

The Real-World Impact of App-Based Mindfulness on Headspace Members with Moderate and Severe Perceived Stress: An Observational Study

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Abstract

Background: Perceived stress in the United States has drastically increased since the COVID-19 pandemic and is associated with negative mental health outcomes such as depression and anxiety. Digital mental health (DMH) interventions are efficacious tools to address negative mental health outcomes and have helped reduce psychological symptom severity such as anxiety, depression, and perceived stress compared to waitlist controls. Although DMH tools have been studied in controlled settings, less is known about the real-world evidence of such interventions.

Objective: 1) Characterize patterns in baseline perceived stress and changes in perceived stress among Headspace members with moderate and severe baseline perceived stress; and 2) examine associations between engagement with Headspace content and changes in perceived stress (evaluate if there is a dose-response relationship).

Methods: We evaluated two timepoints of real-world perceived stress and engagement data from Headspace app members with baseline moderate and severe perceived stress. Perceived stress was measured using the Perceived Stress Scale (PSS-10) and engagement using active days and active minutes engaged with Headspace as well as number of user sessions. Descriptive statistics were computed for all variables. Correlations examined relationships between PSS-10 baseline and follow-up scores, PSS-10 percent change, days between PSS-10, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week. T-tests investigated the differences in baseline PSS-10, follow-up PSS-10, PSS-10 percent change, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week between: 1) those who did and did not improve PSS-10 scores (yes vs. no improvement); and 2) those who improved ≥30% vs. those with <30% improvement.

Results: Overall 21,088 Headspace members were included in these analyses. On average, members saw a 23.52% decrease in PSS-10 scores from baseline to follow-up. On average members had 2.42±1.76 active days/week, 25.89±33.40 active minutes/day, and completed 7.11±8.34 sessions/week. T-tests suggest that members who improved PSS-10 scores from baseline to follow-up had significantly higher baseline PSS-10 scores ($d=0.56$), more active days/week ($d=0.33$), and more sessions/week ($d=0.27$) than those who did not improve PSS-10 scores (all $P<0.001$). Additional t-tests suggest that members with ≥30% PSS-10 improvement had significantly higher baseline PSS-10 scores ($d=0.35$), more active days/week ($d=0.36$), and more sessions/week ($d=0.31$) than those with <30% PSS-10 improvement (all $P<0.001$).

Conclusions: Findings suggest that real-world use of Headspace is associated with decreased perceived stress. Furthermore, data suggest that more engagement, specifically weekly active days and sessions, is associated with greater likelihood of stress reduction.

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Original Manuscript

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Abstract

Background: Perceived stress in the United States has drastically increased since the COVID-19 pandemic and is associated with negative mental health outcomes such as depression and anxiety. Digital mental health (DMH) interventions are efficacious tools to address negative mental health outcomes and have helped reduce psychological symptom severity such as anxiety, depression, and perceived stress compared to waitlist controls. Although DMH tools have been studied in controlled settings, less is known about the real-world evidence of such interventions.

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Methods: We evaluated two timepoints of real-world perceived stress and engagement data from Headspace app members with baseline moderate and severe perceived stress. Perceived stress was measured using the Perceived Stress Scale (PSS-10) and engagement using active days and active minutes engaged with Headspace as well as number of user sessions. Descriptive statistics were computed for all variables. Correlations examined relationships between PSS-10 baseline and follow-up scores, PSS-10 percent change, days between PSS-10, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week. T-tests investigated the differences in baseline PSS-10, follow-up PSS-10, PSS-10 percent change, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week between: 1) those who did and did not improve PSS-10 scores (yes vs. no improvement); and 2) those who improved $\geq 30\%$ vs. those with $< 30\%$ improvement.

Results: Overall 21,088 Headspace members were included in these analyses. On average, members

saw a 23.52% decrease in PSS-10 scores from baseline to follow-up. On average members had 2.42 ± 1.76 active days/week, 25.89 ± 33.40 active minutes/day, and completed 7.11 ± 8.34 sessions/week. T-tests suggest that members who improved PSS-10 scores from baseline to follow-up had significantly higher baseline PSS-10 scores ($d=0.56$), more active days/week ($d=0.33$), and more sessions/week ($d=0.27$) than those who did not improve PSS-10 scores (all $P < 0.001$). Additional t-tests suggest that members with $\geq 30\%$ PSS-10 improvement had significantly higher baseline PSS-10 scores ($d=0.35$), more active days/week ($d=0.36$), and more sessions/week ($d=0.31$) than those with $> 30\%$ PSS-10 improvement (all $P < 0.001$).

Conclusions: Findings suggest that real-world use of Headspace is associated with decreased perceived stress. Furthermore, data suggest that more engagement, specifically weekly active days and sessions, is associated with greater likelihood of stress reduction.

