

# **HHS Public Access**

Author manuscript *Health Informatics J.* Author manuscript; available in PMC 2021 May 11.

# Published in final edited form as:

Health Informatics J. 2020 December ; 26(4): 3201-3214. doi:10.1177/1460458220954613.

# Improving mental health in U.S. Veterans using mHealth tools: A pilot study

Chase Latour, Washington University in St. Louis, USA; University of North Carolina at Chapel Hill

Lorcan O'Byrne, University College Dublin, Ireland

# Margaret McCarthy,

Washington University in St. Louis, USA

Ravi Chacko, University of Chicago; DataDog Health Inc

Elizabeth Russell, DataDog Health Inc; Washington University in St. Louis, USA

Rumi Kato Price Washington University in St. Louis, USA

# Abstract

Rates of PTSD remain elevated among U.S. Veterans, highlighting a need for innovative management tools. Previous studies have shown mobile apps to have positive effects on PTSD symptoms, but few apps have been examined systematically. This pilot study evaluated the perceived effectiveness and usability of Mindset, a novel mobile app that monitors user stress level via heart rate to encourage e-therapy use. The study sample included 30 community-residing Veterans who completed baseline assessments. They used the Mindset app and associated smartwatch until their approximate 1-month follow-up. Self-reported assessments included preand post-deployment experiences; experience with Mindset; and standard screeners for PTSD (PCL-M), anxiety (GAD-7), depression (PHQ-9), and alcohol use problems (AUDIT). Among the 24 participants who completed follow-up interviews, a significant decrease (p < 0.05) was found in

Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (https://creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (https://us.sagepub.com/en-us/nam/open-access-at-sage).

**Corresponding author:** Rumi Kato Price, Department of Psychiatry, Washington University School of Medicine, 660 S. Euclid Ave. Medical Box 8134., St. Louis, MO 63110, USA., pricerk@wustl.edu.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: CL, LO, MM, and RK declare no conflicts of interest. RC and ER have financial interests in the company Data Dog; however, they were not involved in data collection and analysis for this manuscript. All data collection and analyses were completed only by CL, LO, MM, and RK, who also wrote and maintained editorial control over this manuscript. RC and ER were involved in grant preparation, Mindset technical assistance, and completion of this manuscript.

Ethical approval

This pilot study was approved by the Washington University in St. Louis Institutional Review Board.

PCL-M, PHQ-9, and modified AUDIT scores. Respondents reported moderate to high acceptance and satisfaction with Mindset features, though considerable frustration with the associated smartwatch. These findings highlight mHealth apps such as Mindset as potentially useful tools for PTSD and depression symptom management. These findings are also encouraging in the context of the current COVID-19 pandemic, which may accelerate further innovation and implementation of mHealth technologies to improve mental health self-care.

### Keywords

mental health; mobile applications; post-traumatic stress disorder; stress monitor; U.S. Veterans

# Introduction

Post-traumatic stress disorder (PTSD) is a debilitating psychiatric condition, with an estimated lifetime prevalence of approximately 7% in the U.S. general population.<sup>1</sup> Prevalence rates among U.S. Veterans are even higher: ranging from 14% (cross-sectional prevalence) in Operation Enduring Freedom and Operation Iraqi Freedom Veterans<sup>2</sup> to 19% (lifetime prevalence) among Vietnam Veterans.<sup>3</sup> The characteristic PTSD symptom clusters consist of: (1) the re-experiencing of intrusive, traumatic memories; (2) avoidance of thoughts, feelings, or situations that may trigger memories of the traumatic events; (3) negatively altered cognition and mood; and (4) hyperarousal and reactivity symptoms.<sup>4</sup> Other psychiatric disorders such as anxiety, depression, and suicidality often co-occur with or follow the presence of PTSD symptoms.<sup>5,6</sup> PTSD has also been associated with numerous physiological concerns.<sup>7–9</sup> However, remission is possible. A 2014 systematic review of the natural course of PTSD found that, among varied populations, an average of 44% of individuals no longer experienced diagnosable levels of PTSD symptoms after a mean of 40 months, without specific treatment.<sup>10</sup> The severe systemic effects of PTSD and co-occurring disorders with the positive prospect of successful recovery highlight the importance of early interventions.

Despite the need for intervention, provision of effective, evidence-based PTSD treatment is challenging, particularly among Veterans.<sup>11</sup> One study documented that only half of Veterans returning from Iraq and Afghanistan who sought treatment for PTSD received at least minimally adequate care.<sup>12</sup> Factors contributing to this disparity include geography, financial or medication concerns, time constraints, and occupational or cultural barriers.<sup>12,13</sup> Additionally, Veterans with psychiatric disorders have been found more likely than those without to show concerns about stigmatization and other barriers, further preventing them from obtaining treatment.<sup>14</sup> Thus, self-management tools for PTSD symptoms may augment traditional clinician-led therapies.

