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Meditation Smartphone Application Effects on Pre-Hypertensive Adults' Blood Pressure: Dose-Response Feasibility Trial

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Abstract

Objective—Essential hypertension (EH) is the most common chronic disease in the United States and a major cause of morbidity and mortality. Lifestyle interventions (e.g., diet, exercise, stress management) to reduce blood pressure (BP) are often complex with varying effectiveness. Breathing awareness meditation (BAM) is a stress management strategy with encouraging effects on BP, though widespread dissemination is hampered by the lack of an easy-to-use methodology

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to train and monitor BAM practices. A smartphone application (Tension Tamer, TT) that implements BAM and tracks adherence has shown promise in addressing these gaps. This 6-month dose-response feasibility trial evaluated effects of the app on BP to further optimize BAM user guidelines.

Methods—Sixty-four adults with pre-hypertension were randomized to complete TT-guided BAM sessions for 5-, 10-, or 15-minute intervals twice daily over 6 months. Continuous heart rate readings derived from the phone's video camera via reflective photoplethysmography were used as feedback and as an index of time-stamped adherence. Outcomes (resting BP, HR) were collected at baseline, 1-, 3-, and 6-months.

Results—Mixed modeling results showed a significant time effect for systolic BP (SBP) with a dose-response effect at months 3 and 6. Adherence declined over time and was lowest in the 15-minute dose condition, though SBP reductions were maintained. Generally, adherence was negatively associated with dose as the study progressed.

Conclusions—Smartphone-implemented BAM appears to reduce SBP and can be a low cost method to reach large populations.

Keywords

essential hypertension; blood pressure; breathing meditation; mobile health; smartphone application

Essential hypertension (EH) is the most common chronic disease in the United States impacting approximately one third of adults. EH is a primary risk factor for stroke, myocardial infarction, heart disease, chronic kidney disease and retinopathy (Go et al., 2014; Guo, He, Zhang, & Walton, 2012; Kannel, Vasan, & Levy, 2003). EH results from a complex interplay between an individual's genetic predisposition, lifestyle behaviors, and exposures to various environmental toxins culminating in disease (Imumorin et al., 2005; Kurland, Lind, & Melhus, 2005; Lewontin, 2001). Chronic stress (e.g., repeated exposures to discrimination, family dysfunction, marital/relationship discord, financial strain, job strain, etc.) is a key environmental factor that has been implicated in development of EH (Esler et al., 2008; Rutledge & Hogan, 2002; Spruill, 2010; Tennant, 2001) and a target for preventive interventions.

Stress Reduction Treatments for EH

Evidence that chronic stress exposure contributes to EH and cardiovascular disease has resulted in a plethora of behavioral mind–body stress reduction programs, including various forms of meditation. Meditation is an empirically supported stress reduction technique. The quality of research designs to investigate these programs' effects upon BP varies and studies have shown mixed results, but overall findings trend toward a positive effect (Büssing, Michalsen, Khalsa, Telles, & Sherman, 2012; Cohen & Townsend, 2007; Dickinson et al., 2008; Okonta, 2012; Rainforth et al., 2007). In one review of 20 RCTs, Transcendental Meditation® (TM) was the only treatment to significantly reduce BP (average systolic BP (SBP) reduction = −5.5 mmHg), with effects comparable to more complicated and demanding lifestyle programs (e.g., diet, physical activity) (Dickinson et al., 2006; Rainforth

et al., 2007). Although useful in reducing BP, the financial costs and training demands (i.e., multiple sessions with certified instructor) of TM limits its scalability. The easy to learn and virtually cost-free nature of breathing awareness meditation (BAM) – a basic form of mindfulness meditation – makes it a promising alternative to TM (Goldsetin, Josephson, Xie, & Hughes, 2012). In BAM, practitioners engage in slow, diaphragmatic breathing while attending to breathing sensations in the body. Unlike TM, mantras are not used and training does not require special certification; BAM can be learned quickly and via a variety of modalities including books, online tutorials, videos, and in-person instruction. RCTs in adults with preEH and EH who used BAM 10 minutes, twice daily for 3 months resulted in SBP reductions of −4.3 and −7.2 mmHg, supporting its potential efficacy as a non-pharmacologic adjunct BP reduction therapy (Mourya, Mahajan, Singh, & Jain, 2009; Wang et al., 2010). BAM is also a foundational component of mindfulness-based stress reduction (MBSR), which has been shown to reduce SBP in adults with preEH (Hughes et al., 2013).

Critical Gaps in Meditation BP Control Research

Despite promising findings for TM and BAM, several critical gaps remain regarding meditation's impact on BP prior to addressing its potential in the prevention/delay of EH onset and as an adjunct therapy for EH management. First, few RCTs have involved at-risk adults with preEH (for reviews see: (Anderson, Liu, & Kryscio, 2008; Ospina et al., 2007; Rainforth et al., 2007)). SBP and diastolic BP (DBP) levels are monotonically associated with future development of cardiovascular morbidity and mortality (Kannel et al., 2003). Adults with stage 1 preEH (i.e., SBP/DBP 120-129/80-84 mmHg) have a 40% increased risk, and those with stage 2 preEH (SBP/DBP 130-139/85-89 mmHg) have twice the risk of developing EH compared to those with optimal BP levels (<120/<80 mmHg;(Kannel et al., 2003)). Second, RCT-evaluated meditation programs have typically involved multiple individual and/or group training and follow-up sessions, limiting reach and scalability. Third, there has been a lack of objective adherence measurements where non-instructor observed sessions have been based upon self-report (e.g., journaling, retrospective reporting). True dosage received is unknown and may partially account for heterogeneity in individuals' BP changes within and across meditation RCTs (Barnes, Gregoski, Tingen, & Treiber, 2010; Barnes, Pendergrast, Harshfield, & Treiber, 2008; Barnes, Treiber, & Johnson, 2004; Gregoski et al., 2012; Nidich et al., 2009; Ospina et al., 2007; Rainforth et al., 2007; Wright, Gregoski, Tingen, Barnes, & Treiber, 2011). TM and BAM studies have typically prescribed twice daily sessions of 10- or 20-minute durations each, but a dose-response evaluation has never been conducted. It is unknown whether, for instance, 10 vs. 20 vs. 30 minutes/day will have graded responses upon BP or which regimen would yield the best patient adherence. These questions are critical when developing evidence-based guidelines for delivery of BAM in clinical contexts.

