the past week from Time 1 to Time 2, while third trimester women reported more nights of poor sleep (Table 3). Post-hoc nonparametric analyses indicated that second trimester women demonstrated significantly improved sleep by total GSDS scores (Z = -1.9, p = .06) and by fewer number of nights during the week with poor sleep (Z = -2.1, p=.03). In contrast, third trimester participants reported worsening sleep reflected in GSDS scores (Z = 1.7, p = .09) and number of nights with poor sleep (Z = 1.6, p =1.0).

Pain was common in this sample. Prevalence of pain was similar by trimester at the baseline measure (75% for second trimester and 62% for third trimester), and there were large group variances even after excluding the two women without pain (see Table 4). RMANOVA indicated no significant changes over time, and no differences in pain parameters between trimester groups at baseline. At post-intervention, only two women, both in the third trimester group reported no pain. There was a time-by-group effect for the overall BPI scale (p = .04) and for the pain interference subscale (p = .04), with post

hoc analysis indicating that second trimester women had significantly lower BPI scores (Mann-Whitney U = -2.4, p = .02) after the intervention and had less pain interference after the intervention (Mann-Whitney U= -2.4, p = .05) compared to the third trimester group.

There were significant group differences in pain intensity and hours of pain at both time points (see Table 4). Pain intensity remained higher after the intervention for third trimester women compared to second trimester women (Mann-Whitney U = 2.5, p=.01) For second trimester women, hours of pain decreased after the intervention (z=2.0, p = .02) compared to an increase for third trimester women. After the intervention, the third trimester group still reported significantly more hours of pain than second trimester women (Mann-Whitney U = -2.0, p = .05).

Behavioral change

Behavioral change was assessed with mindfulness (FFMQ) and physical activity (RAPA) questionnaires. There were improvements in two of the five mindfulness subscales: Non-react (p = .07) and Observe (p = .07) for both trimester groups (Table 3). There were no time-by-group interactions, however, scores suggest improvement in second trimester women compared to third trimester women.

The majority of participants reported partaking in regular moderate physical activities each week. The mean RAPA score was 5.8 ± 1.9 at baseline and 7.0 ± 1.8 after the intervention. The change over time was significant (p = .01). As seen in Table 3, second and third trimester groups did not differ at baseline. However, there was a significant time-by-group interaction (p = .04) with second trimester participants

increasing their activity from Time 1 to Time 2 compared to third trimester women with no change in their RAPA scores.

Acceptability of the group intervention

Participant satisfaction was assessed at post-intervention. Most (94%, n = 15) reported they were satisfied with the class and would recommend it to others; 81% said the class had been important to them. As a direct result of the class, 63% (n = 10) reported feeling more hopeful and confident, having a greater knowledge of what is stressful in their lives and knowing how to take better care of themselves, having greater awareness of a stressful situation at the time it occurs, and having the ability to appropriately handle stressful situations. Eight of the 16 women said they were taking better care of themselves as a result of mindful-yoga. Half reported that it was easy to attend the classes and the other half reported that it was difficult to attend. In examining home addresses, we concluded that if a woman lived near where the mindful-yoga sessions were held, or if the site was located between work and home, they characterized attendance as easy. Women who found it difficult to attend lived further from the facility and contended with road congestion and traffic.

From the telephone follow up call after women delivered, all 17 participants were asked to comment prospectively on their experience with the intervention. Women continued to practice aspects of mindfulness (e.g., the body scan, mindfulness sitting meditation, or mindful-yoga) after the sessions ended. Five (29%) reported practicing at least three times per week for the remainder of pregnancy; 10 (59%) reported continuing to practice 1-2 days per week; and 2 (12%) reported no further mindfulness practice after the 7-week intervention.

Discussion

This is the first study to examine change in perceived stress, anxiety, sleep disturbance, pain, mindfulness, and physical activity following a seven-week program with weekly group sessions of a mindfulness-based yoga intervention. It is also the first prenatal study using principles set forth by Ivengar.⁵³ Prenatal voga is a popular mindbody practice during pregnancy and this study observed benefits at the end of the intervention. The primary aim of this study was to evaluate the feasibility of a program for stress reduction and somatic complaints during pregnancy among first time mothers. The sample size was small and dispersed across pregnancy, and it was not possible to obtain the statistical power necessary to demonstrate significant change in all outcome variables of interest. However, there were some significant improvements, notably in perceived stress, pregnancy stress and hassles, trait anxiety, and two mindfulness subscales (Non-react and Observe). For women beginning the intervention in third trimester, anxiety and perceived stress demonstrated greater attenuation. For women beginning the intervention in second trimester of pregnancy, physical pain and sleep improved.

These pilot data describe an underlying pattern whereby second trimester women experienced increased physical well-being over the 7-week sessions while third trimester women did not experience increased physical well-being but had less psychological distress after the intervention. One explanation for group differences in response to the intervention is to ascribe reductions in perceived stress and trait anxiety to normal changes of pregnancy that dampen physiologic arousal.^{55, 56} Glynn and colleagues^{57, 58} showed that advanced gestation attenuates perceived stress. In contrast to Glynn's

study,⁵⁸ there were no trimester group differences in anxiety or stress at either time point. However, trait anxiety and perceived stress were attenuated for the third trimester group.

Trait anxiety did show change over time. In contrast, state anxiety did not. Other studies have demonstrated attenuation of trait anxiety following a mind-body intervention^{29, 30, 59-61} that in some cases, was significantly lowered even when state anxiety was not. These results challenge the notion that trait anxiety yields enduring scores. Alteration in the more stable trait anxiety is desirable, and may indicate neuroplasticity.

Sleep disturbance and pain are frequent complaints of pregnancy.⁶² that usually worsen as pregnancy progresses.^{16, 21} However, second trimester women did not experience worse pain or sleep problems between the two time points, unlike the third trimester group. As pain increases during pregnancy, sleep may be affected. An alternate explanation is that increased physical activity or a component of mindful-yoga could directly influence sleep in the second trimester. Although Iyengar⁵³ has indicated specific *asanas* (such as inversions) for insomnia, most of these were not included in the intervention.

The prevalence of pain in this study was 69% at Time 1 (11 women out of 16), similar to previous studies.^{15, 16} Low back pain (LBP) during pregnancy becomes more intense with advancing gestation,^{15, 18} yet second trimester women in this sample did not experience worsening pain over the 7-week intervention. In fact, women in the second trimester of pregnancy had significantly less hours of pain and less pain interference with activity from baseline to post-intervention as they moved into their third trimester (see Table 3). A mindful-yoga intervention has a more positive effect earlier in pregnancy,

when good postural habits and awareness of movement can best influence the trajectory of stress and pain. It may also be that mindfulness skills, when obtained earlier in pregnancy, alter how stress is perceived, and leads to reduction in both perceived stress and pain. Pain reduction is an important finding, as pregnant women ascribe pain as the reason for sleep disturbance, impaired activities, and work absenteeism.^{15, 16} Pregnant women in the second trimester demonstrated significant improvements in physical activity, an important aspect of healthy lifestyle. Feeling good in their body may have contributed to greater levels of physical activity outside of the weekly intervention.

Most participants reported that they practiced the yoga, mindfulness skills, and body scan they learned in class sessions either in their homes or in situations outside of class, but the actual dose of mindful-yoga was not directly measured. Duration and frequency in the practice of mindful-yoga may be an important element in relieving stress, pain, and sleep disturbance. Some mindfulness-based studies have identified a dose response in practice^{26, 63} while another has not.⁶⁴ Assessment of adherence to and preference for mindfulness-based techniques are recommended in future research.

Major limitations of this study include the absence of a placebo control group and the small sample size, both of which diminished the strength of this study's findings and external validity. Psychometric limitations include the use of newly developed self-report measures (e.g., mindfulness and physical activity). This was also the first time they were used in a pregnant sample. Mindfulness is newly conceptualized and the instrument has never before been applied to an intervention consisting of mindful-yoga. The sample may have been inadvertently biased by selection process, since participation was partially

dependent on subjects' work schedules and the distance they lived from the location of the intervention.

Despite these limitations, variables in this feasibility study serve as a starting point for studying effects of prenatal mindful-yoga on physical and psychological stress, behavioral changes, and acceptability. This intervention, if started early, may be an important aspect of limiting physical and psychological distress during pregnancy. In view of the results and women's satisfaction with the intervention, further research is merited to learn more about minimizing stress and somatic complaints during pregnancy. To determine whether the benefits of a mindful-yoga intervention are enduring, future research could include assessment of postpartum maternal and infant sleep, postpartum physical and psychological distress, parental attachment, and infant temperament. Additional forms of assessment (e.g., biomarkers of stress) could extend and strengthen self-report measures.

There are currently no recommendations from professional organizations regarding the safety of yoga during pregnancy⁴⁰ and experts do not always agree on the efficacy of certain poses during pregnancy. Therefore, studies that evaluate efficacy of a specific program of yoga asanas are crucial. Traditional goals of childbirth education have been to reduce pain and anxiety⁶⁵ through relaxation techniques that have their roots in yoga⁶⁶ and include breathing techniques, focusing attention, and adopting specific physical positions.⁶⁷ Mindfulness-based strategies extend childbirth preparation to include posture and breath awareness, cultivation of nonjudging, acceptance of how things are, opening to difficulties without avoidance, and nonreactive observation of

personal experience. Mindfulness-based practices have been found to increase pain tolerance⁶⁸ and predict level of functioning despite pain.⁶⁹

This feasibility study is the first that we know of in which a mindful-yoga intervention has been applied to pregnant women and evaluated for effects on mindfulness, psychosocial distress, and physical pain and sleep disturbance. Despite the increasing popularity of yoga during pregnancy and its potential role as a protective factor in mental and physical health and perinatal outcomes, little is known about its effects. The potential to enhance protective factors during pregnancy and the early puerperium is great. Pregnancy presents a unique window of opportunity to enhance well-being, minimize distress, and improve perinatal outcomes. This pilot study suggested that a mindfulness-based pregnancy intervention is feasible and preliminary evidence from this sample supports its efficacy in these areas, particularly if started early in the pregnancy.

| Characteristic | Number | Percentages |
|----------------------|----------------|-------------|
| Age | 30.4 ± 3.3 | |
| 25-29 | 6 | 37% |
| 30-37 | 10 | 63% |
| Race | | |
| Caucasian | 14 | 88% |
| Hispanic | 2 | 12% |
| Education | | |
| Some college | 1 | 6% |
| College degree | 3 | 18% |
| Some graduate school | 6 | 38% |
| Graduate degree | 6 | 38% |
| Monthly Income (\$) | | |
| \$3,000 to 4,999 | 4 | 25% |
| 5,000+ | 12 | 75% |
| Marital Status | | |
| Married | 15 | 94% |
| Living with partner | 1 | 06% |
| Work Status | | |
| Fulltime | 8 | 50% |
| Part-time | 6 | 37% |
| Not working | 2 | 13% |
| Student Status | | |
| Full-time student | 3 | 19% |
| Non-student | 13 | 81% |

TABLE 1. Baseline Demographic Characteristics (N = 16)

| # | Gestation on 1 st day of treatment | Trimester |
|----|---|-----------|
| 1 | 13 0/7 | 2 |
| 2 | 17 1/7 | 2 |
| 3 | 20 4/7 | 2 |
| 4 | 21 1/7 | 2 |
| 5 | 23 1/7 | 2 |
| 6 | 23 2/7 | 2 |
| 7 | 24 0/7 | 2 |
| 8 | 25 2/7 | 2 |
| 9 | 27 1/7 | 3 |
| 10 | 27 1/7 | 3 |
| 11 | 27 5/7 | 3 |
| 12 | 27 6/7 | 3 |
| 13 | 27 6/7 | 3 |
| 14 | 30 5/7 | 3 |
| 15 | 31 6/7 | 3 |
| 16 | 32 1/7 | 3 |

TABLE 2. Week of Gestation on the first day of the 7-week intervention.

| | 2nd Trimester (n = 8) Means (SD) | | 3rd Trimester (n = 8) Means (SD) | | Repeated Measures ANOVA | | |
|---------------------------------|--|-----------------------|--|-----------------------|--|------------------|------------------------|
| | Baseline | Post- intervention | Baseline | Post- intervention | Mean Square 1)Within 2)Betwe en 3)Time by group | F [df 1,14] | Sig. (2- tailed) |
| PSS | 14.0 (9.7) | 13.9 (12.2) | 15.4 (6.9) | 10.3 (6.6) | 54.4 8.5 48.6 | 4.6 .1 4.1 | .05 NS .06 |
| РРР | 17.7 (3.4) | 16.4 (5.1) | 19.2 (5.4) | 17.5 (5.1) | 7.4 24.6 3.7 | 3.1 .6 1.5 | .10 NS NS |
| STAI-T | 33.6 (17.0) | 33.7 (17.8) | 38.4 (10.9) | 34.1 (9.2) | 34.1 54.1 38.9 | 5.8 .2 6.6 | .03 NS .02 |
| STAI-S | 26.7 (5.4) | 31.4 (16.0) | 30.4 (12.1) | 31.9 (9.0) | 76.7 33.5 21.2 | 1.0 .2 .3 | NS NS NS |
| GSDS | 2.9 (1.0) | 2.4 (1.0) | 1.8 (.5) | 2.4 (1.0) | .0 2.5 2.2 | .2 1.7 9.2 | NS NS .09 |
| sleep poorly GSDS item | 3.6 (1.5) | 2.1 (1.1) | 1.4 (1.8) | 2.9 (2.8) | .0 4.5 18.0 | .0 .8 10.5 | NS NS .006 |

Table 3. Means (Standard Deviations) and Repeated Measures Analysis of Variance Tests for Differences by time and trimester group.

| | 2nd Trimester (n = 8) Means (SD) | | 3rd Trimester (n = 8) Means (SD) | | Repeated Measures ANOVA | | |
|-------------|--|-----------------------|--|-----------------------|---|----------------|------------------------|
| | Baseline | Post- intervention | Baseline | Post- intervention | Mean Square 1) Within 2) Between 3) Time X Group | F [df 1,14] | Sig. (2- tailed) |
| Mindfulness | | | | | | | |
| Act Aware | 28.6 (8.7) | 26.8 (11.7) | 24.1 (11.2) | 26.5 (8.2) | .1 | .1 | NS |
| | | | | | 73.1 | .4 | NS |
| | | | | | 20.6 | 1.5 | NS |
| Describe | 34.1 (4.4) | 33.6 (7.3) | 26.4 (9.8) | 28.6 (9.2) | 3.3 | .3 | NS |
| | | | | | 297.2 | 2.6 | .13 |
| | | | | | 25.3 | 2.0 | .12 |
| Non-judge | 30.9 (10.1) | 33.0 (15.0) | 30.2 (10.2) | 35.0 (4.5) | 19.6 | .5 | NS |
| | | | | | 53.0 | .3 | NS |
| | | | | | 64.6 | 1.6 | NS |
| Non-react | 20.9 (5.9) | 22.4 (4.6) | 19.4 (4.5) | 20.6 (3.9) | 14.7 | 3.9 | .07 |
| | | | | | 11.8 | .3 | NS |
| | | | | | .1 | .1 | NS |
| Observe | 29.4 (3.4) | 31.6 (2.6) | 30.7 (3.5) | 31.5 (4.2) | 19.5 | 3.8 | .07 |
| | | | | | 5.2 | .3 | NS |
| | | | | | 2.6 | .5 | NS |
| RAPA | 5.4 (1.6) | 7.5 (1.1) | 6.2 (2.1) | 6.5 (2.3) | 11.3 | 8.2 | .01 |
| | | | | | .0 | .0 | .94 |
| | | | | | 7.0 | 5.1 | .04 |

BPI = Brief Pain Inventory, PSS = Perceived Stress Scale, PPP =Prenatal Psychosocial Profile, STAI-T = Trait Anxiety, STAI-S = short form of State Anxiety, GSDS = General Sleep Disturbance Scale, Frequency poor sleep =item #5 of the GSDS for poor sleep during past week, Intensity of Sleep Quality = single item global measure of sleep quality past week, RAPA = Physical Activity

NS = not statistically significant at p < .10)

| | 2nd Trimester (n = 8) Means (SD) | | 3rd Trimester (n = 6) Means (SD) | | Repeated Measures ANOVA | | |
|----------------------|--|-----------------------|--|-----------------------|---|------------------|------------------------|
| | Baseline | Post- intervention | Baseline | Post- intervention | Mean Square 1)Within 2)Between 3)Time by group | F [df 1,12] | Sig. (2- tailed) |
| ВРІ | 23.5 (20.8) | 16.1 (11.7) | 33.3 (29.0) | 43.3 (23.9) | 11.3 2,359.4 520.9 | .1 2.9 5.5 | NS .12 .04 |
| Pain Interference | 14.3 (15.0) | 9.1 (9.2) | 16.2 (14.7) | 22.0 (10.7) | .9 375.1 205.9 | .0 1.3 5.4 | NS NS .04 |
| Pain Intensity | 4.8 (4.5) | 4.5 (3.2) | 9.0 (8.6) | 11.3 (5.5) | 7.4 210.6 11.4 | .9 4.0 1.4 | NS .07 NS |
| Hours of Pain | 4.5 (3.3) | 1.6 (2.8) | 20.5 (24.1) | 30.5 (45.6) | 87.0 3452.2 284. | .3 4.3 .9 | NS .06 NS |

TABLE 4. Pain Parameters for Second and Third Trimester Groups Before and After the Intervention (N =14 who experienced pain).

