Randomized Controlled Trial to Evaluate a Self-Guided, Web-Based Mindfulness Program for Stress Reduction and Wellbeing Promotion

A DISSERTATION
SUBMITTED TO THE FACULTY OF
UNIVERSITY OF MINNESOTA
BY

Aimee Prasek

IN PARTIAL FULFILLMENTS OF THE REQUIRMENTS
FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

Linda Halcón, Advisor

August 2015

Acknowledgements

For my funders:

Dalai Lama Fellows

Irish Titan

Sofia Public Health Fellowship

For my daily mindfulness teachers and steadfast supporters:

Donald Cartwright

Marcia Cartwright

Charlie Prasek

Alycia Morell

Jamie Hedin

For my *ah-ha moment* mentors and committee members who model trailblazing work grounded by rigorous inquiry and compassion:

Linda Halcón (advisor), PhD, MPH, RN

Cynthia Gross, PhD

Carolyn Porta, PhD, MPH, RN

Susan O'Conner-Von, PhD, RN

Dr. Miriam Cameron, PhD, MS, MA, RN

Olga Gurvich, MA

Dedication

For you, dad.

Abstract

Background: Stress is a public health issue that has costly personal and societal effects. Stress-reduction interventions, such as those integrating mindfulness practices, have demonstrated significant improvements for stress and wellbeing outcomes when delivered to small, in-person groups. The effectiveness of self-guided, web-based mindfulness programs to address barriers of in-person programs deserves more attention.

Objective: The purpose of this randomized controlled trial (RCT) was to determine the effectiveness of a self-guided, web-based mindfulness program ("Sherman Project") in reducing perceived stress and improving wellbeing for a group of University students, staff, and faculty.

Method: A randomized controlled trial was used to evaluate the effectiveness of a self-guided, web-based mindfulness program. Students, staff, and faculty from a large University were recruited to participate.

Results: 192 participants were randomized to either the intervention group or the waitlist control. Participants were predominantly Caucasian females. The study was powered to detect statistically significant differences in PSS-10 scores at the mid-assessment point. Compared to the waitlist control, the intervention group demonstrated significantly improved PSS-10 scores at both the mid and post-assessments. The intervention group also demonstrated improved wellbeing when compared to the waitlist. Intervention participants engaged in the 7-week program for roughly 120 total minutes. A small, but non-significant association between program engagement and PSS-10 scores was found,

suggesting that as individuals engaged more in the program, perceived stress may decrease.

Conclusions: This RCT demonstrated effectiveness for the use of Sherman Project, a self-guided, web-based mindfulness program, to reduce perceived stress for a sample of University students, staff, and faculty. Wellbeing also showed tendency for improvement for the intervention group. Results may support the use of low-intensity, web-based mindfulness interventions as an effective option to address common access barriers of in-person services and as an efficient component of public health initiatives for stress reduction and wellbeing-promotion.

Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

BSS	Brief serenity scale
CBT	Cognitive behavioral therapy
CeHRes roadmap	Center for eHealth Research Roadmap
CSPH	Center for Spirituality & Healing
GLM	General linear model
iCBT	Internet-delivered cognitive behavioral therapy
IP address	Internet protocol address
ISM	Intentional Systemic Mindfulness
ITT	Intention to treat
MBCT	Mindfulness Based Cognitive Therapy
MBSH	Mindfulness based self-help
MBSR	Mindfulness Based Stress Reduction
PHQ-9	Patient Health Questionnaire (9-item)
PROMIS global	Patient Reported Outcomes Measurement Information System-Global Health Scale
PSS-10	Perceived stress scale, 10-item
RCT	Randomized controlled trial
WHO	World Health Organization
WHO-5	WHO Five Well-Being Questionnaire

Chapter 1: Introduction

Background

Approximately 35% of North American adults experience severe ntspsychological stress (Yusuf et al., 2004). This is a significant public health issue as prolonged stress states are associated with negative effects on both physical and mental health (Brosschot, Gerin, & Thayer, 2006; Selye, 1956). However, few individuals receive professional services for stress due to barriers specific to in-person care (Berger, Hammerli, Gubser, Andersson, & Casper, 2011; Kessler et al., 2003).

Mindfulness-based interventions have been associated with stress reduction and enhanced wellbeing (Brown & Ryan, 2003; Cavanagh, Strauss, Forder, & Jones, 2014; Chiesa & Serretti, 2009; Grossman, Niemann, Schmidt, & Walach, 2004; Shapiro, Oman, Thoresen, Plante, & Flinders, 2008) and may offer broad relevance for interventions aimed at large populations (Boettcher et al., 2014). However, mindfulness-based programs suffer from barriers to access that are similar to those of more traditional in-person treatment approaches (Bergen-Cico, Possemato, & Cheon, 2013; Carmody & Baer, 2009; Morledge et al., 2013). Delivering mindfulness-based interventions through technology-assisted resources may be one effective solution to address this need (Cavanagh et al., 2013). Though the literature is limited, self-guided, web-based mindfulness interventions may be a particularly scalable strategy to address the public health issue of stress and also improve wellbeing.

A self-guided, web-based mindfulness program ("Sherman Project;" Appendix A) was created as a low-intensity resource to address unmanaged stress, improve wellbeing, and avoid some common treatment barriers specific to in-person approaches. Two conceptual frameworks guided this research: the mindful coping model (Garland, Gaylord, & Park, 2009) primarily informed the behavior change strategy and the Center for eHealth Research Roadmap (CeHRes roadmap; van Gemert-Pijnen et al., 2011) informed intervention development and evaluation. Both frameworks also informed the study design for this research.

Study Purpose and Aims

The purpose of this randomized controlled trial (RCT) was to determine the effect of a self-guided, web-based mindfulness program on perceived stress and wellbeing for a group of University students, staff, and faculty. To avoid confusion, the intervention will be referred to by its branded name, "Sherman Project," to differentiate it from other mindfulness programs discussed in this research. It was also of interest in this study to examine the impact of Sherman Project after adjusting for a priori selected participant demographic and clinical characteristics, examine the association of program engagement with perceived stress, and identify how participants interacted with Sherman Project. Thus, five specific aims guided this study:

Primary aim. Determine the effect of Sherman Project on perceived stress at the intervention mid-point (4 weeks from baseline) and at post-intervention (8 weeks from baseline).

H1: It was hypothesized that there would be a clinically significant reduction in perceived stress at the mid (4 weeks from baseline) and post-assessments (8 weeks from baseline) in the intervention group, compared to the waitlist control group.

Exploratory aims.

Aim 2. Examine the effect of Sherman Project on perceived stress at the intervention mid-point and at post-intervention while adjusting for participant characteristics (age, gender, and current treatment from a practitioner for an anxiety or depressive condition).

Aim 3. Examine the effect of Sherman Project on wellbeing at the intervention mid-point and at post-intervention while adjusting for participant characteristics (age, gender, and current treatment from a practitioner for an anxiety or depressive condition).

Aim 4. Examine the association between total program engagement and perceived stress at post-assessment.

Aim 5. Examine participants' engagement with program features with regard to frequency of use and participant feedback.

Conflict of Interest Statement

The PI created Sherman Project, the program evaluated in this research. The PI has an equity interest in Sherman Project, LLC, a company which may benefit from the results of this research. This interest was reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Chapter 2: Review of the Literature

This literature review synthesized findings of self-guided, web-based mindfulness intervention studies that had a primary aim of either stress reduction or wellbeing promotion. Evaluated interventions that mimicked more conventional, in-person mindfulness-based interventions were of specific interest to this research. Few studies met these criteria. In light of the limited pool of published research, the broader category of prevention-focused eHealth intervention studies was included to contribute to understanding.

Key concepts and their importance to this synthesis are introduced in this chapter, followed by a discussion of the following topics related to this study: stress as a public health issue, the use of mindfulness-based interventions for stress reduction and wellbeing promotion, barriers to mindfulness-based programs, and characteristics and effectiveness of previously evaluated self-guided, web-based mindfulness interventions. A description of the conceptual frameworks used to ground this study concludes the chapter.

Key Terms and Concepts

Mindfulness. Interpretations of mindfulness vary widely. Some identify the concept as a conscious practice or skill (Kabat-Zinn, 1994), while others describe it as an inherent human capacity (Brown & Ryan, 2004), emerging state of awareness (Kabat-Zinn, 2003), or a personality trait (Baer, Smith & Allen, 2004; Sternberg, 2000). The present study used two definitions of mindfulness: one to operationalize mindfulness as a

practice and another to operationalize it as a state of awareness. Kabat-Zinn (1994) defined the practice of mindfulness as "paying attention in a particular way, on purpose, in the present moment, and non-judgmentally" (p. 4). Mindfulness practices are often categorized by researchers and mindfulness instructors into formal and informal practices. Formal practices are generally interpreted as more structured meditation techniques (e.g., seated meditation focused on body sensations or breathwork) whereas informal practices include daily activities that are infused with mindfulness (e.g. mindful eating, mindful dish washing, or mindful walking; Dimidjian & Linehan, 2003). Garland, Gaylord, and Fredrickson (2011) proposed that engagement of mindfulness practices, both formal and informal, can lead to a state of mindful awareness that decreases perceived stress. This was the second interpretation of mindfulness used in this study. Mindful awareness is a metacognitive state that is characterized by "broadened attention and increased cognitive flexibility" (p. 2).

Stress. Lazarus and Folkman (1984) defined stress as the interaction between an individual and his or her environment that the individual appraises as a potential danger to wellbeing. This definition highlights the unique and evolving nature of stress for each individual; not only in the severity of impact that the stressor may carry, but the appraisal of what actually constitutes a stressor (Geary & Rosenthal, 2011). Types of appraisal important to this study are described below.

Primary and secondary appraisal. Primary appraisal is the initial assessment of potential harm. If harm is perceived, secondary appraisal is activated. Secondary

appraisal is a dynamic evaluative process in response to the perceived harm. The process includes assessment of the available coping option(s), likelihood these coping option(s) will be effective, and the ability one has to effectively apply the coping strategy or strategies (Lazarus & Folkman, 1984). Coping skills may include cognitive and behavioral tools and efforts an individual uses to manage stress and adversity (Lazarus & Folkman, 1984).

Reappraisal. Altering either the primary or secondary appraisal processes, reappraisal is a cognitive change process that involves interpreting a potentially emotion-eliciting situation in a way that transforms its emotional impact (Lazarus & Alfert, 1964).

Positive appraisal. Positive reappraisal is a health-promoting type of reappraisal (Garland et al., 2009). It is considered an adaptive coping strategy rather than a defense or avoidant strategy (Folkman & Moskowitz, 2000) that aims to reappraise the stressor(s) as benign, valuable, or beneficial.

Wellbeing. Wellbeing is identified as a macro concept by some theorists (La Placa, McNaught, & Knight, 2013). Consequently, the concept is rife with disagreements throughout the literature (McNaught, 2011). This study relied primarily on the World Health Organization's (WHO) definition of health to operationalize wellbeing: "Health is physical, mental, and social well-being, and not merely the absence of disease and infirmity" (WHO, 1958, p. 459). Conflation of the concepts of health and wellbeing is common as this definition is prominent in wellbeing research. This study also used a sub-definition of wellbeing that was consistent with the messaging of Sherman Project and

reflects the evolving conceptual work happening in the field of wellbeing: “Wellbeing is a state of balance or alignment in body, mind, and spirit. In this state, we feel content; connected to purpose, people, and community; peaceful and energized; resilient and safe” (Center for Spirituality and Healing, n.d.).

eHealth. eHealth has been defined as a new field “in the intersection of medical informatics, public health, and business, referring to health services and information delivered or enhanced through the Internet and related technologies” (Eysenbach, 2001, para. 3). Eysenbach further conceptualized eHealth beyond its technological advancements and noted a type of foundational mission for eHealth that is committed to “networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology” (para. 3).

Self-guided eHealth. Self-guided eHealth interventions have been defined as resources that can be completed by an individual without human support. This is compared to guided interventions which rely on varying levels of support from a program representative (Geraghty, Torres, Leykin, Perez-Stable, & Munoz, 2012). The terms self-guided, self-help, fully-automated, and unguided are often used synonymously in the eHealth literature.

Web-based eHealth. Web-based eHealth has been characterized as mostly prescriptive online health programs that are used by consumers and operated through a website (Barak, Klein, & Proudfoot, 2009).

Stress as a Public Health Issue

Stress is believed to be the largest primary risk factor for healthcare utilization and expenditures in the United States (Azagba & Sharaf, 2011). Radley, Morilak, Viau, and Campeau (in press) reported that "the cumulative effects of chronic stress are linked to a variety of adverse health consequences, such as hypertension, atherosclerosis, metabolic syndrome, diabetes, infertility, immunosuppression, osteoporosis, psychopathologies, and even neurodegenerative diseases" (p. 2). Additionally, many people living with chronic and/or severe stress symptoms do not receive professional services due to barriers to in-person care, such as access to treatment and perceived stigma (Berger et al., 2011; Gulliver, Griffiths, & Christensen, 2010; Kessler et al., 2003; Mackenzie, Reynolds, Cairney, Streiner, & Sareen, 2012).

It is possible that an intervention incorporating coping skills and reappraisal can offer an individual relief from stress and improve wellbeing (Andreotti et al., 2013; Elliot, Thrash, & Murayama, 2011). Mindfulness-based practices may be particularly effective to accomplish this as mindfulness can foster coping skills (Grossman et al., 2004) and may facilitate positive reappraisal (Garland, Gaylord, & Fredrickson, 2011; Garland, Gaylord, & Park, 2009). Further, the broad relevance of mindfulness may enable the concept and its related practices to reach large audiences and serve as an effective public health intervention (Boettcher et al., 2014).

Mindfulness-Based Interventions for Stress Reduction and Wellbeing Promotion

Mindfulness has become increasingly attractive for stress-reduction and wellbeing interventions (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Kabat-Zinn, 1994; Victorson et al., 2015), due in part to the rising consumer interest in mindfulness practices (Cavanagh et al., 2013) and the concept's transdiagnostic nature, which emphasizes one's relationship to experiences rather than symptom suppression. A 2009 review and meta-analysis of stress-management interventions for healthy participants that utilized the popular Mindfulness Based Stress Reduction protocol (MBSR; Kabat-Zinn, 1990) consistently found a significant effect in stress reduction compared to waitlist controls (Chiesa & Seretti, 2009). A meta-analysis of 39 mindfulness-based studies by Eberth and Sedlmeier (2012) found that mindfulness interventions were associated with improved psychological wellbeing. These findings support the use of mindfulness-based interventions to address stress and wellbeing, however, many of these studies were limited by small sample sizes, participant self-selection, and nonrandomization (Bishop, 2002; Chiesa & Serretti, 2009; Grossman et al., 2004; Hofmann, Sawyer, Witt, & Oh, 2010).

Barriers to Mindfulness-Based Programs

Access to in-person mindfulness-based programs is limited by barriers such as cost, need for skilled practitioners, scheduling conflicts, and restrictions due to geographic locations (Bergen-Cico et al., 2013; Carmody & Baer, 2009; Morledge et al., 2013). Mindfulness interventions may also appear too intense and prove difficult to adopt or adhere to by individuals unfamiliar with meditation (Kabat-Zinn, 2005; Segal,

Williams, & Teasdale, 2002). These concerns suggest a need for increased access and less intense mindfulness resources to address large-scale public health objectives such as stress reduction and wellbeing promotion.

Low-intensity mindfulness-based resources. Low-intensity approaches are often characterized by their use of fewer conventional healthcare resources, delivery systems that often utilize technology, and an assumption of safety that enables support to be offered (if necessary) by technicians or guides who do not have formal healthcare training (National Collaborating Centre for Mental Health, 2011). Low-intensity resources are also the foundation of stepped-care models (van Straten, Seekles, van't Veer-Tazelaar, Beekman, & Cuijpers, 2010). Resources within the early steps of this model can rely on efficient use of human assistance or electronic monitoring to move patients/users to higher levels of care as needed (van Straten et al., 2010).

Cavanagh et al. (2013) suggested that dissemination of low-intensity mindfulness based self-help (MBSH) resources could increase availability and efficient dissemination of mindfulness programs and practices. MBSH approaches can include books, audio tools, online programs, mobile applications, and other resources that either make practitioner time more efficient or do not require practitioner time at all (Cavanagh et al., 2013). Cavanagh et al. (2014) conducted a meta-analysis of 15 MBSH (primarily book or audio-based self-help tools) and found that compared to controls, MBSH resources were associated with significant improvements for measures of mindfulness and symptoms of anxiety and depression. Victorson et al. (2015) also suggested that technology-assisted

mindfulness resources may enable "applications that parallel the specific intricacies and mechanisms of the mindfulness construct itself, so that intervention and method of delivery go hand in hand" (p. 207).

Utilization of self-guided, web-based eHealth. Delivery of low-intensity mindfulness-based resources and interventions through self-guided, web-based strategies may be a particularly effective method of dissemination to address barriers common to mindfulness programs. eHealth interventions aimed at conditions with high prevalence (such as chronic stress) and those that can be delivered cost-effectively are particularly suited to make a substantial impact on public health issues (Geraghty et al., 2012; Klein, Meyer, Austin, & Kyrios, 2011; Munoz, Cuijpers, Smit, Barrera, & Leykin, 2010). Further, self-guided, web-based eHealth interventions have demonstrated positive effects for high prevalence public health issues such as stress, anxiety, depression, grief, headaches, and chronic back pain (Berger et al., 2011; Christensen, Griffiths, Mackinnon, & Brittliffe, 2006; Strecher, 2007). These type of interventions can offer treatment tailoring and increased intervention control for providers (Griffiths, Lindenmeyer, Powell, & Thorogood, 2006). Users/patients can also benefit from convenience, reduction of geographic and time barriers, and accessibility for those with mobility or social-interaction concerns (Berger et al., 2011; Griffiths et al., 2006). Anonymity is also a commonly cited advantage of self-guided, web-based eHealth programs and may have particular value for conditions about which users feel stigma or shame (Andersson & Culjpers, 2009; Hardiker & Grant, 2011).

Self-guided, web-based interventions have also been met with criticism. Like many new fields, early interventions lacked quality and the studies to evaluate those interventions were often not methodologically-sound (Eysenbach, Powell, Kuss & Sa, 2002; Murray, Burns, Tai, Lai, & Nazareth, 2009). A flawed 2004 Cochrane review also fueled criticisms of self-guided, web-based programs (Eysenbach & Kummervold, 2005). The review accidentally reversed study outcomes, concluding that self-guided, web-based programs were of no benefit or even harmful to users. The review was retracted thirteen days later, but the retraction was not as widely publicized. Debates also have occurred regarding whether or not mindfulness or mindfulness-based practices can be effectively taught via self-guided, web-based programs that lack the traditional therapeutic relationship of in-person approaches. Some mindfulness researchers and practitioners argue that a relationship with a mindfulness teacher may be a large contributor to positive outcomes seen in mindfulness-based interventions and caution against more universal strategies that lack this therapeutic relationship (Teasdale, Segal, & Williams, 2003).

Review of the Literature for Self-Guided, Web-Based Mindfulness Interventions

Six studies (Table 1) met the criteria of interest for this research. This small pool was expected considering that few mindfulness-based programs have a primary aim of improving stress or wellbeing (Morledge et al., 2013; Powell et al., 2013) and that even fewer are self-guided and web-based. Descriptions of these studies in regard to participant characteristics, intervention effectiveness, and program features are discussed below.

Participant characteristics for the six reviewed studies. Samples were similar in gender and age distribution. This is a common limitation in the broader field of eHealth as the majority of participants/users are white, middle-aged females (Strecher, 2007; Van Voorhees et al., 2013). All six studies reviewed had samples of 75% or more females and a mean age of about 40 years, with the exception of Cavanagh et al. (2013). Their sample was recruited from a university population and reported a mean age of 25.

Table 1

Studies Evaluating a Self-Guided, Web-based Mindfulness Intervention: Design, Methods, and Participant Characteristics

Author	Study design	Sample size (n)	Attrition in intervention group (%)	Participant characteristics			Results (measure[sig])
				Mean age	Female (%)	Ethnicity	
Cavanagh et al. (2013)	RCT	104	57	25	91	-	PSS[b]
Gluck & Maercker (2011)	RCT	49	7	35	74	"Austrian, German, and Swiss."	PSQ[c]
Krusche et al. (2012)	Pre-post	100	-	48	74	-	PSS[d]
Krusche et al. (2013)	Pre-post	273	-	48	78	-	PSS[d]
Morledge et al. (2013)	RCT	551	58[a]	Aged 40-59	89	89% Caucasian	PSS[b;]; PWB-SA[b]
Powell et al. (2013)	RCT	3070	74	41	88	92% white	WEMWBS[b]

Note. PSS= Perceived Stress Scale (4 or 10 item versions); PSQ = Perceived Stress Questionnaire; PWB-SA = Psychological Well-being Self-acceptance scale; WEMWBS = Warwick-Edinburgh Mental Well-being scale. Krusche et al. (2012; 2013) reported data only from participants who completed the post-assessment and follow-up. Several authors (including Krusche and colleagues) did not report ethnicity.
[a]Morledge et al. (2013) had two active mindfulness arms, mean attrition for active arms was 58%.
[b]Significant change compared to waitlist at post-intervention.
[c]No significant change compared to waitlist at post-intervention.
[d]Significant change from baseline to post-intervention (no control group).