Tension Tamer: A Smart Phone BAM Application (App)

One solution to address these gaps in existing meditation programs is to develop, rigorously test, and refine a smartphone app designed to deliver BAM. Smartphone apps for preventive medicine and chronic disease management hold great promise in terms of reach for widespread dissemination. Their portability also increases capacity for users to engage in

BAM at times and in places that are most convenient to them. In 2016, 77% of adults in the U.S. owned smartphones (up from 35% in 2011), irrespective of race/ethnicity, socioeconomic status or geographical location (Poushter, 2016; Smith, 2015), and rates continue to rise steadily. There also is substantial public interest in meditation – and use of meditation smartphone apps, specifically – as a complementary and alternative approach to BP and stress management as evidenced by the millions of U.S. adults who practice meditation (Cramer et al., 2016) or who have downloaded commercial meditation apps (e.g., Birkner, 2016; Weiczner, 2017). Despite a proliferation of apps purporting to provide training in mindfulness meditation, there is little published evidence about their impact on targeted health outcomes (Mani et al., 2015).

Tension Tamer (TT) smartphone BAM app was developed using a patient-centered iterative design approach guided by behavioral change and technology utilization theories. Behavioral content and implementation formats were guided by theoretical constructs in the self-determination (Ryan & Deci, 2000) and social cognitive theories (Bandura, 2001), which posit that fostering self-efficacy, competence, and autonomous regulation (i.e., intrinsic motivation) for the desired behavior changes are critical for initial engagement and sustaining adherence over time. The People, Activity, Context and Technology Approach (PACT) has guided prior development of TT usability and posits users must feel at ease with and perceive the technology as useful in reaching a desired goal (Beynon-Davies & Holmes, 2002). It is expected that, over time, with positive feedback (including immediate HR feedback charts, reinforcement and motivational text messages), self-efficacy, autonomous regulation, internalization, and integration will occur, leading to adoption and maintenance of BAM for stress reduction and BP management.

Promising results were observed in a 3-month proof-of-concept study where 3 pre-EH adult participants completed twice daily 10-minute BAM sessions via TT on an Android phone (Gregoski, Vertegel, Shaporev, & Treiber, 2013). Participants received a feedback chart of average HR/minute and maximum decline immediately after each session. Motivational and social reinforcement text messages were sent based upon the previous day's adherence levels. Clinically relevant BP decreases from pre- to post-intervention were observed in resting (−8.8 mmHg) and ambulatory (e.g., −3.7 mmHg for 24-hr; −4.3 mmHg for daytime) SBP (Gregoski, Sieverdes, et al., 2013). Time stamped HR signal transmission to the server indicated participants' average adherence rates by month were 74.9%, 76.9% and 75.9%, supporting use of the HR data as a measure of engagement.

Additional user input guided content and implementation format refinement, including background image content and themes. Four focus groups of adults with preEH (total n=34) were conducted to guide refinement of TT's training content, experience, and user feedback. Participants gained hands-on experience using a demo version of TT on smartphones then reported on perceived usability and preferences for use, features, and graphical feedback. They also reported a strong preference for participating in BAM via smartphone app rather than face-to-face instruction, with 66% of participants indicating they would be unwilling to participate in a trial where they may be randomized to in-person, clinic-based BAM instruction rather than smartphone-delivered BAM. These findings underscore the potential for large-scale adoption for app-based BAM interventions.

Dosage requirements of BAM delivered via the TT app to emphasize optimal adherence usage and changes in BP to prevent EH are still unknown and are the focus of this study. Dose-response efficacy outcomes are needed to inform investigators of the optimal treatment strategy in the development of a large-scale efficacy RCT using mHealth BAM approaches. Therefore, this study reports the feasibility outcomes (i.e., adherence, duration) and dose-response effects of a 6-month mHealth BAM intervention conducted with adults with preEH randomized to twice a day 5-, 10-, and 15-minute dosage conditions. Results will provide insight into the BAM dosage that strikes an optimal balance of participant adherence and beneficial effects in reducing the primary outcome SBP.

Method

Participants

Adults (*N*=287) were recruited by flyers and clinic referral from a southeastern US costal city (population approximately 120,000). Potential subjects either contacted study personnel or were contacted via phone to determine eligibility and interest in participation. Inclusion criteria were (1) ≥21years of age, (2) Non-Hispanic White or African American (in keeping with formative work), and (3) preEH (i.e., SBP 121-139 mmHg on 3 consecutive occasions). Exclusion criteria included: (1) unwillingness to accept randomization into one of three dosage groups, (2) any chronic disease or medical condition that required regular pharmacological intervention or use of medications that may affect BP, (4) inability to use a smartphone (e.g., unable to open and navigate the app even after in-person instruction; inability to operate smartphone or hold finger to camera due to excessive tremor; inability to see content; etc.), (5) pregnant, lactating or intention of becoming pregnant during the trial, (6) participant in another study, (7) inability to speak, hear, or understand English, and (8) poor home cellular coverage.

Of the 287 candidates, 223 were excluded, most commonly due to BP being below the preEH range (*n* = 155; see Figure 1). The remaining 64 eligible candidates consented to participate in the dose response trial and provided baseline data. Two participants withdrew before or within the first month due to loss of interest or daily schedule conflicts, and 3 participants were dropped from analyses due to complete non-adherence in the first 3 weeks. For these 5 participants, no follow-up data were available, resulting in a final sample of 59 participants for follow-up analysis. Withdrawals were evenly distributed across dosage conditions. No participants withdrew due to technical issues or inadequate cellular signal.

Procedure

All procedures were approved by the Medical University of South Carolina institutional review board (Pro00020894). The study spanned August 2014 to October 2016.

