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# The Stony Brook Health Enhancement Program: The development of an active control condition for mind–body interventions

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## Abstract

This article describes the development of a manualized, eight-session multiple health behavior change program which addresses sleep, exercise, nutrition, substance use, and working with one's healthcare team. Our goal was to design a structured, evidence-based program that could be facilitated by a single health professional and could act as an active, credible control for mind–body intervention studies. Psychoeducational content was adapted from the latest government and peer-reviewed guidelines. Preliminary work suggests the program is acceptable and feasible for use in patients of varying ages with heterogeneous mental and physical health problems. It is adaptable for both face-to-face and online delivery.

## Keywords

health behavior, health enhancement program, mind–body, multiple health behavior change, treatment development

## Introduction

The availability of adequate comparison treatments is an important consideration in evaluating the efficacy of behavioral health interventions, including mind–body treatments. Nonetheless, the majority of previous mind–body intervention trials have relied upon waitlist control or treatment as usual (TAU) conditions. Such comparison treatments often lack an acceptable treatment rationale and do not adequately control for therapist-treatment allegiance and other nonspecific treatment factors (MacCoon et al., 2012). This is problematic given that treatment allegiance (Gaffan et al., 1995) and other nonspecific ingredients such as treatment outcome expectations (Mohr et al., 2009) and treatment

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rationale credibility (Mooney et al., 2014) are well-established predictors of treatment response in randomized clinical trials (RCTs). Finally, the interpretation of waitlist and TAU controlled trials is also further complicated by the lack of structural equivalence between the interventions under evaluation. That is, waitlist and TAU comparator conditions do not control for factors such as time in treatment or homework exercises. Meta-analysis suggests that the effect size of mind–body programs such as Mindfulness Based Stress Reduction (MBSR) decreases substantially when structural equivalency is properly controlled for (Baskin et al., 2003). Thus, in the absence of adequate, credible time-matched control conditions, it is not possible to directly test the efficacy of the active components of mind–body interventions.

The present study sought to develop and pilot a credible control treatment matched for the Stress Management and Resilience Training Program (also known as the Relaxation Response Resiliency Program; SMART-3RP; Park et al., 2013). The SMART-3RP is an eight-session group-based mind–body intervention that was developed to target the effects of chronic stress in various clinical populations, principally including patients with co-occurring mental and physical health problems. The SMART-3RP incorporates a number of active treatment components including techniques to elicit the relaxation response (e.g. meditation), cognitive-behavioral skills, positive psychology strategies, and techniques to enhance social connectedness. This treatment also incorporates education on health behaviors such as sleep, nutrition, and exercise.

Health enhancement programs (HEPs) are active behavioral health interventions that target both mental and physical health (Strohle, 2009), making them the preferred control intervention for mind–body programs such as SMART-3RP (MacCoon et al., 2012). Previous mind–body trials have largely relied upon non-manualized HEPs led by multiple specialized healthcare professionals, making such programs expensive to implement and difficult to replicate for larger-scale trials. For example, MacCoon and colleagues designed a program to be structurally equivalent to MBSR with weekly 2.5 hours group meetings and a full-day workshop after week 6. Program content was developed and implemented by a team of three allied healthcare professional including a dietician, music therapist and master's level exercise physiologist. Program content was chosen to match MBSR activities as closely as possible, with the exception of mindful meditation. Topics covered included nutrition, exercise, functional movement (e.g. posture, balance), and music therapy. Instructors were encouraged to "flexibly apply class material while maintaining as much similarity in repeated class offerings as possible."

Existing manualized or semi-manualized are generally tailored programs designed to target a specific population or health problem with few details provided on the specifics of program content, rendering them difficult to adapt for other applications. For example, Johns et al. (2016) developed a manualized psychoeducational support group (PES) as an active control for a trial of MBSR in breast and colorectal cancer survivors. Their PES was time and attention matched to the MBSR program and involved support on life after cancer and topics such as managing fatigue and self-care. Reading-based homework assignments and self-monitoring were assigned but not time-matched to the MBSR protocol. Similarly, Pbert et al. (2012) developed a comparator course for a trial of MBSR in individuals with asthma. Their program was matched for time, instructor attention, and format. Groups consisted of discussion of healthy nutrition, physical activity, coping with stress (not including mindfulness), sleep hygiene, balancing work and personal life, and living a drug-free life. Homework was assigned consistent in time with MBSR. Few details, however, are provided on the background of group leaders, group-specific group content, or the extent to which the content of individual treatment sessions was manualized. Although these approaches allow for increased flexibility, the lack of a standardized, manualized protocol

among existing HEP programs has contributed to significant heterogeneity in the format, content, and methods of delivery of HEP programs, making them difficult to rigorously evaluate.

