A MINDFULNESS-BASED TREATMENT

FOR WOMEN WITH BULIMIA NERVOSA: A PILOT STUDY

A Research Grant Proposal

Presented to the faculty of the School of Nursing

California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

In

Nursing

Psychiatric Mental Health Nurse Practitioner Specialty

By

Suzanne Kent Nieman

FALL 2015

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Suzanne Kent Nieman

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DEDICATION

I would like to dedicate this work to all the women who suffer from bulimia nervosa. May you discover liberation and peace of mind, body, and spirit.

ACKNOWLEDGEMENTS

I would like to acknowledge my loving life partner Michael for all of his steadfast support, for feeding me great meals and sustaining me over these long years of study. To my grandchildren, thanks for being patient when grandma couldn't be available.

For my committee Dr. Nancy Coffin Romig and Dr. Pamela Kohlbry, my sincere thanks for their generous and dedicated mentoring and support throughout this graduate project.

I thank Dr. Jean Kristeller for her brilliant work in helping those with eating disorders and supporting me with the conceptual model of my proposal.

I also thank Dr. Lee Hulbert-Williams for granting permission in using the instrument for measuring the study outcomes.

Abstract

of

A MINDFULNESS BASED TREATMENT

FOR WOMEN WITH BULIMIA NERVOSA: A PILOT STUDY

by

Suzanne Kent Nieman

Bulimia Nervosa (BN) is an eating disorder that affects up to 4% of young women in the United States. Men are also affected, but they are outnumbered ten to one by women. The disorder occurs with equal prevalence in all racial and ethnic groups. Suicide risk is high and the mortality rate for bulimia is 0.3%, related not only to suicide but also to serious complications (Harrop and Marlatt, 2010; APA, 2013). The functional consequences can be significant; some individuals have severe role impairment, especially in the social domain (American Psychiatric Association, 2013). In addition, bulimia incurs high direct medical costs along with societal costs related to decreased productivity (Stuhldreher et al., 2012; Crow, et al., 2013). Remission after treatment is no better than 31% to 74%, and relapse is common (Wilson, Grilo & Vitousek, 2007). Current standard treatment interventions such as cognitive behavioral therapy, interpersonal psychotherapy, and medications are unsuccessful in 40-50% of bulimics (American Psychiatric Association, 2010; Proulx, 2008; Wilson et al, 2007). For this reason, exploration of deep mindfulness interventions for eating disorders has been taking place (Hepworth, 2011; Proulx, 2008; Kristeller et al, 1999, 2006, 2011, 2014); however, studies on bulimia are limited by small sample sizes and methodology.

This pilot study will attempt to measure quantitatively the impact of the Mindfulness-Based Eating Awareness Training (MB-EAT) program, originally designed for Binge Eating Disorder, on the eating behaviors of a sample of women affected specifically by Bulimia Nervosa. Two research questions are posed in order to learn these effects: Research Question #1) Does MB-EAT increase mindful eating behaviors? Research Question # 2) Does MB-EAT decrease the number of Binge-Purge cycles per week?

Marrie Clonuc, Committee Chair Nancy C. Romig, DNSc, PMHONS-BC

<u>||-30-15</u> Date

Student: Suzanne Kent Nieman

I certify that this student has met the School of Nursing format requirements, and that this project is suitable for shelving in the Library and credit is to be awarded for the project.

Denis Woren, Graduate Coordinator Dr. Denise Boren

<u>30 November 2015</u> Date

School of Nursing College of Education, Health, and Human Services California State University San Marcos

CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

NURSING

PROJECT TITLE: A Mindfulness-Based Treatment for Women with Bulimia Nervosa

AUTHOR: Suzanne Nieman

DATE OF SUCCESSFUL DEFENSE: August 19, 2015

THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING.

Nancy Coffin Romig, DNSc PROJECT COMMITTEE CHAIR

Pam Kohlbry, PhD PROJECT COMMITTEE MEMBER

Autor 8/19/. DATE 8/19/15 SIQ 8/19/15 DATE

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-	3-449-9052 FAX:		suzkeni@gmail.	com			
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Title	Director, School of Nursing		Title				
Address	333 S. Twin Oaks Valley Road	l	Address				
	San Marcos, CA 92096-0001						
Tel: (76	0)750-7578 FAX:	760-750-3646	Tel:		FAX:		
E-Mail:	dboren@csusm.edu		E-Mail:				
14. APPLIC	CANT ORGANIZATION CERTIFICATION AN		SIGNATURE OF OF			DATE	
accept the o	nts herein are true, complete and accurate to obligation to comply with Public Health Servic	es terms and conditions if a grant	(In ink. "Per" signatu	ire not accepta	ble.)		
	as a result of this application. I am aware that or claims may subject me to criminal, civil, or						
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PROJECT SUMMARY (See instructions):

Bulimia Nervosa (BN) is an eating disorder that affects up to 4% of young women in the United States. Men are also affected, but they are outnumbered ten to one by women. The disorder occurs with equal prevalence in all racial and ethnic groups. Suicide risk is high and the mortality rate for bulimia is 0.3%, related not only to suicide but also to serious complications (Harrop and Marlatt, 2010; APA, 2013). The functional consequences can be significant; some individuals have severe role impairment, especially in the social domain (American Psychiatric Association, 2013). In addition, bulimia incurs high direct medical costs along with societal costs related to decreased productivity (Stuhldreher et al., 2012; Crow, et al., 2013). Remission after treatment is no better than 31% to 74%, and relapse is common (Wilson, Grilo & Vitousek, 2007). Current standard treatment interventions such as cognitive behavioral therapy, interpersonal psychotherapy, and medications are unsuccessful in 40-50% of bulimics (American Psychiatric Association, 2011; Proulx, 2008; Wilson et al, 2007). For this reason, exploration of deep mindfulness interventions for eating disorders has been taking place (Hepworth, 2011; Proulx, 2008; Kristeller et al, 1999, 2006, 2011, 2014); however, studies on bulimia are limited by small sample sizes and methodology.

This pilot study will attempt to measure the impact of the Mindfulness-Based Eating Awareness Training (MB-EAT) program, originally designed for Binge Eating Disorder, on the eating behaviors of a sample of women affected specifically by Bulimia Nervosa. Two research questions are posed in order to learn these effects:

Research Question #1) Does MB-EAT increase mindful eating behaviors?

Research Question # 2) Does MB-EAT decrease the number of Binge-Purge cycles per week?

RELEVANCE (See instructions):

In addition to the study's potential to expand research in a new direction, individual participants may derive considerable benefit, as illustrated in former clinical trials using this program and other similar programs. The qualities of mindfulness they develop may help them decrease or even eradicate the dysfunctional bingeand-purge cycles in which they engage. These mindfulness qualities may permeate other areas of participants' lives, and become permanently embodied in their life practices.

DATICIDANTS TIVES. AND DECOME DEFINATION EMDODIED IN THEIR THE DRACTICES. PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location					
Organizational Name: Sharp Mesa Vis	ta Hospital				
DUNS:					
Street 1: 7850 Vista Hill Ave.			Street 2:		
_{City:} San Diego		County:	San Diego		State: CA
Province:	Country: L	JSA		Zip/Postal	Code: 92123
Project/Performance Site Congressional Distric	cts: 52				
Additional Project/Performance Site Location	on				
Organizational Name:					
DUNS:					
Street 1:			Street 2:		
City:		County:			State:
Province:	Country:			Zip/Postal	Code:
Project/Performance Site Congressional Distric	cts:				
PHS 398 (Rev. 08/12 Approved Through 8/31/2	2015)				OMB No. 0925-0001

Name	eRA Commons User Name	Organization	Role on Project
Nieman, Suzanne		CSUSM	PI
Axman, Linnea		CSUSM	Consultant
Coffin-Romig, Nancy		CSUSM	Committee Chair
Kohlbry, Pamela		CSUSM	Committee
Kristeller, Jean		ISU	Consultant
Kohlbry, Pamela			

SENIOR/KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

OTHER SIGNIFICANT CONTRIBUTORS Name	Organization	Role on Project
Human Embryonic Stem Cells 🛛 No		
If the proposed project involves human embry http://stemcells.nih.gov/research/regi		e registration number of the specific cell line(s) from the following list . Use continuation pages as needed.
If a specific line cannot be referenced at this time	, include a statement that one fror	om the Registry will be used.

Cell Line

The name of the program director/principal investigator must be provided at the top of each printed page and each continuation page.