Keywords: digital mental health, meditation, PSS-10

Introduction

Stress in the United States has increased, with significant impacts from the COVID-19 pandemic. While the pandemic itself caused a drastic increase in stress from 2019 to 2020 [1], stress levels still remain high and continue to impact the majority of Americans [2]. Higher perceived stress is associated with poorer mental health outcomes such as depression and anxiety [3]. Further meta-analytic research indicates small to medium effects between the relationship of perceived stress and mental health outcomes suggesting that how people appraise stressful situations in their life might be a predictor of mental health outcomes [4,5]. Higher perceived stress also has economic costs with researchers estimating that perceived stress, primarily work-related perceived stress, accounts for 221 million to 187 billion dollars in both direct (e.g., medical) and indirect costs (e.g., absenteeism, burnout, decreased productivity) [6]. This is important in the larger context of mental health costs and outcomes and how people manage stressors daily in their lives. Digital mental health (DMH) interventions may provide an accessible, scalable way to mitigate perceived stress.

DMH interventions are scalable and accessible; incorporate evidence-based practices (i.e., mindfulness meditation, cognitive behavioral therapy techniques); are efficacious for a range of mental health concerns including anxiety, depression, and post-traumatic stress disorder (PTSD) [3]; and have shown to be effective in a wide range of populations with all levels of mental health concerns (i.e., mild, moderate, severe) including college students, employees, graduate trainees, and rural communities [7-9]. Studies suggest that digital mindfulness-based interventions significantly reduce perceived stress [10-12]. Specifically, another app-based mindfulness tool completed a randomized control trial in those with moderate and severe baseline perceived stress with results suggesting a 30.12% decrease in perceived stress from baseline to 8 weeks (intervention completion) with reductions maintained at a 12 week follow-up (31.24% decrease) [12]. In addition to randomized control trials, current meta-analytic and systematic review data suggest medium effect sizes for DMH interventions for perceived stress from baseline to post-intervention [4,13]. Beyond

clinical outcomes, DMH interventions improve access to mental health care and provide individuals with effective, cost-effective care readily available via a mobile application or website.

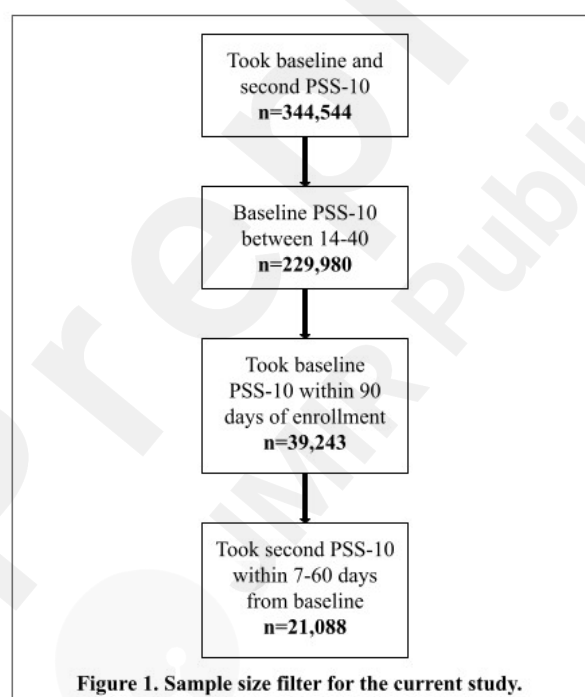
While DMH interventions in clinical trials have been shown to be effective, less is known about the use of DMH interventions in real-world settings. Real-world evidence builds upon clinical trials to improve our understanding of an intervention's efficacy in a person's daily functioning, providing data on the effectiveness and accessibility of DMH products as well as the external validity of interventions. As DMH interventions are delivered via mobile device or computer to use within one's own environments, real-world evidence highlights intervention effectiveness outside of controlled settings. As such, there is an increasing need to understand the real-world effectiveness of widely used commercial apps and DMH interventions that help improve mental health outcomes for the overall population.

Headspace is a popular and evidence-based DMH platform with over 100 million downloads and 50+ published peer-reviewed studies. The Headspace app offers a range of services, most notably to this study, mindfulness and meditation-based content that teaches coping strategies to manage daily stressors. Previous research in clinical trials on the efficacy of the Headspace app shows evidence for improved mindfulness, focus, stress, sleep quality, burnout, resilience, anxiety, depression, and quality of life. Given the reach and scale of Headspace's membership, there is an opportunity to better understand real-world outcomes beyond clinical trials. As such, the current study aims to use real-world data to evaluate perceived stress among Headspace members. To accomplish this goal, this study's aims are: 1) characterize patterns in baseline perceived stress and changes in perceived stress among Headspace members with moderate and severe baseline perceived stress; and 2) examine associations between engagement with Headspace content and changes in perceived stress (evaluate if there is a dose-response relationship).

Methods

Study Design and Members

This real-world observational study examined perceived stress among Headspace members. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) framework for reporting observational studies [14]. Members were included in this study if they enrolled in Headspace between March 2020 and January 2023, completed a baseline and follow-up perceived stress questionnaire, completed the baseline perceived stress questionnaire within 90 days of enrollment, completed the follow-up perceived stress questionnaire >7 and <60 days from the baseline, and reported moderate or severe perceived stress levels at baseline (Figure 1).