The objectives of the present study were to (1) develop a comprehensive, evidence-based manualized HEP treatment that could be administered by a single trained health care provider in a group format and would be structurally equivalent to the SMART-3RP and (2) test the acceptability and feasibility of the protocol in a sample of participants with co-occurring mental and physical health problems. Our goal was to produce a program based on the principles of behavioral therapy including active goal setting, self-monitoring of behavior change, and hands-on learning techniques. In order to demonstrate the flexibility of the program, we also briefly describe other populations (e.g. patients with neurofibromatosis (NF)) for which the protocol has been successfully adapted.

## *The Stony Brook Health Enhancement Program*

The Stony Brook Health Enhancement Program (SB-HEP) is a structured eight-session, 90 minutes/session, weekly program that was developed based on multiple health behavior change (MHBC) literature (Prochaska et al., 2008). This program was designed to be used in individuals with co-occurring mental and physical health problems but can be adapted for a variety of different populations and applications. The key health behaviors targeted by the SB-HEP (i.e. sleep, physical exercise, nutrition, substance use, and managing health care) were chosen because they are the primary behaviors involved in managing many chronic health conditions and are the same health behaviors addressed in the SMART-3RP protocol. The essential components of the SB-HEP program include (1) education on the co-occurrence of mental and physical problems and healthy living principles, (2) goal setting for health behavior change, and (3) self-monitoring. Psychoeducational content was adapted from the most recently published guidelines available from the National Sleep Foundation (NSF), US Department of Health and Human Services (HHS), US Department of Agriculture (USDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the Centers for Disease Control and Prevention (CDC). Goal setting is based on the SMART goals framework (i.e. goals that are Specific, Measurable, Attainable, Relevant, and Time-based; Doran, 1981). SMART goal setting is widely used in behavioral interventions (Lawn and Schoo, 2010). Self-monitoring involves keeping a daily diary of engagement in targeted health behaviors and ratings of mood, anxiety, and stress symptoms. Self-monitoring is considered a cornerstone of behavioral interventions (Baker and Kirschenbaum, 1993).

Each session uses a multimodal approach to introduce and reinforce new skills. Teaching techniques include interactive hands-on exercises and group discussion. Didactics are designed to be inclusive of different learning styles. The session facilitator uses open-ended questioning, affirmation, reflection, and summarizing statements to help clients identify personalized-goals and obstacles related to each health behavior. At the conclusion of each session, a new or continued SMART goal is set and a between-session practice assignment is assigned. See Table 1 for a summary of treatment sessions.

The SB-HEP is intended to be administered by a facilitator who is trained in behavioral intervention techniques (e.g. social worker, psychologist, nurse, or physician). Facilitator and patient manuals were developed to enable assessment of treatment fidelity and to ensure consistent application of the intervention. Given that the SB-HEP was designed to be structurally equivalent to the SMART-3RP, it employs a similar group format, is time-matched for number and length of sessions, has a similar treatment structure (i.e. psychoeducation coupled with in-session exercises and group discussion), and at home practice. As such, the SB-HEP controls for treatment outcome expectations, treatment credibility, therapist contact, and group-based social support. For the current study, the program was administered by a clinical psychologist (Brittain Mahaffey PhD).