Intervention effectiveness. Five of the six studies reported statistically significant improvement for a primary aim of either stress or wellbeing. The one exception being Gluck and Maercker (2011). Stress did not improve significantly between the intervention and waitlist control groups after their brief (13-day) mindfulness program. However, Gluck and Maercker (2011) found improvement trends for intervention participants on all instruments. Cavanagh et al. (2013) evaluated a brief mindfulness program similar in length to Gluck and Maercker (2011). Although only 43% of the intervention group completed the post-assessment, Cavanagh et al. (2013) found a significant reduction in perceived stress compared to the waitlist control. Krusche, Cyhlaroya, King, and Williams (2012) and Krusche, Cyhlaroya, and Williams (2013) also found significant reductions in PSS scores after participants completed the mindfulness program. However, neither of these studies had a comparison group.

Powell et al. (2013) utilized a large RCT to evaluate MoodGYM, a 5-week program grounded in Cognitive Behavioral Therapy (CBT) and that includes a mindfulness component. The primary aim of the study was to measure changes in wellbeing for participants considered more representative of the general population. Intervention participants reported significant wellbeing improvements compared to the waitlist control at the post-assessment. MoodGym has also demonstrated reduction of depression and anxiety with community samples in multiple studies (Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004; Christensen, Griffiths, & Jorm, 2004; Christensen et al., 2006; Lintvedt et al. 2013; Mackinnon, Griffiths, & Christensen,

2008). Morledge et al. (2013) evaluated a longer 8-week program through a three-armed RCT. The authors' reported both statistically and clinically significant differences for the two active mindfulness arms compared to the waitlist control in perceived stress and wellbeing. These outcomes persisted at the 4-week follow-up.

The studies in this review reported high attrition rates, a common finding in self-guided, web-based eHealth interventions (Eysenbach, 2005). Of the four RCTs, only two maintained appropriate power to detect outcomes. Powell et al. (2013) maintained power, but experienced 74% attrition in the intervention arm. This is noticeably higher than the attrition rate Morledge et al. (2013) reported, even though the program evaluated by Powell et al. (2013) was three weeks shorter. Across all six studies, most participants who dropped out did not notify researchers. This is a common occurrence in self-guided, web-based programs (Christensen, Griffiths, & Farrer, 2009).

It was also evident that participants who completed assessments of these six studies were not necessarily adhering participants. Gluck and Maercker (2011) discovered that six of the 28 intervention participants who completed the post-assessment did not engage in the second week of the two-week intervention. Eysenbach (2005) highlighted this issue, writing "In the intervention group a (sometimes substantial) proportion of people will not be using the intervention or using it sparingly. It is difficult to measure an effect of an intervention if participants in the intervention group do not use the application" (para. 3). Adherence is also difficult to interpret as many eHealth intervention studies do not use objective tracking systems to measure participant use of

the program. Morledge et al. (2013) was the only study of the six for this review that reported use of an objective tracking measure. Specifically, participant logins were automatically tracked. Logins were then assessed with participants' self-reported weekly activity logs to gauge program adherence.

Features of the evaluated mindfulness programs. Lack of reported information about the interventions made synthesis of program features difficult. Lack of transparency and poor clarity of intervention details have been identified as common issues in eHealth research (Eysenbach, 2011). Additionally, little work has been done in the broad field of eHealth to understand how user engagement and utilization of program features influence intervention outcomes (Donkin & Glozier, 2012; Moritz, Schilling, Hauschildt, Schröder, & Treszl, 2012). Program features were assessed as accurately as possible based on information provided by the studies (Table 2). Specific attention was given to common features of the programs and the use of tailoring.

Common features. Many of the evaluated programs appeared to include three common features:

1. Most programs were accessed through a password-protected website with content delivered primarily through text-based education.
2. All programs included weekly or other strategically-timed email communications to deliver content and/or remind users to visit the program website.
3. Five of the studies evaluated programs that incorporated audio to guide users through mindfulness practices.

Table 2

Program Characteristics and Features of Self-Guided, Web-based Mindfulness Programs

Author	Program length	Ideal program engagement	Program features (Y/N)				
			Email	Audio	Video	Tailored	Forum
Cavanagh et al. (2013)	14 days	Daily: 10 min	Y	Y	N	N	N
Gluck & Maercker (2011)	13 days	Daily: 20 min	Y	Y	N	Y	N
Krusche et al. (2012)	4 weeks	Weekly: 10-30 min	Y	Y	Y	N	N
Krusche et al. (2013)[a]	4 weeks	Daily: 10-30 min	Y	Y	Y	N	N
Morledge et al. (2013)	8 weeks	Daily: 20-25 min (5 days/ week)	Y	Y	N	N	Y
Powell et al. (2013)	5 weeks	Weekly: 45-60 min	Y	N	N	N	N

Note. Tailored = A program feature that included a personalization, adaptation, or feedback component.
[a]Krusche et al. (2013) utilized the same program as Krusche et al. (2012) but suggested an increased ideal engagement for participants of the 2013 study.

Use of tailoring. Tailoring has been defined as "any combination of information or change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and have been derived from an individual assessment" (Kreuter & Skinner, 2000, p. 1). Tailored programs have been suggested over static systems to improve engagement and impact of self-guided interventions; even for interventions that may include non computer-savvy participants (Johansson et al., 2012; Strecher 2007). Though they share similarities, tailored programs are often conflated with programs that include *interactive* features. Potential differences between these concepts may be particularly important for low-intensity programs that aim to build a stronger alliance with a user to improve personal relevance of and

adherence to an intervention (Lustria et al., 2013). Broadly interpreted, interactive programs can be compared to static programs in that interactive programs enable exchange of information between the user and the program (Murray et al., 2009). For example, Gluck and Maercker (2011) included an interactive mindfulness activity that instructed participants to non-judgmentally identify distressing thoughts, feelings or sensations while focusing on the image of a blue sky on the screen. Participants were then instructed to consciously press the spacebar, an action that prompted a cloud to appear on the screen, and imagine placing the distressing experience on the cloud while watching the cloud slowly drift out of sight. Tailoring often builds off an interactive activity such as this by adding elements of *personalization*, *adaptation*, or *feedback* to make the activity and program experience more personally relevant (Wangberg, Nilsen, Antypas, & Gram, 2011).

Personalization can be achieved simply by calling the person by name within program communications. None of the six studies noted this strategy, but it is likely that some of the programs addressed participants by name (or pseudonym) through email correspondence. *Adaptation* refers to content changes based on user characteristics and underlying theories. Krusche et al. (2012) enabled adaptation by allowing participants to pause their program and return back when ready. *Feedback* can be offered by providing the user with relevant responses to her/his work in the program or offering visual illustrations of overall progress. None of the studies noted the use of feedback.

As evidenced by these studies, the use of tailoring for self-guided, web-based mindfulness interventions is limited. Lack of tailoring is common across eHealth programs, as Barrazzone, Cavanagh, and Richards (2012) noted that programs differ tremendously in their ability to establish consistency and trust in communications and respond to participant-intervention activity.

Though the evidence is limited, self-guided web-based mindfulness interventions appear to address treatment barriers of in-person programs and have demonstrated effectiveness for the reduction of perceived stress and improvements in wellbeing. The six primary studies included in this review reported findings with positive trends or significant impact as result of the self-guided, web-based mindfulness intervention. Most of the studies evaluated programs that did not include interactive features or tailoring strategies. It is likely that more feature-rich and tailored programs will be developed in light of the growing popularity of mindfulness and eHealth.

Theoretical and Conceptual Frameworks

Integrating multiple theories may improve the effectiveness of behavior change interventions (Glanz & Rimer, 2008; Smedley & Syme, 2000). For example, Krusche et al. (2012; 2013) utilized MBSR and MBCT as the grounding framework for their mindfulness intervention. Sherman Project was similarly informed by MBSR and other mindfulness-based interventions. Additionally, two frameworks were utilized for this research: the mindful coping model helped inform the behavior change approach and the

CeHRes roadmap primarily guided the iterative development and evaluation of Sherman Project. Both frameworks also informed the study design for this research.

Mindful coping model. The mindful coping model (Garland et al., 2009; Figure 1) expands on Lazarus and Folkman's (1984) transactional model of stress by addressing the potential mechanism(s) at work between stress appraisal and positive reappraisal. Garland et al. (2009) proposed that mindfulness can serve as a key mechanism of that relationship. Specifically, the authors suggested that mindfulness is an "intrinsic and central component" of positive reappraisal (p. 6) and that engagement in mindfulness practices can "augment one's ability to make positive reappraisals in the face of acute and chronic stressors" (p. 6).

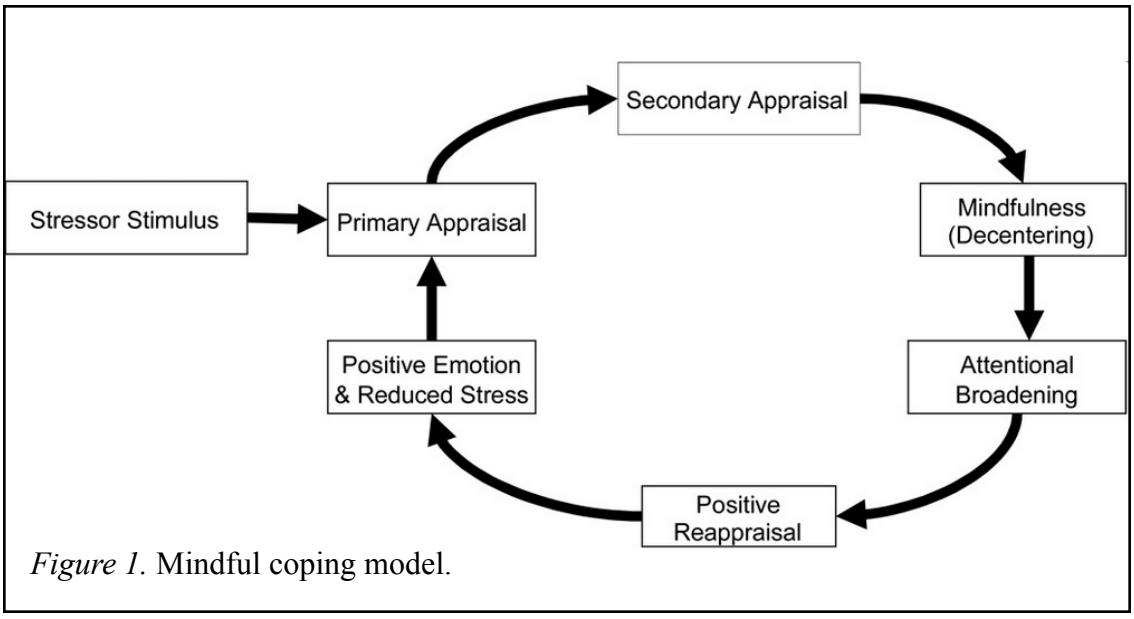


Figure 1. Mindful coping model.

Garland et al. (2009) posited that mindfulness practices can help individuals step back and shift attention from a primary or secondary appraisal and toward reappraisal. Thus, mindfulness practices function within the "decentering" stage of the model and

work to create a state of mindfulness awareness. This state is characterized by broadened attention and the cognitive flexibility to facilitate a positive reappraisal process. Ultimately, this pathway works to reduce perceived stress and enhance positive emotions.

Garland et al. (2011) also suggested that mindfulness interventions could repeatedly guide individuals through mindfulness practices followed by socratic questioning by a practitioner to generate positive reappraisals in regard to perceived stressors. Considering the self-guided, low-intensity nature of Sherman Project, in-person questioning strategies were not relevant. However, Sherman Project aimed to mimic a low-intensity version of this through an interactive, tailored text messaging meditation feature. This feature functioned by sending a daily text message to the user (at a time chosen by the user during registration) that prompted her/him to engage in one of the provided mindfulness meditations. After the 2-8 minute practice, the individual was encouraged to reply back to the text with three words that described positive experiences that were noticed. The reply sent by the participant appeared at the top of the user's weekly module page and changed with each new text reply.

Garland et al. (2011) noted that repeatedly practicing mindfulness and positive reappraisal in this manner can create a process that builds on itself. Namely, when awareness of positive perspectives is practiced, more positive emotions result, leading to more awareness of positive perspectives. The process continues in an upward spiral (Figure 2), demonstrating the reciprocal nature of the mindful coping model.

Figure 2. Longitudinal view of the mindful coping model.

CeHRes roadmap. The CeHRes roadmap was built on the insights of multiple theories and may offer a grounding framework for a diversity of eHealth interventions (van Gemert-Pijnen et al., 2011). The interdisciplinary approach of the CeHRes roadmap weaves technological, human, and contextual factors into a holistic model that aims to improve uptake and impact of eHealth technologies. Five iterative, interdependent cycles make up the CeHRes roadmap (Figure 3). These cycles and their relationship to this study are described below.

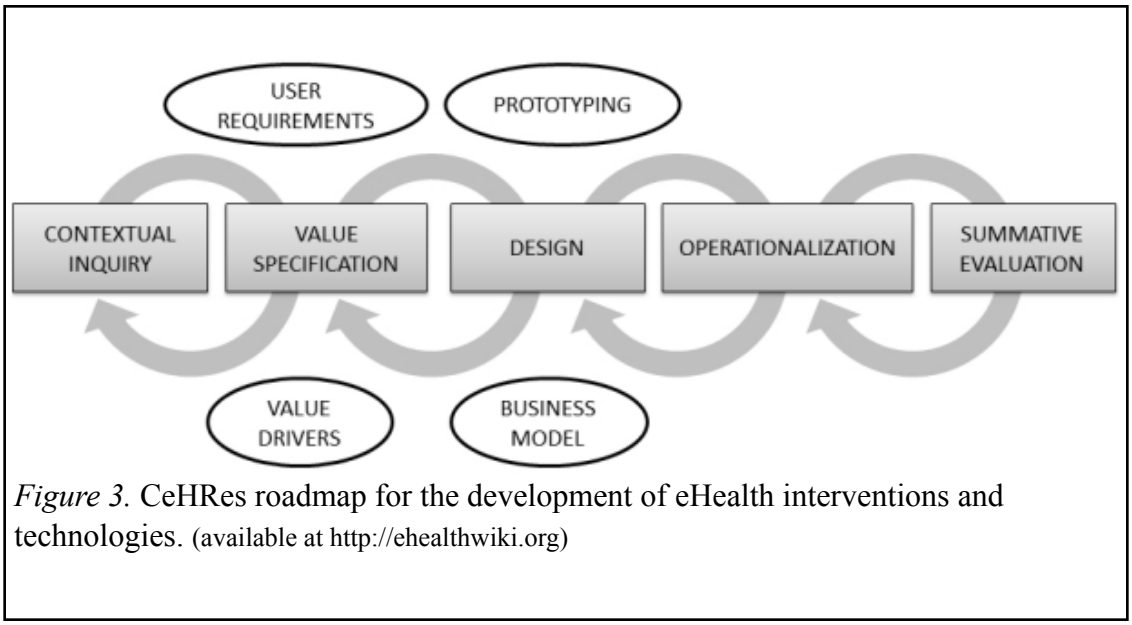


Figure 3. CeHRes roadmap for the development of eHealth interventions and technologies. (available at http://ehealthwiki.org)

Contextual inquiry. The first cycle of contextual inquiry includes information gathering from both intended target users and the environment where the intervention or technology will be implemented. This includes strategies like potential user interviews and field observations to identify goals, tasks, actions, or decisions that must occur toward the development of a successful intervention. This cycle occurred prior to this study through a series of interviews with potential users and also practitioners (i.e., nurses and health coaches) who were open to potential collaborative delivery of such a program.

Value Specification. The value specification cycle includes a complex assessment of key stakeholder values and motivations in addition to the specific user requirements that will be included in the technology to address those needs. O'Conner-Von (2009) demonstrated this cycle through the use of interviews with "adolescent experts" and their parents. These interviews informed essential content and coping strategies that were implemented into the web-based program to assist early and middle adolescents during

cancer treatment. In regard to the current study, this cycle included synthesis of the relevant literature (Chapter 2 of this dissertation) and interviews with potential funding partners, web-based development experts, and potential users (occurred prior to this research).

Design. van Gemert-Pijnen and colleagues (2011) highlighted that the design cycle is fully informed by the preceding phases, "The design cycle involves the translation of functional requirements into technical requirements and prototypes, given the specified values and goals of the eHealth project" ("Research and Development Activities," para. 5). This phase also occurred prior to this research and included in-depth work with user experience experts in addition to testing multiple iterations of the program with individuals who had expressed interest in the program.

Operationalization. The operationalization cycle is broadly focused on adoption and sustainability of the technology/program. This cycle can be effectively informed through business modeling practices, particularly those grounded in modeling methodologies that emphasize limited-resource, iterative, and collaborative technology/ program development. This cycle also occurred prior to this study and included use of the business modeling strategy laid out by Osterwalder and Pigneur (2010) in their book, *Business Model Generation*.

Summative evaluation. The cycle of summative evaluation assesses the uptake and impact of the eHealth technology in regard to clinical or behavior change, organizational assessment, and other stakeholder values that are critical to the success of

the eHealth technology or intervention. This phase addresses the inputs and perhaps untested assumptions of earlier phases. It also allows gathering of information to inform a return to an earlier cycle of the roadmap, as necessary, for continued iterations to improve adoption and impact of the intervention or technology. This summative evaluation cycle was the focus for this research. A randomized controlled trial was determined to be the best evaluation strategy to assess the intervention's effectiveness and benchmark the program to address key stakeholder values. Although Sherman Project is intended to function within a stepped-care model, this collaborative context (i.e., working with nurses to disseminate the program) was not feasible for the current study. Thus, the summative evaluation cycle was focused on uptake of the intervention (i.e., successful recruitment and not excessive dropout), effect of the intervention in regard to statistically significant changes in perceived stress, trends in wellbeing, and information on features to inform future iterations of Sherman Project. Broadly, the findings from this evaluation will also inform which cycles of the CeHRes roadmap need to be revisited before the program is more widely disseminated.

Insights from MBSR and other popular mindfulness-based programs in addition to utilization of the mindful coping model and the CeHRes roadmap have created a unique grounding framework for Sherman Project. It is possible that this more holistic framework may help to create an effective, efficient, and sustainable self-guided, web-based mindfulness intervention that can address the barriers of in-person approaches and contribute positively toward the public health issue of stress.

Chapter 3: Research Method

Study Design

This was a RCT designed primarily to determine the effect of a self-guided, web-based mindfulness program on perceived stress and wellbeing for a group of University students, staff, and faculty. Participants were randomly assigned to one of two groups, intervention or waitlist control using 1:1 randomization. Participants were blinded to group assignment until after completion of the baseline assessment. Participants randomized to the intervention group were asked to participate in the 7-week mindfulness program and complete study assessments after the 4th and 7th weeks (Figure 4). Participants randomized to the waitlist control were asked to engage in normal daily activities and also complete assessments after the 4th and 7th weeks. After the 7th week, all participants of the waitlist group were provided access to Sherman Project.

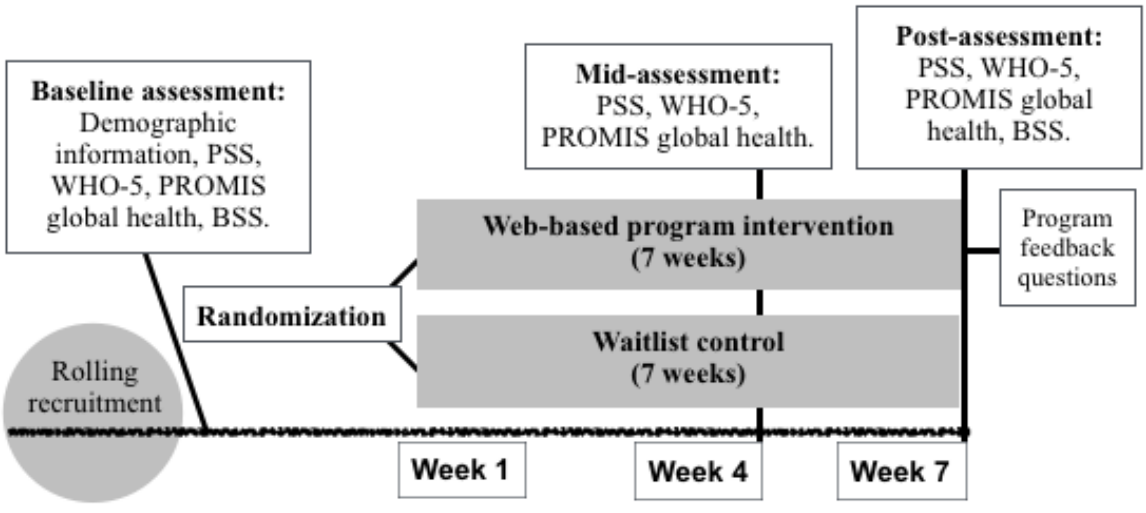


Figure 4. Study design and timeline.
PSS = perceived stress scale, 10-item. WHO-5 = World Health Organization 5-item wellbeing measure. PROMIS global health = Patient Reported Outcomes Measurement Information System global health scale. BSS = Brief Serenity Scale.