BP screening and enrollment—A trained research assistant screened participants for preEH on three separate sessions spaced at least 24 hours apart. Sessions were conducted in a quiet, private conference room at the academic medical center. Resting heart rate (HR), SBP and diastolic blood pressure (DBP) were recorded from the right arm at heart level, while the patient remained in a seated position using a properly sized cuff and the GE

Carescape V100 monitor (GE Healthcare, Milwaukee, WI). Readings were recorded at minutes 0, 5, and 7. The first measurement was discarded and the last two measurements were averaged for a final session reading. Individuals were invited to participate in the clinical trial if their average SBP was in the preEH range (i.e., SBP 120-139 mmHg) on all 3 screening days (Chobanian et al., 2003). After preEH status was confirmed, written informed consent was obtained, sociodemographic (age, sex, education, income) and anthropometric (height, weight, waist circumference) data were gathered, and the TT orientation training was completed. BPs and HR were collected at 1-, 3-, and 6-month follow-up appointments using the same clinical laboratory procedures described above. Staff who assessed BP and other outcomes were blind to participants' group assignment.

TT Intervention—During the one-on-one, in-person orientation session, the TT app was downloaded to each participant's personal smartphone (i.e. Android or Apple iPhone). Research staff instructed participants in navigating the TT app, then participants completed their first BAM session and were provided opportunities to ask questions about the app and its functionality before leaving the medical center. All participants successfully completed a TT BAM session under staff supervision before taking the app home for daily sessions. Participants were randomized to one of three TT dosage conditions (5, 10, or 15 minutes twice daily) using a pre-defined randomization table. Dosage conditions were based on prior RCTs with input from focus groups of preEH patients during formative stages of this research. Participants were told to complete each TT session in a quiet, distraction-free place. To start each TT session, participants opened the app, placed their index finger over the rear-facing camera of their smartphone, and pressed 'start' on the app's main screen. The TT app would verify a stable HR response within 20-30 seconds and then allow initiation of the session. A user-selected tone (gong or chime) would notify participants when the sessions were over and give vibration feedback if the device could not capture the HR signal due to poor connection of fingertip with camera or excessive body movement. The instructional session included mandatory use of a recorded voice to guide participants in BAM. Following the training session, participants could select whether to keep the audio guide during sessions. During each BAM session, participants were directed to sit comfortably, close their eyes, and attend to the movement of their diaphragm while breathing in a slow, deep, relaxed manner. Participants were given written and audio instructions regarding strategies for optimizing BAM practice within the app that could be accessed at any time. An on-screen timer was displayed for the duration of each session and tones signaled the start and finish of each session. Participants were compensated $145 for their time and effort after each of the clinical visits (baseline, 1-mo, 3-mo, 6-mo), irrespective of their TT regimen adherence.

TT Adherence—Adherence was operationalized as completion of the two daily TT sessions per day. Partial adherence (.5) was allocated to full completion of 1 of 2 assigned sessions for the day. Encrypted time stamped HR data measured via built-in photoplethysmograph (PPG) from the participant's TT app were automatically transferred to the university's server infrastructure (Gregoski et al., 2012; Gregoski et al., 2013). These HR data were used as objective indices of adherence (i.e., 1.0 adherence indicated the app was used across the full dosage duration on two sessions over a 24 hour period with > 5 minutes

separation between sessions). Adherence was reported as a monthly percentage calculated as the average of the daily adherence scores (0, 0.5, or 1.0) across the number of days in the month. When compared with BP changes, adherence value represents the 1-month percentages leading up to that study month's BP measure (i.e. BP month 3 is compared with month 3 adherence %). Adherence categories were defined as <75% or ≥ 75% based on preliminary studies and other previous meditation RCTs where 75% adherence was associated with adequate BP reductions.

TT Accumulated Duration—Duration represents the cumulative monthly total of minutes using TT with the estimate calculated as (dose in minutes x 2 sessions per day x number of days in the particular month) and categorized by tertiles (0-300 min/month, 301-600 min/month, 601-900 min/month). Duration of completed sessions was collected by the TT app.

Physical Activity—The sweat index measured the number of days per week that activity was performed vigorously enough to work up a sweat (i.e., scored 0 days = 1, 1 day = 2,…8 etc.).

Satisfaction and Usefulness—The Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ; Bakken et al., 2006) was administered to participants at the 6-month time point. The TSUQ asks participants to rate how satisfied they were with the app, how easy it was to use the app, and how easy it was to learn the app. Ratings were made using a 5-point Likert scale (1=strongly disagree; 5=strongly agree). The percentage of participants who provided positive ratings (4 or 5) for satisfaction, ease of use, and ease of learning the app were examined.

Statistical Analyses

All BP and HR data were tested for outliers using box-plots and Iglewicz and Hoaglin robust tests for multiple outliers (two-sided). Outliers per both conditions (Hoaglin & Iglewicz, 1987) were excluded to meet assumptions of statistical procedures. The outliers in change scores consisted of the following: 2 from SBP-month 1 [+10.0, +9.8 mmHg]; 1 from SBP-month 3 [+26.8 mmHg]; 1 from DBP-month 1 [+8.0 mmHg]; 1 from DBP-month 3 [+11.5 mmHg]; 1 from HR-month 1 [−28.2 b/min]; 2 from HR-month 3 [−28.2, −29.3 b/min]. After data cleaning, data were tested for normality using Shapiro-Wilk testing.

Demographics were compared by dosage conditions using one-way ANOVA for continuous variables and Chi-square tests for categorical variables. Analyses for overall longitudinal intervention effects from baseline to follow-up month for SBP, DBP, HR, and adherence were performed using mixed modeling using maximum likelihood estimation and fixed effects. Further modeling included adjustments for covariates including age, gender, race, and physical activity. Physical activity was adjusted for in model 2 with the sweat index scale using change scores from baseline to follow-up month. Correlations between SBP and adherence and SBP and duration were calculated. Lastly, mean adherence and proportions of participants meeting at least 75% of sessions were reported by study month. ANOVA and chi-square tests were used to compare across dosage conditions. Significance was evaluated

based on $p = 0.05$. Analyses were carried out using SAS/STAT® software (SAS Institute Inc., USA) and IBM SPSS Statistics, Version 24.0 (Armonk, NY: IBM Corp.).