**Table 1.** The SB-HEP outline.

| Chapter title | Goals |
|---|---|
| Chapter 1<br>SB-HEP Overview and<br>Comorbidity between Physical and Mental Illness | • Welcome and Overview<br>• Set agenda<br>• Setting group rules and facilitate patient introductions<br>• Psychoeducation on mental–physical health comorbidity<br>• Between Session Practice: Setting SMART goals, sleep monitoring log |
| Chapter 2<br>Sleep Hygiene and Wellness | • Set agenda and review last session<br>• Discuss importance of monitoring and goal setting<br>• Psychoeducation on sleep hygiene<br>• Set sleep SMART goal<br>• Between Session Practice: Continue sleep monitoring log |
| Chapter 3<br>Physical Activity and Wellness | • Set agenda and review last session<br>• Psychoeducation on exercise<br>• Strength training tutorial and in-session practice<br>• Set physical activity SMART goal<br>• Between Session Practice: Physical activity monitoring log |
| Chapter 4<br>Nutrition I: The Basics | • Set agenda and review last session<br>• Psychoeducation on Nutrition I (Basics)<br>• Introduce food diary<br>• Set nutrition SMART goal<br>• Between Session Practice: Food log and meal planning practice |
| Chapter 5<br>Nutrition II: Healthy Eating | • Set agenda and review last session<br>• Review food diary and meal planning practice<br>• Psychoeducation on Nutrition II (Smart Meal Planning)<br>• Set nutrition SMART goal<br>• Between Session Practice: Food log and meal planning practice |
| Chapter 6<br>Alcohol and Substance Use | • Set agenda and review last session<br>• Review food diary and meal planning practice<br>• Psychoeducation on alcohol and substance use<br>• Set substance use SMART goal (if applicable)<br>• Between Session Practice: Food log with substance use monitoring |
| Chapter 7<br>Managing your Healthcare | • Set agenda and review last session<br>• Review food and substance use diary log<br>• Psychoeducation on managing health care<br>• Set healthcare SMART goal<br>• Between Session Practice: Develop personal health care plan |
| Chapter 8<br>Relapse Prevention and Review | • Set agenda and review last session<br>• Review personal healthcare plan<br>• Review personal health behaviors and future goals<br>• Continue self-monitoring, set long-term goals |

SB-HEP: Stony Brook Health Enhancement Program; SMART: Specific, Measurable, Attainable, Relevant, and Time-based.

### *Intake session*

The individual intake session focuses on assessing overall mental and physical health and treatment goals. A clinician conducts a clinical interview and relevant self-report measures are administered. Participants are introduced to the principles of SMART goal setting and assisted with setting at least one personal treatment goal. Open-ended questioning and reflection are used to help participants identify personal goals.

### Session 1: treatment overview and rationale

The first session begins with group introductions, group rules (i.e. confidentiality and mutual respect), and an overview of the treatment rationale. The treatment rationale is intended to be adjusted for the specific target population. The facilitator explains that poor physical health is a risk factor for mood and anxiety problems (Scott et al., 2007) and that mental health problems and stress may also increase the risk for chronic physical illness and/or exacerbate health problems (Prince et al., 2007). In this manner, the program is presented with a strong scientific rationale as a means of improving mental and physical health.

During this session, the group facilitator also reviews each individual's SMART goals and assists participants with identifying and refining goals that can be accomplished within 8 weeks. An overview of the five target health behaviors (i.e. sleep, exercise, nutrition, substance use, and managing medical care) is provided. As part of the between-session practice, participants are instructed to self-monitor their sleep using the provided "Sleep Log."

### Session 2: sleep hygiene and wellness

The second session is designed to target factors related to recuperative sleep and its relationship to mental and physical health, and overall well-being. Sleep-related disorders affect between 25% and 30% of the adult US population (Colten and Altevogt, 2006) and up to 65% of Americans report at least some difficulty sleeping (NSF, 2008). Poor sleep is associated with numerous health conditions (Buxton and Marcelli, 2010), as well as increased risk of other poor health behaviors. Techniques used in this session were adapted from NSF guidelines (Hirshkowitz et al., 2015) and cognitive-behavioral therapy for insomnia (e.g. Edinger and Carney, 2014).

Education is provided regarding the importance of sleep, changes that may improve sleep, and other factors impacting sleep (e.g. sleep apnea, normative age-related changes in sleep quality). Patients reporting symptoms of sleep apnea are assisted in obtaining a referral to a sleep clinic. The group facilitator leads discussions and activities including a self-review designed to help participants identify and modify problematic sleep behaviors (e.g. over stimulation prior to bedtime). The session concludes with setting a personalized SMART goal related to sleep hygiene (e.g. I will turn off the TV 30 minutes before bed each day this week). Participants are asked to monitor their sleep using the provided "Expanded Sleep Log."