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Other Biographical Sketches (Not to exceed four pages each – See instructions)		
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10. Vertebrate Animals		
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12. Multiple PD/PI Leadership Plan		
13. Consortium/Contractual Arrangements		
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15. Resource Sharing Plan (s)		;
Appendix (Five identical CDs.)	🔨 Арр	eck if endix is uded

^{*} Follow the page limits for these sections indicated in the application instructions, unless the Funding Opportunity Announcement specifies otherwise.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD	FROM	THROUGH
DIRECT COSTS ONLY	TBD	2 years

List PERSONNEL (Applicant organization only) Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

Enter Dollar Amounts Requested (
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS		TOTAL		
Nieman, Suzanne, RN, MSNc	PD/PI	24				25,000			25,000		
Axman, Linnea	Mentor	24				1,250			1,250		
Coffin-Romig, Nancy	Chairman	24				2,500			2,500		
TBD	Interventionis t	24				15,750			15,750		
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	SUBTOTALS				│ →	60,250		0	60,250		
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BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD	
DIRECT COSTS ONLY	

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD (from Form Page 4)	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: Salary and fringe benefits. Applicant organization only.	60,250	60,250			
CONSULTANT COSTS	625	625			
EQUIPMENT	1,520	0			
SUPPLIES	263	262			
TRAVEL	0	2,240			
INPATIENT CARE COSTS	0	0			
OUTPATIENT CARE COSTS	0	0			
ALTERATIONS AND RENOVATIONS	0	0			
OTHER EXPENSES	2,955	16,300			
DIRECT CONSORTIUM/ CONTRACTUAL COSTS	0	0			
SUBTOTAL DIRECT COSTS (Sum = Item 8a, Face Page)	65,613	79,677			
F&A CONSORTIUM/ CONTRACTUAL COSTS	0	0			
TOTAL DIRECT COSTS	65,613	79,677			
TOTAL DIRECT COSTS FOR	ENTIRE PROPOSE	D PROJECT PERIO	D		\$ 145,290

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Suzanne Nieman, RN, MSN(c) is the principal investigator (PI) for this research study. She is completing a Master's in Nursing at the CSUSM School of Nursing, in the specialty for Psychiatric Mental Health Nurse Practitioner. She has been a registered nurse for over 13 years, focused on maternal-child health, public health and pediatric medical case management. In psychiatric mental health nursing, she has provided direct care to diverse patient populations in both inpatient and outpatient settings. She successfully completed Master's level coursework in Nursing Research and Biostatistics for Advanced Nursing Practice. She utilized quantitative design methods and corresponding data collection and analysis methods in the current study to identify impacts of a mindfulness-based intervention on women struggling with bulimia nervosa. She will be presenting the project to the Institutional Review Boards (IRB) of CSUSM and of the hospital eating disorders program. She will recruit participants for a sample of 65 women, complete all data collection and analysis, collaborate with personnel through team meetings and other means, and provide budget review. Over the two-year duration of the study, the PI will spend approximately 25% of her time devoted to study proceedings. She will be reimbursed \$25,000 per year, totaling \$50,000 for the entire grant period.

The two interventionists will administer the trainings in tandem for the MB-EAT program. They will co-lead groups of 10-15 women in the MB-EAT 12 session program, with a total of 5 groups over 24 months. Prior to facilitating the groups, they will complete the Professional Certification Training in MB-EAT offered by Dr. Jean Kristeller. They will be devoting approximately 5% of their time to complete the training, attend team meetings, and lead groups. They will both be licensed mental health practitioners, either Master's- or Doctoral-prepared. They may practice under the license of a Psychiatric Mental Health Nurse Practitioner, a Licensed Clinical Social Worker, or a Clinical Psychologist. They must each have a substantive mindfulness meditation practice, as well as professional/clinical experience with eating disorders, including bulimia nervosa. They will each be reimbursed for \$31,500 over the 2 year grant period.

MB-EAT Professional Training for interventionists. The 5-day training taught by Dr. Jean Kristeller and Andrea Lieberstein at Esalen Institute is estimated at \$1215 for each facilitator, including standard accommodations. With the addition of gasoline allowance the estimated total would be \$2,730.

Dr. Linnea Axman, DrPH, MSN, FNP-BC, is a lecturer at CSUSM School of Nursing, helping many graduate students with their quantitative data analysis. She has worked for several years as a lead research facilitator and project director at Naval Medical Center San Diego. As a consultant in software data analysis, she will provide mentoring expertise in SPSS 23, supporting the PI throughout the project in analyzing data for demographics and survey results. She will provide 25 hours at \$100 per hour, totaling \$2,500 for the 2 year project.

Dr. Nancy Coffin-Romig, DNSc, PMHCNS-BC, is a tenured associate professor at CSUSM School of Nursing since 2007, and coordinates the Psych FNP specialty program. She also maintains a private therapy practice. She has conducted and published both quantitative and qualitative research focused on domestic violence. Areas of specialty include chronic/acute illness, parenting, relationships, loss, bereavement, and she employs expressive arts, dream analysis, humanistic and Jungian psychotherapy, among other methods. As the primary consultant on this novice project, she will provide leadership and guidance in the IRB process, team meetings, budgeting review and quantitative research methodology. She is Chairman of the project and will provide oversight at \$100 per hour, reaching a total of \$5,000 over the two years.

Dr. Jean Kristeller, Ph.D, is a clinical psychologist with a specialty in clinical health psychology. She is the MB-EAT founder and co-founder of the Center for Mindful Eating. She completed post-doctoral training in eating disorders at McClean Hospital and in Behavioral Medicine and Epidemiology at University of Massachusetts Medical School. She is currently a faculty member and research project director at Indiana State University. She began developing MB-EAT over 15 years ago, drawing on work with Jon Kabat-Zinn's MBSR program and on her research and clinical training in food intake regulation and eating disorders. She recently completed an NIH funded clinical trial for MB-EAT with patients diagnosed with Binge Eating Disorder. She has just received \$1.8 million funding to continue this research from the National Center for Complementary and Alternative Medicine "Mindfulness Meditation: Regulating Eating and Obesity". Dr. Kristeller will be providing 10 hours consultation time by phone to the PI and interventionists at the rate of \$125 per hour, for a total of \$1,250 over the entire project.

Research Related Equipment and Supplies

IBM SPSS 23 Statistics Software, 12 mos support & SW subscription. The SPSS 23 Statistics Base Software will be utilized to analyze data related to coding of demographic variables, length of time diagnosed with bulimia, length of time of treatment and type of treatment, and comorbid diagnoses. It will facilitate the matching up of demographic data with corresponding data from surveys. The estimated cost of IBM SPSS 23 Statistics Base package is \$2850 for the entire 24 month period.

Digital Audio Recorder. A digital audio recorder will be utilized for each MB-EAT program session for quality control and monitoring purposes to ensure uniformity and continuity throughout the 2 years. This will include a

head-set and microphone. Estimated cost of this equipment is \$110.

Laptop computer and dedicated printer. A moderately-priced laptop computer and printer will be required for a variety of research correspondence, recruitment of sample, data storage, data analysis, and production of reports. The laptop's estimated cost is \$1410; the printer cost is \$110. This brings the combined cost to \$1520 for the entire grant period.

General office supplies. Printer/copy paper will be required for recruitment flyers, consent forms, correspondence, surveys, program hand-outs, and study reports. Estimated costs for multi-use paper is \$47/case x 8 cases over the 2 year period for \$376. Printer replacement ink will be needed for all printing pieces. Estimated cost over the two year period is \$125 total. Add-on costs for miscellaneous office supplies such as stapling supplies (\$24)will bring the estimated total to \$525.

Other Expenses

Copier costs. Recruitment flyers, consent forms, program hand-outs for participants, progress reports and small research posters for conference participants are estimated at a total of \$100.

Postal expenses. Postage will be required for various correspondence among investigative team, submission of reports, and communication with conference supervisory committees. Estimation of cost is \$125 for total grant period.

Compensation for Participants: Each participant who completes all the trainings, including every survey will be awarded with a gift card of their choice valuing \$250. The total for 65 participants, a generous estimate of the number who will complete the study, comes to \$16,250.

Graphic Media Services. For dissemination of findings at one conference in the second year, a 36" x 48" wall poster will be utilized. Total cost of the creation of this poster is \$50.

Travel for Dissemination of Findings. In year two, the PI (Principal Investigator) will present study findings at a national nursing conference (APNA). The conference registration fee, airfare, hotel and meals bring the estimated total cost to \$2,240.

Total Expenses for the 2 year budget proposal is \$145,290.

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015) Page 8

Continuation Format Page

Specific Aims

Bulimia Nervosa (BN) is an eating disorder that affects up to 4% of young women in the United States. Men are also affected, but they are outnumbered ten to one by women. The disorder occurs with equal prevalence in all racial and ethnic groups. Suicide risk is high and the mortality rate for bulimia is 0.3%, related not only to suicide but also to serious complications (Harrop and Marlatt, 2010; APA, 2013). The functional consequences can be significant; some individuals have severe role impairment, especially in the social domain (American Psychiatric Association, 2013). In addition, bulimia incurs high direct medical costs along with societal costs related to decreased productivity (Stuhldreher et al., 2012; Crow, et al., 2013).