Sample size was determined via *a priori* power calculations, where primary outcomes were % of dosage group reaching 75% adherence target and % of dosage group reaching target clinically significant SBP reductions. It was determined that 18 participants randomized to each intervention group (total N=54) would result in at least 80% power to detect a difference in proportions of each group reaching the 75% adherence target. Similarly, 18 participants randomized to the three dosage groups was also calculated to give 80% power to detect at least a 0.96 sd unit effect size at alpha = .05, two-tailed for continuous adherence and SBP measures. Additional participants were recruited to account for potential attrition.

Results

Demographic results

Table 1 displays participant characteristics. Overall mean age of the 64 participants was 34.9 (SD=12.6) years with nearly equal distribution between genders (52.5% male) and race (49.2% African American). Most participants were college educated (54.2%) or had completed trade school (16.9%). No demographic variable was significantly different among dosage conditions.

Overall BP and HR results

Mixed modeling analyses for overall intervention effects showed significant decreases in SBP during all follow-up months for raw and adjusted models (all *p-values* < .001) (see Table 2). Similar changes were found for DBP at month 1 which remained significant at month 3 ($p = .003$) and 6 ($p = .034$) after adjusting for covariates. Modeling for HR changes resulted in mixed findings with *p-values* ranging between .01 and 0.36 after adjustment. A better fit was found in model 1 compared to raw values with lower AICs on all regression outputs. Change scores resulted in large effect sizes for SBP at each follow-up visit (average, Cohen's $d = 1.13$ to 1.80), medium to large effect sizes on DBP (Cohen's $d = 0.70 – 1.12$) with low effect sizes on HR (Cohen's $d = 0.079$-0.67). Of notable importance, paired differences in BP measures showed clinically relevant reductions in SBP in months 1-3 (−9.1 to −8.1 mmHg) with moderately reductions in DBP (−5.8 to −3.4 mmHg).

Dose Response Findings for BP and HR

SBP change scores among categories of TT dose, adherence, and duration between months 1, 3, and 6 are reported in Table 3. Mixed modeling analysis revealed a significant effect of dosage and adherence upon SBP. Generally, greater SBP reductions were observed as dose increased. Higher TT dose resulted in greater reductions in SBP at months 3 ($p = .015$) and 6 ($p = .018$), following adjustment for age and gender. Comparisons within month 3 revealed differences between the 5-min and 15-min dosages (LSD: $p = .022$) and the 10-min and 15-min dosages (LSD: $p = .010$; Tukey-Kramer: $p = .027$). Multiple comparisons within month 6 showed differences between 5-min and 15-min dosage conditions (LSD: $p = .007$; Tukey-Kramer: $p = .18$) (See Figure 2). No significant findings for DBP or HR were observed by dosage condition between or within each month.

Participants with higher adherence at month 1 demonstrated greater reductions in SBP than participants with adherence below the 75% cutoff, but no adherence related effects were observed at subsequent time points (see Table 3).

Using the duration variable (total min/month), results generally illustrated that as TT use duration categories increased, SBP reductions increased, especially in the high duration category (601-900 min/month). Within-month differences were found at month 1 ($p = .011$) and remained significant after adjusting for covariates, indicating greater reductions with greater TT duration.

Correlations showed a significant, moderate, inverse relationship between SBP change scores and adherence at month 1 ($r = -0.30$ $p = .024$), and with total duration at month 1 ($r = -0.38$, $p = .004$). No significant correlations were found at months 3 or 6 (p-values range . 12-.43).

Retention Rates

Initial study withdrawals were similar across dosage condition. Study retention was strong across the duration of the study. The 5-minute dosage group experienced a retention rate of 95% for month 3, and 81% for month 6. The 10-min dosage experienced a retention rate of 94% for month 3 and 78% for month 6. Lastly, the 15-min dosage group experienced a retention rate of 100% for months 3, and 75% for month 3.

Adherence

Mean monthly adherence measures by dose are reported in Table 4a and proportions of participants meeting at least 75% of TT sessions are shown in Table 4b. At month 1 there were no differences in adherence levels between the 3 dosage groups ($p = .91$). However, at months 2, 3, 5, and 6, the 15-min dosage group was significantly less adherent than the other dosage groups (ps < .05). Analyses using a ≥75% adherence criterion revealed significant differences between dosage groups in months 2, 3 and 6 (p-*values* < 0.034) showing the 15-min group exhibited the lowest proportion of success in months 2 and 6, whereas in month 3 the 5-min group showed the lowest success rate (though still 60%; see Table 4b). Intention to treat analysis (Table 4c) showed similar results but finding a significant difference at month 6 ($p = 0.006$) where only 14% in the 15-min dosage group met the 75% adherence criterion compared to 57% in the 5-min and 37% in the 10-min condition.

Satisfaction and usefulness

At the 6-month time point, 89% of participants reported high satisfaction,; 94% found the app easy to use, and 96% reported it was easy to learn how to use the app.

Discussion

There is need for effective, inexpensive, acceptable interventions that can be widely disseminated to reduce the public health burden of EH. This study evaluated TT, a smartphone-based app designed to teach and monitor BAM techniques among adults with preEH. Statistically significant and clinically relevant reductions in SBP were observed

between baseline and evaluations at 1, 3 and 6 months irrespective of dosage conditions. In addition, a significant dose-response association was found for SBP at months 3 and 6, with the 15-min dosage group showing the greatest reductions.

It appears the first month of intervention is a critical time frame for establishing BAM effects upon SBP, given the observed trends across dosage conditions, adherence levels, and TT duration (total min/month) over the course of the trial. In initial weeks, users build BAM skills that carry across to subsequent time periods. Given first-month adherence was high across all dosage conditions, participants in the 15-min dosage group practiced and experienced the highest duration of BAM in the first month compared to other groups. Indeed, higher duration was found to be associated with greater SBP reduction in the first month, and participants in the 15-min condition showed greatest SBP reductions at months 3 and 6. This suggests it may be valuable to recommend a TT starting dosage of 15-min twice-daily in the first intervention month intervention to maximize early exposure to BAM practice and promote durable SBP reductions.