### Session 3: physical activity and wellness

The third session focuses on education and goal setting related to physical activity. Fewer than 20% of adults participate in sufficient amounts of physical activity (HHS, 2008). Physical activity can result in improvements in health including reduced disability and mortality risk (Macera et al., 2003) and improvements in anxiety and depression (Barbour et al., 2007). The content for this session is based on guidelines for cardiovascular health published by the HHS (2008).

The group facilitator leads a discussion about the health benefits of physical activity. National guidelines are reviewed for the type (i.e. aerobic vs strengthening), intensity and amount of physical activity recommended for the average adult by HHS (2008). Participants with unique health concerns are referred to their primary care doctor for individual consultation regarding activity limitations. The group facilitator elicits discussion of common barriers to physical activity and practical ways of increasing daily movement. Participants also engage in a 20 minute strength training exercise with resistance bands (SparkPeople TV, 2013). Participants create a SMART goal pertaining to exercise and are asked to self-monitor their physical activity for 1 week using the "My Aerobic and Strength Training Exercise Log." Each participant is provided with a resistance band and encouraged to practice at home.

### Session 4: nutrition I—the Basics

The fourth session focuses on psychoeducation and activities aimed at helping participants to learn about healthy food choices and portion control. Poor dietary behaviors are a major contributor to obesity (Wright and Aronne, 2012), numerous chronic medical conditions, and all-cause mortality (Dixon, 2010). All nutrition guidelines were adapted from the most recent USDA and the HHS dietary recommendations (United States Department of Health and Human Services and United States Department of Agriculture 2015-2020, 2016).

The group facilitator reviews education about calories and nutrition labels. Interactive tools are used to teach about portion size, serving size, and reading food labels. Activities include using different plate sizes and measuring cups to estimate portion size and to illustrate the impact of perception on meal satisfaction. Participants set a SMART goal pertaining to nutrition. The between-session practice includes exploring the nutritional content of favorite foods and tracking daily food intake using the provided "Food Diary."

### Session 5: nutrition II—healthy eating

The fifth session delves deeper into nutrition and attaining and maintaining healthy eating. The facilitator helps participants to identify behavioral strategies for eating healthfully both at home and at restaurants. Participants also learn about body mass index (BMI) and how BMI may inform health status. Session 5 activities include practicing using real menus from quick-service restaurants to order healthier meals and comparing the items in a healthy pantry to their own. As part of the between-session practice, participants create a SMART goal related to the nutrition information from the past two sessions. Participants continue to monitor their daily food intake using the "Food Diary."

### Session 6: alcohol and substance use

The sixth session focuses on teaching participants to identify symptoms of addiction, the difference between high- and low-risk drinking, and the harmful effects that alcohol, cigarettes, and other substances can have on their health. Excessive alcohol consumption is associated with disability, morbidity, and mortality for more than 60 disease conditions (Gutjahr et al., 2001) and smoking remains the leading cause of preventable death (HHS, 2014). Using materials adapted from the NIAAA (2016), participants are taught how to examine their own substance use and drinking habits and consider reasons to make a change.

The facilitator leads a discussion of warning signs of problematic substance use. Participants are encouraged to identify any habit they see as problematic for them and employ behavioral harm-reduction techniques, making this module easily modifiable based on individual needs. Methods for identifying whether a habit is a problem and strategies for making changes are discussed. Participants set a SMART goal for changing problematic alcohol use or other interfering behaviors. As part of the between-session practice, participants monitor their daily food intake using the "Expanded Food Diary," which now includes alcohol intake.

### Session 7: managing your healthcare

The seventh session focuses on teaching participants how to work more effectively as a team with their health providers and taking personal responsibility for their own health. Nonadherence to medical advice is associated with disease progression, reduced functional abilities and quality of life, increased use of medical resources and hospital admissions and increased healthcare costs (Iuga and McGuire, 2014). Proper communication with providers during the treatment-decision-making process can promote better adherence and, thus, improved outcomes (Haynes et al., 2002).

The facilitator provides education regarding the importance of communicating with health providers and techniques for identifying obstacles (e.g. anxiety, not planning ahead). Participants learn how to prepare for a healthcare visit, how to ask relevant questions, how to

adhere to the provider's recommendations, and when to seek additional advice. Participants are encouraged to become an advocate for their health and to work more effectively with providers. During the second half of the session, participants learn how to cope with medical emergencies and to identify signs of stroke and heart attack. Materials provided on these topics are adapted from the CDC (2011) guidelines. Participants set at least one healthcare-related SMART goal. Between-session practice assignments include either creating a personal health diary card, planning for an upcoming medical visit, or working on strategies for taking medications as prescribed.

