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Development and Initial Testing of a Brief, Integrated Intervention Aimed at Reducing Heavy Alcohol Use and PTSD among Military Veterans in Primary Care

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Abstract

There is a need for integrated treatment approaches that address heavy alcohol use and posttraumatic stress disorder (PTSD) concurrently among Veterans as interactions between heavy drinking and PTSD are frequent. Veteran engagement in specialty mental health services after referral is limited with poorer outcomes following empirically-supported, exposure-based PTSD treatments that do not explicitly address alcohol use. The current project aimed to incorporate two evidenced-based interventions: Brief Motivational Intervention (BMI) with Prolonged Exposure for Primary Care (PE-PC) for Veterans with heavy drinking and PTSD. Delphi methodology was applied to adapt an intervention protocol using subject matter expert (SME) feedback to guide the refinement of a preliminary treatment manual. The newly developed brief intervention (PC-TIME) was then tested in an open trial (n=9) to gather Veteran participant feedback to modify the treatment manual. Two rounds of SME feedback resulted in 80% agreement that manual content

was “acceptable as-is” across all intervention domains. The resulting protocol is a five-session, integrated intervention with session 1 primarily focused on alcohol use reduction and sessions 2–5 consisting of narrative exposure and in-vivo exercises for PTSD symptoms with brief alcohol use check-ins. Open trial results indicated high Veteran acceptance of PC-TIME structure and content, and reductions in heavy drinking and PTSD symptoms. Preliminary data suggest PC-TIME to be a promising approach for treatment of heavy alcohol use and PTSD. A pilot randomized controlled trial is necessary to demonstrate the intervention’s efficacy with Veterans in a PC setting.

Keywords

Heavy Alcohol Use; PTSD; Intervention; Veteran; Primary Care

1. Introduction

Heavy drinking and posttraumatic stress disorder (PTSD) are common and debilitating conditions among military Veterans (Jakupcak, Luterek, Hunt, Conybeare, & McFall, 2008; McDevitt-Murphy et al., 2010a). Heavy drinking, defined by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as more than four drinks per day or fourteen drinks per week for men and more than three drinks per day or seven drinks per week for women (National Institute on Alcohol Abuse and Alcoholism, 2020) exacerbates common medical and psychiatric conditions (e.g., hypertension, diabetes, PTSD) and leads to a variety of alcohol-related injuries (Anderson, Cremona, Paton, Turner, & Wallace, 1993). PTSD is associated with higher rates of medical utilization, poorer health functioning, and a higher likelihood of suicide (Gillock, Zayfert, Hegel, & Ferguson, 2005; Rauch, Morales, Zubritsky, Knott, & Oslin, 2006; Stein, McQuaid, Pedrelli, Lenox, & McCahill, 2000).

Past work has demonstrated that daily interactions between heavy drinking and PTSD symptoms are frequent and that one problem can exacerbate the other (Possemato et al., 2015). The confluence of evidence to date supports simultaneous treatment of alcohol use disorder and PTSD (Flanagan, Korte, Killeen, & Back, 2016). As such, treatments that target both heavy alcohol use and PTSD are needed, especially among military Veterans who prefer interventions that focus on drinking and PTSD concurrently, further justifying the need for integrated treatment approaches (Back et al., 2014; Hagedorn, Noorbaloochi, Bangerter, Stitzer, & Kivlahan, 2017). Although alcohol use and PTSD are commonly assessed in primary care (PC) settings, many Veterans do not engage in specialty mental health/addictions services following referral (Possemato et al., 2011; Seal et al., 2010b). Further, Veterans exhibit poorer outcomes following empirically-supported, exposure-based PTSD treatments that do not explicitly address alcohol use (Brown, 2003). To this end, the current study describes the initial testing and patient evaluation of integrated brief treatments for PTSD and alcohol reduction for Veterans receiving Veterans Affairs (VA) Primary Care.

1.1. Alcohol Use and PTSD in Veterans

Research has found as many as 22% of Veterans screen positive for heavy alcohol use (Hawkins, Lapham, Kivlahan, & Bradley, 2010), while varying rates of PTSD prevalence have been noted among Gulf War (10.1%) and Operation Enduring Freedom/Operation

Iraqi Freedom (OEF/OIF; 13.8%) Veterans. Past research consistently supports that heavy alcohol use (including Alcohol Use Disorder; AUD) commonly cooccurs with PTSD. National studies have shown 63% of OEF/OIF combat Veterans (Seal et al., 2010a) and 73% of Vietnam Veterans (Kulka et al., 1990) with AUD also met criteria for PTSD. When considering the broader picture of the co-occurrence of heavy alcohol use and PTSD, individuals who have PTSD experience more alcohol-related consequences than those who do not (Read et al., 2012; Stappenbeck, Bedard-Gilligan, Lee, & Kaysen, 2013). As rates of AUD and PTSD co-occurrence are even higher among Veterans than in community samples (Bailey & Stewart, 2014), it is clear many Veterans are in need of intervention to address these co-occurring concerns. Identifying opportunities to deliver these treatments outside of specialty care has the potential to increase treatment uptake and access to care.

1.2. Treatment for Veterans with Heavy Drinking and PTSD in Primary Care

Uniform implementation of screening for heavy drinking and PTSD in VA PC settings has increased awareness of the behavioral health needs of patients. Individuals with heavy drinking and PTSD are more likely to attend appointments in PC settings than specialty mental health or substance treatment clinics (Seal et al., 2010a; Spont, Murdoch, Hodges, & Nugent, 2010). Integration of mental health providers into PC clinics provides a unique opportunity to conduct brief assessments and interventions for individuals in need of services for co-occurring heavy alcohol use and PTSD. VA has a well established, nationwide system of Primary Care Mental Health Integration (PCMHI) services. However, significant systemic barriers exist in relation to successfully linking patients with adequate care (Hoge, 2011; Vogel, Kanzler, Aikens, & Goodie, 2017). Veterans who receive PTSD diagnoses in PC are significantly less likely to receive adequate treatment compared to Veterans receiving PTSD diagnoses in specialty mental health settings (Spont et al., 2010). This gap in treatment services may be due to available services not matching patient preferences for care settings (primary care vs. specialty care) and for treatment content (integrated vs. treatment that focus on a single concern). As such, individuals with heavy drinking and PTSD may perceive fewer barriers and less stigma associated with integrated PC-based interventions.

