EFFECT OF A MINDFUL EATING INTERVENTION ON OBESITY OUTCOMES IN POSTMENOPAUSAL BREAST CANCER SURVIVORS

by

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(Under the Direction of Elisabeth Lilian Pia Sattler)

ABSTRACT

Obesity in postmenopausal breast cancer survivors is associated with increased morbidity and mortality. Mindful eating (ME) may be effective as a weight management strategy; yet, evidence in breast cancer survivors is limited. This study examined the effect of a ME intervention on obesity outcomes in breast cancer survivors. A quasi-experimental one-group study design was used. Participants (*n*=10) completed eight 2-hour ME group-based training sessions. Data were collected pre- and post-intervention, and paired t-tests were conducted. Mean age was 64.4 $\pm$ 6.0 years. At baseline, participants' mean BMI was 33.7 $\pm$ 7.6 kg/m^2 and mean weight was 89.2 $\pm$ 16.8 kg. At follow-up, mean change in BMI was -0.4 $\pm$ 0.21 kg/m^2 ($p = 0.0002$) and weight was -0.8 $\pm$ 0.8 kg ($p = 0.015$). This study provides preliminary evidence that a ME intervention can produce weight loss in this population. Further research is needed to determine sustainability of weight loss.

INDEX WORDS: postmenopausal, breast cancer survivors, mindful eating, mindfulness, weight loss

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DEDICATION

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CHAPTER 1

INTRODUCTION

Overweight and obese breast cancer survivors face health complications that increase their risk for chronic disease development and premature death. A breast cancer survivor is someone living with, through, and beyond the breast cancer diagnosis.[1] It is estimated that 3.1 million women in the United States are breast cancer survivors.[1] Approximately 50% of breast cancer survivors are overweight or obese, increasing their risk for morbidity and mortality.[2] A review that assessed weight gain in breast cancer survivors found that many women remain weight stable during cancer treatment but report weight gain in the months and years after diagnosis.[3] Even in the absence of weight gain, there are unfavorable changes in body composition, including gain in fat and loss in lean tissue mass. Excess body weight at or after diagnosis is associated with a 20-43% higher risk of breast cancer specific and overall mortality, and twice the risk of breast cancer recurrence, compared to healthy weight women.[2] It is recommended that cancer survivors achieve and maintain a healthy body weight, or modest weight loss, in order to have favorable changes in comorbidities and improve overall health outcomes.[2,4]

There are multiple factors that likely play a role in the development and maintenance of obesity in this population. Systemic treatment methods, particularly adjuvant chemotherapies, have been shown to lead to significant weight gain.[3] Specifically, duration of chemotherapy has recently been shown to be a better predictor of weight gain.[3] In addition to treatment methods, lifestyle behaviors that affect energy balance are well documented and may explain weight gain not associated with chemotherapy.[3] Several studies have shown that there is a significant reduction in

physical activity during and after treatment, which may partially explain weight gain.[3] Weight gain and sedentary behavior increase the risk of recurrence and all-cause mortality in breast cancer survivors, therefore need to be addressed within the context of unique characteristics of this population.

Breast cancer survivors are increasingly exploring complementary alternative options after treatment, including mindfulness meditation, to help alleviate the psychological and emotional stress that is gained during cancer diagnosis and treatment.[5] Mindfulness is defined as a non-judgmental awareness of the present moment.[6] It is associated with the calming of emotions and self-regulation and an overall increase in activity levels.[5] Several mindfulness-based studies have reported positive effects on body weight, weight loss, and weight maintenance in overweight and obese individuals.[6] Mindfulness may indirectly address the post-diagnosis components of weight gain in breast cancer survivors, including sedentariness and dietary intake.[5]

Mindful eating (ME) is a branch of mindfulness meditation that includes consuming food with intention and attention, and identifying emotional triggers that cause overconsumption.[7] Traditional diet restriction interventions are successful in weight loss, however months into the program, adherence typically wanes, and weight regain begins.[7] Mindful eating has been suggested as a complementary alternative weight loss strategy in place of calorie counting due to better long-term sustainability.[7] Mindful eating has also been associated with reducing behaviors associated with weight gain, such as binge eating, emotional eating, and food cravings.[8] However, little is known about the effects of ME as weight loss strategy for breast cancer survivors.

This study examined the effects of an 8-week ME intervention on clinical obesity markers in overweight or obese postmenopausal breast cancer survivors in remission. Mindful eating as a complementary alternative intervention and its relationship with obesity outcomes is not well studied in the target population. Understanding this

relationship will further our knowledge of the specific types of intervention needed to lead to weight loss and maintenance in postmenopausal breast cancer survivors.

CHAPTER 2

LITERATURE REVIEW

Obesity in Breast Cancer Survivors

According to the American Cancer Society, there were approximately 3.1 million breast cancer survivors living in 2014.[1] Obesity at diagnosis and post-diagnosis weight gain is a prevalent problem in this population, with over 50% of breast cancer survivors being overweight or obese.[2,3,9] Excess body weight is associated with unfavorable breast cancer outcomes, all-cause mortality, and poor overall health.[2,3] A systematic review and meta-analysis by Chan et al. found a 68% increased risk for breast cancer mortality 12 months or more after diagnosis in obese women as compared with normal weight women.[10] Higher body mass index (BMI), both pre- and post-diagnosis, was consistently associated with lower survival rates, and this association followed a dose-response relationship.[10] Body mass index at diagnosis was shown to be the strongest predictor of increased breast cancer risk, with a risk ratio of 2.85.[11] Obese postmenopausal breast cancer survivors were shown to have a 70% greater risk for recurrence as compared to their normal weight counterparts.[12] In addition to weight and BMI, waist and hip circumference measures of central obesity have shown to be good predictors of breast cancer risk in this population, with risk ratios of 1.99 and 2.43, respectively.[11] In summary, cancer prognosis and survival were poorer in breast cancer survivors that were overweight or obese at or after breast cancer diagnosis.

Cardiovascular Morbidity and Mortality in Breast Cancer Survivors

Women diagnosed with postmenopausal breast cancer are more likely to develop cardiovascular diseases compared to non-cancer postmenopausal women.[13]

Cardiovascular diseases are the primary causes of death, followed by breast cancer recurrence, in the target population.[14] In a retrospective study, it was noted that comorbid cardiovascular conditions negatively influenced mortality in breast cancer survivors.[14] Women who did not have any cardiovascular comorbidities had longer life spans than those who had any of the following comorbidities: cardiovascular diseases, diabetes, or chronic obstructive pulmonary disease (COPD).[14] Breast cancer survivors were more likely to have cardiovascular disease risk factors, including higher blood pressure, higher body fat percentage, higher BMI, and larger waist circumference, as compared to non-cancer patients.[15] However, whether these outcomes were a result of the adjuvant chemotherapy was not clear.[15] Bardia et al. studied 10-year cardiovascular disease risk in postmenopausal breast cancer survivors and found that over 60% of participants had a moderate-to-high predicted cardiovascular disease risk.[13] In addition, studies have shown that cancer survivors were less likely to receive cardiovascular preventive care, such as cholesterol monitoring as compared to the general population.[13] Therefore, it is important to measure cardiovascular disease risk factors when assessing cancer prognosis and survival in breast cancer survivors.

Physical Activity and Postmenopausal Breast Cancer Risk

Physical activity is a modifiable risk factor for many cancers. Several prospective studies have identified the importance of physical activity in reducing cancer recurrence and improving survival, compared to those who are inactive.[4] In a longitudinal study conducted by Thune et al. over a period of 14 years, moderate-intensity leisure time physical activity protected against breast cancer, particularly in young postmenopausal women.[16] The authors also found that the relative risk of developing breast cancer was lower (0.63) in women who exercised 4 hours a week or more, as compared to those who did not.[16] These findings parallel a meta-analysis of 22 prospective studies which

also found that breast cancer survivors who met the recommendations of 150 minutes of moderate-intensity physical activity a week, significantly reduced their breast cancer mortality risk.[9] In a 6-month study conducted by Jones et al., exercise alone as a weight loss intervention showed a significant reduction in body fat percentage in women who exercised at least 120 minutes per week.[17] There appears to be a clear inverse dose-response relationship between physical activity and breast cancer risk. Yet, a review of lifestyle modifications for improved breast cancer prognosis noted that vigorous exercise did not have the same inverse dose response relationship, as moderate-intensity exercise.[9] Overall, there is a lack of consensus on the frequency, intensity, and duration of physical activity for postmenopausal breast cancer risk reduction. Kobayashi et al. studied the different aspects of physical activity, and found that leisure-time moderate-vigorous physical activity was strongly associated with reduced postmenopausal breast cancer risk.[18] This study also found that the energy expenditure dose associated with most significantly reduced risk was greater than 22.9 metabolic equivalents (MET) hours per week which equates to approximately 7 hours of brisk walking a week.[18] These results were consistent with Hildebrand et al. which found a 14% lower breast cancer risk in women who were walking greater than 7 hours a week.[19] In addition, studies have found that aerobic and resistance exercise combined, have the most beneficial metabolic effects on this population.[9] However, even with physical activity recommendations from the American Cancer Society, only 13% of breast cancer survivors are meeting the exercise recommendations.[9]

Nutrition and Postmenopausal Breast Cancer Risk

Improved dietary intake quality in this population has been viewed as a way to improve cancer outcomes and address chronic disease risk. In a prospective study of 1,490 breast cancer survivors, higher mortality was found in women who consumed

fewer than 3.43 servings of fruits and vegetables per day.[20] Findings also showed a decreased mortality risk in women who consumed the recommended 5 servings of fruits and vegetables per day.[20] However, less than 50% of breast cancer survivors are meeting this recommendation.[20] In addition to fruit and vegetable intake, decreased mortality was found in those who were consuming the recommended servings of whole grains.[20] Increased mortality was found in those who consumed a higher amount of animal fat.[9] A systematic review of observational studies has shown that high consumption of saturated fats and high-fat dairy can lead to increased breast cancer mortality (HR 1.49).[9] Yet, low fat dairy did not show this same risk.[9]

Dietary patterns have also been studied in the target population as a way to improve cancer prognosis. However, no dietary pattern has been chosen as the gold-standard for reducing the risk of breast cancer recurrence.[9] A study by Thompson et al. looked at the effects of a low-fat compared to a low-carbohydrate diet in overweight and obese breast cancer survivors, and their respective effects on weight and long-term survival.[21] They found that both dietary patterns improved breast cancer survival by reducing body weight by an average of 9.3 kilograms (kg) within 6 months.[21] These findings are in line with the Women's Intervention Nutrition Study (WINS) findings which noted that low-fat diets lowered breast cancer recurrence through a lower mean body weight in a 5-year follow-up study.[22] In a study conducted by Izano et al., breast cancer survivors who had high compliance with the Dietary Approaches to Stop Hypertension (DASH) diet or Dietary Guidelines had lower non-breast cancer mortality.[22] In addition, high compliance to the Mediterranean diet, without red wine, has been shown by several studies to lead to increased breast cancer survival.[9]

Cancer Treatments Effect on Weight Status in Breast Cancer Survivors

In addition to unfavorable lifestyle behaviors, adjuvant chemotherapy cancer treatments have been shown to lead to weight gain in breast cancer survivors, although the underlying mechanisms are unclear.[3] A prospective study in pre- and postmenopausal women with breast cancer showed that 34% of breast cancer survivors treated with chemotherapy gained between 2.5-5 kg of weight, as compared to women who were not.[3] It was also not uncommon to see weight gain of more than 10 kg during treatment which the authors assumed to be due to reasons including, but not limited to, stress eating, reduced physical activity, lowered metabolic rate from chemotherapy, and the chemotherapy medications themselves.[9] A review examining weight gain in breast cancer survivors found that women treated with chemotherapy were 65% more likely to gain weight during treatment than those who received localized treatment (i.e. surgery).[3] Tamoxifen, an estrogen modulator used to treat breast cancer along with chemotherapy, has been shown in earlier studies to lead to weight gain, however, recent and larger studies have shown that it did not to lead to any significant weight gain.[3,23] Length of tamoxifen treatment was not a significant variable.[23] While the type of chemotherapy may play a role in weight gain, the duration of treatment may be important as well. Shorter chemotherapy treatments have shown to lead to minimal, non-significant weight gain, as compared to longer treatments, yet these findings are still inconsistent.[3,23]

In addition to chemotherapy, radiation therapy has shown to lead to an increase in body fat percentage and reduction in fat free mass in breast cancer survivors, as measured by dual-energy x-ray absorptiometry (DXA).[3] Radiation therapy was also associated with a 50% reduction in physical activity levels, as compared to the 24% reduction in those who were treated by surgery alone.[23] However, despite evidence on body composition changes, radiation cancer treatment has not shown any significant effects on weight gain.[23]

Weight Management Interventions for Breast Cancer Survivors

There is substantial evidence showing a positive effect of weight loss interventions on breast cancer survivors' weight and waist circumference.[2] A systematic review by Reeves et al. reported that weight loss interventions were not only safe, but were also successful in achieving weight loss and reductions in central adiposity in breast cancer survivors.[2] In particular, interventions that combined diet, physical activity, and behavior modification were most effective in achieving a weight loss of $\geq$ 5% of body weight which is the recommendation for improvement of comorbidities in this population.[2] Rock et al. conducted a 2-year, cognitive-behavioral weight loss randomized controlled trial of 692 obese postmenopausal breast cancer survivors.[24] The intensive weight loss intervention took place during the first year, and included weekly, group-based, nutrition and physical activity sessions, telephone counseling, and tailored newsletters.[24]. After 1-year study duration, 55% of the participants had lost $\geq$ 5% of their baseline body weight.[24] During the second year, the telephone counseling and weekly sessions were significantly reduced.[24] By the end of year 2, only 44% of the intervention group participants had lost $\geq$ 5% of their baseline body weight.[24] The study showed how intensive weight loss programs can lead to prevention of weight regain in this population.[24] Further, in a 12-week single-arm intervention study conducted by Travier et al., 37 overweight breast cancer survivors completed a diet and physical activity intervention.[25] The intervention included weekly meetings with a dietitian, and biweekly exercise sessions with trained physical activity monitors.[25] After the intervention, an average of 7.8 $\pm$ 2.9% decrease in the participants' baseline weight was observed, along with statistically significant positive changes in BMI, waist and hip circumference, fat percentage and fat mass.[26] In an 8-week weight loss intervention study by McTieren et al., breast cancer survivors met with an exercise physiologist three times a week, and a nutritionist at baseline and multiple times via telephone.[27] At follow-up, there was a

statistically significant decrease in weight, body fat percentage, and waist and hip circumference, and a significant increase in lean body mass.[27] This evidence is confirmed by other studies that have shown significant weight loss in the target population in interventions lasting less than 6 months.[25]

Mindfulness, Mindful Eating, and Obesity Outcomes

Mindfulness and ME are increasingly being utilized as weight management strategies for overweight and obese individuals, presenting alternatives to restrictive dieting.[6] Mindfulness is the non-judgmental awareness of the present moment, and ME brings that awareness to the eating process.[6] According to a large-scale, prospective cohort study conducted by Camilleri et al. in a sample of women representative of the general population, women with higher mindfulness scores were more likely to have a lower BMI and were more likely to be physically active than women with lower scores.[6] Inversely, women with lower mindfulness scores were more likely to be struggling with unhealthy eating behaviors like emotional eating, overconsumption, binge eating, and food cravings.[6] Therefore, it was hypothesized that mindfulness may be an instrumental component in self-regulation, appetite control, reduced portion sizes, or emotional and stress-eating cues.[6] In addition, a systematic review and meta-analysis by Robinson et al. noted that mindful/attentive-eating as an intervention increased the participant's memory of the food that was consumed, thereby reducing their food intake a later occassion.[7] It was also noted that lower awareness led to increased immediate food intake.[7] It was suggested that this method be used in place of conscious calorie counting because patients were more mindful of total daily energy consumption in the long-term.[7] Several studies have also noted that mindful eating had a positive effect on eating behaviors common in the overweight and obese population, such as binge eating, emotional eating, reactivity to food cravings, etc.[8] In a pilot study by Dalen et al. that

implemented ME as an intervention technique, obese patients showed a statistically significant increase in mindfulness and negative eating behaviors, within 12 weeks.[28] The participants lost an average of 4 kg of body weight, but there were not significant changes in cardiovascular outcomes.[28] There is evidence that ME can be an effective weight loss and maintenance strategy in overweight and obese individuals.