### *Session 8: relapse prevention and review*

The final session of the SB-HEP program includes a review of the previous sessions and education about relapse prevention. The facilitator emphasizes continued use of the SMART goal-setting tool to promote maintenance of gains and address behavioral lapses/relapses. Participants review the SMART goals they have set and the progress made. This review allows the participants to acknowledge any positive changes they have made since the start of the program. Participants are asked to write a "Letter to Self" including their hopes for the future and ongoing goals. The letter is mailed to them 6 months after program completion.

## Pilot study

Participants were six Caucasian male responders to the WTC disaster aged 51–66 ($M = 55.00$, standard deviation ($SD$) = 5.55) recruited from the SB WTC Health Program, a federally funded program that provides yearly health monitoring and treatment for WTC-related conditions. Four participants reported being married, one was cohabitating, and the other was divorced. Two participants reported being employed (one full-time, one part-time), two were retired, and two were unemployed. The SB-HEP was administered by a clinical psychologist (B.L.M.). For the pilot study, we evaluated the credibility, acceptability, and feasibility of the SB-HEP. Clinical outcomes of interest included PTSD, depression and lower respiratory symptoms, and health-related behaviors.

All self-report measures and structured clinical interviews were administered prior to treatment (T1) and again at three follow-up visits (T2 = 1 week post-treatment, T3 = 3 months post-treatment, T4 = 6 months post-treatment). An exit interview was administered at T2. In line with previous research (e.g. Haddock et al., 2016), session attendance and treatment completion were used as behavioral indicators of the feasibility and acceptability of the treatment protocol (Mendelson et al., 2010).

### *Measures*

*Session attendance, treatment completion, and exit interview.* Session attendance and treatment completion was used to evaluate the credibility, acceptability, and feasibility of the SB-HEP. Treatment completion was defined as attending $\geqslant 5$ sessions. Make-up sessions were offered and completed prior to the following week's session. An exit interview was used to assess participants' qualitative reactions to the program.

*PTSD checklist for DSM-5.* The PTSD Checklist for *DSM-5* (PCL-5; Weathers et al., 2013) is a 20-item self-report questionnaire assessing the severity of *DSM-5* PTSD criterion symptoms. Participants were asked to rate how bothered they were by problems in the past week "in relation to 9/11" on a scale of 0 (not at all) to 4 (extremely). The PCL-5 has shown good reliability and validity (Blevins et al., 2015).

*Patient health questionnaire.* Depressive symptoms were measured using the Patient Health Questionnaire (PHQ-9; (Kroenke et al., 2001), a 10-item self-report questionnaire. The PHQ-9 assesses the frequency of the nine *DSM-5* symptoms for Major Depressive Disorder over the previous 2 weeks rated on a 4-point

Likert-type scale ranging from 0 (not at all) to 3 (nearly every day).

*Health Promoting Lifestyle Profile–II.* The Health Promoting Lifestyle Profile–II (HPLP-II; Walker et al., 1995) is a 52-item self-report questionnaire that measures the extent to which participants practice positive health behaviors. Each item is rated on a 4-point Likert-type scale (1 = never to 4 = routinely). The HPLP-II has good internal consistency and test–retest reliability.

*St.* George's respiratory Questionnaire for COPD Patients. The St. George's Respiratory Questionnaire for COPD Patients (SGRQ-C; Meguro et al., 2007) is a 40-item self-report questionnaire designed to assess the presence of lower respiratory symptoms (LRS) and their impact on daily functioning. Each item is weighted on a unique, empirically derived scale, and total scores range from 0 to 100 with higher scores indicating greater symptoms and impairment. The SGRQ-C has shown good reliability in past studies (Meguro et al., 2007).

### *Data analysis*

Descriptive analyses were conducted to summarize participant demographics and scores on clinical outcome measures at each assessment point. Our primary outcome was feasibility and acceptance of the SB-HEP intervention. Session attendance and qualitative data from the exit interview were reviewed to evaluate the feasibility and acceptability of the program. Because the sample was not large enough to evaluate significant changes overtime, individual scores were plotted to visually examine clinical outcomes over time.