References

- Albrecht SA, Rankin M. Anxiety levels, health behaviors, and support systems of pregnant women. *Matern Child Nurs J.* Spring 1989;18:49-60.
- McCormick MC, Brooks-Gunn J, Shorter T, Holmes JH, Wallace CY, Heagarty MC. Factors associated with smoking in low-income pregnant women: Relationship to birth weight, stressful life events, social support, health behaviors and mental distress. *J Clin Epidemiol.* 1990;43:441-448.
- Andersson L, Sundstrom-Poromaa I, Wulff M, Astrom M, Bixo M. Implications of antenatal depression and anxiety for obstetric outcome. *Obstet Gynecol*. Sep 2004;104:467-476.
- Saunders TA, Lobel M, Veloso C, Meyer BA. Prenatal maternal stress is associated with delivery analgesia and unplanned cesareans. *J Psychosom Obstet Gynaecol.* Sep 2006;27:141-146.
- Paarlberg KM, Vingerhoets AJ, Passchier J, Dekker GA, Heinen AG, van Geijn HP. Psychosocial predictors of low birthweight: A prospective study. *Br J Obstet Gynaecol.* Aug 1999;106:834-841.
- 6. Dayan J, Creveuil C, Herlicoviez M, et al. Role of anxiety and depression in the onset of spontaneous preterm labor. *Am J Epidemiol*. Feb 15 2002;155:293-301.
- Dole N, Savitz DA, Hertz-Picciotto I, Siega-Riz AM, McMahon MJ, Buekens P.
 Maternal stress and preterm birth. *Am J Epidemiol.* Jan 1 2003;157:14-24.
- Beck CT. Predictors of postpartum depression: An update. *Nurs Res.* Sep-Oct 2001;50:275-285.

- 9. Van Den Bergh BRH. The influence of maternal emotion during pregnancy on fetal and neonatal behavior. *Pre- and Peri-Natal Psychology*. 1990;5:119-130.
- O'Connor TG, Heron J, Golding J, Beveridge M, Glover V. Maternal antenatal anxiety and children's behavioural/emotional problems at 4 years. Report from the Avon Longitudinal Study of Parents and Children. *British Journal of Psychiatry*. Jun 2002;180:502-508.
- Otchet F, Carey MS, Adam L. General health and psychological symptom status in pregnancy and the puerperium: What is normal? *Obstet Gynecol*. Dec 1999;94(6):935-941.
- Albert HB, Godskesen M, Korsholm L, Westergaard JG. Risk factors in developing pregnancy-related pelvic girdle pain. *Acta Obstet Gynecol Scand*. 2006;85(5):539-544.
- Field T, Hernandez-Reif M, Diego M, Schanberg S, Kuhn C. Stability of mood states and biochemistry across pregnancy. *Infant Behav Dev.* Apr 2006;29(2):262-267.
- Paarlberg KM, Vingerhoets AJ, Passchier J, Heinen AG, Dekker GA, van Geijn HP. Psychosocial factors as predictors of maternal well-being and pregnancyrelated complaints. *J Psychosom Obstet Gynaecol.* Jun 1996;17(2):93-102.
- Kristiansson P, Svardsudd K, von Schoultz B. Back pain during pregnancy: A prospective study. *Spine*. Mar 15 1996;21:702-709.
- Wang SM, Dezinno P, Maranets I, Berman MR, Caldwell-Andrews AA, Kain ZN. Low back pain during pregnancy: Prevalence, risk factors, and outcomes. *Obstet Gynecol.* Jul 2004;104:65-70.

- Field T, Diego M, Hernandez-Reif M, Figueiredo B, Schanberg S, Kuhn C. Sleep disturbances in depressed pregnant women and their newborns. *Infant Behav Dev*. Feb 2007;30(1):127-133.
- Fast A, Shapiro D, Ducommun EJ, Friedmann LW, Bouklas T, Floman Y. Lowback pain in pregnancy. *Spine*. May 1987;12(4):368-371.
- Mens JM, Vleeming A, Stoeckart R, Stam HJ, Snijders CJ. Understanding peripartum pelvic pain. Implications of a patient survey. *Spine.* Jun 1 1996;21(11):1363-1369; discussion 1369-1370.
- Sydsjo A, Sydsjo G, Wijma B. Increase in sick leave rates caused by back pain among pregnant Swedish women after amelioration of social benefits. A paradox. *Spine*. Sep 15 1998;23(18):1986-1990.
- 21. Lee KA, Zaffke ME, McEnany G. Parity and sleep patterns during and after pregnancy. *Obstet Gynecol.* Jan 2000;95(1):14-18.
- Lee KA. Alterations in sleep during pregnancy and postpartum: A review of 30 years of research. *Sleep Med Rev.* Nov 1998;2:231-242.
- Hertz G, Fast A, Feinsilver SH, Albertario CL, Schulman H, Fein AM. Sleep in normal late pregnancy. *Sleep*. Jun 1992;15:246-251.
- USDepartmentofHealthandHumanServices. *Mental health: A report of the surgeon general*. Rockville, MD: U.S. Department of Health and Human Services; 1999.
- Breitkopf CR, Primeau LA, Levine RE, Olson GL, Wu ZH, Berenson AB. Anxiety symptoms during pregnancy and postpartum. *J Psychosom Obstet Gynaecol.* Sep 2006;27(3):157-162.

- 26. Beddoe AE, Murphy SO. Does mindfulness decrease stress and foster empathy among nursing students? *J Nurs Educ*. Jul 2004;43:305-312.
- Rosenzweig S, Reibel DK, Greeson JM, Brainard GC, Hojat M. Mindfulnessbased stress reduction lowers psychological distress in medical students. *Teach Learn Med.* Spring 2003;15:88-92.
- Williams KA, Kolar MM, Reger BE, Pearson JC. Evaluation of a wellness-based mindfulness stress reduction intervention: A controlled trial. *Am J Health Promot*. Jul-Aug 2001;15:422-432.
- Woolery A, Myers H, Sternlieb B, Zeltzer L. A yoga intervention for young adults with elevated symptoms of depression. *Altern Ther Health Med.* Mar-Apr 2004;10:60-63.
- 30. Michalsen A, Grossman P, Acil A, et al. Rapid stress reduction and anxiolysis among distressed women as a consequence of a three-month intensive yoga program. *Med Sci Monit*. Dec 2005;11:CR555-561.
- Williams KA, Petronis J, Smith D, et al. Effect of Iyengar yoga therapy for chronic low back pain. *Pain*. 2005/5 2005;115:107-117.
- 32. Khalsa SB. Treatment of chronic insomnia with yoga: A preliminary study with sleep-wake diaries. *Appl Psychophysiol Biofeedback*. Dec 2004;29:269-278.
- 33. Kelly RH, Russo J, Katon W. Somatic complaints among pregnant women cared for in obstetrics: Normal pregnancy or depressive and anxiety symptom amplification revisited? *Gen Hosp Psychiatry*. May-Jun 2001;23:107-113.

- Wang SM, Zinno PD, Fermo L, et al. Complementary and alternative medicine for low-back pain in pregnancy: A cross-sectional survey. *J Altern Complement Med.* Jun 2005;11:459-464.
- Urizar GG, Milazzo M, Le HN, Delucchi K, Sotelo R, Munoz RF. Impact of stress reduction instructions on stress and cortisol levels during pregnancy. *Biol Psychol.* Nov 2004;67:275-282.
- Teixeira J, Martin D, Prendiville O, Glover V. The effects of acute relaxation on indices of anxiety during pregnancy. *J Psychosom Obstet Gynaecol*. Dec 2005;26:271-276.
- 37. Bastani F, Hidarnia A, Kazemnejad A, Vafaei M, Kashanian M. A randomized controlled trial of the effects of applied relaxation training on reducing anxiety and perceived stress in pregnant women. *J Midwifery Womens Health.* Jul-Aug 2005;50:e36-40.
- Bastani F, Hidarnia A, Montgomery KS, Aguilar-Vafaei ME, Kazemnejad A. Does relaxation education in anxious primigravid Iranian women influence adverse pregnancy outcomes? A randomized controlled trial. *J Perinat Neonatal Nurs*. Apr-Jun 2006;20:138-146.
- Narendran S, Nagarathna R, Narendran V, Gunasheela S, Nagendra HR. Efficacy of yoga on pregnancy outcome. *J Altern Complement Med.* Apr 2005;11:237-244.
- 40. Narendran S, Nagarathna R, Gunasheela S, Nagendra HR. Efficacy of yoga in pregnant women with abnormal Doppler study of umbilical and uterine arteries. *J Indian Med Assoc.* Jan 2005;103:12-14, 16-17.

- Lazarus RS, Folkman S. *Stress, appraisal, and coping*. New York: Springer; 1984.
- Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav. Dec 1983;24:385-396.
- Curry MA, Burton D, Fields J. The Prenatal Psychosocial Profile: A research and clinical tool. *Res Nurs Health*. Jun 1998;21:211-219.
- 44. Curry MA, Campbell RA, Christian M. Validity and reliability testing of the Prenatal Psychosocial Profile. *Res Nurs Health*. Apr 1994;17:127-135.
- 45. Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. *Manual for the State-Trait Anxiety Inventory (form Y)*. Tampa, Florida: University of South Florida; 1989.
- Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger state-trait anxiety inventory (STAI). *Br J Clin Psychol*. 1992;31:301-306.
- 47. Daut RL, Cleeland CS, Flanery RC. Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. *Pain*. Oct 1983;17:197-210.
- 48. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. *J Pain*. Mar 2004;5(2):133-137.
- Lee KA. Self-reported sleep disturbances in employed women. *Sleep*. Dec 1992;15:493-498.

- Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. *Assessment*. Mar 2006;13:27-45.
- Glasgow RE, Ory MG, Klesges LM, Cifuentes M, Fernald DH, Green LA.
 Practical and relevant self-report measures of patient health behaviors for primary care research. *Ann Fam Med.* Jan-Feb 2005;3:73-81.
- 52. Topolski TD, LoGerfo J, Patrick DL, Williams B, Walwick J, Patrick MB. The Rapid Assessment of Physical Activity (RAPA) among older adults. *Prev Chronic Dis.* Oct 2006;3(4):A118.
- 53. Iyengar BKS. *Light on Yoga*. 2nd ed. New York: Schocken Books; 1979.
- 54. Kabat-Zinn J. Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness. New York: Dell Publishing; 1990.
- 55. Schulte HM, Weisner D, Allolio B. The corticotrophin releasing hormone test in late pregnancy: Lack of adrenocorticotrophin and cortisol response. *Clin Endocrinol (Oxf)*. Jul 1990;33:99-106.
- 56. DiPietro JA, Costigan KA, Gurewitsch ED. Fetal response to induced maternal stress. *Early Hum Dev.* Nov 2003;74:125-138.
- 57. Glynn LM, Wadhwa PD, Dunkel-Schetter C, Chicz-Demet A, Sandman CA.
 When stress happens matters: Effects of earthquake timing on stress responsivity in pregnancy. *Am J Obstet Gynecol.* Mar 2001;184:637-642.
- Glynn LM, Schetter CD, Wadhwa PD, Sandman CA. Pregnancy affects appraisal of negative life events. *J Psychosom Res.* Jan 2004;56:47-52.

- 59. Tsai JC, Wang WH, Chan P, et al. The beneficial effects of Tai Chi Chuan on blood pressure and lipid profile and anxiety status in a randomized controlled trial. *J Altern Complement Med.* Oct 2003;9:747-754.
- Gupta N, Khera S, Vempati RP, Sharma R, Bijlani RL. Effect of yoga based lifestyle intervention on state and trait anxiety. *Indian J Physiol Pharmacol*. Jan-Mar 2006;50(1):41-47.
- Shapiro SL, Schwartz GE, Bonner G. Effects of Mindfulness-based stress reduction on medical and premedical students. *J Behav Med.* Dec 1998;21:581-599.
- 62. Baratte-Beebe KR, Lee K. Sources of midsleep awakenings in childbearing women. *Clin Nurs Res.* Nov 1999;8(4):386-397.
- 63. Speca M, Carlson LE, Goodey E, Angen M. A randomized, wait-list controlled clinical trial: The effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosom Med.* Sep-Oct 2000;62:613-622.
- Carlson LE, Speca M, Patel KD, Goodey E. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosom Med.* Jul-Aug 2003;65:571-581.
- Beck NC, Geden EA, Brouder GT. Preparation for labor: A historical perspective.
 Psychosom Med. May 1979;41(3):243-258.
- Collins C. Yoga: Intuition, preventive medicine, and treatment. J Obstet Gynecol Neonatal Nurs. Sep-Oct 1998;27(5):563-568.

- Brown ST, Douglas C, Flood LP. Women's Evaluation of Intrapartum
 Nonpharmacological Pain Relief Methods Used during Labor. *J Perinat Educ*.
 Summer 2001;10(3):1-8.
- Kingston J, Chadwick P, Meron D, Skinner TC. A pilot randomized control trial investigating the effect of mindfulness practice on pain tolerance, psychological well-being, and physiological activity. *Journal of Psychosomatic Research*. 2007/3 2007;62(3):297-300.
- 69. McCracken LM, Gauntlett-Gilbert J, Vowles KE. The role of mindfulness in a contextual cognitive-behavioral analysis of chronic pain-related suffering and disability. *Pain.* 2007;In Press, Corrected Proof.

Chapter Four

Paper 3

Effects of Mindful-Yoga on Sleep in Pregnant Women:

A Pilot Study

Chapter Four

Effects of Mindful-Yoga on Sleep in Pregnant Women: A Pilot Study Abstract

The purpose of this pilot study was to test the preliminary efficacy of a 7-week intervention for second and third trimester pregnant women that combined mindfulness meditation and prenatal Hatha yoga in the Iyengar tradition. Fifteen healthy, nulliparous women with singleton pregnancy attended the weekly mindful-yoga program. Effects of the intervention on sleep variables, as estimated by 72 hours of continuous wrist actigraphy monitoring, were measured at baseline (Time1) and post-intervention (Time2). Due to small sample size, data were analyzed using nonparametric statistics. Results: Pregnant women who began mindful-yoga in the second trimester had significantly fewer awakenings and less wake time during the night. In contrast, women who began mindful-yoga during the third trimester had poorer sleep over time. Second trimester women at post-intervention had less awake time after sleep compared to third trimester controls at Time1. Mindful-yoga may be a promising intervention for second trimester pregnant women to diminish total number of awakenings at night. Relationships between mindful yoga and sleep during pregnancy merit further exploration.

Key words: sleep, actigraphy, pregnancy, yoga, mindfulness

Chapter Four

Effects of Mindful-Yoga on Sleep in Pregnant Women: A Pilot Study

Pregnancy is a time of profound physiologic change coupled with emotional adjustments to anticipation of childbirth, the infant, and parenthood. These experiences can be perceived by a woman as threatening, stressful, and anxiety provoking. Reflecting these changes, many women experience a cluster of symptoms that include sleep disturbance, physical pain, and anxiety. Sleep disturbance is common during pregnancy and recently, sleep changes have been proposed as contributing to perinatal mood disturbance, the prevalence of which is linked to somatic complaints (Andersson, Sundstrom-Poromaa, Bixo, Wulff, Bondestam et al., 2003; Kelly, Russo, & Katon, 2001). Moreover, distress and anxiety during pregnancy are largely overlooked issues, yet they may contribute to sleep deprivation and poor perinatal outcomes.

