

DEVELOPMENT OF A PERSONALIZED FEEDBACK INTERVENTION
TARGETING PAIN-RELATED ANXIETY FOR HAZARDOUS DRINKERS WITH
CHRONIC PAIN

by
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ABSTRACT

Objective: Hazardous alcohol use contributes to mental and physical health problems, disability, and may lead to an increased risk of premature death. Among individuals with chronic pain, the rate of hazardous alcohol use is elevated compared to the general population, yet, hazardous alcohol users with chronic pain remain an underserved group. There is a critical need to test alternative and complementary approaches to the implementation of effective interventions to reduce hazardous alcohol use among this high-risk segment of the general population; doing so in an integrated fashion may provide a more efficient and targeted intervention approach. Targeting pain-related anxiety, a transdiagnostic vulnerability factor that is prospectively associated with both hazardous drinking and chronic pain, may be beneficial. Thus, more work is needed to evaluate the benefit of targeting elevated pain-related anxiety among hazardous drinkers with chronic pain. **Method:** Our approach followed a staged model (1a/1b) consistent with NIH guidelines for developing and standardizing behavioral interventions. Phase IA involved collecting qualitative feedback from hazardous drinkers with chronic pain ($N = 9$; 77.8% female, $M_{age} = 33.86$, $sd = 8.75$) to refine intervention content and evaluate treatment acceptability and feasibility. For phase 1b, hazardous drinkers with chronic pain ($N=118$; 57.3% male, $M_{age} = 35.24$, $sd = 11.90$) participated in a pilot randomized clinical trial designed to compare pain-related anxiety/alcohol PFI (PA-PFI) to a health information control condition. assessment only among a sample of 130 hazardous drinkers with chronic pain. The primary aims focused on examining the effects of the PA-PFI on alcohol use, intention/motivation to reduce drinking, pain-

related anxiety, and expectancies for alcohol analgesia/pain coping. **Results:** Results indicated that participants reduced drinking and primary outcomes changed in the expected directions. However, there was no effect of treatment condition on the changes in outcomes. Mean differences were in the expected directions, but did not reach statistical significance. **Conclusion:** Current data provide preliminary evidence for the utility of computer-based brief interventions to encourage behavior change, and targeting pain-related anxiety in the context of chronic pain may impact drinking behavior. However, the effects were limited in magnitude, and future work in this domain is warranted.

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INTRODUCTION

Overview of Hazardous Drinking and Chronic Pain

Hazardous Drinking. Alcohol consumption engenders a significant burden in the United States (U.S.) and has been estimated to cost over \$250 billion in healthcare, lost wages, and criminal justice expenses each year (Blackwell et al., 2014; Sacks et al., 2015). Hazardous drinking is defined as a pattern of alcohol consumption that increases the risk for harmful consequences (WHO, 1994). Although not all hazardous drinkers meet the criteria for Alcohol Use Disorder (AUD), such drinking patterns increase the risk for AUD and are a significant public health concern (WHO, 1994). The Alcohol Use Disorders Identification Test (AUDIT), developed by the WHO, identifies hazardous patterns of alcohol use. Specifically, the AUDIT assesses consumption (e.g., frequency/quantity of drinking), dependence (e.g., impaired control over drinking), and consequences (e.g., alcohol-related injuries) over the last 30 days. AUDIT scores ≥ 8 for males and ≥ 7 for females are indicative of hazardous drinking (Cunningham et al., 2015; Palfai et al., 2011; Sinadinovic et al., 2014). Hazardous drinking is responsible for over 5% of worldwide deaths (World Health Organization, 2018) and is the 3rd leading cause of preventable death in the U.S. (CDC, 2013).

Chronic Pain. Pain motivates 50% of annual physician visits in the U.S. (Turk & Melzack, 2001) and is affected by biological, behavioral, cognitive-affective, and physiological-sensory processes (Gatchel et al., 2007). Pain also represents a significant public health burden, with an annual economic impact up to \$300 billion and lost productivity (Gaskin & Richard, 2012; Nahin, 2015). Chronic pain, defined as persistent pain of more than three months (Treede et al., 2015), affects over 100 million American

adults (Dahlhamer, 2018) and is associated with a number of deleterious consequences, including mental health and substance use problems.