### *Results*

Based on session attendance and treatment completion, the SB-HEP was very well tolerated and received. Participants attended an average of 6.5 of the 8 sessions, with all participants completing the program. Exit interviews for the SB-HEP were overwhelmingly positive. One participant noted that the SB-HEP was "a new beginning to help myself grow in the future," while another stated that "the [SB-HEP] was a port in the storm for me and my quality of life has improved dramatically." Participants felt that the program was a good fit to their treatment needs with one stating, "The program has been well run and constructed to fit my issues." Two participants also reported that the program was "very helpful," and another described the program as being a "life changer." Another group member reported, "[I] gained knowledge on how to take care of myself and also enjoyed sitting with others who had the same experiences." One group member indicated the program, "helped [me] to pay more attention to myself and my health." Negative feedback generally pertained to logistical factors such as the location of groups, "I wish the clinic were closer to my home" or being asked to complete our questionnaire battery, "The survey should be shorter."

Means and *SD*s for all time points and outcome measures are presented in Table 2. Changes for each participant on all outcome measures are displayed in Figure 1. Four participants reported sustained reductions in PTSD symptoms from T1 to T4. Five participants reported reductions in depression symptoms from T1 to T3. At T4, three participants still reported reduced depression, while two others reported the same level of symptoms as T1. All participants reported reductions in LRS from T1 to T3. Three maintained improvements in LRS at T4. Five participants reported improvements in their health behaviors from T1 to T2, and three maintained treatment gains at T4.

## Protocol adaptations

The SB-HEP protocol has been successfully modified to act as an active control condition in several other studies, including one evaluating the efficacy of the SMART program for adults with NF, a chronic tumor suppressor syndrome (Vranceanu et al., 2016). In this trial, the SB-HEP was modified to include a module

**Table 2.** Descriptive data on outcome measures for six pilot participants.

| Measure | T1 | | T2 | | T3 | | T4 | |
|---|---|---|---|---|---|---|---|---|
| | *M* | *SD* | *M* | *SD* | *M* | *SD* | *M* | *SD* |
| PCL-5 | 27.17 | 11.79 | 22.42 | 9.14 | 19.17 | 7.05 | 28.17 | 14.34 |
| PHQ-9 | 10.17 | 4.62 | 8.67 | 6.77 | 6.83 | 5.71 | 8.00 | 5.62 |
| HPLP | 2.11 | 0.48 | 2.51 | 0.63 | 2.36 | 0.86 | 2.26 | 0.81 |
| SGRQ-C | 30.86 | 12.69 | 25.59 | 15.43 | 23.15 | 13.76 | 31.79 | 11.36 |

T1: Baseline visit prior to treatment; T2: 1 week post-treatment; T3: 3 months post-treatment; T4: 6 months post-treatment; PCL-5: PTSD Checklist for *DSM-5*; PHQ-9: Patient Health Questionnaire; HPLP: Health Promoting Lifestyle Profile; SGRQ-C: St. George Respiratory Questionnaire.