Nearly all activities of the study occurred online and were fully-automated. Two exceptions were flyers posted around campus for recruitment purposes and personal delivery of gift bags to participants who completed a post-assessment. A fully-automated, self-guided approach enabled individuals to learn about the study and participate fully and anonymously without any interaction with the investigator. Recruitment and data-collection through the fully-automated system also enabled partial-blinding for the investigator. Full blinding of the investigator could not occur on occasions when a participant contacted the investigator via email regarding technical difficulties with Sherman Project or other study protocol. In these situations, the investigator knew the participant's group assignment through their email address.

Study Population and Sample

Study population. The study population for this analysis included all persons who were students, staff, and faculty at a large Midwestern University at the time of recruitment (July 28, 2014 - December 30, 2014). The campus population consists of an even gender balance (OIR, 2015). Individuals who self-reported as a person of color represent 13% of the staff and faculty population and 16% of the student population (OIR, 2015).

Sample and setting description. A convenience sample of students, staff, and faculty was recruited from a large Midwestern University. Self-selecting participants did not attend any in-person study activities, as the setting of this research occurred entirely online. Interested individuals accessed a recruitment website for more information about

the study. The name of the program (Sherman Project) was not provided on the recruitment website, in any recruitment materials, or in the assessment emails sent to participants.

Sample size and power. Sample size determination was informed by a general linear model (GLM) approach for the analysis of the primary outcome of perceived stress at the mid-assessment. A conservative estimate of a within-participant correlation between the PSS-10 over time of 0.5 and a standard deviation of 6.5 points, with the effective sample size of 112 participants (56 participants per group), would enable detection of a statistically significant difference of about 3 points on the PSS-10 between the waitlist and intervention groups at the mid-point assessment (4 weeks from baseline) with 80% power at 5% type I error rate. A difference of 3 points was considered a clinically meaningful difference based on interpretations of minimally important differences by Ware (1995) and PSS-10 mean change scores demonstrated in other self-guided, web-based programs. A recruitment goal was set for a total of 224 participants to account for an expected dropout rate of 50% of the total randomized sample. This was a conservative attrition rate estimate considering self-guided eHealth interventions often experience higher rates of participant dropout compared to guided interventions, even reaching 60-80% attrition (Eysenbach, 2005). Lower attrition was predicted based on informal testing of Sherman Project through earlier cycles of the CeHRes roadmap and because the text messaging feature of the program were expected to improve intervention adherence and reduce attrition.

Recruitment strategy. A rolling recruitment strategy was utilized to mimic how Sherman Project would function outside of a research context. Recruitment began July 28, 2014. Recruitment efforts included: approximately 40 emails sent to health-related student groups and University cooperatives/Centers, 150 flyers posted throughout campus (Appendix B), one Facebook ad that ran for 18 weeks, and one free classified ad that ran for two weeks in the online version of the campus newspaper. Printing costs for the flyers and the Facebook advertisement were the only paid recruitment strategies. Recruitment stopped on December 30, 2014, at which time it was predicted based on previous participants' behavior that at least 56 participants of the intervention group would complete the mid-assessment.

During the five month recruitment period, 1358 new user visits were logged at the recruitment website. New user visits offer a rough gauge of interest for a website, although inflation can occur for reasons such as access of the website by a single user on multiple devices or through multiple browsers, clearing of Internet history after visiting the website and then visiting again, or use of ad blocking software. Alternatively, multiple users accessing the recruitment website from an on-campus public computer would not accurately track unique visitors. Thus, new user visits may be skewed both positively and negatively.

Email and Facebook were the most successful recruitment strategies, bringing in more than half of all study participants. The Facebook advertisement ran for 118 days at a cost of $219.13. The advertisement prompted 395-490 total clicks to the website

(analytics from Google and Facebook provided varying click estimates). Thus, the cost-per-click for the advertisement was between $0.45 and $0.55. These clicks resulted in a minimum of 53 individuals joining the study, equating to a $4.13 recruitment cost per participant.

Inclusion and exclusion criteria. Inclusion and exclusion criteria were liberal to obtain the broadest possible sample within the study population (Table 3). These broad criteria also reflected the projected open access use of the program as it is intended to function in the future. Individuals were presented with the inclusion and exclusion criteria questions (Appendix C) and the PHQ-9 (Appendix D) after reading the information page on the study recruitment website.

Table 3

Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
≥ 18 years old	Pregnant
University student, staff, or faculty	Score ≥ 20 points on the PHQ-9
Willing to provide an email address	Checked item 9 on the PHQ-9 (indicating suicidal ideation)
Willing to provide a cell phone number and receive text messages at that number	
Willing to engage with the web-based mindfulness program for about 2-3 hours per week	
Willing to complete online assessments at three set periods	
Reliable home internet access	
Capable of moderate-intensity exercise	
Can read, understand, and digitally sign the English consent form	

All completed inclusion and exclusion criteria surveys were logged with the total score to indicate whether the survey passed the inclusion/exclusion survey. Frequencies for specific questions were also compiled. A total of 279 inclusion/exclusion criteria surveys were completed. It is possible that multiple individuals attempted the survey more than once as only 267 of these completions were logged as unique users. A total of 35 survey completions did not pass the criteria check. Twenty of these exclusions were due to self-reported suicidal ideation(s), equating to 7% of total survey completions. It is possible that these 20 incidents were logged by fewer than 20 unique individuals. It is possible that an adverse event may have occurred during the inclusion criteria check, however.

Incentive. Participants who completed the post-assessment were offered a wellbeing gift bag. The gift bag included products from local companies that were considered healthy and wellbeing-promoting (i.e., organic shampoo and conditioner, lip balm, tea, lavender sachet, and a wellbeing magazine). The value of each gift bag was approximately $40.00. The final page of the post-assessment enabled staff and faculty to provide an on-campus address to which the gift bag would be delivered. Students were advised that they could pick up their gift bag during any one of five gift bag pick up days. All participants also received free access to Sherman Project ($49.00 value) either immediately as participants of the intervention group or after 8 weeks if randomized to the waitlist control.

Protection of Participants

The PI completed the University's Human Subjects Protection training and the study proposal was approved for human subjects research by the University of Minnesota Institutional Review Board as a Social and Behavioral Sciences expedited review application (Appendix E). Specific efforts to protect participants of the study are described in the sections below.

Benefits and risks. Sherman Project had not been formally evaluated for effectiveness prior to this study. Thus, there were no clear benefits to participants. It was hypothesized, however, that participants would experience a statistically significant reduction in perceived stress. It was also believed that participants would demonstrate improvements in wellbeing. The PI was also confident that the low-intensity nature of the program presented no greater than minimal risk to participants. Despite the low risk, measures were taken to address potential mental health issues. Data management and security concerns were also addressed.

Measures taken to address potential mental health issues. Frequent communication about on-campus mental health resources was the most prominent strategy to address mental health issues that might have arisen during a participant's involvement with the study. The recruitment website was available throughout the entire study period and included information about on-campus mental health resources and contact information for the PI and the PI's advisor. These resources and contact information were also linked in all study-related emails. Social spaces of Sherman Project

(i.e., forum, blog, Facebook, Pinterest, YouTube, and Twitter) were also monitored by the PI daily and surveyed by a licensed mental health counselor weekly. If a concerning interaction arose, the PI planned to respond by redirecting the conversation in a more healthy way and, if needed, provide information for additional on-campus health resources. No concerning situations arose throughout the study period.

Data management and security. Security of private data is an important concern for eHealth (Murray, 2009). A primary measure to protect participant data was to disseminate Sherman Project through a secured website (hypertext transfer protocol secure; https). This protocol ensured that communications passed between the user and the website's server were encrypted and safe from eavesdropping. Additionally, all data for this study were collected electronically through secure, password protected platforms (i.e., the basic tracking system of Sherman Project, Survey Monkey, MailChimp, MixPanel, and Twillio). Survey Monkey offered enhanced security and encryption and was used to collect all data for the baseline, mid, and post-assessments. MailChimp was used to automatically send participants all study-related emails. Thus, participant email addresses and the first name or a pseudonym that the participant provided were stored securely in MailChimp.

MixPanel and Twilio also utilized robust security and privacy systems to protect collected data. Data collected by MixPanel were limited to intervention participants' use of the website with no sensitive information collected. Twilio stored participant private

data by logging a cell phone number each time a participant engaged with the text message feature of Sherman Project.

De-identified raw data files were exported from all platforms and saved to an external hard drive that was password protected and stored in a locked location during the study period. After results of this study are published, all data logged by these platforms will be deleted. De-identified raw data will be kept for five years. During this period, data will remain encrypted, password protected, stored on a dedicated external hard drive, and kept in a locked drawer. After five years, the hard drive will be destroyed through a security-enhanced electronics recycling service.

Data Collection

All data were collected online. Study variables and instruments are described in detail below.

Variables and instruments. Dependent variables measured were perceived stress, wellbeing, global health, and serenity. Measurement occurred online at three time points. Instruments were selected primarily based on their established validity and frequent use in studies that had evaluated self-guided, web-based interventions and mindfulness-based programs.

Measure of stress. The 10-item Perceived Stress Scale (PSS-10; Cohen, Kamarck, & Mermelstein, 1983) was used to measure an individual's perception of and response to everyday stress (Appendix F). The PSS (4 and 10-item versions) is the most widely used tool for measuring perceived stress (Andreou et al., 2011) and is used often

in eHealth and mindfulness research. The PSS-10 has demonstrated good internal consistency (α = .78). The scale scores range from 0 to 40, with higher scores representing higher levels of perceived stress. The US population average for the PSS-10 is 13.02 (*SD*= 6.35; Cohen & Williamson, 1988). Based on this average, a post-assessment score of 13 is often set as a benchmark of success for stress reduction interventions. However, a 2009 population average for the PSS-10 was reported at 15.21 (*SD* = 7.28), perhaps supporting a shift in the benchmark (Cohen & Janicki-Deverts, 2012). The PSS-10 was completed by participants at baseline, mid, and post-assessment.

Measures of wellbeing.

World Health Organization Well-Being Questionnaire (WHO-5). The WHO-5 is a five-item wellbeing measure that ranges in raw score from 0 to 25, with higher scores representing greater wellbeing (Appendix G). Standardized percentage scores are calculated by multiplying the raw score by 4 to obtain a score between 0 and 100. The 0 to 25 scale was used in this study for most analyses. Standardized scores were only used to compare the study sample means to population averages. The standardized general population average on the WHO-5 has been estimated at approximately 70 (Bech, 2012a). The tool has demonstrated better sensitivity in measuring psychological wellbeing than the SF-36 Mental Health subscale (Bech, Olsen, Kjoller, & Rasmussen, 2003). It appears to have cross-cultural relevance, is psychometrically sound, and has adequate internal consistency (α = .84; Bech, 2012b). The WHO-5 was completed by participants at baseline, mid, and post-assessment.

PROMIS Global Short Form v.1.1 (PROMIS global). The PROMIS global has been identified as an efficient tool to assess wellbeing and functioning and may be most applicable for large studies with participants of diverse demographic characteristics (Cella et al., 2010; Appendix H). The PROMIS global uses 10 items to assess the five primary PROMIS domains of physical function, fatigue, pain, emotional distress, and social health. The measure can also be scored in two subscales to separately measure physical and mental health (PROMIS Physical Health and PROMIS Mental Health, respectively), as was done in this study. The growing collection of PROMIS tools are unique in that they have been iteratively developed and refined through modern measurement theory, quantitative and qualitative methods, and rigorous calibration and validation studies. Hays, Bjorner, Revicki, Spritzer, and Cella (2009) utilized what was considered a fairly representative sample of the 2000 US census data to established internal consistency of the global physical and mental health subscales ($\alpha = .81$ and $\alpha = .86$, respectively). Raw scores of the tool are converted to T-score values with a US general population average of 50 points on either of the subscales ($SD = 10$). For analysis, higher scores on the subscales represent higher wellbeing status and functioning. The PROMIS global health scale was completed by participants at baseline, mid, and post-assessment.

Brief Serenity Scale (BSS). The BSS (Kreitzer, Gross, Waleekhachonloet, Reilly-Spong, & Byrd, 2009) is an iteration of Roberts and Aspy's Serenity Scale (1993) and builds off of previous conceptual work related to spirituality in healthcare (Appendix I).

The BSS was selected because the concept of serenity is a potentially important wellbeing outcome of mindfulness-based interventions. Kreitzer et al. (2009) noted that the BSS "may complement other instruments of spiritual health and well-being as well as serve as a unique and distinct measure of the outcomes of spiritual care" (p. 7). The scale has also been used to evaluate an adapted, technology-assisted MBSR intervention (Bazarko, Cate, Azocar, & Kreitzer, 2013). The 22-item scale ranges in scores from 1 to 5, with higher scores representing higher levels of serenity. The scale demonstrated high internal consistency ($\alpha = .95$) in the original clinical sample used to validate the tool. The BSS was completed by participants at baseline and post-assessment.

Use of Sherman Project. Use of the web-based program was measured using a) the basic tracking system of Sherman Project, b) a robust analytics platform (MixPanel), and c) the analytic features provided by the email provider (MailChimp) and text messaging service (Twilio) that were integrated into the program. Measurement of program engagement began when a participant registered for Sherman Project and was logged by the tracking system of Sherman Project using a unique participant ID. This ID was imported to MixPanel, the primary tracking system used in this study to assess participant-level engagement. MixPanel tracked clicking incidents for each user ID on 20 a priori selected tracking points located within Sherman Project. Registration also added the participant to an email list in MailChimp so that program emails would automatically be sent. MailChimp was also used to track engagement with those emails (i.e., opens, clicks on any hyperlinks, and unsubscribes from the email list). Twilio was utilized to

send and track text message delivery (successful or unsuccessful) and whether or not the user responded to the text message with a reply as prompted. The actual replies to text messages were compiled in aggregate and not attributable to specific participants.

Participant communications on the private forum and blog of Sherman Project were manually collected by the PI and recorded in an excel spreadsheet by participant ID. Participants were also encouraged to participate in the social media spaces. However, engagement on those platforms could not be not attributed to specific participants.

Program engagement score. Data collected through MixPanel, Twilio, MailChimp, and Sherman Project were used to calculate a program engagement score for each intervention participant. The maximum weekly score was 7 points and the maximum total program engagement score was 49 points. Each point roughly represented 10 minutes of program activity, equating to an ideal program engagement time of 70 minutes per week for every week of the program. Weekly tracked activities included in this score were opening of the weekly email (1 point), replying to the text message meditations (up to 3 points), play of the movement videos for at least half of the video's duration (up to 2 points), and opening of the weekly mindful eating PDF (1 point; Table 4). Use of additional program activities was also compiled, but was not included in a participant's program engagement score. These extra activities included forum use, bonus content access, and clicks on external links contained in the weekly email.

Table 4

Calculation of Program Engagement Score.

Key program activity (weekly)	Point given for completion of activity
Replied to 2 text messages	1
Replied to 4 text messages	1
Replied to 6 text messages	1
Played video for at least 1/2 the time	1
Played video for at least 1/2 the time	1
Opened email	1
Opened mindful eating PDF	1

Program feedback questions. Four program feedback questions were administered at post-assessment to intervention participants only. These questions were:

1. What practices (if any) will you continue as result of your participation in the program?

2. What did you like most about the program?

3. What did you like least about the program?

4. Do you have any additional comments? Please share below.

Answers to these questions were categorized according to subject.

Materials and Procedures

Description of the Intervention. Once registered, intervention participants received a welcome email and the week 1 email. Six more emails were sent weekly to a) provide education around that week's mindfulness theme, b) outline the mindfulness practices, and c) provide encouragement for continued engagement. A final email after

week 7 summarized the program content and provided additional mindfulness resources for continued learning.

After registration, participants were directed to their private *dashboard* (Appendix A). This dashboard delivered one module of content each week until all seven modules had been made available to the participant. Content was communicated through three categories titled Flow, Nourish, and Pause which provided education about and guided participants through formal and informal mindfulness practices. *Flow* included two mindful movement videos, *Nourish* included one mindful eating PDF, and *Pause* included two mindful interactive meditation practices (one audio guided meditation and another that was read and practiced by the participant). Weekly content for each module was different and built on the theme and practices from the previous week. Each module also included the participant's responses to the interactive text message meditation practice that aimed to prime positive reappraisal and also tailor the intervention for each participant. As noted previously, the reply sent by the participant appeared at the top of the user's weekly module page and changed with each new text reply. Each weekly module page also had a section that tracked all replies during that week. Participants were encouraged to complete the exercise daily so that all seven boxes would be filled in with the positive reflections. If the participant did not reply within 24 hours of receiving that day's message, the practice box for the respective day would remain blank.

Procedures

Participants were recruited through anonymous recruitment strategies noted earlier in this chapter. Individuals who received an email or who viewed a social media message were able to click a link that took them directly to the recruitment website. Once an individual accessed the recruitment website, she/he could proceed to the study information page that informed individuals of the purpose and scope of the study, the required inclusion criteria, general procedures, and risks and potential benefits of participation. Contact information for the PI, advisor of the PI, and other on-campus wellbeing and mental health resources were provided.

Interested individuals could then proceed to the inclusion criteria check. If the individual met all inclusion criteria, then she/he was taken to a digital consent form. The conflict of interest statement was included in this consent form to ensure that consent in the research was fully informed. If the individual consented, a prompt appeared for the individual to provide a frequently-checked email address that was used for all study-related activities. Submission of this contact information resulted in an automatic 1:1 randomization procedure, however the participant was not notified of group assignment until after completion of the baseline assessment.

After randomization, individuals were automatically sent an email to confirm the contact email provided. Confirmation of the contact email redirected the participant to the baseline assessment. Submission of the baseline assessment triggered an email timeline for each participant. This series of emails included assessment emails with links to the

mid and post-assessments and also a series of assessment reminder emails (maximum of three, spaced two days apart for the mid and post-assessment). The participant was then redirected to a page that revealed group assignment. This page included next steps based on group allocation, as described below.

Study protocol: Intervention group. A participant randomized to the intervention group received the following message,

> Welcome to the web-based group! This means: 1) During the next 7 weeks, you have the opportunity to engage with the web-based program. 2) It is requested that you complete the mid and post-assessments no matter your level of engagement with the program. 3) And don't forget, after completing your final assessment, you will receive a wellbeing gift bag!

The participant was provided with contact information for the PI and the PI's advisor at the bottom of this page and was asked to complete the registration process for Sherman Project:

> Final steps to confirm your participation in the web-based group: 1) The link below will take you to a special FREE registration page for the web-based program. Please use this link so that you receive the program free. 2) At that page, you can enter any username and password that you like. 3) In the email box, you must enter the same email that your email confirmation was sent to. 4) Your cell phone number should also match the one you provided in the baseline assessment. 5) After submitting, you'll receive two emails that will help you begin your program. You can also click on your "Dashboard" page at the top of your web-based program screen to find your first week of content (and a link to your emails if they don't arrive to your inbox as quickly as you need). 6) Your participation in this study is sincerely appreciated!

Registration for Sherman Project also initiated the program's text messaging and email components to arrive appropriately to the participant.

Study protocol: Waitlist control group. After completion of the baseline assessment, a participant randomized to the waitlist group received the following message,

> Welcome to the waitlist group! You will receive access to the wellbeing program after seven weeks. After seven weeks, you will receive an email with an access code that is valid anytime before April 31, 2015. During the next seven weeks, the only study-related request is that you complete the mid and final assessments. Other than that, simply engage in your normal routine as if you were not in the study. And don't forget, after completing your final assessment, you will receive a wellbeing gift bag. Your participation in this study is sincerely appreciated!

The participant was also provided with contact information for the PI and the PI's advisor at the bottom of this page.

Treatment Integrity

Sherman Project is a self-guided and fully-automated, web-based program. Thus, every participant randomized to and who registered for Sherman Project had access to an identical treatment. However, technical errors within the program, connectivity issues, and a participant's ability to navigate program features as directed likely impacted individual experience of the intervention.

Analysis

Descriptive statistics, such as means (standard deviations; *SD*) and medians (ranges) for continuous data and frequencies (percentages) for categorical data, were used to summarize study outcomes at each assessment time point. Chi-square tests were utilized to examine any realized group imbalances in demographic and clinical characteristics between the groups at baseline. Cronbach's alpha and means (*SDs*) were

calculated and compared to the available norms for all validated scales used in the study to examine instrument reliability. Missing data patterns were also evaluated and summarized. Very little missing data occurred and were handled according to appropriate scoring procedures for each instrument and the conventions for each statistical test. All statistical analyses were conducted under a modified intention to treat (ITT) principle. Specifically, all available data was used for each outcome and no imputations were made due to very low missing data. Data management and statistical analyses were performed using IBM SPSS Statistics (version 22; SPSS Inc., Chicago, IL, USA). Specific analyses by study aims are described below.

Primary Aim. Determine the effect of Sherman Project on perceived stress at the intervention mid-point and at post-intervention.

GLM (ANCOVA) was conducted to assess the differences in the PSS-10 score between the waitlist and intervention groups at mid and post-assessment while controlling for the baseline PSS-10 score. GLM is considered a powerful and parsimonious approach to assess RCT intervention outcomes while controlling for baseline measures (Van Breukelen, 2006). A baseline-adjusted GLM can reduce error variance and increase power of between-group statistical comparisons. Assumptions of normality, homogeneity of variances and homogeneity-of-slopes were verified. A type I error rate of .05 was used to assess statistical significance. No adjustment for multiple comparisons was performed per assumption underlying the original sample size

estimation. This was deemed a suitable approach considering the efficacy of the intervention was determined based on results of the analysis at mid-assessment only.

