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EFFECT OF A YOGURT INTERVENTION ON ADIPOSITY AND METABOLIC OUTCOMES IN WOMEN

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EFFECT OF A YOGURT INTERVENTION ON ADIPOSITY AND METABOLIC OUTCOMES IN WOMEN

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Abstract

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Over 40% of women in the United States are obese. The Strategic Plan for NIH Obesity Research focuses on "ways to hasten the translation of research evidence from discovery to intervention." The Strategic Plan also calls on investigators to look at influential points in the lifespan which may affect obesity. Few interventional studies on obesity in women during the perimenopausal time period have been completed. Research in broader populations suggests increased dairy, particularly full-fat products, may decrease central adiposity and improve metabolic indicators of diabetes and cardiovascular disease. The objective of this study was to investigate the effects of dairy yogurt intake in women on body composition and factors related to metabolism and adiposity. Women (n=59) were randomly assigned to either a full-fat yogurt, non-fat

yogurt, or a control group. Demographic data, health behaviors, anthropometric measures (Blood Pressure (BP), Body Mass Index (BMI), waist/hip circumference, body fat %), and metabolic indicators (glucose, insulin, cortisol, and lipid panels) were assessed. Forty-seven (n=47) women completed the 12-week study. There were no significant differences between changes in body weight, body composition, or metabolic indicators in the yogurt or control groups. There was a favorable decrease in systolic, F (2, 46)=10.06, p<.001 and Diastolic F(2, 46)=6.847, p=.003, blood pressures in the full-fat yogurt group. This study gives no clear support to the hypothesis that intakes of yogurt beneficially affects aspects of adiposity or metabolism. The positive effects on blood pressure with consumption of full fat yogurt suggest a possible relation to effects on the vasculature.

Chapter 1

Introduction and General Information

Obesity Concerns

According to the Center for Disease Control (CDC) over 70% of adult US (>20 years old) men and women were overweight in 2013-2014; of these over 37% were obese (Center for Disease Control, 2016). Obesity is known to play a critical role in the morbidity and mortality of many cardiovascular and metabolic diseases in adults (Kaur, Sharma, & Singh, 2015; Kazuhiro et al., 2014; Mantatzis et al., 2014; Park et al., 2013). From 1980 through 2014, the number of Americans with diagnosed diabetes has increased fourfold (from 5.5 million to 22.0 million) (Center for Disease Control, 2015). Likewise, in 2014-2015, an estimated 27 million people had heart disease and 6.3 million incurred a cerebrovascular accident. Additionally, over 24% of the adult population had hypertension, and 12% were battling hyperlipidemia (Center for Disease Control, 2016). Women are not immune to these statistics, as 11% of the US population of adult women were diagnosed with diabetes between 2011 to 2014, and close to 10% of adult women had some form of cardiovascular disease (coronary heart disease, hypertension, stroke) in 2014 (Center for Disease Control, 2014).

In 2011, a taskforce for the National Institutes of Health (NIH) created the *Strategic Plan for NIH Obesity Research* (National Institutes of Health, 2011). The purpose of this plan was to motivate researchers to undertake projects aimed at

interventional discoveries in obesity treatments. Additionally, one purpose of this plan was to focus on particular critical time periods or points in life which may play a role in the development of obesity. Childhood, pregnancy, or perimenopause may be some examples of such time points in a women's life that may play a role in the risk development. These time points and their relationship to the increase in, or future development of obesity have been understudied. The goal of this program of research has been to help close these gaps of knowledge.

Women's Health/Perimenopause

Over 40% of adult US women (>20 years old) were obese in 2013-2014 (Center for Disease Control, 2016). In 2010, approximately 118 million US women were over 20 years old and potentially faced the challenges associated with increased adiposity or obesity (Census.gov, 2010). Signs of increased risk such as increased abdominal adiposity during critical time points (childhood, adolescence, perimenopause) have received much less research attention (Davis et al., 2012; Dasgupta et al., 2012; Jull et al., 2014; Pimenta, Maroco, Ramos, & Leal, 2014; Sutton et al., 2010).

Perimenopause is typically defined as the time between onset of menstrual irregularity and complete cessation of menstruation. Hormonal changes (namely declining estrogen and progesterone) during the transition may be associated with worsening changes in adiposity. Studies show a relationship between visceral fat accumulations with declining estrogen levels (Nicola et al., 2012). Of note, these changes of increased body fat during this time have been seen independent of the aging process (Datspuga et al., 2012). Inquiry into these relationships and this critical time period for women are still being investigated by multiple interdisciplinary groups.

Dairy Effects

Emerging evidence suggests an inverse relationship between dairy consumption and reduced measures of adiposity in adult populations (Bhurosy & Jeewon, 2013; Faghih, Abadi, Hedayati & Kimiager, 2011, Jones et al., 2013; Josse, Atkinson, Tarnopolsky & Phillips, 2011; Holmberg & Thelin, 2013; Murphy et al., 2013; Satija et al., 2013; Wang et al., 2014; Zemel et al., 2005). Additionally, new findings suggest full-fat dairy may have a more influential effect than non- or low-fat products; those who consume whole fat dairy may have significant lower odds of being obese (Crichton & Alkerwi, 2014). This is demonstrated by Danish women who consumed less butter and full fat dairy products in their diet and were more likely to have increased waist circumferences (Halkjaer, Tjonneland, Overvad, & Sorenson, 2009).

Investigations of dairy consumption related to weight, BMI, and body composition with mixed results have been published over the past few years (Bhurosy & Jeewon, 2013; Crichton & Alkerwi, 2014; Faghih et al., 2011, Halkjaer et al., 2009; Holmberg & Thelin, 2013; Jones et al., 2013; Martinez et al., 2014; Murphy et al., 2013; Satija et al, 2013; Wang et al., 2014). Unfortunately, most research related to dairy and obesity measures has been prospective or observational, with very few interventional studies. Even fewer of these studies have focused solely on women. Of the few studies utilizing experimental designs, several demonstrated significant findings when using dairy as an intervention for reducing adiposity and improving metabolic measures in specific populations. Josse et al. (2011) found increased consumption of dairy foods in premenopausal obese women helped promote fat mass loss while on a diet and exercise weight loss program. Similarly, men and women who consumed yogurt during energy

restriction lost 81% more trunk fat than those on the control diet (Zemel, 2005). Faghih et al. (2011) found significant decreases in waist circumference in obese women who consumed high doses of dairy in their experimental study (Faghih et al., 2011). These findings promote the need for further inquiry into these complex dairy-adiposity relationships.

Research has also identified a beneficial role of dairy on other metabolic markers and blood pressure (Josse et al., 2011; Nestel et al., 2013; Van Meijl & Mensink, 2013). Wang, Livingston, Fox, Meigs, & Jacques (2013) found yogurt consumption was associated with lower levels of circulating triglycerides, and glucose, lower systolic blood pressure, and decreased insulin resistance in American adults.

Yogurt

Very few studies have specifically utilized yogurt as a dietary intervention. However, yogurt may reduce the risk of becoming obese in adult populations (Austep, 2014; Martinez et al., 2014; Murphy et al., 2013; Wang, Livingston, Fox, Meigs, & Jacques, 2013; Zemel et al., 2005.) Martinez et al. (2014) found yogurt consumption was inversely associated with the incidence of obesity, while Wang, Fox, Troy, Mckeown, & Jaques (2015) found each serving of yogurt was associated with a 6% reduced risk of incident hypertension. Although few experimental yogurt studies have been completed, a flagship research project in 2005 utilizing obese male and female adults found an intervention of yogurt yielded significant results for a reduction in waist circumference (Zemel et al., 2005). Since then further research on yogurt has been emerging in the literature, but further investigations of the relationship of dairy to adiposity are warranted.

Program of Research

The program of research reported in this portfolio focuses on the health issues associated with perimenopause and examines the effectiveness of yogurt consumption on metabolic outcomes in women. This program of research began with an exploration of the common concerns incurred during the critical time period of perimenopause. Results from this review are reported in Chapter Two in the manuscript titled *Current Treatment options for the Menopausal Transition: A Brief Review*. This manuscript is currently in revision to resubmit to the *Journal of Midwifery and Women's Health*, per request of the reviewers. Findings from this review led to the identification and discussion of potential contributors of cardiovascular and metabolic risks in women at a certain time in the lifespan.

Although emerging research on the perimenopause experience in general is increasing, very few researchers have investigated the complicated relationships between this time period, increase in adiposity, and risk factors for disease. Even fewer nutritional interventions have been assessed. In response to this gap in knowledge, a grant proposal was submitted to the Southern Nursing Research Society in spring 2015. A copy of the proposal is included in Chapter Three. While scored, but not funded, the grant application served as the basis for an interventional study, reported in Chapter Four. This manuscript, titled *Effect of Dairy Consumption on Adiposity and Metabolic Outcomes in Women*¸ reports the results of that study.

Prior to study initiation, The University of Texas at Tyler's Institutional Review Board (IRB) approval was secured for implementation of a randomized clinical trial to address this need of increased interventional studies (Appendix A). Recruitment

challenges led to a subsequent increase in scope to include all adult women meeting inclusion criteria. The IRB approval of the modification is found in Appendix B. Protection of the rights of the participants in this project was upheld through a variety of measures implemented to ensure safety, privacy, and confidentiality for all of those involved**.** Procedures evaluating the health status of all participants at baseline were documented. Safety issues related to diet, allergies, and potential drug and disease interactions with the intervention were also assessed. Those with disclosed dairy allergy, lactose intolerance, or certain enzyme deficiencies were excluded. Prior to signing the informed consent, full disclosure of the study's general purpose, benefits, risks, participants' rights, and responsibilities was discussed with all participants. Regulations for the Health Insurance Portability and Accountability Act (HIPAA) for protected health information was maintained at all times. Participants were notified that they could have terminated participation at any time for any reason without penalty. Data was stored on a password protected computer supplied to the researcher by the University of Texas at Tyler. Selection of confidential facilities when collecting sensitive data was maintained at all times. Also, results are being disseminated as aggregate data, with no identification of individual participants.

This study's aim was to examine the relationships between yogurt intake and measures of adiposity and metabolic outcomes in perimenopausal women. Participants were invited to participate via a recruitment flyer (Appendix C) and letters sent to patients served by an obstetrics and gynecology office (Appendix D). Following informed consent (Appendix E) and HIPAA consent (Appendix F), participants completed a demographic survey (Appendix G), report of dairy consumption (Appendix

H), and kept a log of dairy intake (Appendices I and J). Acceptability of the intervention was assessed at the end of the study (Appendix K). Results from this study are reported in Chapter Four. Findings from this research provide clinical data to help guide further inquiry of the complex relationships between nutrition, metabolism, health disease risk, and critical time periods in a woman's life. A summary of this program of research, along with recommendations for practice and research, are discussed in Chapter Five.

Chapter 2

Current Treatment options for the Menopausal Transition: A Brief Review

Abstract

The menopause transition is marked by a period of erratic and declining sex hormones which potentially result in a variety of physical and emotional concerns in middle aged women. Some women are asymptomatic while others report severely debilitating complaints. Mainstream hormonal treatment options vary in safety and efficacy. Millions are spent every year by perimenopausal women to treat their symptoms. A multitude of disciplines are eagerly seeking answers to help this population. Despite these efforts much still remains in question for healthcare practitioners on how to best handle this transitional period. Non-hormonal options are beginning to emerge with some support from the Food and Drug Administration. A multi-disciplinary approach, and further research investigation is needed. The following will review current treatment options for some of the most commonly reported perimenopausal symptoms.

Keywords: menopause, perimenopause, hormone replacement, symptoms, safety

Current Treatment options for the Menopausal Transition: A Brief Review

The menopause transition is typically defined as the time between onset of menstrual irregularity and complete cessation of menstruation. There is increasing evidence that lifestyle, socioeconomic status, body mass index, mood, climate, and beliefs and attitudes towards menopause might explain the cultural variations in reported symptoms. Reproductive aging can span many years typically in a woman's 40-50's (O'Neil & Eden, 2012). A review of the current literature was performed utilizing the CINAHL Complete, Health Source, and MEDLINE databases. The following search terms were used: menopause, perimenopause, transition, hormone, non-hormonal, alternative, vasomotor, symptoms, sexuality, depression, and obesity. Only peer reviewed journal articles written in English were included. With the exception of the Women's Health Initiative (WHI) published in 2002, all other studies reviewed were less than 5 years old. Twelve original research studies and seven reviews were used. The following material will briefly review common symptoms and treatment options for perimenopause with discussion related to safety and efficacy.

A Review of Common Symptoms

Vasomotor Symptoms (VMS). The most common menopause transition complaints are related to thermoregulation—hot flushes/flashes and night sweats. Studies show 87% of women who report hot flashes experience them on a daily basis (O'Neil & Eden, 2012). The hot flash episodes vary in duration and may be associated with clamminess, anxiety, and palpitations. The median age of symptom onset is 51 and

typically lasts 1–6 years, but can persist longer than 15 years in some women (O'Neil & Eden, 2012).

The pathophysiology of the hot flash remains unknown. Disturbed thermoregulation appears to be related to changes in hypothalamic activity. Reduced estrogen levels are thought to effect endorphins causing changes in norepinephrine and serotonin levels (Huntley, 2011). The rise in core body temperature is not well understood, but changes in estrogen alone are not believed to account for vasomotor symptoms (O'Neil & Eden, 2012). Also, there appears to be a correlation with pulsations of luteinizing hormone and the onset of the hot flash, although a direct cause and effect has been disproven, so much still remains unclear on causation of poor regulation of temperature (O'Neil & Eden, 2012).

Urogenital Effects and Sexual Functioning. Vaginal dryness, dyspareunia, reduced libido and arousal, and difficulty achieving orgasm increases through perimenopause and is associated with declining estrogen (O'Neil & Eden, 2012; Abernethy, 2013). Decreased vaginal secretions, irritation, decreased vaginal elasticity, decreased blood flow, and thinning vaginal walls are the result of declining circulating estrogen levels at menopause (Abernethy, 2013). These events, in turn, can lead to an increase in vaginal and urinary infections as well as decreases in sexual satisfaction.

Weight Gain and Increased Body Fat. Hormonal changes in the transition are associated with an increase in total and abdominal fat which adds risk of cardiovascular and metabolic disease, as well as affects quality of life. Studies show a relationship between visceral fat accumulations with declining estrogen levels (Nicola et al., 2012).

Other researchers have found perimenopause increased body fat mass and central adiposity, independent of age (Datspuga et al., 2012).

Cognitive Decline. A long-standing, yet unconfirmed hypothesis is that cognitive difficulties occur as a result of declining estrogen. Estrogen promotes neuronal growth and survival and acts on the cholinergic system, which is linked to cognitive functioning/memory. Many report forgetfulness and concentration difficulties during perimenopause, but further investigation is needed.

The Study of Women's Health across the Nation (SWAN) which was a 6-year epidemiologic research project, explained that perimenopausal women did not show the expected improvements in verbal memory and processing speed that pre- and postmenopausal women did (Greendale et al., 2010). In addition, they looked at whether depression, anxiety, sleep, and VMS affected cognitive performance/processing speed and found the variables did not account for the transient decrement in the learning observed during late perimenopause (Greendale et al., 2010). Other investigators attempted to compare pre, peri, and postmenopausal women in cognitive measures and found postmenopausal women performed significantly worse than pre- and perimenopausal women on delayed verbal memory tasks, and significantly worse than perimenopausal women on phonemic verbal fluency tasks (Webber, Maki, & McDermott, 2014) demonstrating conflicting results.

The interplay between other components such as age, mood, and sleep disturbance, make the “cognitive decline” variable difficult to assess. In addition, it is possible that other life factors during this time period may influence stress and cognitive function in ways independent of hormonal fluctuations.

Other Physical Symptoms. Most evidence suggest sleep disturbance increases significantly in middle-aged women. The relationship between self-reported sleep problems and the menopause transition have inconsistent results (O'Neil & Eden, 2012; Tom, Kuh, Guralnik, & Mishra, 2010). There is question if sleep disturbance is independent of night sweats and hot flashes. Also, a somewhat less studied symptom of perimenopause includes migraine headaches. Estrogen withdrawal is a recognized trigger and has been associated with worsening migraines in perimenopausal women (MacGregor, 2012).