Prevalence and Interrelations of Co-Occurring Pain, Drinking, and Opioids. Pain and hazardous drinking are highly co-occurring conditions (Brennan et al., 2005; Brennan & Soohoo, 2013; Institute of Medicine (U.S.) Committee on Advancing Pain Research, Care, and Education, 2011; Larson et al., 2007; McDermott et al., 2018; Zale et al., 2015). Co-occurring pain is substantially higher among hazardous drinkers compared to non-problem drinkers (Brennan et al., 2005), and one study found that nearly 75% of patients who identified alcohol as their drug of choice also reported moderate-to-severe past-month pain (Larson et al., 2007). Similarly, greater pain-related interference has been associated with a 33% increased risk of meeting criteria for past-year alcohol dependence (McDermott et al., 2018), and individuals who endorse chronic pain (vs. no pain) are two times more likely to also meet diagnostic criteria for alcohol dependence (Von Korff et al., 2005). Hazardous drinking and chronic pain share overlapping neural substrates, and repeated episodes of pain, alcohol intoxication, and/or withdrawal may result in pathological changes to neural structure and/or function (Egli et al., 2012; Harvey & Yee, 2013; Schunck et al., 2015).

Further complicating pain-alcohol relations, upwards of 20% of individuals with pain-related diagnoses are prescribed opioids (Daubresse et al., 2013). Moreover, although drinking alcohol is contraindicated in the context of prescription opioid use, 20% of individuals prescribed opioids consume alcohol and opioids in the same day (Peacock et al., 2016), and 12.4% of daily opioid users drink alcohol within 2 hours of taking their medication (Saunders et al., 2012), contributing to the overall exacerbation of pain.

Concurrent use of alcohol and opioids may also interfere with the treatment of chronic pain via disruption of pain signaling in the brain (Egli et al., 2012). Initial work has been conducted to increase awareness of opioid overdose risk behaviors among individuals who either present with an opioid use disorder (Carrà et al., 2017) or are prescribed opioids for pain management (Huhn et al., 2018). However, no treatments have been developed to educate chronic pain patients on the risks of concurrent alcohol and prescription opioid use, despite the prevalence and consequences of co-use (Witkiewitz & Vowles, 2018).

Pain-Alcohol Bi-directional Relations

Pain Motivates Alcohol Consumption and Expectancies for Pain Coping/Reduction via Drinking. Pain can increase motivation to drink alcohol (Lawton & Simpson, 2009; Moskal et al., 2018; Sheu et al., 2008). Moreover, alcohol can confer acute analgesia (Gatch & Lal, 1999), and individuals with chronic pain report using alcohol to cope with pain (Goebel et al., 2011), particularly among individuals with long-term opioid use (Lee et al., 2011). Heavy drinkers who experience greater pain and pain-related negative affect during an attempt to reduce or abstain from drinking may return to heavy drinking, in part, to alleviate increased pain experience (Zale et al., 2016). Pain increases the likelihood of post-intervention alcohol consumption and drinking lapse among persons with AUD (Witkiewitz et al., 2015). Yet, while alcohol may confer acute analgesia, recent work suggests that prolonged alcohol use in the context of pain is associated with hyperalgesia and more severe intractable pain (Fu et al., 2015).

Hazardous Alcohol Use Effects on Pain. Hazardous alcohol use may precipitate, exacerbate, and maintain the experience of pain (Apkarian et al., 2013; Egli et al., 2012). Specifically, alcohol-induced neuropathy is a chronically painful condition that develops

from excessive hazardous alcohol use (Chopra & Tiwari, 2012). Further, stress has been found to mediate the associations between hazardous alcohol consumption and pain (Dina et al., 2008), indicating that psychological mechanisms may account for these relations. Thus, hazardous drinkers who reduce their consumption of alcohol may experience clinically meaningful reductions in psychological aspects of pain (Egli et al., 2012).