Multiple comorbidities are associated with bulimia, including mood and anxiety disorders, substance abuse, impulse control disorders and personality disorders. Nearly 95% of all respondents to the National Comorbidity Survey Replication who were diagnosed with BN also met criteria for at least one of the above DSM-IV disorders (Hudson, Hiripi, Pope & Kessler, 2007). The compulsivity, secrecy and guilt associated with bulimic behaviors also gradually replace normal pleasures and interpersonal relationships, constricting psychological growth and development of a genuine self (Proulx, 2008). Remission after treatment is no better than 31% to 74%, and relapse is common (Wilson, Grilo & Vitousek, 2007). Current standard treatment interventions such as cognitive behavioral therapy, interpersonal psychotherapy, and medications are unsuccessful in 40-50% of bulimics (American Psychiatric Association, 2010; Proulx, 2008; Wilson et al, 2007). This failing has ushered in a new paradigm of mindfulness-based approaches to eating disorders. One program in particular, Mindfulness-based Eating Awareness Training (MB-EAT) has shown considerable efficacy in the treatment of Binge Eating Disorder (Kristeller & Hallet, 1999; Kristeller, Baer, & Quillian-Wolever, 2006; Kristeller & Wolever, 2011; Kristeller, Wolever & Sheets, 2014).

Purpose: This quantitative pilot study will evaluate the effectiveness of the Mindfulness-based Eating Awareness Training (MB-EAT) in the treatment of women diagnosed with Bulimia Nervosa, specifically its impact on eating behaviors. It will utilize two measurement tools for the accomplishment of two aims: **Specific Aim #1:** Measure the degree of mindfulness related to eating behaviors before and after the MB-EAT intervention.

Specific Aim #2: Measure the change in Binge & Purge cycles weekly throughout the 18 week study.

Background and Significance

The new diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-V) distinguish bulimia nervosa from other eating disorders. It is first characterized by recurrent episodes of *binge eating*, defined by eating (within any 2-hour period) an amount of food that is significantly larger than what most persons would consume in a comparable time period under comparable circumstances.

Accompanying these episodes is a sense of not having control over how much one eats. Furthermore, the person has recurrent inappropriate behaviors to compensate for overeating and to prevent weight gain: self-induced vomiting, fasting or excessive exercise, and misuse of laxatives, diuretics or other medications. Medical complications associated with these behaviors include: fluid and electrolyte imbalances resulting from purging, and menstrual irregularity or amenorrhea, possibly related to nutritional deficiencies, weight fluctuations, and emotional distress. Also reported is erosion of dental enamel, gastrointestinal symptoms such as laxative dependence, and rectal prolapse. Potentially fatal complications include: esophageal tears, gastric rupture, and cardiac arrhythmias. The binging and compensatory behaviors both occur at least weekly for at least 3 months. Compounding these behaviors is a tendency to evaluate oneself unduly in terms of weight and body shape. During binges, individuals tend to eat foods they would normally avoid. Levels of severity are assigned according to the number of episodes of inappropriate compensatory behaviors

per week (American Psychiatric Association, 2006, 2013).

There are two conceptual models from which this proposal is drawn. The original model is Mindfulness-Based Stress Reduction (MBSR), a secularization of Buddhist meditation practices developed by Jon-Kabat-Zinn and colleagues at the University of Massachusetts Medical Center in 1979, to relieve the suffering of patients with chronic pain, anxiety, depression and other chronic disease states. The second model is the Mindfulness-based Eating Awareness Training (MB-EAT), which springs from MBSR and was adapted throughout a series of studies with patients affected by Binge Eating Disorder.

An operational working definition of mindfulness as described by Jon Kabat-Zinn, the founder of Mindfulness Based Stress Reduction, is "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" (Kabat-Zinn, 2003, p. 145). Mindfulness, which has historically been called 'the heart' of Buddhist meditation, is the origin of MBSR. Kabat-Zinn described the 7 factors forming the attitudinal foundation of mindfulness practice. They are (1) Non-judging, (2) Patience, (3) Beginner's Mind, (4) Trust, (5) Non-striving, (6) Acceptance, and (7) Letting Go. Also essential are a strong commitment to working on oneself and enough self-discipline to persevere in the process. Though these are perhaps not difficult concepts to understand, they are more difficult to cultivate as a lifetime practice. However, the teaching and learning of this process has proven to be quite popular, as evidenced by the now over 834 programs operating worldwide, and the fact that more than 20,000 laypeople have completed MBSR courses at the Center for Mindfulness in Massachusetts since 1979 (Center for Mindfulness, U of Mass).

The Mindfulness-based Stress Reduction program features didactic and experiential training in a small group format, using meditation, simple yoga postures, and the body scan. According to Kabat-Zinn, "the experience of wholeness transcending your problems comes naturally out of regular practice of the body scan. It is nurtured every time you breathe out from a particular region and let it go" (1990, p. 77-78). All thoughts are considered equal, without attaching importance, and always returning to the breath as the major focus of observation. The aim is not to cure people of their illnesses, but to help them access their deep inner resources for healing, calming the mind, operating more effectively in the world, coping with stress, feeling better about their bodies, and feeling more engaged in life. Kabat-Zinn discussed the therapeutic benefits of doing such intensive training within a group. People are allowed to listen to one others' difficulties with the meditation practice, and learn from one another, with a focus on what's right, rather than what's wrong. He has emphasized that MBSR is offered as a complement to medical treatment, not a substitute (Moyers, 1993).

The burgeoning interest in mindfulness applications in health care is far-reaching and has significant bearing on advanced nursing practice. Psychiatric nurses who work in the field of eating disorders and/or addictions treatment may be particularly interested, as therapies using mindfulness practice are showing efficacy in these areas (Courbasson, Nishikawa, and Shapira, 2011; Daubenmier, J., et al, 2011; Wanden-Berghe, Sanz-Valero, and Wanden-Berghe, 2011; Witkiewitz and Bowen, 2010; Witkiewitz, Bowen, Douglas, and Hsu, 2013). Since the 1980s there has been ongoing research into mindfulness meditation practices in the health care setting. Opportunities may be created for psychiatric mental health NPs or CNSs to be involved in furthering this research and clinical practice.

The Institute of Medicine's 2011 report "The Future of Nursing: leading Change, Advancing Health" made a compelling case for nursing professionals to act as leaders in redesigning health care in the U.S. Citing facts such that nurses represent the largest segment of the health care workforce, their regular close proximity to patients, and their understanding of care processes across the continuum of care, the report holds that nurses should act as full partners with physicians and other health professionals in improving the practice environment and care delivery systems. Inclusive in the report is acknowledgment of the nursing

tradition's holistic practice of attending to patients' and their families' physical, social, mental and spiritual needs. A further requirement for transforming the healthcare system is that nurses call on their capacity as leaders to take on reconceptualized roles in new settings, continually reeducating themselves to adapt (Institute of Medicine, 2011). The use of mindfulness-based interventions has become widespread in health care as evidence-based practice. Advanced practice nurses in particular can be excellent resources in disseminating these holistic interventions, as they embrace effective strategies to educate and empower patients in applications of sustaining self care.

The notion of 'patient-centered care' has been intensely reviewed in health care literature for more than a decade, particularly since the IOM's Committee on Quality of Health Care made recommendations for public policy. One of the aims discussed for the fundamental redesigning of the flawed health care system was patient-centered care, though definitions of this quality and its implementation have varied greatly (Berwick, 2009; Grob, 2013). Defining attributes of patient-centered care that are widely agreed upon include: power (in relationships between health care providers and patients), shared decision-making, patient autonomy, the caring attitude of the provider, and individualizing patient care. One of the essential aspects of teaching mindfulness practices to patients is the cultivation of patient autonomy. It is empowering for patients to learn practices that reduce the stress of anxiety and depression, and to cope more effectively with illness and life's difficulties in general. Another aspect of mindfulness interventions is individualized care: in the creation of a protected healing environment, individual patients' needs are attended to as they learn new ways of experiencing their thoughts, feelings and sensations, and new healing modalities. The Veteran's Health Administration's Office of Patient Centered Care and Cultural Transformation is currently studying the use of MBSR in the treatment of veterans with PTSD. This is another example of the change of approach from a disease-centered model to a patient-centered model, understanding that "the doorways to healing are very often the heart and soul of an individual" (Gaudet, 2014).

MBSR has proven benefits for people suffering from chronic pain, anxiety, and depression associated with chronic illness (Kabat-Zinn, 2003). Praissman (2007) and Proulx (2003) cited several studies that demonstrated increased coping and empathy among healthcare professionals after completion of a MBSR program. This assisted them in the development of positive relationships with patients. Health care professionals with increased self-awareness are in a position to cultivate an authentic therapeutic alliance with each patient, as they are better able to be fully present in their care of patients. Professionals in clinical practice or research with eating disorders can gain increased insight into the psychosocial dimensions of these complex diseases.