Mindfulness, Mindful Eating, and Breast Cancer Survivors

The effects of mindfulness and ME as complementary alternative weight loss strategies for breast cancer survivors have not been well studied. The majority of research in this area examined mindfulness as a way to reduce stress or improve quality of life in cancer survivors, but did not specifically focus on weight management. Larkey et al. studied a biobehavioral model supporting mindfulness meditation and weight loss in breast cancer survivors.[5] They proposed that mindfulness meditation would lead to physiological, psychological, and biological responses, that would directly and indirectly address weight gain in this population.[5] While mindfulness may not inherently lead to energy expenditure, this model cited sources showing that mindfulness was associated with increased physical activity and decreased sedentary time.[5] Their conclusion was that sedentariness, dietary intake, and stress would likely be affected long-term, thus making mindfulness a sustainable treatment option.[5] Finally, a single-group, longitudinal study by Chung et al. examined ME for weight loss in African American breast cancer survivors.[29] At the completion of the 12-week study, there was an increase in mindfulness, and a decrease in weight.[29] There was a significant association between Mindful Eating Questionnaire scores and weight loss amongst this cohort.[29] However, while this study included dietary counseling with a registered dietitian, they did not monitor or report dietary intake nor physical activity.[29] Yet, while there is limited research

on mindfulness and ME in breast cancer survivors, there are positive outcomes that are likely to be achieved from this intervention strategy.

Study Objective

The *objective of the study* was to test the effect of a ME intervention on clinical and anthropometric markers related to obesity in postmenopausal breast cancer survivors.

Specific Aims:

- **To determine the effects of a ME intervention on anthropometric markers (weight, body fat percentage, BMI, waist and hip circumference) of obesity in postmenopausal breast cancer survivors**. Our working hypothesis was that the ME intervention will have a positive effect on the clinical and anthropometric markers of obesity.
- **To determine the effects of a ME intervention on clinical markers (blood pressure, blood lipids, triglycerides) of cardiovascular risk.** Our working hypothesis was that the ME intervention would have a positive effect on clinical markers of cardiovascular risk.

Significance

There is a critical need for research that examines the effects of a complementary alternative weight loss intervention on clinical and anthropometric markers of obesity and comorbid disease risk as proxies of cancer prognosis. Understanding of the effect of such interventions on clinical and anthropometric markers will further our understanding of prognosis and survival of postmenopausal breast

cancer survivors. The inverse association between obesity and breast cancer survival in women is evident and needs to be addressed.

Innovation

This study is innovative in that it examines the effect of ME as a complementary alternative weight management intervention on clinical and anthropometric markers of cancer prognosis. Mindful eating has been theorized to lead to more sustainable weight loss than traditional weight loss interventions in overweight and obese populations, due its ability to change eating behaviors associated with weight gain. Breast cancer survivors may significantly benefit from a ME intervention due to the inverse relationship weight has with breast cancer mortality. Additionally, previous studies did not examine the effect of a ME intervention on clinical markers of cardiovascular disease risk in postmenopausal breast cancer survivors. Identifying the relationship between ME and morbidities can lead to development of successful interventions in this population. This study also provides a weight loss intervention for Athens-Clarke county breast cancer survivors which is an underserved population for intervention-based research. In addition, it is the first study to include dietary and physical activity measures as a part of a ME intervention in this population. Lastly, this is study is novel in that it is intervention-based; previous ME studies have been mostly retrospective or observational.[5,29]

CHAPTER 3

METHODS

Study Design and Participants

This study was a non-randomized, clinical trial using a one group pre-post test design. We tested the effects of an 8-week ME intervention on clinical and anthropometric markers of obesity and cardiovascular disease risk in overweight or obese female postmenopausal breast cancer survivors in remission. Included participants met the following selection criteria: postmenopausal females, 50 years old or older, BMI of equal or greater than 25 kg/m², breast cancer survivors who had completed cancer treatment, and were able to engage in moderate-intensity physical activity. Individuals of all races/ethnicities and socioeconomic backgrounds were included. Stage of breast cancer diagnosis and breast cancer type did not affect selection. We excluded any participants who did not meet the above criteria or had pre-existing cardiovascular conditions without medical clearance for participation in the study. Participants were not excluded for having any chronic medical conditions if they received medical clearance from their physician. Patients were not excluded for taking any medications.

Recruitment

Participants were recruited through regional cancer support centers (e.g., Loran Cancer Support Center), hospital outreach programs (e.g., Athens Regional Medical Center), physician offices, and churches. The poster used for recruitment can be found in **Appendix A.** Interested participants contacted the University of Georgia Clinical and Translational Research Unit (CTRU) via phone call. A study team member then conducted a telephone screening (script can be found in **Appendix B**) to determine

study eligibility. If the participant's self-reported BMI was close to 25 kg/m², they were asked to come into the CTRU to have their BMI confirmed through measurement by CTRU staff. If they met the eligibility criteria, then an appointment was scheduled for the participant to complete informed consent (form found in **Appendix C**) and baseline data collection.

Baseline and Follow-up Data Collection

Participants completed baseline and follow-up testing within 2 weeks of intervention start and completion, respectively. Data collected at baseline and follow-up included (1) anthropometric measures: height, weight, waist and hip circumference, and body fat percentage; (2) clinical markers: blood pressure, fasting blood glucose, blood lipids, and hemoglobin A1c (HbA1c); and (3) information collected by self-administered questionnaires: sociodemographic and socioeconomic information, dietary intake, sleep quality, social support, perceived stress, food insecurity, breast cancer history, and self-reported health. Data collected at follow-up included the following Fitbit® data: sleep length and quality, step count, self-reported weight, food and water intake, and active minutes. All methods and procedures were approved by the University of Georgia Institutional Review Board (IRB) before any procedures with human subjects were initiated (IRB ID#MOD00003306).

Mindful Eating Intervention

The Mindful Eating intervention was taught by Mike Healy, Ed.D, a mindfulness-based stress reduction instructor, certified by the Center of Mindfulness at the University of Massachusetts Medical School. The sessions instructed participants on how to consume food with intention and attention, and improve their emotional relationship with food in a group setting. The Mindful Eating Workshop™ workbook used for these

sessions can be found in **Appendix D.** This intervention was held in the Animal and Dairy Sciences building on the main University of Georgia campus, once a week in the evening for two hours each. Participants were required to attend all sessions. If participants missed a session, they met with Dr. Healy the following week, 30 minutes before the session, to get individual instruction on the missed session.

Measures

Anthropometric Measurements

At baseline and follow-up, participants had the following anthropometric measurements taken at the CTRU by trained research nurses: weight, height, body fat percentage, waist and hip circumference. Height (measured by a stadiometer to the nearest 0.1 centimeter) and weight (measured by a scale to the nearest 0.1 kg) was used to calculate BMI (weight in kilograms divided by height in meters squared). Body fat percentage was measured using a Tanita TBF-300A, Tanita Corporation bioelectrical impedance analyzer (BIA). Waist and hip circumference were measured to the nearest 0.1 centimeter. In order to ensure reliability, all measurements were taken 3 times and the average value used for analyses. The protocol used for these measurements can be found in **Appendix E.**

Fasting Blood Measures

A trained research nurse at the CTRU collected fasting blood samples within 1 week of the beginning and the end of the intervention. The participants were given instructions not to consume any food or drink after midnight except water, not to smoke, and to take any needed medications with water only before their appointment. The blood samples were stored short-term at 4 degrees Celsius before transportation and analysis. The following clinical markers were analyzed by Piedmont Athens Regional Medical

Center's laboratory: fasting blood glucose (compared to reference range of 70-100 mg/dL), cholesterol (compared to normal range of <200 mg/dL), triglyceride (compared to normal range of <150 mg/dL) HDL cholesterol (compared to normal range of ≥60 mg/dL) LDL cholesterol (compared to optimal range of <100 mg/dL) and HbA1c (compared to reference range of 4.3-6.1%).[30] Blood pressure (measured by sphygmomanometer) was measured after the participant sat quietly in the phlebotomy chair for at least 5 minutes prior to the measurements. Three measurements were taken on the same arm and the average was calculated. Protocols for these measurements can be found in **Appendix E.**

Dietary Assessment

The 2014 Block Food Frequency Questionnaire (FFQ) (and Physical Activity Primer) was administered electronically and was used for assessment of usual dietary intake.[31] This questionnaire includes 127 food and beverage items, and additional questions to adjust for fat, protein, carbohydrate, sugar, and whole grain content, developed from the United States Department of Agriculture's (USDA) Food and Nutrient Database for Dietary Studies.[31] Alternative Healthy Eating Index (AHEI) 2010 scores were calculated in order to measure the diet quality of participants in comparison to the 2010 Dietary Guidelines for Americans standard recommendations. The maximum score was 100, with 10 points coming from each dietary component (fruit, vegetables, whole grains, dairy, protein, fatty acids, refined grains, sodium) and 20 points coming from empty calories. [32] A high score indicated intake close to the recommended ranges, while a low score indicated lower compliance to the recommended ranges.[32] The reference period was 1 month, which provided insight on dietary changes that were made during the 8-week intervention. Though this is a subjective measurement, it has been validated for use in this population.[33] In a diet intervention study by Thomson et al., a FFQ and

multiple 24-hour dietary recalls were used indicate a change in dietary intake in breast cancer survivors resulting from a diet intervention.[33] Both dietary collection methods reflected similar changes in dietary intake for target nutrients (carbohydrates, fat, fiber, folate, vitamin A, etc.) and both demonstrated responsiveness.[33] The multiple dietary recalls had an average correlation coefficient of 0.43 across nutrients, while the FFQ has a correlation coefficient of 0.63 across nutrients, which shows the greater reproducibility of the FFQ in this population.[33] It is important to note that the FFQ had lower responsiveness, perhaps due to having a set list of choices versus the open-ended responses of the 24-hour recalls.[33] In addition, the FFQ was shown to have slightly lower reliability, which is thought to be due to the study population in the control group still making changes to their diet, in attempts to have healthier dietary habits.[33] Overall, both methods were able to capture significant differences in the dietary intervention in the target population.[33]

Physical Activity Assessment

Participants were given Fitbit® Flexes which monitored the intensity, frequency and duration of their physical activity over the study period. The Fitbit® Flexes also provided data on step count and active minutes (as well as non-physical activity data: sleep length and quality, food and water intake, and self-reported weight). At baseline, a study team member met with each participant individually to provide in-depth instruction on how to use the Fitbit® Flex. The participants were also given a handout (**Appendix F**) on how to charge and use their Fitbit® Flex. All Fitbit® Flexes were connected to Fitabase, a research platform that collected data from research participants.[34] Additional data (estimated minutes, MET-minutes and kilocalorie expenditure) was collected through the Physical Activity Primer questionnaire (**Appendix G**) which included 11

items that represented usual energy expenditure, developed from the National Human Activities Patterns Survey, and estimates MET-minutes and kilocalorie expenditure.[31]

FitBit® Flex as a Validated Measure of Physical Activity

The Fitbit® Flex is a small, wireless, lightweight, wrist-based accelerometer in the consumer market. It is a validated and accurate tool to use when measuring physical activity in free-living humans.[35] When compared to the gold-standard measurement, the Actigraph accelerometer, the Fitbit® Flex significantly correlated in step counts and active minutes of light activity, moderate activity and moderate-vigorous activity.[35] With respect to step count, the Fitbit® Flex counted more steps than the Actigraph in females by 7% (equivalent to about 556 steps/day).[35] It also estimated higher moderate-vigorous physical activity by 4% in females (about 4 minutes/day). When energy expenditure measured by the Fitbit® Flex is compared to indirect calorimetry, Fitbit®-estimated energy expenditure was 2.6 kilocalories higher than the measured energy expenditure.[34] This was overestimated during moderate and brisk walking.[34] Overall, the Fitbit® Flex reasonably estimates step counts and energy expenditure during walking and running, and it is a validated and reliable alternative to the Actigraph accelerometer and indirect calorimetry.[34,35]

Mindful Eating Measures

In order to measure changes in mindfulness resulting from the intervention, the validated Mindful Attention Awareness Scale (MAAS) was used. The MAAS questionnaire (found in **Appendix H**) is a 15-item scale that was designed to assess mindfulness and receptive awareness throughout an individual's daily life.[36,37] Scores from the MAAS range from 1 to 6, with higher score associated with higher mindfulness.[37] The MAAS was validated for use in cancer populations against the Profile

of Mood States (POMS) scale that is widely used in clinical settings.[37] Carlson et al. found that cancer patients who had low MAAS scores also had high mood disturbances and stress as measured by the POMS.[37] Higher MAAS scores were also significantly correlated with lower POMS scores, further confirming the construct validity of the MAAS questionnaire for assessing mindfulness in cancer populations.[37] This questionnaire was self-administered by the participants. The Kentucky Inventory of Mindfulness Skills (KIMS) scale (found in **Appendix I**) is a 39-item questionnaire that measures four aspects of mindfulness: observing, describing, acting with awareness, and accepting without judgement.[38] Higher KIMS scores are associated with higher mindfulness.[38] The KIMS scale has been validated for use in clinical populations.[38,39] In a study that compared KIMS scores between a community population and a clinical population that lacked mindfulness skills, they found that KIMS scores were negatively associated with mental health, further confirming KIMS's validity and representation of mindfulness skills.[39]

Statistics

For the outcome measures, data was reported using descriptive univariate analysis (means, standard deviation, percentages, etc.). Paired t-tests of the averages were used to identify differences between values at baseline and follow-up. The level of statistical significance was defined at $p < 0.05$. Pearson correlation coefficients were calculated to determine the linear dependence between mindfulness and outcome measures at follow-up. Negative correlations demonstrated that "higher" mindfulness was associated with lower weight status or cardiovascular disease risk.[40]

Data Management and Security

For this study, all electronic data was stored and password-protected on the Principal Investigator's (Dr. Sattler) secured research server, which is physically located in the University of Georgia Department of Clinical and Administrative Pharmacy and can be accessed remotely. All physical copies of data were stored in locked cabinets or drawers located in Dr. Sattler's office or in her student lab. Only the project's team members had access to the data in these locations, and remotely from their own computers by using the university's secure mobility client (Cisco) to gain access to the folders. All identifiable records and contact information from ineligible individuals were destroyed. Non-identifying ID numbers were given to participants for blood sampling to maintain subject confidentiality. The ID numbers included their first and last initial, and a random three-digit number.