The Headspace App

Members in this study had access to all Headspace app offerings and used the app at their own discretion. The Headspace app includes evidence-based, expert-led content including guided mindfulness, meditations with animated guided videos, progressive muscle relaxation, psychoeducation, and gratitude exercises. Mindfulness content ranges from general self-care to

content specific for mental health disorders such as anxiety, stress, and sleep. When members open the Headspace app, they are first directed to the “Today” tab which contains personalized, daily content recommendations to encourage health habit formation throughout the day. Content on the “Today” tab includes a breathing exercise, educational video, and three meditations (one for morning, afternoon, and evening). All other content can be found in the “Explore” tab which includes a search bar; content organized into large categories of meditate, sleep, move, and music at the top; and then, as they scroll, more specific categories and courses such as Beginning Meditation, Mindfulness at Work, Mindful Eating, etc. Finally, all members have a personalized “Profile” tab which tracks activity history and overall app stats (minutes meditated, sessions completed, and days in a row of content engagement). Members in this study had access to all Headspace app offerings and navigated the app to choose their own content (Figure 2).

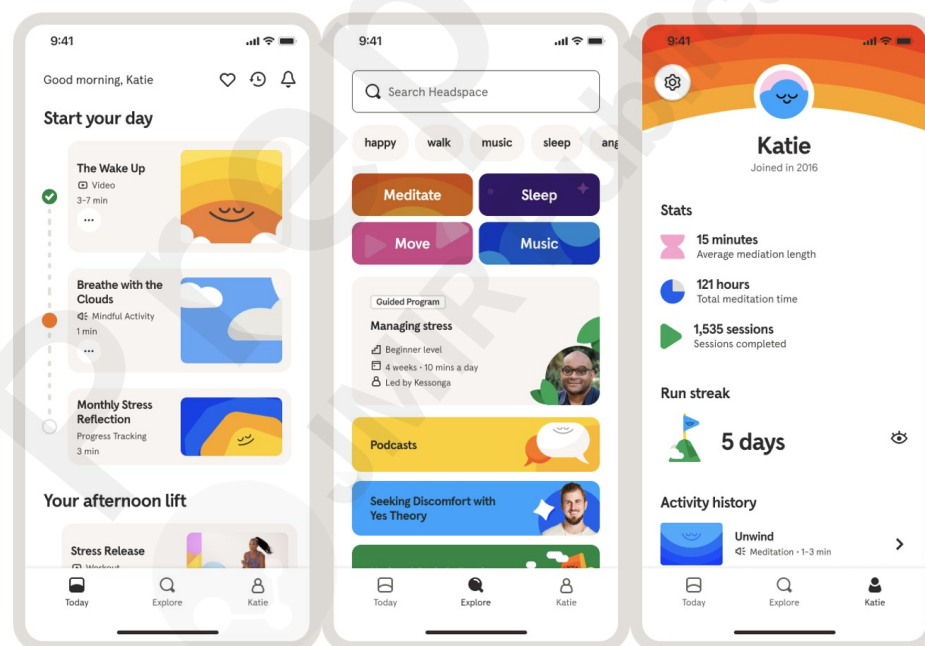


Figure 2. Headspace app “Today,” “Explore,” and “Profile” tabs shown from left to right.

Ethical Considerations

This study represents a secondary analysis of preexisting, de-identified data in which the identity of the human subjects cannot readily be ascertained [15]. The study team does not have access to the members or their identifying information and will not recontact members. Therefore, in

accordance with the US Department of Health and Human Services regulations (45 CFR 46.104), this study is deemed exempt from institutional review board oversight and informed consent. Members are notified through the Headspace terms of service that their de-identified data may be used for research.

Measures

Perceived stress was measured using the Perceived Stress Scale (PSS-10) [16]. Members were prompted to complete the PSS-10 through the Headspace app and answered 10 questions about their perceived feelings and thoughts regarding stress using a 5-point Likert scale (0=never to 4=very often). Scores range from 0–40 with higher scores indicating more perceived stress. The scale has high test-retest reliability ($\alpha=0.85$). Scores on the PSS-10 were categorized to represent low (<14), moderate (14-26), and high (27-40) levels of perceived stress [16]. Those with low levels of perceived stress at baseline were excluded from this study. Members in this study completed a baseline and follow-up PSS-10 questionnaire. Total scores for each timepoint were reported as well as the raw change in PSS-10 score and percent change in PSS-10 score. The PSS-10 was completed by all members within the Headspace app and final scores were pulled directly from the app. Scores are only calculated and pulled for those who complete all questions on the PSS-10 (i.e., no incomplete data were included in this study).

Engagement was assessed using active days and minutes engaged with Headspace as well as the number of sessions started. Additionally, ratios for active days/week, active minutes/day, and sessions/week were calculated to further define engagement. Engagement data are tracked for all members within the Headspace app and were pulled directly from the app.