Literature Review

Beginning in 1982 with Kabat-Zinn's research on the effects of MBSR in pain management, there have been many studies of its application to other chronic conditions, including cancer, heart disease, rheumatoid arthritis, fibromyalgia, solid organ transplant, severe psoriasis, HIV, diabetes, depression, anxiety and PTSD (Proulx, 2003; Marchand, 2012). Most of these studies have been quantitative, some limited by small sample sizes and lack of a randomized control group. Marchand's (2012) comparative review of the literature on Zen meditation, MBSR, and Mindfulness-Based Cognitive Therapy (MBCT) for depression, anxiety, pain and psychological distress is particularly enlightening for those wanting evidence for the use of mindfulness interventions in eating disorders, as these conditions parallel the co-morbidities of eating disorders. Marchand (2012) recommends MBSR as adjunctive treatment for anxiety symptoms, depression, PTSD, Social Anxiety Disorder, pain tolerance and general psychological functioning. He lists caveats. He advises against using it as monotherapy, except for psychological health and stress management in healthy individuals. Also, patients must be relatively enthusiastic about trying this approach, since the level of commitment to ongoing meditation practice is related to outcomes. Segal, Williams, and Teasdale (2002) developed a mindfulness-based cognitive treatment (MBCT) intervention blending the skills of

mindfulness practice with cognitive therapy to prevent relapse of unipolar depression. MBCT teaches recognition of mood deterioration with a goal of disengagement from self-perpetuating patterns of negative ruminations that lead to relapse. In the last decade researchers at the University of Washington have studied the effects of mindfulness and meditation on substance use and relapse (Mindfulness-based Relapse Prevention research). The late Alan Marlatt led this effort in developing Mindfulness-Based Relapse Prevention (MBRP), an outpatient program integrating skills from cognitive behavioral relapse prevention and mindfulness meditation practices to treat addictions. Ongoing treatment for eating disorders may find a good fit in MBRP, since eating disorders are essentially addictive behaviors, and as such, heavily prone to relapse. The schematic below is borrowed with permission from Sarah Bowen, a MBRP clinician and researcher at the University of Washington (S. Bowen, personal communication, November 17, 2013) and illustrates the foundational process underlying MBSR and its various adaptations (MBCT, MBRP, MB-EAT). It shows the progressive nature of the trainings, moving from awareness of the tangible, external environment to awareness of sensation in the body, to awareness of thoughts and emotions (intangible) to the point where a practitioner can experience compassion and respond skillfully to the moment, and then ultimately to a sense of freedom from cognitive and behavioral patterns that perpetuate addiction, or the addictive behaviors of bulimia. More specifically, the initial stage of becoming aware of the tangible is exemplified in the raisin-eating exercise, a playful way to introduce participants to awareness practice by using all of their senses to experience the raisin before they actually eat it. The body scan moves participants into the next more subtle stage of becoming aware of breath and body sensations. Teaching the sitting meditation directs participants to ever more subtle awareness of intangibles: thoughts and emotions and their nature. With more practice in meditation, acceptance and curiosity towards craving can grow, to build skills in self-compassion and ability to respond in new ways to cravings.



Progressive Training

Figure 1. Progressive Training (Reproduced by permission from Sarah Bowen, UW, Addictive Behaviors Research Center, 2013).

Other authors (Wilson et al., 2007; DeSole, 2011; Wanden-Berge, Sanz-Valero, & Wanden-Berge, 2011) also discuss the recent paradigm shift in the treatment of eating disorders, away from thought-driven therapies include Acceptance and Commitment Therapy (ACT) and Mindfulness-Based Cognitive Therapy

(MCBT), as well as Dialectical Behavior Therapy (DBT). They are rooted in research in affective analysis models like CBT (Cognitive Behavioral Therapy) and IPT (Interpersonal Psychotherapy) to multidisciplinary models that incorporate mindfulness and body-centered processes. These "third wave" neuroscience and developmental psychobiology, which has deepened awareness of how body and brain work together in developing, manifesting, and treating eating disorders as well as substance abuse. The remainder of the literature presented will now focus on mindfulness treatments specifically developed in recent years for eating disorders.

Proulx (2008) conducted a phenomenological study with six women who had been diagnosed with bulimia. The purpose was to deepen understanding of how bulimic women experience an MBSR group adapted specifically to their needs, called M-BED (Mindfulness-based Eating Disorders). Proulx as both researcher and therapist conducted initial one-on-one interviews with each participant. Participants created a self-portrait with the art medium of their choice. The group experience consisted of eight 2-hour sessions led by the researcher. Each session had four components, including experiential meditation practice, psychoeducation, discussion, and then home practice. Participants used CDs created by the researcher for guidance in 10- or 30-minute body scans and seated meditation for home practice. Participants also gradually progressed from eating one meal mindfully during the first week to an eventual 7 mindful meals during the final week, using a mini-meditation before meals and as needed to raise self-awareness and lower anxiety. Psychoeducation addressed the mind-body connection, stress-reaction cycle, the value of selfawareness in recognizing triggers of stress that lead to binging and purging, relationships with others and their impact on identity, self-worth and stress levels. All of the components of traditional MBSR are there along with teachings and practices specific to address the bulimic experience. Following the M-BED training, participants were audiotaped individually to learn of their lived experiences, particularly in what ways they may have been affected in self-awareness, impulse control and affect regulation. They again created self-portraits, which contrasted sharply with the initial artwork. Noting the gap in prior studies of examining the concept of intentionality, which is central to MBSR and phenomenology, participants explored how they experienced the mindful intentions of self-compassion, nonjudgment, acceptance and loving kindness during and after the group. Proulx describes for the participants "a journey that began from a lonely, hate-filled relationship with a totally disconnected, disembodied, idealized, objectified image of self. to a relationship with the self that was curious, interested, aware, open, gentler, kinder, and more authentic" (2008, p. 69). Connecting with their inner self enabled the participants to care deeply for one another, and diminished their sense of isolation.

One limitation expressed by the researcher was that the concurrent individual psychotherapy that was ongoing for participants made it impossible to tease out the specific effects of the M-BED group. However, the value of having concurrent psychotherapy should not be minimized. Proulx also noted that inasmuch as the M-BED group is a structured intervention, it is essential for the facilitator to have ample clinical experience to "know when to let go of that structure, be in the moment, and allow process to unfold" (2008, p. 70).

Hepworth (2011) in Australia used a Mindful Eating Group to explore potential benefits as an adjunct to long-term treatment for a variety of eating disorders. The 10-week manualized program was designed by practitioners in an outpatient private clinic. Participants responded to an invitation by mail from the *Mindful Eating* program coordinators. They were 33 women ranging in age from 18-30 years, whose standard treatment included regular meetings with a psychologist and a dietician, along with monitoring by a medically trained professional. Only 10 of the total participants were diagnosed with bulimia. The other 23 participants were diagnosed either with anorexia nervosa (17) or EDNOS-Eating Disorder Not Otherwise Specified (6).

The average length of time suffering from eating problems was 4.28 years, and average length of treatment was 11.12 months. The majority reported experience of comorbid psychiatric problems with

depression the most frequent, followed by a combination of depression and anxiety and anxiety disorders. Six closed groups conducted over an 18-month period contained 5-8 participants. A trained psychologist and a dietician conducted the groups. Of the participants, 30.3% met criteria for bulimia, 51.5% for anorexia, and 18.2% for Eating Disorder Not Otherwise Specified. The instrument of measure was the Eating Attitudes Test-26 (EAT-26, 1982), administered prior to start of the group, and post completion. Results demonstrated significant reductions in avoidance of foods and a desire to be thin. Limitations were acknowledged. One was the fact that there was no control group to clarify whether improvements were a result of the mindfulness intervention or other variables such as being part of longer-term treatment, or just to normal improvement over time (maturation). Another limitation was that the study did not include a follow-up to ascertain whether the improvements identified were sustained over time. In addition, only 10 participants diagnosed with bulimia is a very small sample from which to draw generalizations. However, a novel result was that there were no significant differences in change scores between the different eating disorder diagnoses, suggesting that mindfulness interventions can broaden their scope to include all the eating disorder subtypes (Hepworth, 2011). Though that outcome is helpful in planning further research and treatment, the mixed diagnosis sample makes specific outcomes for bulimia difficult to follow.

