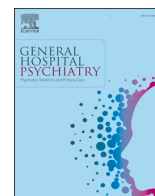




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Redesign of a brief PTSD treatment in safety net integrated primary care: Supporting implementation in the context of the COVID-19 pandemic

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ABSTRACT

Objective: We conducted a formative evaluation to understand the impact of the COVID-19 pandemic on the safety net integrated primary care setting and to identify (and respond to) new implementation barriers prior to a hybrid type I effectiveness-implementation trial of a posttraumatic stress disorder (PTSD) treatment.

Method: We used surveys and qualitative interviews with employee stakeholders ($N = 27$) to (1) understand pandemic-related factors that may influence implementation, including changes in patient needs, provider experiences, and the practice, and (2) assess the need for augmentation to study design, implementation plan, or intervention.

Results: Conventional content analysis and survey findings suggest that patient acuity and volume increased provider burden, leading to high burnout. Although the shift to telehealth improved behavioral health access, issues with technology access and literacy were common. Changes to the study design and implementation plan, based on findings, included the provision of multi-modality treatments (in person, telehealth, web-administered), technology and administrative support, and other strategies for reducing provider burnout.

Conclusions: This study describes how an ongoing research study adapted to major changes to the implementation setting during the pandemic. Changes to study design and implementation plan were responsive to the shift to telehealth and therapist burden (and burnout) concerns.

1. Introduction

Since March 2020, the COVID-19 pandemic [1] has led to disruption across economic, healthcare, and social structures [2–5]. The pandemic in the U.S. has drawn attention to issues of health equity, with low-income and racial and ethnic minorities the most vulnerable due to higher community transmission, low healthcare access, and employment as essential workers [6–14]. The pandemic has highlighted the limitations of the U.S. healthcare system in responding to (1) the increased demand for behavioral health services [15,16], and (2) the professional and personal toll of the pandemic on the healthcare workforce [17,18]. If unaddressed, provider burnout, turnover, and associated workforce shortages may impact quality of care [19,20].

In February 2020, the Center for Disease Control and Prevention (CDC) began to urge health care providers to adapt their practices based on social distancing guidelines by utilizing virtual platforms [21]. In

March 2020, federal and state policies expanded insurance coverage of telehealth [22–25]. Given the large shift to telehealth, there is a need to understand the impact of such changes on patient care and provider experiences. For example, issues of technology access and literacy may increase concerns around health equity [26] even though some barriers to access and engagement in care may be removed, such as transportation and child care challenges [27,28]. Further, understanding patient and provider experiences in the “new normal of COVID-19” is critical for successful intervention implementation in hybrid systems of care.

We present findings from a formative evaluation [29] that was conducted in 2020 as part of a parent NIMH-funded study (K23MH117221). The parent study aims to inform the development of a stepped care model for posttraumatic stress disorder (PTSD) treatment that spans specialty and nonspecialty care in a safety net hospital setting. The clinical trial within the parent study focuses on testing a “step one”

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intervention in primary care, and utilizes a hybrid type 1 effectiveness-implementation design [30] to assess the feasibility, acceptability, and effectiveness of the intervention while gathering data on implementation (For trial details, see Table 1 and our clinicaltrials.gov registration NCT 04937504).

The original clinical trial was slated to begin in March 2020, but was

halted due to the COVID-19 pandemic before any participants were enrolled. The impact of COVID-19 on the local setting raised major concerns about the feasibility of our original plan. Therefore, we conducted the present formative evaluation to maximize implementation success prior to a new trial start date of June 2021. We used surveys and qualitative interviews with employee stakeholders to (1) re-characterize

Table 1
Overview of modifications to the study in response to COVID-19 and PC-CAB feedback.