CHAPTER 4

RESULTS

Power analysis

An online power analysis calculator from the University of British Columbia Department of Statistics was used to estimate power (alpha = 0.05, power = 80%, one-sided test).[41] A one-sided test was chosen to detect a reduction in anthropometric values demonstrated a similar study by Chung et al.[29] Based on previous research in similar populations measuring anthropometric values, it was estimated that the intervention groups would have weight loss of 2.6 $\pm$ 3.0 pounds (mean $\pm$ standard deviation (SD)).[27] To detect a significant change in body weight and other anthropometric values, a total sample size of approximately n=30 was required. After accounting for an expected attrition rate of 10%, we required a total of n = 33 to detect changes in body fat percentage in our study sample. However, due to recruitment difficulties, this study arm only included n=11. One participant was excluded from our analytical sample due to weight gain being 3 SDs above the average weight change.

Participant Recruitment

A flowchart illustrating recruitment and enrollment of participants can be found in **Appendix J**. After screening participants at the CTRU, 19 participants were found to meet the eligibility criteria. However, due to time conflicts, surgery, loss of interest, and unknown reasons, 6 participants dropped out before and an additional 2 participants dropped out after the intervention started. Therefore, the number of participants included in the ME intervention was n=11. One participant was excluded, post-intervention, because her body fat percentage increase of 7.7% was more than 3 SDs of the mean

change of the sample (0.34 $\pm$ 1.12), characterizing her as an outlier.[42] Her data were then omitted for the analysis.

Results

Demographics

Baseline characteristics of the analytic sample can be found on **Table 1**. Participants in the analytical sample ranged in age from 54 to 72 years, with a mean age of 64.4 $\pm$ 6.0 years. Fifty percent of the participants were married and had an average annual household income of greater than $80,000. Ninety percent of the participants were non-Hispanic white. Ninety percent of participants were college-educated, with 50% of them completing graduate education. Fifty percent of the participants were retired, and the other 50% were employed at least part-time. While 90% of participants have never been told that they had diabetes, 40% of participants have been told they had pre-diabetes.

Table 1. Baseline Demographic Characteristics of Study Sample (*n*=10)			
Characteristics	Percent (%)	Range	Mean (SD)
Age (y)		54-72	64.4 (6.0)
Race			
American Indian/Alaskan Native	10.0		
White	90.0		
Yearly Income			
$20-29k	10.0		
$30-39k	20.0		
$40-49k	10.0		
$50-59k	0.0		
$60-69k	10.0		
$70-79k	0.0		
more than $80k	50.0		
Marital Status			
married	50.0		
not married	20.0		
divorced	20.0		
widowed	10.0		
Abbreviation: SD, standard deviation			

Anthropometric measurements

Anthropometric measurements for baseline and follow-up are shown in **Table 2.** At baseline, participants had a mean BMI of 33.7 + 7.6 kg/m^2, mean body fat percentage of 45.5 + 4.4%, mean weight of 89.2 + 16.8 kg, and mean waist to hip ratio of 0.8 + 0.04.

Following the ME intervention, there were statistically significant positive changes in weight and BMI. Changes in weight by participant are depicted on **Figure 1.** At follow-up, there was a mean change in in BMI of -0.4 $\pm$ 0.21 kg/m^2 and a mean change in

weight of -0.8 ± 0.8 kg. There was little to no change in body fat percentage, hip circumference, and waist to hip ratio.

Table 2. Anthropometric Measures at Baseline and Follow-up (n=10)

Measure	Baseline		Follow-up		*p*
	Mean	SD	Mean	SD	
Weight (kg)	89.2	16.8	88.4	16.5	**0.015**
BMI (kg/m²)	33.7	7.6	33.3	7.5	**<0.001**
Body Fat Percentage	45.5	4.4	45.8	4.5	0.362
Waist Circumference (cm)	100.1	12.3	98.1	9.9	0.205
Hip Circumference (cm)	119.7	14.4	120.2	12.8	0.665
Waist to Hip Ratio	0.8	0.04	0.8	0.02	0.101

Abbreviation: SD, standard deviation
Bold p-values indicate significance ($p < 0.05$)

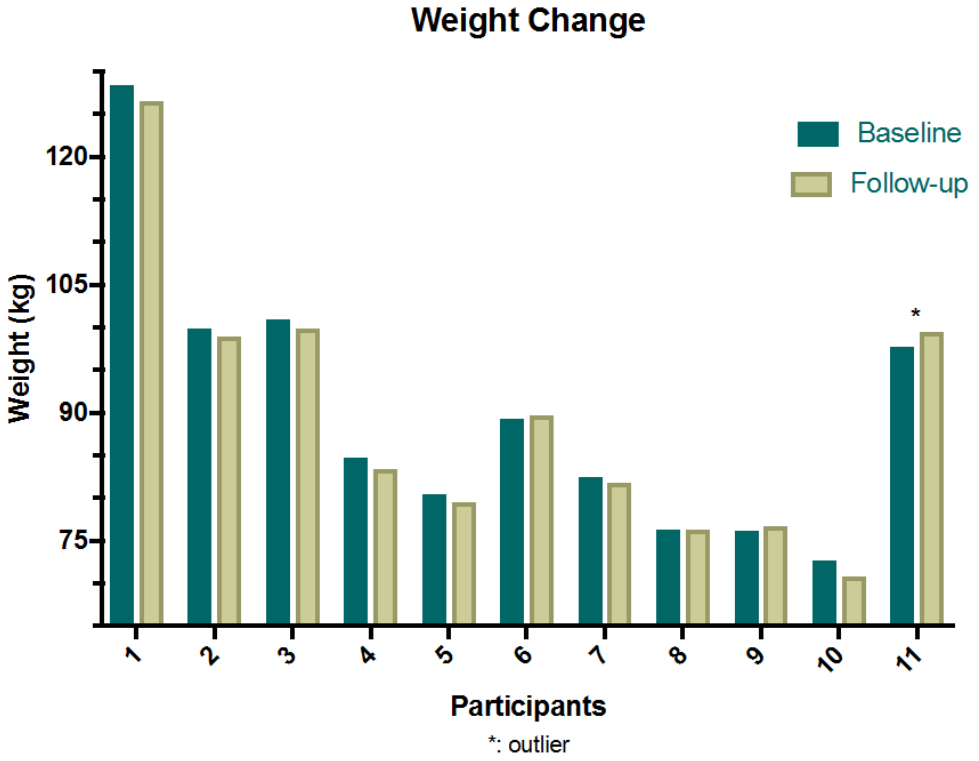

Figure 1: Participants' Weight at Baseline and Follow-up of Mindful Eating Intervention

Clinical Markers of Cardiovascular Risk

All clinical markers from baseline and follow-up can be found in **Table 3.** At follow-up, participants had a statistically significant increase in triglycerides, with a mean change of 28.9 $\pm$ 26.88 mg/dL, and a statistically significant decrease in diastolic blood pressure with a mean change in diastolic blood pressure of 4.1 $\pm$ 4.1 mmHg. Although not statistically significant, there was also an unfavorable trend towards increased LDL cholesterol and glucose levels, and decreased HDL cholesterol levels; and a favorable trend towards systolic blood pressure. Hemoglobin A1C percentage did not change at follow-up.

Table 3. Clinical Markers at Baseline and Follow-up (n=10)					
Measure	Baseline		Follow-up		Change
	Mean	SD	Mean	SD	*p*
Blood Pressure (mmHg)					
Systolic	121.8	11.6	114.6	8.4	0.055
Diastolic	75.0	6.8	70.9	7.1	**0.012**
Glucose (mg/dL)	106.5	16.3	113.0	22.4	0.055
Cholesterol (mg/dL)	175.5	27.4	174.9	15.6	0.943
HDL	54.3	17.2	50.4	17.1	0.137
LDL	95.3	23.5	124.1	97.6	0.411
Triglycerides (mg/dL)	129.3	74.1	158.2	99.2	**0.008**
A1C (%)	5.8	0.6	5.7	0.6	0.095

Abbreviation: SD, standard deviation
mg/dL, milligrams per deciliter
Bold p-values indicate significance ($p < 0.05$)

Dietary Intake

Complete dietary intake of the participants, at baseline and follow-up can be found in **Table 4.** One participant did not complete the follow-up FFQ, therefore, her baseline and follow-up data were excluded from the analysis. The average caloric intake at baseline was 1238 kilocalories $\pm$ 304.2, with intakes ranging from 890 kilocalories to 1707 kilocalories per day. At follow-up, there was a mean change in caloric intake of -143.7 $\pm$ 227.5 kilocalories (p=0.09)

Post intervention, the participants significantly decreased the dietary intake of fat (mean change -10.6 $\pm$ 7.1 g), saturated fat (mean change -3.6 $\pm$ 3.0 g), and monounsaturated fat (mean change -4.1 $\pm$ 2.2 g). Protein and carbohydrate intake were not significantly different at the end of the intervention. Yet, there was a trend towards increasing percentage of carbohydrate intake (mean change 2.8 $\pm$ 4.5%, p = 0.09); and

trend towards decreasing grams of protein consumed (mean change 7.9 ± 12.1 g, p = 0.09). There was also an average 2.54% decrease in the percentage of sweets consumed (p = 0.0034). Cholesterol and dietary fiber intake were not significantly different at follow-up.

With regards to food group servings, the participants also decreased the number of servings of meats, beans, and eggs that they were consuming at follow-up, by approximately one serving (p=0.023). The other food groups, whole grains (mean change (0.03 ± 0.4), vegetables (mean change 0.1 ± 0.3), fruits (mean change 0.2 ± 0.5), and dairy (mean change -0.002 ± 0.5), showed little or no change at follow-up.

Table 4. Dietary Intake at Baseline and Follow-up (*n*=9)

Item	Baseline		Follow-up		Change
	Mean	SD	Mean	SD	*p*
Caloric Intake	1239.0	304.2	1094.0	319.4	0.095
Fat					
Fat (%)	40.7	3.8	37.7	7.3	0.088
Fat (g)	56.2	16.4	45.7	15.3	**0.002**
Saturated fat (g)	18.9	5.0	15.3	5.5	**0.008**
Monounsaturated fat (g)	20.9	5.4	16.9	5.3	**0.001**
Polyunsaturated fat (g)	11.5	5.7	9.5	3.8	0.066
Protein					
Protein (%)	16.8	3.2	15.9	2.0	0.408
Protein (g)	51.3	12.8	43.4	13.7	0.085
Carbohydrates		0.0			
Carbohydrate (%)	40.9	8.0	43.7	9.7	0.092
Carbohydrate (g)	128.4	44.8	122.5	53.1	0.643
Cholesterol (g)	184.8	54.4	171.2	103.0	0.528
Dietary Fiber (g)	11.4	4.4	11.1	4.2	0.779
Alcohol (%)	3.6	8.1	5.5	12.4	0.220
Sweets (%)	13.9	9.7	11.3	10.0	**0.003**
Food groups (servings)					
Whole grains (oz)	0.8	0.5	0.8	0.4	0.808
Vegetables (cup)	1.1	0.4	1.2	0.4	0.297
Fruits (cup)	0.6	0.5	0.9	0.7	0.214
Dairy (cup)	1.2	0.5	1.2	0.6	0.989
Meat, beans, eggs (oz)	5.2	2.1	4.2	1.9	0.023

Abbreviation: SD, standard deviation
g, grams
oz, ounces
Bold p-values indicate significance ($p < 0.05$)

Physical Activity

During week 1 of the ME intervention, the participants were taking an average of 4445 ± 2234 steps per day. By week 8 of the intervention, the participants had decreased their average daily steps to 2451 ± 1620 steps (p=0.0920). During week 1 of the intervention, the participants were getting an average of 100.2 ± 96.5 minutes of MVPA per week. By week 8, the participants had decreased their weekly MVPA to 66.7 ± 115.2 minutes (p=0.1002). Weekly Fitbit® measurements throughout the intervention can be found on **Figure 2.**

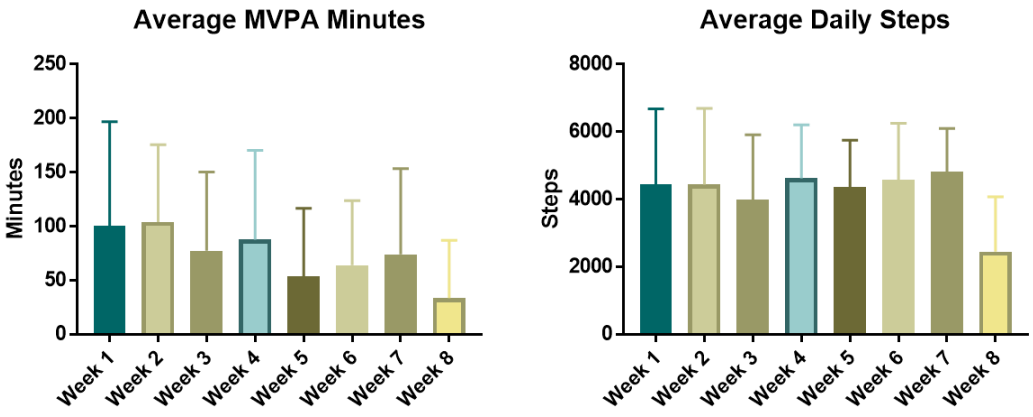

Figure 2: Weekly Physical Activity Measurements during Mindful Eating Intervention as Measured by Fitbit® Flexes

Mindfulness Scores

At baseline, participants had average MAAS scores of 57.4 ± 15.6, with scores ranging from 33 to 87. Higher scores indicate higher mindfulness. At follow-up, there was a trend towards increased MAAS scores, 62.2 ± 12.39 (p=0.0902), indicating higher mindfulness was achieved following the intervention.