Emotional Symptoms. Estrogen has a role in neurotransmission involved in depression. Many theories suggest estrogen acts as a serotonergic agonist by increasing receptor binding sites, synthesis and uptake (Simon et al., 2013). Symptoms of depression may be attributed to factors other than just changing hormone level. Hot flashes/night sweats, insomnia, lifestyle, feelings for a partner, marital status, and interpersonal stress may significantly affect mood during the menopause transition. Cross-sectional studies consistently report the highest prevalence of depression occurs in women during reproductive years, but longitudinal studies during perimenopause have demonstrated conflicting results (Bromberger et al., 2011; Judd, Hickey, & Bryant, 2014; Soares & Frey, 2010).

The risk of major depression may be greater for women during perimenopause compared to those who are pre-menopausal (Judd, Hickey, & Bryant, 2014). Mood changes are reported more often in Caucasian women and some concede that several biological and environmental factors seem to be independent predictors (Bromberger et al., 2011; O'Neil & Eden, 2012). In a recent literature review of 23 population based

studies, authors looked for evidence to support the idea that depression was the result of a biological response to hormone changes, but they found no proof to support this (Soares & Frey, 2010).

Existing and Emerging Practice: Treatment Options

Hormone Replacement. Hormone replacement therapy (HRT) is frequently used for symptoms associated with estrogen withdrawal (O'Neil & Eden, 2012). Although most commonly prescribed for vasomotor symptoms, new studies suggest HRT may partly prevent deleterious body composition changes, namely visceral fat (Nicola et al., 2012). HRT may also be helpful for estrogen withdrawal migraines (MacGregor, 2012) and is effective in preventing bone loss (O'Neil & Eden, 2012). Since bone protection decreases after cessation of therapy, the long-term use remains controversial (O'Neil & Eden, 2012). HRT use declined some as a result of the Women's Health Initiative (WHI) (Rossouw et al., 2002). This study was intended to define risks and benefits related to the incidence of heart disease, breast/colorectal cancer, and fractures in postmenopausal women aged 50–79 years. Investigators concluded the, "overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy postmenopausal US women" (Rossouw et al., 2002).

One common misconception is that WHI data should be extrapolated to the perimenopausal population. The potential benefits of HRT initiated during the perimenopause was not evaluated in the WHI as the population was mostly asymptomatic postmenopausal women. Hypotheses suggest endogenous sex steroids may be cardioprotective but the same theory using HRT has produced conflicting results. Findings of the WHI suggested a helpful effect in younger postmenopausal women but an

increased risk of heart disease/clots in older postmenopausal women (O'Neil & Eden, 2012). Contraindications to estrogen therapy include: history of female cancers, blood clots, cerebrovascular or heart disease, and liver dysfunction, among others.

It should also be noted, "bioidentical hormones," refers to hormones that are identical on a molecular level with endogenous hormones but are individually compounded by some pharmacies (Moriea, Silva, Santos, & Sarado, 2014) Marketing strategies claim these are more "natural," and efficacious than synthetic forms, but this is not supported by clinical evidence and their purity and risks are not known (O'Neil & Eden, 2012). For now, it is widely assumed by experts that benefits and adverse effects are likely similar to synthetic forms of HRT, although further investigation is warranted (Huntley, 2011).

Non-Hormonal Therapies and Interventions. ***SSRI/SNRI***. Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) have been marketed for off label use to treat VMS and are gaining popularity. Some suggest these drugs should be first line therapy for depression in perimenopause (Soares & Frey, 2010) while others feel adjuvant use with estradiol may be best for treatment of depression and VMS (Bromberger et al., 2011). Although higher doses of paroxetine have long been used to treat depressive and anxiety symptoms in general populations, the lower dose (Brisdelle) has only been approved for VMS (Simon et al., 2013). Fluoxetine (Prozac) and venlafaxine (Effexor) have been used for many years in perimenopausal women, but are not currently FDA approved. These drugs may also be helpful for treating migraines as well (MacGregor, 2012).

Anti-epileptic. Several random controlled trials show gabapentin demonstrated consistent and statistically significant benefits over placebo for VMS. Despite investigational uses for over a decade, the first largely publicized research emerged in 2012 under the phase 3 clinical trial known as BREEZE 3. Researchers studied 600 postmenopausal women to test extended-release gabapentin (Serada, Depomed) for effects on sleep and hot flashes in menopausal women (Lowry, 2012). The trial showed gabapentin significantly reduced the average frequency and severity of hot flashes at 4 and 12 weeks of therapy compared to placebo (Lowry, 2012). Sleep was measured using both the Insomnia Severity Index (ISI) score and the Daily Sleep Interference (S/I) score. There were clinically meaningful reductions in the gabapentin group, compared with the placebo group (Simon et al., 2013).

Unfortunately, not all experts agreed with the significance of the BREEZE study findings. Several members of an advisory panel for the FDA strongly opposed approval of the drug, suggesting the effects were only marginal and did not justify the risks. In 2013, the FDA rejected the approval for gabapentin in menopause, claiming the drug failed to show superiority to the placebo. Interestingly, this same advisory panel also rejected their support of the low dose paroxetine (Brisdelle), but the FDA ended up still approving it in 2013.

SERM. The "pink pill" or "Viagra for women" was coined in 2013 when the FDA approved ospemifene (Osphena), a selective estrogen receptor modulator (SERM) which acts similarly to estrogen on the vaginal epithelium, building vaginal wall thickness. SERM's are synthetic non-steroidal agents which have varying estrogen agonist and antagonist activities in different tissues. Ospemifene aims to reduce

dyspareunia in menopausal women. Although approved, some experts are concerned about long term adverse effects of ospemifene on other body systems.

TSEC. A new class of drug combination currently under clinical trial is the tissue selective estrogen complexes (TSEC's), which combine estrogen with a SERM. It is believed that different changes in the ER receptors may occur with different complexes or combinations of drugs. Therefore the drug could be utilized for either agonist or antagonist effects in their corresponding targeted tissues. Thus far, only bazedoxifene (combined with conjugated equine estrogen) has shown to be safe and effective in early testing. This particular combination has shown relief of menopausal hot flashes, vaginal atrophy, and prevention of bone loss without stimulation of the breast or uterus. Due to its anti-proliferative effect on the uterus, progesterone would not need to be added (Pinkerton & Thomas, 2014).

Complementary and Alternative Medicine. The use of complementary or alternative medicine (CAM) is high in perimenopause. The concern is lack of regulation and little evidence to support their efficacy or safety. A systematic review of the prevalence of CAM usage showed the average 12-month prevalence of use was 47.7% (Posadzki et al., 2013). Also, 55% of women studied did not disclose their use of CAM to their healthcare professional. Herbal medicine, followed by soy/phytoestrogens, evening of primrose oil, relaxation, and yoga were the most common in the review (Posadzki et al., 2013).

Phytoestrogens are plant-derived estrogens often sold over the counter with effects that vary according to plant species. Soy isoflavones and red clover have shown inconsistent results for effects on VMS (Crawford et al., 2013). Moriea, Silva, Santos, &

Sardao (2014) state in a recent review that phytoestrogens "have structural similarities to estradiol, interacting with cell proteins and organelles, presenting several advantages and disadvantages versus traditional HRT in the context of menopause."

Black cohosh, which has no estrogenic effects, may help decrease vasomotor complaints by increasing dopamine and serotonin activity of the hypothalamus. However, in controlled trials the evidence is conflicting and there are concerns regarding liver toxicity (O'Neil & Eden, 2012). Although several other complementary options have been investigated (vitamin E, evening of primrose, wild yam, ginseng, and others) research on soy, red clover, and black cohosh have been the most prominent in the literature. Despite occasionally producing promising results, most of these products still lack evidence for efficacy for menopausal symptoms.

Calcium and Vitamin D. Both calcium and vitamin D supplement use among women is controversial. Necessary for the maintenance of bone health, calcium may also play a role in weight loss, hypertension, and a variety of cancers. The Institute of Medicine (2010) currently recommends 1,200 mg of calcium per day, for women 51 years and older to reduce risk of osteoporosis. Declining estrogen is associated with impaired intestinal calcium absorption. Vitamin D levels and obesity have been heavily investigated, with more research of perimenopausal populations emerging (Truesdell, Shin, Liu, & Ilich, 2011). Mixed opinions exist between relationships of calcium, soy protein, isoflavones, bone metabolism, sarcopenia, and adiposity. Little research has been performed on the relationship between vitamin D/calcium and other common symptoms of perimenopause.

Diet, Yoga, and Exercise. Diets of cyclic weight loss and gain are common in women and are especially harmful in perimenopause, as weight loss occurs more often from muscle loss. Promotion of a diet high in nutrient density and lower in energy density is promoted by experts (Haimov-Kochman, Constantini, Brzezinsk, & Hochner-Celnikier, 2013) Also, mind–body, self-relaxation, and paced breathing has shown a reduction in severity and frequency of vasomotor symptoms in some small studies (O'Neil & Eden, 2012).

No specific perimenopause exercise regimen has been recommended by experts, however a recent study indicated the higher frequency of exercise (aerobic and non-aerobic), the lower severity of climacteric symptoms (Haimov-Kochman, Constantini, Brzezinsk, & Hochner-Celnikier, 2013). These findings contradict a recent review from Stojanovska, Apostolopoulous, Polman, and Borkoles (2014) who concluded there is "insufficient evidence demonstrating that exercise was effective in treating vasomotor menopausal symptoms, and, it was not clear whether exercise was more beneficial compared to HRT or yoga." Furthermore, in an arm of the SWAN study, authors suggest acute increases in physical activity were actually associated with increased hot flashes without physiologic justification (Gibson, Matthews, & Thurston, 2014).

Conclusions

Healthcare providers of women likely feel perplexed about the current body of scientific literature. Menopausal symptoms are poorly understood combinations of genetic, psychological, and environmental factors. There is not only discrepancy between objectifying symptoms, but more importantly, what to actually do about them. In addition, some symptoms mimic other potentially age related concerns which makes

them difficult to assess independently. Reliable treatments have controversial safety profiles. Women are living longer and most will go through the menopause transition at some point. A team approach is best to tackle all of the health issues of this population.

Individually tailored care plans may be needed to address symptom relief verses health risks. A table was developed to highlight the efficacy of currently marketed interventions (see Table 1). Thankfully, the interdisciplinary approach allows experts in the fields of endocrinology, gynecology, orthopedics, nutrition, psychiatry, and many others to contribute to the gaps of knowledge collectively. The WHI provided a wealth of information for the health of postmenopausal women. However, it also created fear of HRT which in turn has led to investigation of other options. Larger random controlled trials should be performed on the safety, efficacy, and side effects of non-hormonal therapies being utilized. With the widespread, and poorly regulated distribution of some of these substances, the potential for long term safety is concerning.

Table 1. Current Interventions for Perimenopausal Symptoms

Intervention	**Category**	**VMS**	**Depression/ Mood**	**Sleep Disturbance**	**Weight Gain/ Abdominal Fat**	**Vaginal Symptoms**	**Reference**
HRT estrogen/ progesterone	Hormonal	Sufficient	Sufficient	Sufficient	Sufficient	Sufficient	O'Neil (2012) Rossouw (2002)
Paroxetine (Brisdelle) Venlafaxine (Effexor)	SSRI/NRSI	Sufficient	Sufficient	Inadequate	Not Suggestive	Not Suggestive	Soares (2010) Simon (2013)
Gabapentin (Serada, Depomed)	Anti-Epileptic	Sufficient	Not Suggestive	Suggestive	Not Suggestive	Not Suggestive	Lowry (2012)
Ospemifene (Osphena)	SERM	Not Suggestive	Not Suggestive	Not Suggestive	Not Suggestive	Sufficient	Pinkerton (2014)
Soy Extracts, Yams Black Cohosh, Red Clover	Herbal/ Isoflavone	Inadequate	Not Suggestive	Suggestive	Not Suggestive	Not Suggestive	Posadzki (2013) Crawford (2013) Moriea (2014)
Calcium and Vitamin D	Mineral	Not Suggestive	Not Suggestive	Not Suggestive	Suggestive	Not Suggestive	Truesdell (2011)
Exercise and Yoga	Physical	Inadequate	Inadequate	Inadequate	Sufficient	Suggestive	Haimov (2013) Stojanovska (2014) Gibson (2014)

Level of Evidence:

1. Evidence is **sufficient** to infer a causal relationship.
2. Evidence is **suggestive** but not sufficient to infer a causal relationship.
3. Evidence is **inadequate** to infer the presence or absence of a causal relationship (evidence is sparse, poor quality, conflicting).
4. Evidence is **not suggestive** of a causal relationship.

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Chapter 3

Effect of Dairy Consumption on Adiposity and Metabolic Outcomes in Perimenopausal Women

Southern Nursing Research Society Grant Submission Proposal

Abstract

Nearly 71% of U.S. women aged 40-59 are at risk for diabetes and cardiovascular disease due to increased obesity. The *Strategic Plan for NIH Obesity Research* suggests identifying factors unique to a specific point in the lifespan to guide obesity interventions. One of these critical time periods, perimenopause, has been understudied. Hot flashes and night sweats are familiar perimenopause complaints; symptoms such as increased central adiposity and decreased ability to maintain a healthy weight have received less attention. Research in other populations suggests increased dairy, particularly full-fat, may decrease central adiposity and improve metabolic indicators of diabetes and cardiovascular disease.

Guided by the Integrated Theory of Health Behavior Change, a randomized controlled trial will determine the effect of a dietary intervention on adiposity and metabolic outcomes in perimenopausal women. Participants will be randomly assigned to either a full-fat yogurt, non-fat yogurt, or a control group. Demographic data, health behavior practices, anthropometric measures (BMI, waist and hip circumference), and metabolic indicators (glucose, lipid panels, vitamin D levels) will be assessed before and after the 12-week intervention. Yogurt consumption will be documented in a food diary.

Outcomes will be evaluated using MANOVA. A post-study survey will assess feasibility of the intervention.

Effect of Dairy Consumption on Adiposity and Metabolic Outcomes in Perimenopausal Women

Objectives and Specific Aims

The objective of this feasibility study is to improve the nutritional and metabolic health of perimenopausal women. Specific aims include:

Aim 1: Determine the effect of full-fat versus non-fat yogurt consumption on metabolic outcomes of perimenopausal women.

Aim 2: Determine the effect of full-fat versus non-fat yogurt consumption on adiposity outcomes of perimenopausal women.

Aim 3: Determine the feasibility of yogurt consumption as a dietary intervention for improving metabolic and adiposity outcomes in perimenopausal women.

Background and Significance

According to the Center for Disease Control (CDC) nearly 71% of women aged 40-59 were overweight or obese in 2011-2012.1 Obesity, or adiposity, is an increasing problem in the US (Ogden, Carroll, Kit, & Flegal, 2014). Specifically, central adiposity plays a critical role in the morbidity and mortality associated with diabetes, metabolic syndromes, and cardio/cerebral vascular disease in adults (Mantatzis et al., 2014; Kaur, Sharma, & Singh, 2015; Kazuhiro et al., 2014; Park et al., 2013). A taskforce for the National Institutes of Health (NIH) (2011) created the *Strategic Plan for NIH Obesity Research*. The purpose of this plan was to "serve as a guide to accelerate a broad

spectrum of research toward developing new and more effective approaches to address the tremendous burden of obesity" (NIH, 2011). One way the plan broadly proposed to do this was to "design and test interventions to promote healthy weight" (NIH, 2011). In addition, one objective of this plan emphasizes the importance of investigating factors related to excess weight gain during "critical periods and life events" (NIH, 2011). The taskforce indicated identifying factors unique to a specific point in the lifespan could provide important insights for intervention development. Perimenopause, one of these critical time periods, has been significantly under researched.