Recent technological advances have led to the development and implementation of novel mobile health (mHealth) interventions that use mobile devices to offer convenient and inexpensive approaches to mental health care. This is driven by the increasing use of smartphones among civilians and military personnel alike: in 2019, 81% of the U.S. adult population reported owning a smartphone.<sup>15,16</sup> Mobile technology offers a plausible avenue

for mental healthcare delivery while alleviating some barriers associated with traditional mental health treatments.<sup>17</sup>

Indeed, studies have found that U.S. Veterans are both willing and able to incorporate smart technology into their mental health care. Wilson et al. conducted a study to understand knowledge, attitudes, and experiences of 352 U.S. soldiers with mHealth technologies. They found that most participants were familiar with and open to engaging with mHealth-based services. Notably, 33% of participants who were averse to seeking traditional treatment indicated being willing to use technology to access mental health resources.<sup>18</sup> These results support the idea that technology-based treatments may provide feasible options to overcome barriers to care faced by Veterans. Given the popularity of smartphones and mobile apps, it is unsurprising that over 1800 PTSD-related apps are currently available.<sup>13</sup> Preliminary evidence, through studies of apps such as PTSD Coach<sup>13,19</sup> and PE Coach,<sup>20</sup> suggest that smartphone apps help reduce PTSD symptoms. However, many of these apps have not been validated through methods such as feasibility studies or randomized control trials.<sup>21</sup>

The rapidly evolving COVID-19 pandemic has amplified the need and potential for digital health, including mHealth, to increase access to and delivery of mental health care.<sup>22</sup> On the one hand, access to traditional mental health care has been hampered due to imposition of stay-at-home orders, cancellation of elective procedures, and heightened fear of going to hospitals and clinics. On the other hand, experts expect increasing negative consequences on mental health and well-being in the near future due to the pandemic's unimaginable tolls and the mitigation measures that have isolated people.<sup>23</sup> There may be reasons to anticipate that the negative consequences of COVID-19 could be disproportionately worse for U.S. Veterans: over a quarter of Veterans are 70 years and older with a considerable degree of comorbid medical risk factors such as cardiovascular and pulmonary diseases.<sup>24</sup> Further, COVID-19-related events could potentially trigger acute stress disorder or recurrent PTSD symptoms among those with past traumatic experiences.

In this study, we examined Mindset, a mindfulness app that combines self-help intervention features with a commercially available heart rate monitoring watch. This combination allows the app to track the location and time of stress events and notify users in real-time of apparently elevated physiological stress, prompting engagement with the app's stress-management modules. The aim of this study was to assess the self-perceived effectiveness, acceptance, and usability of the Mindset system among a sample of community-residing U.S. Veterans.

# Materials and methods

#### Mindset

Mindset, developed by DataDog Health Inc. (mindset-app.com), includes self-help therapy modules that have been shown effective in clinical settings.<sup>25–27</sup> The three primary modules consist of (Figure 1): (1) Good Things (provides a forum for users to post positive things, privately or publicly); (2) Journal (offers various options for assessing and re-orientating the user's emotions based on Cognitive Behavioral Therapy); and (3) Meditations (consists of two parts – a simple breath-timing exercise and pre-recorded therapies).

The wearable device used in this study was the Mio ALPHA2 (Mio Global, Vancouver, Canada), which was recommended to be worn around the user's wrist. This device monitors the user's pulse rate using optical plethysmography, which the app then converts into a proxy for physiological stress level through an algorithm based on both pulse rate and pulse rate variability. When the pulse rate increases beyond a certain threshold, it is considered a candidate stress event. This threshold is set as the current pulse rate plus a multiple of the standard deviation in pulse rate over the prior 5 minutes. This multiple begins at two but can be adjusted by the user if too many or too few stress notifications are detected. If the candidate stress event occurs in the setting of motion activity, indicated by inertial measurement units from the phone, the candidate stress event is rejected. Candidate stress events are also rejected if the last stress event was less than 20 minutes in the past. Mindset notifies the user of stress events that are not rejected and prompts engagement with the app's e-therapies through phone notifications (Figure 2). Information regarding time and location of these events is also recorded and can be accessed through the "Time Stamp" and "GPS" features, respectively, located in the online Web Dashboard.

#### **Participants**

Thirty Veterans meeting the following criteria were included in the study: 50 years of age or younger with combat experience; resident of the St. Louis, MO region; and a smartphone owner. We further excluded individuals with pacemakers, due to its potential interference with heart rate variability measures, and individuals with severe psychiatric disorders that could compromise the validity of a respondent's answers (e.g. active schizophrenia, schizoaffective disorder, or severe cognitive impairment). This screening was conducted at the initial contact enrollment time as well as prior to starting survey questions. Participants were recruited through outreach to Veteran organizations and by word of mouth. Recruitment and interviewing occurred between June 2017 and March 2018. Six participants did not complete the follow-up survey, resulting in a final follow-up sample size of 24. No significant differences were found for age (mean difference = 3.54 years; t = -1.7 (df = 9.9); p = 0.13), sex ( $\chi^2 = 0.0$  (df = 1); p = 1.00), or race ( $\chi^2 = 0.6$  (df = 2); p = 0.75) between those who did and did not complete a follow-up interview using a two-sample *t*-test for age and Chi-squared test for sex and race. The demographic characteristics of the follow-up study sample are shown in Table 1. Two-thirds of participants that completed follow-up interviews were male. Participants were predominantly white, and their average age was 36.7 years.

#### Procedure

Study interviewers contacted Veterans who expressed interest in study participation, further explained the study, and assessed inclusion criteria through participant responses to screening questions. If eligible, an in-person baseline interview was scheduled. Informed consent was completed immediately before the baseline interview. After interview completion, participants were introduced to the Mindset app and associated smartwatch and were given instructions on how to use the watch with the app and the app's modules. The research team provided participants with an anonymous username for Mindset. All data recorded by Mindset were transmitted to a secure server only accessible by the authorized

personnel of DataDog Health. However, data summarized in the study was obtained separately by a university research team.