Kristeller and Hallet (1999) published the first exploratory study integrating elements from MBSR and CBT with guided eating meditations specifically for binge eating disorder (BED). This intervention was named Mindfulness-based Eating Awareness Training (MB-EAT). Central to this program are the concepts of self-acceptance and emergent "wisdom", which are core elements of traditional meditation practice. It is only with self-acceptance, compassion and forgiveness that the dysfunctional cycles of binging, selfrecrimination and over-restraint can be interrupted. "Mindfulness meditation is further used to cultivate the capacity to disengage undesirable reactivity, and to engage processes that can more wisely inform behavior" (Kristeller & Wolever, 2011, p. 51). The first MB-EAT study was a non-randomized, extended baseline/follow-up design in 1999 with a completed sample of 18 obese women with BED. They participated in a 7-session group program over 6 weeks. Binges per week dropped from over 4 to about 1.5. Amount of food consumed during residual binging decreased substantially, yet four women still met diagnostic criteria for BED at 1-month follow-up. The instrument used for self-report was the Binge Eating Scale and scores fell from the 'severe' range to just over having 'little or no problem' with binge eating. Depression also dropped from clinical to subclinical levels, although they do not report how depression was measured. Awareness of satiety cues improved, and this was significantly correlated with a reduction in number of binges reported.

Kristeller, Wolever and Sheets (2014) subsequently undertook an NIH-funded randomized controlled trial with a larger sample (N=85 completed), similar to the first but which also included 15% men. Participants were randomized to the MB-EAT group, to a psychoeducational (PE) treatment, or to a wait-list control group, with follow-up at 1 and 4 months. The treatment components were somewhat revised and expanded, and the sessions increased from 7 to 9. Mindfulness of satiety was separated into two sessions: taste awareness and fullness awareness, and a session was added that included a wisdom meditation. The PE group received educational materials from the renowned obesity treatment program at the Duke Diet and Fitness Center. The MB-EAT and PE groups showed somewhat comparable improvements in behavior and on the Binge Eating Scale, but the MB-EAT group showed significantly better scores on the Disinhibition Scale of the Stunkard and Messick Eating Inventory of 1985, a marker of greater internalization of change. Kristeller had completed another trial in 2011 with only preliminary results published with BED participants, expanding the recruitment to include participants with a BMI of at least 35. The treatment was increased to 10 sessions with two follow-up sessions. Additional components address "outer wisdom" specific to nutritional and caloric guidelines, with "inner wisdom" themes of hunger, satiety and choice awareness remaining unchanged. Improvement on key variables appears comparable with previous research. The

authors recommend further work using MB-EAT being adapted for weight loss, as well as for bulimia and anorexia nervosa (Kristeller & Wolever, 2011).

Research Design and Methods

Conceptual Framework

As discussed in the literature review, the MB-EAT program is designed to "cultivate awareness of both inner and outer triggers to eating; interrupt dysfunctional cycles of binging, self-recrimination, and over-restraint; and re-engage natural physiological processes of eating regulation" (Kristeller, 2015, p. 203). In this process, the pleasurable and nurturing capacities of eating are also emphasized. The process of cultivating mindfulness (Figure 2) occurs in four stages: 1) Cultivating nonjudgmental awareness; 2) Cultivating the capacity to interrupt reactivity and mindless choice; 3) Awareness of alternatives and development of mindful eating; and 4) Access to "wiser"/novel responses.

The top half of the figure (A) is representative of the conditioned cycle of dysfunctional eating. Starting with **Stage 1**. Awareness of Triggers, it uses an example common to binging (Trigger "X"): coming home from work, feeling stressed and overly hungry, seeing a box of tempting cookies, intending to eat just two but ending up eating the entire box (reaction "Y"). Over time, the repeated experience of a situation like Trigger "X" leading to an out of control and automatic Reaction "Y" can cause a person to feel helpless and distressed. However, by practicing mindfulness, the person develops awareness of the triggers (certain feelings, thoughts, foods), which can be quite complex.

Stage 2 emerges (also in the top half of the figure) represented by the arrows (mindfulness) penetrating awareness. The person starts to notice a lessening compulsion to react the same way to the set of triggers (2a). The cycle of conditioned reactivity is interrupted (2b).

In the bottom half of the figure (B), **Stage 3** brings a change in perception of the strength of both triggers and reaction: they are smaller and weaker. Triggers may still be present, but their strength and the reinforcement cycle have decreased. In contrast, the arrows of mindfulness toward both triggers (X) and responses (Y) are larger and stronger, as the person learns to observe these habitual patterns in a nonjudgmental way. S(he) gains awareness of alternative responses (circles A and B) to trigger situations (3a), such as calling a friend when stressed. Mindful eating responses become available (3b), represented by circles C and D, as the person is able to engage the old response system (eat for comfort), but in better balance. By cultivating mindful awareness of food choice and cues of physical hunger, satiety and taste satisfaction, gradually the uncontrolled reactivity shifts into balanced response to choices. Mindfulness appears to more fully engage neural networks, thus novel responses emerge into consciousness (**Stage 4**). These "wiser" insights can occur during sitting meditation or in a moment while eating, not as solutions offered by others, but growing out of personal experience (Kristeller, 2015).



Fig. 15.1 Mindfulness practice and mindful eating: moving from awareness (A) to wise choice (B)

Figure 2. Kristeller (2015) Mindfulness, Eating Disorders, and Food Intake Regulation. In B.D. Ostafin, M.D. Robinson, & B.P. Meier (Eds.), *Handbook of Mindfulness and Self-Regulation* (p. 204)

Design

The aim of this pilot study is to determine the effects of the manualized MB-EAT program applied to a sample population of women diagnosed with bulimia nervosa, specifically to understand the impact on eating and purging behaviors.

Two research questions are posed in order to learn these effects:

1) Does MB-EAT increase mindful eating behaviors? And 2) Does MB-EAT decrease the number of Binge-Purge cycles per week?

This is a nonrandomized quasi-experimental, prospective repeated measures design, using one group with pre-test and post-test measures, illustrated by the following schematic:

$$O_1 X O_2$$

This design is a logical choice for the research question of "what is the impact of a MB-EAT group intervention (**X**) on mindful eating behaviors and binge-purge cycles in bulimic women? The dependent variables/outcomes (mindful eating behaviors as measured by MES and # of binge-purge cycles) are measured prior to the training (**O**₁) and again two months following the training (**O**₂)?" One limitation identified with this proposed design is that a quantitative design is limited in capacity for understanding the essences and subtleties of phenomena such as mindfulness and bulimia. Self-report tools such as the MES are limited in scope.

Sample/Sampling Plan

A nonprobability method of sampling will be followed, with a purposive convenience sample recruited from women diagnosed with bulimia nervosa from an intensive outpatient eating disorders clinic. According to G* Power Analysis version 3.1.7 (Faul, Erdfelder, Lang, & Buchner, 2009), a sample size of 51 was initially determined to meet the need for a power of .80 and an effect size of 0.30. To account for average attrition, 20% is added to make the final sample size 61. A total of 61 participants will be recruited, unless the distribution is skewed; in that case a Wilcoxon Matched-Pairs Signed Rank will be used, and the sample size will be slightly higher at 65. Sample size had to be larger than originally anticipated, based on the decision to use a 2-tailed paired t test with no directional hypothesis. The alpha level of .10 is appropriate for a pilot study.





A limit to generalizability is that this sample includes only women, thus it is unknown if the results can be generalized to the male population, or to a transgender population. It is also only testing women with a diagnosis of bulimia, therefore there is no assurance that results can be generalized to other eating disorder diagnoses, although it has already been tested in samples with Binge Eating Disorder with good results. The sample size itself (n=61) seems adequate, especially for a pilot study.

Inclusion criteria are (1) adult women age 18-39 diagnosed with bulimia nervosa, (2) English is the primary language; (3) full participation in the manualized 12 -session group intervention led

by a clinician experienced in eating disorders who has taken the professional MB-EAT training, (4) concurrent individual psychotherapy not focused on eating issues, and (5) a physical exam within past year and relationship with a primary care provider. Exclusion criteria are: (1) previous regular meditation practice, and (2) comorbid diagnosis of Schizophrenia, Dissociative Personality Disorder, or substance abuse, or another chronic medical condition that may make participation in the entire program too difficult; and (3) pregnant or breastfeeding women.

Setting

The setting chosen will be a local adult intensive outpatient program for individuals with Bulimia Nervosa who need more structure and supervision that can be provided in an outpatient program setting. These individuals are medically stable enough to not require hospitalization, and in some cases, are "stepping down" from an inpatient/residential setting, and need help generalizing skills to an outpatient environment. This outpatient clinic offers the standard care, including medical exams, medication (usually antidepressants), appropriate lab work, nutrition assessment and counseling, body-image counseling, individual and family therapy based on models of CBT or IPT (not mindfulness-based models). The MB-EAT would replace any other group offered as adjunctive therapy, and be led by an experienced eating disorders clinician professionally trained in the MB-EAT program.