Stress is defined as an imbalance between the person and the environment and is relational in nature. When an individual appraises that threats or demands exceed one's personal resources, stress ensues and coping behaviors appear (Lazarus, 1984). Stress is not exclusively dependent on stressors or events (such as objective, physical, or major life event stress) but also depends on personal and contextual factors including emotion and cognitions. Exposure to stress over both short and long term may lead to anxiety reactions and physiological changes. Prenatal stress and anxiety predict low birth weight, prematurity (Neggers, Goldenberg, Cliver, & Hauth, 2006; Wadhwa, Sandman, Porto, Dunkel-Schetter, & Garite, 1993), cesarean birth (Bastani, Hidarnia, Montgomery, Aguilar-Vafaei, & Kazemnejad, 2006; Saunders, Lobel, Veloso, & Meyer, 2006),

postpartum depression (Beck, 2001), and behavior problems in children (O'Connor, Heron, Golding, Beveridge, & Glover, 2002; Van den Bergh & Marcoen, 2004).

Over the last two decades, stress reduction programs have increasingly been integrated into health care practice as a way to treat or prevent many stress-related conditions (Eisenberg, Davis, Ettner, Appel, Wilkey et al., 1998; Everly & Benson, 1989). However, the health effects of stress reduction and relaxation for pregnant women are largely unexamined. Narendran and colleagues (2005a; 2005b) taught stress reduction skills when they implemented a prenatal yoga intervention that consisted of postures, breathing practice, and meditation and demonstrated lower incidences of low birth weight, prematurity, and intrauterine growth restriction in the treatment group compared to controls. Bastani and colleagues (2005; 2006) implemented a progressive relaxation program in a randomized clinical trial of 110 pregnant women and found similar results. They also demonstrated lower incidence of cesarean as well as instrument births and attenuation of self-reported stress and anxiety in the treatment group. Urizar et al. (2004) evaluated the efficacy of a simple reminder to avoid stressful circumstances during healthy pregnancy and demonstrated improved mood, lower perceived stress, and lower cortisol concentrations on the days in which women avoided stress-inducing situations. Field and colleagues (2004) found that 84 depressed pregnant women in the second trimester who received massage therapy for 16 weeks had significantly lower cortisol levels, lower self-reported anxiety, and less sleep disturbance than controls by the end of the treatment. An earlier study (Field, Hernandez-Reif, Hart, Theakston, Schanberg et al., 1999) consisting of only 5 weeks of massage for 26 second trimester women with depression reported similar findings.

Mindfulness meditation is an intervention that has not been examined for its efficacy among pregnant women. Mindfulness is defined as a universal capacity to pay purposive attention to the present moment (Hanh, 1976; Kabat-Zinn, 1990). Aspects of mindfulness practice include self-reflection, acceptance, opening to difficulties without avoidance, and learning to be less judgmental and reactive (Kabat-Zinn, 1990; Kornfield, 1993). Mindfulness meditation can be practiced in several formal ways including sitting meditation, the body scan, Hatha yoga, and walking meditation. Informal aspects of mindfulness include purposeful attention on activities of daily living. Mindfulness meditation has stimulated much research in both clinical and nonclinical populations and its practice is linked to attenuation of anxiety (Miller, Fletcher, & Kabat-Zinn, 1995; Rosenzweig, Reibel, Greeson, Brainard, & Hojat, 2003; Williams, Kolar, Reger, & Pearson, 2001) and improved sleep in cancer patients (Carlson & Garland, 2005; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003). However, no mindfulness-based studies have evaluated its efficacy for improving sleep in healthy pregnant women.

Sleep During Pregnancy

The amount and quality of sleep during pregnancy is an important and often overlooked component in stress research. Stress hormones have a diurnal rhythm, responding to light and dark as well as sleep and wake. Lee and colleagues (1998; 2000b) have found that pregnant women often have greater subjective sleep complaints than nonpregnant women and that alterations in sleep architecture begin in early pregnancy and include frequent arousals and awakenings. Worse sleep is reported as pregnancy progresses (Lee, et al, 2001; Greenwood & Hazendonk, 2004) and in general, women experience less slow wave sleep, longer wake time, and reduced sleep efficiency as

pregnancy advances (Lee, 1998). These problems may result in insufficient sleep and excessive daytime somnolence (Hertz, Fast, Feinsilver, Albertario, Schulman et al., 1992; Lee, 1998). Field and colleagues (2007; 2006) found that serum cortisol levels and sleep disturbance are closely associated in the second and third trimesters, while Hall and colleagues (1998; 2000) demonstrated a relationship between the stress-immune response and sleep disturbance by polysomnography, self-reports of stress-related intrusive thoughts and avoidance behaviors, and natural killer cell serum activity. Sleep disturbance may reflect allostatic load associated with stress appraisal.

Purpose and Research Questions

Although recent studies have established relationships between psychological stress during pregnancy, rising stress hormone levels, and increased risk for adverse perinatal events, no published studies describe objective sleep variables in healthy pregnant women undergoing a mind-body intervention. Prenatal mindful-yoga is proposed as an approach to alter stress appraisal and thereby attenuate the stress response. Mindful-yoga is a participatory intervention based on Iyengar style Hatha yoga tailored to pregnancy and Mindfulness-Based Stress Reduction. Both are explained in greater detail in a previous publication (Beddoe & Lee, in press) that describes the effects of the intervention on dimensions of mindfulness as well as anxiety, pain, perception of stress, and perceived sleep disturbance in this same sample.

The purpose of this pilot study was to investigate whether sleep disturbance, measured by 72 hours of continuous wrist actigraphy, could be influenced by a 7-week mindful-yoga intervention during pregnancy. Specifically we explored the extent to which the intervention could improve sleep in healthy pregnant women and, because

sleep disturbance generally worsens as pregnancy progresses, we tested whether sleep disturbance differed between trimester groups.

Materials and Methods

Sample

A community sample in central California was recruited from posting approved recruitment flyers throughout the community, including at offices of prenatal providers and perinatal programs. Emailed notices to a 'birth network' alerted doulas, midwives, and childbirth educators of the program; childbirth education programs in two hospitals hand-delivered or mailed out flyers; and 5-minute presentations were made about the study to selected childbirth classes. The flyers, emails, and mini presentations explained the purpose of the study and that women would be paid up to \$100 for participating.

Pregnant women interested in participating were enrolled if they met the following eligibility criteria: at least 18 years old, able to read and write English, expecting a first baby, carrying a singleton pregnancy, planning a hospital birth, and between 12 and 32 week's gestation when the 7-week mindful-yoga intervention began. Women were excluded if they reported a history of psychiatric illness, currently used medications, worked nightshift, had a diagnosed sleep disorder, or had diabetes, hypertension, HIV infection, or history of back surgery. We screened 42 pregnant women for eligibility, enrolled 23 women, and 19 were able to meet on the day and time of the mindful-yoga group. Two women did not complete the study due to pregnancy complications (one preterm birth, and one on bed rest for preterm labor). Actigraph monitors failed for two additional subjects at the post-intervention assessment. The final sample consisted of 15 women with complete actigraphy data. Seven women were less

than 27 weeks' gestation on the first day of the intervention and categorized as second trimester group. The other eight women were at least 27 weeks' gestation at the start of the intervention and were categorized as the third trimester group.

Procedure

The Committee on Human Research at the University of California, San Francisco approved this study. Participation was voluntary; each was assured confidentiality and freedom to withdraw from the study at any time. A wrist actigraph was worn at two time points for 72 continuous hours to monitor sleep and activity at baseline and post-intervention. When each participant joined the study, a home visit was made to instruct in data collection. Therefore, home visits (and baseline data collection) occurred at different times relative to the first day of the 7-week intervention.

Intervention

The 7-week, mindfulness-based yoga intervention combined elements of two methods. It was patterned after the yoga methods of Iyengar (1979) and the curriculum of Mindfulness-Based Stress Reduction (MBSR), stress management program developed by Kabat-Zinn (1990). Each weekly class was two hours in length. Although the total intervention was only 14 hours in length, its aim was to maintain fidelity with MBSR's emphasis on mindfulness. Mindfulness is a purposive process of learning how to pay attention from moment-to-moment to one's present experience while becoming less judgmental and reactive. Aspects of mindfulness practice include self-reflection, acceptance, and being open to difficulties without avoidance (Beddoe & Murphy, 2004).

The study's intervention differs from MBSR in its focus and emphasis on principles of Iyengar yoga, a form of Hatha yoga that emphasizes use of props to tailor

poses to each individual, careful anatomical alignment, and correct muscular actions. In weekly sessions conducted by the first author, mindfulness was taught sequentially so participants could discover relationships between mindful practice and their ability to cope more effectively with stress. Mindfulness was presented using various techniques traditionally presented in MBSR and is described in more detail elsewhere (Beddoe, et al, in review)

Instruments

To objectively estimate sleep and wake time, each participant was asked to wear a wrist actigraph (Ambulatory Monitoring, Inc, Ardsley, NY) for 72 consecutive hours at baseline and again after completing the 7-week intervention. Actigraphy monitoring is a method used to distinguish sleep time from wake time, and ascertain circadian rhythm patterns for wake-sleep cycles. The monitor is a battery-operated wristwatch-size micro-processor that detects wrist movement by sensing motion in all three axes with a piezo-electric linear accelerometer (Lee & Gay, 2004). Actigraphy is reliable and valid for detecting sleep in normal healthy populations (Littner, Kushida, Anderson, Bailey, Berry et al., 2003). Actigraph sleep and wake time has a high degree of agreement with polysomnography recordings of wake and sleep states in a laboratory setting (Ancoli-Israel, Cole, Alessi, Chambers, Moorcroft et al., 2003; Cole, Kripke, Gruen, Mullaney, & Gillin, 1992).

Actigraphy data were analyzed blinded to participant's characteristics by the senior author using Action4 software (Ambulatory Monitoring, Inc). The autoscoring algorithm yielded five sleep variables: a) total night time in bed (SPT); b) total sleep time (TST) during the night); c) sleep onset latency (SOL) or the length of time it took to fall

asleep after the subject pressed the event marker on the monitor to indicate that she had turned out the light and was ready to go to sleep; d) number of awakenings during the night, using Cole and Webster criteria (1992; 1982) to score wake episodes and e) wake after sleep onset (WASO) as percent minutes awake during minutes in bed after falling asleep. WASO is an estimate of sleep disruption, with 5% to 10% typical for healthy, nonpregnant women (Lee et al., 2000b). A WASO greater than 15% represents more than one hour of wake time after falling asleep during a typical 7-8 hour sleep and was considered severe sleep disruption for this study of healthy pregnant women.

Statistical Methods

Actigraph variables were analyzed to obtain descriptive means and standard deviations. Actigraphy data were tested for stability over the three days with intraclass correlation coefficients (ICC). The ICCs ranged between .74 and .96 for the three nights and are presented in sleep results. There was no evidence of a first-night effect, even at the baseline measure. Therefore, actigraphy values were derived from an average of the 3 nights at each assessment point.

Relationships for all continuous variables were analyzed using Pearson product moment correlations after assumptions of linearity were met. Due to small sample size, data were also analyzed using nonparametric Wilcoxon signed ranks test for paired comparisons between Time1 (baseline) and Time2 (post-intervention) for each trimester group. Mann-Whitney *U* tests were used to compare the second trimester group's outcomes after the seven-week intervention with the third trimester group's baseline data prior to intervention. Effect sizes and 95% Confidence Intervals (CI) were also calculated

(see Table 2). Analyses were done with SPSS version 14 for Windows following HIPAA guidelines for secure network connections.

Results

Sample

Seventeen of the 19 enrolled subjects participated in the mindful-yoga intervention and completed the study. Two of the 17 women had missing actigraphy data. The characteristics of the sample are shown in Table 1. They were middle-class, married, college-educated, and 53% worked full time. None reported currently smoking cigarettes, taking prescription drugs, illicit drugs, or having medical problems. None were obese. All women were having their first baby, planned on attending childbirth class, intended to breastfeed, and wanted a vaginal birth. All of the working women were planning to return to work after the baby was born. Although none of the women had current mental or physical health problems, 20% reported a history of depression or anxiety in the past.

As shown in Table 2, women in the third trimester group were 29.1 ± 2.0 weeks' gestation on the first day of the intervention. Women in the second trimester of pregnancy on the first day of the intervention were 21.0 ± 4.1 weeks' gestation. For the third trimester group, baseline data were collected, on average, 2.7 weeks prior to the first day of the intervention when their mean gestation was 26.4 weeks (\pm 2.3 weeks; range: 23.7 to 29.4 weeks). Second trimester baseline data were collected, on average, at 19.8 weeks' gestation (\pm 4.0 weeks; range: 12.0 to 23.3 weeks) which was 1.2 weeks prior to the intervention beginning. Post-intervention data collection for all participants occurred immediately following completion of the 7-week intervention and on the same days of the week. On the first day of the three-day collection cycle, the third trimester group

averaged 36.1 ± 2.0 weeks' gestation and the second trimester group averaged $27.1 (\pm 4.1)$ week's gestation.

Adherence

Pregnant women attended the 7-week mindful-yoga group program and were instructed to practice at home at least 5 times during the week between the group sessions. On average, they reported mindfulness-based formal practice two times per week in their home, with a range 0 to 6 times a week. Women reported that they would readily recommend it to other pregnant women. However, they also reported difficulties practicing at home alone.

Sleep

Reliabilities between three consecutive 24 hour periods for actigraphy data were estimated by intraclass correlation (ICC). An ICC of at least .60 reflects acceptable stability and reliability and indicates that the variation achieved between baseline and postintervention was due to subject scores and not error between the two time points. The majority of the sleep variables demonstrated a high degree of stability and reliability across the three nights of data and these variables became more stable over time. The ICC for sleep efficiency at Time 1 was .82 and at Time 2 was .96; total sleep time ICC at Time 1 was .75 and at Time 2 was .88; the ICC for Awakenings at Time 1 was .74 and at Time 2 was .89; and the WASO ICC at Time 1 was .81 and at Time 2 was .97.

At baseline there were no significant differences by trimester group for any of the sleep parameters. The total amount of night time spent in bed (SPT) at baseline averaged 9.7 \pm .65 hours and 9.1 hours \pm .75 hours at post-intervention; a statistically significant reduction (*Z* = -2.39, p = .02). Total slept time (TST) also significantly decreased by an

average of 30 minutes from baseline (8.3 hours \pm 1.1) to post-treatment (7.8 hours \pm 1.4; Z = -1.99; p = .02).

As shown in Table 3, there were important differences in sleep by trimester group even in this small sample. Although women who began the intervention in their second trimester spent nearly 38 minutes less in bed from Time1 to Time2 (ES -.97; 95%CI -1.75, -.19; Z = -1.69; p = .05), their TST only decreased by seven minutes. Despite less time spent in bed, women beginning mindful-yoga in the second trimester actually improved their sleep efficiency by nearly 5%, with significantly fewer awakenings (Z =-1.86, p = .03) and less WASO. This was in contrast to women who began mindful-yoga in the third trimester and experienced significant deterioration in sleep efficiency (Z =-1.96, p = .02), with less TST (Z - 2.24, p = .01), longer sleep onset latency (Z = 1.61; p=.05; ES .83, 95%CI .11, 1.55) and greater WASO (Z = 1.82, p = .04).

To examine whether these trimester differences in sleep outcomes were influenced by advancing pregnancy, post-intervention data for the second trimester group was compared with baseline data from the third trimester women who had not yet started the mindful-yoga intervention and could be considered as a control group for comparison with the second trimester group. After seven weeks of the mindful-yoga intervention, the second trimester women had fewer awakenings and less WASO compared to third trimester women who had not yet started the intervention. As seen in Table 4, the postintervention group at 27.5 wks gestation spent less time in bed and had better sleep efficiency with fewer awakenings and less WASO than controls at 26.1 weeks. However, most notable was the wide variance in the third trimester group compared to the second trimester group after they received the intervention.

Discussion

This is the first study we are aware of that tested a mindfulness-based intervention emphasizing yoga rather than sitting meditation for pregnant women. Additionally, no other published studies have documented the effects of a mind-body intervention on sleep in healthy pregnancy. Our findings are the first to document changes in sleep variables as a function of mindful-yoga.