Pearson correlation coefficients were calculated between MAAS mindfulness scores and anthropometric and clinical measures. There was a moderate correlation between MAAS scores and post-intervention weight (r=-0.42, p=0.22), body fat

percentage (r=-0.48, *p*=0.16) and BMI (r=-0.52, *p*=0.12). There was a weak positive association with systolic blood pressure (r=0.40, *p*=0.26) and diastolic blood pressure (r=0.37, *p*=0.30).

CHAPTER 5

DISCUSSION

The purpose of this study was to test the effect of a ME intervention on clinical obesity markers and comorbid cardiovascular disease risk in postmenopausal breast cancer survivors. The study found that ME as a complementary alternative weight loss strategy can lead to reduced post-diagnosis weight, favorable changes in obesity outcomes, and increased mindfulness in this population.

Anthropometric measures were the primary outcomes of this study. The meaningful improvement in clinical obesity markers following this 8-week ME weight management intervention parallels findings from other studies that have shown significant weight loss in the target population in similar behavioral interventions lasting less than 6 months.[26,27,29] In particular, a 12-week ME intervention found significant decreases in average weight and average BMI in obese individuals, confirming our results and suggesting that ME can be successful for weight loss in overweight and obese populations.[8,28] It is likely that our intervention showed similar results since it followed a group based design, which has been shown to be successful in the target population.[29] Since the length of the intervention in this pilot study was only 8 weeks, it was unlikely to see the recommended $\geq$ 5% reduction in body weight needed for favorable changes in breast cancer recurrence and survival.[2] Still, a majority of mindfulness interventions do not last longer than 3 months; therefore, testing a short-term intervention is in line with programs available to breast cancer survivors in the community. Mindfulness programs similar to this study are currently being offered to cancer survivors attending the Loran Cancer Support Center at Piedmont Athens Regional Medical Center, and provide an example of the programs being accepted by

this population. Given the predominance of short-term programs, testing whether a longer intervention duration would be successful at producing the recommended weight loss for this population may not be useful.[8] However, the results from this study provide promising preliminary evidence that mindfulness can lead to weight loss in overweight and obese breast cancer survivors, even with a short-term intervention.

In addition to weight loss, improved dietary intake quality can lead to positive changes in cancer outcomes. The present study, in particular, did not include any nutritional or calorie counting education, therefore significant changes in dietary intake were not expected. While a majority of ME interventions train patients on the effects of mindfulness on eating behaviors, such as binge eating and emotional eating, a few mindfulness studies noted in a literature review have shown decreases in caloric intake among target populations.[8] Our study demonstrated similar trends in caloric intake reductions in overweight and obese postmenopausal breast cancer survivors, which may be an indirect result of increased mindfulness. However, the participants in our study reported an average daily energy intake too low compared to their energy needs based on the Mifflin St. Jeor equation, a predictive equation of daily energy expenditure needs, suggesting that the participants may have significantly underreported their overall dietary intake, even at baseline. This is very common for our target population.[33] However, researchers have recommended the use of FFQ as a measure of change in dietary behavior to account for underreporting, therefore supporting our study approach.[33]

To identify dietary quality effects from the ME intervention, changes in the five food groups (fruits, vegetables, dairy, meat, grains) were identified. Studies show that breast cancer survivors with the lowest mortality risk were more likely consuming the recommended 5 servings of fruits and vegetables per day.[20] Yet, our participants were consuming less than 2 servings of fruits and vegetables per day at baseline, and slightly over 2 servings at follow-up. With such low fruit and vegetable consumption, the

participants in our study are may be at a higher mortality risk based on prospective studies that find consumption of at least 3.43 servings of fruits and vegetables per day will lead to decreases in risk.[20] The trend towards increased intake may indicate lower mortality mediated through fruit and vegetable consumption, although our study did not examine this relationship. There was a trend toward a decrease in meat, beans, and egg consumption over the course of the intervention. Protein intake in women 50 years of age and older is critically important for prevention of sarcopenia, the degenerative loss of skeletal muscle mass quality and strength which is associated with aging.[43] In fact, protein needs increase in older adults in order to ensure prevention of sarcopenia.[43] Yet, post-intervention, our study cohort was not meeting the recommendations for protein consumption for their age, which could lead to physical frailty and increased risk of fractures due to low bone mass.[43] While increased mindfulness has not been correlated with a decrease in protein intake, it is an important nutritional factor to be addressed in this population. Therefore, future studies should include nutrition education stressing the importance of protein intake, or resistance-training physical activity to preserve muscle mass in the target population. It is also important to note that the data collected did not differentiate animal protein versus plant protein sources, which makes it difficult to determine whether this decrease lead to changes in clinical markers in our population. Yet, the decrease in meat consumption may explain the decrease in saturated fat intake observed in our study. High consumption of saturated fats has been found in several observational studies to lead to increased breast cancer mortality in this population, as noted in a review article by Hamer et al.[9] Therefore, the significant decrease in saturated fat by the present ME intervention may lead to decreased breast cancer mortality and improved survival.

Mindfulness is inversely associated with obesity, comorbid disease risk, and reduced mortality risk in obese populations. In order to determine the effect of ME on

these outcomes, it was important to monitor mindfulness scores in the present study. Post-intervention, there was a trend of increased MAAS scores, and therefore increased mindfulness, which is supported by the literature. A systematic review conducted by O'Reilly et al. found improvement in mindfulness after mindfulness-based interventions as measured by a variety of mindfulness questionnaires.[8] Increased mindfulness can lead to positive changes in physiological, psychological, and biological responses in breast cancer survivors that affect all aspects of their lives, as demonstrated by a biobehavioral model illustrating evidence of the effect of mindfulness on weight gain in this population.[5] The model established how mindfulness may lead to favorable changes in physical activity, perceived stress, emotional self-regulation, fatigue, and sleep quality. Therefore, the increased mindfulness confirmed by our study may have also had promising changes on breast cancer survivors quality of life and stress-related emotions.[5] The present study also noted a moderate correlation between MAAS scores and weight and BMI, which parallels a prospective study that demonstrated an association between higher mindfulness and lower BMI and weight status in women in the general population.[6] This suggests that mindfulness and ME may have changed the participants' association with food or obesogenic eating behaviors, and adds to the growing evidence that ME can be effective as a weight loss or maintenance strategy in overweight and obese individuals.

The biobehavioral model also noted that mindfulness may lead to increased physical activity and decreased sedentary time.[5] This expected change is extremely important because of the inverse dose-response relationship physical activity has with breast cancer recurrence. However, our study found a trend towards decreased MVPA and total daily steps at follow-up. Without any information reinforcing the benefits of physical activity during the ME intervention session, one explanation is that participants' interest in completing daily physical activity waned, therefore leading to decreased levels

of physical activity. Another explanation for the decreased activity is that Fitbit® Flex compliance could have decreased. If participants were not wearing their Fitbit®, then physical activity would not have been tracked. Lastly, since this intervention took place in July, it is reasonable to speculate that participants could have been swimming for exercise. In this case, they would have to remove their Fitbit® Flex, causing lower activity to be recorded.

Finally, with breast cancer survivors more likely to develop cardiovascular diseases than their non-cancer counterparts, clinical markers are important to monitor for cancer survival and morality risk. With regards to clinical markers, Rosenzweig et al. conducted an 8-week mindfulness-based stress reduction (MBSR) intervention on overweight and obese individuals with type 2 diabetes, which found a downward trend in HbA1c post-intervention, and statistically significant decrease at the 12-week follow-up.[44] Yet, a 6-week ME intervention in obese participants found no significant changes in glucose or cholesterol levels.[28] The present study did not identify any significant differences in HbA1c and glucose values post-intervention. However, the present study differs from Rosenzweig et al. because our study was focused on ME and food-based meditation, as opposed to stress reduction through mindfulness. It was hypothesized by the researchers that the mindfulness training mediated the glycemic response by changes in stress hormones.[44] This may explain why our study did not see the same significant decreases in HbA1c and glucose as the mindfulness-based stress reduction intervention. Lastly, increases in LDL cholesterol and significant increases in triglycerides were found post-intervention. Since there were significant decreases in saturated fat intake, it is unlikely that diet was a main factor in these changes in LDL cholesterol. However, increases in carbohydrate intake, similar to the ones found in our study, may lead to increases in triglycerides.[45] In addition, estrogen therapy medications have been shown to increase triglyceride levels as side effect, which might also explain

the high levels of triglycerides at the end of the intervention. However, our study did not include the participants' addition or changes in medications in the data collection, so it is difficult to determine the exact reason for this result.

Limitations

There were a number of limitations in this study. First, due to the pilot nature of the study we used a small sample size and a single group design. Not using a two-group design, it is difficult to determine the intervention effect size. Yet, a single group design allows individual differences, in response to the intervention, to be highlighted.[29] Another limitation is that this study used convenience sampling of the Athens-Clarke county area. Athens-Clarke county has a higher percentage of people who are college educated, than both Georgia and the United States; thus, this is not representative of a typical breast cancer survivor. This prevented the study sample from being a complete representation of postmenopausal breast cancer survivors; however, it provided valuable information about the breast cancer survivors in the Athens-Clarke county and their motivation to complete a ME intervention. Further, although we described dietary intake and physical activity of the sample at baseline and follow-up, we could not control statistically for dietary intake and physical activity. It was therefore difficult to determine how much of the weight loss was independently attributed to the ME intervention. In addition, this study had a short duration of only 8 weeks. It is recommended that weight loss interventions for breast cancer survivors have a least a 6-month follow-up to assess maintenance of outcome measures.[2] However, previous studies have seen significant results in interventions conducted in less than 6-months.[25] Lastly, we did not collect data on the participants' smoking habits or medication changes making it difficult to determine if changes in clinical markers were due to the intervention or outside factors.

Strengths

The present study has a few strengths. It was the first study to include dietary and physical activity measures as a part of a ME intervention in this population. With this additional information, the effects of a ME intervention these outcomes could be explored. In addition, this data may be useful in developing nutrition and physical activity interventions for this population in future studies. We utilized validated methods for dietary intake and physical activity measures, which allowed reproducibility of our work. Finally, our study and existing literature supports findings that breast cancer survivors are a motivated and compliant group, willing to make positive lifestyle behavior changes.[27] Their motivation and low drop-out rate demonstrated that this cohort is extremely receptive to weight loss interventions. Working with this population will allow us to potentially develop weight loss and maintenance interventions that will address obesity in this breast cancer community.

Future Research/Implications

Our pilot study provides preliminary evidence to support ME as a weight loss intervention in this population. A more diverse group in SES, race, and geographic location will allow results to be generalizable to a larger population of postmenopausal breast cancer survivors in future research. This would be influential and lay the groundwork in developing recommendations and community interventions that address obesity and weight maintenance in this population. Also, a longer study intervention may not be useful, a longer follow-up would be helpful in determining whether the weight loss from the intervention was sustainable in the long term. A longer study follow-up would also help determine the relationship of this intervention on cancer mortality, recurrence, and survival. Understanding this relationship will further our knowledge on the duration

and qualities needed in an intervention to lead to weight loss and maintenance in postmenopausal breast cancer survivors.

Lastly, since previous studies in breast cancer survivors have shown the recommended $\geq$ 5% of body weight loss with interventions that combined nutrition, physical activity and behavioral components, it might be helpful to include nutrition education and physical activity to this ME intervention.[2] Reaching the recommended amount of weight loss will lead to improvement in comorbidities in this population.[2] This is greatly beneficial to this population since cardiovascular morbidities are the primary cause of death. Also, breast cancer survivors without comorbidities had longer life spans than those with even one comorbidity. Lastly, since BMI is considered a strong predictor in breast cancer recurrence risk, a significant reduction in weight will critically improve survival rates in this population.

Conclusion

A majority of breast cancer survivors are overweight or obese, and at risk for cardiovascular disease. It is therefore necessary to develop weight management intervention strategies that are effective and sustainable in order to decrease their risk for recurrence and all-cause mortality. While complementary alternative weight loss methods are being sought by breast cancer survivors, ME can lead to increased adherence to behavior change interventions, and decreased binge eating, emotional eating, food cravings and sedentary time, thus leading to weight loss in this population. This ME intervention was successful in increasing mindfulness and decreasing weight and BMI, and provides preliminary evidence that ME can lead to modest weight loss can improve health outcomes. Interventions longer than the recommendation of greater than 6 months that include a diverse and nationally representative sample may be able to

shed light on changes in body composition and sustainability of the weight loss in this population.

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APPENDIX A

HEELS Study:

Healthy **E**ating, Mindfulness, **E**xercise and **L**ifestyle in Breast Cancer **S**urvivors*

Eligible Participants:

- **Female 50 years or older**
- **Diagnosis of breast cancer and in remission (treatment completed)**
- **Physical ability to engage in moderate-intensity physical activity**
- **Body Mass Index (BMI) equal or greater than 25 kg/m²**

Attend 8 Sessions:

Once per week for eight weeks
@ the UGA Health Sciences Campus

***includes an incentive valued at $185 for completing the study.**

If you are interested in participating in the study, call the Clinical and Translational Research Unit front desk and leave a message at 706-713-2721 or fill out a contact information slip.

For questions about the study, call Dr. Lilian Sattler at 706-542-1040.

APPENDIX B

Telephone Screening Script

Thank you for calling to find out more about our research study. My name is [Clinical and Translational Research Unit staff or research team member], and I am a researcher at the University of Georgia.

1. The purpose of this study is to determine the impact of a physical activity, nutrition, and behavior modification compared to a mindful eating program on health indicators among overweight women on health indicators among overweight women with a history of post-menopausal breast cancer. Do you think you might be interested in taking part in this study?

    {if No}: Thank you very much for your time.

    {if Yes}: Move to question 2.

But before enrolling people into this study, we need to ask you some questions to determine if you are eligible for our study. And so what I would like to do is ask you a series of questions about your cancer diagnosis and heart health. This should take about 5 to 10 minutes of your time.

There is a possibility that some of these questions may make you uncomfortable or distressed; if so, please let me know. You don't have to answer those questions if you don't want to.