Data Collection

IRB approval will be obtained from the University and selected eating disorders program. The program manager for the adult intensive outpatient program will then be contacted via cover letter for permission to recruit participants. Once permission is granted, the principal investigator (PI) will make one or more visits to the program site at a time when potential participants are available to congregate in a brief meeting. The PI will introduce the study goals, benefits, and process. Recruitment flyers to be distributed at the meeting will include an explanation on informed consent and the PI's contact information (Appendix A). Letters to the therapy team will also be submitted to request assistance in recruiting participants. If a face-toface group meeting is not practical or permitted, the PI will request permission to place recruitment flyers in the program site and in any newsletter published for patients. The flyer will invite responses by phone or email. If the informational meeting takes place, interested patients may sign up at that time for a telephone interview. Initial phone interviews will be conducted as potential recruits respond to solicitation for the study. Screening for inclusion criteria will be done in the interview. Potential participants who meet inclusion criteria will be invited to an orientation meeting scheduled within the same month. At the orientation meeting, the PI will provide further information about the study's program content and specific requirements for participants. Any concerns that participants with religious affiliations may have regarding a meditation-based intervention will be addressed at this time. Participants will be assured that their personal spiritual practice will not be compromised by the intervention. The PI will distribute consent forms (Appendix B) and answer participants' questions regarding study participation. Once consent forms have been signed and collected, participants will complete the demographic data forms (Demographic Survey, Appendix C). Numeric coding will be utilized for the variables of age, race/ethnicity, level of education, length of time diagnosed with bulimia, type of treatment utilized for bulimia, length of treatment time, and any comorbid diagnoses. Each of the demographic forms will be assigned a number, to be matched with upcoming surveys. At the start of session one and the final session, participants will be asked to complete the initial Mindful Eating Scale (MES) via pen and paper. The initial questionnaire regarding the number of

binge-purge episodes (B/P survey) experienced by clients in the previous week will also be administered via paper and pen at the start of the first MB-EAT session, and at each subsequent session, including the follow-ups, by the principal investigator. This B/P survey consists of the single question: "What is the total number of binge/purge cycles you experienced over the past week?"

The study will be conducted over a 2-year period, since the sample size of (n=65) would require 5 groups to keep the MB-EAT group sizes at 10 to 15 participants. The trainings will be conducted sequentially over 18 week periods (10 weekly sessions, with follow-up sessions at one and two months). Sessions meet weekly for 2.5 hours. The Mindful Eating Scale will be administered via paper and pen preceding the first session of the program, and again at the second monthly follow-up session. Identifying variables will be age, race/ethnicity, educational level, length of time diagnosed with bulimia, length of treatment, type of treatment, and co-morbid diagnoses. Gender is limited to women in this study, so it will not be entered as a variable. All participants will be listed and coded by assigned ID numbers, in order to protect confidentiality. Paper records will be stored in a locked secure file drawer. No names or addresses will be given by participants for initiation into study and follow-up, and this information will not be associated with any of the surveys completed by participants.

Coding and Scoring

The Instruments: Mindful Eating Scale and Binge/Purge Survey. While the general focus on studies involving mindfulness interventions has been on participant outcomes, much less work has been published regarding the processes that underlie improvements. The question is "how does one measure mindfulness"? A number of psychometric self-report scales for mindfulness have been developed over the years for this and are widely used in research and clinical applications. Most scales do not address mindfulness in particular domains of behavior, but some have been developed. A new instrument still in developmental stages shows more promise with regard to true congruence with standard theoretical definitions of mindfulness. Called the Mindful Eating Scale, its developers state that the previously developed Mindful Eating Ouestionnaire does not agree well with accepted definitions of mindfulness such as that of Kabat-Zinn's and has a factor structure very different from those of generic mindfulness measures (Hulbert-Williams, Nicholls, Joy & Hulbert-Williams, 2013). The Mindful Eating Scale is a domain-specific psychometric measure of eating-related mindfulness that pooled together items from a few well-reputed generic mindfulness measures and edited them to be specific to eating. The authors state that it is important to explore further the structure of mindfulness in this domain-specific manner since recent research shows that certain sub-components of mindfulness might especially impact certain types of eating behaviors and disorders. According to Hulbert-Williams and colleagues, all mainstream definitions of mindfulness include at the very minimum, attention to, and non-judgmental acceptance of present-moment experiences. Furthermore, many of the generic mindfulness measures have undergone factor analysis, which is used to discover latent structure in complex mental phenomena, resulting in a variable number of subscales. Regardless of the precise number of components, all include an attention/awareness component and a nonjudgment/acceptance component. The researchers pooled items from three well-developed mindfulness scales, adapted them to reference eating behaviors such as hunger and satiety, and subjected the resulting pool to an exploratory factor analysis. The two specific goals were that (1) the new scale should include subscales that measure at least the central features agreed upon for mindfulness: attention and non-judgment; and (2) it should be better aligned with subcomponents of generic mindfulness scales. The two are considered important if the scale is to assist in development of targeted intervention studies and manualized treatment with minimal redundancy.

The original draft Mindful Eating Scale had 74 items pooled from the three extant measures that all claimed sound internal reliability. These were eventually reduced to 28 in the interest of brevity, while retaining the highest possible internal consistency. This reduction process did lead to minor changes in Cronbach's alpha; five of the six subscales have good internal consistency (alphas .75 or higher). The subscale of Unstructured Eating has an alpha of .60 and is still being worked on. The instrument provides for self-report on a four-point Likert scale from (1) never to (4) usually. The six subscales are Acceptance, Awareness, Non-reactivity, Routine, Distractibility, and Unstructured Eating. All subscales are scored so that higher scores reflect a more mindful or intuitive eating style. Many items are reverse-scored, and several subscales are made up entirely of negatively worded items; evidently these items produced responses with greater variance and created more coherent subscales (Hulbert-Williams, et al, 2013). See Appendix D for a sample of the Scoring Key and instructions of the MES, as well as an adaptation of the instrument itself.

The authors of the MES are continuing to work on confirming the psychometric properties of the tool, and hope that it may become useful in the clinical setting to monitor development of mindfulness skills in clients, providing therapists and teachers a guide for experiential work in areas that need progress (Hulbert-Williams et al, 2013).

Factor 1 (*Acceptance*), is seen on questions 7, 8, 11, 16, 23, and 28 for a total possible range of score of 6 to 24. Factor 2 (*Awareness*) is on questions 13, 15, 17, 18 and 26 for a total range of scores from 5 to 20. Factor 3 (*Nonreactivity*) is on questions 1, 5, 6, 9, and 21 for a total range of scores from 5 to 20. Factor 4 is *Routine* on questions 10, 12, 19, and 22 for a range of scores from 4 to 16. Factor 5 is *Distractibility* on questions 2, 4, 14, and 25 for a range of scores from 4 to 16 as well. The 6th factor is *Unstructured* (and should be getting discarded in the confirmatory factor analysis, per the author) on questions 3, 20, 24, and 27, for a range of scores from 4 to 16. The total possible score from each participant is the sum of answers to each of the 28 questions for a total possible score of 28 to 112.

The same ID number for each participant assigned to the MES will also be assigned to the Binge-Purge (B/P) surveys that are collected at weekly intervals throughout the study. These scores will be paired together. A total of 14 surveys will be collected from each participant, coded with each participant's number: the pre- and post-MES, and the B/P questionnaire, collected on a weekly basis preceding the 10 sessions and at two follow-up sessions. The 12 B/P Surveys (Appendix E) collected will be scored with the number of binge/purge cycles listed by each participant.

Data Analysis

IBM SPSS 23 Statistics Base software will be used for the data analysis. The analyses will include descriptive statistics using frequency distributions of all sample demographic variables. A paired t test to compare the means in the outcome variables will be used if the two outcome measures are normally distributed, or not too skewed. The measurement scale for the MES Likert scale is considered interval for purposes of this study, though theoretically is considered ordinal. According to Polit & Beck (2012), many analysts believe that treating Likert scales as interval measures results in too few errors to warrant using the less powerful ordinal scale. Plichta & Kelvin (2013) agree, stating "it is usually best to gather data at the highest level of measurement for research variables because this permits the researcher to perform more mathematical operations and gain greater precision in measurement" (p. 25). If the distribution for variables is not normal, a Wilcoxon Matched-Pairs Signed Rank Test will be performed. Psychometric analysis on the MES included Cronbach's alpha for the factor analysis (Hulbert-Williams et al, 2013). The alpha level will be set at .10, as is customary and acceptable for a pilot study. Demographic characteristics will be entered in appropriate scales, i.e., age, years since diagnosis, and length of treatment for bulimia all on a ratio scale; ethnicity, type of treatment for bulimia, and co-morbid diagnoses all on a nominal scale, and level of education on an ordinal scale.