Statistical Analysis

Means, standard deviations (SD), median, and 95% confidence intervals (95%CI) were computed for PSS-10 baseline and follow-up scores, raw PSS-10 change, PSS-10 percent change, days between PSS-10 assessments, active days, active days/week, active minutes, active minutes/day,

sessions, and sessions/week. Frequencies and percentages were computed for baseline and follow-up PSS-10 scores (moderate vs. high).

Mean PSS-10 percent change scores were segmented out by active days/week, active minutes/day, and sessions/week to outline the relationship between engagement and PSS-10 percent change. Correlations examined relationships between PSS-10 baseline and follow-up scores, PSS-10 percent change, days between PSS-10, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week.

T-tests evaluated the differences in baseline PSS-10, follow-up PSS-10, PSS-10 percent change, active days, active days/week, active minutes, active minutes/day, sessions, and sessions/week between: 1) those who did and did not improve PSS-10 scores (yes vs. no improvement); and 2) those who improved $\geq 30\%$ vs. those with $< 30\%$ improvement. A 30% improvement threshold was chosen to coincide with a clinically meaningful change in perceived stress [17]. P-values < 0.05 were identified as significant and effect size was reported using Cohen's D to determine magnitude of significance.

Results

Sample and Perceived Stress Descriptives

Overall 344,544 Headspace members completed two PSS-10 surveys between March 2020 and January 2023. Of those members, 21,088 met this study's inclusion criteria and were included as members in this study (Figure 1).

At baseline 15,127 (71.73%) reported moderate levels of perceived stress and 5,961 (28.27%) reported severe levels of perceived stress with a mean baseline PSS-10 score of 23.14 ± 5.69 . On average, members completed their follow-up PSS-10 33.25 ± 11.17 days after their first with the mean follow-up PSS-10 score being 20.41 ± 6.47 . At follow-up, 2,878 (13.56%) reported mild moderate levels of perceived stress, 14,376 (68.17%) moderate levels of perceived stress, and 3,834 (18.18%) high levels of perceived stress. On average, members saw a 23.52% decrease in PSS-10 scores from baseline follow-up and 13,692 members (64.93%) decreased their PSS-10 score (Table 1).

Table 1. Engagement and primary outcome descriptive statistics.

	Mean	SD	Median	95%CI
PSS-10				
Baseline	23.14	5.69	23	23.06, 23.21
Follow-Up	20.41	6.47	20	20.33, 20.50
Raw Change in PSS	-2.72	6.06	-3	-2.80, -2.64
% Change in PSS	-23.52	62.6	-13.04	-24.37, -22.68
Days Between PSS	33.25	11.17	31	33.10, 33.40
Engagement Metrics				
Active Days	18.04	11.42	17	17.89, 18.20
Active Days/Week	2.42	1.76	2.01	2.39, 2.44
Active Minutes	547.4	1004.81	281.95	533.83, 560.96
Active Minutes/Day	25.89	33.4	16.68	25.44, 26.34
Sessions	49.73	48.14	35	49.08, 50.38
Sessions/Week	7.11	8.34	4.33	7.00, 7.23

Engagement

On average, members engaged in Headspace content for 18.08 ± 11.42 days and

547.40±1004.81 minutes and started 49.73±48.14 sessions. On average, members had 2.42±1.76 active days/week, 25.89±33.40 active minutes/day, and completed 7.11±8.34 sessions/week (Table 1). Percent change in PSS-10 scores by active days/week, active minutes/day, and sessions/week are found in Table 2 with data suggesting peak PSS-10 change scores at 7 active days/week, 11-15 active minutes/day, and 19-20 sessions/week.

Table 2. Mean PSS-10 percent change distributed out by active days/week, active minutes/day, and sessions/week.

Active Days/Week	Mean PSS-10 Percent Change
1	-21.11
2	-21.55
3	-23.48
4	-28.94
5	-23.69
6	-32.61
7	-43.24
Active Minutes/Day	Mean PSS-10 Percent Change
0-5 minutes	-19.86
6-10 minutes	-21.33
11-15 minutes	-24.41
16-20 minutes	-24.26
21-25 minutes	-23.84
26-30 minutes	-25.65
>30 minutes	-21.33
Sessions/Week	Mean PSS-10 Percent Change
1-2 sessions	-17.18
2-4 sessions	-21.75
5-6 sessions	-25.88
7-8 sessions	-23.25

9-10 sessions	-27.56
11-12 sessions	-27.89
13-14 sessions	-29.64
15-16 sessions	-32.21
17-18 sessions	-35.94
19-20 sessions	-41.71
>20 sessions	-25.39

Engagement and Perceived Stress

Correlations between engagement and perceived stress are reported in Table 3. T-tests investigating the association between engagement and perceived stress are reported in Table 4. T-test p-value and effect size results suggest that members who demonstrated an improvement in perceived stress had significantly higher baseline PSS-10 scores [$t(16575)=-40.08$, $P<0.001$, $d=0.56$] and significantly more active days [$t(14774)=-9.00$, $P<0.001$, $d=0.13$], active days/week [$t(17152)=-24.18$, $P<0.001$, $d=0.33$], sessions [$t(16515)=-11.18$, $P<0.001$, $d=0.16$], and sessions/week [$t(19025)=-20.53$, $P<0.001$, $d=0.27$] than those who did not improve