Brief Interventions

Need for a Brief Motivational Alcohol Intervention for Individuals with Chronic Pain. According to NIAAA, "brief interventions are gaining favor as a means of addressing the problems associated with hazardous and harmful drinking" (Moyer & Finney, 2004). Some studies suggest that brief interventions have demonstrated utility and cost-effectiveness in reducing hazardous alcohol consumption across a variety of settings, including those conducive to "teachable moments" when patients are especially open to changing their alcohol use behavior (Riper et al., 2009). Yet there is mixed evidence as to the efficacy of brief interventions for substance and alcohol use, particularly among those with more severe drinking and substance use patterns (Saitz, 2010; Saitz et al., 2014; Saitz, Palfai, Cheng, et al., 2007; Saitz, Palfai, Freedner, et al., 2007). Therefore, there is merit in further investigating how to improve the efficacy of brief interventions for vulnerable populations, including individuals with chronic pain.

Brief, Single Session, Computer-based Personalized Feedback Interventions (PFIs). PFIs hold great promise for addressing pain and hazardous drinking in an integrated fashion. PFIs motivate behavior change via psychoeducation and personalized (e.g., profiles of current health behaviors, assessment of risk severity) and normative feedback (i.e., comparisons to relevant sociodemographic groups (Bandura, 1994; Miller &

Rollnick, 2002)). According to Social Norms Theory (Lewis & Neighbors, 2006; Werch et al., 2000), perceptions of how peers think and act can influence behavior. Thus, normative comparisons are hypothesized to alter behavior by correcting misperceptions and highlighting discrepancies. PFIs have been developed to promote behavior change for a variety of conditions, including polysubstance use (Rooke et al., 2010). PFIs are often administered in a computer-based format, given that they are portable, readily adaptable, easy to implement, and can be delivered to a large number of patients (including those with limited access to health care) by non-specialized providers, thereby reducing patient/provider burden (Cadigan et al., 2015; Cunningham, 2007). Meta-analytic evidence indicates that brief single-session PFIs consistently produce small-to-moderate-sized effects in terms of stimulating health behavior change (Noar et al., 2007) and enhancing health-related outcomes (Lustria et al., 2013). A meta-analysis comparing in-person vs. computer-delivered PFIs for alcohol observed no differences between delivery modalities at up to 4 months post-treatment (Cadigan et al., 2015). Given their potential for broad reach/dissemination (relative to in-person treatments), even small-to-moderate-sized effects of single-session PFIs can yield significant impact at the population level.

Pain-Alcohol PFI's. PFIs for pain have encompassed various computer-based formats (e.g., web programs, smartphone apps) and targeted primary (e.g., pain intensity) and secondary outcomes (e.g., physical/emotional functioning in the context of pain). PFIs for pain have successfully been implemented among patients with chronic pain (Dekker-van Weering et al., 2012, 2015; Kristjánsdóttir et al., 2013; Naylor et al., 2008), and have been shown to improve pain outcomes (Kristjánsdóttir et al., 2013; Nes et al., 2017; Rod, 2016), and increase patient-provider communications (Sciamanna et al., 2006).

Additionally, PFIs for alcohol typically aim to reduce hazardous drinking and progression/maintenance of AUD by providing personalized feedback regarding current alcohol consumption (e.g., frequency of drinking, binge drinking) and comparison of current drinking behavior to normative groups (Bandura, 1994; Miller & Rollnick, 2002). Meta-analytic evidence indicates efficacy for PFIs reducing frequency of drinking (Riper et al., 2011) by primarily targeting descriptive norms, protective behavioral strategies, alcohol outcome expectancies, self-efficacy for quitting, and emotions/mental health (Reid & Carey, 2015). A previous critical review indicates that computer-based PFIs can reduce alcohol consumption, alcohol-related problems (Boon et al., 2011; Cunningham et al., 2009) and increase planning/motivation to reduce drinking among hazardous drinkers (Kuerbis et al., 2017).

Need for Integrated Pain-Alcohol PFI. Despite the high prevalence/substantial impact of co-occurring chronic pain and hazardous drinking, and emerging research documenting deleterious pain-alcohol interrelations (Zale et al., 2015), integrated treatments have yet to be developed (Powers et al., 2019). Brief computer-based PFIs are conducive to integrated treatment, as their structure/content can be easily and dynamically customized, and they can be administered across a variety of settings and platforms. An integrative approach to address the heterogeneity of chronic pain conditions that co-occur with hazardous drinking is to focus on transdiagnostic processes that may **underpin both** chronic pain conditions and hazardous drinking (Stewart & Conrod, 2008; Watt et al., 2008).