Exploratory Aims. Analyses of these aims were exploratory and mostly hypotheses-generating or descriptive in nature because the sample size estimate was based solely on an estimated difference in the PSS-10 between the groups at mid-assessment (primary outcome).

Aim 2. Examine the effect of Sherman Project on perceived stress at the intervention mid-point and at post-intervention while adjusting for participant characteristics (age, gender, current treatment from a practitioner for an anxiety or depressive condition).

Aim 2 analyses mimicked that of the primary aim with the inclusion of the a priori selected baseline participant characteristics in the model.

Aim 3. Examine the effect of Sherman Project on wellbeing at the intervention mid-point and at post-intervention while adjusting for participant characteristics (age, gender, current treatment from a practitioner for an anxiety or depressive condition).

GLM was conducted for each wellbeing instrument (PROMIS mental health, PROMIS physical health, WHO-5, and BSS) in the same manner as the aim 2 analyses. Each model included the baseline score of the respective instrument as a continuous covariate and the categorical covariates of age, gender, and current treatment from a practitioner for an anxiety or depression at baseline.

Aim 4. Examine the association between total program engagement and perceived stress at post-assessment.

A Pearson correlation was used to assess the strength and direction of the potential relationship between program engagement and perceived stress. Assumptions were met in that assessment of a bivariate plot confirmed a linear relationship between program engagement scores and mean change on the PSS-10 from baseline to post-assessment. Program engagement scores and mean change on the PSS-10 were also found to be normally distributed, as assessed by visual inspection of a Normal Q-Q Plot.

Aim 5. Examine participants' engagement with program features with regard to frequency of use and participant feedback.

Use of Sherman Project was measured by the objective tracking systems noted earlier. Weekly and total program engagement scores were calculated for each participant based on data from the tracking systems. Potential differences in total program engagement across the key participant characteristics were measured by an Independent Samples Kruskal-Wallis H test and a Mann Whitney U test. Answers to the four program feedback questions were categorized and compared alongside overall utilization of program features to gain a better understanding of program engagement.

Chapter 4: Results

Sample

Participation. A total of 279 visits were assessed for eligibility to participate in this study. It is likely that multiple assessments by single individuals occurred. Some visits did not meet eligibility criteria (n = 35), others left before beginning the baseline assessment (n = 50), and two users began, but did not complete the baseline assessment. The remaining 192 individuals were randomized, completed the baseline assessment, and became participants in the study. Attrition was lower than originally estimated as 62% of intervention participants completed the mid-assessment, compared to 85% of the waitlist group. This was similar at post-assessment with 65% and 83%, respectively (Figure 5).

There were no significant associations between completion of assessments and key participant characteristics (gender, age, or current treatment from a practitioner for an anxiety or depressive condition). Baseline PSS-10 scores were also not associated with attrition. Attrition in the intervention group was similar to the overall sample with no significant associations between participant characteristics or baseline PSS-10 scores and attrition.

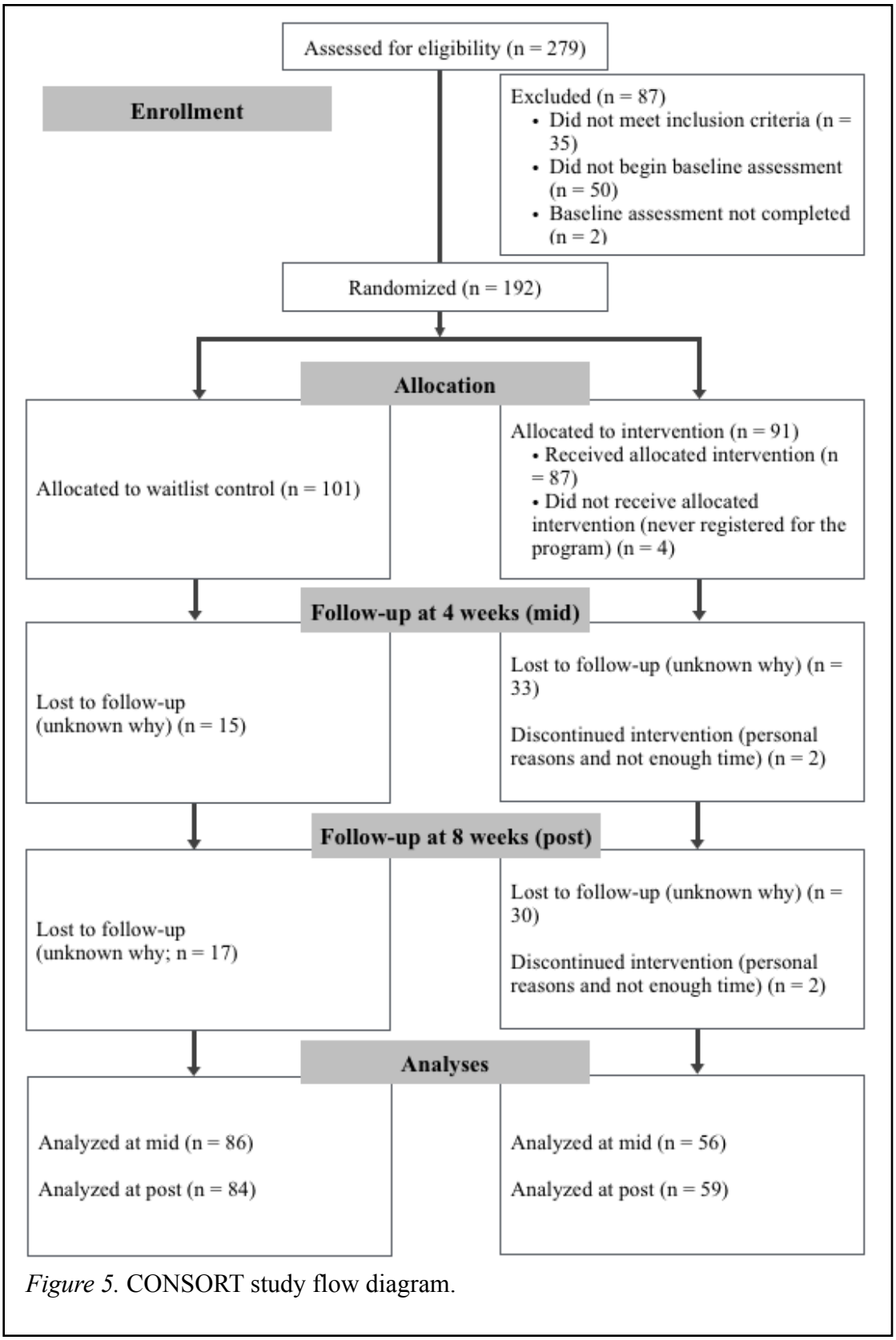


Figure 5. CONSORT study flow diagram.

Characteristics of the study sample. There were no statistically significant differences between groups in their measured demographic or clinical characteristics at baseline (Table 5). The overall sample consisted of mostly females (90%) and individuals who identified as non-Hispanic white (90%). Most participants were students and staff (85%) and 24% of the total sample reported current treatment from a practitioner for anxiety and/or depression.

Table 5

Characteristics of the Sample by Study Group

Characteristic		**Intervention (*n* = 91)**		**Waitlist (*n* = 101)**		**Total (*n* = 192)**		***p*-Value[a]**
		n	(%)	n	(%)	n	(%)	
Gender	Male	11	(12)	8	(8)	19	(10)	0.36
	Female	80	(88)	91	(92)	171	(90)	
Age	18-24	15	(16)	15	(15)	30	(16)	0.64
	25-34	28	(31)	24	(24)	52	(27)	
	35-44	16	(18)	21	(21)	37	(19)	
	45-54	17	(19)	17	(17)	34	(18)	
	55+	15	(16)	24	(23)	39	(20)	
Ethnicity	White or Caucasian	80	(89)	93	(92)	173	(91)	0.45
	Non-White	10	(11)	8	(8)	18	(9)	
Affiliation with the University	Student	41	(45)	34	(34)	75	(39)	0.22
	Staff	43	(47)	53	(53)	96	(50)	
	Faculty	7	(8)	13	(13)	20	(11)	
Current Treatment[b]	Yes	24	(27)	23	(23)	47	(25)	0.56
	No	65	(73)	76	(77)	141	(75)	

[a] Pearson's chi square test
[b] Reported current treatment by a practitioner for an anxiety or depressive condition.

Descriptive Summaries and Reliability of Instruments

Unadjusted means (*SD*) and medians (ranges) were calculated for all instruments at each assessment time point (Table 6). There were no statistically significant differences in unadjusted baseline means between the intervention and waitlist control groups for any of the instruments.

Table 6

Descriptive Summaries for Study Instruments: Intervention Group vs. Waitlist Control

Instruments		Intervention			Waitlist		
		n	mean (*SD*)	median [min, max]	*n*	mean (*SD*)	median [min, max]
PSS-10	Pre	91	17 (7)	17 [2, 32]	101	17 (6.51)	16 [4, 34]
	Mid	56	16 (6.48)	16 [4, 31]	86	17 (7.05)	17 [3, 34]
	Post	59	14 (7.08)	13 [3, 35]	84	16 (7.39)	16 [4, 37]
WHO-5	Pre	91	12 (4.71)	13 [2, 21]	101	13 (4.69)	13 [3, 22]
	Mid	56	14 (4.42)	15 [4, 22]	86	13 (4.44)	14 [1,22]
	Post	59	15 (5.01)	16 [1, 22]	84	14 (4.53)	13 [4, 23]
PROMIS Global Health: Physical	Pre	91	49 (6)	50.8 [34.9, 61.9]	101	49.7 (6.7)	50.8 [32.4, 67.7]
	Mid	56	50.4 (6)	50.8 [34.9, 61.9]	84	49 (7.2)	50.8 [29.6, 61.9]
	Post	58	52.1 (6.2)	52.5 [32.4, 67.7]	83	50 (7.3)	50.8 [19.9, 67.7]
PROMIS Global Health: Mental	Pre	91	45.5 (7.6)	45.8 [21.2, 67.6]	101	45.6 (7.3)	45.8 [28.4, 67.6]
	Mid	56	46.6 (6.6)	45.8 [31.3, 59]	85	45.6 (7.7)	48.3 [28.4, 67.6]
	Post	59	48.7 (8.4)	50.8 [21.2, 67.6]	84	47.7 (8.2)	47.1 [28.4, 67.6]
BSS	Pre	91	2.93 (0.66)	2.86 [1.27, 4.64]	101	3.06 (0.56)	3.09 [1.59, 4.18]
	Post	59	3.32 (0.74)	3.45 [1.59, 4.86]	84	3.27 (0.61)	3.23 [1.86, 5]

Note. Scale scores are unadjusted. *n* = number of participants, *SD* = Standard Deviation. Score ranges: PSS-10 (0-40), WHO-5 (0-25), PROMIS physical (t-score: 16.2-67.7), PROMIS mental (t-score: 21.2-67.6), BSS (1-5).

Unadjusted baseline means for each instrument were also compared to available population means (Table 7). The study sample demonstrated higher perceived stress and

lower scores on the WHO-5 and PROMIS mental health as compared to population means. The sample mean score of 49.34 on the PROMIS physical health subscale was very close to the reported population mean of 50.

As a measure of reliability, Cronbach's alpha was calculated for each of the instruments (Table 7). Cronbach's alpha was .67 for the PROMIS physical health, demonstrating somewhat low reliability of the instrument in this study sample. Cronbach's alphas for the rest of the instruments ranged between .82 and .92, suggesting good to excellent reliability in this sample.

Table 7

Reliability of Study Instruments: Population Norms vs. Study Sample

Instrument	Scoring Range	Population Norms		Study Sample	
		Mean	Cronbach's α	Mean	Cronbach's α
PSS-10	0-40	13	0.78	17	0.89
WHO-5 (standardized)[a]	0-100[a]	70	0.84	50	0.85
PROMIS Global Health: Physical (T-Score Value)[b]	16.2-67.7	50	0.81	49.34	0.67
PROMIS Global Health: Mental (T-Score Value)[b]	21.2-67.6	50	0.86	45.54	0.82
BSS	1-5	na	0.95	3.16	0.92

[a] Raw scale range is 0-25, but the WHO-5 uses a standardized score of 0-100 for population averages.
[b] Raw scores are computed to T-score values for analyses of the mental and physical health subscales.

Primary Aim

A GLM was performed to examine differences in PSS-10 scores at mid and post-assessment between the waitlist control and intervention groups while controlling for baseline PSS-10 scores. Models initially included treatment group by baseline PSS-10 score interaction. The interaction was not statistically significant at mid-assessment (p = .37) or post-assessment (p = .11) and thus was not included in the final models.

There was a statistically significant difference in mean PSS-10 scores between the waitlist control and intervention groups at both mid and post-assessment while controlling for baseline PSS-10 scores ($F(1,139) = 4.53$, p = .04, partial η2 = .03 and $F(1,140) = 8.08$, p = .01, partial η2 = .06, respectively; Table 8). The GLMs explained 45% of variation in PSS-10 scores at mid-assessment ($R^2_{Adjusted}$ = .45) and 50% at post-assessment ($R^2_{Adjusted}$ = .50). Baseline PSS-10 score was a significant covariate in both models, with higher baseline scores associated with higher scores later (both $p < .001$). The intervention accounted for about 3% of variance in PSS-10 scores at mid-assessment and 6% at post-assessment, while holding constant the baseline PSS-10 score, as assessed by a partial η2. Partial η2 is the variance in the dependent variable that can be explained by a single covariate after the other covariate variances are excluded. Partial η2 can be interpreted as .01 representing a small effect size, .06 as medium, and .14 is considered large (Olejnik & Algina, 2000).

Table 8

GLM Models for PSS-10 at Mid and Post-Assessment While Controlling for Baseline PSS-10 Score

Variables	Mid-Assessment[a] (*n* = 142)	Post-Assessment[b] (*n* = 143)
	β(*SE*); [95% CI] *p*-value	
Intercept	3.84 (1.30); [1.27, 6.41] .004	1.20 (1.310); [-1.39, 3.79] .36
Group: Waitlist (reference intervention group)	1.86 (0.88); [0.01, 3.59] .04	2.51 (0.88); [0.77, 4.26] .01
PSS-10 Baseline	0.68 (0.06); [0.55, 0.80] <.001	0.75 (0.06); [0.62, 0.87] <.001

Note. β values represent the difference in slopes when adjusting for baseline PSS-10 scores.
[a] $R^2_{Adjusted}$ = 0.45; *p*-value for model <0.001 (Adjusted R squared indicates amount of variation in the dependent variable explained by all variables included in the model)
[b] $R^2_{Adjusted}$ = 0.50; *p*-value for model <0.001

Compared to the intervention group, the waitlist control had on average about 2 points higher PSS-10 score (representing more perceived stress) at mid-assessment (*SE* = 0.88; 95% CI [0.13, 3.59]) and about 3 points higher at post-assessment (*SE* = 0.88; 95% CI [0.77 to 4.26]) while adjusting for baseline PSS-10 (Table 9).

Table 9

Baseline Adjusted Mean (SE, 95% CI) PSS-10 at Mid and Post-Assessment by Group

Group	Mid-Assessment				Post-Assessment			
	n	***M***	***SE***	**CI**	***n***	***M***	***SE***	**CI**
Waitlist	86	17.26	0.55	[16.18, 18.35]	84	16.53	0.57	[15.44, 17.67]
Intervention	56	15.39	0.68	[14.07, 16.77]	59	14.02	0.68	[12.73, 15.39]

Note. Models adjusted for baseline PSS-10 score; PSS-10 score range is 0-40; *n* = number of participants; *M* = mean PSS-10 score; *SE* = standard error, CI = confidence interval.

Exploratory aims

Aim 2. GLMs for mid and post-assessment PSS-10 were conducted while adjusting for the baseline PSS-10 as a continuous covariate and for the categorical covariates of gender, age, and current treatment from a practitioner for an anxiety or depressive condition at baseline. After controlling for the baseline PSS-10 scores and participant characteristics, the effect of the intervention at mid-point was not significant, $F(1, 128) = 3.78$, $p = .05$, partial $\eta 2 = .03$. However, at post-assessment, the effect of the intervention was significant $F(1, 128) = 7.76$, $p = .01$, partial $\eta 2 = .06$ (Table 10). Baseline PSS-10 score was also significant in both models, with higher baseline scores associated with higher scores later (both $p < .001$). At mid-assessment, there was a significant effect of age on PSS-10 scores, $F(4, 128) = 3.13$, $p = .02$, partial $\eta 2 = .09$. Pairwise comparisons were assessed with the Sidak adjustment to identify which age groups may have differed. Participants aged 35 to 44 scored higher on the PSS-10 compared to all other age groups, though only statistically higher than the 55+ age group ($p = .01$). Gender and current treatment were not associated with perceived stress in the mid-assessment model ($p = .73$ and $p = .41$, respectively) or the post-assessment model ($p = .99$ and $p = .29$, respectively).

Table 10

GLM Models for PSS-10 at Mid and Post-Assessment While Controlling for Baseline PSS-10, Age, Gender, and Current Treatment from a Practitioner for an Anxiety or Depressive Condition

Variables	**Mid-Assessment[a] (*n* = 137)**	**Post-Assessment[b] (*n* = 137)**
	β(*SE*); [95% CI] *p*-value	
Intercept	2.93 (1.97); [-1.02, 6.88] .15	0.29 (2.23); [-4.11, 4.69] .90
Group: Waitlist (reference intervention group)	1.70 (0.88); [-0.03, 3.44] .05	2.58 (0.93); [0.75, 4.41] .01
PSS-10 Baseline	0.6 (0.07); [0.46, 0.74] <.001	0.69 (0.07); [0.54, 0.84] <.001
Age: 18-24[c]	2.27 (1.47); [-0.65, 5.18] .13	3.01 (1.53); [-0.03, 6.04] .05
Age: 25-34[c]	3.01 (1.25); [0.54, 5.49] .02	1.82 (1.36); [-0.87, 4.51] .18
Age: 35-44[c]	4.73 (1.38); [2.00, 7.45] .001	2.2 (1.45); [-0.68, 5.07] .13
Age: 45-54[c]	2.67 (1.32); [0.06, 5.28] .05	0.85 (1.42); [-1.96, 3.65] .55
Gender: Female (reference male)	-0.53 (1.52); [-3.54, 2.49] .73	-0.02 (1.69); [-3.37, 3.33] .99
Current Treatment (reference no treatment)	0.89 (1.09); [-1.26, 3.05] .41	1.23 (1.15); [-1.05, 3.51] .29

Note.
[a] $R^2_{Adjusted}$ = 0.47; p-value for model <0.001
[b] $R^2_{Adjusted}$ = 0.48; p-value for model <0.001
[c] Reference is 55 and over for all age groups

Compared to the intervention group, the waitlist control had on average about 3 points higher PSS-10 score (representing more perceived stress) at post-assessment (*SE* = 0.93; 95% CI [-4.41, -0.75]) while adjusting for baseline PSS-10, age, gender, and current treatment from a practitioner for an anxiety or depressive condition (Table 11).

Table 11

Mean (SE, 95% CI) PSS-10 at Mid and Post-Assessment Adjusted for Baseline PSS-10 score, Age, Gender, and Current Treatment from a Practitioner for an Anxiety or Depressive Condition

Group	Mid-Assessment				Post Assessment			
	n	***M***	***SE***	**CI**	***n***	***M***	***SE***	**CI**
Waitlist	82	17.48	0.87	[15.76, 19.20]	80	16.86	0.95	[14.98, 18.74]
Intervention	55	15.78	0.97	[13.87, 17.69]	57	14.28	1.05	[12.21, 16.35]

Note. PSS-10 score range is 0-40; *n* = number of participants; *M* = mean PSS-10 score; *SE* = standard error, CI = confidence interval.

Aim 3. In order to assess differences in wellbeing, GLMs for mid and post-assessment scores of wellbeing instruments (WHO-5, PROMIS global health, and BSS) were conducted while adjusting for the baseline score of each respective instrument as the continuous covariate and for the categorical covariates of gender, age, and current treatment from a practitioner for an anxiety or depressive condition. Models also initially included the interaction between treatment group by baseline score for each instrument. These interactions were not statistically significant and thus were not included in final models. Results of the GLMs are provided (Tables 12 and 13).