Results revealed variability in adherence across dosage conditions in later months, which potentially masked the association between adherence and SBP changes. The decline in adherence among participants in the 15-min dosage condition may have been due to higher burden associated with setting aside 30 minutes daily for BAM sessions. The lower dosage conditions may have been more easily and conveniently integrated into participants' daily routines, facilitating higher adherence over time. Still, participants in the 15-min dosage condition demonstrated greatest SBP reductions over time. Participants assigned to the 15-min condition may have mastered BAM more rapidly than participants in the other groups, rendering adherence to the pre-specified twice-daily sessions less important later in the trial. Participants in the 15-min dosage group may have started TT sessions but ended them prematurely later in the trial as they became more efficient in achieving stress reduction goals or practiced BAM in shorter sessions outside the TT app as part of their routine or in response to onset of stress, anxiety, rumination, etc. Engagement in such partial sessions where participants did not use the app for the full assigned dosage time would have contributed to lower observed adherence rates, despite ongoing consistent use of BAM in participants' daily lives and persistent reductions in SBP for that group. Participants may have also used BAM as part of their repertoire of coping mechanisms which may have impacted BP and HR during the trial.

Benefits in the form of BP reduction were obtained even at the lowest TT dosage condition. Assigning twice daily 5-minute BAM sessions with TT may be sufficient for achieving desired clinical outcomes among preEH users even though a larger benefit could be found in higher doses. It is unknown if briefer or less frequent BAM sessions may result in similar BP reductions and higher adherence. It is also unknown whether more dramatic improvements in BP and HR would have been observed with even higher TT dosage conditions. Findings from the cumulative duration per month seemingly support the notion that total monthly duration may be more important than length of individual sessions, though nearly all the highest duration group were from the 15-minute dosage condition. To maximize duration of exposure and adherence over time, it may be worthwhile to assign a relatively high dose of TT initially followed by a lower dose maintenance regimen to maintain practice.

In the current trial, clinically meaningful SBP reductions were observed in adults with preEH that were observable within 1 month of TT use (range for average SBP reduction across dosage: −7.9 to −10.9 mmHg) and maintained up to 6 months post-baseline (range for average SBP reduction across dosage: −5.1 to −12.4 mmHg). The magnitude and durability of these effects is notable given the intervention was entirely app-based and dosage was as low as 10 minutes per day (i.e., 5 minutes twice daily) and did not exceed 30 minutes per day (i.e., 15 minutes twice daily). Few other studies have reported effects of BAM on SBP at 6-mo follow-up (Dickinson et al., 2008). In this trial, the effects of TT upon BP were similar compared to other in-person interventions involving meditation or other stress reduction interventions. For example, in a review of 17 RCTs, Transcendental Meditation was found to significantly reduce BP by −5.0 mmHG (Rainforth et al., 2007). Moreover, current results suggest TT-guided BAM may yield similar, if not better, average SBP reductions that have been observed in lifestyle programs involving EHs and preEHs: exercise (−4.6mmHg), weight loss diet (−5 mmHg), low sodium (−3.6 mmHg) and low alcohol intake (−3.8 mmHg) (Dickinson et al., 2006). Another meta-analysis of 25 RCTs involving relaxation meditation and breathing approaches showed large heterogeneity and weak overall methodology quality (e.g. reported medications, control groups, short study length, etc.), thought results showed an overall −5.5 mmHg reduction in SBP for high BP groups (Dickinson et al., 2008). Various other slow breathing studies incorporating in-session biofeedback (e.g. EMG, breathing belt feedback) compared to simple slow breathing control groups found significant SBP reductions (i.e. intervention ranging −8.4 to −12.8 mmHg compared to −2.0 to −7.7 mmHg from controls) in preEHs (D. E. Anderson, McNeely, & Windham, 2010; Lin et al., 2012; Wang et al., 2010). Many of these studies used approximately 10 sessions, were completed over a 4-5 weeks and used a dosage around 10 minutes. These studies' findings are also similar to the reductions found in TT though the dose was half of that in the highest TT condition (i.e. 15-min, twice a day), though TT only showed graphical feedback after the session was over. Use of personalized HR feedback after each TT session may have promoted engagement and increased the efficacy of TT across all dosage conditions. Overall, TT showed similar responses to more complicated and expensive interventions that require in-person sessions or specialized equipment, which underscores the potential value of smartphone-guided BAM for BP reduction.

A significant advantage of TT is the capacity to automatically and objectively assess adherence to BAM practice through use of the built-in photoplethysmograph that captured pulsatile fingertip HR throughout each TT session. This allows monitoring of the BAM sessions, and provides actionable data for personalized motivational feedback when sessions are missed or discontinued prematurely. Here, adherence to TT was high across all three dosage conditions for the first month, suggesting all participants were engaged in BAM practice in the weeks immediately following orientation to the app. This is encouraging given that participants were not being paid or otherwise incentivized to complete daily practice sessions, particularly in light of evidence that health behavior change apps have poor overall uptake and long-term engagement (Krebs & Duncan, 2015).

Limitations

This study showed a strong effect of BAM using TT to lower BP in adults with preEH, though some methodological decisions should be considered when interpreting results. Although each session was automatically measured through TT, it was not designed to capture the frequency of BAM practice beyond the required session or without TT. Additionally, partial completion of individual sessions within a day was not counted towards adherence. These limitations could have introduced variability by underestimating the duration participants were exposed to BAM. Comments by participants suggested this was not a strong concern in the delivery of the intervention. Regardless, the measurement method to capture dosage was automatic, quantitative, and stronger than self-report measures.

From a technology use standpoint, the TT application also uses the built-in LED and camera for the photoplethysmograph to capture continuous HR data. This uses some additional battery power, which may influence users' ability or decision to use the app consistently in their daily lives. Even so, using built-in sensors rather than external wearables reduces opportunities for equipment to be lost, broken, or not being appropriately charged and eliminates multi-device connection issues (i.e., Bluetooth pairing wearable with smartphone).