Findings from this study suggest that pregnant women in their second trimester can improve their sleep with a mindful-yoga intervention as pregnancy progresses. Previous research has shown that Mindfulness-Based Stress Reduction (MBSR) improves sleep in cancer patients. However, this is the first study to show improved sleep among healthy women who are expected to have poorer sleep over the course of their pregnancy. Only women who began mindful-yoga in their second trimester, however, experienced improved sleep, as indicated by better sleep efficiency with fewer number of awakenings and less total wake time. These results are significant because clinicians expect sleep efficiency to decrease as pregnancy advances and the majority of women in the second trimester group were well into their third trimester at the end of the 7-week intervention. In contrast, sleep continued to deteriorate for women beginning mindful-yoga when already in their third trimester at the start of the intervention.

Results from this pilot study suggest that mindful-yoga, if initiated in the second trimester, may improve sleep, but the mechanism remains unclear. This is important because sleep during pregnancy may indirectly contribute to labor outcomes. Reduced time in bed and increased wake time in bed has been associated with longer labors and increased risk for cesarean birth (Lee & Gay, 2004). Moreover, the amount of sleep a

woman has the night before labor begins has been associated with pain perception (Beebe & Lee, 2007). Improving sleep in pregnancy may also have positive effects on mental health. Lee and colleagues (2000a) found that negative mood in pregnancy was associated with more time awake at night. An intervention that improves sleep might also improve mood and these relationships may be the function of neurotransmitter systems that are involved in multiple regulatory systems (sleep, mood, stress, and labor progression). To our knowledge, this is the first data linking improved sleep to mindful-yoga in healthy, second trimester pregnant women.

Limitations

There are several limitations of this pilot study. Without an adequate control group matched on gestation at the time of enrollment and randomly allocated into treatment and control groups, the changes observed over time cannot be strictly attributed to mindful-yoga. We attempted to control for this in this small feasibility study by analyzing the data by trimester and by using baseline data of women who began mindful-yoga in their third trimester as the control group for post-treatment data of women who began the itnervention in their second trimester. However, perhaps due to the small sample, some results may have lacked the power to reach statistical significance. Since participants in this sample were predominantly Caucasian, middle class, employed, well-educated, and married, results cannot be generalized to other ethnicities or socio-economic groups; nor should results be generalized to women with pregnancy complications. This was a self-selected convenience sample of women who may have been more responsive to the intervention than the general population of pregnant women.

Given the limitations of this pilot study, the preliminary results of mindful-yoga for improving sleep time and sleep efficiency for second trimester women entering the third trimester, participation in mindful-yoga may be a promising area for further supporting pregnant women dealing with sleep disturbance.

Summary

In this pilot study we examined the influence of mindful-yoga for relationships with, sleep during pregnancy. Mindful-yoga may have attributes that moderate sleep disturbance and thereby improve perinatal health. Women who began mindful-yoga in the second trimester experienced better sleep efficiency while women who began the intervention in the third trimester did not. Based on these findings, we propose mindfulyoga as a promising treatment to promote maternal sleep and diminish the potential negative impact of sleep disturbance in pregnancy. However, the biobehavioral mechanisms underlying improved sleep for second trimester participants are not understood. Mindful-yoga is a practice and a skill that works with self observation and helps to harness the ordinary capacities of the mind and body. Benefits of developing skills in self-observation may include improved sleep.

In conclusion, this pilot study documents a mindful-yoga intervention administered during pregnancy that resulted in improved sleep efficiency in the second trimester using objective sleep measures. To our knowledge, no other mindfulness-based study has evaluated a pregnant woman's sleep, an integral part of the physiological responses to stress. Future studies could extend our findings by recruiting a larger sample size, including an attention control group, and following women from early pregnancy until delivery to compare the effects of mindful-yoga on women in all three trimesters.

| Characteristic | Number (n =15) | Percentages | |
|-------------------|-------------------|-------------|--|
| Age | 30.9 ± 3.2 | | |
| 25-29 | 4 | 27% | |
| 30-37 | 11 | 73% | |
| Work Status | | | |
| Fulltime | 8 | 53% | |
| Part-time | 5 | 34% | |
| Not working | 2 | 13% | |
| Student Status | | | |
| Full-time student | 3 | 20% | |
| Non-student | 12 | 80% | |
| Weeks' Gestation | | | |
| 12 -24 weeks | 7 | 47% | |
| 25-32 weeks | 8 | 53% | |
| Prenatal Care | | | |
| Obstetrician | 8 | 53% | |
| Midwife | 7 | 47% | |

TABLE 1 Baseline Demographic Characteristics (N = 15)

TABLE 2.

Comparisons of gestation (mean ± standard deviations weeks) at Time1 and Time2 data collection points by trimester group.

| Group | Number | Mean ± S.D. | Minimum | Maximum |
|------------------------------|--------|----------------|---------|---------|
| | | | (weeks) | (weeks) |
| Baseline (T1) | | | | |
| Whole Group | 15 | 23.3 ± 4.6 | 12.0 | 29.4 |
| 3rd Trimester | 8 | 26.5 ± 2.3 | 23.7 | 29.4 |
| 2nd Trimester | 7 | 19.8 ± 4.0 | 12.0 | 23.3 |
| First Day of Intervention | | | | |
| Whole Group | 15 | 25.3 ± 5.2 | 13.0 | 31.1 |
| 3rd Trimester | 8 | 29.1 ± 2.0 | 27.1 | 32.1 |
| 2nd Trimester | 7 | 21.0 ± 4.1 | 13.0 | 25.3 |
| Post-treatment (T2) | | | | |
| Whole Group | 15 | 32.3 ± 5.2 | 20.0 | 39.1 |
| 3rd Trimester | 8 | 36.1 ± 2.0 | 34.1 | 39.1 |
| 2nd Trimester | 7 | 27.1 ± 4.1 | 20.0 | 32.3 |

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| Measure | 2 nd trimester Baseline | Post | Wilcoxon Z & 2-tailed P value | 3 rd trimester Baseline | Post | Wilcoxon Z & 2-tailed P value |
|---|--|--------------|-------------------------------------|---------------------------------------|------------------|-------------------------------------|
| Sleep | (n = 7) | | | (n = 8) | | |
| Total time in bed SPT (minutes) | 582.6 (35.9) | 544.8 (36.6) | -1.69 p = .05 | 575.3 (43.1) | 547.3 (53.7) | -1.40 p = .16 |
| Total sleep time TST (minutes) | 507.4 (63.5) | 500.0 (26.2) | 34 p = .72 | 498.5 (71.2) | 436.7 (105.3) | -2.24 p = .01 |
| Sleep efficiency SEI (%TST/SPT) | 87.5 (9.3) | 92.0 (2.9) | .68 p = .50 | 86.8 (9.4) | 79.2 (16.1) | -1.96 p = .02 |
| Sleep onset latency (minutes) | 15.5 (14.5) | 8.1 (2.9) | 68 p = .50 | 5.7 (3.1) | 9.7 (6.0) | 1.61 p = .05 |
| Awakenings (#) | 11.9 (5.7) | 9.2 (4.6) | -1.86 p = .03 | 15.0 (8.5) | 18.0 (8.2) | .98 p = .32 |
| Wake after sleep onset WASO (% of SPT) | 8.9 (7.0) | 5.6 (2.7) | 68 p = .50 | 11.4 (9.3) | 18.7 (15.8) | 1.82 p = .04 |

Sleep data: pre- and post-intervention means (standard deviations), Wilcoxon Z values

| | 3 rd trimester at baseline | 2 nd trimester at post | Mann Whitney U & 2-tailed p-value |
|-----------------|--|--------------------------------------|--|
| Gestational age | (n = 8) | (n = 7) | 0.42 |
| (weeks) | 26.45 (2.26) | 27.08 (4.12) | p = .82 |
| Sleep | (n = 8) | (n = 7) | |
| SPT (minutes) | 575.3 (43.1) | 544.8 (36.6) | -1.27 p = .24 |
| TST (minutes) | 498.5 (71.2) | 500.0 (26.2) | 0.70 p = .54 |
| SEI (% TST/SPT) | 86.8 (9.4) | 92.0 (2.9) | 1.28 p = .24 |
| SOL (minutes) | 5.7 (3.1) | 8.1 (2.9) | 1.28 p = .24 |
| Awakenings (#) | 15.0 (8.5) | 9.2 (4.6) | -1.39 p = .18 |
| WASO (% of SPT) | 11.4 (9.3) | 5.6 (2.7) | -1.62 p = .12 |

TABLE 4. Comparisons between 3rd trimester women before the intervention and 2rd trimester women after completing the intervention.

References

- Ancoli-Israel, S., Cole, R., Alessi, C., Chambers, M., Moorcroft, W., & Pollak, C. P.
 (2003). The role of actigraphy in the study of sleep and circadian rhythms. *Sleep*, 26, 342-392.
- Andersson, L., Sundstrom-Poromaa, I., Bixo, M., Wulff, M., Bondestam, K., & aStrom,
 M. (2003). Point prevalence of psychiatric disorders during the second trimester
 of pregnancy: A population-based study. *American Journal of Obstetrics and Gynecology, 189*, 148-154.
- Bastani, F., Hidarnia, A., Kazemnejad, A., Vafaei, M., & Kashanian, M. (2005). A randomized controlled trial of the effects of applied relaxation training on reducing anxiety and perceived stress in pregnant women. *Journal of Midwifery and Women's Health, 50*, e36-40.
- Bastani, F., Hidarnia, A., Montgomery, K. S., Aguilar-Vafaei, M. E., & Kazemnejad, A.
 (2006). Does relaxation education in anxious primigravid Iranian women influence adverse pregnancy outcomes? A randomized controlled trial. *Journal of Perinatal and Neonatal Nursing, 20*, 138-146.
- Beck, C. T. (2001). Predictors of postpartum depression: An update. *Nursing Research*, 50, 275-285.
- Beddoe, A. E., & Lee, K. L. (in press). A feasibility study of yoga and mindfulness meditation during pregnancy: Effects on perceived stress, anxiety, pain, and sleep. Unpublished manuscript, San Francisco.
- Beddoe, A. E., & Murphy, S. O. (2004). Does mindfulness decrease stress and foster empathy among nursing students? *Journal of Nursing Education*, *43*, 305-312.

- Beebe, K. R., & Lee, K. A. (2007). Sleep disturbance in late pregnancy and early labor. Journal of Perinatal and Neonatal Nursing, 21, 103-108.
- Carlson, L. E., & Garland, S. N. (2005). Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *International Journal of Behavioral Medicine*, 12, 278-285.
- Cole, R. J., Kripke, D. F., Gruen, W., Mullaney, D. J., & Gillin, J. C. (1992). Automatic sleep/wake identification from wrist activity. *Sleep*, 15, 461-469.
- Eisenberg, D. M., Davis, R. B., Ettner, S. L., Appel, S. S., Wilkey, S., Van Rompay, M., et al. (1998). Trends in alternative medicine use in the United States, 1990-1997:
 Results of a follow-up national survey. *Journal of the American Medical Association*, 280, 1569-1575.
- Everly, G. S., Jr., & Benson, H. (1989). Disorders of arousal and the relaxation response: Speculations on the nature and treatment of stress-related diseases. *International Journal of Psychosomatic Medicine*, 36, 15-21.
- Field, T., Diego, M., Hernandez-Reif, M., Figueiredo, B., Schanberg, S., & Kuhn, C.
 (2007). Sleep disturbances in depressed pregnant women and their newborns. *Infant Behavior and Development, 30*, 127-133.
- Field, T., Diego, M. A., Hernandez-Reif, M., Schanberg, S., & Kuhn, C. (2004). Massage therapy effects on depressed pregnant women. *Journal of Psychosomatic Obstetrics and Gynaecology*, 25, 115-122.
- Field, T., Hernandez-Reif, M., Diego, M., Schanberg, S., & Kuhn, C. (2006). Stability of mood states and biochemistry across pregnancy. *Infant Behavior and Development, 29*, 262-267.

- Field, T., Hernandez-Reif, M., Hart, S., Theakston, H., Schanberg, S., & Kuhn, C. (1999). Pregnant women benefit from massage therapy. *Journal of Psychosomatic Obstetrics and Gynaecology*, 20, 31-38.
- Goldenberg, R. L., Goepfert, A. R., & Ramsey, P. S. (2005). Biochemical markers for the prediction of preterm birth. *American Journal of Obstetrics and Gynecology*, 192, S36-S46.
- Greenwood, K. M., & Hazendonk, K. M. (2004). Self-reported sleep during the third trimester of pregnancy. *Behavioral Sleep Medicine*, *2*(4), 191-204.
- Hall, M., Baum, A., Buysse, D. J., Prigerson, H. G., Kupfer, D. J., & Reynolds, C. F.,
 3rd. (1998). Sleep as a mediator of the stress-immune relationship. *Psychosomatic Medicine*, 60, 48-51.
- Hall, M., Buysse, D. J., Nowell, P. D., Nofzinger, E. A., Houck, P., Reynolds, C. F., 3rd, et al. (2000). Symptoms of stress and depression as correlates of sleep in primary insomnia. *Psychosomatic Medicine*, 62, 227-230.
- Hanh, T. N. (1976). The miracle of mindfulness: A manual for meditation. Boston: Beacon.
- Hertz, G., Fast, A., Feinsilver, S. H., Albertario, C. L., Schulman, H., & Fein, A. M. (1992). Sleep in normal late pregnancy. *Sleep*, 15, 246-251.

Hobel, C. J., Dunkel-Schetter, C., Roesch, S. C., Castro, L. C., & Arora, C. P. (1999).
Maternal plasma corticotropin-releasing hormone associated with stress at 20 weeks' gestation in pregnancies ending in preterm delivery. *American Journal of Obstetrics and Gynecology*, 180, S257-263.

Iyengar, B. K. S. (1979). Light on Yoga (2nd ed.). New York: Schocken Books.

- Kabat-Zinn, J. (1990). Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness. New York: Dell Publishing.
- Kelly, R. H., Russo, J., & Katon, W. (2001). Somatic complaints among pregnant women cared for in obstetrics: Normal pregnancy or depressive and anxiety symptom amplification revisited? *General Hospital Psychiatry*, 23, 107-113.
- Kornfield, J. (1993). *A path with heart: A guide through the perils and promises of spiritual life*. New York: Bantam Doubleday Dell.
- Lazarus, R. S. (1984). Puzzles in the study of daily hassles. *Journal of Behavioral Medicine*, *7*, 375-389.
- Lee, K. A. (1998). Alterations in sleep during pregnancy and postpartum: A review of 30 years of research. *Sleep Medicine Reviews*, *2*, 231-242.
- Lee, K. A., & Gay, C. L. (2004). Sleep in late pregnancy predicts length of labor and type of delivery. *American Journal of Obstetrics and Gynecology, 191*, 2041-2046.
- Lee, K. A., McEnany, G., & Zaffke, M. E. (2000a). REM sleep and mood state in childbearing women: Sleepy or weepy? *Sleep, 23*, 877-885.
- Lee, K. A., Zaffke, M. E., & McEnany, G. (2000b). Parity and sleep patterns during and after pregnancy. *Obstetrics and Gynecology*, *95*, 14-18.
- Littner, M., Kushida, C. A., Anderson, W. M., Bailey, D., Berry, R. B., Davila, D. G., et al. (2003). Practice parameters for the role of actigraphy in the study of sleep and circadian rhythms: An update for 2002. *Sleep, 26*, 337-341.
- Mancuso, R. A., Schetter, C. D., Rini, C. M., Roesch, S. C., & Hobel, C. J. (2004).
 Maternal prenatal anxiety and corticotropin-releasing hormone associated with timing of delivery. *Psychosomatic Medicine*, 66, 762-769.

- Miller, J. J., Fletcher, K., & Kabat-Zinn, J. (1995). Three-year follow-up and clinical implications of a mindfulness meditation-based stress reduction intervention in the treatment of anxiety disorders. *General Hospital Psychiatry*, 17, 192-200.
- Narendran, S., Nagarathna, R., Gunasheela, S., & Nagendra, H. R. (2005a). Efficacy of yoga in pregnant women with abnormal Doppler study of umbilical and uterine arteries. *Journal of the Indian Medical Association*, 103, 12-14, 16-17.
- Narendran, S., Nagarathna, R., Narendran, V., Gunasheela, S., & Nagendra, H. R. (2005b). Efficacy of yoga on pregnancy outcome. *Journal of Alternative and Complementary Medicine*, 11, 237-244.
- Neggers, Y., Goldenberg, R., Cliver, S., & Hauth, J. (2006). The relationship between psychosocial profile, health practices, and pregnancy outcomes. *Acta Obstetricia et Gynecologica Scandinavica*, *85*, 277-285.
- O'Connor, T. G., Heron, J., Golding, J., Beveridge, M., & Glover, V. (2002). Maternal antenatal anxiety and children's behavioural/emotional problems at 4 years.
 Report from the Avon Longitudinal Study of Parents and Children. *British Journal of Psychiatry*, 180, 502-508.
- Rosenzweig, S., Reibel, D. K., Greeson, J. M., Brainard, G. C., & Hojat, M. (2003). Mindfulness-based stress reduction lowers psychological distress in medical students. *Teaching and Learning in Medicine*, 15, 88-92.
- Saunders, T. A., Lobel, M., Veloso, C., & Meyer, B. A. (2006). Prenatal maternal stress is associated with delivery analgesia and unplanned cesareans. *Journal of Psychosomatic Obstetrics and Gynaecology*, 27, 141-146.