All information that I receive from you during this telephone interview, including your name and any other information that can possibly identify you, will be strictly confidential and will be kept under lock and key. Remember, your participation is voluntary; you can refuse to answer any questions, or stop this phone call at any time without penalty or loss of benefits to which you are otherwise entitled.

2. Do I have your permission to ask you these questions?

    {if No}: Thank you very much for your time.

{if Yes}: Move to question 3.

3. What is your name? (First name, last name) _____

4. How old are you? (Age in years) _____

5. Have your menstrual periods stopped permanently?
   a) Yes, natural menopause
   b) Yes, but have them now from taking hormones
   c) Yes, surgical procedure
   d) Yes, other reason
   e) No
   f) Not sure

6. Have you ever been diagnosed with breast cancer?
   a) Yes
   b) No

7. Were you diagnosed with breast cancer before or after your menstrual periods stopped permanently?
   a) Before
   b) After

8. When was your first diagnosis of breast cancer?

   (Age in years or date as month/year or year)

   _____

9. Are you currently using Hormone Replacement Therapy, also known as HRT, including pills, patches or cream?
   a) Yes
   b) No

10. Are you currently using any of the following:

No	Yes	Tamoxifen (also called Nolvadex, Istubal, Valodex)
No	Yes	Raloxifene (also called Evista)
No	Yes	Aromatase Inhibitors If yes, which type:
No	Yes	Anastrazole/Arimidex

No	Yes	Letrozole/Femara
No	Yes	Exemestane/Aromasin
No	Yes	Natural hormones for the relief of menopausal symptoms such as prescription herbs like black cohosh and other supplements?

11. Now I am going to ask you a few questions about your general health.

Has your doctor ever said that you have a heart condition OR high blood pressure?	Yes	No
Do you feel pain in your chest at rest, during your daily activities of living, OR when you do physical activity?	Yes	No
Do you lose balance because of dizziness OR have you lost consciousness in the last 12 months? Please answer NO if your dizziness was associated with over-breathing (including during vigorous exercise).	Yes	No
Have you ever been diagnosed with another chronic medical condition other than heart disease, high blood pressure, or breast cancer?	Yes	No
Are you currently taking prescribed medications for a chronic medical condition other than the ones you discussed earlier in the phone call?	Yes	No
Do you have a bone or joint problem that could be made worse by becoming more physically active? Please answer NO if you had a joint problem in the past, but it does not limit your current ability to be physically active. For example, knee, ankle, shoulder or other.	Yes	No
Has your doctor ever said that you should only do medically supervised physical activity?	Yes	No

{if YES to any of these general health questions:} Thank you. I or another member of our research team will be in touch to schedule your enrollment visit at the Clinical

Translational Research Unit. We will need a letter from your doctor stating that it is okay for you to participate in the study (provide medical clearance form). Please bring the form to your enrollment visit.

{If NO to all questions:} Thank you. I or another member of our research team will be in touch to schedule your enrollment visit at the Clinical Translational Research Unit.

If you have any questions about this research project, please feel free to call Dr. E. Lilian Sattler at 706-542-1040 or the Clinical and Translational Research Unit at 706-713-2721. Questions or concerns about your rights as a research participant should be directed to Institutional Review Board, Tucker Hall Research Ctr., 310 E. Campus Rd., Athens, Georgia 30602; telephone (706) 542-3199; email address irb@uga.edu.

APPENDIX C

UNIVERSITY OF GEORGIA
CONSENT FORM

Exercise, Nutrition, Mindful Eating, and Biomarkers in Breast Cancer Survivors

Researcher's Statement
We are asking you to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. This form is designed to give you the information about the study so you can decide whether to be in the study or not. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information about the study. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called, "informed consent." A copy of this form will be given to you.

Principal Investigator: Elisabeth Lilian Sattler, PhD, BS Pharm
Clinical and Administrative Pharmacy & Foods and Nutrition

(706) 542-1040
lilian@uga.edu

Purpose of the Study
The purpose of this study is to determine the impact of a physical activity, nutrition, and behavior modification program compared to a mindful eating program on health indicators among overweight women with a history of postmenopausal breast cancer. We are asking you to take part in this study because you are a postmenopausal breast cancer survivor and are not at your ideal weight. We also want to understand if the planned weekly sessions are helpful, fun and relevant for women with breast cancer.

Study Procedures
If you agree to participate, you will be asked to complete baseline testing at the Clinical and Translational Research Unit (CTRU). This testing includes having your height, weight, and percent body fat measured. If your Body Mass Index (BMI) is equal or greater than 25 kg/m^2 and you can be physically active, then you will be enrolled into the study. If you are not eligible to be in the study, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return or destroy the information.

If you are eligible to enroll in the study, you also will be asked to complete some questionnaires on your demographic information, stress levels, social support, sleep, food security status, medication use, diet, physical activity level, mindfulness, and health. A registered nurse will draw a small amount of blood that will be tested for blood cholesterol, blood sugar, and hemoglobin A1C levels, and markers of inflammation and immune response.

During the baseline data collection appointment, you will receive a FitBit® Flex device that you will be allowed to keep after the study ends. This device has to be worn around the non-dominant wrist (e.g., left wrist for right handed individuals) and measures the intensity, frequency and duration of physical activity, sleep pattern, weight, and food intake. A research team member or CTRU staff member will set up a FitBit® account for you and instruct you on the use of the FitBit device throughout the study. We will ask you to self-report weight and food intake on a regular basis throughout the study period. Sleep and physical activity data will be automatically recorded daily.

People who take part in this study will be assigned to attend 8 weekly 2-hour sessions on mindful eating or 8 weekly 2-hour sessions on physical activity, healthy eating, and behavior modification or no sessions. The mindful eating sessions will be led by a trained instructor and include a workbook and take-home activities. The topics we will cover in the sessions include mindful eating, exploring eating triggers, emotional hunger, and stress-related eating. Each session will have group discussions, goal setting, and practice activities. There will also be activities for you to practice at home. The physical activity, healthy eating, and behavior modification sessions will be led by a graduate student from the Department of Foods and Nutrition at UGA, and will assist you in eating healthier and becoming more active. Each group session will allow participants to learn how to manage weight through nutrition and physical activity and engage in the following activities: 1) practice the nutritional and physical activities, 2) observe and learn from other's experiences, and 3) social support. A set of exercises will be demonstrated and performed during each session. The topics we will cover in this course include healthy lifestyle for cancer survivors, behavioral strategies for weight management, healthy meal planning strategies and portion control, healthy eating on a budget, increasing fruits, vegetables, whole grains and fiber, and recipe modification, reducing empty calories and healthy snacking, and tips for dining out. All sessions will be held in a private room in the Dance Department on the main campus at the University of Georgia.
At the end of the 8 sessions, we will schedule a follow-up visit at the CTRU. At the follow-up visit, you will complete the same measurements and blood draw as at baseline. The total time commitment is estimated at 120 minutes each for the baseline and 180 min for follow-up tests, and 16 hours for the weekly sessions, for a total of 21 hours.

Risks and discomforts

The risks of taking part in this study are minimal. You may experience some discomfort and bruising with the blood draw. A registered nurse will conduct the blood draw according to standard clinical practice. As part of the weekly sessions, you may experience some emotions as eating patterns are often tied to emotion experiences, as you will be asked to reflect on your eating and physical activity habits, and on the factors that cause stress in your life. The mindful eating workshop is not a complete treatment for eating disorders, although it may complement treatment. If you have an eating disorder, you must be working with a qualified counselor and/or physician to be able to participate in this mindful eating workshop. You will not be asked to share or disclose any information if you do not want to. The performance of physical activity or exercise may

make you feel tired, have sore muscles, or experience discomfort in breathing. We will reduce this risk by carefully screening you to make sure you are ready to begin being physically active, encourage warming up before muscle strengthening exercises, and teach you about monitoring your heart rate and breathing during physical activity.

Benefits
Taking part in this study may lead to healthier and more mindful eating and physical activity habits. Completing the weekly sessions also may provide strategies to reduce your feelings of stress. All of these factors can decrease your risk of chronic disease including diabetes and heart disease. Understanding how these sessions can improve health behaviors and to improve biological markers circulating in your blood is important for improving the quality of life of women who have been diagnosed with breast cancer.

Alternatives
People who take part in this study will be assigned to attend 8 weekly 2-hour sessions on mindful eating or 8 weekly 2-hour sessions on physical activity, healthy eating, and behavior modification or no sessions.

Incentives for participation
If you complete the baseline measures, you will receive a FitBit® Flex device. Upon completion of the study at follow-up measures, you will receive a Walmart gift card for $95 to compensate you for your time.

Privacy/Confidentiality
The only people who will know that you are taking part in this study are members of the study team, and other participants who have been assigned to your group. Identifiable information about you or your results will be confidential and will not be shared with others in any way that identifies you without your prior consent unless required by law. In addition, your specific information will not be shared with other study participants. We will collect your name, telephone number, and email address so that we may follow-up with you about your weekly sessions and follow-up testing. We also will create a code that is unique to you. This code will be entered on all forms and at FitBit® registration and data management. We will not use your name or other information to identify you on our forms. Your information will be kept on a password protected computer. Only study team members will be able to access your information.

Taking part is voluntary
Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw from the study, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information.

If you are injured by this research
The researchers will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in an injury, the

sole responsibility of the researchers will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Elisabeth Lilian Sattler right away at (706) 542-1040. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

If you have questions

The main researcher conducting this study is Dr. Elisabeth Lilian Sattler, a professor at the University of Georgia. Please ask any questions you have now. If you have questions later, you may contact Dr. Sattler at lilian@uga.edu or (706) 542-1040. If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at 706.542.3199 or irb@uga.edu.

Research Subject's Consent to Participate in Research:

To voluntarily agree to take part in this study, you must sign on the line below. Your signature below indicates that you have read or had read to you this entire consent form, and have had all of your questions answered.

_____	_____	
Name of Researcher	Signature	Date
_____	_____	
Name of Participant	Signature	Date

Please sign both copies, keep one and return one to the researcher.

APPENDIX D

Mindful Eating Workshop©

Enhancing your relationship with food and eating, realizing greater health and happiness.

Mindful Living Center
Athens, Georgia

Mike Healy (706) 543-0162
mfhealy@bellsouth.net
Please feel free to e-mail or call with any questions you may have.
Mindful Living Center

www.mindfuliving.org

Athens, Georgia

"Mindfulness" means paying attention in a particular way: on purpose, in the present moment, non-judgmentally. – Jon Kabat-Zinn

Overview: What is Mindfulness and Mindful Eating?

How will this workshop benefit you?

This workshop will help you develop a healthier relationship with food and eating through mindfulness practices. You can enjoy the pleasures of eating, while realizing and maintaining a healthy weight. Learn to "listen" to your inner wisdom. Learn to trust yourself to make healthy eating choices.

This workshop includes explorations of your eating triggers, hunger and emotional hunger; exploring patterns and habits around food; and learning ways to reduce stress-related eating. You will learn to relate to your relationship to food and eating with greater compassion, appreciation, and gratitude.

Mindfulness creates "space" to make new and better choices about food and eating. Finding greater peace and balance is possible for you through mindfulness. Savor your life.

People enroll in this workshop for many reasons including: over-eating, under-eating, self-image, mindless- and stress-related eating and/or chronic illness such as high blood pressure, diabetes and heart problems

Note: This workshop is not a complete treatment for eating disorders, though it may complement treatment. If you have an eating disorder, you must be working with a qualified counselor and/or physician to be able to take this Mindful Eating workshop.

What is mindfulness?

Mindfulness "means paying attention in a particular way: on purpose, in the present moment, non-judgmentally," according to Jon Kabat-Zinn, a leader in the field of mindfulness applications and research. Anyone can practice mindfulness – we all have the natural abilities of concentration and awareness. These abilities can be strengthened and enable you to be more present for your life.

Mindfulness helps you gain insight into yourself in many ways. It helps you to see places in your life where you can respond more effectively. This is especially true when situations are tense, hurried, and/or emotionally charged. This workshop helps you develop a healthier relationship toward food and eating through this educational, experiential approach.

How effective is mindfulness?

Research reports many useful applications of mindful practices. Researchers have found that through cultivating mindfulness people find they can relax better; find more energy and gusto for life; improve self-esteem; cope better with life's problems and have a more positive attitude. These findings are seen in an increasing number of studies on the effects of mindfulness. Specifically, mindfulness practices have proved helpful in changing people's relationships to food and eating.

The reference section of this workbook includes resources and recommendations for further reading and study. I have developed this workshop based on many years of mindfulness practices, the study of mindfulness and mindful eating, and my own personal experience with finding and maintaining a healthy weight and managing diabetes.

What is included in the workshop?
This is a life-affirming workshop in conscious, healthy living. The workshop has a practical focus and includes: guided instruction in mindfulness practices – formal and informal; activities that focus awareness on your relationship to food and eating, group dialogue and inquiry exercises to increase awareness.

Although this workshop is relatively short, life-long learning is fostered. The workshop offers an immediate and deliberate shift in your relationship toward food and eating.

What are the key characteristics of the workshop?

- Instruction in a variety of mindfulness practices
- Group and individual educational experiences
- Strongly supportive environment
- Fostering of self-reliance and life-long learning
- Mindfulness methods to meet individual participant needs and learning styles
- Many opportunities to ask questions
- Focus on mindful eating as a part of good health
- View of food as a source of nutrition to be enjoyed

Facilitator/Instructor

Mike Healy, Ed.D. has practiced meditation for 38 years, 30 years of which has been Mindfulness meditation, and has taught mindfulness-based workshops for over ten years at the University of Georgia Center for Continuing Education and Athens Regional Medical Center's Mind Body Institute, and at other locations in Georgia, Florida and Mississippi.

Healy is certified to teach Mindfulness-Based Stress Reduction (MBSR) by the Center for Mindfulness at the University of Massachusetts Medical School. He participated in a seven-day professional training program under the direction of Dr. Jon Kabat-Zinn, founder, and Dr. Saki Santorelli, director of the Mindfulness-Based Stress Reduction Clinic (MBSR) at the University of Massachusetts Medical School, and he has completed the Teacher Development Intensive there.

Healy is a certified Integral Hatha Yoga instructor, and continues to further his training through attending multi-day mindfulness meditation retreats and conferences. He also completed a doctorate in Adult Education at The University of Georgia, studying mindfulness meditation as a transformational learning process.