	Original Plan	Revised Plan	Rationale		
			Provider Factors	Patient Factors	Implementation Science Factors
Intervention	STAIR-PC v. Treatment as Usual	STAIR-PC v. webSTAIR	x	x	
Study design	Nonrandomized Controlled Trial (sequential enrollment)	Randomized Controlled Trial			x
Outcomes	Effectiveness: 1) PTSD symptoms and 2) functioning based on assessment data Implementation: retention [recruitment rate, assessment completion rate, attendance rate]	Added measures to assess for COVID-19 stressors and Racism-based stress. Implementation outcomes will also measure webSTAIR engagement.			x
Treatment Modality	In-person	Flexible: telehealth (video) or in-person v. web-administered		x	
Consent and Data Collection	In-person consent, flexible data collection: in-person or remote	Allowed for flexible consent: in-person or remote			x
Study Eligibility	Inclusion: New patients over the age of 18; trauma exposure and subthreshold or full PTSD; able to receive therapy in English Exclusion: Not appropriate for care in IBH (outpatient level of care); Receiving CBT for PTSD elsewhere	Inclusion: Added new or existing patients; Added patient must have reasonable access to technology necessary for both conditions Exclusion: Added bereavement as primary clinical concern (PTSD treatment not appropriate)		x	x
Study Therapists	Assign 1 case to each therapist at a time	Assign 2 cases to each therapist at a time (typically results in carrying 1 in-person/telehealth case at a time)	x	x	
	One-time training in STAIR-PC, maximal N = 7	Repeated training in STAIR-PC (for new hires and new trainees), maximal N = 11	x		x
Recruitment Procedure	Phase 1 (TAU, appx. 9mo.) 1. Therapist completes the LEC-5 and PCL-5 with patients during intake or refers to the study team if there is not adequate time during the session. 2. Study RA completes screener in person or over the phone, obtains in-person informed consent, and patient completes baseline questionnaires 4. Participant is enrolled, study RA informs therapist, who will deliver TAU Phase 2 (STAIR-PC, appx. 9mo.) 6. Therapists are trained in STAIR-PC 7. Phase 1 recruitment procedures repeated, therapists now deliver STAIR-PC	1. Therapist refers patients who may benefit from PTSD treatment (based on clinical judgment), is not responsible for any screening measures 2. Study RA completes LEC-5, PCL-5, and remaining screener by phone or video call and obtains informed consent, and patient completes baseline questionnaires 3. Participant is randomized and therapist is informed of which intervention they will receive	x		
Administrative Support	Therapists schedule their own participants Patients provided with workbook in person N/A	RA schedules on behalf of study therapists Mail patient workbook to participants Telehealth access and troubleshooting for participants	x x x	x x	
	RA calls participants twice monthly to gather PTSD symptom data RA sends symptom data via clinical message for therapist to document Smarttext and Smartphrases for STAIR-PC sessions to ease progress note documentation	RA calls participants twice monthly to gather PTSD symptom data and encourage engagement RA enters symptom data, creates a documentation note, and sends clinical message to therapist Additional Smarttext and Smartphrases created for pulling PTSD symptom data and treatment progress into progress note	x x x		x
Consultation and Training	Twice monthly group consultation (in-person) Manual materials available on shared drive (accessible onsite and via VPN)	Twice monthly group consultation (virtual) Manual materials available on Box (accessible regardless of therapist location and VPN access) Supplemental training on how to deliver STAIR-PC via telehealth Supplemental training on how to encourage participants to do video (over phone) telehealth visits Supplemental training on differential diagnosis (healthy v. problematic adjustment in context of COVID-19) Supplemental training on differentiating grief/loss v. trauma responses	x x x x x x		

Note. PC-CAB = primary care community advisory board; PTSD = posttraumatic stress disorder; TAU = treatment as usual; STAIR-PC = Skills Training in Affective and Interpersonal Regulation for Primary Care; webSTAIR = web-administered STAIR; CBT = cognitive behavioral therapy; RA = research assistant; DSM-5 = diagnostic and statistical manual of mental disorders (5th ed.) [62]; LEC-5 = life events checklist for DSM-5 [60]; PCL-5 = PTSD checklist for DSM-5 [61]; VPN = virtual private network.

the local setting, including understanding changes in patients' behavioral health needs, shifts in the primary care and integrated behavioral health practices, and providers' own experiences working during the pandemic, and (2) assess the need for augmentation to study design, implementation plan, and PTSD intervention prior to the clinical trial.

2. Method

2.1. Setting and context

This study took place at the largest safety net hospital in New England, with primary care clinics serving approximately 50,000 patients. Safety net hospitals provide health care services to socially vulnerable populations, regardless of their ability to pay [31]. The majority of patients are insured through Medicaid (70%), and, prior to the pandemic, over half of Medicaid patients had behavioral health diagnoses. The hospital employs an Integrated Behavioral Health (IBH) model of care which utilizes collaboration, coordination, and colocation of primary care physicians (PCPs) and behavioral health specialists, and prioritizes low-intensity and time-limited interventions.

2.2. Intervention

Skills Training in Affective and Interpersonal Regulation (STAIR) is an evidence-based cognitive-behavioral treatment for PTSD [32–35]. An abbreviated and low-intensity version of STAIR adapted for primary care (STAIR-PC) is a five-session therapy that utilizes psychoeducation and coping skills training without recounting trauma memory, and has demonstrated effectiveness in Veterans Health Administration primary care [36], and when delivered by peers in a safety net setting [37]. The intervention was further refined to the local setting based on our initial formative evaluation and Community Advisory Board (CAB) engagement from October 2018 – March 2020 [59].