- Shapiro, S. L., Bootzin, R. R., Figueredo, A. J., Lopez, A. M., & Schwartz, G. E. (2003). The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: An exploratory study. *Journal of Psychosomatic Research*, 54, 85-91.
- Urizar, G. G., Milazzo, M., Le, H. N., Delucchi, K., Sotelo, R., & Munoz, R. F. (2004). Impact of stress reduction instructions on stress and cortisol levels during pregnancy. *Biological Psychology*, 67, 275-282.
- Van den Bergh, B. R., & Marcoen, A. (2004). High antenatal maternal anxiety is related to ADHD symptoms, externalizing problems, and anxiety in 8- and 9-year-olds. *Child Development*, 75, 1085-1097.
- Wadhwa, P. D., Dunkel-Schetter, C., Chicz-DeMet, A., Porto, M., & Sandman, C. A. (1996). Prenatal psychosocial factors and the neuroendocrine axis in human pregnancy. *Psychosomatic Medicine*, 58, 432-446.
- Wadhwa, P. D., Garite, T. J., Porto, M., Glynn, L., Chicz-DeMet, A., Dunkel-Schetter,
 C., et al. (2004). Placental corticotropin-releasing hormone (CRH), spontaneous
 preterm birth, and fetal growth restriction: A prospective investigation. *American Journal of Obstetrics and Gynecology*, 191, 1063-1069.
- Wadhwa, P. D., Porto, M., Garite, T. J., Chicz-DeMet, A., & Sandman, C. A. (1998).
 Maternal corticotropin-releasing hormone levels in the early third trimester predict length of gestation in human pregnancy. *American Journal of Obstetrics and Gynecology*, 179, 1079-1085.
- Wadhwa, P. D., Sandman, C. A., Porto, M., Dunkel-Schetter, C., & Garite, T. J. (1993). The association between prenatal stress and infant birth weight and gestational

age at birth: A prospective investigation. *American Journal of Obstetrics and Gynecology*, 169, 858-865.

- Webster, J. B., Kripke, D. F., Messin, S., Mullaney, D. J., & Wyborney, G. (1982). An activity-based sleep monitor system for ambulatory use. *Sleep*, *5*, 389-399.
- Williams, K. A., Kolar, M. M., Reger, B. E., & Pearson, J. C. (2001). Evaluation of a wellness-based mindfulness stress reduction intervention: A controlled trial. *American Journal of Health Promotion*, 15, 422-432.

Chapter Five

Discussion

Chapter Five

Discussion

Mindfulness-meditation and Hatha yoga, with their roots in Eastern philosophic contemplative traditions, have been increasingly used in the clinical domain and wellness programs. Over twenty years, studies have demonstrated the efficacy of mindfulnessbased programs for health problems such as pain (Kabat-Zinn, 1982), sleep disturbance (Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003; Carlson, Speca, Patel, & Goodey, 2003), anxiety, and depression (Reibel, Greeson, Brainard, & Rosenzweig, 2001). These symptoms are also experienced by pregnant women. However, no published studies have evaluated efficacy of these programs during pregnancy.

The primary purpose of this study was to investigate the feasibility, effectiveness, and desirability of a "mindful-yoga" intervention that blended elements of Mindfulness-Based Stress Reduction and prenatal yoga in the Iyengar tradition, for its effects on stress reduction, anxiety, sleep disturbance, pain, physical activity, and mindfulness skills among healthy pregnant women. The effect of a mindful-yoga intervention was studied over time, comparing baseline (Time 1) and postintervention (Time 2) data in a single treatment group. This chapter discusses the findings and implications for future research.

The study was conducted using a convenience sample of 19 English-speaking nulliparous women with healthy pregnancies, all of whom were partnered and agreed to participate in the mindful-yoga intervention that met for seven weekly sessions. Paired data from pre- and post-treatment were collected from 17 women. The sample was fairly homogeneous with respect to age, ethnicity, education, and income level. The participants were well-educated with middle-class income. Although none were currently

being treated for psychiatric disorders, nearly 30% had a history of depression or anxiety in the past. Despite the small sample, significant results were found and are discussed below. Several research questions and related hypotheses were proposed using a combination of physiologic and psychological methods. To achieve the purpose of this feasibility pilot study, the following seven aims and five hypotheses were addressed:

 $\underline{\text{Aim } \#1}$: to determine whether the intervention would raise mindfulness scores.

Hypothesis: The group at 7 weeks post-intervention would self-report significantly higher mindfulness scores.

<u>Aim #2</u>: to determine whether a seven-week mindful-yoga intervention would reduce prenatal distress by significantly lowering levels of perceived stress and anxiety, lowering intensity and frequency of pain and pain interference, improving subjective sleep, and increasing levels of physical activity.

Hypothesis: The group at 7 weeks post-intervention would self-report significantly lower perceived stress and anxiety, lower intensity and frequency of pain, improved sleep, and greater levels of physical activity compared to baseline scores.

<u>Aim #3</u>: to determine whether the intervention would improve objective sleep outcomes as estimated by wrist actigraphy.

Hypothesis: The participants would have significantly more total sleep time and less wake time during the night estimated by wrist actigraphy data at post-intervention compared to baseline.

<u>Aim#4</u>: to identify relationships between salivary cortisol levels, stress appraisal, anxiety, pain, mindfulness, and sleep disturbance assessed by self-report and actigraphy.

<u>Aim #5</u>: to determine whether pregnant second and third trimester women respond differently to mindful-yoga.

Hypothesis: Pregnant women beginning the intervention in the third trimester would respond differently than women beginning the intervention in the second trimester, with second trimester women demonstrating greater response to the intervention.

<u>Aim #6</u>: to evaluate the feasibility and desirability for pregnant women of mindful-yoga, a 7-week intervention that combines elements of Mindfulness-Based Stress Reduction and prenatal Iyengar yoga.

Hypothesis: Women who completed the 7-week intervention would report satisfaction with mindful-yoga, practice it at home, and recommend it to others.

<u>Aim #7</u>: to evaluate whether women who completed the 7-week session would use mindful coping skills during labor and birth.

Lazarus and Folkman's (Lazarus & Folkman, 1984) transactional theory of psychological stress was used as a framework to underpin the study. Mindfulness is a skill and a way of being that can be learned and put into practice through the application of a variety of formal and informal meditative practices. It has been suggested that mindfulness influences the stress response through increased awareness of threat appraisal, the development of inner resources, and the cultivation of novel coping skills.

Interpretation of Results

Results of the mindful-yoga feasibility study were presented in chapters three and four. Chapter three presented baseline and postintervention data resulting from the mindful-yoga pilot study collected by respondent completion of self-report instruments, while chapter four presented data on participants' sleep with wrist actigraphy. These data

are presented in order of study aims. They are interpreted cautiously because of the small sample size and lack of control group.

Aims 1 and 5: Mindfulness.

As described in chapter three, mindfulness was measured by self-report with the Five Factor Mindfulness Questionnaire (FFMQ: Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) that has five subscales: Acting with Awareness, Describing, Nonjudging, Nonreacting, and Observing. Two facets of mindfulness, Observing and Nonreacting, demonstrated moderate improvements from baseline to post-intervention for the whole group (p = .06 and p = .07; respectively. Scores for mindfulness subscales Acting with Awareness, Describing, and Nonjudging were not significantly changed by the seven-week intervention for the sample as a whole.

When effects were examined by trimester, there were differences in mindfulness response. Women who began the intervention in second trimester demonstrated improvements in Observing (p = .07) whereas women who began the intervention in third trimester did not. Women who began the intervention in third trimester achieved improvements in Nonjudging scores (p = .09) but second trimester women did not.

The FFMQ is a new operationalization of mindfulness and was chosen for its subscale called Observing, which is unique among mindfulness instruments. The Observing subscale emphasizes noticing various stimuli including body sensations and sensory awareness, both readily underscored in yoga practice. One explanation for non-uniform improvement in all five facets of mindfulness may be that learning each facet may not occur equally in the beginner. Baer et al. (2004) found that the Observe facet was associated with meditation experience (p < .001) and posited that Observing may be

more sensitive to changes than other facets of mindfulness. Baer (2004) also suggests that for samples with limited meditation experience, the tendency to attend to experiences (i.e., Observe) is associated with a tendency to be judgmental of them. For beginners, greater awareness of how one is feeling may initially be associated with lower levels of acceptance. Over time, and through mindfulness practice, the person is able to both observe personal experience and accept those experiences without judging them. This was consistent with our findings that Observe scores increased over time while for second trimester participants, Nonjudge scores did not. Baer's supposition does not explain the trimester difference in this study's Nonjudge scores.

Another explanation is that mindful-yoga uniquely emphasizes qualities of Observing and Nonreacting, subscales that improved over time, while the other subscales did not. Mindful-yoga's emphasis on observation of physical sensations, awareness of posture, and its instructions that remind participants to pay purposive attention to how they are feeling right now, are directly linked to items within the Observing subscale. For instance, one item: "When I'm walking, I deliberately notice the sensations of my body moving", is a mindfulness practice taught and carried out during the intervention.

The Nonreact facet also showed change over time. An example of a Nonreact item is "In difficult situations, I can pause without immediately reacting." Baer and colleagues (2006) found Nonreact highly correlated with the construct, "selfcompassion." However, Nonreacting may be a function of the sympathetic nervous system, and as such, the capacity to "nonreact" could be linked to the degree of sympathetic nervous system activation. Practices similar to the body scan in mindfulyoga have reduced baseline sympathetic nervous system activity in healthy subjects

(Beary & Benson, 1974; Vempati & Telles, 2002). Alternately, it is well known that the sympathetic nervous system response is dampened as pregnancy progresses.

Nonjudging is the allowance of inner and outer experience to be as it is in the present moment and "to refrain from applying evaluative labels such as good/bad, right/wrong, or worthwhile/worthless" (Baer, 2004, p. 194). An example of a Nonjudge item is "I tell myself that I shouldn't be thinking the way I'm thinking." Baer and colleagues (2006) found a strong inverse correlation between Nonjudging and psychological symptoms. Similarly, third trimester women in this study showed improved Nonjudging scores coupled with attenuation of anxiety and perceived stress while second trimester participants did not.

Baer and colleagues (2006) have noted that Observe's relationships with other variables may change as a function of meditation experience. Observe may be particularly sensitive to the personal changes that occur during Hatha yoga practice. Mindful-yoga may not be fully measured by the currently used operationalization of mindfulness. Conceivably its effects are related to another construct such as somatic awareness, for which there is no adequate measure currently available.

Mindfulness results were not robust and, as a multifaceted construct, did not improve as a result of mindful-yoga. This may be due to the small sample size, an inadequate dose response relationship for a short time frame of only once weekly for seven weeks, or an inadequate ability of the FFMQ to measure mindfulness with sensitivity for change over time. It may also have been a function of the intervention that emphasized yoga asana practice, rather than a sitting meditation.

Aims 2 and 5: Self-Reports

Psychological distress.

In chapter three, outcome data for stress appraisal from the mindful-yoga pilot study were presented. Stress appraisal was measured by two instruments: Cohen's Perceived Stress Scale (PSS; 1983; 1995) and Curry's Prenatal Psychosocial Profile (PPP; 1998). Third trimester women scored higher on the PSS at baseline than second trimester women (p = .05). Perceived stress diminished (p = .03) over time in the third trimester group. The PPP scores also significantly diminished from pre- to post-treatment (p = .10) and there were no significant differences by trimester.

Also in chapter three, pre- and post-intervention data from Spielberger's State Trait Anxiety Inventory (1985) were presented, which demonstrated significant improvement in trait but not state anxiety for the sample as a whole. Trait anxiety dropped significantly from pre- to post-treatment (p = .03). This was due to strong effect for the third trimester group whose scores were higher at baseline while the second trimester showed no change.

The two trimester groups showed differences in anxiety and perceived stress scores at baseline and significant attenuation of perceived stress and trait anxiety for the group was due to effects for third trimester women. Additionally, state anxiety actually increased for second trimester participants from pre- to post-intervention. Several explanations are plausible for group differences in response to the intervention for trait anxiety. The data may have been influenced by various factors such as a small sample size yielding inherent group differences, physiological changes that are a function of gestation, or the intervention may have been perceived as more stressful for third

trimester participants. Glynn and colleagues (2004; 2001) have shown that advanced gestation attenuates perceived stress.

Many third trimester women were working at Time 1 and by Time 2 had taken maternity leave. Since these work-related data were not collected, variations in work schedules may have confounded the results. Although perceived stress was diminished in third trimester participants at Time 2, Thomas and colleagues (2005) found the opposite effect in their epidemiological study, wherein the start of maternity leave actually increased psychological stress in their sample.

This intervention pilot study showed that trait anxiety diminished over time but state anxiety did not. The high standard deviation for state anxiety at Time 2 may have resulted in a p-value that did not meet a .10 level of significance. These results do not support the accepted understanding that state anxiety changes over time and trait anxiety remains stable. However, other studies have demonstrated attenuation of trait-anxiety following yoga (Gupta, Khera, Vempati, Sharma, & Bijlani, 2006; Michalsen, Grossman, Acil, Langhorst, Ludtke et al., 2005; Woolery, Myers, Sternlieb, & Zeltzer, 2004) or a mindfulness-based intervention (Shapiro, Schwartz, & Bonner, 1998), all of which demonstrated greater reductions in trait- than state-anxiety. These results challenge the notion that trait anxiety yields enduring scores. Alteration in the more stable trait anxiety is desirable, and may indicate neuroplasticity.

Physical distress: Pain.

Results from the Brief Pain Inventory (BPI; Daut, Cleeland, & Flanery, 1983) are presented in chapter three. The BPI contains three subscales: pain interference, hours of pain and pain intensity. In a subgroup of women with pain, (n = 14; 2nd trimester n = 8;

 3^{rd} trimester n = 6) BPI scores differed at baseline between second- (23.5±20.8) and third-trimester women (33.3±29.0) but due to high variance in the third trimester group, scores were not significantly different. However, at post-intervention there were significant trimester differences in each dimension of pain at a .05 level of significance. Women beginning mindful-yoga in the second trimester showed reductions in pain as pregnancy progressed. They reported significantly fewer hours of pain in a typical week (p = .04) and showed trends of less pain interference. In contrast, women who began mindful-yoga in the third trimester reported a greater number of hours of pain by posttreatment, and although not statistically significant, it may be clinically significant.

The prevalence of pain in this study was 69% at Time 1 (11 women out of 16), similar to previous studies (Kristiansson, Svardsudd, & von Schoultz, 1996; Wang Dezinno, Maranets, Berman, Caldwell-Andrews et al., 2004). Pain differences by trimester at baseline were expected as women often experience pain with increasing intensity and greater interference with advancing pregnancy. Low back pain (LBP) during pregnancy becomes more intense with advancing gestation (Fast, Shapiro, Ducommun, Friedmann, Bouklas et al., 1987; Kristiansson et al., 1996), yet second trimester women in this sample did not experience worsening pain over the 7-week intervention. In fact, women in the second trimester of pregnancy had significantly fewer hours of pain and less pain interference with activity from baseline to post-intervention as they moved into their third trimester. Outcomes of reducing pain as pregnancy advances have individual and societal financial significance. Women in greater physical pain are more likely to have disturbed sleep (Olsson & Nilsson-Wikmar, 2004), take leave from

work earlier, and experience interference with activities of daily living (MacEvilly & Buggy, 1996; Ostgaard, Zetherstrom, & Roos-Hansson, 1997).

There are no other studies that consider the effects of a mindful-yoga intervention on back pain during pregnancy. Narendran et al. (2005) evaluated the efficacy of yoga in pregnancy but did not examine sleep, pain, or stress variables. However, Martins and Silva (2005; as cited in Pennick & Young, 2007) conducted a randomized study (N = 69), the results of which are not published in English, found that stretching exercises improved low back pain in a sample of Brazilian women. In contrast with this feasibility study, Suputtitada and colleagues (2002) demonstrated improvements in third trimester pain among participants through pelvic tilting exercise.