Mindful Eating Learning Guidelines

To realize the most from this workshop, please consider these learning guidelines:

1. Make a personal commitment to formal mindfulness practices for 40 to 60 minutes daily at least 6 days per weeks during this workshop. This is the most important guideline; it is the *practice* of mindfulness (meditation, body scan, yoga, informal practice) that will enable you to realize the benefits of mindfulness. This commitment of time and energy is often a challenge. You may have to rearrange your schedule to allow time for daily practice. However, once you taste the benefits, the discipline of daily practice becomes easier. But at first, you may have to carve out the time from other activities to make time for cultivating concentration, awareness and self- discovery.

2. Make a personal commitment to practice informal mindfulness during the day. You can bring mindfulness to food choices and eating, walking, driving, interpersonal relationships, anytime throughout the day. This conscious act of remembering and bringing attention to simple activities throughout the day enhances your formal mindfulness practice. Both formal and informal practice are just that, practice at being fully present to the moment as your life unfolds just as it is, without judgment.

3. Complete the weekly assignments noted in this workbook. Completing the Mindful Eating Diary/Journal and other weekly assignments is at the heart of changing your relationship to food and eating. The benefits of mindfulness and realizing your healthy weight are achievable through the ongoing practices explored in this workshop. The practices are relatively simple, but can be challenging to do.

4. Identify a Mindful Eating Partner, either in the class or someone with whom you can share the practices – a wonderful, effective way to deepen your own learning. Check- in regularly with your Mindful Eating Partner to share your successes and challenges.

5. Put goal attainment on hold – this program is about *being* rather than about becoming something other than what you already are. *The practice and the goal are one in the same.* That is, to be fully present with your mind and body, without judgment; listening to the body's intelligence, specifically, its wisdom about food and eating. Remember, Mindful Eating is about developing a way of being in the world, a lifestyle change, and is not a "diet." Your intention, moment by moment, is what is important – right here and now (rather than a goal – which is future oriented). We are learning to "Be Here How."

6. Bring an attitude of wise effort to your practice. Change requires effort on your part, but also compassion for yourself; change is not linear, but works more like a spiral, with two steps forward and one step backward at times. Meet these moments with compassion and understanding. Be open to outcomes, but not attached to outcomes.

7. Remember to bring these attitudes to your practice – kindness for yourself and others; gentleness and compassion; openness and acceptance; inquisitiveness, a gentle curiosity; and equanimity. Mindfulness involves just observing, without judgment; developing a deeper awareness, gaining insights into the choices you make and exploring who you are as a person. The practice can be challenging at times; meet these challenges with compassion for yourself and others.

8. Current events and/or handouts – you are invited to share, in whatever manner you are most comfortable, a brief summary or copy of an article, book, movie, idea, story or anything that is relevant to the formal or informal practice of mindfulness, food and/or eating. This information may be shared during any session and is completely voluntary.

I commit to practicing mindfulness – formal and informal, to completing my diary/journal entries and to complete the mindful eating assignments:
_____ (signature)_____(date).

Weekly Outlines

Mindful Eating – changing your relationship with food and eating; realizing greater compassion, balance, and peace

Session 1 Introduction – Mindfulness and Mindful Eating

Theme

This workshop is an opportunity to work with mindfulness as a way to change your relationship to food and eating in a safe and supportive environment. Present moment awareness is fundamental in this work since the present moment is the only time we have to perceive, learn, grow, or change.

Choices made in the present moment shape our present and future moments. This workshop will help you develop *moment-to-moment awareness* of eating triggers, hunger, and automatic (sometimes unconscious) habits and patterns around food. Mindful eating allows space for healthy and creative food and eating choices. This week you will start to learn and practice mindfulness and mindful eating.

General Workshop Guidelines

Please remember…

- What is shared here, stays here
- Self-care – feel free to take responsibility for your own comfort and needs (there are no planned breaks)
- Communication with instructor – ask questions in-class, after class or via email
- Please refrain from advice-giving; watch your impulse to speak, empathy arising, etc.
- Please refrain from having side conversations

Welcome and Brief Workshop Overview

Mindfulness practice instructions are given over the course of the workshop. We start with mindfulness of the breath and the body scan. Your understanding of mindfulness will deepen with practice over time. Keep in mind "Meditation is not what you may *think* it is."

As you will learn (if you are new to mindfulness), mindfulness is more about *experience* than having an understanding of what mindfulness is intellectually. The benefits of this workshop are realized through the *practice* of mindfulness and mindful eating.

Group Go-around Introductions

Guided individual internal reflection: Who are you (however you choose to define yourself)? What, if any mind-body practices do you have? What has brought you here?

What do you really want to gain from this workshop?

Intentions and Goals

Mindfulness is being fully present in the moment, without judgment. Intentions are with us as each present moment unfolds, while goals are future oriented. When an intention is

not “met” or “achieved” the intention is still with us, moment-to-moment. This is quite a different experience than when a goal is not met (although goals are important as well).

This workshop is not about dieting, but is a change in lifestyle. You will learn to greet each moment with openness, a gentle curiosity, and to be with whatever arises with equanimity. You are learning to acknowledge the way things are right here and now; learning about “being” rather than becoming. Mindfulness offers “space” to make conscious choices in the moment.

Mindfulness and Mindful Raisin Eating Activity

This activity is an introduction to mindfulness and mindful eating. Mindfulness – being fully present in the moment without judgment, using the natural abilities you already have – your five senses and the thinking mind, we will explore the simple experience of eating a raisin. What do you notice?

Another aspect of mindfulness is recognizing a sense of interconnectedness. For example using the raisin activity, we see that the raisin is connected to something larger than itself which nourishes its growth: the sunlight, clouds, rain, earth, farmer, and much more. Through mindfulness you start to know yourself in a new way, experientially. And you can use mindfulness to explore your relationship to food and eating in this same simple yet profound way. Mindful Eating helps you make healthy food and eating choices.

Awareness of Breathing Practice

Awareness of breath involves focusing your attention on the physical sensations of breathing; experience the breath fully. When you notice that the mind has wandered away from your focus on the breath, simply bring your attention gently back its focus on the breath, where ever the breath is in its cycle of inhalation and exhalation. Awareness of the breath guides you in the present moment.

Discussion of *Mindfulness Practices*

After each mindfulness practice and activity we will explore as a group what the experience was like. Feel free to discuss your experience at whatever level of detail with

which you are comfortable. Our focus will be on the processes of our experiences rather than the content or actual details of the experience.

Introduce the Mindful Diary/Journal and the Hunger Scale

Heart of the Matter

Mindfulness: Mindfulness means paying attention in a particular way: on purpose, in the present moment, without judgment. Several mindfulness practices have been introduced that can help you develop your abilities of concentration and awareness. With daily practice mindfulness will deepen.

Mindful Eating: Mindful eating brings a compassionate awareness to the present moment, specifically in this workshop, to your relationship with food and eating. The raisin activity helps you learn how to mindfully explore this relationship – using your five senses and the thinking mind.

And rather than being on "automatic pilot," you are learning to be more present for your life moment-to-moment. "Listening" mindfully, in other words, paying close attention to your body, as well as your thoughts and emotions, enables you to come to know yourself on a different level, in a different way – a non-cognitive, experiential way of knowing.

This way of knowing can help you identify and explore your eating triggers, hunger and emotional hunger, and eating habits and patterns. Mindful eating enables you to make healthy choices around food and eating; it allows insights to emerge about changes you may consider making with your relationship to food and eating; and mindfulness provides calm energy and peace with which to realize greater balance, health, and happiness in your life.

This is not a quick and easy path to developing a healthy relationship with food and eating; it is not a diet. In contrast, mindful eating becomes a way of being, a lifestyle change guided by your inner wisdom and knowledge.

The weekly practices and activities below are what bring about changes in your relationship to food and eating. You will develop mindfulness and mindful eating as you bring these practices more fully into your life.

This Week's Practices and Activities

* Daily practice of Awareness of Breathing for 10-15 minutes
* Daily – eat at least one meal mindfully, as we did with the raisin: eat by yourself, without watching TV, reading, talking, etc. If this is too time consuming on some days, you can start your meal by eating mindfully for the first five minutes, or at least the first few bites.
* Daily – write in your *Mindful Eating Diary/Journal*

Session 2 – Exploring Eating Triggers and Mindfulness

Theme

This session explores the mind-body connect through further practice with the body scan and includes other objects of focus during the mindfulness meditation. We will explore eating triggers through reflections, discussions, and with mindfulness.

Body Scan Practice

The body scan involves moving your awareness from your toes to the top of the head. This practice deepens awareness of the mind-body. You are developing concentration, awareness, learning to move awareness, to let go/let be, and "listening" to the body's intelligence and inner wisdom.

Awareness of Breath and Home Practices Discussion

Eating Triggers

Mindfulness helps in identifying what triggers your eating. There are three primary categories or areas of eating triggers include: trigger foods, trigger environments and people, and trigger feelings/emotions. Eating triggers and their strength are unique for each person. Bringing mindfulness to them allows you to see what may be "behind" these triggers, instead of and/or besides the body's need for nutrition.

Reflecting on Your Eating Trigger Activity (see Eating Triggers handout)

Mindfulness Meditation Practice – We started with bringing awareness to the breath as the primary object of focus. This week we will expand the mindfulness meditation practice as we add other "objects" of awareness. See the mindfulness meditation practice tips handout.

The Hunger Scale

Paying attention to hunger – before, during, and after meals and snacks allows you to start eating before getting too hungry and to stop eating before you are too full. Using the hunger scale is part of your weekly activities and assignments. See the Hunger Scale diagram.

Weekly Practices and Activities

* Continue to reflect on your eating triggers, using the handout; as you identified your eating triggers, include them in your Mindful Eating Diary/Journal
* Practice using the Hunger Scale before, during, and after meals and snacks; record some of your observations; what are you learning about your hunger, about yourself?

* Mindfulness meditation - awareness of breath: 5-15 minutes or more each day
* Listen to CD 1, the body scan: your daily practice strengthens mindfulness
* Informal mindfulness practices: mindfully observe daily activities around food and eating choices; and to build your mindfulness practice, mindfully observe other routine activities – while showering, brushing teeth, washing dishes, taking out garbage
* Daily – complete your *Mindful Eating Diary/Journal*

Session 3 – Hunger and Emotional Hunger

Theme: This session continues to explore the mind-body connection through Awareness of Breath practice, deepening your mindfulness. We will reflect on hunger and emotional hunger. Reflecting on and bringing mindfulness to your experiences – how much you eat, where, when, what, and why is very instructive as you come to a deeper understanding of your relationship with food and eating. Knowing whether your hunger is physiological or psychological and your level of various types or sources of hunger is an important part of making healthy food and eating choices.

Note: It is important to get down on the floor each day. If you are unable to get down onto the floor sit in a chair. Work mindfully with your body every day, even if it is only for a few minutes.

Sitting Mindfulness Meditation

Discussion of sitting mindfulness practice and homework from last week – the body scan, formal sitting meditation, and informal practices. What does it mean to be *embodied* in mindfulness practice and in life?

Review the Hunger Scale and Mindful Eating Diary/Journal and Eating Triggers Reflection Activity during the past week – what have you learned from?

Hunger and Emotional Hunger-Why do we feel like eating?

"When hungry – just eat." This is wonderful advice found in eastern philosophy/psychology. And Evelyn Tribole and Elyse Resch speak of "intuitive eating" and "awakening the intuitive eater" in their book "Intuitive Eating" (1995). But how do we follow this sage advice?

There are different "types" or sources of hunger as well as levels of hunger: you can explore hunger where it is arising – which sense door(s) is registering hunger: seeing, smelling, hunger in the mouth, the stomach, the thinking mind, your heart or emotional hunger and in the body. When hunger is triggered or you notice some sense of hunger, you can explore, mindfully, whether or not it is your body expressing its need for nourishment?

Reflection on Hunger including Emotional

Hunger Identifying Types of Hunger

Weekly Practices and Activities—you are developing a mindful practice that will be the foundation of Mindful Eating, which you can continue after this workshop

* Daily – alternate the body scan and yoga
* Daily – mindfulness meditation practice with attention on the breath, body, sounds, thoughts and emotions, stillness and with "choiceless awareness;" 20 minutes or longer
* Work with the Hunger and Emotional Hunger Activity Reflection – at least once daily

*Informal mindfulness practices – continue to integrate mindfulness into your daily activities as you eat, walk, etc. Add at least one daily/routine activity to do mindfully each week

* Daily – complete your ***Mindful Eating Diary/Journal***

Sessions 4 & 5 – Deepening Practice Gentle Stretching with Awareness, Mindfulness Meditation, and Workshop Review of Eating Triggers, Hunger and Emotional Hunger

Theme:

Mindful Yoga/ Gentle Stretching with Awareness – guided and gentle; being especially careful of your back and neck and with other areas of personal concern; approaching your limits with gentleness and kindness, mindfully. Practice daily – alternating yoga with the body scan this week.

Mindfulness Meditation Practice - focusing on the breath, body, sounds, thoughts, emotions, and stillness - to whatever extent possible when it is present; and "choiceless" awareness; recognizing thoughts as just "mental events."

Discussion of Awareness of Breath and other Weekly Mindfulness Practices and Activities – the body scan, formal sitting meditation, and informal practices. What does it mean to be *embodied* in mindfulness practice and in life?

Review Mindful Eating Workshop so far; Eating Triggers, Hunger Levels and Types of Hunger (earlier reflections) and the Mindful Eating Diary/Journal – what have you learned from journaling – observations about your mindfulness practices, eating triggers, hunger and emotional hunger?

Weekly Practices and Activities—you are developing a mindful practice that will be the foundation of Mindful Eating, which you can continue after this workshop

* Daily – alternate the body scan and yoga
* Daily – mindfulness meditation practice with attention on the breath, body, sounds, thoughts and emotions, stillness and with "choiceless awareness;" 20 minutes or longer
* Work with Eating Triggers, Hunger and Emotional Hunger
*Informal mindfulness practices – continue to integrate mindfulness into your daily activities as you eat, walk, etc. Add at least one daily/routine activity to do mindfully each week
* Daily – complete your ***Mindful Eating Diary/Journal***

Session 6 – Exploring Eating Habits and Patterns around Food and Eating

Theme: We explore eating habits and patterns we have developed around food and eating. Reflecting on your past experiences – the how much you eat, where, when, what, and why, can be very instructive as you come to a deeper experiential understanding of your relationship to food and eating. Bring your eating habits and patterns into greater awareness, and then challenge yourself to experiment with healthier choices. This is not easy work.

Mindfulness Meditation Practice - focusing on the breath, body, sounds, thoughts, emotions, and stillness - to whatever extent possible when it is present; and "choiceless" awareness

Exploring and Working with Eating Habits and Patterns

Conditioning: Reflect on how your relationship with food is conditioned: by parents and family, society, media, access and opportunity, cultural differences and peer group influence, for example.