2.3. Participants and procedures

Study participants were hospital employees, including primary care physicians, psychiatrists, nurse practitioners, clinical social workers, psychologists, administrative staff, and operations managers, with representation across levels (staff, supervisors, leadership). Although most participants worked in the primary care setting, we included two representatives from specialty mental health leadership as stakeholders in the continuum of PTSD treatment. Participants were recruited via email. Participation was voluntary and entailed 20 min of online surveys and a 30-min semi-structured interview conducted over a video call. Participants were remunerated with \$20. The formative evaluation received an exempt determination from the Institutional Review Board.

Data were collected between October 2020 and February 2021. The research team utilized two previously established CABs to develop the interview guide and select surveys, interpret and contextualize findings, and guide refinement of the study design, intervention, and implementation plan. In February 2021, the primary care CAB (PC CAB; $N = 9$), consisting of primary care and hospital employees, assisted in the adaptation of the implementation plan in response to potential implementation barriers raised by interviewees. Then, the adapted plan was presented to the patient CAB ($N = 6$), consisting of primary care patients with a past or current PTSD diagnosis, who offered additional feedback prior to finalizing. Full detail on our approach to CAB engagement is published elsewhere [59].

2.4. Measures

2.4.1. Sample characteristics

Age, gender identity, race, ethnicity, and role were collected as these factors may be related to provider burnout and implementation barriers.

2.4.2. Personal impact of COVID-19 on patients and providers

Select subscales from The Epidemic-Pandemic Impacts Inventory (EPII) [38] were used to assess the presence (yes/no) of pandemic-related experiences (own and patient) across life domains, including Work and Employment (11 items), Home Life (13 items), Social Activities (10 items), Economic (5 items), and Emotional Health and Well-Being (7 items). Psychometric properties are not available [38]. Two investigator-created items were used to assess direct contact with COVID-19 patients and the impact of COVID-19 on workflow and workload.

2.4.3. Provider attitudes toward telehealth use

The Telehealth Usability Questionnaire (TUQ) [39] was used to investigate provider attitudes across the subscales of usefulness (3 items), ease of use and learnability (3 items), interface quality (4 items), reliability (3 items), and satisfaction and future use (4 items). The TUQ has shown high content validity, reliability, and internal consistency [39]. Items were scored on a 7-point scale from 1 (strongly disagree) to 7 (strongly agree).

2.4.4. Professional impact of COVID-19 on provider quality of life

Professional Quality of Life (ProQOL) [40] was used to understand experiences of compassion satisfaction and compassion fatigue (burnout, secondary traumatic stress). The ProQOL consists of 30 items scored on a 5-point scale from 1 (never) to 5 (very often) and has high construct validity [40].

2.5. Interview guide

Semi-structured interviews were conducted to re-characterize the local context and identify the need for augmentation prior to implementation. The interview guide was developed in collaboration with the PC CAB and in consultation with project mentors with expertise in implementation science, PTSD clinical trials, and behavioral health integration (see Table 2). Providers were asked about their perceptions of changes to patients' behavioral health needs, changes to the practice, and to reflect on their own experiences and challenges providing care during the pandemic. A brief trial overview was provided prior to questions on how practice changes may influence implementation success and whether augmentation was needed.

2.6. Data analysis

We ran frequencies and descriptives of survey data to characterize the setting and the sample. Survey data was complementary to our qualitative data, as convergence of these findings sought to inform our adaptation process [41]. We utilized a team-based approach [42] (as defined by Patton) in developing a codebook for qualitative data

Table 2

Interview guide.

1. How has COVID-19 impacted patient behavioral health needs? Worsening? New onset? Coping with loss or trauma directly related to COVID-19 experiences?
2. How are patients' mental health needs being identified and prioritized in light of COVID-19? Is PTSD treatment a priority in the practice? Has this changed as a result of COVID-19?
3. How has the COVID-19 pandemic shifted your practice? What kind of changes do you think will be permanent?
4. Are there any suggestions you have about the need to further adapt the intervention, in light of COVID-19?
5. Do you have new concerns about the feasibility of implementing a 5-session therapy in light of COVID-19 and related practice changes (e.g., workload demands due to increase in referrals)?
6. Let's say that we shift the intervention to telehealth delivery. What barriers do you think patients might face in order to participate in the intervention? How might we overcome these barriers?

Note. PTSD = posttraumatic stress disorder.

analysis. An initial codebook was developed using a rapid coding procedure [43] applied by two members of the study team. The purpose of rapid coding was to provide quick feedback to the PC CAB prior to conventional content analysis of transcribed interviews [44]. Our expanded coding team for content analysis consisted of 3 members, who met weekly to develop, refine, and finalize the codebook. Initial transcripts were double-coded, until >80% inter-coder reliability was established (5 transcripts, or 20% of interviews with 99% agreement). Remaining transcripts were coded independently. The team met weekly to discuss assignment of codes until all coding was complete. NVivo 12 software (QSR International) was used to assign codes and calculate reliability.