1.2.1. Brief Alcohol Interventions in PC.—Reviews provide evidence for the utility of brief motivational interventions (BMI) in PC with non-treatment-seeking drinkers including decreased social consequences, increased referrals, and small-to-medium effect sizes on drinking outcomes (Bertholet, Daepfen, Wietlisbach, Fleming, & Burnand, 2005; Bien, Miller, & Tonigan, 1993; Dunn, Deroo, & Rivara, 2001). When compared to treatment as usual, BMIs consistently result in improved alcohol use outcomes. However, BMIs may be less effective with individuals with PTSD; as standard, one-session BMIs fail to address the bidirectional effects of heavy alcohol use and PTSD. The use of standard alcohol BMI falls short in long-term alcohol use reduction for individuals with PTSD when compared to individuals with no history of PTSD, identifying a need to enhance current BMI approaches (Mastroleo et al., 2014, May).

1.2.2. Brief PTSD Interventions within PC.—Behavioral interventions provided in PCMHI are typically delivered in up to six, 20–30 minute sessions. PCMHI utilizes a

stepped-care approach, providing a small amount of services to a large number of people and then facilitating referrals for individuals in need of more intensive care (Beehler, Finnell, Foltz, & Edwards, 2010). At present, there is a critical absence of evidence based-treatment guidelines on how to briefly treat co-occurring heavy drinking and PTSD. As a result, the quality of patient care is jeopardized. In a review of electronic medical records, Possemato et al. (2011) found Veterans in PC with PTSD most often received supportive counseling and not evidence-based interventions. In response to this gap in treatment for PTSD, a 4–8 session Prolonged Exposure for PC (PE-PC) was developed and tested using four to six, 30-minute sessions (Cigrang et al., 2017; Cigrang et al., 2011). A randomized controlled trial comparing PE-PC to a minimal attention, delayed treatment control, found participants receiving PE-PC experienced statistically and clinically significant declines in PTSD severity compared to controls with gains maintained at 6-month follow-up (Cigrang et al., 2017). However, the sample excluded individuals who endorsed heavy drinking and did not examine alcohol use as an outcome.

1.3. The Current Study

The current study describes the process of developing an integrated, brief intervention to meet the needs of heavy drinking Veterans with PTSD by integrating BMI with PE-PC. This intervention, called **Primary Care Treatment Integrating Motivation and Exposure (PC-TIME)**, was developed using the Delphi technique (Dalkey & Helmer, 1963; Hasson, Keeney, & McKenna, 2000) to establish the initial PC-based intervention consisting of 5, 30-minute sessions to deliver personalized feedback on individual drinking behaviors, and written and in-vivo exposure to trauma stimuli. The Framework for Reporting Adaptations and Modifications-Expanded (FRAME) guided efforts to integrate the two treatments (Stirman, Baumann, & Miller, 2019). FRAME allows for a precise understanding of how and why modifications took place, what specific modifications resulted, and how these are related to observed outcomes. Following treatment development, an open pilot trial was conducted followed by in-person qualitative interviews of participants to further refine the treatment manual and procedures to prepare for a pilot RCT with Veterans across three VA PC clinics.

2. Materials and Methods

The current study employed a mixed-method, multi-component treatment adaptation approach designed to combine two treatments (BMI/PE-PC) into our integrated, five session intervention to be delivered in an integrated PC setting (PC-TIME). Within FRAME, this study is categorized as a planned adaptation that was led by researchers and experts in the Delphi process. Treatment development included a phased process consisting of a two-round Delphi approach to gather subject matter expert (SME) feedback on the PC-TIME manual. Following manual revision, Phase 2 tested PC-TIME in an open trial (N = 9) to gather Veteran participant feedback to ensure the intervention is patient-centered and meeting Veteran-specific needs prior to a larger, pilot RCT. The institutional review board at the participating VA facility approved all study procedures before data collection. Each phase incorporated quantitative and qualitative feedback from key stakeholders. Overall, these phases served a connective function (Palinkas, Horwitz, Chamberlain, Hurlburt, &

Landsverk, 2011) to establish a feasible and acceptable combined treatment for Veterans with PTSD who drink heavily. As described below, the ordering and structure of quantitative and qualitative methods varied within phases.

2.1. Phase 1: Manual Development

Phase 1 involved a proactive manual adaptation process. The study team initially met in-person to discuss development of the manual and logistics. Substantive treatment content edits included: a) integrating BMI into an existing exposure-based intervention (PE-PC); b) adding discussion of the interaction between alcohol and PTSD with PE-PC content; and c) tailoring BMI language specific to military service members/Veterans. Minor changes were made in terms of session length and adding options for booster sessions of BMI when necessary. The primary context edit was to specify a target population of Veterans with PTSD who use alcohol.

The resulting draft treatment manual was then appraised using an approach similar to that described by King and colleagues (2021). Briefly, an expert consensus study was conducted using the Delphi technique (Dalkey & Helmer, 1963; Hasson et al., 2000), with a primary purpose of ensuring treatment feasibility and integrity of the integrated treatment components outlined in the manual. The manual was shared with five purposefully-sampled (Palinkas et al., 2015) SMEs with professional expertise/credentials in content areas germane to the study, including models of integrated care, (specifically VHA primary care mental health integration), clinical domains (i.e., assessment and treatment of PTSD and alcohol use in service members and Veterans), and the two interventions that would be blended in this study (i.e., BMI, PE-PC). SME feedback was received over two rounds of emailed surveys (see Figure 1). In the first round, the SMEs were asked to review the draft treatment manual and to rate specific sections that described the intervention using the following forced-choice options: a) content is *unacceptable*; b) content is *acceptable as-is*; or c) content would be *acceptable with modifications*. For each section rated as “acceptable with modification,” SMEs were asked to provide specific commentary on changes the study team should make to render the content “acceptable.” Once ratings were complete, the study team reviewed the feedback and edited the manual accordingly. In the second round, SMEs rated the revised manual using the aforementioned procedure, and the study team again reviewed the feedback and edited the manual. This (see Table 1) was then used in a Phase 2 open clinical trial.

2.2. Phase 2: Open Trial

Phase 2 operated as a preliminary implementation test of PC-TIME and consisted of an open trial of PC patients. Participants completed a baseline assessment and PC-TIME condition research procedures, allowing us to (a) gain experience with the recruitment process, the intervention, strategies for retention of participants, (b) gather information on participants’ compliance with the study protocol, (c) develop and improve clinician training and fidelity procedures, and (d) gather participant feedback on the integrated intervention’s feasibility and acceptability.