T-tests comparing those with $\geq 30\%$ vs. $<30\%$ PSS-10 improvement suggest that those with $\geq 30\%$ improvement in perceived stress had significantly higher baseline PSS-10 scores [$t(12794)=-23.52$, $P<0.001$, $d=0.35$], more active days/week [$t(11401)=-23.10$, $P<0.001$, $d=0.36$], and more sessions/week [$t(10150)=-18.87$, $P<0.001$, $d=0.31$] than those with $<30\%$ improvement. Although effect sizes suggest smaller relationships, t-test p-value results also suggest that members with $\geq 30\%$ PSS-10 improvement had significantly more active days [$t(12984)=-12.02$, $P<0.001$, $d=0.17$], more active minutes [$t(13569)=-2.61$, $P<0.001$, $d=0.04$], and more sessions [$t(11539)=-12.68$, $P<0.001$, $d=0.19$] than those with $<30\%$ PSS-10 improvement.

Table 3. Pearson correlations (R, p-value) between PSS-10 and engagement outcomes.

	Baseline PSS-10	Follow -Up PSS- 10	PSS- 10 Percent Change	Days Between PSS- 10	Active Days	Active Days/Week	Active Minute s	Active Minutes/Da y	Session s	Sessions/ Week
Baseline PSS-10	N/A	0.51 <0.001 *	-0.14 <0.001 *	-0.03 <0.001 *	-0.12 <0.001 *	0.05 <0.001*	0.01 0.66	0.04 <0.001*	-0.03 <0.001 *	0.08 <0.001*
Follow-Up PSS-10	0.51 <0.001 *	N/A	0.51 <0.001 *	0.03 <0.001 *	-0.17 <0.001 *	-0.13 <0.001*	-0.01 0.05	0.03 <0.001*	-0.11 <0.001 *	-0.09 <0.001*
PSS-10 Percent Change	-0.14 <0.001 *	0.51 <0.001 *	N/A	0.03 <0.001 *	-0.05 <0.001 *	-0.12 <0.001*	-0.01 0.18	-0.01 0.97	-0.07 <0.001 *	-0.10 <0.001*
Days Between PSS-10	-0.03 <0.001 *	0.03 <0.001 *	0.03 <0.001 *	N/A	0.33 <0.001 *	-0.11 <0.001*	0.12 <0.001 *	-0.01 0.12	0.16 <0.001 *	-0.13 <0.001*
Active Days	-0.12 <0.001 *	-0.17 <0.001 *	-0.05 <0.001 *	0.33 <0.001 *	N/A	0.63 <0.001*	0.46 <0.001 *	0.21 <0.001*	0.73 <0.001 *	0.43 <0.001*

Active Days/ Week	0.05 <0.001 *	-0.13 <0.001 *	-0.12 <0.001 *	-0.11 <0.001 *	0.63 <0.001 *	N/A	0.31 <0.001 *	0.19 <0.001*	0.58 <0.001 *	0.78 <0.001*
Active Minutes	0.01 0.66	-0.01 0.05	-0.01 0.18	0.12 <0.001 *	0.46 <0.001 *	0.31 <0.001*	N/A	0.87 <0.001*	0.52 <0.001 *	0.36 <0.001*
Active Minutes/Day	0.04 <0.001 *	0.03 <0.001 *	-0.01 0.97	-0.01 0.12	0.21 <0.001 *	0.19 <0.001*	0.87 <0.001 *	N/A	0.35 <0.001 *	0.30 <0.001*
Sessions	-0.03 <0.001 *	-0.11 <0.001 *	-0.07 <0.001 *	0.16 <0.001 *	0.73 <0.001 *	0.58 <0.001*	0.52 <0.001 *	0.35 <0.001*	N/A	0.78 <0.001*
Sessions/ Week	0.08 <0.001 *	-0.09 <0.001 *	-0.10 <0.001 *	-0.13 <0.001 *	0.43 <0.001 *	0.78 <0.001*	0.36 <0.001 *	0.30 <0.001*	0.78 <0.001 *	N/A

*p<0.05

Table 4. T-tests investigating the differences in PSS-10 scores and engagement metrics between those who did and did not improve PSS-10 scores. Each row represents a different t-test.