Table 12

GLM Models for the WHO-5 and BSS at Mid and Post-Assessment Controlling for the Baseline Scores, Age, Gender, and Current Treatment from a Practitioner for an Anxiety or Depressive Condition

Variables	WHO-5		BSS
	Mid-Assessment[a] (*n* = 137)	**Post-Assessment[b] (*n* = 137)**	**Post-Assessment[c] (*n* = 137)**
	β(SE); [95% CI] p-value		
Intercept	9.96 (1.55); [6.89, 13.04] <.001	10.07 (1.81); [6.50, 13.65] <.001	1.42 (0.32); [0.80, 2.04] <.001
Group: Waitlist (reference intervention group)	-1.56 (0.58); [-2.71, -0.41] .01	-2.03 (0.67); [-3.35, -0.69] .003	-0.21 (0.09); [-0.39, -0.04] .02
Respective Baseline	0.54 (0.07); [0.41, 0.67] <.001	0.52 (0.08); [0.37, 0.68] <.001	0.67 (0.08); [0.50, 0.84] <.001
Age: 18-24[d]	-2.00 (0.97); [-3.90, -0.09] .04	-1.83 (1.10); [-4.00, 0.34] .10	-0.17 (0.14); [-0.46, 0.12] .24
Age: 25-34[d]	-2.57 (0.82); [-4.19, -0.94] .002	-2.88 (0.97); [-4.79, -0.97] .003	-0.18 (0.13); [-0.43, 0.07] .16
Age: 35-44[d]	-4.16 (0.89); [-5.92, -2.40] <.001	-2.07 (1.02); [-4.10, -0.04] .05	-0.28 (0.14); [-0.54, 0.01] .04
Age: 45-54[d]	-1.64 (0.87); [-3.36, 0.08] .06	-1.05 (1.02); [-3.07, 0.97] .31	0.13 (0.14); [-0.13, 0.40] .33
Gender: Female (reference male)	-0.07 (1.01); [-2.07, 1.93] .95	0.72 (1.22); [-1.69, 3.13] .59	0.18 (0.16); [-0.14, 0.49] .27
Treatment (reference no treatment)	-0.56 (0.70); [-1.94, 0.83] .43	-2.26 (0.81); [-3.87, -0.65] .01	-0.27 (0.11); [-0.48, -0.06] .01

Note.
[a] $R^2_{Adjusted}$ = 0.46, *p*-value <0.001
[b] $R^2_{Adjusted}$ = 0.38, *p*-value <0.001
[c] $R^2_{Adjusted}$ = 0.44, *p*-value <0.001
[d] Reference is 55 and over for all age groups

Table 13

GLM Models for PROMIS Global Subscales Adjusted for Baseline Scores, Age, Gender, and Current Treatment from a Practitioner for an Anxiety or Depressive Condition

Variables	PROMIS physical		PROMIS mental	
	Mid-Assessment[a] (*n* = 135)	**Post-Assessment[b] (*n* = 135)**	**Mid-Assessment[c] (*n* = 136)**	**Post-Assessment[d] (*n* = 137)**
	β(*SE*); [95% CI] *p*-value			
Intercept	16.59 (4.23); [8.21, 24.97] <.001	23.84 (4.40); [15.14, 32.54] <.001	22.22 (3.85); [14.59, 29.84] <.001	21.04 (4.56); [11.97, 30.11] <.001
Group: Waitlist (reference intervention group)	-1.77 (0.87); [-3.50, -0.04] .05	-2.53 (0.94); [-4.40, -0.67] .01	-0.62 (0.94); [-2.48, 1.23] .51	-2.14 (1.09); [-4.30, 0.01] .05
Respective Baseline	0.74 (0.08); [0.59, 0.89] <.001	0.64 (0.08); [0.48, 0.80] <.001	0.60 (0.07); [0.47, 0.74] <.001	0.68 (0.08); [0.51, 0.84] <.001
Age: 18-24[e]	-2.44 (1.47); [-5.35, .465] .10	-1.80 (1.56); [-4.89, 1.28] .25	-3.07 (1.57); [-6.17, .027] .05	-3.28 (1.79); [-6.83, 0.27] .07
Age: 25-34[e]	-0.68 (1.24); [-3.13, 1.76] .58	0.08 (1.37); [-2.62, 2.79] .95	-3.86 (1.34); [-6.5, -1.22] .01	-3.85 (1.58); [-6.98, -0.71] .02
Age: 35-44[e]	-0.76 (1.35); [-3.44, 1.92] .58	-0.71 (1.43); [-3.53, 2.12] .62	-4.10 (1.45); [-6.97, -1.23] .01	-3.09 (1.67); [-6.40, 0.22] .07
Age: 45-54[e]	-0.54 (1.32); [-3.15, 2.07] .68	-0.75 (1.43); [-3.59, 2.09] .60	-1.99 (1.42); [-4.79, 0.82] .16	-2.03 (1.66); [-5.32, 1.26] .23
Gender: Female (reference male)	-1.61 (1.51); [-4.6, 1.37] .29	-1.74 (1.71); [-5.11, 1.64] .31	0.33 (1.62); [-2.88, 3.54] .84	1.09 (1.98); [-2.84, 5.01] .59
Treatment (reference no treatment)	-1.68 (1.03); [-3.71, 0.35] .11	-3.87 (1.10); [-6.06, -1.69] .001	-2.93 (1.13); [-5.17, -0.69] .01	-3.76 (1.33); [-6.40, -1.13] .01

Note.
[a] $R^2_{Adjusted}$ = 0.43, *p*-value <.001
[b] $R^2_{Adjusted}$ = 0.40, *p*-value <.001
[c] $R^2_{Adjusted}$ = 0.47, *p*-value <.001
[d] $R^2_{Adjusted}$ = 0.45, *p*-value <.001
[e] Reference is 55 and over for all age groups

The baseline adjusted PROMIS physical health mean score for the waitlist group was about 2 points lower at mid-assessment (representing lower physical health)

compared to the intervention group (*SE* = 0.87; 95% CI [-3.5, -0.04]) and 3 points lower at post-assessment (*SE* = 0.94; 95% CI [-4.4, -0.67]; Table 14). The baseline adjusted WHO-5 mean score for the waitlist group was about 2 points lower (representing lower wellbeing) than the intervention group at the mid-assessment (*SE* = 0.58; 95% CI [0.41, 2.71]) and at the post-assessment (*SE* = 0.67; 95% CI [0.69, 3.35]). The baseline adjusted BSS mean score for the waitlist group was about 0.21 points lower (representing lower reported serenity) compared to the intervention group at post-assessment (*SE* = 0.09; 95% CI [-0.39, -0.04]).

Table 14

Mean Wellbeing Scores at Mid and Post-Assessment Adjusted for Baseline Scores, Age, Gender, and Current Treatment from a Practitioner for an Anxiety or Depressive Condition

Instrument and Group		**Mid-Assessment**				**Post-Assessment**			
		n	***M***	***SE***	**CI**	***n***	***M***	***SE***	**CI**
WHO-5	**Waitlist**	82	12.96	0.57	[11.83, 14.09]	80	12.32	0.68	[10.98, 13.67]
	Intervention	55	14.52	0.64	[13.26, 15.78]	57	14.35	0.75	[12.85, 15.84]
PROMIS Global Health: Physical	**Waitlist**	80	49.22	0.86	[47.51, 50.93]	79	49.63	0.96	[47.74, 51.52]
	Intervention	55	50.99	0.95	[49.11, 52.88]	56	52.16	1.06	[50.07, 54.25]
PROMIS Global Health: Mental	**Waitlist**	81	45.58	0.93	[43.74, 47.41]	80	45.99	1.11	[43.78, 48.19]
	Intervention	55	46.20	1.03	[44.16, 48.24]	57	48.13	1.23	[45.69, 50.57]
BSS	**Waitlist**	na				80	3.06	0.09	[2.88, 3.23]
	Intervention					57	3.27	0.10	[3.07, 3.47]

Note. *n* = number of participants, *M* = mean score on respected measure, *SE* = standard error, CI = confidence interval. Score ranges: WHO-5 (0-25); PROMIS physical (16.2-67.7) and mental (21.2-67.6); BSS (1-5).

Aim 4. The strength and direction of relationship between program engagement and perceived stress at post-assessment was assessed using Pearson's product moment correlation. PSS-10 change scores from baseline to post-assessment were first computed. A Pearson's correlation was then run with PSS-10 change scores and total program engagement scores. Though not significant, there was a small, negative correlation between program engagement and mean change for the PSS-10 ($r(57) = -.26$, $p = .05$), with program engagement explaining 7% of the variation in PSS-10 mean change scores. This negative trend suggests that participants who engaged more in the program reported lower perceived stress.

Aim 5. Program engagement was examined with regard to frequency of program feature use and participant feedback. Intervention participants scored an average of 12 points ($SD = 9$) out of the maximum program engagement score of 49 points. This roughly equates to 120 minutes of program engagement for each participant over the 7-week intervention period. However, many participants scored between 0 and 9 points. Smaller frequencies of participation congregated around 10 and 20 points.

Weekly engagement with Sherman Project. Average weekly program engagement decreased with each passing week of the 7-week program (Figure 6). The average weekly program engagement score for intervention participants was 2 (out of 7 points), representing approximately 20 minutes of weekly program activity. Week 3 and week 6 revealed an increase in participants who scored a weekly engagement score of "0."

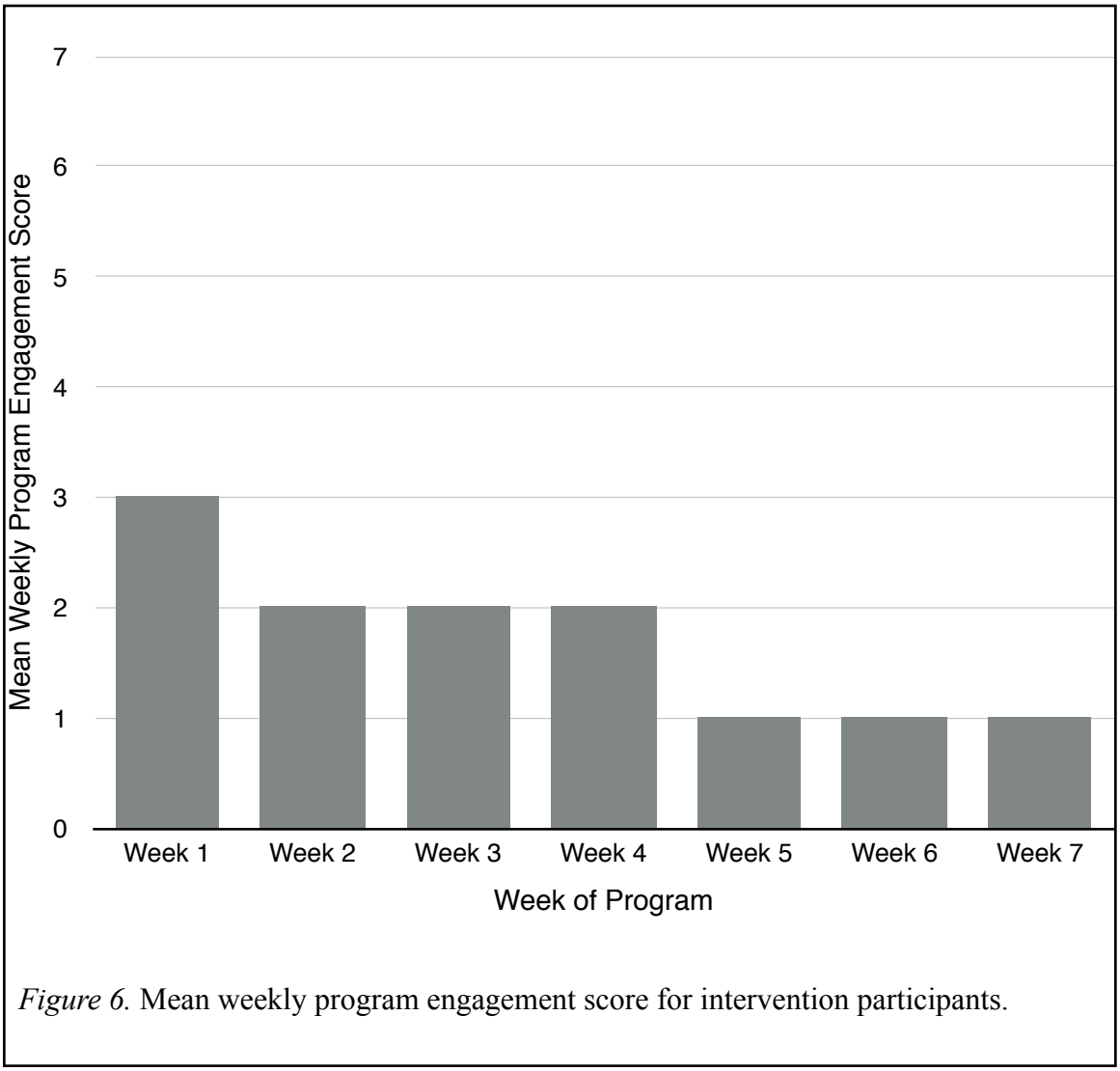


Figure 6. Mean weekly program engagement score for intervention participants.

Participant characteristics and total program engagement. Potential differences in total program engagement scores between the age groups and also between current treatment status were first assessed by visual inspection of boxplots. Boxplots appeared similar for all groups. Differences in median total program engagement scores were not statistically significant between age groups ($\chi 2(4) = 0.64$, $p = .96$) or between those

receiving current treatment and those who were not (Mann-Whitney $U = 759$, $z = -0.19$, $p = .85$).

Use of key program features. Use of key program features was largely consistent throughout each week of the program. The majority of participants opened the weekly email and many participated in the text message meditation two or three times per week. Opening of the mindful eating PDF and participation in additional text message meditations then followed with less frequency. The mindful movement videos were the least used feature (Table 15).

Table 15

Weekly Use of Key Program Features by Intervention Group Participants

Week	Opened Email		Opened Mindful Eating PDF		Replied to Text Messages[a,b]						Watched Video(s)[c,d]			
					2-3 texts		4-5 texts		6-7 texts		1 video		2 videos	
	n	(%)	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Week 1	69	83	35	42	54	65	36	43	7	8	30	36	13	16
Week 2	66	80	36	43	47	57	25	30	9	11	17	20	11	13
Week 3	55	66	22	27	35	42	19	23	7	8	10	12	7	8
Week 4	55	66	18	22	33	40	17	20	9	11	6	7	4	5
Week 5	53	64	15	18	31	37	14	17	8	10	5	6	5	6
Week 6	50	60	7	8	23	28	11	13	4	5	5	6	3	4
Week 7	62	75	13	16	23	28	13	16	6	7	6	7	1	1

Note. *n* = Number of individuals who completed the activity.
[a] A participant who replied to 4-5 texts is counted in both the 2-3 and 4-5 text message columns.
[b] A participant who replied to 6 texts is counted in all three text message columns.
[c] A participant who watched 2 videos is represented in both columns.
[d] A "watched" video required that the video was not closed before 1/2 of it had played.

Use of the forum, bonus content, and external links. The forum was used very little. A total of nine intervention participants entered into the forum during her/his first week of the program and only four participants posted in the forum during the entire study period. The bonus worksheets (journaling exercises) were a more popular feature and external links contained in the email were clicked by some participants (Table 16).

Table 16

Weekly Use of Extra Program Features by Intervention Group Participants

Week	Entered Forum		Visited Blog		Clicked on Bonus Worksheet		Clicked on External Link in Email[a]	
	n	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Week 1	9	11	21	25	44	53	13	16
Week 2	10	12	8	10	21	25	na	na
Week 3	7	8	4	5	9	11	na	na
Week 4	4	5	3	4	9	11	1	1
Week 5	1	1	11	13	14	17	na	na
Week 6	1	1	2	2	3	4	15	18
Week 7	3	4	3	4	9	11	4	5

Note. n = Number of individuals who completed the activity.
[a] Weeks marked "na" did not include an external link in the weekly email.

Participant feedback. In addition to the objective tracking tools, participant use of Sherman Project was assessed through four qualitative questions that were asked at post-assessment. These questions were:

1. What practices (if any) will you continue as result of your participation in the program?

2. What did you like most about the program?

3. What did you like least about the program?

4. Do you have any additional comments? Please share below.

Fifty-six participants answered at least one feedback question. Responses to these questions were grouped into categories of similarly-themed responses. Many participants named multiple practices or features for each question and all were included in the categories as appropriate (Table 17). Short, daily mindfulness practices and mindfulness meditations were most commonly cited by participants as practices that they would continue. Participants noted that they liked most the text message reminders and the portability and convenience of Sherman Project. However, text message reminders were also one of the most frequently noted "least liked" features of the program. Some participants also found the program to be too much work and the program website difficult to access. Access barriers reported by participants included a lack of mobile optimization for the program and simply forgetting that the website existed because the text message feature was so dominant.

Table 17

Responses to Open-Ended Program Feedback Questions at Post-Assessment

Response Category	Feedback Questions					
	"What I'll continue."		"What I liked most."		"What I liked least"	
	n	%	n	%	n	%
Text message reminder	na		16	29	8	14
Reflective practice of 3 words after meditation	5	9	6	11	2	4
Short, daily mindfulness practice	23	41	7	13	0	0
Mindful meditations	21	38	4	7	0	0
Mindful eating	15	27	3	5	6	11
Mindful movement videos	13	23	3	5	3	5
Variety of mindfulness practices	1	2	9	16	0	0
Forum	0	0	1	2	3	5
Weekly themes	2	4	4	7	0	0
No in-person interactions	na		0	0	3	5
Portability, convenience of the program and practices			14	25	0	0
Wasn't tailored enough or I couldn't track my other mindfulness or wellbeing activities			na		4	7
Hard to access the website or use the movement videos with my computer					6	11
Too much work or I couldn't make the time					9	16
Too basic, repetitive, or got bored with it					3	5

Note. A total of 56 participants provided at least one answer to the feedback questions and were included in this analysis. Some participants reported multiple answers for each questions. All answers were grouped accordingly and are represented in this table. *n* = number of participants who provided an answer relevant to that category.

Adverse Events

No adverse events were reported by participants of the study. Four individuals communicated discontinuation from the study, two due to stated lack of time and the other two for unspecified personal reasons. All four of these individuals were in the intervention group. At post-assessment, two intervention participants reported that they sought additional care while participating in the study. Both of these participants also noted that Sherman Project was "not enough" or not the "right fit."

Summary of Results

Self-report survey instruments were used to estimate the effectiveness of Sherman Project in reducing perceived stress and improving wellbeing. Effectiveness was assessed using multiple instruments at mid and post-assessment; however the study was powered only to detect changes in PSS-10 scores at mid-assessment. Effectiveness of the intervention on perceived stress was significant at mid and post-assessment while controlling for baseline PSS-10 scores. After controlling for age, gender, and current treatment from a practitioner for an anxiety or depressive condition, effect of the intervention on perceived stress was significant only at post-assessment. Wellbeing improved more for the intervention group compared to the waitlist control, demonstrating similar trends as was seen for the primary aim analyses. Age and current treatment from a practitioner for an anxiety or depressive condition had a significant effect on wellbeing outcomes in many of the models, particularly at post-assessment. Intervention participants engaged in the 7-week program for roughly 120 total minutes. Features of the

program utilized most by participants were the weekly email and the text message meditation. The text message feature was also noted as a favorite program component by intervention participants.

Chapter 5: Discussion

The purpose of the study was to determine the effect of a self-guided, web-based mindfulness program on perceived stress and wellbeing for a group of University students, staff, and faculty. Investigation of the study aims was achieved through a RCT that compared outcomes of participants who engaged with Sherman Project to a waitlist control group. Inclusion of a comparison group, a fully-automated research process, adequate power to detect changes in perceived stress at the mid-assessment, and utilization of objective tracking systems were strategies that served to improve on the methodologies of previous studies. This chapter provides a summary and discussion of the results in regard to the sample, treatment integrity, investigated aims, and adverse outcomes.

Sample

The number and percent of dropouts were lower than originally estimated. This allowed recruitment of fewer individuals than planned while still maintaining an adequately powered study to detect changes in perceived stress at mid-assessment. Automated randomization of participants into the intervention and waitlist created similar groups without measured demographic or clinical differences at baseline. However, the sample was different than the study population in key respects. The sample was primarily non-Hispanic white and female (90% of the study sample were female compared to a gender-balanced University population). Recruitment efforts unsuccessfully attempted to attract a more diverse sample. Strategies included recruitment emails to student-led

cultural clubs, use of images of men and persons of color on recruitment flyers and Facebook ads, and posting of flyers in more male-dominated departments at the University. Gender diversity may be a particularly difficult hurdle for eHealth programs to address considering women are more likely to use the Internet to gather health information (Kohl, Crutzen, & De Vries, 2013; Strecher, 2007). Compared to men, women may also may feel more comfortable engaging in eHealth programs (Strecher, 2007).

On average, the sample had a slightly higher baseline PSS-10 score than the population mean for the PSS-10; indicating higher perceived stress in the study sample. The sample also had a WHO-5 mean score of 50 compared to the estimated US population average of 70; indicating lower wellbeing in the study sample. These shifts from estimated norms may be expected because the study sample was self-selected for a stress reduction and wellbeing intervention. It may also suggest that a university community experiences higher perceived stress and lower wellbeing than population norms.

Treatment Integrity

Technical problems occurred during this study that may have impacted treatment integrity. A coding error in the text message feature of Sherman Project resulted in missed text messages to eight participants for between one and 10 days. The error prevented Sherman Project from notifying Twilio (the integrated text messaging platform) to send the user her/his text message. As result, the text messaging platform did not log any

errors and the PI was not aware of the coding error until a participant contacted the PI. The problem was resolved in 3 days after knowledge of the error. During those 3 days, the PI manually sent text messages through Twilio to the eight participants who were not receiving them correctly. The tracking system of Sherman Project was also enhanced during that time so that any future text messaging errors that were fault of Sherman Project would be logged.

Another technical error resulted from a non-functioning email integration through MailChimp. As result of the error, completions of the mid-assessment by some participants were not properly recognized. This resulted in the automatic sending of an assessment reminder email to eight participants who had already completed the assessment. One participant contacted the researcher regarding the error and MailChimp developers were immediately informed. The error was not fixed during the study period. Thus, the PI monitored assessment completions and manually removed each participant email from the automatic mid or post-assessment email reminders as needed.