2.3. Participants and Procedures

Potential participants were identified via the VA Computerized Medical Record System, and referrals from their primary care providers. Veterans enrolled in VA PC who evidenced symptoms of heavy alcohol use and PTSD (i.e., positive screens on the Alcohol Use Disorders Identification Test (AUDIT-C) and/or had a diagnosis for an Alcohol Use Disorder and Primary Care PTSD Screen (PC-PTSD)) and were not already engaged in specialty mental health care were screened to participate in this open trial. Veterans (N=311) were sent letters outlining the details of the study before receiving calls from research assistants asking if they were interested in participating in a brief counseling program within their PC clinic to help reduce difficulties related to past traumatic events and drinking. Interested Veterans ($n=22$) were invited to come to their local VA facility for a baseline assessment with a member of the research team. Of the 22 invited to complete a baseline assessment, 16 attended and completed the baseline assessment appointment with nine moving forward to the open trial (see section 3.2.1).

Inclusion criteria assessed at the baseline appointment included reporting a traumatic event on the Life Events Checklist/Criterion A screener, reporting a score greater than or equal to 30 on the PTSD Checklist (PCL-5), scoring 8–25 (male) or 6–25 (female) on the AUDIT, and reporting alcohol use in the past 30 days at the time of assessment. Exclusion criteria included cognitive impairment as assessed by the Blessed Orientation Memory Concentration Test (Katzman et al., 1983), current symptoms of mania or psychosis, a suicide attempt or intent/plan to harm oneself in the last 2 months, active psychotherapy for PTSD or alcohol use outside of VA primary care in the last 2 months, a change in or a new psychotropic medication prescribed in the two months prior to baseline, and a preference to be directly referred to specialty care for PTSD or alcohol use.

Once enrolled, participants commenced PC-TIME sessions within one week. After each session, participants completed a session evaluation form asking their opinions of the treatment and how sessions could be made more helpful. They also took part in an end-of-intervention exit interview with the first author to discuss their perceptions of the helpfulness of each intervention component and their comfort with research procedures (e.g., audio recording and timing of the sessions). These interviews aimed to gather preliminary data on acceptability and treatment satisfaction, and were used to assist the team in manual revisions and identifying necessary protocol modifications prior to testing PC-TIME in the subsequent RCT. Given our selected analytic approach (rapid analysis, described below), detailed interview notes were advantageous over creation of full interview transcripts. Each interview required approximately 30–45 minutes.

2.3.1. Treatment providers and intervention training.—For the open trial, two study investigators who are licensed clinical psychologists with expertise treating Veterans with heavy alcohol use and PTSD completed interventions with participants. Study investigators were chosen for this role so they could understand first-hand what aspects of the intervention was helpful for Veterans and what aspects needed adaptation. Training and preparation consisted of experience and completion of training in Motivational Interviewing (MI) and PE-PC training and consultation cases with Veterans. Prior to beginning the open

trial, both providers conducted standardized role plays of PC-TIME sessions with reviews of adherence to MI skills and intervention protocols.

2.4. Measures

2.4.1. Delphi Surveys—The authors developed SME surveys for each round of feedback. At round 1, forced-choice questions aligned with specific sections of the treatment manual (33-items) and personalized feedback sheet (10-items). Three open-text fields asked for additional feedback on integrating content related to heavy drinking and PTSD, modifications to enhance feasibility of PC-TIME, and ways to improve the breadth, clarity, or patient-centeredness of the intervention. At round 2, identical forced-choice questions were posed on a subset of 20 manual items.

2.4.3. Alcohol Use

2.4.3.1. Alcohol Use Disorders Identification Test (AUDIT; Babor, de la Fuente, Saunders, & Grant, 1992).: The AUDIT is a 10-item questionnaire developed by the World Health Organization (WHO) and identifies patients whose alcohol consumption has become harmful and is widely used within the VA (Bradley et al., 2006). Questions are scored from 0–4 with a cumulative score range of 0–40. A score of 8 or higher reflects heavy use for men (Conigrave et al., 1995) and a cut point of 6 or higher indicates heavy use for females (Reinert & Allen, 2002). The AUDIT was used as a primary screening assessment to establish initial alcohol use eligibility based upon the 8 (male) and 6 (female) cut scores.

2.4.3.2. Timeline Follow Back Interview (TLFB; Sobell & Sobell, 2003).: The TLFB is a measure that retrospectively assess alcohol use over the past 30 days and has demonstrated validity in Veterans (DeMarce, Burden, Lash, Stephens, & Grambow, 2007). In this study, the TLFB was used to identify daily drinking over the past month by asking patients to indicate the number of drinks consumed on each day, tracing back over the past month. The TLFB data was incorporated into the personalized feedback report delivered during Session 1 of PC-TIME. Further, initial trends in heavy drinking days were tracked and are presented as part of the open pilot trial data (see Results section).

2.4.2. PTSD Checklist-5 (PCL-5; Blevins, Weathers, Davis, Witte, & Domino, 2015).—This 20-item self-report measure asks respondents to rate how much they have been bothered by DSM-5 PTSD symptoms in the past month on a 0–4 Likert-type scale. The PCL-5 has good psychometric properties with use among Veterans (Wortmann et al., 2016) and a cut point of 30 along with meeting criterion A was required for study inclusion. PCL-5 scores were used in three ways. First, the participant’s total score on the PCL-5 at baseline was incorporated into the personalized feedback report and presented to patients during Session 1 of PC-TIME. Second, PCL-5 scores were also collected at weekly PC-TIME sessions and information regarding trends in scores was discussed with patients during sessions. Third, initial trends in PCL-5 scores were tracked and are presented as part of the open pilot trial data (see Results section).

2.4.3. Session Satisfaction Questionnaire.—All participants completed a session satisfaction questionnaire after each PC-TIME session (Sessions 1 through 5) aimed

at assessing their experience with the recently completed session. The questionnaire was developed specifically for this project based on past studies examining participant satisfaction with brief interventions (Monti et al., 2016). Likert-type items for Session 1, scored 1 (strongly disagree) to 4 (strongly agree) focused on MI skills (e.g., asked about my ideas before presenting their own, understood me, treated me like an equal) as well as items focused on the content presented scored on a 0 (strongly disagree) to 3 (strongly agree) scale (e.g., content was useful, understood the material, content was relevant). For Sessions 2 through 5, items asked about the experience discussing the trauma memory (e.g., feeling upset when something reminded you of the stressful experience, trouble remembering important parts of the stressful experience) scored 0 (strongly disagree) to 4 (strongly agree). Identical questions from the Session 1 satisfaction survey asking about experience with the session content were also asked for sessions 2 through 5.