Participants used the Mindset app and watch for approximately 1 month. The app gave users three daily tasks to encourage active engagement (prominent buttons on the app's home screen that directed the user to either a gratitude, meditation, or journal exercise), along with any stress notifications. After the month, participants completed a follow-up interview either in-person or over-the-phone if an in-person interview could not be scheduled. Participants were given a \$25 gift card after the completion of each interview and the smartwatch at the end of study participation.

#### Measures

The baseline interview focused on demographic information; experiences pre- and postdeployment; and standardized screening scales, including the PTSD Checklist (PCL-M),<sup>28</sup> Generalized Anxiety Disorder Assessment (GAD-7),<sup>29</sup> Patient Health Questionnaire (PHQ-9; a tool for screening the presence and severity of depression),<sup>30</sup> and modified Alcohol Use Disorders Identification Test (AUDIT, adapted to apply within the last 30 days). <sup>31</sup> The follow-up session concentrated on user experience with Mindset, app helpfulness, and the re-administration of standardized screening scales.

Multiple measures were used to assess Mindset acceptance, including frequency of smartwatch and module use, perceived helpfulness of modules, satisfaction with Mindset hardware and software, and perceived usefulness for stress management. Use frequency was assessed with five categories: "Not at all," "Less than once a week," "Weekly," "Daily," and "Multiple times daily." Response categories for helpfulness of features were "Not at all," "Slightly," "Moderately," "Very," and "Extremely." Questions regarding hardware, software, and stress management had five response categories ranging from "Strongly disagree" to "Strongly agree."

#### Analysis strategy

All quantitative, statistical analyses were completed using SAS 9.4 (SAS Institute Inc., Cary, NC). Further, all analyses, including scoring algorithms for PCL-M, GAD-7, PHQ-9, and modified AUDIT, were verified independently by two of the authors (C.L. & L.O.). Significance level was set at 0.05. Paired *t*-tests assessed significant differences between baseline (pre-intervention) and follow-up (post-intervention) standardized screening scores within participants (baseline to follow-up scores). Two-sample *t*-tests analyzed whether these paired scores differed significantly based upon level of smartwatch use (used the watch every day vs did not use it every day) or module use (used the module at all over the study follow-up vs never used the module). The dichotomizing use levels were determined after a careful review of the distribution of answers across all use questions to arrive at two categories that could be used across all modules while still maintaining a reasonable frequency in each category. In a few instances, participants responded "Don't Know" or "Refused" to questions on the standardized screeners. Such a response was replaced with its associated answer on the other survey, thus assuming no change. This method could result in

a slight underestimate of change over time. However, we chose this conservative strategy to maximize analytical sample size.

The recommended PCL-M cut-off values for probable PTSD vary depending upon the expected prevalence within a population and desired specificity.<sup>28</sup> Our study used a cut-off value of 34 for both interviews to indicate probable PTSD. This followed Bliese et al.'s recommended cut-off range of 30 to 34 for a population of active duty Veterans.<sup>32</sup> We used the cut-off value of 10 for the PHQ-9, as recommended,<sup>33</sup> to indicate probable depression. Finally, to understand the clinical significance of observed changes on the individual level, we used the principle of minimal clinically important difference (MCID). This is defined as "the smallest effect size that would lead [clinicians] to recommend a therapy to their patients."<sup>34</sup> The MCID for a specific condition is derived from evidence for a significant effect size. The proposed MCID for the PCL-M is 5.7 to 10.2 points (with a midpoint of 7.9)<sup>35</sup> and 4.78 points for the PHQ-9.<sup>36</sup> We used these guidelines to assess clinical improvement of PTSD and depression symptoms for participants over the duration of their Mindset use.

# Results

#### Standardized screening scores

Table 2 shows summary information for self-reported screening scores of PTSD (PCL-M), depression (PHQ-9), generalized anxiety (GAD-7), and alcohol use problems (modified AUDIT). This includes the means and standard deviations for the baseline scores, follow-up scores, and paired differences with the associated *p*-values for the paired *t*-test indicating if there was a statistically significant change in scores within-participants from the baseline to follow-up interviews. We observed a statistically significant decrease in the PCL-M, PHQ-9, and modified AUDIT scores from the baseline to follow-up interviews (average decreases of 3.71, 1.58, and 0.88, respectively). There was no statistically significant difference in GAD-7 scores (average increase of 0.17).

Changes in symptom screening scores from the baseline (pre-intervention) to follow-up (post-intervention) interviews did not significantly differ based upon categories of watch use (used every day vs did not use every day) according to two-sample *t*-tests (PCL-M: p = 0.64; PHQ-9: p = 0.27; GAD-7: p = 0.84; modified AUDIT: p = 0.27). Similarly, changes in scores were not significantly different for any symptom screening scales based upon the categories of use of the Journal or Good Things features (used module at all vs never used module; data not shown). We did not do the same analysis for Meditations use because all but one participant used the module over the study period, precluding any meaningful analysis.