	Yes PSS-10 Improvement	No PSS-10 Improvement
--	---------------------------	--------------------------

		Mean±SD	Mean±SD	95%CI	T-Value	p-Value	Cohen's D
Baseline	PSS-10	24.22±5.69	21.14±5.12	-3.23, -2.93	-40.08	<0.001*	0.56
Follow-Up	PSS-10	18.16±5.73	24.60±5.62	6.28, 6.60	78.87	<0.001*	1.13
PSS-10	Percent Change	-43.42±69.50	13.32±11.84	55.55, 57.94	93.07	<0.001*	1.01
Total	Active Days	18.57±11.28	17.07±11.62	-1.82, -1.17	-9.00	<0.001*	0.13
Active	Days/Week	2.62±1.82	2.04±1.57	-0.63, -0.53	-24.18	<0.001*	0.33
Total	Active Minutes	557.59±969.71	528.52±1066.57	-58.31, 0.17	-1.95	0.05	0.03
Active	Minutes/Day	26.10±32.33	25.50±35.29	-1.56, 0.38	-1.20	0.23	0.02
Total	Sessions	52.36±49.64	44.85±44.85	-8.83, -6.20	-11.18	<0.001*	0.16
Sessions/Week		7.90±9.00	5.65±6.72	-2.47, -2.04	-20.53	<0.001*	0.27
		≥30% PSS-10 Improvement	<30% PSS-10 Improvement				
		Mean±SD	Mean±SD	95%CI	T-Value	p-Value	Cohen's D

Baseline PSS-10		24.49±5.59	22.52±5.63	-2.12, -1.80	-23.52	<0.001*	0.35
Follow-Up PSS-10		15.13±4.52	22.81±4.52	7.54, 7.83	104.68	<0.001*	1.42
PSS-10 Percent Change		-74.19±90.34	-0.53±17.34	71.45, 75.85	65.60	<0.001*	1.40
Total Days	Active	19.43±11.21	17.41±11.46	-2.35, -1.69	-12.02	<0.001*	0.17
Active Days/Week		2.85±1.88	2.22±1.66	-0.68, -0.57	-23.10	<0.001*	0.36
Total Minutes	Active	573.54±956.35	535.53±1025.86	-66.52	-2.61	0.01*	0.04
Active Minutes/Day		26.25±31.60	25.73±34.18	-1.46, 0.43	-1.07	0.28	0.01
Total Sessions		56.21±51.62	46.79±46.18	-10.87, -7.96	-12.68	<0.001*	0.19
Sessions/Week		8.88±9.82	6.31±7.44	-2.83, -2.30	-18.87	<0.001*	0.31

Discussion

The current study focused on using real-world data from Headspace members to evaluate changes in perceived stress and association with engagement. Findings suggest that members experienced a significant reduction in perceived stress scores and those who used Headspace more frequently experienced greater reductions in perceived stress. This study builds on prior clinical trials and provides real-world evidence supporting the use of Headspace to improve perceived stress.

On average, members experienced a 23.52% reduction in perceived stress scores from baseline to the follow-up assessment (i.e., about a 30 day period). Furthermore, 64.93% of members decreased their perceived stress scores from baseline to follow-up, suggesting that Headspace improved perceived stress for a majority of individuals. Shifts in perceived stress levels also provide evidence supporting the use of Headspace as 10% of members who reported high levels of perceived stress at baseline no longer met that criteria at follow-up (i.e., reported moderate or mild levels of perceived stress at follow-up). These shifts in individual perceived stress are important to self-management behaviors (e.g., mindfulness/self-regulation) that are associated with improved patient well-being and mental health outcomes [18]. Thus, it is likely that shifts in perceived stress might be an important predictor of patient mental health outcomes. These findings are consistent with previous clinical research examining the impact of DMH interventions to improve perceived stress [19-21] and provide additional real-world evidence to support those claims.

We also identified relationships between engagement and perceived stress changes. Specifically, correlations suggest that active days/week and active sessions/week were associated with higher PSS-10 percent change. App-based mindfulness interventions of longer duration,

such as those from 4-12 weeks, not only have shown improvements in mindfulness and perceived stress, but also improvements in depression, anxiety, and overall well-being [11, 22,23]. Few app-based mindfulness interventions are less than 4 weeks in duration, supporting the use of longer interventions. While the current study identified that higher active days (total and per week) is associated with larger improvements in perceived stress, data did not identify a relationship between active minutes (total and per week) and perceived stress percent change. These data support a previous study comparing 10 versus 30 minutes of daily mindfulness which suggests no difference in mindfulness or psychological distress between dosage groups [24]. The current study findings, in addition to the previous literature investigating mindfulness dosage, may suggest that active days are more important than total time spent practicing mindfulness or engaging with the app. Future research is necessary to further understand these relationships to more accurately suggest mindfulness dosage for clinical practice and research.

Identifying perceived stress change by active days/week, active minutes/day, and sessions/week provide more nuanced data informing mindfulness intervention duration and dosage. The largest percent change in perceived stress occurred with 7 active days/week; however, data show a sizable increase at 4 active days/week with a leveling off in those active for more days. We also note peak PSS-10 percent changes at 11-15 active minutes/day and 19-20 sessions/week. These data support that consistent Headspace use results in more prominent perceived stress improvements. Previous research notes that approximately 25% of patients improved psychologically after one psychotherapy session, with steadier improvements occurring over eight weeks [25]. Current study findings indicate a similar pattern that emphasizes a shift in perceived stress from baseline to the second administration of the PSS-10 during the first 3-weeks of engaging with the Headspace platform.