2.5. Qualitative Interview

A 9-item semi-structured interview was designed by the study team to gather preliminary data on *patient-level acceptability*, which is defined as the degree to which an intervention is perceived to be appropriate relative to actual or anticipated patient experiences in treatment (Sekhon, Cartwright, & Francis, 2017). Areas of emphasis for the interview were *affective attitudes* (e.g., “What motivated you to attend each study session?”, “What was it like for you to engage in a treatment that addressed both your drinking habits and PTSD symptoms at the same time?”), *coherence* (e.g., “Were there any aspects you found difficult to understand?”), *effectiveness* (e.g., “What did you find helpful about the sessions, or skills that you may have learned?”) and *acceptability* (e.g., “How valuable do you think it would be for primary care-mental health clinicians to offer a treatment like this to Veterans with PTSD who drink alcohol?”). Various follow-up prompts include queries germane to *burden* (e.g., “What made it difficult to stick with this treatment?”) and *self-efficacy* (e.g., “Was there any one session that you found more challenging, or difficult to engage in, than another?”). Scripted follow-up prompts were prepared in advance to elicit greater detail in these areas. One cross-cutting question evoked specific changes that would improve acceptability (i.e., “Given your experience participating in the treatment, what suggestions do you have for improving the sessions, or improving Veterans’ overall experience with this treatment?”).

2.6. Analysis

2.6.1. Delphi Analysis.—Descriptive statistics (i.e., % agreement) were calculated for each survey item, at each round. An *a priori* threshold (i.e., at least 80% agreement that manual content was “acceptable as-is”) signaled consensus for each rated manual element. For items that did not reach consensus, the study team reviewed and discussed SME feedback on changes necessary to achieve an “acceptable as-is” rating.

2.6.2. Quantitative Analysis.—Given the sample size of individuals who completed PC-TIME ($n = 5$), quantitative analysis focused not on inferential statistics, but on examining overall session satisfaction ratings, tracking PCL-5, and number of heavy drinking days. As patients completed the PCL-5 and 1-week TLFB prior to each PC-TIME

session, as well as post-session satisfaction, data collected was plotted over time to examine trends in session satisfaction, PTSD symptoms, and weekly drinking behaviors.

2.6.3. Qualitative Analysis.—A rapid analytic process (e.g., Gale et al., 2019) was used to organize and interpret participant interview data. Compared to more traditional qualitative approaches, which often emphasize phenomenology (e.g., Seidman, 2006) and can require many months to process data (Gale et al., 2019), the purpose of rapid analysis is expedient processing of explanatory and/or actionable data. A multi-step procedure transforms raw data (e.g., interview summaries) to an analyzable form. In our case, notes derived from participant interview responses were first organized into a summary table known as a *domain-by-response matrix*. Table rows represented interview questions, and columns represented unique study participants. Participant responses to each question therefore comprised a single cell in the table. The next step in data processing typically involves organizing the summary by participant type (e.g., distinguishing treatment completers vs. non-completers) to allow for between-group comparisons. However, as our qualitative data pool consisted only of treatment completers, this step was omitted. The final step involves a broad thematic analysis. Participant responses to each question were grouped and reviewed to identify major themes, which were then compiled into a bulleted list. List items were reviewed for consistency and ultimately organized according to Sekhon et al.'s (2017) acceptability framework. Author 3 served as the primary qualitative analyst, with reviews for quality assurance conducted by authors 1, 2, and 4.

3. Results

3.1. Delphi Results

During Round 1, SMEs rated 21% of elements as “Acceptable as is,” while 73% of elements were rated “Acceptable with modifications.” Three themes required modification. First, contextual edits were needed to improve fit with typical PCMH practice. Specifically, alignment with the Assess, Advise, Agree, Assist, Arrange model (Glasgow, Davis, Funnell, & Beck, 2003) for each session, and ensuring that functional assessment and coordination of the PC team was present. Second, content edits to strengthen the connection between PTSD and heavy drinking, specifically taking opportunities in the more exposure-focused sessions to discuss how drinking to cope with distress may be present. Third, reducing session content to make 30-minute sessions more feasible was largely accomplished by limiting the number of therapist summary statements in the BMI session. Once initial modifications were made following Round 1 feedback, Round 2 feedback resulted in the majority of manual aspects reaching SME consensus of “Acceptable as is.” Fewer than one half of content areas required minor revisions to reach 80% consensus. See Figure 1 for Delphi flow results.

3.2. Open Trial Results

3.2.1. Participants.—Nine Veterans participated in the open trial. Participants self-identified as male ($n=5$) and female ($n=4$). Most participants were White ($n=8$) and one participant was Black. The ages of participants ranged from 24 to 72, with the mean age being 50 ($SD=16.95$). Participants reported PCL-5 scores that ranged from mild (34) to severe (67) with an average score for the sample of 46 ($SD=10.3$). Participants reported

a range of AUDIT scores from the low cutoff score (6) to the high cutoff score (25) with the average sample score of 16 (SD = 6.86). Most participants were Army/National Guard Veterans ($n=7$), with one being a Marine Corps Veteran and the other not providing an answer to the question. One participant was an OEF Veteran, two were OIF/OND, two Veterans served in Vietnam, two reported other, and two reported that no wartime era was applicable. Of the nine enrolled participants, four did not complete treatment and as a result, did not complete the final exit interview (see below).

3.2.2. Treatment Engagement.—Five of the enrolled Open Trial participants completed all five PC-TIME treatment sessions and completed qualitative interviews. Once treatment was completed, three Veterans were referred for continued care in specialty mental health services. Of those, two continued in care and one declined. The remaining two participants were satisfied with their treatment gains and chose to self-manage any remaining symptoms or concerns. The enrolled participants who did not complete all PC-TIME session completed three sessions ($n=3$), two sessions ($n=1$) while one ($n=1$) was deemed ineligible after enrollment due to psychosis and did not complete any sessions. Of the three eligible participants who did not complete all treatment sessions, two became unable to contact and one opted to stop treatment reporting he was not comfortable with the written exposure exercises.

3.2.2.1. Session Satisfaction.: When examining session satisfaction ratings, trends revealed positive ratings for those who completed all planned sessions and those three participants who did not complete treatment. Specifically, session 1 average rating across the nine items, and across all participants (completers and non-completers), was 3.73 (range 3.67 to 4; 1 = strongly disagree to 4 = strongly agree) indicating strong agreement that the treatment provider was easy to talk to, understood the participant, and followed principles of MI. Similarly, session 2 – 5 feedback (0 = strongly disagree to 3 = strongly agree) average score across all participants (completers and non-completers) was 2.7 (range 2 to 3) where participants evaluated the treatment provider's ability to understand, their own comfortability, and overall satisfaction with the material presented as a part of the treatment. One item stood out concerning participants being comfortable with material related to completing narrative homework regarding the index trauma. While the average score across participants for this item was 2.12, two participants who completed treatment rated this item as a 0 (strongly disagree) and offered feedback stating, "I was definitely not comfortable with the homework but am willing to try it out." For the two individuals who rated session 2 = 0, over the next 3 sessions the scores for this item increased with each session with the final sessions being rated at a 2 (somewhat agree).