PTSD was most prevalent in this sample of Veterans. At baseline interview, 18 (75%) of the 24 study participants had scores at or above the PCL-M cut-off value of 34, indicating a high prevalence of probable PTSD in the study sample. This decreased to 15 (63%) participants at follow-up interview, representing a decrease of 12 percentage points at the 1-month follow-up. At both the baseline and follow-up interviews, 10 (42%) of the 24 participants had PHQ-9 scores of 10 or above, indicating probable depression. Thus, there was no change in

the percentage of probable depression between baseline and follow-up interviews. It is worth noting that, of the participants who showed a decrease in their PCL-M score, 10 (42%) had a score change greater than 6, with 7 (29%) of them having a change greater than 10. These score changes represent the lower and upper bounds of the estimated MCID for the PCL-M. Likewise, 3 (13%) participants reported a decrease in PHQ-9 score greater than 4.78, the estimated MCID criteria for the PHQ-9.<sup>36</sup> Thus, some symptom changes appear clinically significant between interviews.

#### User acceptance of mindset

All participants used the Mio Alpha Smartwatch: 10 wore it "More than twice a week, but not every day," and 14 wore it "Every day." Reasons cited for not wearing the watch every day fell into four general categories, with some overlaps: (1) frustration with the watch (60%), (2) forgetting to put the watch back on (40%), (3) work restrictions (20%), and (4) vacation (10%). App module usage varied. The meditations feature was most popular, with 20 (83%) of users using it weekly or more frequently. This was followed by the Journal and Good Things features with associated counts of 12 (50%) and 10 (42%), respectively. The GPS and Time Stamp modules were used the least among participants, with only 2 (8%) and 1 (4%) of users, respectively, using these weekly or more. Of Meditations users (n = 23), 18 (78%) found it helpful. Of the Journal (n = 15) and Good Things (n = 14) users, 5 (33%) and 11 (79%) of users found the modules at least moderately helpful. Of the 24 Mindset users, only 9 (38%) found the notifications at least moderately helpful.

Figure 3 depicts participant responses regarding their satisfaction with Mindset's hardware and software features. In general, participants were satisfied with the technical features of Mindset: 21 (88%) agreed with the statement "Mindset Meditations opened properly consistently," and 20 (83%) agreed with the statement "Mindset was easy to use." A few hardware issues were also indicated: 13 (54%) of participants agreed with the statement "Mindset band/watch interfered with daily activities," and 10 (46%) agreed with the statement "Mindset used up my phone battery." Notably 18 (75%) agreed with "I will recommend Mindset to my colleagues," and 15 (63%) agreed with "I see myself using Mindset on a regular basis in the future."

Figure 4 shows participant responses regarding the helpfulness of Mindset as a stress management tool. Here results are more mixed. While 18 (75%) agreed with Mindset helping them feel as though there was something they could do about their stress, only 11 (46%) agreed that Mindset helped them understand the stress they were experiencing. Just 12 (50%) were satisfied with Mindset for managing their stress levels. Although not overwhelmingly high, 11 (46%) agreed with the statement "I would discuss with my health professional the possibility of including Mindset in my therapy plan," indicating that those respondents saw therapeutic potential in Mindset.

#### Participants' comments

Qualitative comments were collected to examine more in-depth feedback from respondents regarding the helpfulness of the app and its specific features. These were solicited through open-ended questions. Two authors (R.K. and C.L.) reviewed all responses to assess the

distribution of positive, negative, and neutral feedback, as shown in Table 3. Note that question (6) was only asked if the participant previously gave a negative response about a specific experience so that the individual would have the opportunity to elaborate.

While there were many positive overarching experiences with the app, responses to questions (6) and (7) in Table 3 skewed negatively, indicating that the participants had some concerns. The majority of these focused on technical inadequacies (e.g. watch didn't function as expected, poor Bluetooth connectivity, the app crashing) or the usefulness of the app in varied scenarios (e.g. non-acute moments of anxiety). However, when we asked about respondents' thoughts on e-therapy modules, responses were more spread, with some positive and some negative. Negative comments often questioned the utility of the module or reported technical issues. Positive comments often showed that a participant really enjoyed a specific module as a tool to manage their anxiety. Not unexpectedly, the Meditations module received the most comments, with 60% being positive, whereas 58% of the comments regarding the Journal module were negative. Overall, respondents commented on the Mindset app and features both positively and negatively.

Additionally, many of our respondents verbally indicated having experienced various barriers to mental health care prior to engagement with Mindset. Participants primarily focused on care access during deployment, where some were hesitant to report mental health concerns due to fears of being perceived as "unfit" or "incompetent," and thus risking their careers, for example:

"During my deployment in Saudi Arabia, the war weighed on my mind, and I constantly thought about various 'what if' scenarios, experiencing intense feelings of vulnerability. However, I did not want to seek treatment out of fear of being considered weak or unfit" (Female, age 50).

"I did seek psychiatric care while I was overseas, but I kept it very quiet because I didn't want my fellow service members to know" (Male, age 35).

These represent significant barriers for many individuals. It is thus encouraging that many participants reported a positive experience with Mindset.