McCracken and colleagues' research on chronic pain has led them to suggest that emotional reactions to pain, such as depression and pain-related anxiety, are predictive of the extent to which pain interferes with daily life (2007). In contrast, this present study found that although third trimester subjects experienced greater pain and pain interference from Time 1 to Time 2, they also had reductions in anxiety and perceived stress. This may have been a function of mindful-yoga. However, McCracken and colleagues (2006) posit that acceptance improves pain outcomes. Acceptance is a central feature of mindfulness practice and Baer (2006) argues that Nonreacting and Nonjudging subscales are ways of operationalizing acceptance. Nonjudging has an inverse relationship with psychological symptoms (Baer et al., 2006). Because third trimester participants showed higher Nonjudging scores, attenuation of trait anxiety and perceived stress, and worsening sleep disturbance and physical pain from Time 1 to Time 2, it can

be cautiously concluded that, in spite of physical distress, Nonjudging may mediate psychological distress.

Physical distress: Self-reported poor sleep:

Chapter three also presented data on self-reported sleep disturbance from the mindful-yoga pilot study. The frequency of sleep disturbance was measured with the General Sleep Disturbance Scale (GSDS; Lee & DeJoseph, 1992) and item 5 of the GSDS asks for the number of nights of poor sleep in one week. The group as a whole did not show improvement from pre- to post-intervention but sleep disturbance findings differed by trimester. At baseline there were no significant differences in respondent scores by trimester, however, differences may have been clinically significant. At Time 1, third trimester respondents reported poor sleep for only 1.4±1.8 nights of the week while second trimester participants reported poor sleep for 3.6±1.5 nights. By post-intervention, sleep had deteriorated in third trimester women who reported sleeping poorly for 2.9±2.8 nights out of seven (p = .10). In contrast, women who began the intervention in the second trimester had fewer nights of poor sleep at post-intervention $(2.1\pm1.1, p=.03)$. Second trimester women experienced sleep improvement, even though seven weeks later most of these women were well into the third trimester, a time when many pregnant women commonly experience worsening sleep. Similarly, total GSDS scores showed that second trimester participants perceived their sleep as improving from T 1 to T 2 (p = .06) while third trimester participants perceived it as worsening (p = .09).

These findings indicate that mindful-yoga may be used to improve sleep during pregnancy if it begins by second trimester. This study is the first to find improved sleep effects from yoga for pregnant women in second trimester and showed differing effects

by trimester. Sleep disturbance during pregnancy is well documented (Lee, 1998; Lee & DeJoseph, 1992; Lee & Zaffke, 1999) and women report sleep disturbance as worse in the third trimester (Schweiger, 1972). Yet third trimester women at baseline in this study appraised their sleep as better than the second trimester group. The pattern was reversed at postintervention, when women were further advanced in pregnancy.

These findings of improved self-reported sleep in second trimester women suggest attenuation of physical distress during pregnancy. Women who started the intervention in second trimester were able to benefit from mindful-yoga in terms of diminished pain and improved sleep. Because pain and sleep generally worsen as pregnancy advances, mindful-yoga is a promising intervention. It is essential that pregnant women begin a program of mindful-yoga earlier rather than later in pregnancy.

Physical activity.

Physical activity was measured by the 10-item Rapid Assessment of Physical Activity (RAPA; Topolski, LoGerfo, Patrick, Williams, Walwick et al., 2006), modified to include an additional item that queried frequency of stretching activities. The majority of participants reported partaking in moderate physical activities each week at baseline and post-intervention. At baseline, the mean RAPA score was $5.8 (\pm 1.9)$, and at post-intervention it was $7.0 (\pm 1.8)$. Physical activity did not significantly differ by trimester at baseline. Analyses demonstrated significant change over time (p = .04) with a time by trimester interaction (p = .04). At postintervention, physical activity had increased in the second trimester group (p = .03), while activity reports from the third trimester group remained unchanged.

Increases in physical activity have been linked to lower levels of perceived stress in adults (Aldana, Sutton, Jacobson, & Quirk, 1996) and improved mood in pregnant women (Polman, Kaiseler, & Borkoles, 2007). However, Poudevigne & O'Connor (2005) did not find an association between physical activity and mood in pregnancy. Similarly, in this study, second trimester increases in physical activity did not correspond to lower stress appraisal scores. Physical activity is an important health behavior and increased physical activity may emerge as a predictor variable in perinatal research.

Physical activity has been shown to improve sleep (Youngstedt, 2005; Youngstedt, O'Connor, & Dishman, 1997) and may be an effective preventive and treatment for back pain in pregnancy. In a randomized clinical trial of 300 women, Morkved and colleagues (2007) demonstrated that for second trimester pregnant women, a 12-week training of aerobic and pelvic floor muscle exercises was effective in preventing and treating back pain measured at 36 weeks' (p = 0.03). The intervention also significantly improved functional status (p = 0.01) compared to the control group. *Aims 3 and 5: Wrist Actigraphy*

Wrist activity data on sleep changes are presented in chapter four. At baseline none of the seven measured actigraph sleep variables differed significantly by trimester. Data demonstrated that they spent more than 9.5 hours in bed at night, with 87% of that time actually asleep. By posttreatment, several sleep variables differed by trimester.

By postintervention, when most second trimester subjects were well into the third trimester, total time in bed actually diminished by 38 minutes (p = .05) while their mean sleep efficiency improved from 87.5% to 92%, and there were fewer number of awakenings (p = .03) and shorter sleep onset latency. In contrast, women who began

mindful-yoga in the third trimester experienced significantly less time asleep (p = .01) and lower sleep efficiency (p = .02) with a longer sleep onset latency (p = .05) and more time awake after sleep onset (p = .04).

To attempt to control for gestation, baseline data for women who began mindfulyoga in the third trimester were used to compare with Time 2 data of women who began mindful-yoga in the second trimester. Second trimester women demonstrated improved sleep after the intervention when compared with the third trimester controls. The second trimester group had 5% greater sleep efficiency, fewer nighttime awakenings, and less time awake after sleep at Time 2 when they were at similar gestation as the baseline third trimester group.

This is the first intervention study to demonstrate sleep improvements as pregnancy progresses. Sleep disturbance and pain are frequent complaints of pregnancy (Baratte-Beebe & Lee, 1999) that usually worsen as pregnancy progresses (Wang et al. 2004). However, second trimester women did not experience worse pain or sleep problems between the two time points, unlike the third trimester group. The sleep improvements may have been linked to attenuation of pain as women often ascribe pain as the reason for disturbed sleep during pregnancy (Wang et al., 2004). However, Thomas and colleagues (1989), who evaluated the Ozzlo pillow for nighttime backache, found it an effective treatment for pain but not sleep. An alternate explanation is that increased physical activity or a component of mindful-yoga could directly influence sleep in the second trimester.

Aim 4: Relationships Between Variables

Cortisol.

Presented here are data on salivary cortisol not presented in chapters three and four. Cortisol, the primary stress hormone secreted by the adrenals, has a circadian peak at first rising in the morning. The circadian peak of cortisol was estimated by asking participants to collect three consecutive samples in the morning at first rising. There was no significant difference in cortisol concentration between trimesters and there was a great deal of variance in Time 1 measures over three mornings compared to the Time 2 measures. Relationships between salivary cortisol level, hours in pain, and state anxiety were evident. Higher cortisol level at baseline was correlated with fewer hours of pain (r = -.55, p $\leq .05$) and greater state anxiety (r = .57, p $\leq .05$) whereas post-intervention cortisol concentrations between cortisol as a biomarker of stress as pregnancy advances, supporting the supposition by Glynn and colleagues (2004; 2001) that women respond to stressors more robustly earlier compared to later in pregnancy.

Correlations.

The Describing component of mindfulness refers to the ability to identify and describe, note, or label one's feelings and other observed phenomena (Baer et al., 2004). At baseline the Describing subscale score was strongly and inversely correlated with stress appraisal by the Prenatal Psychosocial Profile (r = -.48, p = .02), with number of hours spent in pain (r = -.63, p = .009), and with self-reported general sleep disturbance (r = -.68, p = .004). At Time 2, Describing did not correlate with pain, sleep, or stress variables.

A similar pattern of association was found for the Observing component of mindfulness, with hours of pain (p = .05) total sleep time (p < .05) and time spent in bed (p < .01) at Time 1, but there was no relationship for Time 2 variables. Observing is the capacity to notice and attend to internal phenomena such as body sensations, cognitions, and emotions, and external phenomena, such as sounds and smells (Baer et al., 2004; Kabat-Zinn, 1990). Pain and sleep disturbance may either have a unique influence on Describing and Observing aspect of mindfulness, or disassociation of pain, sleep, and stress appraisal with mindfulness may be a consequence of mindful-yoga practice, pregnancy, or another variable that was not measured. A person's ability for Describing and Observing may no longer be influenced by good sleep and sleep may become less influenced by experiences of pain and perceived stress.

The mindfulness facet Acting with Awareness is defined as "engaging fully in one's current activity with undivided attention or focusing with awareness on one thing at a time" (Baer, 2004, p. 193). Acting with Awareness was associated with sleep efficiency (r = .57, $p \le .05$) and total sleep time (r = .53, $p \le .05$) measured by actigraph at baseline. Acting with Awareness was also highly inversely correlated with self-report stress measures ($p \le .01$) with correlations indicating collinearity (r = .82 and -.87). These associations were still evident but no longer as highly correlated at Time 2. At post-intervention, higher state- and trait-anxiety scores were associated with reduced Acting with Awareness scores (r = .61, p < .05). Although this intervention study did not demonstrate the increased skill of Acting with Awareness, it is considered a main component of mindfulness meditation. Pregnant women were encouraged to develop mindfulness by practicing mindful-yoga with awareness and by paying attention to

routine activities of daily life, such as bathing and eating. Self-appraisal of Acting with Awareness did not improve over time. However, it was associated with a longer and better night's sleep, and women who practiced mindful-yoga beginning in the second trimester experienced improved sleep efficiency. This suggests that a future study with a larger sample and a "stronger dose" of mindful-yoga may demonstrate improvements in Acting with Awareness.

In this study, nonjudging was inversely associated with state anxiety (r = -.61, p<.05). Baer and colleagues (2006) found strong inverse relationships between Nonjudging and psychological symptoms. In fact, Nonjudging scores significantly predicted symptom levels in their study. Likewise, McKee (2007) found that low negative affect was predictive of higher Nonjudging scores.

Higher Nonreacting scores were associated with lower scores on the PPP pregnancy-specific stress measure (r = -.66p < .01). There were no other significant relationships with Nonreacting in this study. Nonreacting is the most recent facet of mindfulness that Baer and colleagues (2006) have identified.

Data collected from the Perceived Stress Scale and the PPP pregnancy-specific stress measure yielded means that were strongly correlated with one another and with state- and trait-anxiety. The PPP specifically measures stressful events and was significantly associated with self-reported sleep disturbance (r = .52, p < .05) at baseline, whereas perceived stress was not associated with sleep disturbance. There was a strong positive association between pain and self-reported sleep disturbance (r = .70, $p \le .01$) and a strong negative association between pain interference and self-reported sleep quality (r = ..80, $p \le .01$). Conclusions that extend to the effectiveness of mindful-yoga on these outcomes of interest cannot be drawn from correlations. Some of the associations are congruent with research literature. Examples of consistent findings are relationships between perceived stress and anxiety, disassociation between perceived stress and cortisol; and positive associations between pain and sleep disturbance, all of which are well researched. However, relationships between facets of mindfulness and physical distress such as pain and sleep have not been reported in the literature and merit future evaluation. <u>Aim #6: Acceptability of Mindful-Yoga</u>

Acceptability was measured at Time 2 with a questionnaire asking respondents to rate their experience and satisfaction with the intervention. The instrument was modified from an intervention evaluation tool used in a sleep study and from a follow-up questionnaire from the Stress Reduction Program at the University of Massachusetts Medical School. Pregnant women who attended the mindful-intervention were satisfied with the weekly classes. The majority of the women reported satisfaction with mindfulyoga and would recommend the class to others (94%, n = 15) while 81% said the class had been important to them. As a direct result of participation in the class, 63% (n = 10) reported feeling more hopeful, more confident, having a greater knowledge of what is stressful in their lives, knowing how to take better care of themselves, and having the ability to appropriately handle stressful situations. Half of the respondents said they were taking better care of themselves as a result of the mindful-yoga. By the end of the treatment, 19% were doing 30 or more minutes per day of activities to improve flexibility at least three days per week and an additional 56% were doing these activities for 30 minutes per day at least once per week. Half of the women reported that it was easy to

attend the classes. Examination of each woman's home address revealed that if the mindful-yoga was held at a location convenient to a woman, she characterized her attendance as "easy." Women who found it difficult to attend lived further from the facility and contended with traffic.

Data analyzed from a semi-structured interview at 4 weeks postpartum was not included in chapters three and four. The interviews revealed that most women continued formal mindfulness practices such as sitting meditation, yoga, and the body scan. When asked to quantify their continued use for the remainder of pregnancy after the intervention was over, five out of 17 of participants (29%) reported practicing at least three times per week, 10 (59%) reported continuing to practice 1-2 days per week, and two (10%) reported no further formal mindfulness practices during pregnancy. Taken together, these data suggest that subjects were satisfied with the intervention and utilized mindfulness skills outside of class. It is likely that future prenatal mindful-yoga classes would be well attended. Adherence to home practice and dose response could to be explored in the future by incorporation of a prenatal yoga videotape at home or offering more frequent classes during the week throughout pregnancy.

<u>Aim #7: Mindful Coping During Labor</u>

The postpartum interview contained items asking about incorporation of mindfulness skills learned in class during childbirth. All (n = 14) women reported that mindfulness aided them in coping with labor pain and 43% (n = 6) felt it helped a great deal. Eight of the women said that it was not at all difficult to practice mindfulness during labor, four said it was somewhat difficult, and two said it was very difficult. Mindfulness skills used during labor may help women cope with the pain and uncertainty of labor.

Due to a small sample size and no adequately designed control group, conclusions cannot be drawn about the influence of mindfulness on variables related to birth (such as mode of delivery or anesthesia use).

Limitations

A major limitation of this pilot study was the absence of a comparison group, specifically a randomized attention control group. Other limitations included the small sample size which limits statistical power and introduces selection bias, the wide range of expected due dates reported by women that confounded comparisons between baseline and post-treatment, the socioeconomic homogeneity of the sample which prevents generalization of the results, the absence of reliable dose-response information, and the potential influence of social desirability in responses on their self-report data. Other aspects of selection bias that threatened the internal validity of this study were a selfselected convenience sample. The results are therefore not generalizable to all pregnant women. The protocols used for mindful-yoga had not been administered before. Confounding variables such as the activation of a social support group and various activities presented during the intervention when mindful speaking and listening were introduced. Without an adequately designed control group that receives equal type of attention and group interaction, some of these variables may turn out to be active ingredients of the intervention, and were not controlled. Randomized clinical trials are needed to further investigate the effect of mindful-yoga on pregnancy stress and outcomes, and even then the findings would need to be replicated in other samples before the intervention becomes acceptable and implemented more broadly.

Strengths

This was the first study of this kind conducted in the United States that assessed a mindful-yoga intervention for pregnant women and measured its effects on stress appraisal, anxiety, and two common somatic complaints (e.g. sleep disturbance and pain) during pregnancy. A further strength of the study was that both biological markers and self-report measures were utilized in data collection. Studies such as this are long overdue because prenatal yoga is growing in popularity and virtually nothing is known of its effects. Another strength of the study was its intervention that blended Iyengar yoga with Mindfulness-Based Stress Reduction (MBSR). Iyengar yoga, brought from India to the Western continents over 40 years ago, is renowned for its knowledge of and adherence to good musculoskeletal alignment and posture, use of props to assist in physical alignment and support within poses, strengthening paired with flexibility, and poses tailored to fit pregnancy. MBSR has a 25-year clinical track record and has been the subject of research for two decades that has demonstrated its efficacy. A strength of this study is that it adds to the body of knowledge that evaluates both yoga and mindfulness-based participatory interventions. This study yielded more data than could be presented in chapters three and four. Figures in appendices B and C may provide insight into outcomes by trimester.