3. Findings

We present formative evaluation results and then describe how we used findings to modify study design, implementation plan, and intervention prior to our pilot effectiveness-implementation trial for STAIR-PC. An overview original study design and date-driven modifications to study design, implementation plan, and intervention are detailed in Table 1. All stakeholders agreed to participate (N = 27 completed interview; N = 26 completed surveys). The majority of respondents were women (76.9%) and over half (56.3%) identified as a racial or ethnic minority. The average age was 37.23 (SD = 7.37). Full sample characteristics are presented in Table 3. Exemplar quotes from interviews are presented in Table 4 and themes are summarized in text.

3.1. Changes in behavioral health needs of primary care patients

3.1.1. Social determinants

Interviewees described both exacerbation and onset of stressors. Survey responses suggest that COVID-19 had a negative impact on

Table 3
Sample characteristics (N = 26).

Age (years; M,SD)	37.23, 7.37
	n (%)
Gender	
Female/Woman	20 (77)
Male/Man	4 (15)
Non-binary/Third Gender	1 (4)
Race ^a	
White	16 (62)
Black or African American	4 (15)
Haitian	2 (8)
Cape Verdean	1 (4)
Asian ^b	4 (15)
Hispanic, Latinx, Spanish origin ^c	2 (8)
What is your role? ^a	
Primary care physician	9 (35)
Psychiatrist or Nurse Practitioner	2 (8)
Social Worker, Therapist, or Psychologist	14 (54)
Administrative Staff or Operations Manager	1 (4)
Leadership, Supervisor, or Director	4 (15)
How able are you to perform the most important functions of your job right now, in light of COVID-19?	
Extremely	3 (12)
Very much	17 (65)
Somewhat	6 (23)
What percentage of your patients were diagnosed with or suspected to have COVID-19?	
1–10%	17 (68)
11–30%	6 (24)
31–50%	2 (8)
>50%	1 (4)

^a Indicates that participants could select all responses that apply.
^b Specified responses included: Chinese (n = 1), Korean (n = 2), Indian (n = 1).
^c Specified responses included: Mexican (n = 1), South or Central American (n = 1).

Table 4
Exemplar quotes from qualitative interviews (N = 27).

<i>Changes to behavioral health needs of primary care patients</i>
I definitely ask more questions about psychosocial determinants of health. [I] definitely ask, [patients]... [did you lose your] job?... how are the bills? [are you] having a hard time with putting food on the table? (PCP)
Food insecurity has come up a lot. Insecurity around financially being able to pay bills. And I know there's an eviction moratorium in Massachusetts, but several of my patients were already having struggles of being housed [before the pandemic], and... shelters [are] not functioning in the way that they used to, and couch surfing has... posed some barriers [due to] social distancing. (IBH therapist)
I also see a lot of moms who are really struggling right now because, due to gender roles, the child care really is all falling to them right now and they're still working or doing whatever they were doing before their child [was] schooling from home five days a week. (IBH therapist)
The balance between work, childcare, kids at school, kids not at school, not being able to rely on family or friends for support because of social distancing... I think [that has] been the biggest tension point for a lot of patients. (IBH therapist)
[We are] seeing a lot more issues with... housing, ... a lot more violence within the home, likely due to shifts in spending more time at home, more caregiving responsibilities, the kind of the pressure cooker of the additional stress leading to the violent escalation. (IBH therapist)
[For] one patient who had... a tough relationship with her husband, ... being home [has] exacerbated that... (PCP)
[COVID-related stressors are] leading to increased symptoms of depression, increased symptoms of anxiety, and a really significant impact on their functioning in general. (IBH therapist)
I've seen an incredible increase in stress, depression, and anxiety among my patients. (PCP)
Substance use has definitely increased across the board, with everybody. (IBH therapist)
I had one patient who had three family members die of COVID. Talking to this particular patient, he never really had depression before, but obviously there's a pretty clear acute grief reaction from losing three family members. (PCP)
Sometimes patients will come to us and they have not prioritized their mental health needs. There's other stressors that are more salient... or they just take priority over mental health needs. And so I do understand that if we don't have the basic needs like food, shelter...[then]... most... patients are not thinking about mental health. (IBH therapist)
Mental health is being more prioritized in that there [are] new people... coming that have maybe never had any type of treatment before. [Patients are] being referred by primary care [providers] for a lot of difficulty managing these stressors. And it seems like... maybe mental health was on the backburner for the first six months of the pandemic and now it's coming a little bit more into the fore. (IBH therapist)
<i>Changes in the practice: Telehealth as the "new normal"</i>
I really do love telehealth. I think that it works pretty great for almost all aspects of what I'm helping my client with. (IBH therapist)
Particularly with our patient population, telehealth has great potential. They don't have to take five buses to come and see me. (PCP)
I get to... meet my clients wherever they're at. So if someone is severely depressed and can't get out of bed, there I am on an iPad...coaching them out of bed. In a lot of ways that's really helpful. (IBH therapist)
We're also seeing patients that we probably wouldn't have seen [before the pandemic]. We have a higher caseload...of elderly patients, patients with physical disabilities that would typically have a harder time getting out of the home [to travel to appointments]. (IBH therapist)
We're seeing patients that would maybe never engage because they wouldn't have made it to the office. (PCP)
I find it really hard to practice medicine over the telephone. A lot of my patients don't have the internet access or the [literacy], or technology acumen to do video visits. (PCP)
There are a lot of patients where we are able to do video. And that's great, but there's also patients, a fair number, where phone is really the only option. (IBH therapist)
I've been trying to recreate what I did in person onto telemedicine, which is tough especially when it's telephone only, when it's on video it's a little bit easier. (PCP)
I think it's also made me realize how, unfortunately, this [shift to telehealth has] created even more disparities for the patients that I see. Because...I see others being able to connect to [technology platforms] ... but [my patients] don't have the internet, or they don't have smartphones. (PCP)
I think there's also a concern about privacy. A lot of patients don't really have a private space to go, especially if they're living with other people or they have kids around. (IBH therapist)
<i>Increased behavioral health engagement</i>
Our no-show rate has gone down incredibly and on top of that, there are a lot of people who... [are seeking treatment after] after 1 to 2 years [of no care]. (IBH therapist)
We had a 50% rate no-show before [the pandemic] and now I'd be very surprised if it wasn't [as low as] 20[%], you know, half [of] that. (IBH therapist)