Mechanisms and Moderators: Pain-related Anxiety and Biological Sex. Negative reinforcement models of addiction motivation assert that self-administration of a

substance is contingent on the extent to which it serves to terminate or mitigate an aversive event (Baker et al., 2004). Given that alcohol produces acute analgesic effects (Woodrow & Eltherington, 1988), persons with chronic pain often cope with pain and pain-related distress by using alcohol (Thompson et al., 2017; Woodrow & Eltherington, 1988). Among the most prominent and clinically significant transdiagnostic constructs (as supported by the fear-avoidance model of pain (Slade et al., 1983; Vlaeyen & Linton, 2000, 2012)) is pain-related anxiety, a cognitive-affective factor reflecting the tendency to respond to pain or pain-related events with anxiety (McCracken et al., 1998; McCracken & Dhingra, 2002), which has been identified as an especially important psychological mechanism in the effects of pain on alcohol (Zale et al., 2015; Zale & Ditre, 2015). Pain-related anxiety has been identified as a risk and maintenance factor in the progression of chronic pain (Vlaeyen & Linton, 2000), as well as has been linked to increased substance use among adults with chronic pain (Rogers et al., 2021; Shepherd et al., 2021), including the co-use of alcohol and opioids (LaRowe et al., 2020). Among individuals with chronic pain, higher pain-related anxiety has also been associated with a tendency to over predict the intensity of pain (Turk & Wilson, 2010) and cope poorly with pain sensations (Samwel et al., 2006). Importantly, pain-related anxiety can be efficiently and clinically meaningfully reduced via intervention (de Jong et al., 2005; Vlaeyen et al., 2002; Vlaeyen et al., 2001; Watt et al., 2006; Woods & Asmundson, 2008), and treatments designed to decrease pain-related anxiety have been shown to improve pain tolerance and reduce disability among persons with chronic pain (Darnall et al., 2014). Theoretically, addressing pain-related anxiety-alcohol relations may increase motivation to change because: (a) hazardous drinkers may perceive themselves as susceptible to the adverse

pain-related effects of alcohol, (b) pain-related anxiety is likely to be perceived as a severe health outcome, and (c) hazardous drinkers may come to understand the pain-related anxiety benefits of reduced drinking.

There is also a significant body of work that indicates sex differences in both the manifestation and treatment of alcohol-related problems. Specifically, research indicates that while males may report higher levels of alcohol misuse, females typically report greater rates of alcohol-related problems (Ceylan-Isik et al., 2010). These differences are clinically relevant and have been attributed to neurobiological and hormonal differences between males and females (Pfefferbaum et al., 2001; Witt, 2007). Additionally, a small body of work focused on sex differences for substance use interventions found that females improved more than males in a brief intervention for alcohol use (Reinhardt et al., 2008). Although no work has examined sex differences for PFIs for alcohol misuse *and pain*, work examining sex differences in a personalized feedback intervention for cannabis use also found that females benefited more than males (Walukevich-Dienst et al., 2019).

Present Study: Aim and Hypothesis

Aim 1. Pilot Study Phase IA: Develop a brief, single-session, integrated, computer-based pain-alcohol personalized feedback intervention (PA-PFI) designed to (1) enhance knowledge regarding adverse pain-related anxiety-alcohol interrelations; and (2) increase motivation and intention to reduce hazardous drinking. This phase will focus on the development and iterative refinement of the PFI, using qualitative data collected from individuals reporting hazardous drinkers with comorbid chronic pain.

Aim 2. Phase IB.: Conduct a pilot randomized-controlled trial testing the effects of PA-PFI (vs. health information control) on motivation/intention to reduce drinking and expectancies for pain management via drinking among hazardous drinkers with chronic pain.

Hypotheses: At post-test, participants randomized to PA-PFI (vs. health information control) will report:

H_{1A}: greater motivation/intention to reduce (i.e., to non-hazardous) drinking.