# Discussion

In this pilot study assessing the effectiveness and acceptance of Mindset, a mindfulnessbased mental health app synced with a smartwatch, we found a statistically significant decrease in PTSD symptoms, depression symptoms, and alcohol use problems among participants over a 1-month period of use. There was no significant change in generalized anxiety disorder symptoms. Our sample of Veterans reported high rates of both probable PTSD and probable depression. Although satisfaction with Mindset was not uniform, participants generally gave positive feedback regarding its use, though citing a need for technical improvement. These results offer preliminary support for Mindset in managing psychiatric symptoms associated with PTSD and depression.

Perhaps the most important changes to consider are those with clinical implications for participants. Clinically significant changes were observed for PTSD and depression

symptoms. There was a reduction in the number of those considered to have probable PTSD (from 75% to 63% over 1 month), and a large percentage (42%) of participants experienced a clinically significant PTSD symptom reduction using the MCID criteria. A smaller percentage (13%) experienced a clinically significant decrease in depression symptoms. These results suggest that 1-month of Mindset-use may be associated with significant clinical changes in PTSD and depression symptoms.

We were interested to learn whether level of Mindset usage was associated with changes in psychiatric symptoms. However, we did not find PTSD nor depression symptom reduction to be associated with level of watch use nor module usage. This may be due to the modest sample size, or there may be other explanations. Because Mindset offers a suite of e-therapies, use patterns that lead to the best outcomes likely vary for each individual and thus app/module use cannot be assessed singularly. It is also possible that self-report categorical responses do not provide detailed information to assess this question. A better option could involve using pulse rate-related data that can capture the occurrence and timing of a reduction in pulse rate after using an app module. Anecdotally, we have observed such a pattern in individuals after using app modules (not in this study); however, further algorithm modeling could be useful to capture the association of multiple continuous time measures and symptom patterns.

In considering app usage generally, Meditations was the most frequently used module. Interviewers' notes also support this, finding that Meditations was the most-liked feature among participants. In addition, some users indicated performing these exercises outside of the app, suggesting that use of this method of stress reduction may be higher than reported. After Meditations, the Journal and Good Things features were used with similar frequency while features on the Web Dashboard were used very little. Users seemed to find the Meditations and Good Things features the most helpful. Due to the small sample size, general conclusions cannot be drawn about the Web Dashboard.

Although satisfaction with the technical features of Mindset was high, respondents consistently cited connectivity issues between the watch and their phone, as well as high battery usage. This likely influenced the level of dissatisfaction with Mindset notifications and potentially the app itself: only 38% of participants found notifications at least moderately helpful. Thus, further improvement is desirable, with focus on the hardware design and hardware-software synchronization.

Beyond technical concerns, user satisfaction with Mindset was mixed. The majority of participants indicated that Mindset helped them feel as though there was something they could do about their stress (75%) and helped them manage that stress in effective ways (63%). Further, 75% of participants responded that they would recommend the app to their colleagues. However, only half indicated that Mindset helped them feel more comfortable with their stress. Similarly, half reported being satisfied with Mindset in managing their stress levels. Further, only 46% of participants indicated that they would discuss use of Mindset with their health professional. Thus, while there are some significant indicators of satisfaction with Mindset, these results indicate that there exists room for improvement, which should be explored further.

This pilot study presented encouraging preliminary findings regarding the effectiveness of Mindset in alleviating symptoms of PTSD and depression among Veterans. However, there are some limitations. First, because this was a pilot study, the sample size was modest. Effectiveness of Mindset should be assessed using a larger group of Veterans to confirm our findings. Further, once connectivity concerns are improved, a study design should be implemented that more directly assesses positive and negative aspects of wearable inclusion, comparing two groups: one with the wearable and one without. Future studies should assess Mindset use over a longer period to allow understanding of long-term engagement and benefits. We did not systematically examine other potential confounding factors that could have explained the improved level of PTSD, depression and alcohol misuse screening symptoms. Because of the modest sample size, we refrained from conducting multivariate analysis. Finally, a randomized control study is needed to separate out the efficacy of Mindset as a clinically proven tool from sample selection or cohort effect.

# Conclusion

This study examined the effectiveness and acceptance of the Mindset app system in helping Veterans manage symptoms of PTSD and depression. Our findings corroborate existing literature indicating that mHealth technologies can be beneficial in coping with PTSD and depression. Mindset use was associated with decreased PTSD and depression symptoms among this sample of Veterans, with some participants showing clinically significant reductions. User acceptance of Mindset was moderate; most users indicated that Mindset was helpful with stress management and that they would recommend the app to their colleagues. However, some aspects of satisfaction could be improved. Mindset's incorporation of real-time stress level detection with the app is unique, but significant technical issues still exist. In conclusion, a system of app-based mindfulness therapies with a wearable has potential to become a useful tool for PTSD and related psychiatric symptom management for U.S. Veterans. As we expect a long and slow recovery road from the current COVID-19 pandemic as well as a lasting impact on mental health and well-being, patient-centered mHealth apps such as Mindset may provide useful and inexpensive self-care tools for at-risk individuals.<sup>37</sup>

# Acknowledgements

We would like to thank Kathleen Spearman for her contributions as an interviewer. We are most grateful to the Veterans who participated in this pilot study.

#### Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was in part supported by the Washington University, Institute for Public Health, Center for Dissemination and Implementation Pilot Program [CDI grant number 2016–03] (CL, MM, RP) and the Washington University Institute of Clinical and Translational Sciences [grant number UL1TR000448, sub-award number TL1TR000449], from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) (RC). In addition, this work was completed as part of a summer program supported by the Institute for Public Health and its Global Health Center of Washington University in St. Louis; the Departments of Medicine, Molecular Microbiology, and Pediatrics in Washington University's School of Medicine; the Children's Discovery Institute of Washington University and St. Louis Children's Hospital; Mallinckrodt Pharmaceuticals Charitable Giving Program; Stephanie and Chris Doerr; and Dr. and Mrs. Mark Stephen Gold (LO).

# References

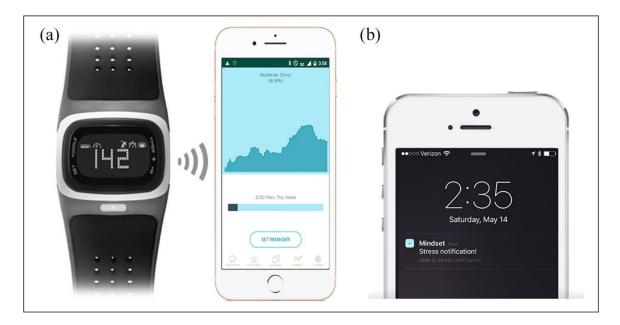
- Kessler RC, Berglund P, Demler O, et al. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the national comorbidity survey replication. Arch Gen Psychiatry 2005; 62: 593–602. [PubMed: 15939837]
- Schell TL and Marshall GN. Survey of individuals previously deployed for OEF/OIF. In: Tanelian T and Jaycox LH (eds) Invisible wounds of war: psychological and cognitive injuries, their consequences, and services to assist recovery. Santa Monica, CA: RAND Corporation, 2008, pp. 87–115.
- 3. Dohrenwend BP, Turner JB, Turse NA, et al. The psychological risks of Vietnam for U.S. veterans: a revisit with new data and methods. Science 2006; 313: 979–982. [PubMed: 16917066]
- Battle DE. Diagnostic and statistical manual of mental disorders (DSM). CoDAS 2013; 25: 191– 192. [PubMed: 24413388]
- Kessler RC, Sonnega A, Bromet E, et al. Posttraumatic stress disorder in the National Comorbidity Survey. Arch Gen Psychiatry 1995; 52: 1048–1060. [PubMed: 7492257]
- Jakupcak M, Cook J, Imel Z, et al. Posttraumatic stress disorder as a risk factor for suicidal ideation in Iraq and Afghanistan War veterans. J Trauma Stress 2009; 22: 303–306. [PubMed: 19626682]
- D'Andrea W, Sharma R, Zelechoski AD, et al. Physical health problems after single trauma exposure: when stress takes root in the body. J Am Psychiatr Nurses Assoc 2011; 17: 378–392. [PubMed: 22142975]
- 8. Ouimette P, Cronkite R, Henson BR, et al. Posttraumatic stress disorder and health status among female and male medical patients. J Trauma Stress 2004; 17: 1–9. [PubMed: 15027787]
- 9. Wolf EJ, Logue MW, Hayes JP, et al. Accelerated DNA methylation age: associations with PTSD and neural integrity. Psychoneuroendocrinology 2016; 63: 155–162. [PubMed: 26447678]
- Morina N, Wicherts JM, Lobbrecht J, et al. Remission from post-traumatic stress disorder in adults: a systematic review and meta-analysis of long term outcome studies. Clin Psychol Rev 2014; 34: 249–55. [PubMed: 24681171]
- 11. Shiner B Health Services Use in the Department of Veterans Affairs among Returning Iraq War and Afghan War Veterans with PTSD. PTSD Res Q 2011; 22: 1–10.
- 12. Burnam MA, Meredith LS, Helmus TC, et al. Systems of care: challenges and opportunities to improve access to high-quality care. In: Tanelian T and Jaycox LH (eds) Invisible wounds of war: psychological and cognitive injuries, their consequences, and services to assist recovery. Santa Monica, CA: RAND Corporation, 2008, pp. 245–428.
- 13. Rodriguez-Paras C and Sasangohar F. Usability assessment of a post-traumatic stress disorder (PTSD) mHealth App. Proc Hum Factors Ergon Soc Annu Meet 2017; 61: 1824–1828.
- Hoge CW, Castro CA, Messer SC, et al. Combat duty in Iraq and Arghanistan, mental health problems, and barriers to care. N Engl J Med 2004; 351: 13–22. [PubMed: 15229303]
- Price M, Yuen EK, Goetter EM, et al. mHealth: a mechanism to deliver more accessible, more effective mental health care. Clin Psychol Psychother 2014; 21: 427–436. [PubMed: 23918764]
- Pew Research Center. Mobile Fact Sheet, http://www.pewinternet.org/fact-sheet/mobile/ (2019, accessed 8 June 2020).
- Erbes CR, Stinson R, Kuhn E, et al. Access, utilization, and interest in mHealth applications among veterans receiving outpatient care for PTSD. Mil Med 2014; 179: 1218–1222. [PubMed: 25373044]
- Wilson JAB, Onorati K, Mishkind M, et al. Soldier attitudes about technology-based approaches to mental health care. Cyberpsychol Behav 2008; 11: 767–769. [PubMed: 18991533]
- Kuhn E, Greene C, Hoffman J, et al. Preliminary evaluation of PTSD coach, a smartphone app for post-traumatic stress symptoms. Mil Med 2014; 179: 12–18. [PubMed: 24402979]
- 20. Reger GM, Skopp NA, Edwards-Stewart A, et al. Comparison of Prolonged Exposure (PE) coach to treatment as usual: a case series with two active duty soldiers. Mil Psychol 2015; 27: 287–296.
- Rodriguez-Paras C, Tippey K, Brown E, et al. Posttraumatic stress disorder and mobile health: app investigation and scoping literature review. JMIR mHealth uHealth 2017; 5: e156. [PubMed: 29074470]