Higher engagement, specifically more active days and sessions, was significantly associated with a higher likelihood of improving stress (both overall and $\geq 30\%$), suggesting that frequent engagement with the Headspace app might be related to improved outcomes. This is an important finding given the breadth of research on increased patient engagement with psychotherapy and improved mental health outcomes [26]. Particularly to note are the effect sizes for active days/week and sessions/week - 0.33 and 0.27 in the perceived stress yes vs. no improvement groups and 0.36 and 0.31 in the $\geq 30\%$ vs. $< 30\%$ improvement groups. These results build upon the correlations suggesting higher engagement days and number of sessions were associated with higher PSS-10 percent change and provide further support for intervention dosage discussion suggesting multiple bouts of mindfulness each day [24]. Previous research highlights positive mental health outcomes for people who establish consistent health behaviors. In light of higher costs and access to mental health care, these preliminary findings suggest that consistently engaging in Headspace may decrease perceived stress - providing data to support the use of DMH in real-world settings to accessibly improve outcomes.

Strengths, Limitations, and Future Research

The current study included several limitations and strengths. As this study was the first real-world study investigating the Headspace app, data largely focused on descriptive and group-mean differences. While this information is important to establish overall benchmarks for the current study, we are limited in the types of questions (e.g., prospective) we can ask with the current study format and recognize that the current statistical approach does not allow for causal inferences. Additionally, current data did not include Headspace member demographic information and, therefore, we were unable to investigate the impact of demographics on the study outcomes. Future research should examine longitudinal data and changes in perceived

stress, while accounting for Headspace member characteristics and engagement factors. As a real-world evidence study, we were unable to identify specific programming used by members - focusing only on overall engagement outcomes. Future studies should include more in depth engagement outcomes to better understand how certain programming is used and impacts perceived stress. Finally, data for this study were collected during the COVID-19 pandemic (March 2020 and January 2023). As noted, stress greatly increased in the United States during this time which may have impacted PSS-10 scores (i.e., increased scores). However, members were only included if they completed their two PSS-10s between 7-60 days and the average days between PSS-10 assessment was about one month, suggesting that if members completed their baseline PSS-10 at the beginning of the pandemic when national stress was higher they would have completed their follow-up at a similar time period within the pandemic.

A primary strength of the study is the methodology incorporated to understand changes in perceived stress and engagement on the platform. The use of a real-world evidence methodology often helps researchers and clinicians to observe the feasibility and generalizability of interventions in daily functioning. Given the current sample size, which included over 20,000 members, it is evident that the Headspace platform provides benefits to people who frequently engage with the platform. Furthermore, the large sample size included in the current study also offers strong evidence for generalizability of our findings in the real world. The large sample size coupled with the current methodology also allowed us to establish reliable findings for our current platform; therefore, establishing a foundational understanding of how much change is possible on the platform, while understanding overall engagement trends.

Conclusion

Findings suggest that members using Headspace experienced significant reductions in

perceived stress in a real-world setting. Furthermore, data suggest that members who engaged with the platform more regularly were more likely to experience improvements in perceived stress. The current study is the first to provide real-world evidence of the DMH Headspace platform aimed to reduce participant's perceived stress. Results from the current study have implications for clinical practice that include incorporating mediation and mental health psychoeducation as an adjunct to psychotherapy or as a preventive intervention to reduce stress.

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CC contributed to study design, data analysis, manuscript writing, and manuscript review; JK contributed to study design, manuscript writing, and manuscript review; EH contributed to study design, data analysis, manuscript writing and manuscript review; LT contributed to data analysis and manuscript review; and SK contributed to study design, data analysis, manuscript writing, and manuscript review.

Conflicts of Interest

Authors CC, LT, and SK are currently employed by Headspace. Authors JK and EH were employed by Headspace at the time of data collection.