Summary of Intervention

This is a pilot study with the aim of understanding more about mindful eating behavioral change as well as frequency of binge eating and purging behaviors in women with bulimia after participating in a Mindfulness-based Eating Awareness Training (MB-EAT). Permission has been obtained from Dr. Jean Kristeller, the author and principal investigator of the MB-EAT program and studies, to use the intervention for this pilot study. The intervention is done in a fairly small group format (10 - 15) and is considered adjunctive to the standard treatment offered in a well-reputed eating disorders intensive outpatient program. Participation is voluntary and based on a convenience sample of women already in treatment. Participants will attend 10 weekly 2.5 hour-long sessions as well as one- and two-month follow-up sessions, under the guidance of two certified facilitators who are experienced in eating disorders and have completed the professional training in MB-EAT. A licensed Marriage and Family Therapist and a board certified Psychiatric Mental Health Nurse Practitioner may be recruited as the interventionists. Currently the best option for completing the professional training is to study under Jean Kristeller, principal investigator of the MB-EAT studies. A five-day retreat training is offered at the Esalen Institute in coastal Northern California for a cost of \$1215 for tuition plus standard accommodations. Training materials include MB-EAT: Mindfulness-Based Eating Awareness Training Treatment Manual, by Kristeller, Quillian-Wolever, and Hallett, as well as CDs/MP3s, and book recommendations.

The MB-EAT program follows a basic outline (Appendix F). Session 1 introduces the self-regulation model and mindfulness meditation. An introduction to mindful eating is done with raisins, in full appreciation of the sensory experience; in essence, learning how to approach food like a connoisseur. In subsequent sessions, the group explores different themes, e.g., mindfully eating high fat food such as cheese and crackers, or stomach fullness and body satiety. The body scan is introduced, simple yoga postures, and other mindful movement such as a walking meditation. Meditation is practiced in every session. Another theme is hunger cues: distinguishing physiological from emotional cues. This progresses to taste satiety cues, fullness cues, forgiveness, inner wisdom, and finally to the last session in which members explore how to maintain change and prevent relapse. A celebratory potluck meal is shared. Home mindfulness practice is an important element of the program, and corresponds with the weekly themes. Meditation practice at home begins with a minimum of 20 minutes using a guided audio recording, progressing to minimal guidance, to the option of not using the recordings at all. Eating practices are also assigned, and progress from eating one snack or meal per day mindfully to eating all meals and snacks mindfully (Kristeller, et al, 2014).

Establishing Intervention Integrity

In order to establish and maintain fidelity of the MB-EAT intervention throughout the study, a clear process will be followed. Training leaders will follow highly structured manuals, which detail activities in 10- to 20-minute segments. Each session will be audiotaped. The principal investigator will review audiotapes within a few days after each session to ensure that facilitators are conveying the material correctly, in content, timing and style. She will then provide feedback immediately to the facilitators, prior to the following session. Random reviews will be conducted throughout the study duration.

Dissemination of Findings

The study's final report will be developed into a manuscript that will include discussion and recommendation sections. This manuscript will be submitted to two peer reviewed journals: *Issues in Mental Health Nursing*, and *Eating Disorders: the Journal of Treatment and Prevention*. In addition, the study's results will be presented at one of the following conferences: 1) the APNA Annual Conference

(American Psychiatric Nurses Association); 2) the IAEDP (International Association of Eating Disorders Professionals) Symposium; or 3) the STTI (Sigma Theta Tau International) Biennial Convention. Each of these conferences offers a large audience who are likely to be quite interested in the findings.

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Appendix A Recruitment Flyer

"In this land of plenty there is so much suffering that revolves around the most basic activity of our life: Eating" -Jan Chozen Bays, MD

FREE PROGRAM OPPORTUNITY FOR WOMEN IN TREATMENT FOR BULIMIA

I am a graduate student at Cal State University San Marcos School of Nursing. I am conducting a research study using Mindfulness-based Eating Awareness Training for women ages 18-39 years diagnosed with bulimia nervosa. This program has shown positive impact with people diagnosed with Binge Eating Disorder in a recent randomized controlled trial funded by the National Institute of Health (Kristeller, Wolever & Sheets, 2014). I would like to determine if any of the benefits already shown by MB-EAT will carry over to women diagnosed with bulimia. Benefits for those with Binge Eating Disorder included less and smaller binges, decreased depressive symptoms, greater awareness of hunger and satiety cues, increased self-acceptance, increased self-regulation related to eating. Benefits for bulimia could include a decrease in binge/purge cycles, obtaining new skills to manage symptoms, and increased overall well-being.

The program will be co-facilitated by two highly qualified licensed therapists with experience in eating disorders and certified in the MB-EAT Professional Training program. The MB-EAT would be adjunctive to the treatment you are already undergoing at Sharp Mesa Vista. There is no financial obligation, only a commitment to completing 10 weekly sessions and 2 follow-up sessions at 1 and 2 months at the Sharp Mesa Vista facility. These sessions last for 2.5 hours. If you complete the entire training you will receive a \$250 gift card of your choice.

If interested, and for further information on how you may qualify for the study, please contact Suzanne Nieman, MSN(c), RN as soon as possible via phone or email: Phone: (858)449-9052 Email: <u>suzkeni@gmail.com</u>

Appendix B

Consent to Participate in MB-EAT Research

Invitation to Participate

Suzanne Kent Nieman, a graduate student in the School of Nursing, California State University San Marcos is conducting a study of a Mindfulness-based Eating Awareness Training for women ages 18-39 years who have been diagnosed with Bulimia Nervosa and are undergoing treatment in an outpatient Eating Disorders clinic. You are invited to experience in this evidence-based intervention as an adjunct to the prescribed standard treatment at the clinic.

<u>Purpose</u>

This study aims to determine if 12 sessions of the Mindfulness-based Eating Awareness Training program, which has proven beneficial for those suffering from Binge Eating Disorder, can provide benefits for women diagnosed with Bulimia Nervosa by offering additional tools to promote awareness and emotional balance.

Requirements of Participation

You will participate first in a short demographic survey at the end of this orientation. At the start of the first session, you will complete a paper and pen survey regarding your eating behaviors that will take about 10 minutes to complete. Each week prior to the start of the session you will also respond to a 1-question survey regarding binge/purge cycles during the previous week. The 2 $\frac{1}{2}$ -hour sessions of MB-EAT will take place on a weekly basis for 10 weeks within the familiar environment at Sharp Mesa Vista. You will meet again with your group for a 2 $\frac{1}{2}$ hour follow-up session at 1 month, and then at 2 months following the completion of the 10 weeks. You will respond to this same 1-question survey at the follow-up sessions. At the final session you will repeat the longer Mindful Eating survey. During the sessions, activities will include mindful eating and mindful experience practices such as meditation, simple yoga, walking meditation, healing self-touch, discussions, and personal values exercise. Meditations will include themes such as hunger awareness, fullness awareness, forgiveness, self-acceptance and wisdom. There will be food sharing. There will be home practice (e.g. mediation and mindful eating) required that may take up to 20 minutes per day. This will enhance your practice skills and has been shown in previous studies to be associated with better outcomes.

Risks and Inconveniences

There are minimal risks associated with this study. You may encounter some emotional discomfort as you practice mindfulness exercises that guide you into greater awareness of your emotions. For this reason, we ask that you have an ongoing relationship with a therapist that you may contact in case you need support in processing difficult emotions. We can provide some therapy resources in the community. Prior to the training you will need to inform us of which therapist you will be using.

Confidentiality

All of your responses to the surveys will be kept confidential, using numerical coding, and no identifying information will be linked with your name or address. Responses will be available only to the researcher for analysis purposes. The group sessions will be audiotaped for the sole purpose of maintaining integrity in the use of the highly structured manuals throughout the series of trainings. Only the principal investigator will review these audiotapes to confirm that manuals are being followed closely and that the content, timing and style are conveyed correctly.

Benefits

There may be significant benefits to you in terms of enhanced self-awareness as a result of participating in the guided mindfulness exercises. Previous study participants have enjoyed decreases in their bingeing episodes, and these decreases were associated with greater time practicing meditation, but this is not a guarantee for participants. You may enjoy the companionship of sharing personal experiences with other women who share similar struggles, and this can have healthful benefits. Beyond personal benefits, your participation will likely enhance the knowledge base for healthcare providers who treat people with eating disorders.

Incentives for Participation

After completing all sessions of MB-EAT and all surveys, you will receive a \$250 gift card of your choice.

Voluntary Participation

Participation in the program is voluntary. If you agree to be in this study but later change your mind, there will be no consequences for you, other than not receiving the \$250 gift card.

Questions

If you have further questions about this study, I am happy to answer them during this orientation, as well as in the future. Please contact Suzanne Nieman at 858-449-9052, or email me at <u>suzkeni@gmail.com</u>. If you have any questions regarding your rights as a research participant, please contact our Institutional Review Board at 760-750-4029.