In 2010, approximately 23 million U.S. women between the ages of 45-54 potentially faced the challenges associated with perimenopause (Census.gov., 2010). Perimenopause, the transition to menopause, is typically defined as the time between onset of menstrual irregularity and complete cessation of menstruation. Reproductive ageing typically occurs in women during their 40-50's and is marked by a period of erratic and declining sex hormones resulting in a variety of physical and emotional issues. Although hot flashes and night sweats are two familiar complaints of perimenopause, other symptoms such as increased abdominal adiposity and decreased ability to maintain a healthy weight have received much less research attention (Datspuga et al., 2012; Davis et al., 2012; Jull et al., 2014; Pimenta, Maroco, Ramosm, & Leal, 2014; Sutton-Tyrell et al., 2010).

Given concerns related to hormone-replacement therapy (Antoine, Ameye, Paesmans, & Rozenberg, 2014; Hou et al., 2013; Marjoribanks, Farquhar, Roberts, & Lethaby, 2012; Ohira et al., 2010; Sharpe et al., 2010) women are seeking safe, non-hormonal interventions to combat perimenopausal symptoms.

One potential non-hormonal intervention for central adiposity is related to nutritional intake. Emerging evidence suggests an inverse relationship between dairy consumption and reduced measures of adiposity in other populations. Some researchers have focused on the effects of dairy on overall weight and BMI, (Bhurosy & Jeewon, 2013; Jones et al., 2013; Josse, Atkinson, Tarnopolsky & Phillips, 2011), while other have focused more on body composition (Crichton & Alkerwi, 2014; Halkjaer, Tjønneland, Overvad, & Sørensen, 2009; Holmberg & Thelin, 2013; Murphy et al., 2013; Satija et al., 2013; Wang et al., 2014; Zemel et al., 2005). Current literature suggests full-fat dairy may be more effective for decreasing adiposity than non or low-fat products (Bhurosy & Jeewon, 2013; Crichton & Alkerwi, 2014; Halkjaer et al., 2009; Holmberg & Thelin, 2013).

Most research related to dairy fat has been prospective or observational, with very few interventional studies. Significant decreases in waist circumference in as little as eight weeks have been seen in obese women who consumed high doses of dairy (Faghih, Abadi, Hedayati, & Kimiagar, 2011). A review of current literature revealed that most dietary RCT's utilizing dairy lasted 8-16 weeks in length. Yogurt may reduce the risk of becoming obese (Martinez-Gonzalez et al., 2014; Murphy et al., 2013; Zemel et al., 2005). Very few experimental studies have utilized yogurt as a dietary intervention. In a study with 34 obese adults ages 18-50, an intervention of yogurt yielded significant results for waist circumference reduction (0.42 $p<.005$) and fat loss (0.52 $p<.005$).28 Limited studies show beneficial findings when yogurt is used as an intervention for reducing adiposity in adults (Martinez-Gonzalez et al., 2014; Wang, Livingston, Fox, Meigs, & Jacques; 2013).; Zemel et al., 2005). In addition, some research on the

beneficial role of dairy on metabolic markers and blood pressure has been identified in other populations (Austep, A, 2014; Josse, Atkinson, Tarnopolsky, & Phillips, 2011; Nestel et al., 2013; Van Meijl & Mensink, 2013; Wang et al., 2013). Specifically, the role of yogurt consumption on pertinent metabolic markers in perimenopausal women have not been well studied and is still unknown. The proposed study will address these gaps in the science.

Research Design

Guided by the Integrated Theory of Health Behavior Change (ITHBC) (depicted in Table 1 of Chapter Four), an experimental design will be utilized to address the study aims. The ITHBC was developed to "increase a person's ability to engage in behavior change to increase his/her self-management behavior" (Ryan, 2009). The ITHBC contributes to better understanding of health behavior by integrating knowledge and beliefs, self-regulation, and social facilitation. The concepts from the ITHBC were used to develop an intervention related to the prevention or reduction of adiposity and improvement of metabolic outcomes in perimenopausal women.

Sample/Subjects

The accessible population for this study is adult perimenopausal women living in North Texas. The study will take place in a private women's health clinic in North Texas. The practice sees approximately 80-100 women each month for well women visits suggesting recruitment could be completed within three months. Since perimenopause relates to the beginning of hormonal changes leading up to the complete cessation of menstruation, the Stages of Reproductive Aging Workshop (STRAW) staging system (see figure 1) will be used to determine perimenopausal status (Harlow, 2012). According

to the STRAW definition, menstrual irregularity is described as, "the onset of menstrual cycle length variability with a persistent difference of 7 days or more in the length of consecutive cycles, with the persistence being defined as at least one recurrence within 10 cycles of the first variable length cycle" (Harlow, 2012).

Inclusion criteria will include: (a) perimenopausal status as defined by STRAW criteria (b) women who are at least 40 years old and (c) those who are able to read, speak, and write English. Exclusion criteria will include women with: (a) diagnosis or currently taking medication for diabetes or hyperlipidemia, (b) lactose intolerance, (c) allergy to dairy products (d) those who have had a greater than 20 pound weight change in the past year, or (e) women who have had a hysterectomy or oophorectomy. Women taking hormone replacement therapy (HRT) will be included as the effects of the nutritional intervention may still be effective even with low doses of HRT.

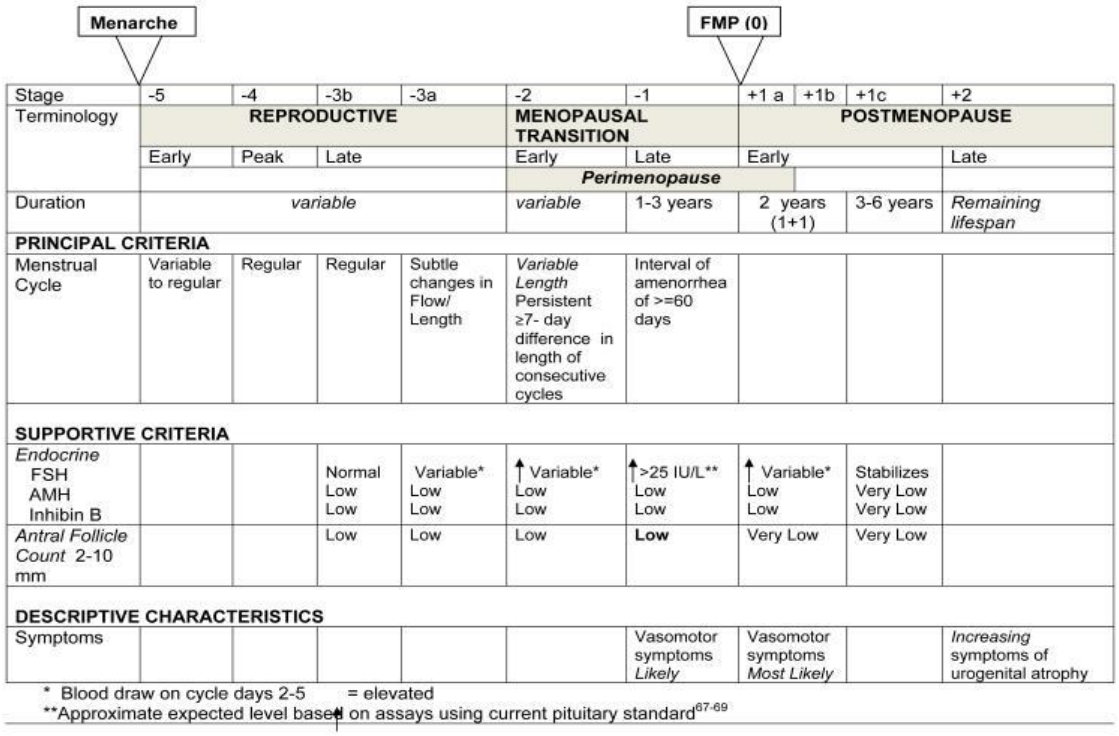

Figure 1. STRAW Menopause Transition Criteria (Harlow, 2012)

Based on an alpha of .05, power of .80, and effect size of .35, power analysis (G-Power 3.1) suggests a total sample size of 45 (15 per group) for repeated measures MANOVA will be required. Anticipated effect size (d) was calculated based on results of previous studies of dairy and adiposity (Crichton & Alkerwi, 2014; Josse et al., 2011; Wang et al., 2014; Zemel et al., 2005). To account for anticipated attrition associated with longitudinal studies, a total of 51 participants will be recruited.

Measures/Instruments

Survey Instruments. The Participant Demographic Survey (Appendix D in Chapter Four) will be used to collect pertinent patient demographic data. Participants will be providing dietary data about their use of yogurt by completing the 8-item Dairy Intake Questionnaire (Appendix E in Chapter Four), Daily Yogurt Form (Appendix F in Chapter Four), and Daily Dairy Form (Appendix G in Chapter Four). A 6-item Post Study Feasibility Survey (Appendix H in Chapter Four) will also be used. After development, the PI sent each of these instruments to content experts, colleagues, and others not familiar with the research to elicit feedback on the wording and face validity. The forms were reorganized and reworded based on feedback.

Metabolic/Physiologic. Outcomes (Aim 1) will be measured by: Blood pressure, fasting serum glucose, serum insulin, fasting serum lipid panel (total cholesterol, low density lipoprotein [LDL], high density lipoprotein [HDL], and triglycerides), fasting serum vitamin D 25 OH, and free serum cortisol. Labs will be collected at the clinical site and will be prepared, stored, and transported according to specific local clinic and lab protocols. A single laboratory will be utilized for all blood analyses. Measurement of blood pressure will be obtained using the equipment and instruction standards described

in the National Health and Nutritional Examination Survey (NHANES) Blood Pressure Procedures Manuals.

Adiposity. Outcomes (Aim 2) will be measured by: body mass index (BMI), waist circumference (cm), hip circumference (cm), and body fat percent. Collection of weight and height (to calculate BMI), as well as waist and hip circumferences will be obtained using the equipment and instruction standards described in the National Health and Nutritional Examination Survey (NHANES) Anthropometry Manuals (CDC, 2009). The longstanding reputable history of NHANES make their manuals an appropriate choice for this study.

Anthropometric measures predicted abdominal fat almost equally as well as Computed Tomography (CT) or Dual energy x-ray absorptiometry (DXA) scanning in recent study of women (Direk et al., 2013), concluding that anthropometric measures can be reliably utilized to derive estimates of visceral fat. Although CT and DXA are considered the gold standard for body fat percent measurement in clinical settings, due to funding limitations and access, this tool will not be utilized for this study. A professional grade bio-impedance scale used to determine body composition, will be used to assess percentage of body fat. Electrical bio-impendence monitoring has been utilized in a number of published studies as an alternative means to CT/DXA to assess total body fat percent.

Compliance. Outcomes (Aim 3) will be assessed using the Daily Yogurt Form. This format will enable participants to exercise control over some of the diet decisions they make as well as promote behaviors of self-regulation, an integral concept in the ITHBC model. This form will be utilized by participants to track the number of ounces,

fat (grams), and brand/flavor of yogurt consumed each day. In addition, the Post Study Feasibility Survey will be administered to assess participants' likelihood to continue the use of yogurt as part of their nutritional intake after the study is completed.

Methods

All participants will be interviewed in person, via phone, or email (depending on how they contact the PI) to assess for initial inclusion into the study. Staff at the women's clinic will be instructed on how to inform prospective participants of the study and next steps for contacting the researcher when interested women are identified. If inclusion criteria are met, potential participants will be asked to meet with the PI in an initial session in which the purpose and procedures of the study will be disclosed. After signing an Institutional Review Board (IRB) approved consent form, participants will be randomly assigned to one of three groups (a control group, a non-fat yogurt group, or a full-fat yogurt group) by drawing a sealed envelope (assignment will be concealed). Baseline demographic surveys, anthropometric measurements, and lab work will then be obtained and entered into the participant's electronic medical record. All data collection will be performed in an exam room to ensure privacy. Following baseline data collection, participants will be instructed not to make any major diet changes during the course of the 12-week study unless instructed to do so as indicated by the group assignment. They will also be asked not to change their activities or exercise regimens during this time.

Participants will be instructed to report any new medications, changes in medications, or changes in health status. Participants in the full-fat and non-fat yogurt groups will be given a Daily Yogurt Form (Appendix F in Chapter Four) to document the amount and type of yogurt consumed each day. Participants in the control group will be

given a comparable Daily Dairy Form (Appendix G in Chapter Four) to document all dairy intake on a daily basis. The forms will be submitted weekly to the PI as a means to encourage and assess compliance with the intervention. Electronic submission via email will be recommended but postage paid options for regular mail will also be available. At the end of the 12-weeks, anthropometric measurements and lab work will be reassessed and again entered into the patient's electronic medical record. In addition, the Post Study Feasibility Survey (Appendix H in Chapter Four) will be distributed to intervention group participants to obtain feedback on the intervention.

Intervention description. The non-fat intervention group (NF) will be asked to consume 12 total ounces of non-fat yogurt per day for 12 weeks. The participant will be allowed to purchase any brand, flavor, or texture of yogurt of their choice. The participant will be instructed to consume commercial dairy milk yogurt (from cows) that cannot exceed 150 calories, 18 grams of carbs, or 0 grams of fat (per 6 ounce serving). They may consume the yogurt at any time each day in combination with another meal, as a meal replacement, or as a snack. They must record the amount in ounces and brand/flavor of yogurt consumed on the Daily Yogurt form (Appendix F in Chapter Four) each day. The participants will be asked to consume all other dairy products in the same amounts and frequencies as before the study and record it on the Daily Dairy Form (Appendix G in Chapter Four).

The full-fat intervention group (FF) will be asked to consume 12 ounces of full fat yogurt per day for 12 weeks. There will not be any upper limitations on calories, carbs, or fat. They will be instructed to consume yogurt with at least 6 grams of fat per 6 ounce serving. They must record the amount, total grams of fat, and brand/flavor of yogurt

consumed on the Daily Yogurt Form (Appendix F in Chapter Four) each day. The participants will be asked to consume other dairy products in the same amounts and frequencies as before the study and record it on the Daily Dairy Form (Appendix G in Chapter Four).

The control group (CG) will be asked to make no changes to their current dietary habits. They will be instructed to complete a daily dairy intake form. Though this heightens awareness of consuming dairy products, the emphasis is not on yogurt. The form will serve as a means to assess typical yogurt intake within the sample.

Data Collection

Baseline demographic survey and dairy intake form, anthropometric measures, and blood draws will be performed by the PI at baseline. Yogurt (intervention groups) and dairy (control group) diaries will be collected every two weeks for 12 weeks. Participants will be asked to submit the diaries either electronically to an email address dedicated to the study or by mail using a postage paid envelope provided by the study. Anthropometric measures and blood samples will also be collected by the PI at the conclusion of the study, along with the post yogurt study survey. All survey data completed on paper will be stored in a locked file in a locked office. Anthropometric measures and lab reports will be recorded in a secure electronic medical record system which is password protected. All study data will be transcribed into a password protected Statistical Program for the Social Sciences (SPSS version 20.0) database for analysis. Double entry will be utilized to assure error free data.

Plans for Statistical Analysis

Data will be assessed for accuracy, outliers, and missing responses prior to conducting analysis. Discrete variables will be examined for accuracy. Continuous variable means and standard deviations will be examined for credibility and to assess for outliers. Descriptive statistics will be calculated for each variable. For continuous variables, range, mean, median, and standard deviation will be used. For categorical variables, mean, frequency, and contingency tables will be used. Chi-square tests (for nominal level data) and ANOVA (for continuous level data) will be used to compare the distribution of the demographics of the three groups at baseline. Multivariate analysis of variance (MANOVA) will be used to analyze the effect of yogurt consumption on adiposity (AIM 1) and metabolic indicators (AIM 2) among groups. If significant differences are noted, post hoc analyses will be conducted to determine where the differences lie.

Feasibility (AIM 3) will be assessed via time required for recruitment, attrition rate, Daily Yogurt/Dairy Intake form completion, and responses to the Post Study Feasibility Survey. Recruitment will be calculated by determining the length (in business days) it takes to obtain the 25th and 51st participant from the start of recruitment. Intervention items will be reviewed by the research team to identify issues that affected the consumption of yogurt in perimenopausal women. The PI, recruitment assistants, and clinic staff will discuss any challenges they faced during recruitment to identify measures to improve the process for future study.