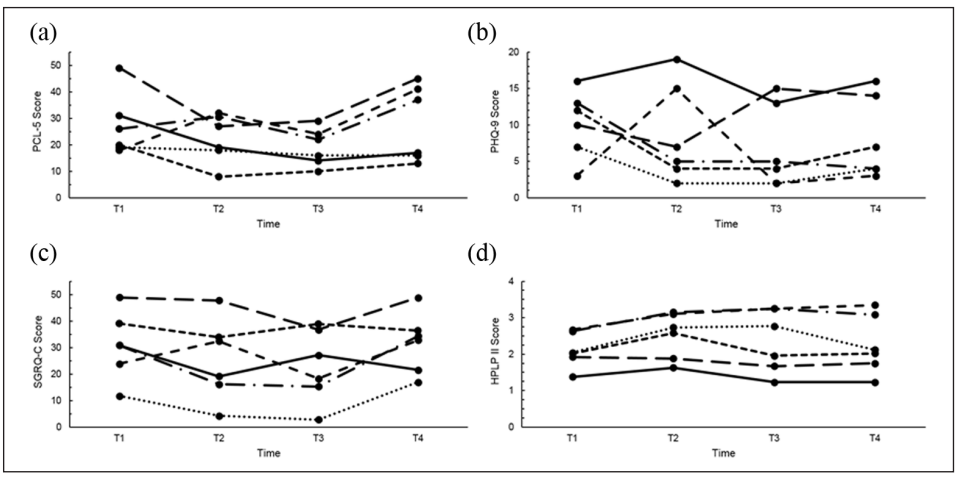


**Figure 1.** Individual trajectories on outcome measures. This figure illustrates the individual trajectories of the six pilot participants' self-reported PCL-5 (1a; top left), PHQ-9 (1b; top right), SGRQ-C (1c; bottom left), and HPLP II (1d; bottom right) scores at their baseline (T1), 1 week post-treatment (T2), 3 months post-treatment (T3), and 6 months post-treatment (T4) visits. Each individual participant ($N = 6$) is represented by the same line type in all figures. PCL-5: PTSD Checklist for *DSM-5*. PHQ-9: Patient Health Questionnaire. SGRQ-C: St. George Respiratory Questionnaire. HPLP II: Health Promoting Lifestyle Profile–II.

specifically on the relationship between NF and stress in place of the module on substance abuse. The protocol was also adapted for delivery via online videoconferencing, and the more active behavioral components (e.g. the intake session) were removed. When these components are removed, SB-HEP functions as a strong attention control intervention for mind–body treatment trials. SB-HEP has also been adapted for adolescents with NF1 and NF2 and adults with NF2 who are deaf (Zale et al., 2017). Additional trials have been proposed using the SB-HEP in populations such as adults undergoing chemotherapy and adolescent cancer survivors.

## Summary, limitations, and future research

Although there is a growing body of literature supporting the effectiveness of mind–body interventions for a variety of mental and mental and physical health conditions,

the rigor of RCTs examining the efficacy of these interventions has been hampered by the lack of manualized, credible comparative programs that are structurally equivalent and matched on non-specific treatment factors. The SB-HEP is among the first, fully manualized programs designed specifically as an active, credible comparative condition for a mind–body program. As a comparator for mind–body protocols, the SB-HEP was specifically designed to be appropriate for individuals experiencing a diverse range of co-occurring mental and physical health problems and is intended to be easily adaptable for the needs of specific research populations or applications. As such, content addressing the target population's specific difficulties (e.g. PTSD, NF, respiratory disease) is limited to the intake session and treatment rationale session 1, which may be modified for other target mental and physical health conditions. The SB-HEP controls for both the non-specific treatment factors associated with participating in an active group intervention as well as treatment ingredients that are often considered secondary interventions in mind–body programs (e.g. goal setting skills, health behavior education, self-monitoring).

There is evidence that the SB-HEP is well received by patients of varying ages (i.e. teens and adults) with different types of mental and physical health problems (i.e. comorbid PTSD and LRS symptoms, NF) and is adaptable for both face-to-face and online delivery. Pilot data from a sample of WTC responders with PTSD and LRS suggest that the SB-HEP is well tolerated by patients with both physical and psychological conditions and may be a promising treatment for improving health outcomes. Nonetheless, there are important limitations which should be addressed in future research. The studies described here included very small samples with particular exposures (i.e. the WTC disaster) and health conditions (i.e. respiratory disease, NF). Thus, additional research is needed to determine the acceptability and credibility of this program in patient populations with more heterogeneous mental and physical health problems. Participants in the WTC pilot were also exclusively male and Caucasian, limiting our ability to conclude how this intervention might be received in more demographically heterogeneous samples. Finally, the small sample size and study design precludes drawing any meaningful conclusions about the efficacy of this program for improving health behaviors. Future research (i.e. large-scale RCTs) is needed to evaluate the efficacy of the intervention for targeted health outcomes (e.g. blood pressure, engagement in physical activity, adherence to dietary guidelines) and to examine mediators and moderators of treatment response.

In summary, we present a new manualized treatment protocol that was developed based on current empirically based best-practice guidelines. The current program is designed to facilitate MHBC, while also matching the structural equivalence, therapist-treatment allegiance and, other non-specific treatment factors of mind–body programs. The SB-HEP was designed as an active control condition but may also be useful as a resource for chronic disease prevention and treatment, and promotion of overall wellness.

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