(continued on next page)

Table 4 (continued)

Because our numbers [patient volume] have increased, it would appear as if there's been a shift... maybe there's more priority given to mental health. (IBH therapist)

Maybe [seeking treatment for mental health is] just less stigmatized now, because mental health seems to be on the forefront of a lot of issues going on in the country right now. So yeah, more of an openness or a willingness [among patients] to engage in therapy. I think has been the biggest thing I've noticed [since the pandemic]. (IBH therapist)

We're hearing messages around protecting and working toward a better mental health and better well-being through social media, through the news, through any kind of platform where people are receiving messages of care. (IBH therapist)

I think there's definitely less stigma, because everyone is talking, there's just so much in the media about stress and anxiety and everyone is experiencing this. (PCP)

Changes in provider's care experiences

It's a sad time. I feel like I'm [going to] cry just talking about it. It just feels very sad and I've never disliked - I've always loved this job, I've always loved this job and I just don't like it now. (IBH therapist)

I don't think I've changed much as a clinician except for maybe the compassion fatigue has come up... more now than in [my prior] two years of practice. Maybe [compassion fatigue has] happened two more times since COVID. So now that feels a little bit more exhausting. (IBH therapist)

They're bringing the trauma in [to your home], literally. I mean it's no longer taking your work home with you - they're one in the same. (IBH leadership)

I find in my own experience of providing care on telehealth I can still do all of the things, but as a provider I don't get the emotional benefit that I [used to] get from my work. I don't get that through telehealth. (PCP)

There's a different level of burnout right now. We're not used to doing 4 h of telemedicine, so I feel I'm more tired by the 4 h of telemedicine than the 4 h of seeing my patients [in person]. That's really a struggle, and I'm really struggling at the end of the 4 h. It's really hard. (PCP)

Recommendations for successful PTSD Treatment Implementation

I think that telehealth is completely conducive to evidence-based treatment, to cognitive behavioral treatment. (IBH therapist)

I'm hoping for some plateau [in patient volume], but if that weren't the case, then I think it's just going to be a staffing issue [that interferes with the feasibility of the study]... and being able to manage the volume and...frequency of visits ... you [study team] were hoping for. (IBH leadership)

Worksheets [are] the big [challenge of telehealth delivery of] CBT ... I think other aspects of the treatment protocol translate great. But because of the strong emphasis on worksheets, that's been my biggest issue in trying to adjust [to telehealth]. (IBH therapist)

If it's traditional CBT where there's worksheets and handouts, it would be great to be able to get more people...to do a screen share or something, but that's just a heavy lift. (IBH therapist)