Limitations and Potential Difficulties

Limitations. As with any longitudinal study, attrition could be a limitation. Oversampling will be done to allow for potential loss of participants. Utilizing one local clinic for assessment completion could be a limitation. Other surrounding clinics in Northeast Texas may be utilized if additional recruitment of participants is needed. Flyers, will be posted in numerous public and private settings with potential sources of perimenopausal-aged women (e.g. local healthcare establishments, shopping venues, beauty salons, churches). Woman in the intervention groups may become tired of consuming 12 ounces of yogurt every day. To address this limitation, no restrictions will be made for the brand, flavor, or texture of yogurt chosen. No constraints on the time of day they will eat yogurt will be mandated, which will aid in flexibility of schedule. The potential for confounding variables, despite exclusion criteria, cannot be entirely controlled. Since standardization of only a few (not all) nutritional parameters will be performed, other nutritional co-variables will still exist. Exercise or energy expenditure will not be measured or controlled. Subjects will be asked not to make any other changes in exercise or diet during the study. Although this opens the possibility of confounding variables, this approach also reflects a real-world approach and will help determine if yogurt consumption is feasible without placing additional demands or restrictions on participants. Maintaining previous behaviors mitigates the source or impact of extraneous behaviors since the participants serve as their own controls.

The possibility of varying degree of ovarian function within the perimenopausal status could be a confounding factor. Assessing menstrual health through STRAW criteria will help provide some commonality for those in perimenopausal states. Some

variability and human error is possible when obtaining anthropometric measurements. Body composition differences, racial and ethnic differences, and clinician technique, can all lead to discrepancy. Body composition differences and racial and ethnic differences are addressed in baseline data. Clinician technique is addressed by using the same person, equipment and lab to collect and analyze data will help reduce this limitation. The self-reported nature of food consumption is also a limitation. Participants may feel inconvenienced by having to write in a daily log. This may lead to falsification or inaccurate recall of consumption. Therefore, a simplified, user friendly form was created to help compliance.

Potential Difficulties. One anticipated challenge is recruitment of an adequate number of participants. To make study participation more appealing, women are being offered free assessments of body composition and several metabolic indicators at two time points. The major challenge in conducting this type of research is the fiscal resources necessary to conduct the study. Women cannot be asked to pay out of pocket to cover blood work; providers cannot be expected to provide services for free. In this study, the PI, who is a women's health nurse practitioner, will provide the assessments at no cost. The lab that supports the PI's practice has negotiated the lowest cost possible to provide lab services and still cover expenses.

Protection of Human Subjects

Protection of the rights of the participants in this project will be upheld through a variety of measures implemented to ensure safety, privacy, and confidentiality for all of those involved. All procedures will be evaluated and approved by the Institutional Review Board at the University of Texas at Tyler. Procedures evaluating the health status

of all subjects at baseline will be documented. Safety issues related to diet, allergies, and potential drug and disease interactions with the intervention will also be assessed. For example, those with disclosed dairy allergy, lactose intolerance, or certain enzyme deficiencies would be excluded. Prior to signing the informed consent, full disclosure of the study's general purpose, benefits, risks, participants' rights, and responsibilities will be discussed with all participants. Regulations for the Health Insurance Portability and Accountability Act (HIPAA) for protected health information (PHI) will be maintained at all times. HIPAA consents will be obtained. Participants will be notified that they may terminate participation at any time for any reason without penalty. Selection of facilities/rooms/privacy interventions when collecting sensitive data (such as anthropometric measurements) will be maintained at all times. Secure record keeping of data and storage with password access will also be utilized during the study. Results will be disseminated as aggregate data, with no identification of individual participants.

Data Safety and Monitoring Plan

Contact information of the research team will be provided to all study participants at the beginning of the research project. They will be instructed to notify the researcher of any emergencies, unforeseen events, or general concerns that arise as a result of participating in this study. If an event is reported, the researcher will promptly notify her adviser, and co-investigators for guidance and documentation of the event in an adverse event log. A written notification will be submitted to the IRB within 24 hours of the reported incident.

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Appendix A: Budget Sheet

Anticipated Expenditures

Laboratory Fees	**$4284.00**
$42 @ baseline x 51 participants=$2142	
$42 @ completion X 51 participants=$2142	
Bio-impedance Body Composition Scale	**$2595.00***
Palm Aneroid Sphygmomanometer	**$50.00**
Printing Costs	
9 pages x $.10 x 51 (all participants)=$45.90 1 page x $.10 x 34 (Intervention participants) $3.40	**$49.30**
Postage for return of diaries. $0.49x12x51=$299.88	**$299.88**
TOTAL	**$7278.18**
Total Requested from SNRS	**$7078.26 – 2595 = $4683.18**

Budget Justifications:

Laboratory Fees: Discounted negotiated (at cost) pricing from the lab utilized at the local OB-GYN clinic are as followed: Cortisol ($13.29), Vitamin D, 25 OH ($19.00), Glucose ($1.70), Insulin ($7.00), Lipid Panel ($2.15).

***Bioimpedance Body Composition Scale:** Professional Grade Bio-impedance Scales vary in pricing with most quality models falling in the $2,000-$6000 range. The price listed here is for a Tanita™ TBF-410 Body Composition Analyzer that includes Tanita HealthWare™ software. The Tanita HealthWare™ provides a bridge to most electronic medical record software packages, which sends the measurements directly to the participants EMR reducing the chance of transcription error. The Tanita™ TBF-410GS Body Composition Analyzer calculates body fat percent in less than ten seconds and has a column-mounted display to decrease unintentional damage of the equipment. Price listed is based on current listing from the Tanita™ website. The The Bodystat™ Quadscan 4000 with Microsoft™ software is also being considered and costs around $5700. This bio-impedance scale has been utilized by numerous healthcare companies and researchers in a variety of peer reviewed published studies with excellent reputation.

*Recognizing the cost of either of these scales exceeds that permitted by the grant, additional funding will be sought to cover the cost of this item.

Sphygmomanometer: Equipment currently utilized at the OB-GYN office will be assessed prior to data collection to determine that it is professional grade, correctly calibrated, and working properly. If it is not, a sphygmomanometer will need to be purchased to record accurate blood pressure readings.

Appendix A: Budget Sheet Continued

Printing Costs: Participant surveys and diaries will be completed on paper. These will be printed at a local print shop such as Kinko's™ (or similar) for efficiency and pricing.

Postage Costs: Participant Yogurt/Dairy Intake diaries will be returned via postage paid envelope every two weeks for participants unable or choose not to utilize email correspondence. This would include 12 postage paid envelopes per participant (51) x $0.49 per stamp, totaling $299.88.

Chapter 4

Effect of Dairy Consumption on Adiposity and Metabolic Outcomes in Women

Abstract

Over 40% of adult women in the United States are obese. The Strategic Plan for NIH Obesity Research focuses on ways to improve and expedite the ways at which research discovery develops into clinical intervention. Research in other populations suggests increased dairy, particularly full-fat, may decrease central adiposity and improve metabolic indicators of diabetes and cardiovascular disease. The objective of this study was to investigate the effects of dairy yogurt intake on body composition and factors related to metabolism and adiposity in women. Women (n=59) were randomly assigned to either a full-fat yogurt, non-fat yogurt, or a control group. The full-fat and non-fat groups were instructed to consume 2 servings of yogurt daily. The control group maintained their habitual diet. Clinical measurements were completed on admission to the study and after 12 weeks. Demographic data, health behaviors, anthropometric measures (BMI, waist/hip circumference, body fat %), and metabolic indicators (glucose, insulin, cortisol, and lipid panels) were assessed. Forty-seven (n=47) women completed the 12 week study. There were no significant differences between changes in body weight, composition, or metabolic indicators across time within the yogurt or control groups. There was a modest favorable decrease in systolic ($p<.001$) and diastolic ($p<.003$) blood pressure in the full-fat yogurt group. This study gives no clear support to they hypothesis that a diet with increased intake of yogurt beneficially affects aspects of

the adiposity or metabolism. The positive effects on blood pressure with consumption of full fat yogurt suggest a possible relationship to effects on the vasculature should be further explored.

Effect of Dairy Consumption on Adiposity and Metabolic Outcomes in Women

According to the Center for Disease Control (CDC) over 40% of adult US women (>20 years old) were obese in 2013-2014 (Center for Disease Control, 2016). Obesity, or adiposity, and specifically increased central adiposity, play a critical role in morbidity and mortality associated with diabetes, metabolic syndromes, and cardio/cerebral vascular disease in adults (Kaur, Sharma, & Singh, 2015; Kazuhiro et al., 2014; Mantatzis et al., 2014; Park et al., 2013). In 2011, a taskforce for the National Institutes of Health (NIH) created the *Strategic Plan for NIH Obesity Research* "serve as a guide to accelerate a broad spectrum of research toward developing new and more effective approaches to address the tremendous burden of obesity" (National Institutes of Health, 2011, p. 7). One way the plan broadly proposed to do this was to "design and test interventions to promote healthy weight" (National Institutes of Health, 2011, p. 15). In addition, one objective of this plan emphasizes the importance of investigating factors related to excess weight gain during "critical periods and life events" (National Institutes of Health, 2011, p. 21). The taskforce indicated identifying factors unique to a specific point in the lifespan that could provide important insights for intervention development. Adolescence, young adulthood, pregnancy, perimenopause, and post menopause are potential critical periods that have been understudied.

In 2010, approximately 118 million US women were over 20 years of age and potentially faced the challenges associated with increased adiposity or obesity

(Census.gov, 2010). Symptoms such as increased abdominal adiposity and decreased ability to maintain a healthy weight during specific critical life events such as perimenopause have received much less research attention (Davis et al., 2012; Dasgupta et al., 2012; Jull et al., 2014; Pimenta, Maroco, Ramos, & Leal, 2014; Sutton et al., 2010). Additional investigation of such critical time periods and their influence on adiposity are needed. Furthermore, interventional research to address the increasing adiposity at all ages is also warranted.

Review of the Literature

The retrieved body of evidence suggests an inverse relationship between dairy consumption and reduced measures of adiposity in adults (Bhurosy & Jeewon, 2013; Faghih, Abadi, Hedayati, & Kimiager, 2011, Jones et al., 2013; Josse, Atkinson, Tarnopolsky, & Phillips, 2011; Holmberg & Thelin, 2013; Murphy et al., 2013; Satija et al., 2013; Wang et al., 2014; Zemel et al., 2005). Current literature also suggests full-fat dairy may be more effective for decreasing adiposity in adults than non- or low-fat products. In the Observation of Cardiovascular Risk Factors in Luxembourg survey, data were analyzed from 1352 men and women and researchers found those consuming the highest amounts of whole-fat dairy intakes (milk, cheese, yogurt) had significantly lower odds of being obese (Crichton & Alkerwi, 2014). Also in another study, Danish women who consumed less butter and full fat dairy products in their diet were found to be more likely to have increased waist circumferences (Halkjaer, Tjonneland, Overvad, & Sorenson, 2009). Outcomes of studies on the effects of dairy products have varied from overall weight, BMI (Bhurosy & Jeewon, 2013; Martinez et al., 2014), and body composition (Crichton & Alkerwi, 2014; Faghih et al., 2011, Halkjaer et al., 2009;

Holmberg & Thelin, 2013; Jones et al., 2013; Murphy et al., 2013; Satija et al., 2013; Wang et al., 2014).

Unfortunately, most research related to dairy and obesity measures has been prospective or observational, with very few interventional studies. Even less of these studies have focused solely on women. Of the few studies found utilizing experimental designs, several demonstrated significant findings when using dairy as an intervention for reducing adiposity and improving metabolic measures. Josse et al. (2011) found increased consumption of dairy foods in premenopausal obese women helped promote fat mass loss for those on a diet and exercise weight loss program. Also, men and women who consume yogurt during energy restriction lost 81% more trunk fat than those on the control diet (Zemel, 2005). Faghih et al. (2011) found significant decreases in waist circumference in as little as eight weeks in obese women who consumed high doses of dairy in their experimental study.

Research has also identified a beneficial role of dairy on metabolic markers and blood pressure (Josse et al., 2011; Nestel et al., 2013; Van Meijl & Mensink, 2013). Wang et al. (2013) found yogurt consumption was associated with lower levels of circulating triglycerides, glucose, and lower systolic blood pressure and insulin resistance in American adults participating in the Framingham Heart Study Offspring (1998-2001) and Third Generation cohorts (2002-2005).

Few studies have specifically utilized yogurt as a dietary intervention, however, this specific dietary choice may reduce the risk of becoming obese in adult populations (Austep, 2014; Martinez et al., 2014; Murphy et al., 2013; Wang, Livingston, Fox, Meigs, & Jacques, 2013; Zemel et al., 2005.) Martinez et al. (2014) focused on yogurt and found

consumption was inversely associated with the incidence of obesity in a group of 8,516 Mediterranean men and women. In a seminal study that utilized yogurt as an intervention for adiposity, Zemel et al. (2005) found obese male and female adults ages 18-50, who consumed an intervention of yogurt yielded significant results for waist circumference reduction (Zemel et al., 2005). The Zemel study provided a new avenue for researchers hoping to find an effective intervention for the obesity epidemic. The role of yogurt consumption on adiposity and other pertinent metabolic markers in women has not been well studied and is still unknown. The following study sought to address these gaps in the science.

Theoretical Framework

The Integrated Theory of Health Behavior Change (ITHBC, Figure 1) was developed to "increase a person's ability to engage in behavior change to increase his/her self-management behavior" (Ryan, 2009). Subjects who engage in these self-management behaviors are expected to achieve the initial (proximal) short term outcome which in turn leads to the longer (distal) outcome of an overall improved health status. Individualized interventions are used to increase knowledge and beliefs, facilitate social support, and improve self-regulation skills and abilities. Ryan (2009) advocated that using a theoretical framework would help advance practice nurses' focus on assessments, utilized evidence based interventions, and improve patient outcomes. Using the ITHBC is expected to help improve interdisciplinary communication and foster holistic comprehensive care (Ryan, 2009). No known dietary studies utilizing dairy in women have previously applied the ITHBC as the theoretical framework guiding their research.

Ryan (2009) proposes that knowledge and beliefs and social facilitations in the

ITHBC contribute to a person's self-regulation skill and ability, which in turn lead to achievement of the health outcomes. The ITHBC was used to guide a yogurt intervention in women (*Figure 2*).