3.2.3. PTSD and Alcohol Use.—For the five participants who completed all PC-TIME sessions, trends in PCL Total scores and number of heavy drinking days were calculated and are presented in Figures 2 and 3. Overall, three participants experienced reductions in PTSD by session 5, while the other two participants did not increase or decrease. All five participants reported fewer heavy drinking days by session 5.

3.3. Qualitative Results

Interview feedback was gathered from five participants who completed the PC-TIME protocol. While we designed each interview question to tap into pre-specified domains described by Sekhon et al. (2017), participant responses often transcended domains. For instance, participant comments related to perceived treatment effectiveness and self-efficacy were often blended, as were comments on affective attitude and ethicality.

3.3.1. Major Themes

3.3.1.1. Affective attitude.: Motivations to enroll in the study were consistent across respondents, predominantly focused on the prospect to help other Veterans as well as oneself. With regard to continuing in treatment, cited motivators included a combination of personal characteristics (e.g., tenacity) and the desire to continue because of perceived treatment gains. Interfacing with the study therapist was uniformly described as positive and perceived as helpful. As would be expected for Veterans with PTSD engaging in exposure to their target traumas, mixed sentiments emerged regarding narrative and written exposure work, at times described as “hard”, “stressful”, or “unsettling”, but also ultimately beneficial. For instance, one participant reflected that her treatment experience began as somewhat negative, because it brought up unpleasant memories. However, her experience improved with time, noting that she began to notice changes and ultimately “broke through” her discomfort, and felt more resilient. Another participant commented that his biggest challenge did not pertain to discussing his traumatic experience but rather selecting a single trauma exposure to focus on in treatment. Alcohol change plans were positively received; while described as “challenging”, these plans were also seen as important to raise awareness of current drinking levels and reinforce underlying motivations to change drinking behaviors. According to one participant: “Once you see the connection, it motivates you to actually make that change.”

3.3.1.2. Intervention Coherence.: Comments suggested that the overall experience was comprehensible, in part due to the highly structured nature of the treatment and treatment sessions. One participant commented that the express connection made between PTSD and alcohol use as an avoidance strategy increased motivation to change. Another reflected on what he termed an “awkward” aspect of the treatment, such that he had to fight the urge to drink in response to increased anxiety following exposure exercises. Several comments pertained to the match or mismatch between actual intervention experiences with *a priori* expectations. Exemplar reactions included a sense of surprise at the level of emotional difficulty experienced during early exposure exercises, and certain treatment logistics (e.g., frequency/ consistency of homework exercises, review of past-week drinking behavior, study chart documentation). One participant relayed a positive surprise, describing the magnitude of her treatment gains. No critiques were offered in terms of intervention clarity.

3.3.1.3. Effectiveness.: Generally positive appraisals were offered in terms of therapist behaviors and a sense that personal insights were gained. All participants cited helpful aspects of treatment gains, with several naming specific benefits, such as “immediate changes in drinking”, “interest in getting back out and closer to [ideal self]”, and “greater self-worth”. While several predictable challenges were identified (e.g., as noted above,

emotional reaction to exposure may temporarily increase urge to drink), no aspects of the treatment were described as unhelpful *per se*.

3.3.1.4. Acceptability.: Participants reflected that PC-TIME would be “very helpful for Veterans” and “a great option”. One stated “they should do it for everybody”. The remaining two participants qualified their remarks, one noting that PC-TIME is “definitely... worth trying, as long as it is the patient’s choice”, and the other agreeing that value depends on the individual. Four of five affirmed that they would recommend PC-TIME to other Veterans, and the fifth again qualified that he would recommend PC-TIME to other Veterans if he thought they would be receptive [to treatment]. With regard to treatment duration, three of five participants appeared satisfied with 30-minute sessions, characterizing session length as “fine”, “about right”, or “not bad”. One participant qualified that, while he would have liked to continue some conversations past 30-minutes, he did not feel rushed or interrupted. Just one participant expressed that 30-minutes “might be short...40 [minutes] may be better”, though another agreed that it would be helpful to go past 30-minutes if needed. Limited comments were offered in terms of the number of sessions. While just one participant expressed the opinion that five sessions were “not enough”, another appreciated the flexibility to add a sixth session.

3.3.2. Minor Themes

3.3.2.1. Burden of Participation.: As interviews were attended only by participants who completed the intervention, no direct data on dropout were available. Overall, those who did complete the treatment reported that it was reasonable and felt that it would be appropriate to engage future patients in this protocol. One participant reflected that the study baseline evaluation (approximately 1 hour) was lengthy, but an acceptable commitment for research that may help other Veterans. Another acknowledged treatment as “a commitment” and elaborated that 30 minutes of daily homework was not feasible, in her view, thus she engaged approximately three times per week (i.e., the minimum recommended interval) under what she felt were personally-appropriate personal circumstances.

3.3.2.2. Participant self-efficacy.: Several participants remarked throughout the interview that treatment was initially more difficult, but became progressively easier as time passed, emotion regulated, and they more consistently engaged in exposure activities. For instance, one participant reflected on the experience of an “uphill climb” that became easier as she confronted her own discomfort with trauma memories. Another, referring to fragmented trauma memories, described coming to the realization that “[he] didn’t remember as much as [he] thought”, but recall became easier with repetition.

3.4. Suggestions to Improve Treatment

Overall, few suggestions were offered to improve the protocol and most of these focused on the context of care rather than specific enhancements to the treatment protocol. Two participants critiqued the treatment space (primary care clinic exam room), one describing it as “not ideal” (e.g., due to noisy clinic operations, bright lights, and uncomfortable space), and reflecting that the clinic space did not feel private enough. A second shared the same privacy concern. One participant shared ways to improve the patient treatment experience,

for instance that therapists could spend more time building alliance, and considering whether family members can become involved (i.e., to encourage patients). Two offered suggestions to ensure that participants do “not feel rushed” and to consider offering a greater number of treatment sessions. One participant shared that greater education would be beneficial (e.g., more explicit acknowledgement of how challenging the treatment can be, self-care planning following exposure-based activities) and recommended that the team provide resource sheets with appropriate contact numbers for ancillary support services.