Already ten minutes of the session... is being spent just trying to get folks on the video... Having to navigate how to do [the PTSD treatment on video] would be a challenge. (IBH therapist)

I have some patients who I try to virtually give them a [depression screener] and it takes us 30 min. And that's all the assessments that we get for that day outside of what we get out of our interview time. (IBH therapist)

Note. IBH = integrated behavioral health; PCP = primary care physician; PTSD = posttraumatic stress disorder.

patients across work and employment, home life, social activities, economic, and emotional health and wellbeing domains. For example, the majority of providers endorsed that patients were experiencing job loss (92.3%), childcare difficulties (96.2%), spending more time caring for a family member (100%), separation from family or close friends (100%), food insecurity (88.5%), inability to pay important bills like rent or utilities (96.2%), homelessness (76.9%), and an increase in conflict in the home (84.6%). Our data suggest that the pandemic introduced a multitude of additional stressors that amplified problems related to social determinants of health and social isolation. In a setting where baseline patient needs are already high, respondents hypothesized that additional stress burden became unmanageable for patients during the pandemic.

3.1.2. Behavioral health symptoms

All providers perceived an increase in mental health symptoms among their patients. Interviewees reported that this was unsurprising given the heightened intensity and frequency of stressor exposures, and described increases across a range of symptoms, including anxiety, depressive symptoms, and substance use, even among patients without preexisting mental health concerns. Respondents described how patients

were also experiencing grief following loss of loved ones to COVID-19, losses that often clustered within families. Interviewees perceived that mental health was increasingly prioritized by patients and their providers, prompting providers to more routinely assess and refer.

3.2. Changes in the practice: telehealth as “new normal”

Beginning on March 16, 2020, the IBH service shifted to entirely remote care. Respondents reported high acceptability and satisfaction of the telehealth model in both surveys and interviews. Respondents endorsed favorable ratings (>4.0 on the TUQ) for usefulness ($M = 6.27$, $SD = 0.82$), ease of use ($M = 5.29$, $DD = 1.39$), and satisfaction and future use ($M = 5.51$, $SD = 1.45$) of the telehealth model. Interviewees noted an overall increase in accessibility to behavioral health care afforded by the telehealth model, as this approach removes barriers that significantly affect this patient population (e.g., transportation, neurovegetative depressive symptoms, hospital avoidance).

Despite the advantages of telehealth, respondents also reported common issues with patient technology access and literacy (e.g. not having access to internet, a computer, or a smartphone to access the telehealth platform) that compromised the quality of care. Although preferred by providers, video visits were often not feasible and providers were burdened by providing technical support. Respondents also noted challenges related to patient privacy and safety, given crowded housing conditions.

Respondents had neutral or slightly negative ratings of interface quality ($M = 4.28$, $SD = 1.59$) and reliability ($M = 3.74$, $SD = 1.85$), suggesting dissatisfaction with the specific technology platforms selected by the hospital.

3.3. Increased behavioral health engagement

Since the start of the COVID-19 pandemic, referral volume increased by 80% (from an average of 308 to 554 referrals per month) and show rates increased by 62% (from 45% to 73%). While the demand for services increased, clinical staffing did not change. The IBH model focuses on improving access, with clinicians' schedules designed to accommodate real-time access (warm handoffs) in addition to scheduled appointments. Thus, having a waitlist is not an option. These factors have placed a heavy strain on the staff and the system. Respondents accurately perceived the increase in patient volume and in engagement (lower no-shows), and interviewees attributed higher patient engagement to receptivity of referrals, and lower mental health stigma due to public health messaging surrounding the pandemic.

3.4. Changes in provider's care experiences

Provider stress, burnout, and turnover potential are all relevant to implementation success, and were an important focus given the burden of the pandemic on healthcare workers.

Overall, survey findings indicated low levels of secondary traumatic stress (STS) ($M = 20.81$, $SD = 0.72$), yet moderate levels of compassion satisfaction ($M = 37.78$, $SD = 0.32$) and burnout ($M = 24.08$, $SD = 0.77$) among provider respondents ($N = 26$). STS ratings are similar to findings among providers practicing in a non-safety net hospital setting ($M = 21.54$, $SD = 5.67$), yet burnout and compassion fatigue ratings are worse (burnout: $M = 22.27$, $SD = 5.43$; compassion satisfaction: $M = 40.85$, $SD = 5.70$) [45], suggesting the additional burden on providers in safety net hospital settings.