Primary Aim

Compared to the waitlist group, intervention participants demonstrated significantly lower perceived stress while adjusting for baseline PSS-10 score at mid and post-assessment. These findings are consistent with the results of Cavanagh et al. (2013), Krusche (2012; 2013), and Morledge et al. (2013) who also demonstrated significant reductions in PSS scores for participants who engaged in a self-guided, web-based mindfulness intervention. However, in all four of those studies, baseline PSS scores

averaged no lower than 21 points, compared to an unadjusted mean of 17 for this study sample. It is possible that participants who engaged in Sherman Project did not have as much room for change in PSS-10 scores considering their baseline mean was closer to the population average of 13 points. At post-assessment, intervention participants had an adjusted mean of 14 points compared to about 17 points for the waitlist control. This mean score for the intervention group is below the 2009 population average for the PSS-10 (Cohen & Janicki-Deverts, 2012), though one point higher than the previous population average of 13 points estimated by Cohen & Williamson (1988). Intervention participants' return back to population norms may further support the primary aim findings.

Results of this primary aim analysis are comparable to Morledge et al. (2013) who evaluated an 8-week intervention owned by the Cleveland Clinic. Features and characteristics of their program are most similar to Sherman Project when compared to other self-guided, web-based mindfulness programs. Morledge et al. (2013) found that compared to the intervention group, the waitlist control had on average 2 to 3 points higher PSS-10 score at post-assessment (adjusted for baseline age, gender, race, education, and income). The current study found similar results with the waitlist control scoring on average about 2 points higher PSS-10 score (adjusted for baseline PSS-10 score) at mid-assessment and about 3 points higher at post-assessment compared to the intervention group.

Measured effect sizes for the primary aim analyses were not strong. Sherman Project accounted for about 3% of variance in PSS-10 scores at mid-point and 6% at post-assessment. It is likely these effect sizes could be improved on and strategies informed by the findings of aim 5 may be particularly useful for future iterations to the program. Additionally, small but reliable effect sizes may be meaningful for interventions aimed at a more general population (Kazdin & Blasé, 2011). Sherman Project may meet these qualifications as the intervention was developed to serve as a low-intensity, open-access option to address unmanaged stress and improve wellbeing. Positioning of the program as a first step in a stepped-care system may also mean that these effect sizes are sufficient for public health use.

Exploratory Aims

This study was not powered to detect statistically significant differences in the aim 2 analyses or wellbeing instruments (aim 3). Thus, discussion of exploratory aims are focused on mean differences for outcomes and findings that help inform the results of the primary analyses.

Aim 2. The estimated treatment effects of the primary aim model (adjusted for baseline PSS-10 score) and the aim 2 model (adjusted for baseline PSS-10 score and the participant characteristics) were very similar. The waitlist control averaged about 2 points higher on the PSS-10 (representing more perceived stress) for both the primary aim and the aim 2 mid-assessment models. At post-assessment, the waitlist scored on average 3

points higher on the PSS-10 for both the primary aim and the aim 2 models. These consistent treatment effects further support the results of the primary analyses.

Gender and current treatment did not significantly impact perceived stress outcomes at either mid or post-assessment. Powell et al. (2013) also found that measured health outcomes were not significantly associated with gender or baseline clinical characteristics in their sample. However, age significantly impacted the mid-assessment model of the current study, with 35-44 year olds reporting more perceived stress than all other age group and significantly higher compared to the 55+ age group. The higher mean PSS-10 score in this age group is not consistent with the population trends as reported by Cohen and Janicki-Deverts (2012) in 1983, 2006, or 2009. These authors identified younger age groups (i.e., less than 25 and 25-34) as more likely to report higher PSS-10 scores compared to older age groups (i.e., 35-44, 45-54, 55-64, and 65 and over). It is possible that the 35-44 age group within a university setting has a unique set of experiences that may increase PSS-10 scores, such as being a graduate student or early-career faculty member.

Aim 3. Compared to the waitlist, intervention participants reported improvements on all wellbeing measures at mid and post-assessment. Additionally, intervention participants had a 10% score improvement on the WHO-5, which is considered meaningful change for the WHO-5 (proposed by Ware, 1995). This measure of change further supports the primary aim analyses and may support hypothesizing Sherman Project as an effective low-intensity intervention to improve wellbeing.

From baseline to post-assessment, intervention participants improved their BSS scores by an average of 0.39 points. Bazarko et al., (2013) reported an improvement of 0.94 points for participants of their 8-week technology assisted MBSR program (tMBSR). Participants of their study were encouraged to participate in at-home daily practices, 6 teleconference calls (1.5 hours each), and two full-day, in-person retreats. When compared to the tMBSR program, change scores on the BSS for Sherman Project participants appear meaningful, particularly considering the low-intensity nature of the program.

Baseline adjusted means for the PROMIS subscales followed a similar pattern as the PSS-10, with the waitlist demonstrating slightly improved mean scores at both mid and post-assessments and the intervention group reporting larger improvements at both time points. Intervention participants also reported greater improvements on the PROMIS physical health subscale compared to the mental health subscale. Sherman Project included mindful movement practices that may have impacted outcomes on this scale, however this component of the program was not well-utilized by intervention participants. Performance of the PROMIS global health scale may have also been impacted by this study's comparatively small and homogeneous sample as the instrument is believed to be most applicable to large studies with demographically diverse participants (Cella et al., 2010).

The decrease that occurred in WHO-5 scores from mid to post-assessment in both groups was not expected. According to the mindful coping model, positive emotions and

reduced stress occur together in response to mindful awareness and positive reappraisal. Thus, it was expected that changes for the WHO-5 would closely mirror changes for the PSS-10. However, it is also possible that these findings are consistent with the mindful coping model and further support the effectiveness of Sherman Project and the findings of the primary analyses for this study sample. Questions on the WHO-5 (i.e., "I wake up feeling fresh and rested" and "I feel active and vigorous") may have been particularly sensitive to the wellbeing effects of increased workloads and responsibilities of the University students, staff, and faculty over the course of the semester. Wang et al. (2014) utilized ecological momentary assessment (EMA) to assess PSS scores over the course of an academic term for a sample of 531 students from a large Midwestern University. Wang et al. (2014) found PSS scores increased during the first half of the term (representing more stress), peaked around mid-term, and plateaued through the week of finals. If wellbeing followed a similar trajectory in the current study, it is possible that participants identified reduced wellbeing over the course of the semester (and study period), but those who engaged in the intervention were able to cultivate or maintain the cognitive flexibility and broadened attention that characterizes the state of mindful awareness. This may have enabled continued practice of positive reappraisal (even amidst reduced wellbeing), and in effect, a reduction in perceived stress.

Decreased wellbeing amidst improved stress scores was also evidenced by participants who reported current treatment from a practitioner for an anxiety or depressive condition at baseline. Current treatment had a significant effect on the post-

assessment scores of all the wellbeing scales, with those receiving current treatment reporting lower wellbeing scores compared to those who were not receiving current treatment. The effect of current treatment was not present for PSS-10 scores at mid or post-assessment. It is possible that amidst lower wellbeing scores, those who were receiving current treatment were still able to utilize the mindfulness practices and positive reappraisal to reduce perceived stress. It is uncertain as to why current treatment had a significant effect at mid-assessment on only the PROMIS mental health scores. The field does not offer much insight as association of illness severity at baseline with attrition, adherence, and health outcomes for eHealth programs has been explored, however the direction of these associations has not been consistent (Van Voorhees et al., 2013). It is possible that those receiving treatment were more sensitive to the escalating stressors over the course of the academic semester (as described above) compared to participants who were were not receiving treatment. These findings may also emphasize the appropriate positioning of Sherman Project as a low-intensity, first step resource that does not aim to replace current treatment from a practitioner.

Aim 4. There was a small, but non-significant negative correlation between program engagement and mean change for the PSS-10, suggesting that as participants engaged more in the program, perceived stress decreased. Krusche et al. (2012) found a similar, non-significant trend between increased program engagement and reduced PSS scores. Gluck & Maercker (2010), Krusche et al. (2013), Morledge et al. (2013) primarily utilized self-report to measure program engagement and had varying levels of ideal

program engagement. All of these studies found a significant relationship between program engagement and lower stress scores.

Aim 5. Use of Sherman Project by intervention participants decreased each week, with an average weekly score of 2 points (out of 7), equating to approximately 20 minutes of weekly program engagement. Based on the provided data of the six reviewed studies, it appears that the majority of participants who completed assessments in those studies engaged in about 50% of their respective program. This level of engagement is roughly consistent with the findings of this study.

Emails and the text message meditations were utilized most frequently by participants of this study. The text message feature was used about two or three times per week by participants. This feature served as a tailoring strategy in that after a participant practiced the mindful meditation and then replied to the text message with their positive reappraisal, the reply then appeared on the participant's private weekly module page. Additionally, the text message aimed to improve participant engagement by bringing the program more directly to the participant via their mobile phone. This strategy appeared successful as many participants self-reported that the convenience and portability of the program in addition to the daily text message feature helped to keep them engaged and accountable to the practices. The positive replies to the text message feature may further support the effectiveness of Sherman Project, the findings of the primary analyses, and the conceptual framework of this study. Specifically, after the text message meditation, individuals commonly replied back with words such as "more peaceful," "open,"

"connected," and "focused." These words may support a state of mindful awareness and successful positive reappraisal. Whitton, et al. (2015) found similar results, identifying that text messages in their self-guided, web-based program for depression, anxiety, and stress served as a program reminder and therapeutic tool.

Lack of mobile optimization may have reduced engagement and impacted outcomes for this study as some participants noted that they "felt disconnected" from the website or it was "hard to remember to connect with the website." Sherman Project was not fully optimized for mobile use, however the text message meditations were responsive to mobile phones. The six studies reviewed did not utilize mobile features or note that the program was optimized for mobile use.

Very few intervention participants used the interactive social component of Sherman Project. These components, which included the forum, blog, and social media spaces, aimed to create an active online community that could offer peer support for participants and improve intervention engagement. Morledge et al. (2013) utilized a similar feature and compared a waitlist control to two active mindfulness arms, one of which had access to a forum/message board. The message board group demonstrated larger change trends for some outcomes and a larger percentage completed the post-assessment and follow-up measures. However, of participants who visited the message board at least once, 85% reported it to be of little or no help. Lack of impact on intervention outcomes from the forum utilized by Morledge et al. (2013) and the social spaces of Sherman Project may be result of the infancy of these features. Namely, online

communities take time to build. Without an existing and active community, it is likely that the effect of a mostly vacant social space on intervention outcomes would be limited at best.

Qualitative feedback regarding Sherman Project was positive. Only one intervention participant reported not liking any of the features and seemed to dislike the overall program, noting that he got "bored with it" after the first week. Other participants noted features that they did not like, but these were all accompanied by cited features that they did enjoy and found helpful. Several participants also noted in the qualitative questions that they received the text message meditation, meditated either at that time or soon after, but forgot to text the system back. Tracking of text message engagement, and ultimately the calculation of the program engagement score, was based on a participant's text replies to the system. This may suggest that participants engaged in more text message meditations than were measured.

Adverse Effects

There were no reported adverse events by any participants of the study. At post-assessment, two intervention participants reported in the qualitative questions that they sought additional care while participating in the study. It is uncertain what role Sherman Project may have played in this treatment-seeking behavior.

Chapter 6: Limitations

A number of potential limitations and methodological issues must be considered in interpreting the results of this study. These limitations and issues may have impacted external and internal validity.

External Validity

This study had broad inclusion criteria to maximize generalizability and mirror the low-intensity, stepped-care context in which the program aims to serve. However, primary limitations of this research include low statistical power for the exploratory aims and the use of a self-selected convenience sample of students, staff, and faculty from a large Midwestern University. The sample was very similar to the samples of other self-guided eHealth interventions, but not representative of the campus population in terms of gender and ethnicity. It is likely that a campus population differs from the general population as well. In effect, the sample has limited generalizability to the campus population and the larger public health context within which it aims to serve.

Though there was lower attrition in this study than many self-guided, web-based eHealth programs, it is still uncertain as to why 35% of the intervention group dropped out. Some authors suggest that high levels of attrition may be a unique characteristic of self-guided, web-based eHealth and perhaps should be interpreted differently than in-person interventions or clinical trials (Leykin, Aguilera, Torres, Perez-Stable, & Munoz, 2012). Leykin et al. (2012) suggested that attrition does not necessarily imply the intervention was unsuccessful. Instead, a user may stop engaging with a program in

response to successful behavior change and a belief that the intervention is no longer relevant (Strecher, 2007).

An additional limitation concerns the use of the wellbeing gift bag incentive. It is possible that this incentive improved adherence to the program. Because an incentive is not currently offered for participation in Sherman Project, it is possible that adherence might be lower for Sherman Project outside of a research context.

Internal Validity

This RCT utilized partial researcher blinding and a fully-automated research protocol to improve internal validity. These strategies minimized experimenter bias and selection bias. However, the study relied fully on self-report for all participant outcomes, a common bias in eHealth studies and survey research. The impact of the intervention may have also been moderated by unidentified demographic characteristics. Few demographic data were collected and it is possible that an unmeasured difference between the two groups had an impact on the dependent variables. Additionally, due to the instruments used in the study and the study design, it was not possible to identify definitively that mindfulness or positive reappraisal influenced outcomes. Mindfulness was not measured in the current study as many mindfulness instruments lack quality and conceptual consistency (Park, Reilly-Spong, & Gross, 2013) and were created to evaluate outcomes of specific mindfulness interventions (Brown, Ryan, & Creswell, 2007).

The technical issues noted earlier also impacted internal validity. However, it is also likely that errors and bugs will occur for self-guided, web-based programs as they

function outside of a research context. Lack of precision in measuring participant engagement with Sherman Project is another concern. As noted earlier, several intervention participants noted in the qualitative questions that they received the text, meditated either at that time or soon after, but forgot to text the system back. This suggested that participants may have engaged in more of the program than was identified by the program engagement score. On the other hand, if the participant received the text, did not participate in the meditation, but replied to the text message anyway, then that action would be counted toward his/her engagement score. These tracking concerns are not limited to the text messaging feature. For example, a participant may have played a video and then walked away without watching. This would have counted toward his/her engagement score because the video was played for longer than half of its full length. A participant may have also simply clicked an email to appear engaged in the program and then immediately deleted it without reading any content. These potential incidents may identify a different type of self-report bias in eHealth. Namely, participants can, with little effort, simulate intervention adherence.

Three responses from participants on the post-assessment feedback questionnaire also revealed internal validity issues. One participant dropped her phone in the toilet early in the intervention and thus did not engage in the text message meditations. Another participant was not able to log in to access content due to work restrictions. A third participant was not able to see the movement practices well on her phone. Similar

situations and concerns may have occurred more frequently within the sample but went unreported by participants.

Many limitations of previous studies were addressed in this research through the use of an adequately powered RCT, a fully-automated study protocol, and more objective program engagement measures. However, internal and external validity issues were still present. Most notably, generalizability of the study results were impacted by a homogeneous study sample. Further, even though the text message meditation was a favorite feature of the program, it is uncertain what role mindfulness and positive reappraisal had for the reduction of perceived stress and improvements in wellbeing. Future research should include psychometrically sound instruments to address these potential mechanisms.

Chapter 7: Recommendations and Conclusions

Implications and Recommendations for Nursing Practice and Research

A stepped care model has been proposed to improve the effectiveness and safety of eHealth tools and interventions (van Straten et al., 2010). Nurses and health coaches may be the most knowledgeable and cost-effective professionals to lead this model. Kreitzer (2015) proposed six principles of integrative nursing that are consistent with and may uniquely inform the leadership role nurses may take in a stepped-care approach. Kreitzer's (2015) fifth principle identified that "integrative nursing is informed by evidence and uses the full range of therapeutic modalities to support/augment the healing process, moving from least intensive and invasive to more, depending on need and context (Kreitzer, 2015, p. 4). Consistent with this principle, nurses and health coaches could help individuals find the most appropriate and lowest-intensity eHealth intervention to fit their needs. The nurse or coach could then guide or help monitor a participant's progress through a program to improve outcomes and, if necessary, refer the individual to a higher or different level of care. For example, a nurse or coach could help an individual choose between a self-guided, web-based mindfulness program and a program with more support, but that is still technology-assisted (e.g., a teleconferencing MBSR intervention; Reilly-Spong, Reibel, Pearson, Koppa, & Gross, 2015).

Stepped-care delivery of eHealth programs also situates these resources within a broader system. This may be a more effective strategy (versus stand alone programs) so that users are more able to access in-person services if needed (Sherry & Ratzan, 2012).

Sherman Project was developed to serve in a stepped-care model and future research could investigate the effectiveness of the program within this model.

Recommendations for Future Research

A primary next step for future research would be a larger and more diverse study powered to detect both wellbeing outcomes and changes in perceived stress. Additionally, an active control that matches Sherman Project but excludes the positive reappraisal exercise would help explore the mechanisms of change. An active control design would contribute greatly to the field as these are rare in mindfulness research (MacCoon et al., 2012), although active control may have their own limitations. Studies with different primary outcomes central to public health, such as insomnia, may also demonstrate whether or not the intervention might effectively address more targeted public health issues related to stress. For example, the study design could replicate that of Gross et al. (2011) for chronic primary insomnia with the substitution of Sherman Project for the in-person MBSR intervention.

Program engagement findings also suggest the need to revisit the value specification cycle of the CeHRes roadmap and work forward through the cycles to determine how program engagement can be increased particularly after the second week of the program. In a stepped-care model, this may include an email check in with a nurse or health coach. Additional iterations informed by the CeHRes roadmap to improve adherence to and effectiveness of the intervention may include 1) refinements to the

mindful movement and eating components, 2) mobile optimization of the program, and 3) improved integration and community building for the social features.

A study design with more attention to attrition and adherence would also help address a black box in the field of self-guided, web-based eHealth. Some experts have suggested that a subgroup of participants could be randomly selected to participate in live follow up assessments during the intervention or at the very least, at post-assessment (Geraghty et al., 2012; Leykin et al., 2012). Another suggestion is to utilize dismantling studies and moderator and mediator analyses, as is often suggested in intervention research (van Voorhees et al., 2013). However, that approach may prove too slow in the fast-paced world of consumer health technologies (Whittaker et al., 2012). Low-burden assessment tools could also help fill in this gap. For example, real time data collection via a text message prompt could gather more information from a participant before the user drops out while also reducing user-burden, increasing tailoring options, and establishing a support system for the user (Glasgow, Phillips, & Sanchez, 2014). Garcia et al. (2014) successfully utilized this type of strategy through a text-message based ecological momentary assessment system that collected data about "individual- and social-level factors that influence physical, mental, emotional, and social wellbeing" (para. 2) for a sample of Latina adolescents. Use of a similar mobile assessment system with Sherman Project may offer insight into the attrition while also adding an additional support feature for participants.

Conclusions

This RCT addresses a gap in the mindfulness and eHealth literature by providing an adequately powered and more objective investigation of the effectiveness of and engagement with a self-guided, web-based mindfulness intervention to reduce perceived stress. Results of this study demonstrate that Sherman Project can reduce perceived stress as soon as the intervention mid-point. Results also support further investigation of the potential effects of the intervention on wellbeing. Though it cannot be stated that mindfulness or positive reappraisal were primary mechanisms that impacted results, this study demonstrated that mindfulness-based practices and positive reappraisal exercises can be delivered without in-person interaction. These findings further demonstrate that self-guided, web-based mindfulness interventions may be an effective strategy to address barriers of in-person programs and may be helpful as part of a larger strategy to address the public health issue of unmanaged stress.

References

Andersson, G., & Culjpers, P. (2009). Internet-based and other computerized psychological treatments for adult depression: A meta-analysis. *Cognitive Behaviour Therapy, 38*(4), 196-205. doi:10.1080/16506070903318960

Andreotti, C., Thigpen, J. E., Dunn, M. J., Watson, K., Potts, J., Reising, M. M., … Compas, B. E. (2013). Cognitive reappraisal and secondary control coping: Associations with working memory, positive and negative affect, and symptoms of anxiety/depression. *Anxiety, Stress, & Coping, 26*(1), 20-35. doi:10.1080/10615806.2011.631526

Andreou, E., Alexopoulos, E. C., Lionis, C., Varvogli, L. Gnardellis, C., Chrousos, G. P., & Darviri, C. (2011). Perceived Stress Scale: Reliability and validity study in Greece. *International Journal of Environmental Research and Public Health, 8*(8), 3287-3298. doi:10.3390/ijerph8083287

Azagba, S., & Sharaf, M. F. (2011). Psychosocial working conditions and the utilization of health care services. *BMC Public Health*, *11*, 1-7. doi:10.1186/1471-2458-11-642

Baer, R. A., Smith, G. T., & Allen, K. B. (2004). Assessment of mindfulness by self-report: The Kentucky inventory of mindfulness skills. *Assessment, 11*(3), 191-206. doi:10.1177/1073191104268029

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13*(1), 27-45. doi:10.1177/1073191105283504

Barak, A., Klein, B., & Proudfoot, J. G. (2009). Defining Internet-supported therapeutic interventions. *Annals of Behavioral Medicine, 38*, 4-17. doi:10.1007/s12160-009-9130-7

Barazzone, N., Cavanagh, K., & Richards, D. (2012). Computerized cognitive behavioural therapy and the therapeutic alliance: A qualitative enquiry. *British Journal of Clinical Psychology, 51*, 396–417. doi:10.1111/j.2044-8260.2012.02035.x

Bazarko, D., Cate, R. A., Azocar, F., & Kreitzer, M. J. (2013). The impact of an innovative Mindfulness Based Stress Reduction Program on the health and well-being of nurses employed in a corporate setting. *Journal of Workplace Behavioral Health, 28,* 107-133. doi:10.1080/15555240.2013.779518

Bech, P. (2012a). *Clinical psychometrics.* Oxford: Wiley-Blackwell.