- 22. Torous J and Keshavan M. COVID-19, mobile health and serious mental illness. Schizophr Res. Epub ahead of print 16 4 2020. DOI: 10.1016/j.schres.2020.04.013.
- Galea S, Merchant RM and Lurie N. The mental health consequences of COVID-19 and physical distancing: the need for prevention and early intervention. JAMA Intern Med 2020; 180: 817–818. [PubMed: 32275292]
- 24. Shura RD, Brearly TW and Tupler LA. Telehealth in Response to the COVID-19 pandemic in rural veteran and military beneficiaries. J Rural Heal 2020; 00: 1–5.
- 25. Kabat-Zinn J, Massion AO, Kristeller J, et al. Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. Am J Psychiatry 1992; 149: 936–943. [PubMed: 1609875]
- Grossman P, Niemann L, Schmidt S, et al. Mindfulness-based stress reduction and health benefits. a meta-analysis. J Psychosom Res 2004; 57: 35–43. [PubMed: 15256293]
- Polusny MA, Erbes CR, Thuras P, et al. Mindfulness-based stress reduction for posttraumatic stress disorder among veterans a randomized clinical trial. JAMA 2015; 314: 456–465. [PubMed: 26241597]
- Wilkins KC, Lang AJ and Norman SB. Synthesis of the psychometric properties of the PTSD checklist (PCL) military, civilian, and specific versions. Depress Anxiety 2011; 28: 596–606. [PubMed: 21681864]
- 29. Löwe B, Decker O, Müller S, et al. Validation and standardization of the generalized anxiety disorder screener (GAD-7) in the general population. Med Care 2008; 46: 266–274. [PubMed: 18388841]
- Martin A, Rief W, Klaiberg A, et al. Validity of the Brief Patient Health Questionnaire Mood Scale (PHQ-9) in the general population. Gen Hosp Psychiatry 2006; 28: 71–77. [PubMed: 16377369]
- 31. Reinert DF and Allen JP. The Alcohol Use Disorders Identification Test (AUDIT): a review of recent research. Alcohol Clin Exp Res 2002; 26: 272–279. [PubMed: 11964568]
- Bliese PD, Wright KM, Adler AB, et al. Validating the primary care posttraumatic stress disorder screen and the posttraumatic stress disorder checklist with soldiers returning from combat. J Consult Clin Psychol 2008; 76: 272–281. [PubMed: 18377123]
- Manea L, Gilbody S and McMillan D. Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. Can Med Assoc J 2012; 184: E191–E196. [PubMed: 22184363]
- van Walraven C, Mahon JL, Moher D, et al. Surveying physicians to determine the minimal important difference: implications for sample-size calculation. J Clin Epidemiol 1999; 52: 717– 723. [PubMed: 10465315]
- 35. Stefanovics EA, Rosenheck RA, Jones KM, et al. Minimal clinically important differences (MCID) in assessing outcomes of post-traumatic stress disorder. Psychiatr Q 2018; 89: 141–155. [PubMed: 28634644]
- Löwe B, Unützer J, Callahan CM, et al. Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care 2004; 42: 1194–1201. [PubMed: 15550799]
- 37. Golinelli D, Boetto E, Carullo G, et al. How the COVID-19 pandemic is favoring the adoption of digital technologies in healthcare: a rapid literature review. medRxiv. Epub ahead of print 2020. DOI:10.1101/2020.04.26.20080341.

ull Verizon ♥	4:47 PM		%■)f .all Verizon 🗢 ⑦ <\(b)		4:47 PM		70% ••••••••••••••••••••••••••••••••••••		4:47 PM			4:47 PM	*** () ** ()	70% <b>—</b> ) (?)
A GOOD THING Write something you're groteful for			HOW ARE YOU FEELING?				BREATHE IN			Meditation Challenge Day 1 Debbie Granick				
				MAD		GLAD								
				SAD		STRESSED								
	SUBMIT				OTHER	STRESSED								
	DASHEDARD			сосо тинся	DADHEGARD				DASHEGARD	COURMAL SETTINGS			JOSZEWAL	SETTINGS

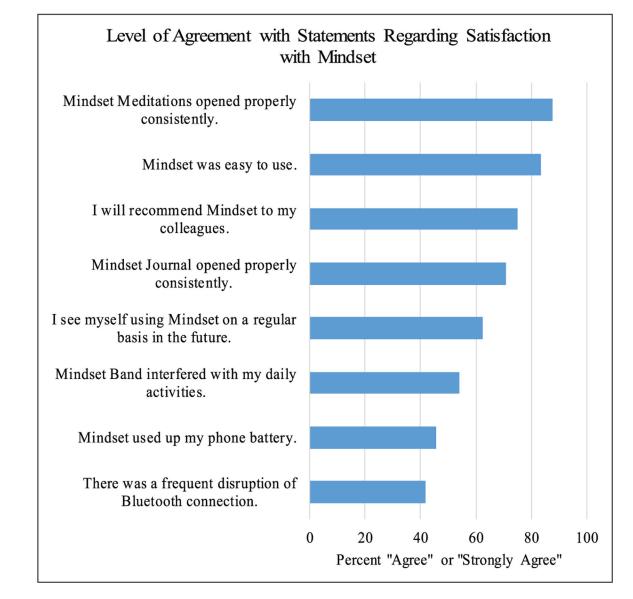
# Figure 1.