H_{1B}: lesser positive expectancies for pain-coping/reduction via drinking and greater knowledge regarding adverse pain-alcohol-opioid interrelations.

Hypotheses: At two weeks and 1-month follow-up, participants randomized to PA-PFI (vs. health information control) will evince:

H_{2A}: a reduction in the number of drinks consumed (at week 2 and 1 month – using timeline follow back).

H_{2b}: reduced pain-related anxiety (at week 2 and 1 month).

Aim 3. Explore change in motivation (H_{1A}), and pain-related anxiety (H_{2b}) as mediators, and sex as a moderator of 1-month follow-ups.

H_{3A}: Effects of PA-PFI (vs. health information control) on 2 week and 1-month follow-up outcomes will be mediated by the following follow-up outcomes: (1) motivation/intention to reduce drinking, (2) expectancies for pain-coping/reduction via drinking, and (3) reductions in pain-related anxiety (for H_{2A}), and moderated by (1) sex.

PILOT STUDY (PHASE 1A)

METHOD

Participants

The sample consisted of 9 (77.8% female, $M_{age} = 33.86$, $sd = 8.75$) hazardous drinkers with chronic pain. Eligibility criteria for the study include 1) ≥ 21 years of age, 2) current hazardous drinking pattern evinced by elevated AUDIT score (≥ 8 for males and ≥ 7 for females), 3) current chronic pain (4 or more days per week of pain, rated at a severity of 3/10 or greater, for at least three months), and fluency in English. Exclusion criteria include 1) concurrent substance or alcohol use treatment, 2) psychotic/thought disorder, and 3) imminent risk of suicidality.

The sample was approximately half (44.4%) White, 44.4% Black, and 11.1% other, with 66.7% of participants reporting that they were not Hispanic or Latino. In terms of education, 44.4% of participants reported graduating college or graduate school, 44.4% reported completing some college, and 11% reported graduating high school. All of the sample reported current employment, with 44.4% reported a managerial/professional role, 33.3% reported a skilled labor role, and 22.2% reporting an administrative/clerical role, and income levels for the sample were variable, with 33.3% reporting income below \$34,999 per year, 33.3% reporting income between \$35,000 and \$49,999, and 33.3% reporting income greater than \$50,000.

Participants reported an average AUDIT score of 15.71 ($sd = 6.26$) and reported drinking an average of 3.11 ($sd = 2.80$) standard drinks per occasion, a maximum of 7.22 ($sd = 3.56$) standard drinks per occasion, with an average of 3.78 ($sd = 2.91$) drinking days per week. In terms of non-alcohol substance use, 11.1% of participants reported taking a prescription opioid for pain, 11.1% of participants reported using amphetamines, 11.1% reported currently using tobacco, and 44.4% reported using cannabis. One participant reported experiencing substance-related problems for 2 days over the past 30 days.

In terms of pain, participants reported experiencing chronic pain for an average of 5.57 ($sd = 0.98$) days per week at an average intensity of 6.86 ($sd = 2.04$)/10, for an average of 4 years and 8 months ($sd = 5$ years 7 months). Validated measures of pain (PROMIS) indicate a pain intensity T score of 63.00, and a pain interference T score of 61.40, indicating higher levels of pain intensity and interference than average, consistent with chronic pain samples (Amtmann et al., 2010; Cook et al., 2016).

Procedures

Participants were recruited via community posting and online advertising. Interested individuals called or emailed the laboratory and completed an online initial screener assessing basic eligibility criteria. Individuals eligible following the screener were scheduled for a single in person or virtual baseline appointment in which full eligibility criteria were evaluated. The baseline appointment included a 20-minute interview assessment, 20-minute pre-intervention survey, 30-minute intervention, 15-minute post-intervention survey, and 20-minute exit interview. During the initial interview, research staff assessed for eligibility by verifying chronic pain status and hazardous alcohol use, and conducted an assessment to capture past month drinking and other substance use behavior. Self-report measures were administered at pre- and post-intervention assessments.