Implications

The study incorporated a biobehavioral approach to both understand and positively influence prenatal maternal stress appraisal, anxiety, and symptoms of sleep disturbance and pain during pregnancy. The collection of data at baseline and postintervention on instruments that measured respondent stress appraisal, anxiety, pain, and sleep disturbance as well as the use of objective cortisol and actigraphy measures

provide important information toward understanding complex and potentially bidirectional interactions between these variables and the role of mindful-yoga in reducing unpleasant symptoms during pregnancy, thereby improving health. These data will assist in designing future intervention studies. Further research is needed to determine how these factors interrelate, to examine mindful-yoga intervention's potential to attenuate pain and sleep disturbance throughout pregnancy, and to explore further whether mindfulness is a mechanism of symptom improvement for pregnant women.

Future Directions for Nursing Research

This intervention study was intended to develop an effective stress management and relaxation program that nurses, nurse midwives, and other health care providers could use in clinical care of pregnant women. The measurement of the effect of mindfulyoga on sleep disturbance and pain proved moderate for women who began the intervention in the second trimester of pregnancy. Given the serious and deleterious consequences of back and pelvic pain and sleep disturbance during pregnancy, the mindful-yoga intervention merits further research in pregnancy. Research could include the effects of mindful-yoga on pain and sleep in first trimester women. If the intervention and measurement points were extended for a longer period, it would be important to see if second trimester participants maintain sleep and pain improvements until 40 weeks' gestation. A stronger dose of the intervention, one in which the mindful-yoga is delivered at least twice weekly should also be tested to assess improvement in sleep and pain reports for women beginning the mindful-yoga sessions in the third trimester. Another possible future direction for nursing research on this topic would be to examine the effect of the intervention on labor and the childbirth process itself. In this present

study, women in the treatment group reported practicing mindfulness, defined as purposive attention to the present moment, during labor. They also reported that mindfulness was helpful during labor without analgesia. Future research could evaluate the effects of the intervention on fear of childbirth, length of gestation, length of labor, induction rates, and rate of cesarean births. Additional variables to be explored are infant birth weight, gestational age, vagal tone measured by heart rate variability, and temperament. Future leadership and policy reform may be needed to find ways of including mindful-yoga, as a novel type of childbirth education, for women with disparate socioeconomic strata and ethnicity.

Conclusion

Mindful-yoga was proposed as an intervention to improve the experience of pregnancy through diminished stress appraisal, anxiety, and somatic complaints. The study hypothesized that as a result of participation in a 7-week mindful-yoga intervention, pregnant women would have reductions in stress appraisal, anxiety, pain, and sleep disturbance. It was also hypothesized that pregnant women would become more mindful from pre- to post-treatment. Mindful-yoga participants did report lower levels of stress appraisal and trait anxiety from baseline to posttreatment. They demonstrated improved scores in two facets of mindfulness (Observing and Nonreacting). Mindful-yoga participants who began the intervention in the second trimester demonstrated improvements in pain and sleep. The findings of this study provide insight into a previously unstudied area. Mindful-yoga is a promising new intervention for future evaluation in perinatal nursing.

References

- Aldana, S. G., Sutton, L. D., Jacobson, B. H., Quirk, M. G. (1996). Relationships between leisure time physical activity and perceived stress. *Perceptual and Motor Skills*, 82, 315-321.
- Baer, R. A., Smith, G. T., & Allen, K. B. (2004). Assessment of mindfulness by selfreport: The Kentucky Inventory of Mindfulness Skills. *Assessment*, 11, 191-206.
- Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using selfreport assessment methods to explore facets of mindfulness. *Assessment*, 13, 27-45.
- Baratte-Beebe, K. R., & Lee, K. (1999). Sources of midsleep awakenings in childbearing women. *Clinical Nursing Research*, 8, 386-397.
- Beary J. F., & Benson H. (1974). A simple psychophysiologic technique which elicits the hypometabolic changes of the relaxation response. *Psychosomatic Medicine*, 36, 115-120.
- Carlson, L. E., Speca, M., Patel, K. D., & Goodey, E. (2003). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosomatic Medicine*, 65, 571-581.
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. Journal of Health and Social Behavior, 24, 385-396.
- Cohen, S., Kessler, R., & Underwood Gordon, L. (Eds.). (1995). *Measuring Stress: A guide for health and social scientists*. New York: Oxford University Press.

- Curry, M. A., Burton, D., & Fields, J. (1998). The Prenatal Psychosocial Profile: A research and clinical tool. *Research in Nursing and Health*, *21*, 211-219.
- Daut, R. L., Cleeland, C. S., & Flanery, R. C. (1983). Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. *Pain*, 17, 197-210.
- Fast, A., Shapiro, D., Ducommun, E. J., Friedmann, L. W., Bouklas, T., & Floman, Y. (1987). Low-back pain in pregnancy. *Spine*, 12, 368-371.
- Glynn, L. M., Schetter, C. D., Wadhwa, P. D., & Sandman, C. A. (2004). Pregnancy affects appraisal of negative life events. *Journal of Psychosomatic Research*, 56, 47-52.
- Glynn, L. M., Wadhwa, P. D., Dunkel-Schetter, C., Chicz-Demet, A., & Sandman, C. A. (2001). When stress happens matters: Effects of earthquake timing on stress responsivity in pregnancy. *American Journal of Obstetrics and Gynecology*, 184, 637-642.
- Gupta, N., Khera, S., Vempati, R. P., Sharma, R., & Bijlani, R. L. (2006). Effect of yoga based lifestyle intervention on state and trait anxiety. *Indian Journal of Physiology and Pharmacology*, 50(1), 41-47.
- Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General Hospital Psychiatry*, *4*, 33-47.
- Kabat-Zinn, J. (1990). Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness. New York: Dell Publishing.

- Kornfield, J. (1993). *A path with heart: A guide through the perils and promises of spiritual life*. New York: Bantam Doubleday Dell.
- Kristiansson, P., Svardsudd, K., & von Schoultz, B. (1996). Back pain during pregnancy: A prospective study. *Spine*, *21*, 702-709.
- Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York: Springer.
- Lee, K. A. (1998). Alterations in sleep during pregnancy and postpartum: A review of 30 years of research. *Sleep Medicine Reviews*, *2*, 231-242.
- Lee, K. A., & DeJoseph, J. F. (1992). Sleep disturbances, vitality, and fatigue among a select group of employed childbearing women. *Birth, 19*, 208-213.
- Lee, K. A., & Zaffke, M. E. (1999). Longitudinal changes in fatigue and energy during pregnancy and the postpartum period. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 28*, 183-191.
- MacEvilly, M., & Buggy, D. (1996). Back pain and pregnancy: A review. *Pain, 64*, 405-414.
- McCracken, L. M., & Eccleston, C. (2006). A comparison of the relative utility of coping and acceptance-based measures in a sample of chronic pain sufferers. *European Journal of Pain*, 10, 23-29.
- McCracken, L. M., Gauntlett-Gilbert, J., & Vowles, K. E. (2007). The role of mindfulness in a contextual cognitive-behavioral analysis of chronic pain-related suffering and disability. *Pain, In Press, Corrected Proof.*
- McKee, L., Zvolensky, M. J., Solomon, S. E., Bernstein, A., & Leen-Feldner, E. (2007). Emotional-vulnerability and mindfulness: A preliminary test of associations

among negative affectivity, anxiety sensitivity, and mindfulness skills. *Cognitive Behavioral Therapy*, *36*, 91-101.

- Michalsen, A., Grossman, P., Acil, A., Langhorst, J., Ludtke, R., Esch, T., et al. (2005).
 Rapid stress reduction and anxiolysis among distressed women as a consequence of a three-month intensive yoga program. *Medical Science Monitor*, *11*, CR555-561.
- Morkved, S., Salvesen, K. A., Schei, B., Lydersen, S., & Bo, K. (2007). Does group training during pregnancy prevent lumbopelvic pain? A randomized clinical trial. *Acta Obstetricia et Gynecologica Scandinavica*, 86, 276-282.
- Narendran, S., Nagarathna, R., Narendran, V., Gunasheela, S., & Nagendra, H. R. (2005). Efficacy of yoga on pregnancy outcome. *Journal of Alternative and Complementary Medicine*, 11, 237-244.
- Olsson, C., & Nilsson-Wikmar, L. (2004). Health-related quality of life and physical ability among pregnant women with and without back pain in late pregnancy. *Acta Obstetricia et Gynecologica Scandinavica*, 83, 351-357.
- Ostgaard, H. C., Zetherstrom, G., & Roos-Hansson, E. (1997). Back pain in relation to pregnancy: A 6-year follow-up. *Spine*, *22*, 2945-2950.
- Pennick, V. E., & Young, G. (2007). Interventions for preventing and treating pelvic and back pain in pregnancy. *Cochrane Database System Review*, CD001139.
- Polman, R., Kaiseler, M., & Borkoles, E. (2007). Effect of a single bout of exercise on the mood of pregnant women. *Journal of Sports Medicine and Physical Fitness*, 47, 103-111.

- Poudevigne, M. S., & O'Connor, P. J. (2005). Physical activity and mood during pregnancy. *Medicine and Science in Sports and Exercise*, 37, 1374-1380.
- Reibel, D. K., Greeson, J. M., Brainard, G. C., & Rosenzweig, S. (2001). Mindfulnessbased stress reduction and health-related quality of life in a heterogeneous patient population. *General Hospital Psychiatry*, 23, 183-192.
- Schweiger, M. S. (1972). Sleep disturbance in pregnancy. A subjective survey. American Journal of Obstetrics and Gynecology, 114, 879-882.
- Shapiro, S. L., Bootzin, R. R., Figueredo, A. J., Lopez, A. M., & Schwartz, G. E. (2003).
 The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: An exploratory study. *Journal of Psychosomatic Research*, 54, 85-91.
- Shapiro, S. L., Carlson, L. E., Astin, J. A., & Freedman, B. (2006). Mechanisms of mindfulness. *Journal of Clinical Psychology*, 62, 373-386.
- Shapiro, S. L., Schwartz, G. E., & Bonner, G. (1998). Effects of Mindfulness-based stress reduction on medical and premedical students. *Journal of Behavioral Medicine*, 21, 581-599.
- Spielberger, C. D. (1985). Assessment of state and trait anxiety: Conceptual and methodological issues. *The Southern Psychologist*, 2, 6-16.
- Suputtitada, A., Wacharapreechanont, T., & Chaisayan, P. (2002). Effect of the "sitting pelvic tilt exercise" during the third trimester in primigravidas on back pain. *Journal of the Medical Association of Thailand, 85 Suppl 1*, S170-179.

- Thomas, C., Benzeval, M., & Stansfeld, S. A. (2005). Employment transitions and mental health: An analysis from the British household panel survey. *Journal of Epidemiology and Community Health, 59*, 243-249.
- Thomas, I. L., Nicklin, J., Pollock, H., & Faulkner, K. (1989). Evaluation of a maternity cushion (Ozzlo pillow) for backache and insomnia in late pregnancy. *Australian and New Zealand Journal of Obstetrics and Gynaecology, 29*, 133-138.
- Topolski, T. D., LoGerfo, J., Patrick, D. L., Williams, B., Walwick, J., & Patrick, M. B.
 (2006). The Rapid Assessment of Physical Activity (RAPA) among older adults. *Prevention of Chronic Disease, 3*, A118.
- Vempati, R. P., & Telles, S. (2002). Yoga-based guided relaxation reduces sympathetic activity judged from baseline levels. *Psychological Reports*, 90, 487-494.
- Wang, S. M., Dezinno, P., Maranets, I., Berman, M. R., Caldwell-Andrews, A. A., & Kain, Z. N. (2004). Low back pain during pregnancy: Prevalence, risk factors, and outcomes. *Obstetrics and Gynecology*, 104, 65-70.
- Woolery, A., Myers, H., Sternlieb, B., & Zeltzer, L. (2004). A yoga intervention for young adults with elevated symptoms of depression. *Alternative Therapies in Health and Medicine*, 10, 60-63.
- Youngstedt, S. D. (2005). Effects of exercise on sleep. *Clinics in Sports Medicine, 24*, 355-365, xi.
- Youngstedt, S. D., O'Connor, P. J., & Dishman, R. K. (1997). The effects of acute exercise on sleep: A quantitative synthesis. *Sleep, 20*, 203-214.

Appendix A

Appendix A.1: Approval of the internal review board

COMMITTEE ON HUMAN RESEARCH OFFICE OF RESEARCH, Box 0962 UNIVERSITY OF CALIFORNIA, SAN FRANCISCO www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp chr@ucsf.edu (415) 476-1814 CHR APPROVAL LETTER TO: Kathryn Lee, Ph.D. Amy Beddoe, Ph.D.; MS Box 0606 2 Koret Way, Nursing Bldg .: RE: Relaxation and Stress-Reduction in Pregnancy: A Mindfulness-Based Intervention Pilot Study The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter. Specifically, the review included but was not limited to the following documents: Consent Form, Dated 9/1/06 The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's. APPROVAL NUMBER: H5464-29321-01. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate. APPROVAL DATE: September 8, 2006 EXPIRATION DATE: July 27, 2007 Full Committee Review GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects. HIPAA "Privacy Rule" (45CFR164): This study does not involve access to, or creation or disclosure of Protected Health Information (PHI). Sincerely, Vice Chair, Committee on Human Research cc:

affered for the second second

Appendix A.2: Consent

University of California, San Francisco Department of Family Health Care Nursing

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Relaxation and Stress-Reduction in Pregnancy: A Mindfulness-Based Intervention Pilot Study

Purpose and Background

The purpose of this study is to learn whether certain techniques help pregnant women feel better and manage stress during pregnancy and after a baby is born. The study is being conducted by Amy Beddoe, RN, PhD(c), a nurse and doctoral student, who is under the supervision of Dr. Kathryn Lee, Professor in the School of Nursing. The study is being funded by the National Institute of Nursing Research and the Yoga Research and Education Center. Since you will be having your first baby between **January 01, 2007** and April 15, 2007, you are being asking to participate in this study.

Procedures

If you agree to participate in this study, the following things will happen:

1. FIRST MEETING: You will meet with us either in your home or be asked to come to a place of convenience so that you can learn more about the study and the relaxation and stress-reduction classes. This first meeting will take about 1 hour. You will be asked to answer questions about your feelings and your sleep on a questionnaire you can take home. You will also be asked to collect saliva samples at home for 3 days in a row, once each morning. You will be shown a simple way to collect a saliva sample that takes about one minute. You will be given a saliva collection kit. You will store the samples in your home freezer.

You will be asked to wear an actigraph for 3 days and nights during the time you are collecting saliva samples. An actigraph is a small computer that weighs about 2 ounces. You wear it on your wrist like a watch. It records when you are moving and when you are still, and is waterproof so you can wear it in the shower. You should <u>not</u> wear it in the bathtub or while swimming.

You will also be asked to fill out a sleep log each morning and evening that you wear the actigraph. In the log, you will keep track of the time you go to bed, the time you wake up, where you sleep, and if you take naps. The log takes less than 5 minutes to fill out each time, for a total of about 20 to 30 minutes over the 3 days. A member of the research team will call your home and arrange to pick up the saliva samples and actigraph from your house.

2. GROUP ASSIGNMENT: After your first visit, **you will be assigned** to one of two groups: Group A or Group B. Group A is a yoga and mindfulness meditation class that meets for 2 hours each week where you will be shown some things to do. Group B is a

discussion group that meets for 1 hour each week to discuss health topics. Both groups might help you to relax and deal with stress. You will receive a phone call at home two days after the first visit to tell you which group you are in. Each group will meet weekly for 6 weeks. Group A will be asked to devote 30 minutes per day to following CDs/audiocassettes provided to participants of a guided yoga and mindfulness meditation as learned in class. Group B will be asked to read educational material.

Group Meetings

1. Group A will meet on a weekly basis for 6 weeks in a row for 2 hours each. The last class will take an extra half-hour. Group B will meet on a weekly basis. The class will be held for 6 weeks in a row for 1 hour. The last class will take an extra half-hour.

The things you are shown during the classes might be helpful and they might not. Please do not tell other pregnant women about the things you are shown.

2. POST-MEETING ASSESSMENTS: About 7 weeks after you have answered the initial questions and after the classes are over, you will be given a questionnaire on the last day of class (Group A and Group B) to complete at home with items you are asked to answer about how you are feeling and sleeping. This will take about 1 hour.

You will again be shown how to collect your saliva at home for 3 consecutive days in the morning when you wake up. You will be asked to collect morning saliva samples 3 days in a row and

to store samples in your home freezer until a member of the research team phones you and arranges to pick up the samples and the actigraph from your house. You will also be shown again how to wear the actigraph which you will be asked to wear for 3 days and 3 nights. This should be the same 3 days you are collecting saliva. You will also be asked to write your sleep log for the days you are wearing the actigraph.