Abbreviations

95%CI: 95% Confidence Interval

DMH: Digital Mental Health

PSS-10: Perceived Stress Scale

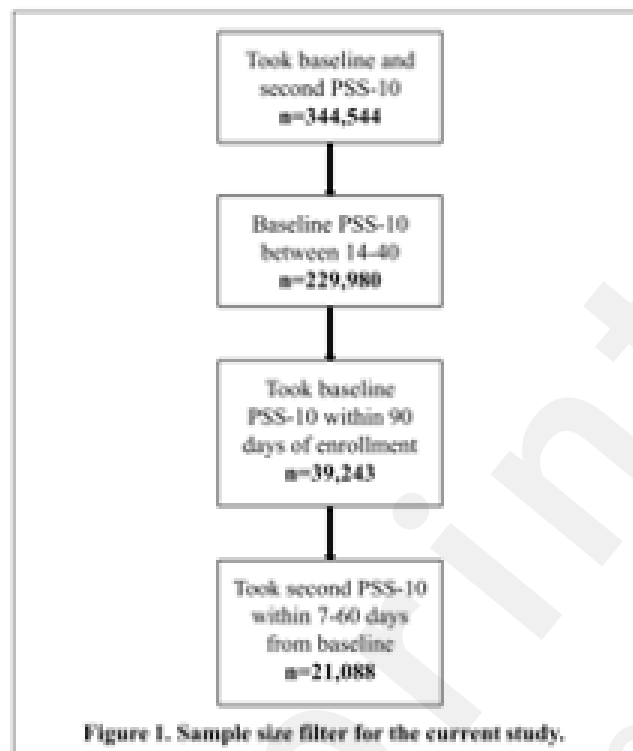
PTSD: Post-traumatic Stress Disorder

SD: Standard Deviation

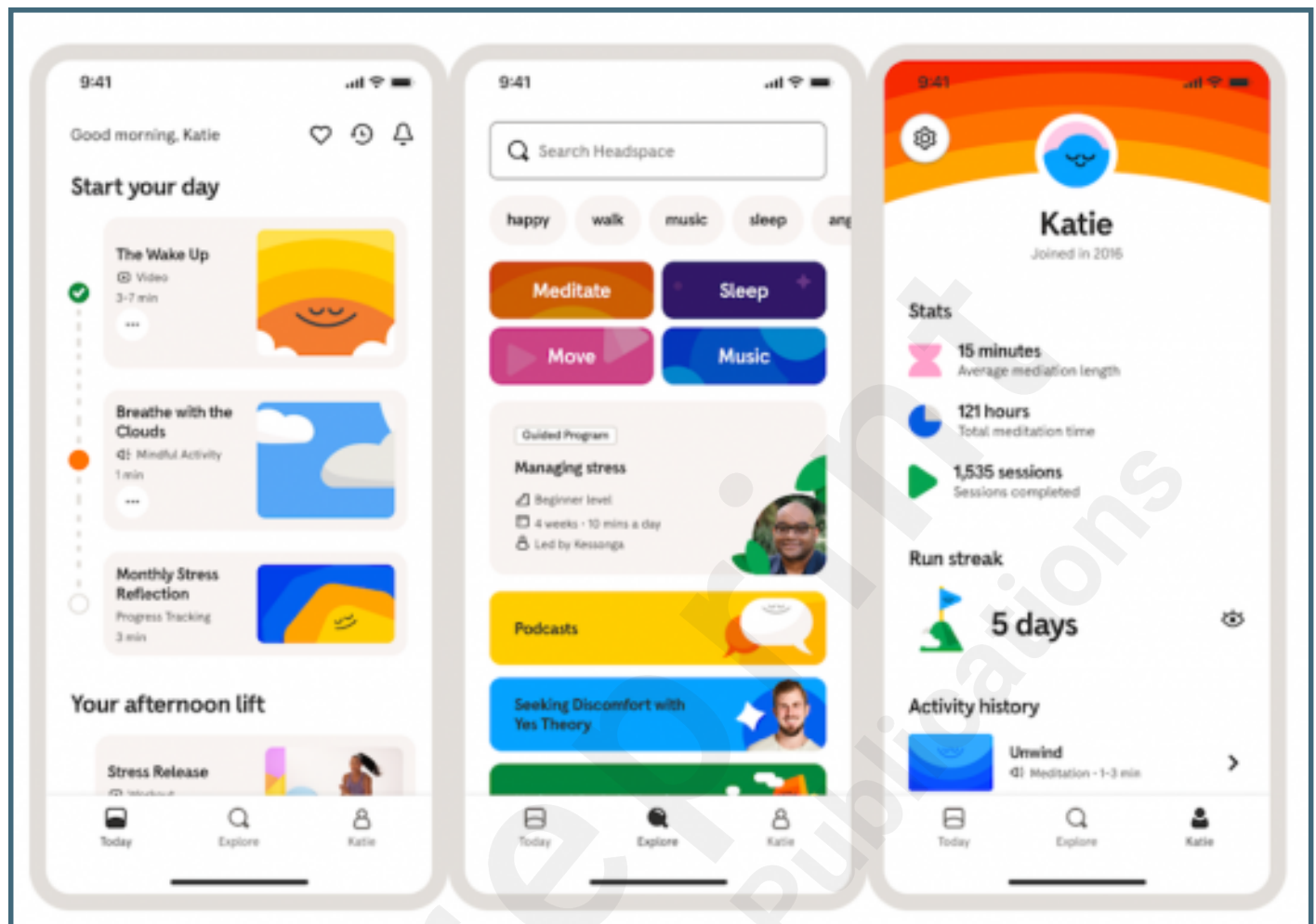
Supplementary Files

Figures

Sample size filter for the current study.



Headspace app "Today," "Explore," and "Profile" tabs shown from left to right.



CONSORT (or other) checklists

STROBE checklist of items that should be included in reports of cross-sectional studies.

URL: <http://asset.jmir.pub/assets/a0a22e68164c12f731610f5914208535.pdf>