In terms of their own functioning, respondents reported the most change in their social activities, work and employment, and emotional health and well-being, with 80.8% of respondents endorsing increases in workload and responsibilities. Interviews detailed the emotional toll from working during the pandemic and reported compassion fatigue at levels that they had previously never experienced. Clinicians had to expand their role to respond to social determinant stressors, as many

Patient Navigators typically responsible for providing socioeconomic resources were furloughed during the pandemic. Respondents expressed distress with not being able to meet the varied and complex demands of a high volume of patients. Interviewees also described how remote work further contributed to burnout and compassion fatigue. For example, respondents described how the telehealth model increased patient volume while decreasing collegial interactions and the emotional support these interactions provide. Respondents also reported increased difficulties in setting work-life boundaries in the remote environment, and overall feeling exhausted from remote practice.

3.5. Recommendations for successful PTSD treatment implementation

We asked respondents if they had recommendations for modifying the implementation plan or intervention, and if there were any additional factors that we should consider regarding study design (e.g., treatment conditions). Stakeholders affirmed that the intervention remained appropriate for the current practice, suggesting no need for adaptation to the intervention. Stakeholders had no recommendations for changes to study design. In terms of modifications to the implementation plan, respondents suggested ways to address provider burden and technology barriers. The primary concern of respondents was to reduce provider burden as this may pose major challenges to implementation (e.g., recruitment of study therapists). Respondents suggested that there may need to be more support from study staff for recruitment, eligibility screening, medical chart documentation, and preparing for and delivering the intervention. Respondents also noted the need for technology support to increase video visits and adapt intervention materials to multiple delivery formats.

3.6. Collaborative augmentation to study design, implementation plan, and intervention

Full detail of CAB-informed modifications are presented in [Table 1](#).

3.6.1. Use of telehealth delivery

The PC CAB advised that we expand the STAIR-PC condition to include both in-person and telehealth delivery, and that we add a new condition, webSTAIR as a comparator, given recent effectiveness data for this intervention [46] and potential advantages in addressing COVID-19 related implementation barriers. WebSTAIR is a self-administered web-based program that includes the same content as STAIR-PC divided into 10 modules that are completed at the participants' own pace. The addition of webSTAIR was well-received by the CAB, as it 1) allowed study design to shift to a randomized controlled trial, wherein all participants had access to active treatment at the same time (the original study design, as described in [Table 1](#), was a non-randomized control trial with sequential enrollment of each condition); 2) allowed us to expand patient access while not reducing therapist capacity, effectively doubling enrollment capacity; 3) allowed us to expand access to new and existing patients, and 4) allowed for rolling recruitment and training of study therapists, thus expanding our maximum number of study therapists to 11 (previously, 7).

3.6.2. Study measures and inclusion/exclusion criteria

Main effectiveness and implementation outcomes did not change, however, we added measures of COVID-19 stress and racism-based stress to our data collection plan. The latter was suggested by interviewees and CAB members given racial inequities in the impact of COVID-19, candid conversations about racism in medicine, and racialized trauma experiences commonly reported by patients. We revised all study procedures to be fully remote.

Although we largely expanded eligibility by offering the study to both new and existing patients, we added two new exclusion criteria: 1) does not have reasonable access to technology needed to support either condition (phone, computer, internet access), and 2) recent loss

suggesting treatment focused on bereavement and not PTSD treatment is most appropriate. We do not anticipate these new criteria will limit access too severely, but will be keeping track of this as we consider sustainability.

3.6.3. Efforts to reduce therapist burden

Several changes to the implementation plan were made to reduce therapist burden. These include: 1) shifting pre-screening from therapist to Research Assistant (RA) responsibilities; 2) shifting patient scheduling to RA responsibilities; 3) capping therapist capacity to two cases at a time, and 4) tapering consultation frequency over time by shifting from twice monthly to once monthly after written individual feedback on first two cases, as opposed to twice monthly for 18-month duration of the trial. To support the multiple modalities without adding therapist burden, the study RA will mail intervention materials and troubleshoot patient technology access issues.

3.6.4. Supplementary training and consultation

Core components of the intervention remain unchanged. However, supplemental trainings were added to the training and consultation plan including: 1) delivering manualized treatments via telehealth, 2) encouraging patients to use video as opposed to phone, 3) training on differential diagnosis (healthy v. problematic adjustment in context of COVID-19), and 4) training on differential diagnosis of adaptive grief versus traumatic loss responses.

4. Discussion

We conducted a formative evaluation during the pandemic to assess changes to patient needs, provider experiences, and the safety net primary care practice, and to understand barriers to implementation that would need to be addressed prior to a hybrid type 1 effectiveness-implementation trial [30] of a brief PTSD treatment. Implementation research focuses on translating evidence-based treatments to real-world settings [30,47,48]. Therefore, acknowledging and quickly adapting to drastic changes to the setting is necessary for implementation success [30,47,48]. Our study described how the research team was able to adapt to major changes to the implementation setting, in preparation for a clinical trial. Our approach leaned on established relationships with two CABs that helped the team respond to key challenges identified in stakeholder interviews.