Anger: Anger can alert you to unhealthy eating patterns and habits. Exploring anger that arises around eating habits with mindfulness can help you identify and work with these habits.

Desire: Desire or attachment is another common aspect of eating habits and patterns to explore.

In summary, mindful eating involves bringing mindfulness to habits associated with conditioning, anger, and desire. A deeper understanding of mind-body leads to a change in your relationship with food and eating.

Reflection (Reflect-Pair-Share) Identifying Your Eating Habits and Patterns

Weekly Practices and Activities—you are developing a mindful practice that will be the foundation of Mindful Eating, which you can continue after this workshop

* Daily – alternate the body scan and yoga
* Daily – mindfulness meditation practice with attention on the breath, body, sounds, thoughts and emotions, stillness and with "choiceless awareness;" 20 minutes or longer
* Work with Eating Habits and Patterns in your own life
*Informal mindfulness practices – continue to integrate mindfulness into your daily activities as you eat, walk, etc. Add at least one daily/routine activity to do mindfully each week
* Daily – complete your ***Mindful Eating Diary/Journal***

Week 7 – Exploring Stress-Related and Mindless Eating

Theme: Stress-related and mindless eating are other areas where mindfulness can lead to healthy changes in your relationship with food and eating.

Mindfulness Meditation Practice - focusing on the breath, body, sounds, thoughts, emotions, and stillness - to whatever extent possible when it is present; and "choiceless" awareness

Stress-Related Eating

One common way of dealing with the stress in our lives is making unhealthy eating choices around what and how much we eat and drink. Our relationship to food and eating can be soured by stress.

Stress-Related Reflection-Stress Reaction versus Response: What effects has stress had on your relationship to food and eating? What are some of your experiences of stressors, stress, and how are you coping with them? Has eating become a way of coping with stress in your life?

> "It's not the stressors per se but how you handle them which influences the short and long-term health effects they may have on your mind and body" (John Kabat-Zinn, 1990).

Weekly Practices and Activities—you are developing a mindful practice that will be the foundation of Mindful Eating, which you can continue after this workshop

* Daily – alternate the body scan and yoga
* Daily – mindfulness meditation practice with attention on the breath, body, sounds, thoughts and emotions, stillness and with "choiceless awareness;" 20 minutes or longer
* Work with Stress-Related and Mindless Eating
*Informal mindfulness practices – continue to integrate mindfulness into your daily activities as you eat, walk, etc. Add at least one daily/routine activity to do mindfully each week
* Daily – complete your ***Mindful Eating Diary/Journal***

Session 8 – Deepening Compassion, Appreciation and Gratitude

Theme: *Developing Compassion* – practicing the LovingKindness meditation helps develop more compassion for yourself around food and eating challenges. We bring
together all elements of the Mindful Eating Workshop. Being mindful is a way of being, a life-long change in your relationship with food and eating. Review resources and references.

Loving Kindness Meditation

Practice compassion, appreciation, and gratitude toward yourself and others, every day.

Mindful Eating Workshop Review

Review ongoing practices and activities and the references and resources; continue to

deepen your understanding of mindfulness and mindful eating.

Awareness is the most important ingredient in mindful eating.

Benefits of a Mindfulness Practice

- **Responding Rather than Reacting**
- **Gaining Insights: Patterns and Habits you may wish to change**
- **Developing a Reservoir of Peace and Calm**
- **Connectedness**

Mindfulness is an antidote for mindless and stress-related eating. Being more present with your mind-body allows you to listen to the cues and signals when you go on automatic pilot (mindlessness) or start to react rather than respond to stress (stress-related eating).

Mindful eating allows for conscious, informed, and healthier eating and food choices. This is a challenging but effective approach. Practice compassion for yourself as you engage with these challenges. Gratitude and appreciation will also support your work.

Ongoing Practices and Activities

* Review your Mindful Eating Diary/Journal and decide on one or two areas to focus your mindful eating efforts; being patient with yourself; working with compassion; and recognizing and appreciating all for which you have to be grateful.
* Develop one to three, short-term (3 months) and long-term (12 months) goals, which come out of your direct experience of this workshop and your mindfulness practices. Include potential obstacles to reaching these goals and develop strategies for working with them to keep the momentum of your practice moving and growing. Set your intentions to meet these goals.
* Find a community of people who meditate regularly and sit with them or

form your own group.
* Consider attending a mindfulness retreat (see references and resources section)
* Daily for as long as you find it useful– complete your ***Mindful Eating Diary/Journal***

Keep up your Mindful Eating practices, making them your own! Remember mindfulness is a way of being in the world.

See the resources and references on the following pages.

Mindfulness Resources

Mind Body Institute, Athens, GA; www.armc.org/mbi, mbiprograms@armc.org
(706) 475-7329

Red Lotus Institute, 2080 Prince Ave., Athens, GA,

Rubber Soul Yoga Revolution – contact by writing to calclements(at)gmail(dot)com;
675 Pulaski St., Suite 1200, Athens, GA 30601. www.rubbersoulyoga.com/

Southern Dharma Retreat Center – www.southerndharma.org/

Insight Meditation Society, Barre, MA – www.dharma.org/

Barre Center for Buddhist Studies -- www.dharma.org/bcbs/index.html

Mindfulness meditation and body scan tapes available at – www.mindfulnesstapes.com/

Center for Mindfulness, Worcester, MA – www.umassmed.edu/Content.aspx?id=41254

Meditation tips of the day (free) – www.deeshan.com

Mindful Living Center (Mike Healy) – www.mindfuliving.org, mfhealy@bellsouth.net,
706-543-0162

References and Recommended Readings

Mindful Eating

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Robert M. Sapolsky (1994). *Why Zebras Don't Get Ulcers*. New York: W. H. Freeman and Company.

Research References

American Mindfulness Research Association (AMRA) is a comprehensive electronic resource and publication database that provides information to researchers, practitioners, and the general public on a wide variety of mindfulness research, including mindful eating: https://goamra.org/ / Editor: David S. Black, Ph.D., founder

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Mindful Eating Diary/Journal							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
*Meditation							
*Body Scan							
*Yoga							
**Informal Mindfulness							
**Eating Triggers							
Hunger Sources							
***Hunger Scale	B L D	B L D	B L D	B L D	B L D	B L D	B L D
**Habits & Patterns							
√Appreciation							
√Gratitude							
√Compassion							
*Mindful Movement							
Journaling space for observations, insights, comments on the above							

*List time in minutes; **List Items; ***Circle when done-B-breakfast, L-lunch, & D-dinner; √Check when noticed

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√Compassion							
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Sitting Mindfulness Practice Guidelines

Self-discipline
The self-discipline needed to maintain a daily practice is a challenge for most people. Understanding the process and tasting its benefits can help you maintain your practice. You are asking a lot of yourself – to make a significant lifestyle change, arranging your life so you will have 20 minutes to an hour each day for your formal mindfulness practices.

In terms of the time commitment, the resulting benefits – deeper awareness of mind and body, increased energy, relaxation, sense of peace, and clarity of mind, will more than compensate for the time you invest in your practice. And mindfulness during daily living (informal practice) takes no additional time; mindfulness actually takes us out of time, allowing us to be more fully present in the moment – the aim and practice of mindfulness are one.

When
Experiment and find what works best for your current needs. A regular time for practice helps with maintaining the practice. In the morning, is often a good time to practice.

Place
A quiet place is helpful but not necessary; a place suitable for the study of your mind and body. Remember, *all* mind-body phenomena are suitable objects of awareness, even "disturbing" sounds, body sensations, thoughts, and emotions. These are what we work with using awareness. Observing "disruptions" can deepen understanding.

Body
Your posture reflects the attitude that you bring to practice. Bring an attitude of dignity to your sitting practice. Maintain a relaxed but alert position, without moving, except when necessary and then bringing mindfulness to this movement. Be aware of the intention to move and the entire mind-body processes of all that is present in each movement.

It is useful to begin practice with some stretches or yoga and breathing practices.

Breathing
The formal sitting practice is done with a natural breath, that is, let the breath breathe itself. Deep, three-part breathing done prior to practice is both relaxing and energizing; however, during meditation, let the breath find its own natural rhythm.

Intentions or Attitudes to Bring to Your Practice
Openness and an allowing attitude Without

expectations Non-judging – these are just

thoughts

Acknowledging Letting be

Letting go – not holding on to what is pleasant and not pushing away that which is unpleasant

Gentleness and kindness toward one's self and others; LovingKindness

Equanimity, an evenness, or balance of mind that develops with practice

Beginner's Mind

Formal Sitting Practice
Practice *being*, that is, non-doing:

Just to observe, bring awareness to…
The breath, expanding to the entire body (physical sensations), sounds, thoughts (process, not their content), emotions, choiceless awareness (opening to whatever is most predominate in your awareness in the present moment), and stillness or sense of peace

Focusing inward toward consciousness and all mind and body phenomena manifested in consciousness.

Concentration: Building your capacity or ability to concentrate by focusing on the physical sensations of your breathing.

Expanded Awareness: Expand the field of awareness from the breath to include, a sense of the entire body (physical sensations), sounds, thoughts, feelings (the mind's immediate reaction to all arising objects: pleasant, unpleasant, and neutral), emotions and mind states, volitions/urges, stillness/silence/peace, and consciousness itself (the knowing faculty of mind). Bringing attention to whatever is the most predominating object in consciousness (choiceless awareness).

Choiceless Awareness: Allowing the focus of awareness to naturally find its own way/place…not meditating, no one meditating, just being…resting in awareness, making no choices.

APPENDIX E

Exercise, mindful eating, and biomarkers in breast cancer survivors-

CTRU Protocol Orders

Visit #1 (scheduled time in the morning)

Study Visit Date:	
Study Subject ID#:	
Principal Investigator:	E. Lilian Sattler, PhD
Study #: (IRB #)	STUDY00002818
IRB:	UGA
Study Title:	Exercise, mindful eating, and biomarkers in breast cancer survivors

Time of check-in: _____

CTRU RN/Staff Signature_____

CTRU RN/Staff Initials_____

Contacts (Specify telephone numbers of at least 2 study personnel)

1. Dr. Lilian Sattler 706-542-1040 or 706-255-6660

2. Annette Washington xxx-xxx-xxxx

Action item #	**Action**	**Results**	**Performed by**	**Completed** (initials)
1.	**Admit** to CTRU (specify date) 1. Greet the subject 2. Explain the general procedure and timeline for the day	N/A	CTRU/Study staff	
2.	**Informed Consent** - Review consent with participant	N/A	CTRU/Study staff	
	- Have participant and consenting staff sign	N/A	CTRU/Study staff	
	- Give a copy to study subject, leave original with CTRU staff to put in participant chart	N/A	CTRU/Study staff	

3.	**Vitals and Anthropometric measures**	N/A	CTRU/Study staff	
	Height #1 Record measurement to the nearest 0.1 cm.	**cm**	CTRU/Study staff	
	Height #2 Record measurement to the nearest 0.1 cm. If this measurement disagrees with measurement #1 by more than 0.2 cm, then take a third measurement.	**cm**	CTRU/Study staff	
	Height #3 (if needed)	**cm**	CTRU/Study staff	
	• Calculate mean for 2 measures, median for 3	**cm**	CTRU/Study staff	
	Weight #1 Record measurement to the nearest 0.1 kg.	**kg**	CTRU/Study staff	
	Weight #2 Record measurement to the nearest 0.1 kg. If this measurement disagrees with measurement #1 by more than 0.2 kg, then take a third measurement.	**kg**	CTRU/Study staff	
	Weight #3 (if needed)	**kg**	CTRU/Study staff	
	• Calculate mean for 2 measures, median for 3	**kg**	CTRU/Study staff	
	Have participant sit quietly in phlebotomy chair for 5 minutes before doing blood pressure measurements.	N/A	CTRU/Study staff	
	• **Calculate BMI on exam room computer using the mean or median height/weight values based on above instructions- if 25.0 or higher, continue with procedures. If not, they are disqualified from the study.**	**BMI:**	CTRU/Study staff	
	Blood Pressure Patient must be seated in a quiet room for at least 5 minutes prior to	N/A	CTRU/Study staff	

	measurements; use same arm for each measurement. Wait 1 minute between measurements.			
	Blood pressure #1		CTRU/Study staff	
	Blood pressure #2		CTRU/Study staff	
	Blood pressure #3		CTRU/Study staff	
	Calculate average blood pressure		CTRU/Study staff	
	Waist circumference #1 (All raw measurements should be recorded on the data collection form.) Record measurement to the nearest 0.1 cm.	cm	CTRU/ Study Staff	
	Waist circumference #2 Record measurement to the nearest 0.1 cm. If this measurement disagrees with measurement #1 by more than 0.2 cm, then take a third measurement.	cm	CTRU/ Study Staff	
	Waist circumference #3 (if needed)	cm	CTRU/ Study Staff	
	• Calculate mean for 2 measures, median for 3	cm	CTRU/Study staff	
	Hip circumference #1 (All raw measurements should be recorded on the data collection form.) Record measurement to the nearest 0.1 cm.	cm	CTRU/ Study Staff	
	Hip circumference #2 Record measurement to the nearest 0.1 cm. If this measurement disagrees with measurement #1 by more than 0.2 cm, then take a third measurement.	cm	CTRU/ Study Staff	
	Hip circumference #3 (if needed)	cm	CTRU/ Study Staff	
	• Calculate mean for 2 measures, median for 3	cm	CTRU/Study staff	
	Measure bioelectrical impedance - Participant should be in light clothing, without socks and shoes. Input 0.6kg for clothing correction. Select the appropriate sex for the	N/A (Results included on output paper)	CTRU/ Study Staff	

	participant. Enter participant's age. Input the mean or median height value, rounded to the nearest cm. Have participant stand still, arms at sides, looking straight ahead. The device will not provide a reading unless the participant stands still. - Staple the output paper to the last page of this order.			

4.