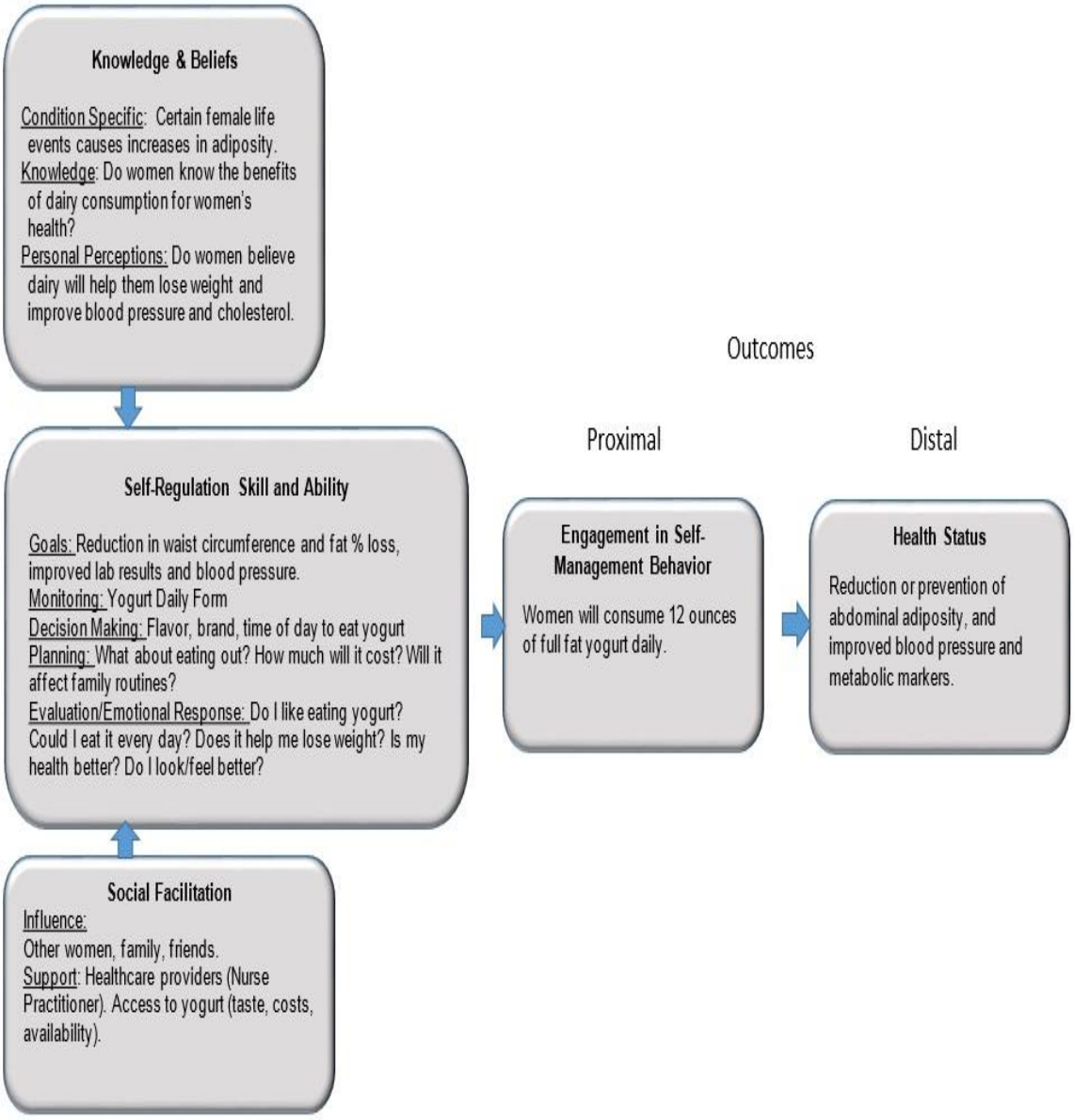

Figure 2. Integrated Theory of Health Behavior Change for a Yogurt Intervention (Adapted from Ryan, 2009)

Knowledge and beliefs includes condition specific and personal perception factors. For use in women, this included women's knowledge about dairy consumption as

well their perception that dairy could help them lose weight, decrease abdominal fat, and improve their metabolic health (such as BP and cholesterol levels.)

Social facilitation for this study was support from other women, family, and/or friends. Other social facilitation came from healthcare providers who taught the participant about the yogurt intervention. Access to yogurt (availability, ease of purchase, financial burden) also were components of the ITHBC's social facilitation category.

Self-regulation and ability in the ITHBC framework are further broken down into goals, monitoring, decision making, planning, and evaluation/emotional response. For this study, goals were related to decrease measures of adiposity (such as waist circumference/BMI) and improving metabolic outcomes (such as increase HDL levels). Choosing what brand, flavor, and time of day to consume the yogurt was part of the decision making category of self-regulation. Planning the consumption of yogurt was influenced by work, home life, vacations, and typical eating schedules. Although typically an inexpensive food, cost of yogurt also played a role in planning and grocery budgeting. Evaluation and emotional response were completed at the end of the study when the participants reflected on whether they like the yogurt, if they were able to eat it twice daily, if they felt they could continue eating it routinely after the study, and if they felt it was helping them lose weight and improve their health.

The outcomes from the yogurt intervention were measured by engagement in self-management behaviors during the study. The proximal outcome was that women would consume 12 ounces of yogurt daily. This in turn was expected to lead to the distal outcome of improvement in health status by reducing measures of adiposity and improving metabolic outcomes through serum laboratory results.

Conceptual and Operational Definitions

Several variables were utilized to help measure the research hypotheses/question for this study. The following table (Table 2) outlines the conceptual and operational definitions of the utilized variables in this study.

Table 2. Conceptual and Operational Definitions

Variable	Conceptual Definition	Operational
Non-Fat Yogurt	A food produced by bacterial ("yogurt cultures") fermentation of milk. Fermentation of lactose creates lactic acid, which acts on milk protein to give yogurt its texture and its taste. The fat content of milk is the proportion of milk, by weight. Non-fat yogurt has had the butterfat removed. According to the USDA regulations skim milk or "nonfat" milk, can be labeled "fat free" if it contains less than ½ gram of fat per serving.	Any brand/flavor/texture of yogurt made from dairy cow's milk which contained 0 grams of total fat were to be used in this study.
Full-Fat Yogurt	A food produced by bacterial ("yogurt cultures") fermentation of milk. Fermentation of lactose creates lactic acid, which acts on milk protein to give yogurt its texture and its taste. The fat content of milk is the proportion of milk by weight. Typically in the United States, "whole milk," or full fat products contains at least 3.25% butterfat.	Any brand/flavor/texture of yogurt made from dairy cow's milk which contains at least 6 grams of total fat were to be used in this study.
Body Mass Index (BMI)	The body mass index (BMI) is a measure of relative weight based on an individual's mass and height.	BMI was calculated by dividing the subject's weight in pounds (lbs.) by height in inches (in) squared and multiplying by a conversion factor of 703 (to convert from metric to standard measurement.
Waist Circumference	Numerical measurement of waist often measured in cm using an anthropometric (soft flexible) tape measure. A high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia,	Anthropometric tape was used to measure half way between the inferior margin of the last rib and the crest of the ilium in the mid-axillary plane.

	hypertension, and cardiovascular disease. Waist circumference can provide an estimate of abdominal fat.	Centimeters were utilized. Detailed procedure steps described in NHANES Anthropometric Procedure Manual (CDC, 20011).
Hip Circumference	Hip circumference is a measurement of a person's hip size in centimeters (cm) using anthropometric tape. Hip circumference is a measurement of obesity. People with "apple-shaped" bodies (with more weight around the waist) face more health risks than those with "pear-shaped" bodies who carry more weight around the hips.	Anthropometric tape was used to measure the circumference of the hips at the widest part of the buttocks. Centimeters were utilized. Detailed procedure steps described in NHANES Anthropometric Procedure Manual (CDC, 20011).
Fat Mass %:	The percentage of a person's body that is not composed of fluids, muscle, bone, and vital organs.	Number in percent (%) calculated via bio-impedance weight scale.
Blood Pressure	The pressure exerted by circulating blood upon the walls of blood vessels. "Blood pressure" usually refers to the arterial pressure of the systemic circulation, and is often measured in the upper arm. Blood pressure is expressed in terms of the systolic pressure over diastolic pressure and is measured in millimeters of mercury (mm Hg). Normal resting blood pressure for an adult is approximately 120/80 mm Hg.	Same as conceptual definition. Specific procedure described in NHANES BP Procedure Manual (CDC, 2009).
Insulin	A peptide hormone produced by beta cells in the pancreas. It regulates the metabolism of carbohydrates and fats. It promotes the absorption of glucose from the blood to skeletal muscles and fat tissue.	Level of (8+ hour) fasting insulin obtained from serum blood draw.
Glucose	A monosaccharide found in plants that is absorbed directly into the bloodstream during digestion and aids in cellular function.	Level of (8+ hour) fasting glucose obtained from serum blood draw.
Cortisol	A glucocorticoid steroid hormone, produced in adrenal glands. It is released in response to stress and low blood glucose levels. Cortisol increases blood sugar, suppresses the immune system, and helps with metabolism of fat, protein, and carbohydrate.	Level of (8+ hour) fasting cortisol will be obtained from free cortisol levels drawn from serum blood.

Total Cholesterol	A lipid molecule that is biosynthesized by all cells since it is a component of cell membranes. Cholesterol is also a precursor for the biosynthesis of steroid hormones, bile acids, and vitamin D. All foods containing animal fat contain cholesterol.	Level of (8+ hour) fasting total cholesterol obtained from serum blood draw.
Low Density Lipoprotein (LDL) Cholesterol	LDL is one of the five major groups of lipoproteins whose particles pose a risk for cardiovascular disease when they invade the endothelium and become oxidized. Lipoproteins are complex particles composed of multiple proteins which transport all lipids. They are typically composed of 80-100 proteins/particles. LDL particles are often called "bad cholesterol" because they can transport their content of fat molecules into artery walls, attract macrophages, and high levels are associated and an increased risk of atherosclerosis.	Level of (8+ hour) fasting LDL cholesterol obtained from serum blood draw.
High Density Lipoprotein (HDL) Cholesterol	HDL is one of the five major groups of lipoproteins. Lipoproteins are complex particles composed of multiple proteins which transport all lipids. They are typically composed of 80-100 proteins/particles. Unlike the larger lipoprotein particles which deliver fat molecules to cells, HDL particles remove cholesterol molecules from the blood decreasing their risk of atherosclerosis.	Level of (8+ hour) fasting HDL cholesterol obtained from serum blood draw.
Triglycerides	Triglycerides are esters created from glycerol and fatty acids that act as a blood lipid to aid in transfer adipose fat and blood glucose from the liver.	Level of (8+ hour) fasting Triglycerides obtained from serum blood draw.

Research Hypotheses and Question

The objective of this study was to improve the nutritional and metabolic health of women. Specific research hypotheses (Ha) and the research question (RQ) were as follows:

Ha1: Yogurt consumption will have a beneficial effect on metabolic outcomes of women.

Ha1a: This effect will be greater in those consuming full fat products.

Ha2: Yogurt consumption will have a beneficial effect on measures of adiposity in women.

H2a: This effect will be greater in those consuming full fat products.

RQ1: Will yogurt consumption be a feasible dietary intervention for improving metabolic and adiposity outcomes in women?

Research Design

Guided by the ITHBC (Ryan, 2009), an experimental design was utilized to address the study objectives. The concepts from the ITHBC were used as a basis to develop an intervention related to the prevention or reduction of adiposity and improvement of metabolic outcomes in women. The study participants were randomly assigned to one of two intervention groups or a control group. The two interventional groups received yogurt (i.e., the independent variable) while the control group was asked to consume their typical diet during the study, making no alterations to foods typically consumed. After 12 weeks, all groups were measured on the same measures of adiposity and metabolic markers (i.e., the dependent variables).

Methods

Sample. The accessible population for this study was adult women living in north Texas. Recruitment was performed at a large obstetrics and gynecology practice as well as several other community locations in north Texas. Inclusion criteria included: (a) women who were at least 18 years old and (b) those who were able to read, speak, and

write English. Exclusion criteria included women with: (a) a diagnosis or currently taking medication for diabetes or hyperlipidemia, (b) lactose intolerance, (c) allergy to dairy products, (d) those who have had a greater than 20-pound weight change in the past year and/or (e) those who were pregnant or were within six weeks after delivery.

Informed Consent/Human Subjects Protection. Protection of the rights of the participants in this project was upheld through a variety of measures implemented to ensure safety, privacy, and confidentiality for all of those involved. All procedures were evaluated and approved by the IRB at the University of Texas at Tyler. Prior to signing the informed consent, full disclosure of the study's general purpose, benefits, risks, participants' rights, and responsibilities were discussed with all participants. Regulations for the Health Insurance Portability and Accountability Act (HIPAA) for protected health information was maintained at all times and HIPAA consents were obtained.

Measures/Instruments. ***Survey instruments***. A researcher-developed Participant Demographic Survey was used to collect pertinent patient demographic data. Participants provided dietary data about their use of yogurt by completing an 8-item Dairy Consumption Questionnaire, Daily Yogurt and Dairy Form, and a Daily Dairy Form). A 6-item Post Study Feasibility Survey was also used. After development, the researcher sent each of these instruments to content experts, colleagues, and others not familiar with the research to elicit feedback on the wording and face validity. The forms were reorganized and reworded based on feedback.

Metabolic/Physiologic Outcomes. Ha1 was tested by measuring the effect of the yogurt on: blood pressure, fasting serum glucose, insulin, lipid panel (total cholesterol, low density lipoprotein [LDL], high density lipoprotein [HDL], and triglycerides), and

free cortisol levels. Labs were collected at the contracted laboratory and were prepared, stored, and transported according to specific local lab protocols. To reduce bias, a single laboratory was utilized for all blood analyses; measurement of blood pressure was obtained using the equipment and instruction standards described in the National Health and Nutritional Examination Survey (NHANES) Blood Pressure Procedures Manuals (Centers for Disease Control, 2009).

Adiposity outcomes. Ha2 was tested by measuring the effect of the yogurt intervention on: body mass index (BMI), waist circumference (cm), hip circumference (cm), and body fat percent. Collection of weight and height (to calculate BMI), as well as waist and hip circumferences was obtained using the equipment and instruction standards described in the National Health and Nutritional Examination Survey (NHANES) Anthropometry Manuals (Centers for Disease Control, 2011). The longstanding reputable history of NHANES made their manuals an appropriate choice for this study.

In a recent study of women, Direk and colleagues (2013) found that anthropometric measures predicted abdominal fat almost equally as well as Computed Tomography (CT) or Dual Energy X-ray Absorptiometry (DXA) scanning. Although CT and DXA are considered the gold standard for body fat percent measurement in clinical settings, due to funding limitations and access, these tools were not utilized for this study. Direk and colleagues' study (2013) lends support to the use of anthropometric measures as estimates of visceral fat. Furthermore, a professional grade bio-impedance scale was used to determine body fat composition to assess percentage of body fat. Bio-impedance uses electrodes similar to an electrocardiogram (EKG) to run an imperceptible electrical current through the body. Lean tissue is a good conductor of electricity while fat tissue is

not. The resistance of the flow of the electrical current is measured by an analyzer to calculate the body composition. Electrical bio-impendence monitoring has been utilized in a number of published studies as an alternative means to CT/DXA to assess total body fat percent.

Compliance and feasibility. The Daily Yogurt and Dairy Form was used to provide an answer to RQ1. This format enabled participants to exercise control over some of the diet decisions they made as well as promote behaviors of self-regulation, an integral concept in the ITHBC model. This form was utilized by participants to track the number of ounces, fat (grams), and brand/flavor of yogurt consumed each day. In addition, the Post Study Feasibility Survey was administered to assess participants' likelihood to continue the use of yogurt as part of their nutritional intake after the study was completed.

Intervention description. The non-fat intervention group (NF) was asked to consume 12 total ounces of non-fat yogurt per day for 12 weeks. Participants were allowed to purchase any brand, flavor, or texture of yogurt of their choice. Participant were instructed to consume commercial dairy milk yogurt (from cows) that did not exceed 160 calories, 18 grams of carbs, or 0 grams of fat (per 6 ounce serving). They could consume the yogurt at any time each day in combination with another meal, as a meal replacement, or as a snack. They were instructed to record the amount in ounces and brand/flavor of yogurt consumed each day. The participants were asked to consume all other dairy products in the same amounts and frequencies as before the study keeping their habitual diet. They were also asked to record both the yogurt and dairy consumption for each day on the Daily Yogurt and Dairy Form.

The full-fat intervention group (FF) was asked to consume 12 ounces of full fat yogurt per day for 12 weeks. There was no upper limitation on calories, carbs, or fat. Participants were instructed to consume yogurt with at least 6 grams of fat per 6 ounce serving. They were also asked to record the amount in ounces, grams of fat, and brand/flavor of yogurt consumed each day. The participants were asked to consume all other dairy products in the same amounts and frequencies as before the study to maintain their habitual diet. They were asked to record both the yogurt and dairy consumption for each day on the Daily Yogurt and Dairy Form.

The control group (CG) was asked to make no changes to their current dietary habits. They were instructed to document dairy consumption on the Daily Dairy Form. Though this could have heightened the awareness of consuming dairy products, with the emphasis not on yogurt it was expected that they would not consume more yogurt than usual. The form also served as a means to assess typical yogurt intake within the sample.