Bech, P. (2012b). Subjective positive well-being. *World Psychiatry, 11*(2), 105-106. doi: 10.1016/j.wpsyc.2012.05.021

Bech, P., Olsen, L. R., Kjoller, M., & Rasmussen, N. K. (2003). Measuring well-being rather than the absence of distress symptoms: A comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being scale. *International Journal of Methods in Psychiatric Research, 12*(2), 85-91. doi:10.1002/mpr.145

Bergen-Cico, D., Possemato, K., & Cheon, S. (2013). Examining the efficacy of a brief mindfulness-based stress reduction (Brief MBSR) program on psychological health. *Journal of the American College Health, 61*(6), 348-360. doi:10.1080/07448481.2013.813853

Berger, T., Hammerli, K., Gubser, N., Andersson, G., & Caspar, F. (2011) Internet-based treatment of depression: A randomized controlled trial comparing guided with unguided self-help. *Cognitive Behaviour Therapy, 40*(4), 251-266. doi:10.1080/16506073.2011.616531

Bishop, S. R. (2002). What do we really know about Mindfulness-Based Stress Reduction? *Psychosomatic Medicine, 64*, 71-84. Retrieved from http://www.psychosomatic.org/ home/index.cfm

Boettcher, J., Astrom, V., Pahlsson, D., Schenstrom, O., Andersson, G., & Carlbring, P. (2014). Internet-based mindfulness treatment for anxiety disorders: A randomized controlled trial. *Behavior Therapy, 45*, 241-253. doi:10.1016/j.beth.2013.11.003

Brosschot, J. F., Gerin, W., & Thayer, J. F. (2006). The perseverative cognition hypothesis: A review of worry, prolonged stress-related physiological activation, and health. *Journal of Psychosomatic Research*, *60*, 113-124. doi:10.1016/j/jpsychores.2005.06.074

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*(4), 822-848. doi:10.1037/0022-3514.84.4.822

Brown, K. W. & Ryan, R. M. (2004). Perils and promise in defining and measuring mindfulness: Observations from experience. *Clinical Psychology: Science and Practice, 11*(3), 242-248. Retrieved from http://www.personal.kent.edu/~dfresco/mindfulness/Brown_%26_Ryan.pdf

Brown, K., Ryan, R., & Creswell, J. (2007). Addressing fundamental questions about mindfulness. *Psychological Inquiry, 18*(4), 272-281. doi:10.1080/10478400701703344

Carmody, J., & Baer, R. A. (2009). How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *Journal of Clinical Psychology, 65*(6), 627-638. doi: 10.1002/jclp.20555

Cavanagh, K., Strauss, C., Cicconi, F., Griffiths, N., Wyper, A., & Jones, F. (2013). A randomised controlled trial of a brief online mindfulness-based intervention. *Behavior Research and Therapy, 51*, 573-578. http://dx.doi.org/10.1016/j.brat.2013.06.003

Cavanagh, K., Strauss, C., Forder, L., & Jones, F. (2014). Can mindfulness and acceptance be learnt by self-help?: A systematic review and meta-analysis and acceptance-based self-help interventions. *Clinical Psychology Review, 34,* 118-129. http://dx.doi.org/10.1016/j.cpr.2014.01.001

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., … Hays, R. (2010). The Patient-Reported Outcomes Measurement Information System (PROMIS)

developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *Journal of Clinical Epidemiology, 63*(11), 1179-1194. doi: 10.1016/j.jclinepi.2010.04.011

Center for Spirituality & Healing (CSPH, n.d.). *Taking charge of your health & wellbeing: Glossary.* Retrieved from http://www.takingcharge.csh.umn.edu/glossary

Chiesa, A., & Serretti, A. (2009). Mindfulness-based stress reduction for stress management in healthy people: A review and meta-analysis. *Journal of Alternative and Complementary Medicine, 15*(5), 593-600. doi:10.1089/acm.2008.0495

Christensen, H., Griffiths, K. M., & Farrer, L. (2009). Adherence in Internet interventions for anxiety and depression: Systematic review. *Journal of Medical Internet Research, 11*(2), e13. doi:10.2196/jmir.1194

Christensen, H., Griffiths, K. M., & Jorm, A. F. (2004). Delivering interventions for depression by using the internet: Randomised controlled trial. *British Medical Journal, 328*(7434), 1-5. doi:10.1136/bmj.37945.566632.EE

Christensen, H., Griffiths, K. M., Korten, A. E., Brittliffe, K., & Groves, C. (2004). A comparison of changes in anxiety and depression symptoms of spontaneous users and trial participants of a cognitive behavior therapy website. *Journal of Medical Internet Research, 6*(4), e46. doi:10.2196/jmir.6.4.e46

Christensen, H., Griffiths, K. M., Mackinnon, A. J., & Brittliffe, K. (2006). Online randomized controlled trial of brief and full cognitive behaviour therapy for depression. *Psychological Medicine, 36*(12), 1737-1746. doi:10.1017/S0033291706008695

Cohen, S., & Janicki-Deverts, D. (2012). Who's stressed?: Distributions of psychological stress in the United States in probability samples from 1983, 2006, and 2009. *Journal of Applied Social Psychology, 42*(6), 1320-1334. doi:10.1111/j.1559-1816.2012.00900.x

Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24*(4), 385-396. Retrieved from http://www.jstor.org/stable/2136404

Cohen, S. & Williamson, G. (1988). Perceived Stress in a Probability Sample of the United States. In S. Spacapan & S. Oskamp. (Eds.) *The social psychology of health* (pp. 31-67). Newbury Park, CA: Sage.

Dimidjian, S., & Linehan, M. M. (2003). Defining an agenda for future research on the clinical application of mindfulness practice. *Clinical Psychology Science and Practice, 10*(2), 166-171. doi:10.1093/clipsy/bpg019

Donkin, L., & Glozier, N. (2012). Motivators and motivations to persist with online psychological interventions: A qualitative study of treatment completers. *Journal of Medical Internet Research, 14*(3), e91. doi:10.2196/jmir.2100

Eberth, J., & Sedlmeier, P. (2012). The effects of mindfulness meditation: A meta-analysis. *Mindfulness, 3*(3), 174-189. doi:10.1007/s12671-012-0101

Elliot, A. J., Thrash, T. M., & Murayama, K. (2011). A longitudinal analysis of self-regulation and well-being: Avoidance personal goals, avoidance coping, stress generation, and subjective well-being. *Journal of Personality, 79*(3), 643-674. doi:10.1111/j.1467-6494.2011.00694.x

Eysenbach, G. (2001). *What is eHealth? Journal of Medical Internet Research, 3*(2), e20. doi:10.2196/jmir.3.2.e20

Eysenbach, G. (2005). The law of attrition. *Journal of Medical Internet Research, 7, e11*. doi:10.2196/jmir.7.1.e11

Eysenbach, G. (2011). CONSORT-eHealth: Improving and standardizing evaluation reports of web-based and mobile health interventions. *Journal of Medical Internet Research, 13*(4), e126. doi:10.2196/jmir.1923

Eysenbach, G., & Kummervold, P. E. (2005). Is cybermedicine killing you?: The story of a Cochrane disaster. *Journal of Medical Internet Research, 7*(2), e21. doi:10.2196/jmir.7.2.e21

Eysenbach, G., Powell, J., Kuss, O., & Sa, E. R. (2002). Empirical studies assessing the quality of health information of consumers on the World Wide Web: A systematic review. *Journal of the American Medical Association, 287*(20), 2691-2700. doi: 10.1001/jama.287.20.2691

Folkman, S., & Moskowitz, J. T. (2000). Positive affect and the other side of coping. *American Psychologist, 55*(6), 647-654. doi:10.1037//0003-066X.55.6.647

Garcia, C., Hardeman, R. R., Kwon, G., Lando-King, E., Zhang, L., Genis, T. … Kinder, E. (2014). Teenagers and texting: Use of a youth ecological momentary assessment system in trajectory health research with Latina adolescents. *Journal of Medical Internet Research, 2*(1), e3. doi:10.2196/mhealth.2576

Garland, E., Gaylord, S., & Fredrickson, B. (2011). Positive reappraisal mediates the stress-reductive effects of mindfulness: An upward spiral process. *Mindfulness, 2*(1), 59-67. doi:10.1007/s12671-011-0043-8

Garland, E., Gaylord, S., & Park, J. (2009). The role of mindfulness in positive reappraisal. *Explore: The Journal of Science and Healing, 5*(1), 37-44. doi: 10.1016/j.explore.2008.10.001

Geary, C., & Rosenthal, S. L. (2011). Sustained impact of MBSR on stress, well-being, and daily spiritual experiences for 1 year in academic health care employees. The *Journal of Alternative and Complementary Medicine, 17*(10), 939-944. doi:10. 1089/acm.2010.0335

Geraghty, A. W. A., Torres, L. D., Leykin, Y., Perez-Stable, E. J., & Munoz, R. F. (2012). Understanding attrition from international internet health interventions: A step towards global eHealth. *Health Promotional International, 27*(3), 1-11. doi: 10.1093/heapro/ das029

Glanz, K. & Rimer, B. K. (2008). Perspectives on using theory: Past, present and future education. In K. Glanz, B. K. Rimer, & K. Viswanath, (Eds.). *Health behaviour and health education: Theory, research and practice* (pp. 509-519). San Francisco, CA: Jossey-Bass.

Glasgow, R. E., Phillips, S. M., & Sanchez, M. A. (2014). Implementation science approaches for integrating eHealth research into practice and policy. *International Journal of Medical Informatics, 83*(7), e1-e11. doi:10.1016/j.ijmedinf.2013.07.002

Gluck, T. M., & Maercker, A. (2011). A randomized controlled pilot study of a brief web-based mindfulness training. *BMC Psychiatry*, *11*, 1-12. doi:10.1186/1471-244X-11-175

Griffiths, F., Lindenmeyer, A., Powell, J., Lowe, P., & Thorogood, M. (2006). Why are health care interventions delivered over the internet? A systematic review of the published literature. *Journal of Medical Internet Research, 8*(2), 1-22. doi:10.2196/jmir.8.2.e10

Gross, C. R., Kreitzer, M. J., Reilly-Spong, M., Wall, M., Winbush, N. Y., Patterson, R. … Cramer-Bornemann, M. (2011). Mindfulness-based stress reduction versus pharmacotherapy for chronic primary insomnia: A Randomized controlled clinical trial. *EXPLORE: The Journal of Science and Healing, 7*(2), 76-87. doi:10.1016/j.explore.2010.12.003

Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress

reduction and health benefits: A meta-analysis. *Journal of Psychosomatic Research, 57*(1), 35-43. doi:10.1016/S0022-3999(03)00573-7

Gulliver, A., Griffiths, K. M., & Christensen, H. (2010). Perceived barriers and facilitators to mental health help-seeking in young people: A systematic review. *BMC Psychiatry, 10,* 1-9. http://www.biomedcentral.com/1471-244X/10/113

Hardiker, N. R., & Grant, M. J. (2011). Factors that influence public engagement with eHealth: A literature review. *International Journal of Medical Informatics, 80*, 1-12. doi:10.1016/ j.ijmedinf.2010.10.017

Hays, R. D., Bjorner, J. B., Revicki, D. A., Spritzer, K. L., & Cella, D. (2009). Development of physical and mental health summary scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) global items. *Quality of Life Research, 18*, 873-880. doi:10.1007/s11136-009-9496-9

Hofmann, S. G., Sawyer, A. T., Witt, A. A., & Oh, D. (2010). The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *Journal of Consulting and Clinical Psychology, 78*(2), 169-183. doi:10.1037/a0018555

Johansson, R., Sjöberg, E., Sjogren, M., Johnsson, E., Carlbring, P., Andersson, T., ... & Andersson, G. (2012). Tailored vs. standardized internet based cognitive behavior therapy for depression and comorbid symptoms: A randomized controlled trial. *PLoS ONE, 7*(5), 1-9. doi:10.1371/journal.pone.0036905

Kabat-Zinn, J. (1990). *Full catastrophe living.* New York, NY: Bantam Dell.

Kabat-Zinn, J. (1994). *Wherever you go, there you are.* New York, NY: Hyperion.

Kabat-Zinn, J. (2003). Mindfulness-based interventions in context: Past, present, and future. *Clinical Psychology: Science and Practice, 10*(2), 144-156. Retrieved from http://ftp.sci.kun.nl/CompMath.Found/kabat-zinn.pdf

Kabat-Zinn, J. (2005). *Coming to our senses: Healing ourselves and the world through mindfulness.* New York, NY: Hyperion.

Kazdin, A. E., & Blasé, S. L. (2011). Rebooting psychotherapy research and practice to reduce the burden of mental illness. *Perspectives on Psychological Science, 61*, 21-37. doi:10.1177/1745691610393527

Kessler, R. C., Berglund, P., Demler, O., Jin, R., Koretz, D., Merikangas, K., ... Wang, P. (2003). The epidemiology of major depressive disorder: Results from the national comorbidity survey replication (NCS-R). *Journal of the American Medical Association, 289*(23), 3095-3105. doi:10.1001/jama.289.23.3095

Klein, B., Meyer, D., Austin, D. W., & Kyrios, M. (2011). Anxiety online: A virtual clinic: Preliminary outcomes following completion of five fully automated treatment programs for anxiety disorders and symptoms. *Journal of Medical Internet Research, 13*(4), 1-21. doi:10.2196/jmir.1918

Kohl, L., Crutzen, R., & De Vries, N. (2013). Online prevention aimed at lifestyle behaviors: A systematic review of reviews. *Journal of Medical Internet Research, 15*(7), e146. doi:10.2196/jmir.2665

Kreitzer, M. J. (2015). Integrative nursing: Application of principles across clinical settings. *Rambam Maimonides Medical Journal, 6*(2), 1-8. doi:10.5041/RMMJ.10200

Kreitzer, M. J., Gross, C. R., Waleekhachonloet, O., Reilly-Spong, M., & Byrd, M. (2009). The brief Serenity Scale: A psychometric analysis of a measure of spirituality and well-being. *Journal of Holistic Nursing, 27*(1), 7-16. doi: 10.1177/0898010108327212

Kreuter, M. W., & C. S. Skinner, C. S. (2000). Tailoring: What's in a name? *Health Education Research, 15*(1), 1–4. doi:10.1093/her/15.1.1

Krusche, A., Cyhlarova, E., King, S., & Williams, J. M. G. (2012). Mindfulness online: A preliminary evaluation of the feasibility of a web-based mindfulness course and the impact on stress. *BMJ Open, 2*, 1-5. doi:10.1136/bmjopen-2011-000803

Krusche, A., Cyhlarova, E., & Williams, J. M. G. (2013). Mindfulness online: An evaluation of the feasibility of a web-based mindfulness course for stress, anxiety and depression. *BMJ Open, 3,* 1-10. doi:10.1136/bmjopen-2013-003498

La Placa, V., McNaught, A., & Knight, A. (2013). Discourse on wellbeing in research and practice. *International Journal of Wellbeing, 3*(1), 116-125. doi:10.5502/ijw.v3i1.7

Lazarus, R. S., & Alfert, E. (1964). Short-circuiting of threat by experimentally altering cognitive appraisal. *Journal of Abnormal and Social Psychology, 69*(2), 195-205. Retrieved from http://psycnet.apa.org.ezp1.lib.umn.edu/journals/abn/69/2/195.pdf

Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York, NY: Springer Publishing.

Leykin, Y., Aguilera, A., Torres, L. D., Perez-Stable, E., & Munoz, R. F. (2012). Interpreting the outcomes of automated internet-based randomized trials: Example of an international smoking cessation study. *Journal of Medical Internet Research, 14*(1), e5. doi:10.2196/jmir.1829

Lintvedt, O. K., Griffths, K. M., Sorensen, K., Ostvik, A. R., Wang, C. E. A., Eisemann, M., & Waterloo, K. (2013). Evaluating the effectiveness and efficacy of unguided internet-based self-help intervention for the prevention of depression: A randomized controlled trial. *Clinical Psychology and Psychotherapy, 20*(1), 10-27. doi:10.1002/cpp.770

Lustria, M. L. A., Noar, S. M., Cortese, J., Van Stee, S. K., Glueckauf, R. L., & Lee, J. (2013). A meta-analysis of web-delivered tailored health behavior change interventions. *Journal of Health Communication: International Perspectives, 18*, 1039-1069. doi:10.1080/10810730.2013.768727

MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., … Lutz, A. (2012). *Behaviour Research and Therapy, 50*, 3-12. doi:10.1016/j.brat.2011.10.011

Mackenzie, C. S., Reynolds, K., Cairney, J., Streiner, D. L., & Sareen, J. (2012). Disorder-specific mental health service use for mood and anxiety disorders:

Associations with age, sex, and psychiatric comorbidity. *Depression and Anxiety, 29,* 234-242. doi:10.1002/da.20911

Mackinnon, A., Griffiths, K. M., & Christensen, H. (2008). Comparative randomised trial of online cognitive-behavioural therapy and an information website for depression: 12-month outcomes. *British Journal of Psychiatry 192*(2), 130-134. doi:10.1192/bjp.bp.106.032078

McNaught, A. (2011). Defining wellbeing. In A. Knight & A. McNaught (Eds.). *Understanding wellbeing: An introduction for students and practitioners of health and social care* (pp. 7-23). Banbury: Lantern Publishing.

Moritz, S., Schilling, L., Hauschildt, M., Schröder, J., & Treszl, A. (2012). A randomized controlled trial of internet-based therapy in depression. *Behaviour Research and Therapy, 50*(7), 513-521. doi:10.1016/j.brat.2012.04.006

Morledge, T. J., Allexandre, D., Fox, E., Fu, A. Z., Higashi, M. K., Kruzikas, D. T. ... Reese, P. R. (2013). Feasibility of an online mindfulness program for stress management: A randomized, controlled study. *Annals of Behavioral Medicine, 46*, 137-148. doi:10.1007/ s12160-013-9490-x

Munoz, R. F., Cuijpers, P., Smit, F., Barrera, A. Z., & Leykin, Y. (2010). Prevention of major depression. *Annual Review of Clinical Psychology, 6*, 181-212. doi: 10.1146/annurev-clinpsy-033109-132040

Murray, E., Burns, J., Tai, S. S., Lai, R., & Nazareth, I. (2009). Interactive health communication applications for people with chronic disease. *Cochrane Database of Systematic Reviews, 4*, 1-83. doi:10.1002/14651858.CD004274.pub4

National Collaborating Centre for Mental Health (UK). (2011). Low-intensity psychological interventions in *Generalized anxiety disorder in adults: Management in primary, secondary, and community care* (pp. 95-131). Retrieved from: http://www.ncbi.nlm.nih.gov/books/NBK83459/pdf/Bookshelf_NBK83459.pdf

O'Conner-Von, S. (2009). Coping with cancer: A web-based educational program for early and middle adolescents. *Journal of Pediatric Oncology Nursing, 24*(4), 230-241. doi:10.1177/1043454209334417

Office of Institutional Research (OIR). (2015). Student data and human resource data. Retrieved from http://www.oir.umn.edu/

Olejnik, S., & Algina, J. (2000). Measures of effect size for comparative studies: Applications, interpretations, and limitations. *Contemporary Educational Psychology, 25*(3), 241-286. doi:10.1006/ceps.2000.1040

Osterwalder, A., & Pigneur, Y. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers.* Hoboken, NJ: John Wiley & Sons.

Park, T., Reilly-Spong, & Gross, C. R. (2013). Mindfulness: A systematic review of instruments to measure an emergent patient-reported outcome (PRO). *Quality of Life Research, 22*(10), 2639-2659. doi:10.1007/s11136-013-0395-8

Powell, J., Hamborg, T., Stallard, N., Burls, A., McSorley, J., Bennett, K., … Christensen, H. (2013). Effectiveness of a web-based cognitive behavioral tool to improve mental well-being in the general population: Randomized controlled trial. *Journal of Medical Internet Research, 15*(1), e2. doi: 10.2196/jmir.2240

Radley, J., Morilak, D., Viau, V., & Campeau, S. (in press). Chronic stress and brain plasticity: Mechanisms underlying adaptive and maladaptive changes and implications for stress-related CNS disorders. *Neuroscience & Biobehavioral Reviews*, 1-13. http://dx.doi.org/10.1016/j.neubiorev.2015.06.018

Reilly-Spong, M., Reibel, D., Pearson, T., Koppa, P., & Gross, C. R. (2015). Telephone-adapted mindfulness-based stress reduction (tMBSR) for patients awaiting kidney transplantation: Trial design, rationale, and feasibility. *Contemporary Clinical Trials, 42*, 169-184. doi:10.1016/j.cct.2015.03.013

Roberts, K., & Aspy, C. (1993). Development of the serenity scale. Journal of Nursing Measurement, 1(2), 145-164.

Segal, Z. V., Williams, J. M. G., & Teasdale, J. D. (2002). *Mindfulness based cognitive therapy for depression: A new approach to preventing relapse.* New York, NY: Guilford.

Selye, H. (1956). *The stress of life*. New York, NY: McGraw-Hill.