Labs	**Performed by**	**Completed**
1. Organize materials for draw including gauze, band aid, tourniquet, butterfly needle, labeled vacutainer tubes, and Athens Regional blood lab order sheet.	CTRU RN	
2. The Athens regional sheet and vacutainers (green top and purple top) should be **labeled with the subject's de-identified ID**. **The first and last initial of the subject** would go in the spot for the first name, and the **number the subject is on the list of possible subjects** would go in the spot for the last name. 3. Also included should be the **date, subject DOB, phlebotomist's initials, and time of draw**. The Athens Regional sheet should also be labeled in the top left corner with departmental information, Fax number, point of contact (Kim Schmitz), and Kim Schmitz's phone number (706-713-2722) in case of issues.	CTRU RN/Staff	
4. Collect **5 mL of blood in each of two GREEN top tubes** (blood lipids and glucose). Invert tubes gently 10 times to mix (turning tube down and up = 1 inversion).	CTRU RN	
5. Collect **3 mL of blood in PURPLE top tube** (HbA1c). Invert tube gently 10 times to mix (turning tube down and up = 1 inversion).	CTRU RN	
6. Collect **6 mL of blood in PINK top tube** (Luminex assay). Invert tube gently 10 times to mix (turning tube down and up = 1 inversion).	CTRU RN	

	7. Process Blood - 3000 RPM for 15 min at 4°C. • 5 mL in green top tube (blood lipids) ARMC • 5 mL in green top tube (glucose) ARMC - Leave purple and pink top tubes on ice for now.		CTRU RN/Staff	
	8. Both green tubes and purple top tube are packaged in biohazard bag with order sheet for ARMC pickup. May store at room temperature for up to 8 hours. Call courier dispatch (Robert Simms) to arrange a pick up at CTRU: **706-475-7821.** **(NOTE: For Saturday pick-up call 706-296-5501. For Sunday blood draws drop off at Athens Regional Lab in Customer Support area).**		CTRU RN/Staff	
	9. Pink top tube (Luminex assay) is packaged in biohazard bag for pickup by Melissa Davis. Store at 4°C until pickup.		CTRU RN/Staff	
5.	**Questionnaires** Have participants sit in a room with computer and fill out the following questionnaires online: • Demographics and Socioeconomic Status • Sleep Quality (Pittsburgh Sleep Quality Index) • Social Support for Exercise • Social Support for Diet • Diabetes History • Perceived Stress Scale • Food Insecurity (6 item US Household Food Security Module) • Brief Medication Questionnaire • Daily Stress Inventory (page 13 and 14 of the attached questionnaire) • Breast Cancer History Questionnaire • Diet Quality (2014 Food Frequency Questionnaire and Physical Activity Primer) • Self-reported Health	N/A	CTRU/Study staff	
6.	**Fitbit Orientation**	N/A	CTRU/Study staff	

	• Provide the participant with the Fitbit device and instruction how to use the device.			
7.	**Intervention Scheduling (if participant is not in control group)** • Participants in the 2 intervention arms will be participating in 8 2-hour (once/week) intervention sessions, respectively.	N/A	CTRU/Study staff	
8.				

Action	Performed by	Completed
Discharge from CTRU - Instructions: Prior to each of the intervention sessions, a member of the study team will contact the participant via telephone and/or email to remind him/her of the upcoming intervention session. Participants will be asked to come back to repeat today's activities in approximately 10 weeks (scheduling for this to be done at a later date). - Time of check-out: _____	Study / CTRU staff	

PI: E. Lilian Sattler, PhD	Signature:	Date:
CTRU Director: Brad Phillips, PharmD	Signature:	Date:
CTRU RN: Angelia M Lorrain, ADN, RN	Signature:	Date:

Deviations and Actions	Nurse Signature	Initials

APPENDIX F

Fitbit Flex Instructions

1. Wristband
2. Wireless Sync Dongle
3. Charging Cable

Your Fitbit is ***water-resistant*** which means that you can wear it in the shower or out in the rain with no worries!

Wear your Fitbit on your ***non-dominant*** hand.

(Do not wear it on the hand you write with.)

How to Charge Your Flex:

1. Insert the tracker with the three dots side first, into the charger until you hear a snap
2. Plug the charger into a USB port.
3. 5 dots flashing means that it is fully charged.

It takes ***3 hours*** for your Fitbit to charge completely.

Your Fitbit will last ***5 days*** on a charge.

snugly into the wristband.

Inserting the tracker

back into the wristband:

1. With the arrow facing you, insert the tracker into the wristband, pointing toward the clear band.
2. Slide the tracker in as far as possible.
3. Press the other end

Your Fitbit will sync to your smartphone, or when within 20 feet away the wireless sync dongle plugged into a computer or laptop.

LOGIN

EMAIL:_____

__

PASSWORD:_____

How to Use Your Fitbit

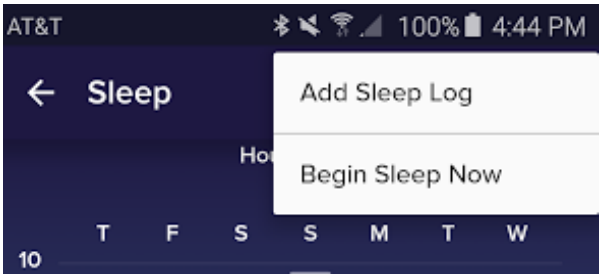
Sleep Mode

You can enter sleep using method 1 or 2

Method 1

1. Once you are in bed and ready to sleep, tap your Fitbit Flex quickly for 1-2 seconds. Your Fitbit will vibrate and display two slowly dimming lights. This means Sleep Mode has started.

2. Once awake, tap your Fitbit quickly for 1-2 seconds again until it vibrates and 5 lights flash three times. This will confirm that sleep mode is off.



Method 2

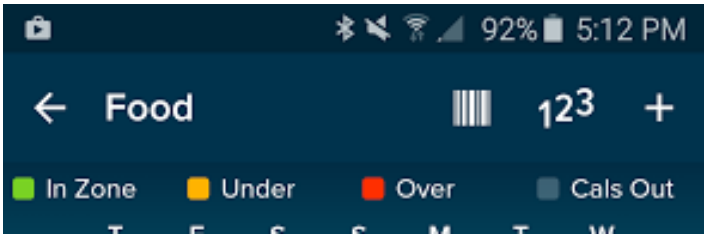
1. Wear your Fitbit to sleep. In the morning, choose "Add Sleep Log" under the sleep bar.

2. Enter the time you went to bed (Sleep Start) and the time you woke up (Sleep End). Click Save in the top right corner.

Enter Food and Water

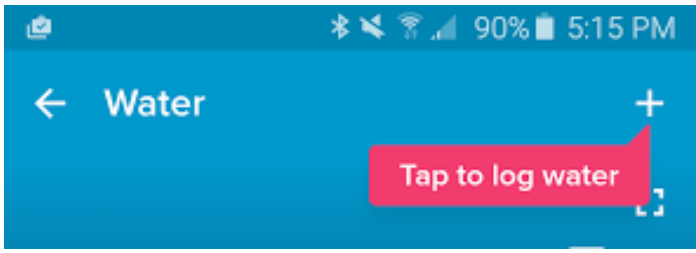
Enter your food and water intake twice a week

(1 weekday and 1 weekend)

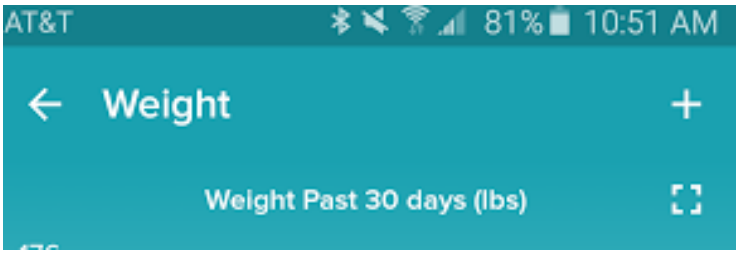


1. Under the food or water bar. Click the "+" in the top right hand corner.

2. For food, click on the magnifying glass icon in the top right hand corner. Type the name of the food you want to add.



3. Once you have chosen your food, adjust serving size to match what you consumed. Click "Log This" when completed.



Enter Self-Reported Weight

Enter your weight once a week.

1. Under the weight bar. Click the "+" in the top right hand corner.

2. Enter your current weight. Click "Save" when completed

If you are having trouble with your Fitbit in any way, visit

help.fitbit.com

Click on "Flex" and then choose the category that you are having trouble with.

FOOD AND ACTIVITY QUESTIONNAIRE

RESPONDENT ID #

TODAY'S DATE

	DAY	YEAR
Jan		
Feb		
Mar		2014
Apr		2015
May		2016
Jun		2017
Jul		2018
Aug		2019
Sep		2020
Oct		2021
Nov		2022
Dec		2023

ABOUT THIS SURVEY

Please answer each question as best you can. Estimate if you aren't sure.

- **DETACH THE LAST PAGE OF THIS BOOKLET.** These are your portion pictures.
- **USE ONLY A NUMBER 2 PENCIL.**
- **FILL IN THE CIRCLES COMPLETELY** and erase completely if you make any changes.

ABOUT YOU

SEX
- Male
- Female

If female, are you pregnant or breast feeding?
- No
- Yes
- Not female

AGE

WEIGHT pounds

HEIGHT feet inches

INSTRUCTIONS

This form is about the foods you usually eat. Think about your intake over the last 6 months. This includes all meals or snacks, at home, in a restaurant, or carry-out.

Please tell us...

1. **HOW OFTEN,** on average, did you eat the food?
   DO NOT SKIP any foods. Mark "Never" if you didn't eat any of the food.
2. **HOW MUCH** of the food did you usually eat on the days you ate it?
   Sometimes we ask 'how much' as A, B, C or D. LOOK AT THE PORTION PICTURES.
   Pick the picture that looks the most like the serving size you usually eat.
   (If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.)
3. **WHAT TYPE?** For some foods we ask the type (low-fat, low-sugar...) near the end of the survey.

EXAMPLE: This person drank orange juice twice a week, and had one glass each time.
Once a week this person ate a "C"-sized serving of cold cereal (about 1 cup).

	HOW OFTEN in the past 6 months?									HOW MUCH on these days? SEE PORTION SIZE PICTURES PAGE A-B-C-D			
	NEVER	A FEW TIMES PER 6 MONTHS	ONCE PER MONTH	2-3 TIMES PER MONTH	ONCE PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	EVERY DAY				
Orange juice	○	○	○	○	○	●	○	○	○	How many glasses	1 ●	2 ○	3 ○	4 ○
Cold cereal	○	○	○	○	●	○	○	○	○	Which bowl	A ○	B ○	C ●	D ○

PLEASE DO NOT WRITE IN THIS AREA

SERIAL #

APPENDIX H

Mindful Attention Awareness Scale

Description:

The MAAS is a 15-item scale designed to assess a core characteristic of dispositional mindfulness, namely, open or receptive awareness of and attention to what is taking place in the present. The scale shows strong psychometric properties and has been validated with college, community, and cancer patient samples. Correlational, quasi-experimental, and laboratory studies have shown that the MAAS taps a unique quality of consciousness that is related to, and predictive of, a variety of self-regulation and well-being constructs. The measure takes 10 minutes or less to complete.

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6

I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6

It seems I am "running on automatic," without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6
I drive places on "automatic pilot" and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention.	1	2	3	4	5	6
I snack without being aware that I'm eating.	1	2	3	4	5	6

Scoring information:

To score the scale, simply compute a mean of the 15 items. Higher scores reflect higher levels of dispositional mindfulness.

Reference:

Brown, K.W. & Ryan, R.M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. Journal of Personality and Social Psychology, 84, 822-848.

APPENDIX I

Kentucky Inventory of Mindfulness Skills Ruth A. Baer, Ph.D.

University of Kentucky

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your <u>own opinion</u> of what is <u>generally true for you</u>.

1	2	3	4	5
Never or very rarely	**Rarely true**	**Sometimes true**	**Often true**	**Very often or always**

_____1. I notice changes in my body, such as whether my breathing slows down or speeds up.
_____2. I'm good at finding the words to describe my feelings.
_____3. When I do things, my mind wanders off and I'm easily distracted.
_____4. I criticize myself for having irrational or inappropriate emotions.
_____5. I pay attention to whether my muscles are tense or relaxed.
_____6. I can easily put my beliefs, opinions, and expectations into words.
_____7. When I'm doing something, I'm only focused on what I'm doing, nothing else.
_____8. I tend to evaluate whether my perceptions are right or wrong.
_____9. When I'm walking, I deliberately notice the sensations of my body moving.
_____10. I'm good at thinking of words to express my perceptions, such as how things taste, smell, or sound.
_____11. I drive on "automatic pilot" without paying attention to what I'm doing.
_____12. I tell myself that I shouldn't be feeling the way I'm feeling.
_____13. When I take a shower or bath, I stay alert to the sensations of water on my body.
_____14. It's hard for me to find the words to describe what I'm thinking.
_____15. When I'm reading, I focus all my attention on what I'm reading.
_____16. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.
_____17. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.
_____18. I have trouble thinking of the right words to express how I feel about things.
_____19. When I do things, I get totally wrapped up in them and don't think about anything else.
_____20. I make judgments about whether my thoughts are good or bad.
_____21. I pay attention to sensations, such as the wind in my hair or sun on my face.

1	2	3	4	5
Never or very rarely true	**Rarely true**	**Sometimes true**	**Often true**	**Very often or always true**

_____22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.

_____23. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.

_____24. I tend to make judgments about how worthwhile or worthless my experiences are.

_____25. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.

_____26. Even when I'm feeling terribly upset, I can find a way to put it into words.

_____27. When I'm doing chores, such as cleaning or laundry, I tend to daydream or think of other things.

_____28. I tell myself that I shouldn't be thinking the way I'm thinking.

_____29. I notice the smells and aromas of things.

_____30. I intentionally stay aware of my feelings.

_____31. I tend to do several things at once rather than focusing on one thing at a time.

_____32. I think some of my emotions are bad or inappropriate and I shouldn't feel them.

_____33. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.

_____34. My natural tendency is to put my experiences into words.

_____35. When I'm working on something, part of my mind is occupied with other topics, such as what I'll be doing later, or things I'd rather be doing.

_____36. I disapprove of myself when I have irrational ideas.

_____37. I pay attention to how my emotions affect my thoughts and behavior.

_____38. I get completely absorbed in what I'm doing, so that all my attention is focused on it.

_____39. I notice when my moods begin to change.

KIMS Scoring instructions

For all items marked "R" the scoring must be reversed. Change 1 to 5, 2 to 4, 4 to 2, and 5 to 1 (3 stays unchanged). Then sum the scores for each subscale.

Observe:

1, 5, 9, 13, 17, 21, 25, 29, 30, 33, 37, 39

Describe:

2, 6, 10, 14R, 18R, 22R, 26, 34

Act with awareness:

3R, 7, 11R, 15, 19, 23R, 27R, 31R, 35R, 38

Accept without judgment:

4R, 8R, 12R, 16R, 20R, 24R, 28R, 32R, 36R

For more information, see:

Baer, R. A., Smith G. T., & Allen, K. B. (2004). Assessment of mindfulness by self-report: The Kentucky Inventory of Mindfulness Skills. *Assessment, 11*, 191-206.

APPENDIX J

Mindful Eating Recruitment Flowchart