3.5. Data Integration

Quantitative and qualitative data were consolidated during and across phases of this study. Within regard to Phase 1, Delphi procedures often mix methodologies in a cyclical fashion. In this application, qualitative and quantitative methods expanded upon one another: while SMEs’ quantitative ratings were essential to evaluate consensus, their qualitative feedback provided actionable steps to build consensus. In Phase 2, qualitative data were emphasized as the best vehicle to gain insights into patients’ lived experience participating in PC-TIME and their perceptions of the treatment as a whole. Data suggest an overall positive and coherent characterization of the treatment experience, with relatively few suggestions for modification. Nonetheless, feedback from both SMEs (prior to open trial) and patients (in preparation for a follow-up study [pilot randomized trial]) was incorporated. Specific benefits were cited by participants who completed the study, with predictable qualification that treatment can be challenging and at times evoke powerful emotions. Though only a small sampling of standard patient outcome data are available, these data points generally converge with patient perceptions of concurrent and retrospective effectiveness (both critical considerations in appraising treatment acceptability (Sekhon et al., 2017)), and also highlight the likelihood of variability in treatment course relative to baseline, treatment adherence, and other unspecified personal factors.

4. Discussion

Veterans who present to primary care within the VA report high prevalence rates of heavy drinking and PTSD compared to the general population and experience a number of short- and long-term psychosocial and physical health concerns, resulting in these individuals using medical services more frequently (Fuehrlein et al., 2014; McDevitt-Murphy et al., 2010b; Rodriguez, Jenzer, & Read, 2019). Despite the distress and disability associated with co-occurring heavy drinking and PTSD, individuals infrequently engage in specialty care substance use and/or mental health services (Seal et al., 2010b; Spont et al., 2010), suggesting a brief, integrated intervention delivered within PC might best serve the needs of Veterans. The current study aimed to develop and offer an initial test of feasibility and acceptability of PC-TIME, an integrated, brief intervention focused on reducing alcohol use and PTSD simultaneously using 5, 30-minute sessions. As individuals with heavy drinking and PTSD are more likely to attend PC settings than mental health or addictions clinics (Seal et al., 2010a; Spont et al., 2010), mental health providers integrated into VA primary care clinics are well poised to deliver PC-TIME to patients.

Our results provide preliminary support that PC-TIME is feasible to deliver as a brief treatment and is acceptable to patients. Feedback from clinical SMEs raised several important feasibility considerations, perhaps most notably the importance of attending to practice management (timekeeping, session structure). Though an important consideration in PCMHI fidelity broadly, this is especially relevant to PC-TIME given the emphasis on simultaneous intervention for heavy drinking and PTSD. Specifically, SME feedback resulted in identifying time estimates for each segment of intervention sessions, while also suggesting more directive and concise discussion of topics related to alcohol use, PTSD, and the intersection of alcohol and PTSD.

Feedback from participants who completed treatment also provided meaningful insights into drivers of positive acceptability appraisals, among them the motivating effect that treatment had, perceived fit with treatment goals and personal values, positive therapeutic alliance, and perceived benefit from treatment, which itself appeared linked to increased motivation. Indeed, individual patient data suggest that treatment completers experienced improvements in PTSD symptoms and alcohol use (see Figures 2 and 3). At the same time, potential threats to acceptability also emerged, including initial difficulty with, and low self-efficacy in exposure exercises, and initial surprise at the routine revisitation of both exposure exercises and drinking behavior. However, challenges such as these are both frequent and predictable with intervention for both heavy drinking and PTSD, and in part addressable through patient-centered education and reassurance that new skills and adaptive behaviors can be developed in these areas with practice.

Overall, when considering feedback from SMEs, patients, and lessons learned from the open trial, several implications for care and next steps toward the randomized controlled pilot trial were identified. First, within training therapists for the RCT we offered specific time estimates for intervention segments to help guide the session and content focus. We also encouraged therapists to adhere to MI principles while shortening and more concisely reflecting on patient experiences to move through the session within the 30-minute PCMHI framework. We identified points where patients may be challenged to engage in exposure and in-vivo treatment experiences and trained therapists to help mitigate these by setting specific dates and times for conducting each homework exercise as well as approaches to reduce alcohol use through a formal change plan to be completed at the end of session 1. Most importantly, relaying to therapists that buy-in from patients is critical and that while the patient may be unsure of the outcome of treatment, therapists should support self-efficacy and belief in a positive treatment outcome. While the patient may have less confidence, it is critical the therapist offer continued belief that engagement in treatment can result in both reduced alcohol use and reduction in PTSD symptoms. This was echoed by patients in that they sensed the therapist believed in the efficacy of the treatment, which gave them the confidence to stick with it and engage in homework assignments as directed.

Another lesson learned to carry forward to the RCT was the importance of consistency and routine measurement of alcohol use and PTSD symptoms at the start of weekly appointments. The data collected allowed therapists and patients to track treatment progress and identify areas in need of more support (i.e., when alcohol use increased after exposure treatment engagement). It was also noted the personalized, visual feedback was impactful

in helping patients characterize their drinking in a way not previously considered. SME feedback was critical in streamlining the feedback report and helped to focus Session 1 on important topics tied to alcohol use reduction and direction towards change.

Participant feedback led to additional considerations in designing the implementation of the RCT. Regarding comments on the comfort of PC exam rooms, it was decided that the treatment needed to remain in the PC setting for the RCT, however, attention was paid to reducing outside noise and making the exam rooms more inviting. Participant feedback about incorporating family members into treatment was seen as a valid suggestion for future treatment development, but beyond the scope of the current PC-TIME research agenda. Based on patient feedback about being surprised about the content and repetition of exposure exercises, the manual was reviewed to ensure that content covered setting patient expectations for exposure activities and discussing self-care following exposure. Also, a resource sheet was used in the RCT to help connect participants to useful self-care resource and crisis numbers.

4.1. Limitations

Limitations to this study are evident and warrant mention. Among them, the small sample size for the open trial limits our ability to make conclusive statements about treatment feasibility or satisfaction. Further, because we lacked interview data for individuals who did not complete treatment, we are unable to comment directly on which, if any, aspects of the treatment may have directly influenced dropout. At best, we can hypothesize potential explanations as perhaps these patients did not feel as motivated to reduce PTSD or alcohol use. Further, these patients may have failed to experience early change and/or perceived treatment was too difficult or time intensive. Finally, based on the timing of the exit interview (i.e., all were done at the end of treatment), feedback is considered retrospective (Sekhon et al., 2017). Feedback might have been different if interviews had been prospective (prior to intervention) or concurrent (in the midst of intervention). Given that many patients commented on changing reactions (e.g., things started hard but got easier), lessons learned may have impacted potential changes or adaptations to PC-TIME during the open trial.