Findings suggest that overall behavioral health needs and engagement in integrated behavioral health services among safety net primary care patients have increased. Increased patient volume has increased burden on providers who feel that they are unable to meet the complex demands of patients while also managing their own personal impact of the pandemic [17,18]. The shift to telehealth is a major change to the practice, and one that will likely remain beyond the pandemic [25,49]. This shift has helped to improve access and utilization of behavioral health services [26–28,50], but there are some notable limitations with technology access and literacy in the patient population [26]. Respondents also highlighted that technology platforms and time spent addressing patient technology access and literacy challenges added provider burden. Respondents reported greater exhaustion in delivering care via telehealth largely due to increases in show-rates, lower contact with supportive colleagues, and challenges setting work-life boundaries in the remote environment. Working with our CAB, we were able to adapt our implementation plan and study design to further reduce therapist burden, including increased staff support for pre-screening for PTSD, appointment scheduling, and video telehealth access. We were also able to add a web-administered treatment condition (webSTAIR) which did not require any therapist time delivering the intervention. Our ability to use formative evaluation during the pandemic has allowed us to respond and efficiently adapt to major changes to the implementation setting. This is paramount for implementation success and a clear advantage of clinical trials conducted by implementation scientists

[29,30,51,52].

In implementation research, we often make trade-offs between provision of a higher level of research team support and the sustainability of the intervention after the research is completed [48]. The majority of changes to the implementation plan involved more research staff support (to minimize therapist burden), which may reduce the sustainability of the intervention. We felt that these additional supports were necessary in the current context, and that *not* providing additional support would result in low therapist engagement in the study. We fully believe that this approach is the reason that all 11 eligible therapists trained in 2021 agreed to stay on as study therapists. We do not anticipate that patient volume (or therapist burden) will decrease even long after the pandemic, therefore, system changes may be necessary to ensure that manualized treatments are fully supported in usual care.

The team is currently reintegrating into the practice and adjusting to a hybrid model of in-person and remote work. This is allowing for more social interaction with primary care team members and opportunities to connect informally with peers. That said, anxiety about COVID-19 transmission is still high and many clinicians have expressed apprehension about returning to in-person work despite the need for social contact. Other practice adaptations to mitigate provider burnout include adding administrative blocks in templates to compensate for lost administrative time due to higher show rates and weekly team meetings to discuss concerns. These administrative blocks were implemented to prevent provider turnover, which would worsen access further. Our findings also highlighted the important consideration of racial stress on providers. For example, in post-hoc analyses, we found that racial and ethnic minority respondents endorsed higher secondary traumatic stress than their white, non-Latinx counterparts ($M = 24.23$, $SD = 8.77$ v. $M = 17.86$, $SD = 4.52$, respectively; $t(24) = 0.03$, $p < .05$; 95% CI). The team has utilized individual supervision to directly discuss the impacts of racism on providers.

Additionally, telehealth delivery was only made feasible by government mandates and the sustainability of telehealth or hybrid care delivery models remains uncertain [22,23,25]. Web-administered interventions are also difficult to maintain due to lack of institutional funding and reimbursement [53–55]. Patient engagement in these interventions also remains a concern [55], and may be further affected by low technology literacy and access among our patients [56–58]. Therefore, we plan to gather trial data on engagement and retention and assess ways to support sustainability of multi-modality interventions.

Our findings are derived from the perspectives of a small, although interdisciplinary, set of employee stakeholders. Like all qualitative research, findings may not generalize to other settings or provider types. We also acknowledge that patient perspectives are essential, although not part of this evaluation, and that in-depth qualitative interviews would have provided richer detail on the patient experience and patient-related barriers to PTSD treatment engagement.

4.1. Conclusion

The COVID-19 pandemic posed major challenges to implementation of behavioral health treatments, and necessitated redesign of an ongoing clinical research project. The current study illustrates the use of formative evaluation to inform pragmatic adaptations to study design, intervention, and implementation plan for a hybrid type 1 effectiveness-implementation trial [30] of a brief treatment for PTSD in safety net primary care. Insights gained from our data highlighted the need for adjustment to the implementation plan, including the provision of multi-modality treatments (in person, telehealth, web-administered) and additional technology and administrative support to reduce therapist burden. Findings also highlight how providers are struggling with the impact of the pandemic and the racial inequities that it exposed on both their professional and personal lives—and that attention to provider burnout is critical to implementation success.

Conflicts of interest

None.

Data availability

Data are qualitative interviews; not readily sharable

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