Images of the main modules offered on the app: (a) Good Things, (b) CBT Journal, (c) Simple Breathing Exercise (part of Meditations), and (d) Meditations Recording.



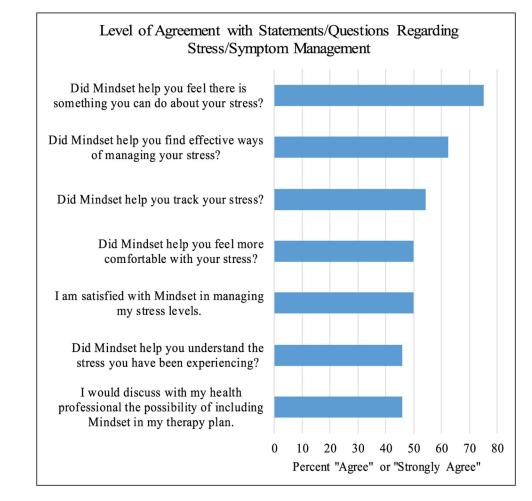
#### Figure 2.

Images of Mindset and associated user-interactions. (a) Wearable sends pulse rate data continuously to Mindset over Bluetooth. (b) User receives notification of elevated stress to prompt an intervention.



#### Figure 3.

Bar chart with participant responses for questions regarding satisfaction with Mindset and modules. Associated with each statement is a bar representing the percentage of participants that responded "Agree" or "Strongly Agree" when asked to rate their level of agreement with each statement. Data were collected from all 24 participants.



#### Figure 4.

Bar chart with participant responses for questions regarding usefulness of Mindset with stress and/or symptom management. Associated with each question or statement is a bar representing the percentage of participants that responded "Agree" or "Strongly Agree" when asked to rate their level of agreement. Data were collected from all 24 participants.

# Table 1.

Demographic characteristics of study participants who completed follow-up interviews (n = 24).

Characteristic	Descriptive measure			
	Sample size (%)			
Gender:				
Male	16 (66.7)			
Female	8 (33.3)			
Race:				
White	19 (79.2)			
Black	3 (12.5)			
Mixed Race/other	2 (8.3)			
Ethnicity:				
Hispanic or of Latino origin	1 (4.2)			
	Mean (± SD)			
Age (years)	36.7 (± 5.7)			

#### Table 2.

Standardized screening scores for PTSD, depression, generalized anxiety, and alcohol use problems. Means ( $\pm$  standard deviations) at the baseline, 1-month follow-up, and changes from baseline to follow-up (baseline – follow-up score). *P*-values from paired *t*-tests are 2-sided.

Scale	Baseline score Mean (± SD)	1-month follow-up score Mean (± SD)	Paired differences Mean (± SD)	<i>p</i> -value for paired <i>t</i> -test
PTSD: PCL-M	45.6 (± 16.8)	41.9 (± 16.3)	3.7 (± 8.5)	0.04
Depression: PHQ-9	9.8 (± 6.1)	8.2 (± 6.1)	1.6 (± 3.4)	0.03
Generalized Anxiety: GAD-7	9.4 (± 5.9)	9.5 (± 5.3)	$-0.2 (\pm 3.3)$	0.81
Alcohol Use Problems: modified AUDIT	3.5 (± 2.9)	2.6 (± 2.4)	0.9 (± 1.8)	0.02

#### Table 3.

Respondents' comments on Mindset watch and e-therapy module use obtained by interviewers at the followup (post-intervention) interviews. Frequencies and percentages based on positive, neutral or negative ratings by authors.

Question	Negative (%)	Neutral (%)	Positive (%)	Total (%)
(1) Additional thoughts about Journal feature	7 (58)	2 (17)	3 (25)	12 (100)
(2) Additional thoughts about Meditations feature	5 (25)	3 (15%)	12 (60)	20 (100)
(3) Additional thoughts on the Good Things feature	3 (23)	2 (15)	8 (62)	13(100)
(4) Additional thoughts on the GPS feature	1 (25)	2 (50)	1 (25)	4 (100)
(5) Additional thoughts on the Time Stamp feature	0	0	0	0
(6) Additional comments on "lack of satisfaction", "not foreseeing regular use," or "wouldn't recommend to healthcare professional"*	6 (86)	1 (14)	0	7 (100)
(7) Your concerns, suggestions and remarks	10 (53)	3 (16)	6 (32)	19 (100)
(8) Any additional feedback?	4 (40)	2 (20)	4 (40)	10 (100)
TOTAL	36 (42)	15 (18)	34 (40)	85 (100)

\* This question was only asked when the participant previously indicated "lack of satisfaction" with Mindset, "not foreseeing regular use" of Mindset, or "wouldn't recommend [Mindset] to a healthcare professional." Thus, this question intentionally solicited only non-positive feedback.