4.2. Conclusions

When considering the overall findings from treatment development to an initial open trial with Veteran patients, five 30-minute sessions was identified as both feasible and acceptable. Patients generally reported this treatment option as a “good” one, especially for patients who are looking to make changes or reduce their PTSD symptoms. While patients did report challenges as a part of completing exposure homework and in-vivo experiences, they also reported seeing how it was working and noting improvements encouraged them to stick with it. Similarly, patients reported immediate changes in drinking that was measurable and noticeable, which offered continued interest in treatment. While some challenges were experienced in maintaining a 30-minute structure, patients suggested the timing was reasonable and felt supported and helped during each session. The flexibility in allowing for a 6th session, which is customary in PCMHI, allowed patients to continue with their progress while preparing for transitions to future care in specialty mental health when indicated. Overall, patients were accepting of the approach used in PC-TIME and early outcomes

examining weekly data suggest a successful reduction in high-risk drinking and PTSD symptoms for most participants. Next steps include a pilot RCT followed by examination of within-process examination of behavior change for patients randomized to PC-TIME.

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Public Significance Statement:

This study found the development of the new, integrated intervention (PC-TIME) for heavy alcohol use and post-traumatic stress disorder for Veterans attending Primary Care is both an acceptable and promising approach to treating both simultaneously. Most Veterans participating in the open trial reduced drinking and experienced reduced PTSD symptoms, suggesting a larger efficacy trial is warranted.

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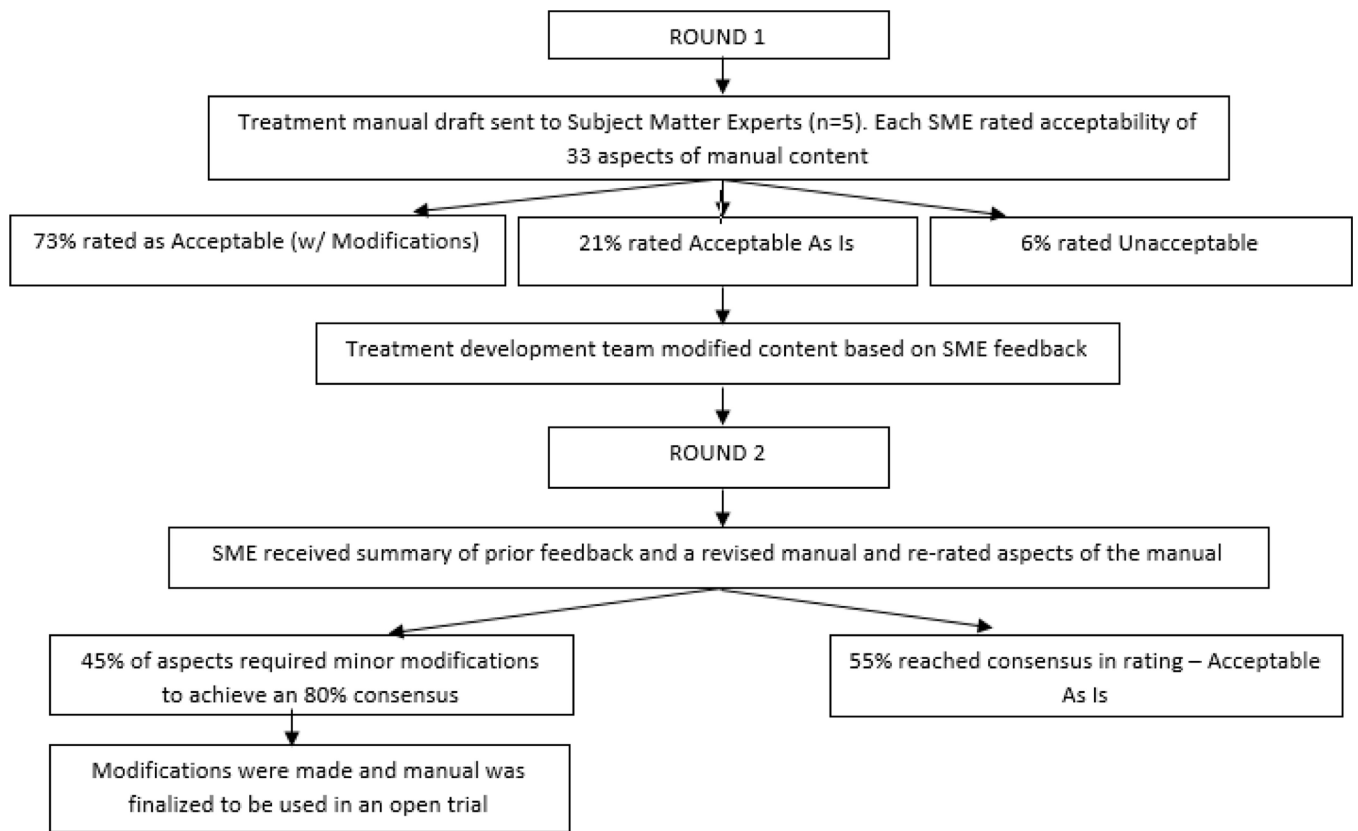