This study was designed as a quasi-experimental study to determine optimal dosing for the TT app, so participants were assigned to one of three dosage conditions for the same intervention and not to any non-TT control group. Input from patients and clinics in formative research suggested there would be low participation and uptake of in-person BAM training. Therefore, no in-person arm was included in this trial, preventing conclusions about optimal modalities for teaching and implementing BAM in clinic. Given the lack of these comparison groups, results on efficacy should be interpreted with caution. Additionally, a finite set of twice daily dosing conditions were examined, and it is possible other dosing regimens involving different durations and frequencies of BAM sessions would result in similar or better outcomes. Future work may test a broader set of practice regimens. Only White and African-American participants were included here, potentially limiting generalizability of findings to other racial and ethnic groups. Finally, people taking medications that may affect BP were excluded here; future work should evaluate acceptability and effects of TT among people with elevated BP due to medication or as an adjunct therapeutic approach for people on medications to manage BP.

Future Directions

These results imply a potential use for BAM techniques in the prevention or treatment of EH as other in-person TM programs have shown (Barnes & Orme-Johnson, 2012). Findings guided design of a clinical trial currently underway to test efficacy of TT on BP and other stress-related health outcomes compared to a lifestyle education program in a large sample of adults with preEH (ClinicalTrials.gov Identifier: NCT03168789). This study will also afford a greater capacity to explore mechanisms underlying TT effects upon BP and other outcomes (e.g., perceived stress, physiological stress response). Our team is also developing strategies for leveraging the biofeedback and motivational capabilities of TT further improve BP outcomes. Additional studies in this line will evaluate staged or multi-phase dosing

protocols with respect to BP reductions, adherence, and user acceptability of mHealth directed BAM interventions. Further effectiveness trials will compare TT to other stress reduction modalities, as well as evaluate uptake, implementation, and clinical outcomes among people who independently choose to download TT from publicly accessible app stores. The field would benefit from additional research investigating other mHealth strategies for delivering BAM for BP reduction, including trials to test the utility of other available apps, the integration of a broader array of sensing technologies to track progress, and studies in other at-risk populations (e.g., preEH youth).

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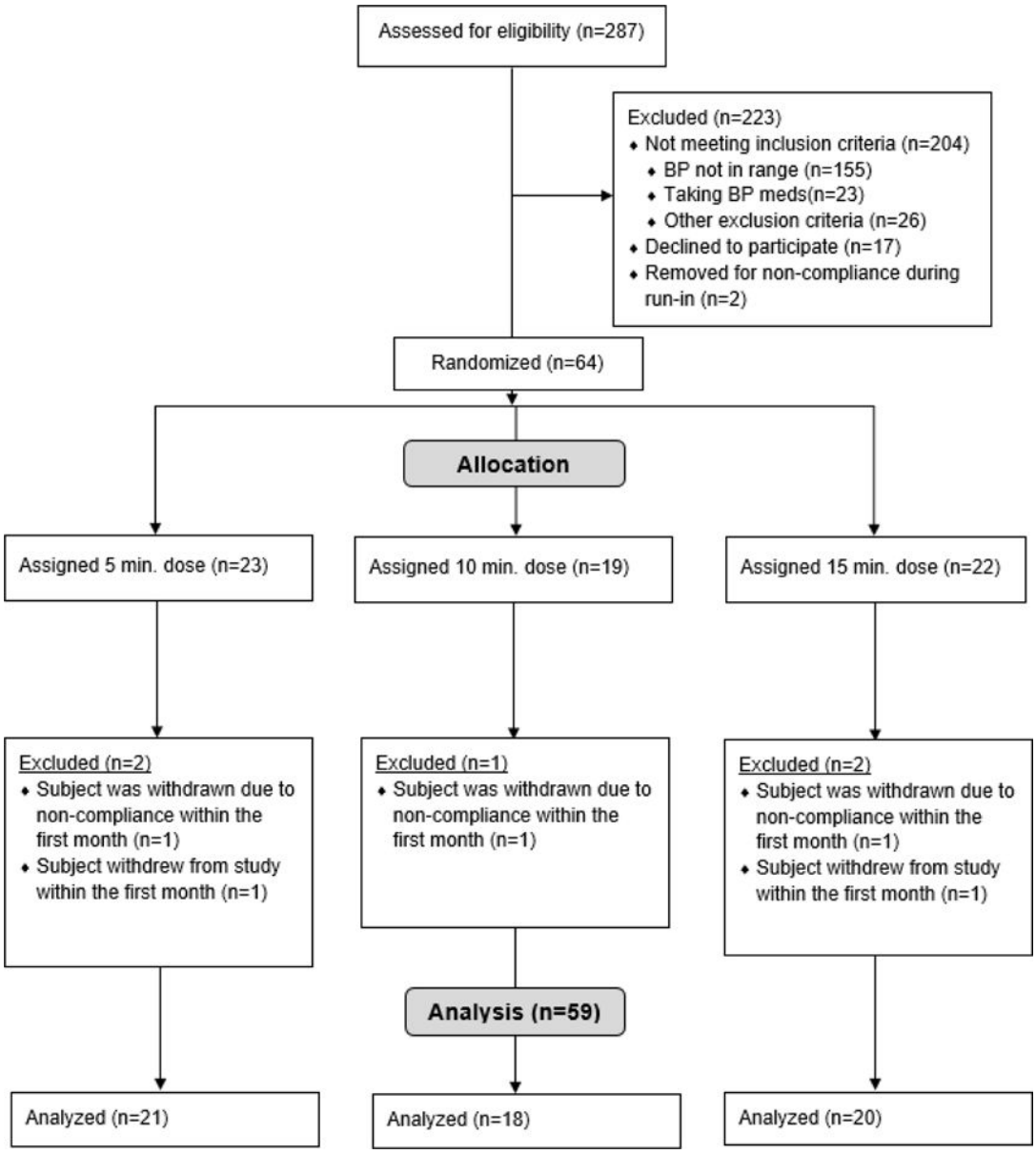
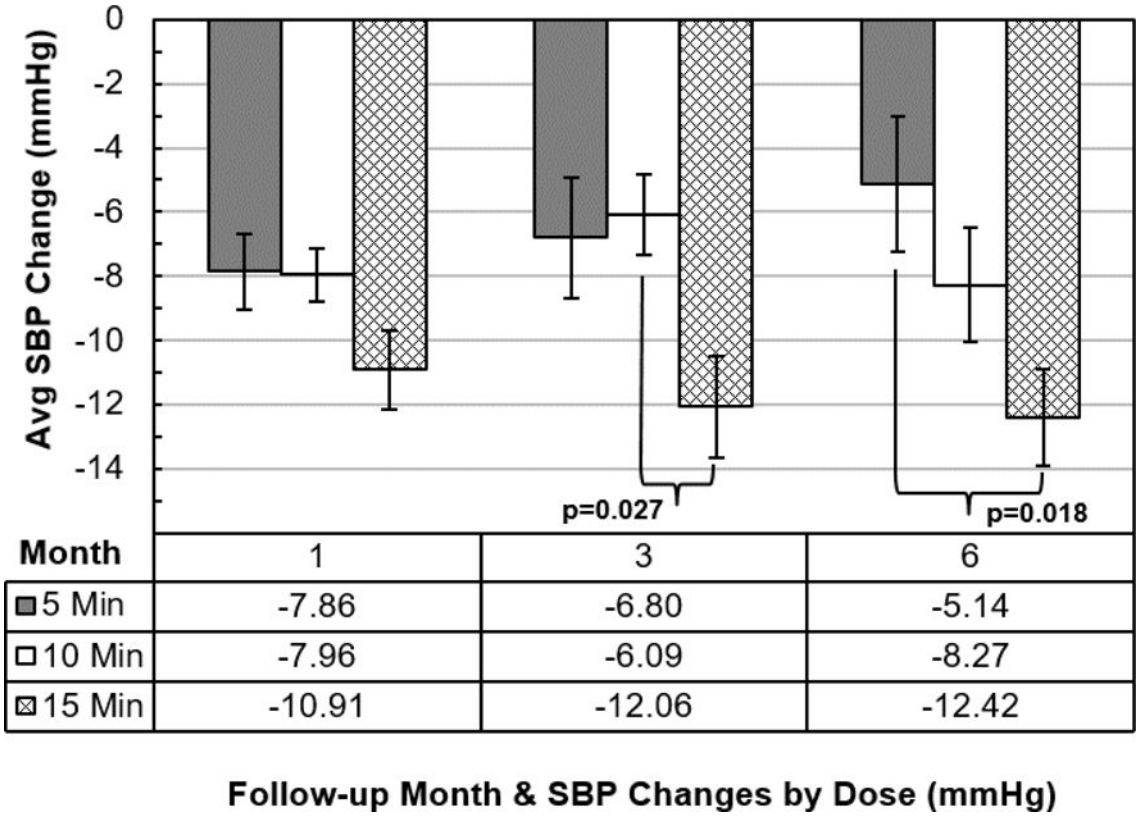