- I agree to participate in this research study.
- I agree to participate in audiotaped sessions.

Participant's Name

Participant's Signature

Date

Researcher's Signature

Appendix C

Demographic Survey

Please choose the best response for each area (fill in the small bubble):

Your Age:

- o 1.18-24 years
- 2. 25-31 years
- 3. 32-39 years

Your race/ethnicity:

- o 1. African American
- 2. Non-Hispanic White American
- 3. Hispanic American
- 4. Native American
- o 5. Asian American
- o 6. Other

Your Level of Education:

- 1. Some High School Education
- 2. High School Graduate
- 3. Some college/no degree attained
- 4. Bachelor's degree
- o 5. Master's degree
- o 6. Doctoral degree

Your Length of Time since diagnosed with Bulimia Nervosa:

- o 1. Under 1 year
- 2. 1-2 years
- 3. 2-3 years
- 4. 3-5 years
- o 5. 5-10 years
- 6. More than 10 years

Type of treatment for Bulimia Nervosa so far:

- 1. Antidepressant medication
- o 2. Other medication such as mood stabilizer (ex: lithium, topiramate)
- 3. Individual Psychotherapy
- 4. Group Psychotherapy
- o 5. Family Therapy
- $\circ~~$ 6. Support Groups/12 Step Programs such as OA
- 7. Self-help approaches

Length of treatment for Bulimia Nervosa:

- o 1. Under 6 weeks
- 2. 6 to 16 weeks
- 3. 16 to 24 weeks
- 4. 24 or more weeks

Co-morbid Diagnoses:

- 1. Mood and Anxiety Disorders
- 2. Impulse Control Disorders
- 3. Personality Disorders

Appendix D Mindful Eating Scale, Scoring Key, and MES Questionnaire

Mindful Eating Scale Scoring Instructions

The Mindful Eating Scale is a 28-item psychometric instrument designed to assess mindfulness specifically in the domain of eating behaviours. Unlike generic mindfulness measures, each item refers to food, eating, or hunger. Studies are currently underway to assess whether this results in greater sensitivity and specificity to eating-related mindfulness than generic scales.

The scale is completed as a written self-report with response options on a four-point Likerttype scale from (1) never to (4) usually. Numerous items are reverse-scored, and several subscales comprise entirely negatively worded items. In the development study these items produced responses from participants with greater variance and created more coherent subscales.

All subscales are scored so that higher scores reflect a more mindful or intuitive eating style.

For further information see Hulbert-Williams, L., Nicholls, W., Joy, J., Hulbert-Williams, N. (under review). Initial Validation of the Mindful Eating Scale. Submitted to Appetite. [Manuscript available from the lead author.]

Factor	Name	Number of items	Cronbach's α	
I	Acceptance	6	0.89	
2	Awareness	5	0.82	
3	Non-reactivity	5	0.77	
4	Routine	4	0.75	
5	Distractibility	4	0.81	
6	Unstructured	4	0.60	
Wh	ole scale	28	0.86	

MES Scoring Key

I become very short tempered if I need to eat.rnonreactivityI snack without being aware that I'm eating.rdistractibilityI multi-task whilst eating.runstructuredI don't pay attention to what I'm eating because I'm daydreaming, worryingrdistractibilityI need to eat like clockwork.rnon-reactivityI can tolerate being hungry for a while.non-reactivityI tell myself I shouldn't be hungry.racceptanceI criticise myself for the way I eat.rnon-reactivityI have a routine for what I eat.racceptanceI tend to evaluate whether my eating is right or wrong.racceptanceI tend to evaluate whether my eating is right or wrong.rawarenessI eat something without really being aware of it.rroutineI stay aware of my food books.awarenessawarenessI eat something without really being aware of it.rawarenessI wish I could control my hunger.racceptanceI's easy for me to concentrate on what I'm eating.awarenessI eat the same thing on the same day of each week.rroutineI eat between meals.rnon-reactivityI have a routine for when I eat.rnostructuredOnce I've decided to eat, I have to eat straight away.rnon-reactivityI have a routine for when I eat.rnostructuredI teat between meals.runstructuredI wish I could control my eating more easily.rawareness <th>Questionnaire Item</th> <th>*</th> <th>Factor</th>	Questionnaire Item	*	Factor
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r = reverse scored

Mindful Eating Scale

Statement	Never	Rarely	Sometimes	Usually
I become very short tempered if I need				
to eat.	1	2	3	4
I snack without being aware that I'm				
eating.	1	2	3	4
I multi-task while I'm eating.	1	2	3	4
I don't pay attention to what I'm eating				
because I'm daydreaming, worrying, or	1	2	3	4
distracted.	1	2	5	4
I need to eat like clockwork.	1	2	3	4
I can tolerate being hungry for a while.	1	2	3	4
I tell myself I shouldn't be hungry.	1	2	3	4
I criticize myself for the way I eat.	1	2	3	4
When I get hungry, I can't think about				
anything else.	1	2	3	4
I have a routine for what I eat.	1	2	3	4
I tend to evaluate whether my eating				
is right or wrong.	1	2	3	4
I eat the same thing for lunch each day.	1	2	3	4
I notice how my food looks.	1	2	3	4
I eat something without really				
being aware of it	1	2	3	4
I stay aware of my food while I'm eating.	1	2	3	4
I wish I could control my hunger.	1	2	3	4
It's easy for me to concentrate on eating.	1	2	3	4
I notice the smells and aromas of food.	1	2	3	4
I eat the same thing on the same day				
of each week.	1	2	3	4
I eat between meals.	1	2	3	4
Once I've decided to eat, I have to eat				
right away.	1	2	3	4
I have a routine for when I eat.	1	2	3	4
I wish I could control my eating				
more easily.	1	2	3	4
I snack when I'm bored.	1	2	3	4
I eat automatically without being				
aware of what I'm eating.	1	2	3	4
I notice flavors and textures			-	-
when I'm eating my food.	1	2	3	4
I eat at my desk or computer.	1	2	3	4
I tell myself I shouldn't be eating	*		2	•
what I'm eating.	1	2	3	4
······································	1	-	5	•

Appendix E

Binge/Purge Survey

Session 1 (labeled Session 1-12, respectively)

1. What is the total number of binge/purge cycles you experienced over the past week?

2. For the 1- and 2- month Follow-up Sessions:

What is the total number of binge/purge cycles per week you experienced since your last session one month

ago? (Please list a number for each week in the preceding month).

Appendix F:

MB-EAT Program Outline (Courtesy of Dr. Jean Kristeller)

Session 1: Introduction: Inner Wisdom/ Outer Wisdom; Raisin Exercise; Basic Meditation Instruction; Introduction to KEEP IT OFF.

Session 2: Mini-Meditation; Mindfully Eating High Fat Food: Cheese and Crackers; Food Labels/Serving Sizes; 500 Calorie Challenge

Session 3: Hunger Awareness; Emotional Eating and Other Triggers; Body Scan

Session 4: Introduction to Physical Activity/Pedometers; Chocolate: Taste Satiety/Satisfaction; Healing Self-Touch

Session 5: Stomach Fullness and Body Satiety; Making Food Choices: Cookies vs. Chips; Eating and Emotions; Forgiveness Meditation.

Session 6: Outer Wisdom: Nutrition; Hourly Energy Balance; Mindfully Eating Fruits and Veggies; Integrated Mindful Eating Meditation.

Session 7: Mindful Choice Meditation; Pot Luck Meal; Review of 500 Calorie Challenge.

Session 8: Mindful Movement/Physical Activity; Walking Meditation; Chain Analysis; Stress and Eating; Eating Trigger Meditation.

Session 9: Chain Analysis continued; Personal Values Exercise; My Favorite Food Meditation; Maintaining Change.

Session 10: Wisdom Meditation; Mindfully Snacking; KEEP IT OFF review.

Follow-up 1: One Month Follow-Up; Continuing Change; Self-Acceptance Meditation.

Follow-up 2: Final Follow-Up Meeting; KEEP IT OFFs; Overall review; Celebratory eating.

Full Outline of Session 5 as Example of Content and Flow

Welcome and Mindfulness Meditation (5 minutes)
Check-In: Meditation Experiences from Previous Week (5 minutes)
Check-In: Mindful Eating, Awareness of Hunger and Taste Satisfaction (15 mins)
Check In: Pedometer Use (10 minutes)
Stomach Fullness and Body Satiety (30 minutes)

Break (10 minutes)

Making Mindful Choices: Cookies and Chips (15 minutes) Discussion of Mindful Choice Experience (10 minutes) Chain Reactions: Emotions and Eating (10 minutes) Emotional Eating, Anger and Forgiveness Meditation (15 minutes) Reactions to the Forgiveness Meditation (15 minutes) Preparation for Pot Luck (5 minutes) Home Practice Review (5 minutes) Brief Closing Meditation