Data Collection. Participants were recruited through locally posted community flyers and letters to current patients at a large obstetrics and gynecology practice. All participants were interviewed in person, via phone, or email (depending on how they contacted the PI) to assess for study eligibility. The researcher's contact information was listed for all flyers posted in the community. Staff at the obstetrics and gynecology practice was instructed on how to inform prospective participants of the study and next steps for contacting the researcher when interested women were identified.

If inclusion criteria were met, potential participants were asked to meet with the PI in an initial session in which the purpose and procedures of the study were disclosed. After signing the IRB-approved consent and HIPAA forms, participants were randomly

assigned to one of three groups (a control group, a non-fat yogurt group, or a full-fat yogurt group) by drawing a sealed envelope.

After randomization, baseline demographic surveys, anthropometric measurements, and lab work were then obtained by the PI and entered into each of the participant's individual file. All data collection was performed in a private room to ensure privacy. Following baseline data collection, participants were instructed not to make any major diet changes during the course of the 12-week study unless instructed to do so as indicated by the group assignment. They were also asked not to change their activities or exercise regimens during this time. Participants were instructed to report any new medications, changes in medications, or changes in health status. Participants in the full-fat and non-fat yogurt groups were given a Daily Yogurt and Dairy Form to specifically document the amount and type of yogurt consumed each day, as well as other dairy products consumed. Participants in the control group completed the Daily Dairy Form to document all dairy intake on a daily basis. The PI advised participants to submit forms weekly to encourage and assess compliance with the intervention. Electronic submission via email was recommended but postage paid options for regular mail were also available. Subjects were then sent to the contracted lab to have their blood drawn after the initial body assessments. At the end of the 12-weeks, anthropometric measurements and lab work were reassessed. In addition, the Post Study Feasibility Survey was distributed to group participants to obtain feedback on the intervention study. All survey data and assessment findings were completed on paper and were stored in a locked file in a locked office accessible only to the PI.

Procedure. All study data were transcribed into a password protected Statistical Program for the Social Sciences (SPSS version 20.0) database for analysis. Data was assessed for accuracy, outliers, and missing responses prior to conducting analysis. Discrete variables were examined for accuracy. Continuous variable means and standard deviations were examined for errors and to assess for outliers. Descriptive statistics were calculated for each variable. For continuous variables, range, mean, median, and standard deviation were used. For categorical variables, mean, frequency, and contingency tables were used. Chi-square tests (for nominal level data) and ANOVA (for continuous level data) were used to compare the distribution of the demographics of the three groups at baseline. Post hoc analyses were conducted to determine the differences.

Feasibility (RQ1) was assessed via time required for recruitment, attrition rate, Daily Yogurt/Dairy Consumption Form completion, and responses to the Post Study Feasibility Survey.

Results

Participant Characteristics. A total of 59 healthy adult women aged 18 to 69 (mean 34.1 SD 12.48) were initially enrolled in this study and 47 completed the research study. Table 1 shows the full fat (18), non-fat (14), and control subjects (15) were similar overall based on demographics. The participants in the study were primarily white (72.9%), had some college education (81.4%) and had some current form of health insurance (79.9%). Baseline participant characteristics are summarized in *Table 3*. No significant differences were found for any demographic variable across the groups.

Table 3. Baseline Demographics of Subjects

Variable	Full-Fat (n=18)	Non-Fat (n=14)	Control (n=15)	P Value[1]
Age				.368
18-30	10 (55.6)	6 (42.9)	7 (46.7)	
31-43	4 (22.2)	5 (35.7)	5 (33.3)	
43-56	4 (22.2)	3 (21.4)	1 (6.7)	
57+	0	0	2 (13%)	
Marital Status				.453
Married	8 (44.4)	7 (50.0)	9 (60.0)	
Divorced	3 (16.7)	3 (21.4)	0 (0)	
Never Married	7 (38.9)	4 (28.6)	6 (40.0)	
Race				.300
White	13 (72.2)	8 (57.1)	12 (80.0)	
Black	2 (11.1)	1 (7.1)	3 (20.0)	
Asian	1 (5.6)	1 (7.1)	0 (0)	
Other	2 (11.1)	4 (28.6)	0 (0)	
Education				.535
8th grade	2 (11.1)	0 (0)	1 (6.7)	
High School	3 (16.7)	4 (28.6)	1 (6.7)	
Some College	6 (33.3)	4 (28.6)	3 (20.0)	
College Grad	7 (38.9)	5 (35.7)	8 (53.3)	
Post Grad	0 (0)	1 (7.1)	2 (13.3)	
Working Status				.822
No	11 (61.1)	9 (64.3)	9 (60.0)	
Yes 40+ hrs.	2 (11.1)	2 (14.3)	3 (20.0)	
Yes 30-40 hrs.	2 (11.1)	1 (7.1)	3 (20.0)	
Yes 20-30 hrs.	2 (11.1)	2 (14.3)	0 (0)	
Yes less 20 hrs.	1 (5.6)	0 (0)	0 (0)	
Insurance Status				.753
Employer	11 (61.1)	10 (71.4)	9 (60.0)	
Self-Insured	3 (16.7)	1 (7.1)	1 (6.7)	
Medicaid	0 (0)	2 (14.3)	0 (0)	
Medicare	0 (0)	0 (0)	1 (6.7)	
No Insurance	2 (11.1)	0 (0)	4 (26.7)	
Other	2 (11.1)	1 (7.1)	0 (0)	
Exercise Minutes per Week	125.27 ± 25.48	101.78 ± 33.5	145.33 ± 30.45	.607

[1]P values were created using the x2 statistic for ordinal level data and mean with SE for continuous variables.

Metabolic Indicators (Ha1). Baseline blood values were compared across all groups for Lipid Panel (Total Cholesterol, LDL, HDL, Triglycerides), Glucose, Insulin, and Cortisol, and indicated no difference in these values at baseline (Table 4). For each of these measures, a change score was computed to determine the change for each

participant from baseline to the final measurement. One-way ANOVA was used to compare change scores for each measure across groups. Differences in change scores were not statistically significant when comparing groups according to change in: Total Cholesterol, F (2,42) = .289, p = .753, LDL Cholesterol, F (2,42) = .287, p = .752, HDL Cholesterol, F (2,42) = .621, p = .543, Triglycerides, F (2,42) = .377, p= .688, Cortisol, F (2,41) = .635, p = .535|, Insulin, F (2,42) = .615, p = .546|; or Glucose, F (2,42) = .706, p = .500.

Table 4. Baseline Laboratory Values

Variable	Full-Fat (n=18)	Non-Fat (n=14)	Control (n=15)
Serum Lipid Panel			
Total Cholesterol	171.69 ± 4.82	157.92 ± 8.24	181.72 ± 11.37
LDL Cholesterol	96.05 ± 5.10	84.78 ± 6.92	105.09 ± 10.48
HDL Cholesterol	54.70 ± 3.35	53.48 ± 2.91	59.36 ± 3.45
Triglycerides	101.76 ± 10.45	98.14 ± 17.83	87.09 ± 28.93
Serum Glucose	87.76 ± 1.86	85.92 ± 1.75	87.81 ± 3.89
Serum Insulin	12.17 ± 2.77	9.78 ± 2.71	8.63 ± 2.54
Serum Cortisol	12.47 ± 1.32	11.00 ± 1.657	10.81 ± 1.33

[1]Values are means ± SE

Anthropometric Measures (Ha2). Baseline and post intervention anthropometric measures were compared across all groups for weight, BMI, body fat percent (%), waist circumference, hip circumference, and blood pressure. For each of these measures, a change score was computed to determine the change for each participant from baseline to the final measurement. One-way ANOVA was used to compare change scores for each measure across groups. Differences in change scores were not statistically significant when comparing groups according to change in: Weight F, (2, 46) =.918, p=.407, BMI, F (2, 46) = .263, Body Fat Percent, F (2, 46) = .977, p=.385, p=770; and Hip Circumference, F (2, 46) =.711, p=.497. Waist Circumference showed a significant

change, F (2, 46) =14.17, p<.001, over 12 weeks in all three groups but did not differ statistically between groups (Table 5). There were statistically significant differences when comparing groups according to change in systolic blood pressure, F (2, 46) = 10.06, p < .001, and diastolic blood pressure, F (2, 46) = 6.85, p = .003. The full fat group showed a significantly greater reduction in overall blood pressure over the 12 weeks when compared to the non-fat and control groups.

Table 5. Anthropometric Means at Baseline and at 12 weeks.

Variable (N=47)	Full Fat		Non Fat		Control		P Value
	Baseline	12 weeks	Baseline	12 weeks	Baseline	12 weeks	
Weight	200.84 ± 61.42	202.34 ± 64.80	190.73 ± 44.78	179.07 ± 40.00	176.15 ± 53.62	177.57 ± 55.67	.407
BMI	34.25 ± 9.21	34.32 ± 9.77	32.77 ± 9.21	31.4 ± 7.08	29.18 ± 9.21	29.67 ± 8.87	.385
Waist Circumference	99.02 ± 19.66	94.77 ± 19.32	94.97 ± 13.25	89.71 ± 12.64	88.29 ± 15.62	86.20 ± 15.14	.231
Hip Circumference	118.25 ± 14.41	118.00 ± 14.69	116.72± 14.84	111.28 ± 12.46	111.64 ± 15.08	110.53 ± 14.87	.497
Body Fat %	41.83 ± 9.05	41.92 ± 8.72	40.6 ± 8.68	38.67 ± 8.47	37.04± 10.61	36.32 ± 11.52	.385
Systolic BP	122.60 ± 12.08	117.11 ± 7.84	120.90 ± 11.47	127.35 ± 10.66	118.17± 12.43	126.73 ± 14.09	.000*
Diastolic BP	78.70 ± 8.82	74.67± 7.19	77.27 ± 7.07	79.64 ± 7.12	77.35 ± 9.02	80.33 ± 10.89	.003*

*Denotes Statistically Significant Value

Feasibility. The recruitment of new participants took close to eight months from the initial start date. Fifty-nine participants completed all initial surveys, consents and initial anthropometric body assessments. However, of the 59 participants, 12 never went to the laboratory to have the serum blood markers completed at baseline, thus having incomplete files. Of the 12 who did not have the blood work done at baseline, two of these subjects did continue the study without the lab work portions completed. The other

10 did not finish the study. Forty-seven participants (80%) completed the 12-week study with all baseline and post intervention assessments completed.

Participants in the yogurt groups were instructed to consume 12 ounces of yogurt per day (equating to a projected 1008 ounces during the entire 12 weeks if they consumed all servings). The actual average yogurt consumption was 665.62 (SD= 268.47) ounces for full fat group participants, 652.25 (SD= 258.48) for non-fat group participants and 23.24 (SD= 26.35) ounces for the documentation group (who were instructed to keep their habitual diet). Most participants in the intervention groups indicated they missed more than 10 servings of yogurt during the study according to the Post Study Feasibility Survey.

In addition to ordinal level questioning, the Post Study Feasibility Survey contained a response set that offered participants a narrative section to document comments or concerns with the yogurt intervention or other aspects of the research study. Very few comments were documented by the participants on this portion of the survey. However, it should be noted that several participants from the full fat group did voice some difficulty in finding full fat yogurt which contained at least 6 grams of fat. Many subjects reported that when searching for products utilizing terms such as “traditional,” “whole milk,” or simply looking for products that lacked the terms non-fat or low-fat, was a challenge. Some stated that even products not claiming to be low fat often times had less than 6 grams of fat per serving. Others participants in this group reported they could only find full fat whole milk products at health food or organic type stores and that their typical grocery store’s selection of full fat yogurts was quite limited.

Discussion

Results from this study indicate no statistically significant differences incurred in subjects from consuming yogurt as a dietary intervention for measures of adiposity or body composition. Since yogurt compliance to the full 12 ounces per day procedure was a challenge for many participants, it is possible that a protocol requiring less ounces per day (only 1 serving instead of two) over a longer period of time may offer better compliance. Interestingly there were also no significant differences in participants who consumed full fat verses nonfat products on the outcome measures. Fat sources have historically been marketed as detrimental, particularly to those with cardiovascular disease and diabetes. However, no statistically significant correlation was seen in the biomarkers or body measurements of those consuming full fat, versus non-fat yogurt, versus typical diet, over the 12-week intervention. Further investigation of the role of dietary intake of fat on common metabolic indicators of cardiovascular disease and diabetes is warranted.

A modest decrease in systolic and diastolic blood pressures of full fat group participants was seen. In animal and in vitro studies it has been suggested that bioactive substances found in dairy have been shown to have an inhibitory effect on angiotensin converting enzyme but further research in human participants is needed (Munn, Sibley, Brundage, Ismail, & Earthman, 2013). In a study of 89 adults with hypertension, Drouin-Chartier et al., (2014) found dairy consumption to have a positive blood pressure lowering effect in men with mild to moderate hypertension but found that it may have a worsening effect in women. In a study aimed to examine the longitudinal association of dairy consumption with the changes in blood pressure (BP) and the risk of incident

hypertension (HTN) among adults, Wang, Fox, Troy, Mckeown, and Jacques (2015) utilized 2,636 Framingham Heart Study Offspring Cohort members (1991–2008) to investigate such relationships. They found total dairy and total low-fat/fat-free dairy intakes were inversely related to changes in diastolic blood pressure. Also, they found that each additional serving of yogurt consumed was associated with a 6% (95 % CI 1, 10) reduced risk of incident hypertension. While there has been support for changes in blood pressure associated with yogurt or dairy consumption, there remains a need for relevant research to establish a body of evidence further investigating these relationships.

In terms of feasibility, most participants indicated they would continue to consume yogurt after the study but few felt they would eat it daily. In terms of sustainability the question of convenience in purchasing full fat products needs further scrutiny. Marketing strategies are aimed at low-fat or non-fat products and make up a bulk of the products on stores shelves. Further investigations of the differences in full fat dairy products and the health benefits or concerns of such must come to light if there will be any paradigm shift in the marketing and economics of our food industry. At a minimum, if there is no distinguishable difference in the health benefits or harms of full fat yogurt compared to non-fat, which would most persons prefer to consume? Artificial sweeteners are often utilized in non-fat products to help replace some of the taste lost to the reduction of savory fat content. Emerging evidence demonstrating the impact of artificial sweeteners on obesity may support the marketability of full-fat yogurt.

Strengths, Limitations, and Difficulties

Strengths. The major strength of this study was its experimental design. Many of the studies reviewed in the literature were prospective or cross sectional. Very few

randomized controlled studies utilizing yogurt have been completed. To our knowledge, no experimental studies utilizing yogurt in only women had been done. Utilizing multiple measures of adiposity as well as several biomarkers were also strengths in this study. Additionally, yogurt is typically inexpensive, and is a widely available dietary intervention at most local grocery stores which contributes to sustainability.

Limitations. As with any longitudinal study, attrition was a limitation. Oversampling was done to allow for loss of participants. Utilizing only a few local community sites for assessment completion was a limitation for a few participants who said they had to drive over 20 minutes to get to the clinic. Woman in the intervention groups reported they become tired of consuming 12 ounces of yogurt every day. Very few participants were still eating 12 ounces of yogurt towards the end of 12 weeks. There were no restrictions made for the brand, flavor, texture or time of day to eat the yogurt, but most women stated they were "just tired of eating it every day."

The potential for confounding variables, despite exclusion criteria, could not be entirely controlled. Since standardization of only a few (not all) nutritional parameters was performed, other nutritional co-variables still exist (such as caloric intake). Furthermore, actual exercise or energy expenditure was not measured or controlled. Participants self-reported exercise (in minutes) at the initial and final assessments with no significant differences between groups. Participants were asked not to make any other changes in exercise or diet during the study. Although this opened up the possibility of confounding variables, it also reflected a real-world approach and helped determine if yogurt consumption was feasible without placing additional demands or restrictions on participants. Maintaining their previous behaviors mitigated the source and impact of

extraneous behaviors since the participants served as their own controls.

Some variability and human error was possible when obtaining anthropometric measurements. Body composition differences, racial and ethnic differences, and clinician technique could all have led to discrepancy. Body composition differences and racial and ethnic differences were collected in baseline data. Variances in clinician technique was addressed by using the same person, equipment, and lab to collect and analyze data to help reduce this limitation. The self-reported nature of food consumption was also a limitation. Participants may have felt inconvenienced to write in a daily log. This may have led to falsification, inaccurate recall, or under-reporting of consumption.