3. PHONE CALL: After your baby is born, you will receive a phone call to arrange a phone interview time conducted when your baby is about 4 weeks old. During the phone interview you will be asked about what effect, if any, these 6 classes had on your feelings, sleep, labor and birth experience, and early parenting. The interview will take about 30 minutes.

FOLLOW-UP STUDIES: After this study is over, you might receive a call about participating in follow-up studies. You can choose not to participate in any of these follow-up studies.

Possible Discomfort and Risks

There is little risk of injury to you or your baby from participating in this study. Sometimes gentle exercise may result in sore muscles. Rarely could it result in muscle strain. The class is no more dangerous than the usual activities of daily life. It may be inconvenient for you to attend the 1- or 2-hour group classes for 6 weeks. It may be inconvenient for you to get phone calls at your house. It may also be inconvenient for you to answer questions about how you are feeling. You may feel uncomfortable or become upset answering the questions.

If you have an allergy to metal, the actigraph may cause a rash. If this happens, you may choose to wear the actigraph over clothing or withdraw from this portion of the study. Collecting saliva in small tubes may be unpleasant.

I understand that any responses I give about drug and alcohol use could are reportable in the future.

Confidentiality

Participation in research may involve some loss of privacy. Every attempt will be made to minimize that loss. Your identity will be kept confidential. A number will be used to identify your data, not your name. Only the research team will be allowed to see your data. Your data will be kept in a locked file. Your name will not be used in reports or publications resulting from this study. Any signs of child abuse are required by law to be reported to legal authorities. In addition, if you tell us that you plan to hurt yourself or someone else, appropriate authorities will be notified.

Benefits

There is no direct benefit to you from study participation. If you are in Group A, you may learn how to manage stress and relax during pregnancy and after the baby is born. If you are in Group B you may learn information that helps you during pregnancy and after your baby is born. This study may aid us in learning how to help pregnant women manage stress, worry, and the physical discomforts of pregnancy. You will be given a copy of your sleep actigraphy report. If you would like, you can receive a copy of any published articles that result from this study.

Payment

If you finish all parts of the study, you will receive a total of \$100 to compensate you for incidental expenses, as well as some of your time, effort, and inconvenience.

- All parts of the study means that you attended the 6 classes, you answered and returned the questionnaires, you wore the actigraph at two time periods for three days in a row at each time, you returned the actigraph, you completed the 30-minute postpartum phone interview, and you collected and returned the 6 saliva samples before and after the classes.

- You will receive \$50 if you have completed the questions and the saliva samples, but have not attended at least 5 of the 6 classes.

- You will be asked for your social security number and home mailing address so we can mail you a check no later than 6 weeks after the postpartum phone interview is completed.

Costs

You will not have to pay for pregnancy class or any of the study procedures. The study does not provide transportation to and from the class.

Questions

The person who signs below has explained this study to you and has answered all your questions. If you have any other questions about the study, you may call the Principal Investigator, Amy Beddoe RN, MS, at (831) 688-8206, or her supervisor Dr. Kathryn Lee at (415) 476-4442. In addition, you may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. You may reach the Committee office by calling: (415) 476-1814 from 8:00 a.m. to 5:00 p.m., Monday through Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Consent

Participation in this study is voluntary. You may choose not to answer any questions or choose not to participate in the saliva sampling procedures or the wrist actigraphy monitoring. You can change your mind about being in the study at any time. Changing your mind will not affect your medical care or other benefits. You have been given a copy of this consent form. If you wish to participate, you should sign below.

Signature of Participant

Date

Signature of Person Obtaining Consent

Date

Appendix **B**

| ID# | EDD | Date of T1 collection | Gestational age at T1 | Gestational age on 11/07/06 | Gestational age at T2: 12/22/06 | Trimester on 11/07/06 |
|-----|---------|--------------------------|--------------------------|-----------------------------------|---------------------------------------|-----------------------------|
| 2 | 1/31/07 | 10/12/06 | 24. 1/7 | 27 6/7 | 34.86 | 3 |
| 23 | 2/5/07 | 10/12/00 | 24. 1/7 23. 5/7 | 27 0/7 | 34.80 | 3 |
| | | | | | | |
| 4 | 5/15/07 | 10/25/06 | 12.0/7 | 13 0/7 | 20.00 | 2 |
| 5 | 2/1/07 | 10/14/06 | 24.2/7 | 27 5/7 | 34.71 | 3 |
| 6 | 1/11/07 | 10/15/06 | 27.3/7 | 30 5/7 | 37.71 | 3 |
| 7 | 2/18/07 | 10/14/06 | 23.2/7 | 25 2/7 | 32.29 | 2 |
| 9 | 3/22/07 | 10/18/06 | 17.6/7 | 20 4/7 | 27.57 | 2 |
| 11 | 1/18/07 | 10/29/06 | 28.3/7 | 29 5/7 | 36.71 | 3 |
| 12 | 1/31/07 | 10/19/06 | 25.1/7 | 27 6/7 | 34.86 | 3 |
| 13 | 1/1/07 | 10/19/06 | 29.3/7 | 32 1/7 | 39.14 | 3 |
| 15 | 1/3/07 | 10/20/06 | 29.2/7 | 31 6/7 | 38.86 | 3 |
| 16 | 3/02/07 | 10/24/06 | 21.4/7 | 23 2/7 | 30.29 | 2 |
| 17 | 4/15/07 | 10/31/06 | 16.2/7 | 17 1/7 | 24.14 | 2 |
| 18 | 2/27/07 | 10/27/06 | 22.3/7 | 24 0/7 | 31.00 | 2 |
| 21 | 2/5/07 | 11/01/06 | 26.2/7 | 27 1/7 | 34.14 | 3 |
| 22 | 3/4/07 | 11/02/06 | 22.4/7 | 23 1/7 | 30.14 | 2 |
| 24 | 3/18/07 | 11/05/06 | 22.3/7 | 21 1/7 | 28.14 | 2 |

Table B.1: Participant due dates, length of pregnancy in weeks at data collection points Time1 and Time2, and on first day of the 7-week intervention.

EDD = expected date of delivery; T1 = baseline data collection point; T2 = postintervention data collection point; 11/07/06 = the first day of the intervention

Table B.2: Yoga Asanas Used During the Intervention

Sanskrit Names

Adho Mukha Svanasana Baddha konasana Bharadvajasana I Janu Sirsasana with belt Malasana, supported Marichiyasana III variation Prasarita Padontannasana Savasana variation Siddhasana Supta Baddha Konasana

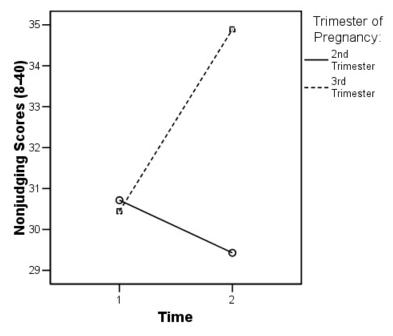
Supta Virasana Tadasana Upavistha Konasana Ustrasana, modified Uttitha Parsvakonasana Uttitha Trikonasana with chair/block Virabhadransansa I Virabhadrasana II Vrksasana N/A

English Name Equivalents

Dog Pose Cobbler's Pose Seated Twist Pose Head-to-Knee Pose Supported Squatting Pose Marichi's Pose, standing with chair Intense Spread Leg Stretch Side-lying relaxation pose Adept's Posture Supported Reclining Bound Angle Pose Supported reclining Hero Pose Mountain Pose Wide Angle Pose Camel Pose, supported with chair Side Angle Pose **Triangle Pose** Warrior I Pose Warrior II Pose Tree Pose Cat-Cow Stretch

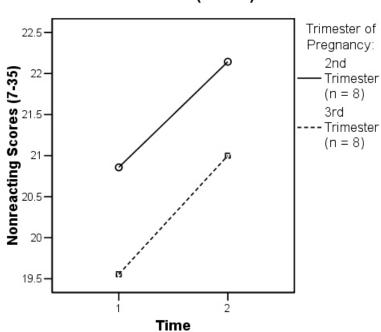
Asanas are listed in alphabetical order according to Sanskrit names.

Figure B.1: Nonjudging Scores for Second and Third Trimester Pregnant Women at Baseline and Post-intervention (n = 16)



Nonjudging Scores by Trimester

Figure B.2: Nonreacting Scores by Trimester at Baseline and Post-intervention.



Nonreacting for 2nd and 3rd Trimester Pregnant Women (N = 16)

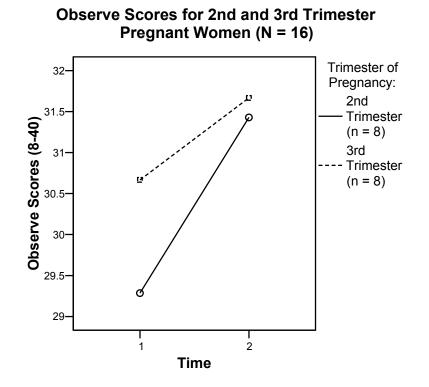
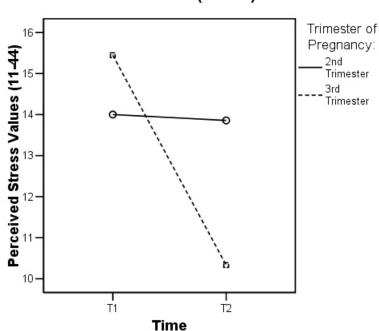
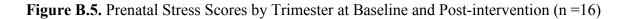


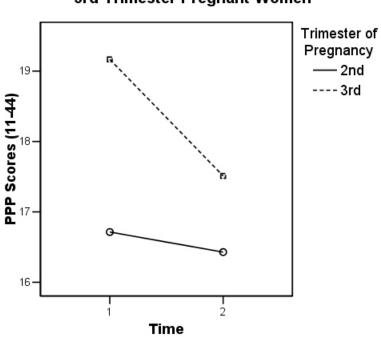
Figure B.3: Observing Scores by Trimester at Baseline and Post-intervention.

Figure B.4: Perceived Stress Scores by Trimester at Baseline and Postintervention.



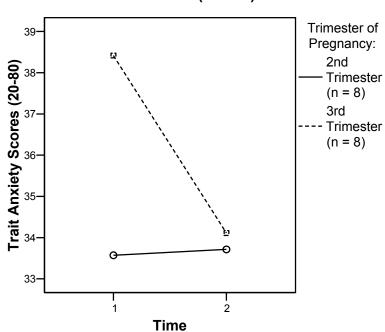
Perceived Stress for 2nd and 3rd Trimester Women (N = 16)



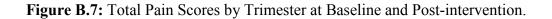


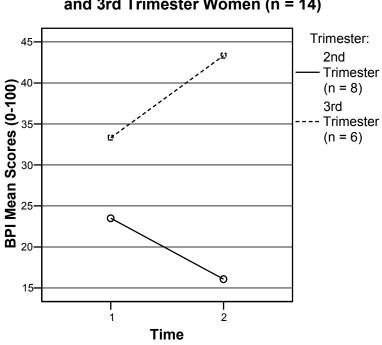
Prenatal Psychosocial Profile (PPP) for 2nd and 3rd Trimester Pregnant Women

Figure B.6: Trait Anxiety Scores by Trimester at Baseline and Post-intervention.



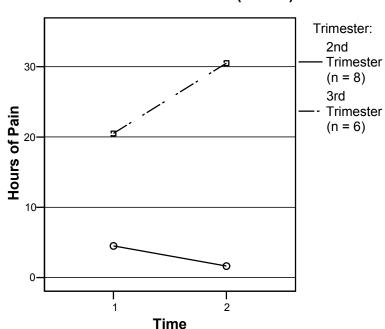
Trait Anxiety for 2nd and 3rd Trimester Pregnant Women (N = 16)



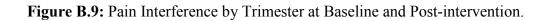


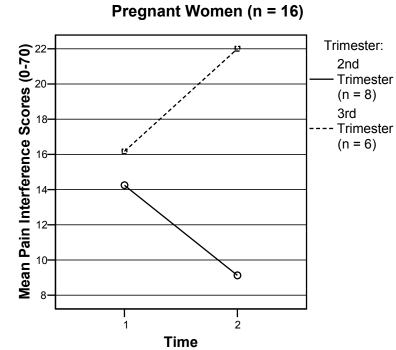
Brief Pain Inventory (BPI) Mean Scores for 2nd and 3rd Trimester Women (n = 14)

Figure B.8: Hours of Pain by Trimester at Baseline and Post-intervention.



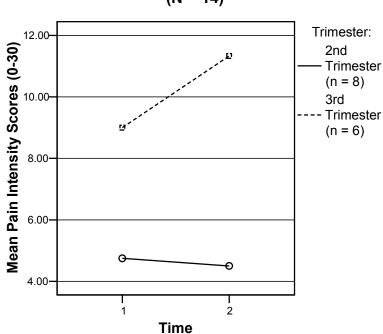
Hours of Pain in the Last Week for 2nd and 3rd Trimester Women (N = 14)





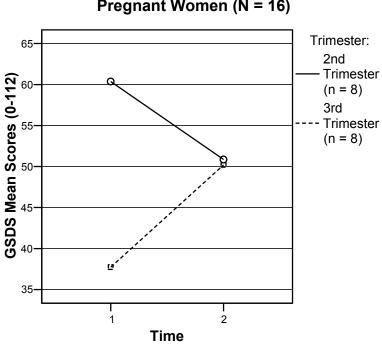
Pain Interference for 2nd and 3rd Trimester

Figure B.10: Pain Intensity by Trimester at Baseline and Post-intervention.



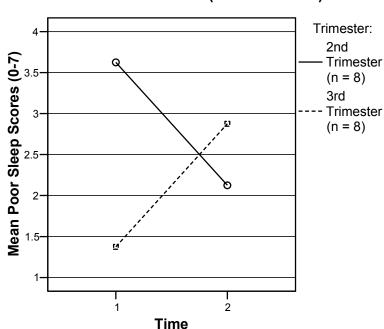
Pain Intensity for 2nd and 3rd Trimester Women (N = 14)





GSDS Mean Scores for 2nd and 3rd Trimester Pregnant Women (N = 16)

Figure B.12: Poor Sleep Over the Past Week at Baseline and Post-intervention.



Poor Sleep During the Past Week in 2nd and 3rd Trimester Women (GSDS Item #5)

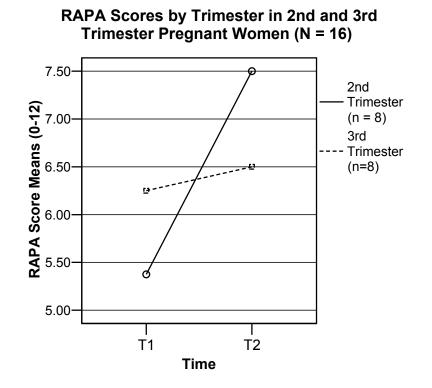
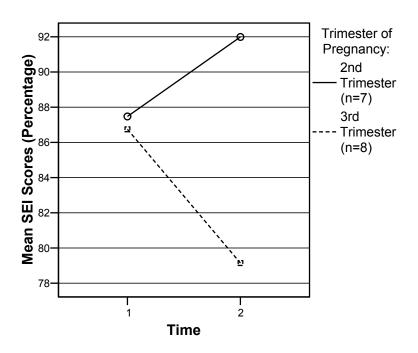


Figure B.13: Physical Activity Scores at Baseline and Post-intervention.

Appendix C

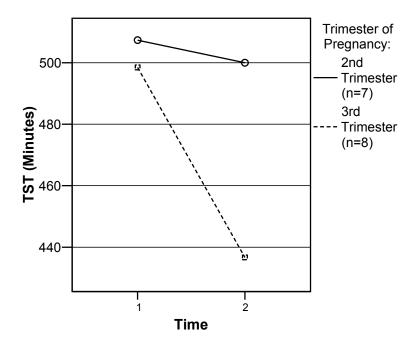
Figure C.1: Sleep Onset Latency by Trimester at Baseline and Post-Intervention



Sleep Efficiency (SEI) by Trimester

Figure C.2: Wake after Sleep Onset by Trimester at Baseline and Post-Intervention.

Figure C.3: Total Sleep Time (TST) by Trimester at Baseline and Post-Intervention.



Total Sleep Time (TST) by Trimester

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