Figure 1.

Participant flow chart following Consolidated Standards of Reporting Trials (CONSORT) guidelines.



Month	1	3	6
5 Min	-7.86	-6.80	-5.14
10 Min	-7.96	-6.09	-8.27
15 Min	-10.91	-12.06	-12.42

Figure 2.

SBP (in mmHg) changes by Tension Tamer dosage conditions (5, 10, and 15 minutes 2x/day) at 1-, 3-, and 6-month follow-up. Significance between dosages tested using Tukey-Kramer adjustments for multiple comparisons. Error bars reported as the standard error of the mean.

Table 1

Baseline characteristics of participants by dosage condition.

Variable	Total (n=64)	Dose			*p*-value
		5 min (*n* = 23)	10 min (*n* = 19)	15 min (*n* = 22)	
Age (y)	35.1 ± 12.5	36.5 ± 10.8	37.9 ± 13.1	31.1 ± 13.1	.17
Sex (*n*, %)					
Male	35 (54.7%)	12 (52.2%)	10 (52.6%)	13 (59.1%)	.88
Female	29 (45.3%)	11 (47.8%)	9 (47.4%)	9 (40.9%)	
Race (*n*, %)					.57
White	33 (51.6%)	10 (43.5%)	10 (52.6%)	13 (59.1%)	
African American	31 (48.4%)	13 (56.5%)	9 (47.4%)	9 (40.9%)	
BMI (kg/m^2)	28.1 ± 5.8	28.7 ± 6.7	27.6 ± 5.2	27.9 ± 5.4	.81
Waist circumference (cm)	93.8 ± 16.5	94.5 ± 14.6	92.0 ± 12.8	94.7 ± 21.1	.85
Hip circumference (cm)	107.2 ± 10.4	108.1 ± 12.2	107.4 ± 9.2	106.1 ± 9.6	.81
Resting SBP	128.3 ± 3.6	127.6 ± 3.7	128.0 ± 3.3	129.4 ± 3.6	.21
Resting DBP	73.1 ± 7.5	74.3 ± 5.4	73.0 ± 7.9	71.8 ± 9.0	.55
Resting HR	75.5 ± 11.6	78.9 ± 10.1	71.3 ± 11.5	75.8 ± 12.5	.11
Education (*n*, %)					.63
High school	6 (9.4%)	2 (8.7%)	3 (15.8%)	1 (4.5%)	
Trade school	13 (20.3%)	6 (26.1%)	3 (15.8%)	4 (18.2%)	
College educated	33 (51.6%)	11 (47.8%)	9 (47.4%)	13 (59.1%)	
Not Reported	12 (18.8%)	4 (17.4%)	4 (21.1%)	4 (18.2%)	
Annual income (*n*, %)					.19
< $15,000	21 (32.8%)	6 (26.1%)	4 (21.1%)	11 (50.0%)	
$15,000-29,999	23 (35.9%)	8 (34.8%)	9 (47.4%)	6 (27.3%)	
$30,000-49,999	12 (18.8%)	5 (21.7%)	4 (21.1%)	3 (13.6%)	
$50,000-74,999	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (9.1%)	
> $75,000	1 (1.6%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	
Not Reported	5 (7.8%)	3 (13.0%)	2 (10.5%)	0 (0.0%)	

P-values for age, BMI, waist circumference, hip circumference, systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) were based on one-way analyses of variance (ANOVA) comparing mean values across dosage conditions. *P-values* for sex and race were based on Chi-square analyses comparing values across dosage conditions. Education groups were collapsed to High/Trade school and College educated groupings due to < 5 observations in subgroups. Annual income *p* represents collapsed groups of <$15,000 and >$15,000.