Challenges. The time it took for recruitment of an adequate number of participants was a challenge in this study. Participants were offered free assessments of body composition and several metabolic indicators at two time points but some still did not seek out these free services. Attrition was also a problem. Two participants reported they did not want to eat the yogurt after 1-2 weeks and decided to stop the study, but the rest who did not finish were lost to inability to follow up. It should be noted that a majority of those who did not follow up were unreachable within the first 2 weeks of the study indicating they likely never began the intervention despite enrolling in the study. Financially, some women found it to be a burden to purchase full fat yogurt which some felt was more difficult to find and often was located at health food or natural/organic type stores instead of their typical grocery store which made it more costly. The major difficulty in conducting this type of research was the fiscal resources necessary to conduct the study. Women could not be asked to pay out of pocket to cover blood work; providers could not be expected to provide services for free. In this study, the PI, who is a

women's health nurse practitioner, provided the assessments at no cost. The lab that supports the PI's practice negotiated the lowest cost possible to provide lab services and still cover expenses. Intramural funding assisted in covering these study-related expenses.

Conclusion

Increased adiposity and declining metabolic health in women results in negative consequences to health. The current literature supports the hypothesis of dairy as an intervention, but too few interventional studies have been completed. This study helps to address the gaps in science that are crucial for this population. Although no known prior use in adiposity studies of women, the ITHBC provided a sound theoretical basis to guide the research. The National Institutes of Health's (NIH) *Strategic Plan for NIH Obesity Research* called researchers to develop effective interventions to alleviate the burden of obesity (National Institutes of Health, 2011). Promoting healthy weight during critical periods and life events is one way NIH proposed to accomplish this. This researcher accepted the challenge from NIH, and the findings from this study will contribute to the body of knowledge in hopes of improving the health outcomes for women.

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Chapter 5

Conclusions and Recommendations

The prevalence of obesity was 36.5% among U.S. adults during 2011–2014 (CDC, 2015). Flegal, Kit, Orpana, & Graubard (2013) performed a systematic review of reported hazard ratios (HRs) of all-cause mortality for overweight and obesity relative to normal weight in the general population. They found relative to normal weight, obesity was associated with significantly higher all-cause mortality. Obesity concerns as risk factors for diabetes and cardiovascular disease have been in the literature for decades. Additionally, obesity related morbidity and mortality issues are also a financial burden on our already suffering healthcare dollars. A recent meta-analysis found that the "annual medical spending attributable to an obese individual was $1,901 ($1,239-$2,582) in 2014 USD, accounting for $149.4 billion at the national level" (Kim & Basu, 2016).

The investigation of concerns of the symptoms of perimenopause is just one vulnerable group that would benefit from further knowledge of the complex relationships between diet and measures of metabolism and adiposity. Findings from the brief review of symptoms of the perimenopause demonstrate that increase abdominal fat does play a role in the menopause transition, but is poorly understood. Some groups have focused on nutrition concerns of this population but again without clear guidelines to direct healthcare providers.

Research stakeholders (NIH Strategic Plan for Obesity, 2011) are actively encouraging intervention research studies. Funding opportunities are available for all

levels of researchers.

The general topic of this dissertation was delivering a yogurt intervention for the expected benefits in the measures of adiposity and metabolism is an emerging research subject. There is conflicting data in the literature regarding dairy consumption, including yogurt specifically, as a health intervention. Observational studies are demonstrating possible relationships but no clear answer has been ascertained. More specifically the benefits for women, and for women at certain life points, is far from clear. Additionally, the correlations between the amounts of dairy fat in the products being studied also provides a covariate for further scrutiny. The findings from this research project demonstrated no acute effect that consuming yogurt had on measures of adiposity but did peak further question into the suggestion that certain types of dairy may play a positive role on blood pressure. This project also creates further questions as to why no significant differences were seen on serum biomarkers with participants consuming full fat versus non-fat product, when for decades, fat has been touted as harmful to our metabolic health.

Understanding these relationships may assist a multitude of health related disciplines as they search for better ways to address problems of health and obesity in the United States. Nursing, medicine (cardiovascular, endocrine), nutrition, mental health, advocates are working tirelessly to seek out answers. Other interest groups such as economists, public health activists, farming/dairy corporations, and financial stakeholders are also actively involved. The problem of obesity spares no gender, race or ethnicity and millions would benefit for further investigation of this research project.

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Appendix A: Institutional Review Board Approval

THE UNIVERSITY OF TEXAS AT TYLER
3900 University Blvd. • Tyler, TX 75799 • 903.565.5774 • FAX: 903.565.5858

Office of Research and Technology Transfer
Institutional Review Board

July 28, 2015

Dear Ms. Boyet,

Your request to conduct the study*: Effect of a Yogurt Intervention on Adiposity and Metabolic Outcomes in Perimenopausal, IRB# SUM2015-105*, has been approved by The University of Texas at Tyler Institutional Review Board under expedited review. This approval includes the written informed consent that is attached to this letter, and your assurance of participant knowledge of the following prior to study participation: this is a research study; participation is completely voluntary with no obligations to continue participating, and with no adverse consequences for non-participation; and assurance of confidentiality of their data.

In addition, please ensure that any research assistants are knowledgeable about research ethics and confidentiality, and any co-investigators have completed human protection training within the past three years, and have forwarded their certificates to the IRB office (G. Duke).

Please review the UT Tyler IRB Principal Investigator Responsibilities, and acknowledge your understanding of these responsibilities and the following through return of this email to the IRB Chair within one week after receipt of this approval letter:

- This approval is for one year, as of the date of the approval letter
- **The Progress Report form must be completed for projects extending past one year.** Your protocol will automatically expire on the one year anniversary of this letter if a Progress Report is not submitted, per HHS Regulations **prior** to that date (45 CFR 46.108(b) and 109(e): http://www.hhs.gov/ohrp/policy/contrev0107.html
- Prompt reporting to the UT Tyler IRB of any proposed changes to this research activity
- **Prompt reporting to the UT Tyler IRB and academic department administration will be done of any unanticipated problems involving risks to subjects or others**
- Suspension or termination of approval may be done if there is evidence of any serious or continuing noncompliance with Federal Regulations or any aberrations in original proposal.
- Any change in proposal procedures must be promptly reported to the IRB prior to implementing any changes except when necessary to eliminate apparent immediate hazards to the subject.

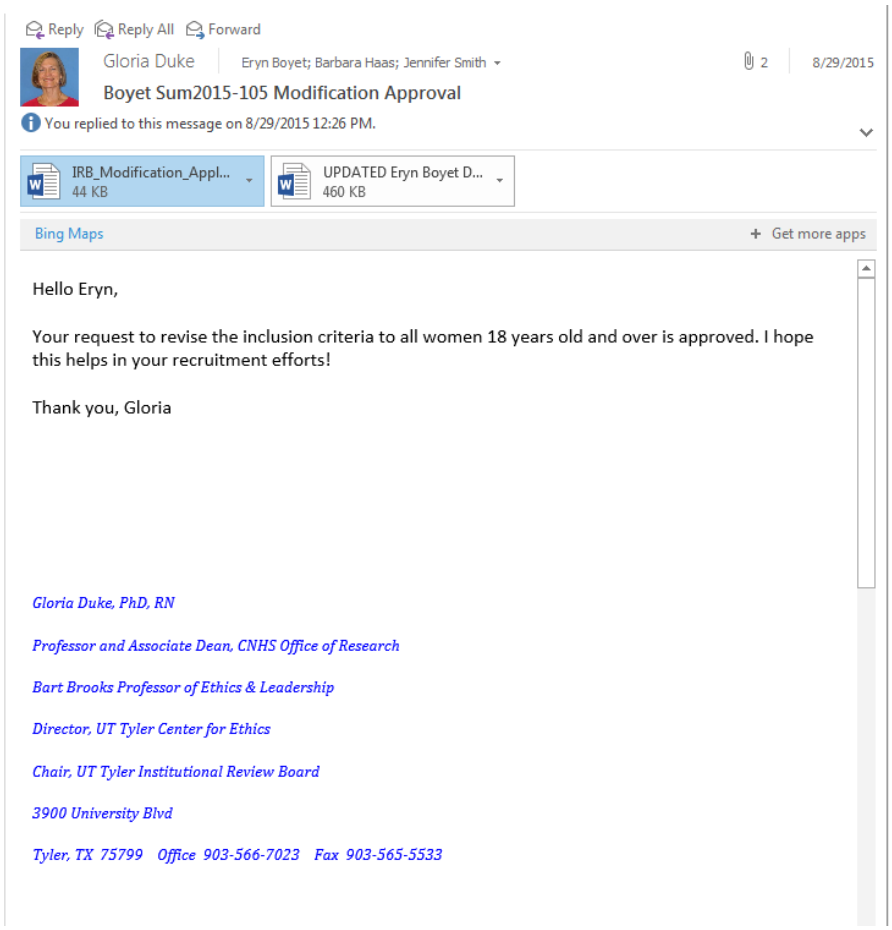
Best of luck in your research, and do not hesitate to contact me if you need any further assistance.

Sincerely,

Gloria Duke, PhD, RN

Gloria Duke, PhD, RN
Chair, UT Tyler IRB

Appendix B: Institutional Review Board Modification Approval



Reply Reply All Forward

Gloria Duke | Eryn Boyet; Barbara Haas; Jennifer Smith | 2 | 8/29/2015

Boyet Sum2015-105 Modification Approval

You replied to this message on 8/29/2015 12:26 PM.

IRB_Modification_Appl... 44 KB

UPDATED Eryn Boyet D... 460 KB

Bing Maps + Get more apps

Hello Eryn,

Your request to revise the inclusion criteria to all women 18 years old and over is approved. I hope this helps in your recruitment efforts!

Thank you, Gloria

Gloria Duke, PhD, RN

Professor and Associate Dean, CNHS Office of Research

Bart Brooks Professor of Ethics & Leadership

Director, UT Tyler Center for Ethics

Chair, UT Tyler Institutional Review Board

3900 University Blvd

Tyler, TX 75799 Office 903-566-7023 Fax 903-565-5533

Appendix C: Recruitment Flyer

The University of Texas at Tyler is looking for participants for a clinical nutrition study here in north Texas.
Are you a female over 18?
Are you interested in being a part of a clinical research study which focuses on weight and nutrition?
We invite you to contact us for more information about this study.

Email: **eboyet@patriots.uttyler.edu** Phone: 940-891-3600
The primary investigator for this research study is Eryn Boyet, RN, MSN, WHNP-BC. Ms. Boyet is a Women's Health Nurse Practitioner at [redacted]. She is also nursing faculty at North Central Texas College. You may contact her at the above email address for any questions

Appendix D: Recruitment Letter

Caring and Compassionate Atmosphere

Dear _____,

As a loyal patient of [redacted] we wanted to let you know about an upcoming research study at our office that you may be interested in participating in. One of our nurse practitioners, Eryn Boyet, RN, MSN, WHNP-BC, is currently initiating a research project for perimenopausal women. This study is done in conjunction with Ms. Boyet's doctoral research (dissertation) at the University of Texas at Tyler.

The focus of this research study is on nutrition, weight, body fat, and the associated risks for cardiovascular disease and diabetes. The research study will involve body composition assessments, blood work, dietary evaluations, and the use of a 12 week long dietary intervention.

The study focuses on women who are over 18 years old. The research study will be completely voluntary and you may stop at any time.

If you would like more information about this study or think you may be interested in participating, please contact the office below so we can see if you qualify to participate. If you would rather, you may also email the researcher directly for more information at the email address listed below.

We look forward to hearing from you!

[redacted]

Researcher's Email: eboyet@patriots.uttyler.edu

Appendix E: Informed Consent

THE UNIVERSITY OF TEXAS AT TYLER

Informed Consent to Participate in Research

Institutional Review Board #

Approval Date:

1. Project Title: Effect of a Yogurt Intervention on Adiposity and Metabolic Outcomes in Women
2. Principal Investigator: Eryn Boyet, RN, MSN, WHNP-BC
3. Participant's Name: _____

To the Participant:

You are being asked to take part in this study at The University of Texas at Tyler

(UT Tyler). This permission form explains:

- Why this research study is being done.
- What you will be doing if you take part in the study.
- Any risks and benefits you can expect if you take part in this study.

After talking with the person who asks you to take part in the study, you should be able to:

- Understand what the study is about.
- Choose to take part in this study because you understand what will happen

4. Description of Project

The purpose of this study is to determine the effects that eating certain dairy products has on women's weight, body fat and certain blood tests. The focus of this study involves women. Doctors and nurses can use findings from your participation in this study to find ways to help women manage their weight and reduce their health risks.

5. Research Procedures

If you agree to be in this study, we will ask you to do the following things:

- You will be asked to set up a meeting with the researcher to talk about your diet, habits, health status, medication usage, and activity level.
- You will be asked to record on paper when you eat certain foods during this study. You will submit these recordings to the researcher on a weekly basis for three months.
- You may be asked to consume specific types of yogurt during this study.
- Your height, weight, waist and hip circumference, blood pressure, and body fat percent will be measured at the beginning and end of this study.
- Your blood will be drawn for cholesterol, triglycerides, glucose, insulin, and cortisol at the beginning and end of this study.

6. Side Effects/Risks

Side effects may occur from changing my diet in this study. Minor discomforts such as upset stomach, increased gas, or changes in bowel habits may occur from participating in this research study. By signing this consent I acknowledge that I do not have any known allergies to any dairy products. However, the possibility of an allergic food reaction could still occur. If any side effects occur during this study I will notify the researcher right away. Injury may result from laboratory phlebotomy procedures necessary for blood collection. Although rare, I acknowledge that tissue injury, hemorrhage, and/or infection are possible risks. If any injury occurs during this study I will notify the researcher right away.

7. Potential Benefits

Healthcare providers can help other women by learning about the role of dairy in our diets.

<u>Understanding of Participants</u>

8. I have been given a chance to ask any questions about this research study. The researcher has answered my questions.

9. If I sign this consent form I know it means that:

- I am taking part in this study because I want to. I chose to take part in this study after having been told about the study and how it will affect me.
- I know that I may choose not be in this study. If I choose to not take part in the study, then nothing will happen to me as a result of my choice.

- I know that I have been told that if I choose to be in the study, then I can stop at any time. I know that if I do stop being a part of the study, then nothing will happen to me.
- I will be told about any new information that may affect my wanting to continue to be part of this study.
- The study may be changed or stopped at any time by the researcher or by The University of Texas at Tyler.
- The researcher will get my written permission for any changes that may affect me.

10. I have been promised that that my name will not be in any reports about this study unless I give my permission.

11. I also understand that any information collected during this study may be shared as long as no identifying information such as my name, address, or other contact information is provided). This information can include health information. Information may be shared with:

- Organization giving money to be able to conduct this study.
- Other researchers interested in putting together your information with information from other studies.
- Information shared through presentations or publications.

12. I understand The UT Tyler Institutional Review Board (the group that makes sure that research is done correctly and that procedures are in place to protect the safety of research participants) may look at the research documents. These documents may have information that identifies me on them. This is a part of their monitoring procedure. I also understand that my personal information will not be shared with anyone.

13. I have been told about any possible risks that can happen with my taking part in this research project.

14. I also understand that I will not be given money for any patents or discoveries that may result from my taking part in this research.

15. If I have any questions concerning my participation in this project, I will contact the principal researcher: (Eryn Boyet) at (940-224-8167) or email (eboyet@patriots.uttyler.edu).

16. If I have any questions concerning my rights as a research subject, I will contact Dr. Gloria Duke, Chair of the IRB, at (903) 566-7023, gduke@uttyler.edu, or the University's Office of Sponsored Research:

The University of Texas at Tyler
c/o Office of Sponsored Research
3900 University Blvd
Tyler, TX 75799

I understand that I may contact Dr. Duke with questions about research-related injuries.

17. CONSENT/PERMISSION FOR PARTICIPATION IN THIS RESEARCH STUDY

I have read and understood what has been explained to me. I give my permission to take part in this study as it is explained to me. I give the study researcher permission to register me in this study. I have received a signed copy of this consent form.