Shapiro, S., L., Oman, D., Thoresen, C. E., Plante, T. G., & Flinders, T. (2008). Cultivating mindfulness: Effects on well-being. *Journal of Clinical Psychology, 64*(7), 840-862. doi:10.1002/jclp.20491

Sherry, J. M., & Ratzan, S. C. (2012). Measurement and evaluation outcomes for mHealth communication: Don't we have an app for that? *Journal of Health Communication: International Perspectives, 17*, 1-3. doi:10.1080/10810730.2012.670563

Smedley, B. D., & Syme, S. L. (2000). *Promoting health: Intervention strategies from social and behavioural research*. Washington, D.C.: National Academy Press.

Sternberg, R. J. (2000). Images of mindfulness. *Journal of Social Issues, 56*(1), 11-26. doi:10.1111/0022-4537.00149

Strecher, V. (2007). Internet methods for delivering behavioral and health-related interventions (eHealth). *Annual Review of Clinical Psychology, 3*, 53-76. doi: 10.1146/annurev.clinpsy.3.022806.091428

Teasdale, J. D., Segal, Z.V., & Williams, M.G. (2003). Mindfulness training and problem formulation. *Clinical Psychology: Science and Practice, 10*(2), 157-160. doi:10.1093/clipsy.bpg017

Van Breukelen, G. J. P. (2006). ANCOVA versus change from baseline: More power in randomized studies, more bias in nonrandomized studies. *Journal of Clinical Epidemiology, 59*, 920-925. doi:10.1016/j.jclinepi.2006.02.007

van Gemert-Pijnen, J., Nijland, N., van Limburg, M., Ossebaard, H. C., Kelders, S. M., Eysenbach, G., & Seydel, E. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. *Journal of Medical Internet Research, 13*(4), e111. doi:10.2196/jmir.1672

van Straten, A., Seekles, W., van't Veer-Tazelaar, N. J., Beekman, A. T. F., & Cuijpers, P. (2010). *Medical Journal of Australia, 192*(11), 36-39. Retrieved from https://www.mja.com.au/system/files/issues/192_11_070610/van11056_fm.pdf

van Voorhees, B. W., Mahoney, N., Mazo, R., Barrera, A. Z., Siemer, C. P., Gladstone, T. R. G., & Munoz, R. F. (2013). Internet-based depression prevention over the life course: A call for behavioral vaccines. *Psychiatric Clinics of North America, 34*, 167-183. doi:10.1016/j.psc.2010.11.002

Victorson, D., Kentor, M., Maletich, C., Lawton, R. C., Hankin Kaufman, V., Borrero, M. … Berkowitz, C. (2015). Mindfulness meditation to promote wellness and manage chronic disease: A systematic review and meta-analysis of mindfulness-based randomized controlled trials relevant to lifestyle medicine. *American Journal of Lifestyle Medicine, 9*(3), 185-211. doi:10.1177/1559827614537789

Wang, R., Chen, F., Chen, Z., Li, T., Harari, G., Tignor, S., Zhou, X., … Campbell, A. T. (2014). StudentLife: Assessing mental health, academic performance and behavioral trends of college students using smartphones. *Proceedings of the 2014 ACM International Joint Conference on Pervasive and Ubiquitous Computing,* Sep 13-17, p. 3-14. doi:10.1145/2632048.2632054

Wangberg, S. C., Nilsen, O., Antypas, K., & Gram, I. T. (2011). Effect of tailoring in an Internet-based intervention for smoking cessation: Randomized controlled trial. *Journal of Medical Internet Research, 13*(4), e121. doi:10.2196/jmir.1605

Ware, J. E. (1995). The status of health assessment. *Annual Review of Public Health, 16*,

327-354. doi:10.1146/annurev.pu.16.050195.001551

Whittaker, R., Merry, S., Dorey, E., & Maddison, R. (2012). A development and evaluation process for mHealth interventions: Examples from New Zealand. *Journal of Health Communication, 17*, 11-21. doi:10.1080/10810730.2011.649103

Whitton, A. E., Proudfoot, J., Clarke, J., Birch, M., Parker, G., Manicavasagar, V., & Hadzi-Pavlovic, D. (2015). Breaking open the black box: Isolating the most potent features of web and mobile phone-based intervention for depression, anxiety, and stress. *Journal of Medical Internet Research, 2*(1), e3. doi:10.2196/mental.3573

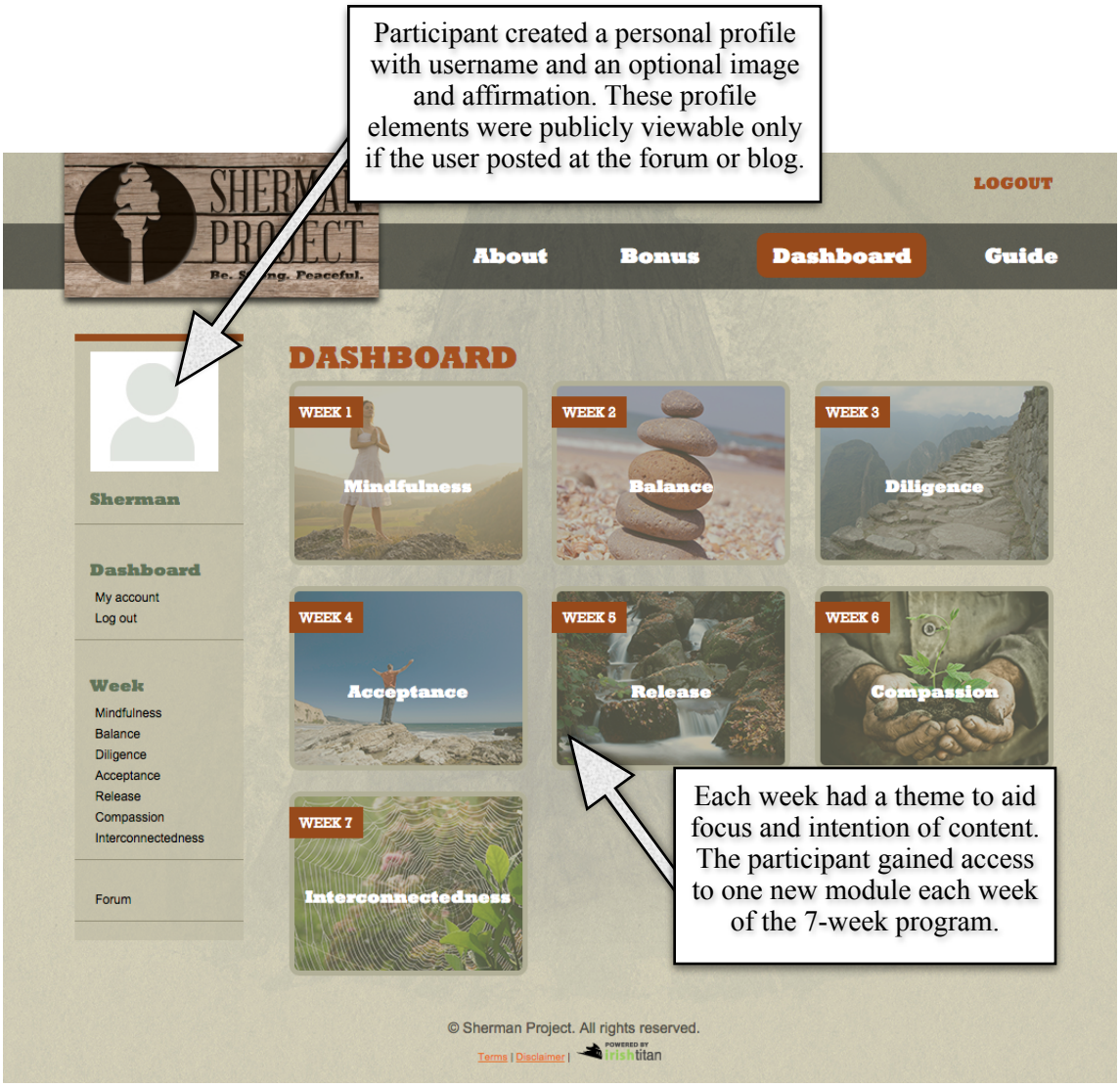
World Health Organization (WHO; 1958). *The first ten years of the World Health Organization*. Retrieved from http://whqlibdoc.who.int/publications/a38153.pdf

Yusuf, S., Hawken, S., Ounpuu, S., Dans, T., Avezum, A., Lanas, F. ... Lisheng, L. (2004). Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): Case-control study. *The Lancet, 364*(9438), 937-952. doi:10.1016/S0140-6736(04)17018-9

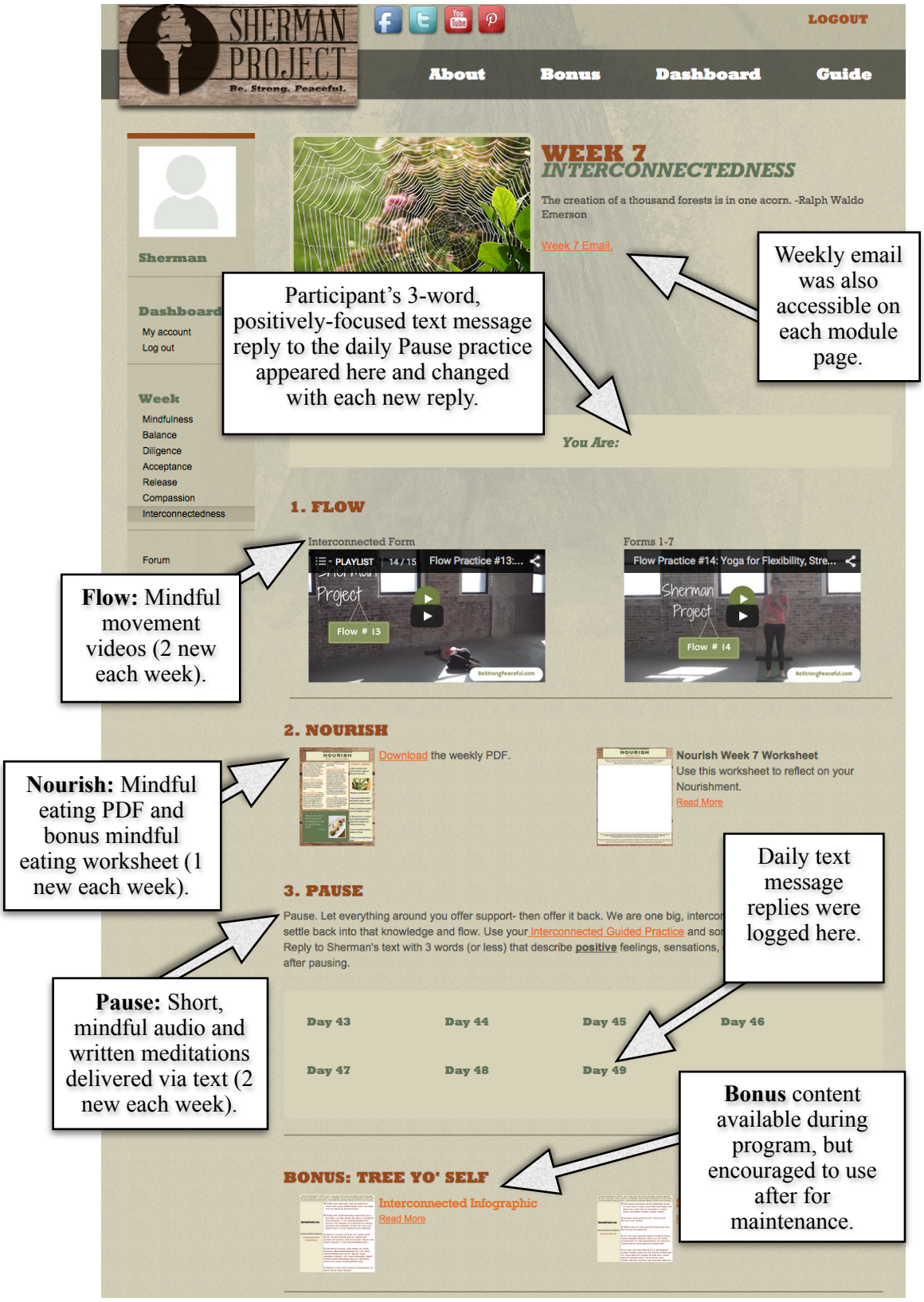
Appendix A

Mindfulness Program Screenshots

Note. The program homepage (pictured above; *https://www.ShermanProject.com*) enables login for members and also links to program information for individuals interested in participating.



Note. The "Dashboard" page (pictured above) appears after the user logs in.



Note. Weekly module pages (Week 7 pictured above) include all content for each week.

Appendix B

Recruitment Materials

BE WELL.

Wellbeing-Study.com

You Are Invited:

Who: Students (18+), staff, & faculty members at the UMN (Twin Cities campus).

What: Participate in a research study to evaluate the effectiveness of a web-based wellbeing & stress-reduction program.

When & Where: Start today! The 7-week program is entirely online.

Learn more:

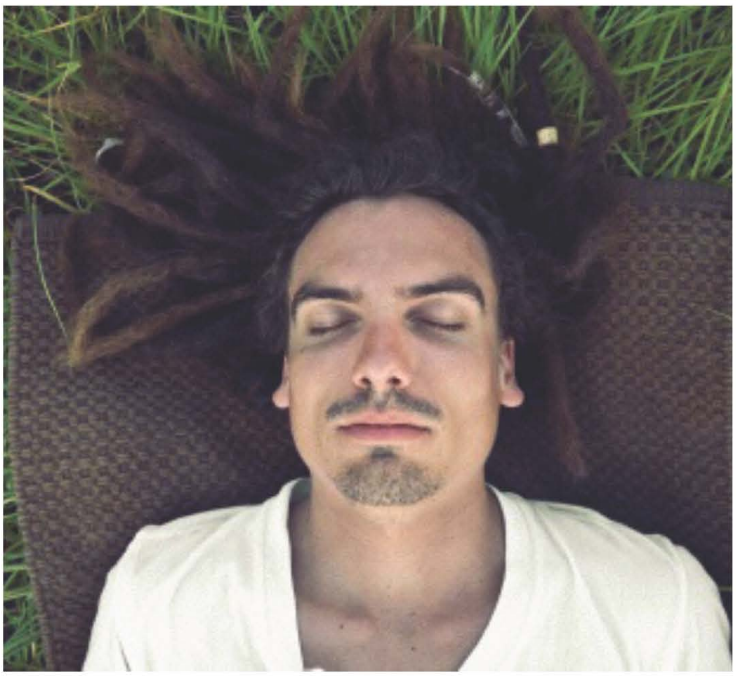
Wellbeing-Study.com

Wellbeing-Study.com Be Well

Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well

BE WELL.

Wellbeing-Study.com



You Are Invited:

Who: Students (18+), staff, & faculty members at the UMN (Twin Cities campus).

What: Participate in a research study to evaluate the effectiveness of a web-based wellbeing & stress-reduction program.

When & Where: Start today! The 7-week program is entirely online.

Learn more:

Wellbeing-Study.com

Wellbeing-Study.com Be Well

Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well
Wellbeing-Study.com Be Well

Appendix C

Inclusion and Exclusion Criteria Survey

1. I am 18 years of age or older? (Y/N)

2. I am a University of Minnesota (Twin Cities campus) student, staff, or faculty? (Y/N)

3. I am willing to complete online assessments at three set periods. (Y/N)

4. I have reliable home Internet access. (Y/N)

5. I own a cell phone that can receive and send text messages. (Y/N)

6. I am capable of participating in moderate-intensity exercise. (Y/N)

7. I am willing to engage with the web-based mindfulness program for approximately three hours per week (if randomized to the web-based group). (Y/N)

8. I can read and digitally sign the English consent form. (Y/N)

9. I am pregnant. (Y/N)

Appendix D

Patient Health Questionnaire-9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix E

IRB Letter of Approval

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

June 10, 2014

Aimee L Prasek
Ctr for Spirituality/Healing
MMC 505 Mayo
8505A
420 Delaware St SE
Minneapolis, MN 55455

RE: "Effectiveness of a Web-Based Wellbeing and Stress Reduction Program."
IRB Code Number: **1404P49942**

Dear Ms. Prasek

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form received May 23, 2014 and recruitment materials received April 21, 2014.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 296 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is May 2, 2014 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

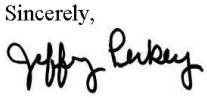
As Principal Investigator of this project, you are required by federal regulations to:
*Inform the IRB of any proposed changes in your research that will affect human subjects, changes should not be initiated until written IRB approval is received.
*Report to the IRB subject complaints and unanticipated problems involving risks to subjects or others as they occur.

*Inform the IRB immediately of results of inspections by any external regulatory agency (i.e. FDA).
*Respond to notices for continuing review prior to the study's expiration date.
*Cooperate with post-approval monitoring activities.

Information on the IRB process is available in the form of a guide for researchers entitled, What Every Researcher Needs to Know, found at http://www.research.umn.edu/irb/WERNK/index.cfm

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,



Jeffery Perkey, MLS, CIP
Research Compliance Supervisor
JP/bw

CC: Linda Halcon

Appendix F

Perceived Stress Scale, 10-Item (PSS-10)

Perceived Stress Scale- 10 Item

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the last month, how often have you been upset because of something that happened unexpectedly?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

2. In the last month, how often have you felt that you were unable to control the important things in your life?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

3. In the last month, how often have you felt nervous and "stressed"?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

5. In the last month, how often have you felt that things were going your way?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

6. In the last month, how often have you found that you could not cope with all the things that you had to do?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

7. In the last month, how often have you been able to control irritations in your life?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

8. In the last month, how often have you felt that you were on top of things?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

9. In the last month, how often have you been angered because of things that were outside of your control?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

Appendix G

WHO-5 Well-being Questionnaire

WHO (FIVE) WELL-BEING QUESTIONNAIRE

Please put a circle on each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better wellbeing.

Over the last two weeks	All the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I feel cheerful and in good spirits	5	4	3	2	1	0
I feel calm and relaxed	5	4	3	2	1	0
I feel active and vigorous	5	4	3	2	1	0
I wake up feeling fresh and rested	5	4	3	2	1	0
My daily life is filled with things that interest me	5	4	3	2	1	0

Scoring:

The **raw score** is calculated by totalling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life.

To obtain a **standardized percentage score** ranging from 0 to 100, the raw score is multiplied by 4. A standardized score of 0 represents worst possible whereas a score of 100 represents best possible quality of life.

Interpretation:

Is it recommended to administer the Major Depression (ICD-10) Inventory (Annex 2) if the raw score is below 13 or if the patient has answered 0 or 1 to any of the 5 items.
A score below 13 indicates poor wellbeing and is an indication for testing for depression using ICD-10

Monitoring change:

In order to monitor possible changes in wellbeing, the standardized percentage score is used. A 10% difference indicates a significant change (ref. John Ware, 1995).

Appendix H

PROMIS Global Health (v.1.1)

PROMIS v.1.1 - GLOBAL

Global Items

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	In the past 7 days…	None	Mild	Moderate	Severe	Very severe
Global08	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Global07	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst imaginable pain**

Appendix I

Brief Serenity Scale

The Brief Serenity Scale

INSTRUCTIONS: The following items describe experiences (thoughts and feelings, or actions). To the right of each statement are numbers that describe how often you have the experience. "1" means *never*, "5" means *always*, or you may select 2, 3, or 4. The lower the number, the less often you have the experience. There are no "right" answers, only answers that best describe you. Do not think about the statement too long. Give the answer you think of first, based on how things have been with you in the last 4 weeks.

(Circle one number on each line)

	Never				Always
	1 ▼	2 ▼	3 ▼	4 ▼	5 ▼
1. I am aware of an inner source of comfort, strength, and security.	1	2	3	4	5
2. During troubled times, I experience an inner source of strength.	1	2	3	4	5
3. I trust that life events happen to fit a plan which is larger and more gentle than I can know.	1	2	3	4	5
4. I see the good in painful events that have happened to me.	1	2	3	4	5
5. I experience peace of mind.	1	2	3	4	5
6. I am forgiving of myself for past mistakes.	1	2	3	4	5
7. I take care of today and let yesterday and tomorrow take care of themselves.	1	2	3	4	5
8. In problem situations, I do what I am able to do and then accept whatever happens even if I dislike it.	1	2	3	4	5
9. I accept situations I cannot change.	1	2	3	4	5
10. I try to place my problems in the proper perspective in any given situation.	1	2	3	4	5
11. I am aware of an inner peace.	1	2	3	4	5
12. I experience an inner quiet that does not depend on events.	1	2	3	4	5
13. I find ways to share my talents with others.	1	2	3	4	5
14. When I get upset, I become peaceful by getting in touch with my inner self.	1	2	3	4	5
15. I attempt to deal with what is, rather than what was, or what will be.	1	2	3	4	5

(Circle one number on each line)

	Never				Always
	1 ▼	2 ▼	3 ▼	4 ▼	5 ▼
16. Even though I do not understand, I trust in the ultimate goodness of the plan of things.	1	2	3	4	5
17. I experience an inner calm even when I am under pressure.	1	2	3	4	5
18. I feel that I have done the best I could in life.	1	2	3	4	5
19. I can feel angry and observe my feeling of anger and separate myself from it and still feel an inner peace.	1	2	3	4	5
20. I trust that everything happens as it should.	1	2	3	4	5
21. I feel forgiving of those who have harmed me.	1	2	3	4	5
22. I feel serene.	1	2	3	4	5