Figure 1.
Delphi Study Process and Summary Results

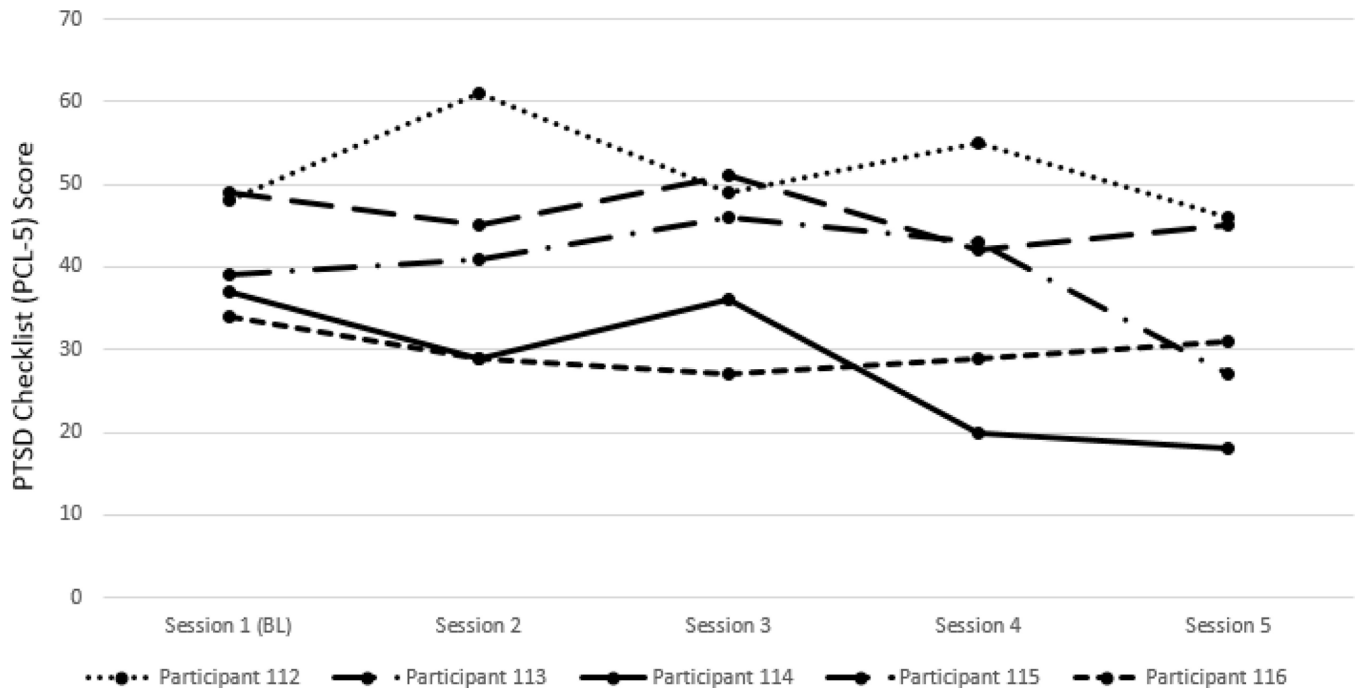


Figure 2.
Total PCL-5 Scores by Patient over PC-TIME Sessions 1–5

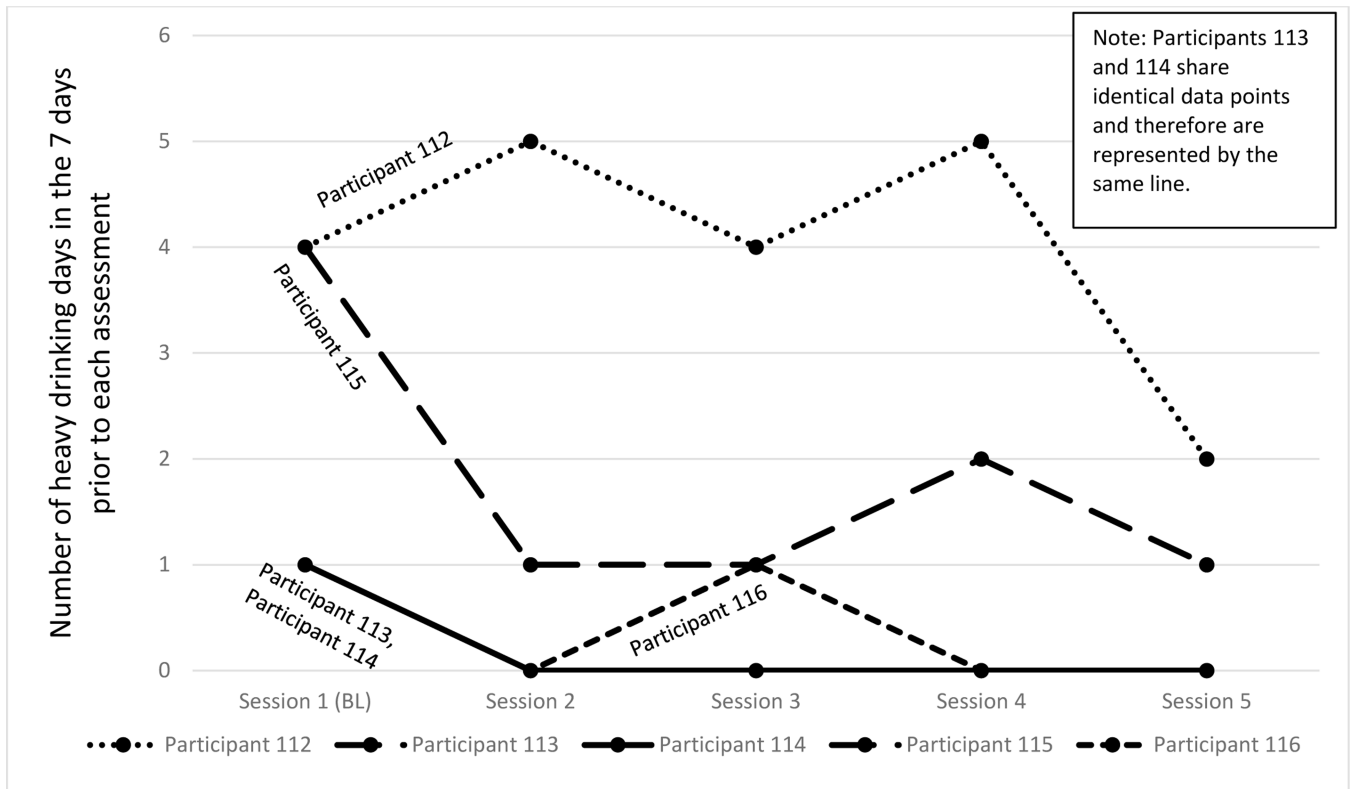


Figure 3.
Number of Heavy Drinking Days by Patient over PC-TIME Sessions 1–5

Table 1.

PC-TIME Manual Final Session Content

Session Content for PC-TIME		
Session 1	Session 2	Session 3 – 5
Motivational interviewing (MI to explore PTSD symptoms and alcohol use to help understand how they are connected and develop motivation to reduce (or cease) alcohol use	Facilitate approaching instead of avoiding trauma related content to experience reduction in negative emotions. Provide support around alcohol change plan.	Narrative exposure exercises to increase ability to handle negative affect and process meaning of the trauma. Follow up on drinking reduction goals or build motivation towards considering change.
Key aspects: • Open-ended exploration • Personalized feedback on alcohol use and PTSD symptoms • Discussion about PTSD symptoms and alcohol related consequences • Development of a change plan	Key aspects: • Identify Index trauma • Present exposure rationale • Describe at home narrative exposure • Plan homework implementation	Key Aspects: • Review homework experiences • Read homework out loud • Facilitate emotional processing • Use MI booster for alcohol use reduction as needed
Session Outline: 1. Open with structuring statement 2. Build Rapport 3. Build Motivation 4. Build Commitment to change 5. Identify goals 6. Create change plan	Session Outline: 1. Welcome/check-in on drinking 2. Memory Exposure Exercise 3. Summarize Session	Session Outline: 1. Monitor plan/recap of drinking change 2. Read and process narrative exposures 3. Discuss in vivo exposures 4. Feedback on progress On final contact: • Consolidate gains • Determine if specialty referral is needed • Assess barriers to care

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