_____ _____
Signature of Participant Date

_____
Witness to Signature

18. I have discussed this project with the participant, using language that is appropriate and the participant understands. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks. I believe the participant understood this explanation.

_____ _____
Researcher/Principal Investigator Date
IRB approved October 2011; rev 03-26-12

Appendix F: HIPAA Consent

The University of Texas at Tyler

Institutional Review Board

RESEARCH PARTICIPANT AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION

This form is to be signed by research participants in addition to the written Informed Consent, or, in the case that a written informed consent is authorized to be waived and is not used, this form must be signed anytime that protected health information will be used during a research project.

This does not authorize release of protected health information from any health care organization or provider.

♦Your records are confidential but may be revealed to appropriate institutional or federal authorities.

There is a federal law (HIPAA), which protects the confidentiality of your health information. This section of the informed consent explains how your health information will be used and disclosed for this study and describes your rights, including the right to see your health information. Any information collected about you in this study is confidential and your name will not be released in any reports or publication without your expressed consent.

By signing this document, you allow the researcher to use your Personal Health Information to carry out this Study. This may include information in your medical records such as medical histories, blood samples, x-rays, physical examinations and any other data created or collected during the Study.

By signing this document, you also allow the researcher to release your Health Information to the Institutional Review Board (a group at the University that oversees all research), the study Sponsor (organization that provides funds for conducting the study) and any representatives who work on behalf of Sponsor to conduct the Study. Other persons/investigators directly involved in this study may also receive your Personal Health Information. Research data sent to the sponsor or other persons does not include

your name, address, or social security number. Instead, you will be assigned a patient identification number. Your non-identifiable information may also be given to the U.S. Food and Drug Administration and other government health agencies around the world upon their request.

The Sponsor may also reanalyze the results of the study at a later date and combine them with results of other studies. While using the information in these ways, the sponsor may give it to its affiliated companies in the US or other countries. The sponsor may also share the information with its business partners or companies it hires to provide study-related services. Again, no identifying information about you will be released at any time except by an identification number.

The information may be given to the FDA or other government health agencies as part of applications to gain approval of treatments or to meet other reporting requirements such as reporting side effects. The results of the study may also be presented to other health care professionals and published in scientific journals or publications but your identity will not be disclosed.

♦**You have a right to see and make copies of your medical records.**

To ensure the reliability of the Study, however, you agree that you will not be able to see or copy your records related to the Study until the Sponsor has completed all work related to the Study. At that time, you may ask to see the Investigator's copy of your medical records.

♦**You may cancel your authorization at any time.**

This authorization to use and disclose your Health Information does not have an expiration date. **You may cancel your authorization at any time by sending a written notice to the** Researcher/Investigator named in this consent **at the following address:**

The University of Texas at Tyler
Institutional Review Board
c/o Office of Sponsored Research
3900 University Blvd
Tyler, TX 75799

If you cancel your authorization, the Investigator will no longer use or disclose your Health Information for this Study. However, we are required to record anything that relates to safety of drugs. I understand the above with regard to my privacy rights.

Research Participant Signature	**Date**
Witness	**Date**

Appendix G: Participant Demographic Survey

PARTICIPANT INFORMATION

1. What is today's date? _____
2. What is the **zip code where you live**? _____
3. What is your age? _____

4. Which of the following best describes your **race**? (select one item)

☐1 American Indian or Alaskan Native
☐2 Asian/Oriental or Pacific Islander
☐3 Black/African-American
☐4 White/Caucasian
☐5 Other

5. Are you of **Spanish or Hispanic** origin or ancestry? ☐1 Yes ☐2 No

6. Which of the following best describes your **current marital status**? (select one item)

☐1 Married ☐2 Widowed ☐3 Separated ☐4 Divorced ☐5 Never married

7. What is the **highest grade** you completed in school? (select one item)

☐1 8th grade or less
☐2 Some high school
☐3 High school graduate
☐4 Some college
☐5 College graduate
☐6 Any post-graduate work

8. Which of the following best describes **your health insurance** status?

☐1 Employer sponsored insurance
☐2 Self-insured
☐3 Medicaid
☐4 Medicare
☐5 No insurance (self-pay)
☐6 Other: _____

9. Are you currently **working**?

☐0 No
☐1 Yes - Full Time 40 hours per week or more
☐2 Yes - Part Time 30-40 hours per week
☐3 Yes - Part Time 20-30 hours per week
☐4 Yes - Part Time less than 20 hours per week

10. When was your **last menstrual period**?

☐1 Within the past month

☐2 Within the last three months
☐3 Within the last 6 months
☐4 Within the last 12 months
☐5 It has been over 12 months since I have had a period

11. Which of the following most closely describes your **menstrual periods over the past year**?

☐1 They have a regular pattern, occurring the same time every month (within 6 days)
☐2 They are mostly regular but long (>60 days between cycles)
☐3 They have an irregular pattern and vary by >7 days each month.
☐4 It has been over 12 months since I've had a period.

12. How old were you when you had your **first menstrual period?** _____

13. How **many times have you been pregnant (write "0" if none)**? _____

14. Are you **currently pregnant** or within **6 weeks of delivery** of a baby? Y N

15. During the past three months, how many minutes on average did you spend exercising per week?

16. How would you best describe your **weight over the past year**?

☐1 My weight has been stable this year (has not changed by more than 5lbs)
☐2 I have gained or lost between 5-10 pounds this past year
☐3 I have gained or lost between 11—19 pounds this past year
☐4 My weight has changed by over 20 pounds this year

Do you currently have any of the following conditions? (Select one item for each condition)

17. Cardiac disease ☐1 Yes ☐2 No
18. High Cholesterol ☐1 Yes ☐2 No
19. Diabetes ☐1 Yes ☐2 No
20. High blood pressure ☐1 Yes ☐2 No
21. Osteoporosis ☐1 Yes ☐2 No

22. Do you smoke? ☐1 Yes ☐2 No

Do you **currently** take any of the following **medications?** (Select one item for each condition)

23. Estrogen ☐1 Yes ☐2 No
24. Progesterone ☐1 Yes ☐2 No

Appendix G: Participant Demographic Survey Continued

25. Testosterone ☐1 Yes ☐2 No
26. Thyroid Medication ☐1 Yes ☐2 No
27. Cholesterol Medication ☐1 Yes ☐2 No
28. Depression/Anxiety Medication ☐1 Yes ☐2 No

*If you answered Yes to any of the above medications please list the name of medication(s) in the space below:

Do you **currently** take any of the following **supplements?** (Select one item for each condition)

29. Calcium Supplement ☐1 Yes ☐2 No
30. Vitamin D Supplement ☐1 Yes ☐2 No
31. Multivitamin Supplement ☐1 Yes ☐2 No

32. Are you aware of any ways to reduce abdominal ("belly") fat in women (other than medications)?

☐1 Yes ☐2 No

If yes, please list:

Appendix H: Dairy Consumption Questionnaire

Please answer the following questions. **Mark one answer for each question**.

1. During the past month, approximately how often did you have any dairy milk? (You may include flavored milk but DO NOT include very small amounts of milk used in coffee or meals)
    - ☐ 1 Never
    - ☐ 2 1-3 times last month
    - ☐ 3 1-4 times per week
    - ☐ 4 1-2 time per day
    - ☐ 5 More than 3 times per day
2. During the past month, what kind of milk did you usually drink?
    - ☐ 1 Whole fat or regular milk
    - ☐ 2 2% fat or reduced fat milk
    - ☐ 3 1% fat or low-fat milk
    - ☐ 4 Fat free, skim, or nonfat milk
    - ☐ 5 Other/Not sure/I did not drink dairy milk
3. During the past month, how often did you eat any kind of cheese? (Including cheese used in foods)
    - ☐ 1 Never
    - ☐ 2 1-3 times last month
    - ☐ 3 1-4 time per week
    - ☐ 4 1-2 times per day
    - ☐ 5 More than 3 times per day
4. During the past month, what kind of cheese did you usually eat?
    - ☐ 1 Whole fat or regular cheese
    - ☐ 2 2% fat or reduced fat cheese
    - ☐ 3 Non-fat cheese
    - ☐ 4 Other/Not sure/I did not drink eat cheese
5. During the past month, how often did you eat any kind of ice cream or frozen dairy product?
    - ☐ 1 Never
    - ☐ 2 1-3 times last month
    - ☐ 3 1-4 time per week
    - ☐ 4 1-2 times per day
    - ☐ 5 More than 3 times per day
6. During the past month, what kind of ice cream did you usually eat?
    - ☐ 1 Regular ice cream
    - ☐ 2 2% fat or reduced fat ice cream
    - ☐ 3 Non-fat ice cream
    - ☐ 4 Other/Not sure/I did not eat dairy ice cream
7. During the past month, how often did you eat any kind of yogurt?
    - ☐ 1 Never
    - ☐ 2 1-3 times last month
    - ☐ 3 1-4 times per week
    - ☐ 4 1-2 times per day
    - ☐ 5 More than 3 times per day

8. During the past month, what kind of yogurt did you usually eat?
   - ☐ 1 Regular, whole milk yogurt
   - ☐ 2 2% fat or reduced fat yogurt
   - ☐ 3 Non-fat yogurt
   - ☐ 4 Other/Not sure/I did not drink eat yogurt

Appendix I: Daily Yogurt and Dairy Consumption Form

Participant Daily <u>Yogurt</u> Consumption (for Intervention Groups)

Week #___	Brand	Type (Regular, Greek, etc…)	Flavor (Plain, Strawberry, etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten	Brand	Type (Regular, Greek, etc…)	Flavor (Plain, Strawberry, etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten
Sun	*Yoplait*	*Regular*	*Banana*	*8 gm*	*5 gm*	*6 oz.*	*Dannon*	*Greek*	*Strawb*	*7 gm*	*4 gm*	*6 oz.*
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												

Frozen Yogurt is not to be included here. If you consume frozen yogurt please count that on the Non-Yogurt form

Appendix I: Daily Yogurt and Dairy Consumption Form Continued

Participant Daily <u>Non-Yogurt</u> Dairy Consumption* (for Intervention Group)

Week #___	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten
Sun	*Cheese*	*5 gm*	*6 gm*	*2 oz.*	*Cheese*	*5 gm*	*4 gm*		*Sour Cream*	*3 gm*	*5 gm*	*3 oz.*
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												

*If more than three servings of different dairy products are consumed during one day you may use additional sheets of paper. If the same item is used more than once per day you may total those servings together.

Appendix J: Daily Dairy Consumption Form

Participant Daily <u>All-Dairy</u> Consumption* (for Control Group)

Week #___	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten	Type of Dairy (Cheese, Milk, Ice cream etc…)	Total Gm of Fat	Total Gm of Protein	Total Ounces Eaten
Sun	*Cheese*	*5 gm*	*6 gm*	*2 oz.*	*Cheese*	*5 gm*	*4 gm*	*1 oz.*	*Sour Cream*	*3 gm*	*5 gm*	*3 oz.*
Mon												
Tues												
Wed												
Thurs												
Fri												
Sat												

*If more than three servings of different dairy products are consumed during one day you may use additional sheets of paper. If the same item is used more than once per day you may total those servings together.

Appendix K: Post Study Feasibility Survey

PARTICIPANT INFORMATION What is today's date? _____

1. Which study group were you assigned to?

☐1 The FULL-FAT dairy group
☐2 The NON-FAT dairy group
☐3 The dairy DOCUMENTATION ONLY group

For participants who were in the FULL or NON FAT dairy groups please answer the following questions. For those in the DOCUMENTATION ONLY group skip to question #5.

2. During this study how many times did you FORGET, or chose NOT to consume a SERVING of yogurt?

☐1 Zero, I consumed every serving
☐2 1-3 times
☐3 3-6 times
☐4 7-10 times
☐5 More than 10 times

3. Which statement best describes the most frequent reason why you did not consume a yogurt serving?

☐1 I forgot
☐2 I was not at home
☐3 I did not feel well
☐4 I did not feel like eating yogurt
☐5 Other reason not listed
☐6 N/A- I consumed all of the servings

4. After completing the study select which of the following statement best fits you?

☐1 I will consume yogurt every day
☐2 I will consume yogurt 2-3 times per week
☐3 I will consume yogurt about once per week
☐4 I will rarely consume yogurt
☐5 I will never consume yogurt

5. During the past three months, how many **minutes on average** did you spend exercising **per week**?

6. Please write any comments that you would like to share with the researcher about this study:

Biosketch

NAME: Boyet, Eryn N. (MSN, R.N., WHNP-BC)

POSITION TITLE: Doctoral Student

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date MM/YYYY	FIELD OF STUDY
Oregon Health & Science University Portland, Oregon	BSN	06/2005	Nursing
Midwestern State University, Wichita Falls, Texas	MSN	08/2010	Nursing Education
University of Texas Health Science Center Houston, Texas	Post-MSN	8/2012	Women's Health Nurse Practitioner Certification
University of Texas at Tyler Tyler Texas	PhD	12/2016	Nursing

A. Personal Statement

My program of research is about promoting the health and well-being for women. For my current doctoral work, my specific interest is helping to develop an intervention to help women reduce or prevent adiposity and improve their metabolic outcomes. This study has set up a program of research for me to further develop the knowledge and advocacy for improving the health outcomes for women. During this dissertation, I conducted the proposed study with the advisement of my co-committee members, and feel I am qualified from my experience in nursing and women's health to contribute to this science. I have counseled countless women in my clinic who are seeking answers to improve their health. As a nurse, and personally as a woman, I have observed first-hand the physical and emotional challenges patients face related to increase adiposity. The multifaceted and lifelong nature of maintaining a healthy weight is exhausting for all women. This problem is only compounded with the physiologic changes of the menopause transition. As a strong advocate for my patient's holistic well-being across their lifespan, this study is an important step to gain further knowledge on this poorly

understood and complicated problem. I am excited and determined to help find a safe and useful intervention to improve the health for women.

B. Positions and Honors

Activity	Beginning Date	Ending Date	Related To	Institution
Medical Missionary	2005	2005	Nursing	Christian Medical and Dental Association
Charge Nurse	2005	2006	Nursing	Bowie Memorial Hospital
Staff Nurse	2006	2007	Nursing	Wise Regional Health System
Treatment Decision Nurse/24 Hour Triage	2007	2008	Nursing	United Healthcare Incorporated
Case Manager	2007	2009	Nursing	Integra Care Home Health
Nursing Instructor	2007	2016	Nursing	North Central Texas College
Chair, Advanced Placement Committee	2010	2016	Nursing	North Central Texas College
Matrix Nursing Education Grant, Content Expert	2010	2012	Nursing	North Central Texas College
Health Sciences Grant Committee Member	2011	2012	Nursing	North Central Texas College
Secretary, Distance Education Committee	2011	2016	E-Learning	North Central Texas College
Chair, Nursing Curriculum Committee	2011	2016	Nursing	North Central Texas College
Women's Health Nurse Practitioner	2012	2016	Nursing	Noble Obstetrics & Gynecology
Adjunct Professor-Family Nurse Practitioner Program	2014	2016	Nursing	Texas Women's University
Clinical Track Professor-BSN to DNP Program	2016	Current	Nursing	Baylor University

C. Academic and Professional Awards

2011 Graduate Studies Scholarship--$1500 Midwestern State University

2012 Faculty Award of Excellence-University of Texas Health Sciences Center Houston
2013 Innovations in Technology Grant--$2500 North Central Texas College
2014-16 Buie Presidential Doctoral Scholarship– $3000, University of Texas at Tyler

D. Memberships in Professional Societies

2013-Current The Honor society of Phi Kappa Phi, University of Texas at Tyler
2013-Current Sigma Theta Tau International, Iota Nu Chapter University of Texas at Tyler
2014-Currnet Christian Medical and Dental Association
2015-Current Southern Nursing Research Society

E. Contribution to Science

Boyet, E. (2014). Current treatment options for the menopausal transition: A brief review. *Journal of Midwifery & Women's Health.* Under Revision.