Table 2

Tension Tamer effects on SBP, DBP, and HR using intention to treat analysis (n=64)

	Unadjusted means (SD)	*p-value*	*Model 1* *p*-value	Cohen's *d*
SBP Baseline	128.3 (3.6)			
SBP Month1	119.2 (5.3)	<.001	<.001	1.80
SBP Month 3	119.9 (6.9)	<.001	<.001	1.20
SBP Month 6	120.2 (7.4)	<.001	<.001	1.13
DBP Baseline	73.1 (7.5)			
DBP Month 1	67.3 (7.7)	<.001	<.001	1.12
DBP Month 3	68.8 (8.0)	.007	.003	.99
DBP Month 6	69.7 (8.0)	.054	.034	.70
HR Baseline	75.5 (11.6)			
HR Month 1	70.5 (10.9)	.015	.01	.67
HR Month 3	73.5 (11.0)	.38	.36	.079
HR Month 6	72.6 (10.7)	.084	.034	.44

Standard deviation: SD, systolic blood pressure: SBP (in mmHg), diastolic blood pressure: DBP (in mmHg), heart rate: HR (bpm). Mixed Modeling was used to test statistical significance for each follow-up time point compared to baseline. Model 1: adjusted for age, race, gender; Model 2: adjusted for all covariates in Model 1 and physical activity (sweat index). Effect size: Cohen's *d* = (Baseline - follow-up month)/SD, Cohen's *d* conventions: (small .2, medium .5, large .8).

Table 3

Effect of dosage condition, adherence, and monthly cumulative duration of Tension Tamer on systolic blood pressure

Variable	Time						
	n	Month 1	*n*	Month 3	*n*	Month 6	*p*-value
Dose							
5	20	−7.9 (5.2)	17	−6.8 (7.7)	16	−5.1 (8.4)	.39
10	17	−8.0 (3.4)	17	−6.1 (5.2)	12	−8.3 (6.2)	.24
15	20	−10.9 (5.5)	18	−12.1 (6.7)	14	−12.4 (5.7)	.74
p-value		0.08		0.02 **		0.02 **	-
Adherence							
0-74.9%	20	−6.4 (5.1)	22	−9.4 (7.3)	20	−10.7 (5.7)	.028 *
75%-100%	37	−10.3 (4.4)	30	−7.6 (6.8)	22	−6.44 (8.4)	.032 **
p-value		.003 **		.36		.058	-
Duration (min/month)							
0-300 min	21	−7.9 (5.0)	23	−7.5 (7.3)	22	−6.6 (8.0)	.82
301-600 min	18	−7.5 (3.6)	21	−7.3 (6.4)	15	−9.9 (6.5)	.35
601-900 min	18	−11.7 (5.2)	8	−13.6 (5.9)	5	−12.3 (6.3)	.72
p-value		0.01 **		0.06		0.20	-
Correlations							
Adherence & SBP	57	−0.30 * (*p*=.02)	52	0.11 (*p*=.43)	42	0.25 (*p*=.12)	-
Duration & SBP	57	−0.38 * (*p*=.004)	52	−0.16 (*p*=.25)	42	−0.20 (*p*=.20)	-

Note. *p-values* based on mixed modeling analysis. SBP (in mmHg) values reflect change scores from follow-up month subtracted from baseline and standard deviation (SD). Correlations were for continuous adherence (% sessions completed/expected sessions) and duration (adherence x dose x 2 daily sessions x 30 days) values and SBP change scores.

* Significance at $p \leq 0.05$.

** Maintains a significance of $p \leq 0.05$ after adjustment for covariates: age, race and gender.

Table 4a

Mean adherence to Tension Tamer prescription by dose

Month	Dose (in min 2x day)			*p*-value
	5 (*n* = 23)	10 (*n* = 19)	15 (*n* = 22)	
1	75.7 ± 29.0	75.8 ± 23.3	73.0 ± 23.3	.77
2	77.2 ± 21.2	83.6 ± 15.3	67.3 ± 23.6	.05*
3	74.7 ± 20.2	76.0 ± 23.2	56.4 ± 27.4	.018*
4	71.5 ± 29.1	69.9 ± 26.5	55.7 ± 27.3	.15
5	76.4 ± 19.9	70.5 ± 26.4	55.1 ± 27.8	.037*
6	78.3 ± 17.7	73.3 ± 21.5	48.4 ± 28.9	.001*

Table 4b

Proportion of participants meeting 75% of Tension Tamer as randomized

Month	Dose (in min 2x day)			*p*-value
	5 (n=21)	10 (n=18)	15 (n=20)	
1	66.7% (14/21)	61.1% (11/18)	70.0% (14/20)	.93
2	65.0% (13/20)	88.2% (15/17)	45.0% (9/20)	.023*
3	60.0% (12/20)	70.6% (12/17)	70.0% (14/20)	.034*
4	55.0% (11/20)	47.1% (8/17)	36.8% (7/19)	.52
5	58.8% (10/17)	53.3% (8/15)	29.4% (5/17)	.19
6	76.5% (13/17)	50.0% (7/14)	20.0% (3/15)	.006*

Table 4c

Proportion of participants meeting 75% of Tension Tamer with intention to treat

Month	Dose (in min 2x day)			*p*-value
	5 (n=23)	10 (n=19)	15 (n=22)	
1	60.9% (14/23)	57.9% (11/19)	63.6% (14/22)	.84
2	56.5% (13/23)	78.9% (15/19)	40.9% (9/22)	.023*
3	52.2% (12/23)	63.2% (12/19)	27.3% (6/22)	.034*
4	47.8% (11/23)	42.1% (8/19)	31.8% (7/22)	.44
5	43.5% (10/23)	42.1% (8/19)	22.7% (5/22)	.22
6	56.5% (13/23)	36.8% (7/19)	13.6% (3/22)	.006*

Comparisons of mean (Table 4a.) by dosage (5, 10, and 15 min, twice daily) and study month using mixed modeling analysis. Tables 4b and 4c show proportion of participants meeting at least 75% adherence with *p* values calculated using Chi-square tests. Adherence was measured by calculating % of completed sessions divided by the expected sessions for the study month via automated recorded data capture by Tension Tamer app uploaded to trial servers.