Upon arrival for the baseline appointment, a trained researcher obtained informed consent and administered the interview assessment, evaluating eligibility criteria. For those participants who did not meet eligibility criteria, they were provided resources in the community for treatment options. Eligible participants then completed the online portion of the study, which included the pre-intervention survey, the intervention, and the post-

intervention survey. These participants were given a preliminary version of the PFI and completed a brief, 20-minute semi-structure interview in which participants provided feedback on how to improve the PFI. Research staff followed an outline of open-ended questions to conduct the interview, and Motivational Interviewing (Hettema et al., 2005; W. R. Miller & Rollnick, 2002) techniques were employed to facilitate feedback from participants. Following the first 5 participants, the PFI was modified based on feedback, and the final 4 participants provided feedback on the amended version. Following the final 4 participants, the PFI was modified based on participant feedback, and this version was the final version included in the randomized controlled trial. Interviewers were the PI and research assistants trained in motivational interviewing with experiencing administering semi-structured interviews, and all interviews conducted mock interviews with supervision prior to administering interviews for the study. Notes were written during the interview and the session was also audio-recorded. Following the interview, participants received \$40 for their time.

Personalized Feedback Intervention

The PFI was modeled from past work in alcohol-specific research, as well as using elements from pain-related treatments. The PFI content was informed and reviewed by leading experts in substance use and PFI development. Specifically, content for the alcohol portion of the PFI was informed by past PFI work (Miller et al., 2013), and included elements that had strong or promising research support for alcohol-specific behavior change (Reid & Carey, 2015), including descriptive norms of alcohol use (including quantity and frequency data, as well as blood alcohol content (BAC) data), protective behavioral strategies, and alcohol outcome expectancies. Pain content focused

both on providing psychoeducation about the relationship between pain and alcohol (Zale et al., 2015), as well as psychoeducation about interactions between alcohol and pain medications, particularly opioids (Witkiewitz & Vowles, 2018). Finally, psychoeducation about the role of pain-related anxiety, as well as self-driven therapeutic activities and exercises, including a mindful breathing exercise (Guan et al., 2021; Zeidan & Vago, 2016), and a graded pain exposure exercise (Leonhardt et al., 2017; Vlaeyen et al., 2002) designed to directly target pain-related anxiety. The PFI was interactive and included videos and moving pictures throughout, as well as activities where participants would answer questions about the material that was presented need to practice a mindfulness exercise and create a pain-related anxiety exposure hierarchy. Personalized feedback was based on data collected during the pre-intervention online survey.

Interview Outline

Semi-structured interviews were conducted using an outline to solicit information from participants. Three main topic areas were covered: 1) the general presentation of the PFI and thoughts on using brief, online interventions to reduce drinking, 2) thoughts on alcohol related information and interventions, and 3) thoughts on pain-related information and interventions. The semi-structured interview outline was developed based on past semi-structured interviews using in PFI development (Garey et al., 2021), and engaged participants to collect qualitative data to guide PFI refinement. The outcome was informed by motivational interviewed, relied on open-ended questions, and provided opportunities for interviews to flexibly engage with participants while collecting data. Sample items included: “What is your view on using a computer-based treatment to help you reduce or stop drinking?”, “What were some things that we didn’t include in the feedback that you

feel would motivate you to change your drinking habits?”, and “What are some things we can do to make the pain and pain-related anxiety portion clearer or easier to understand?”. Interviews were instructed to use the outline as a rubric for the interview, but were not required to follow the guide verbatim, which is consistent with the fundamentals of conducting qualitative interviews (Catterall & Maclaran, 1997).

Measures

Demographic Variables. Participants reported on their age, sex, race, ethnic identity, education, employment, marital status, and income. Additionally, participants completed the Brief Symptom Inventory (Derogatis & Melisaratos, 1983) to assess for thought disorder and imminent risk of suicidality.

Drinking History. Drinking history was assessed with the Lifetime Drinking History form (Skinner, 1984), a valid and reliable measure of alcohol use (Koenig et al., 2009) that assesses lifetime alcohol use, past year alcohol use, initiation of alcohol use, and family history. Additionally, the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993a) was used to evaluate hazardous drinking with scores of 8 or greater (7 or greater for females) indicating hazardous alcohol use; it is a valid, efficient measure used across settings with excellent sensitivity to detect potentially hazardous drinkers (de Meneses-Gaya et al., 2009; Paulus et al., 2023).

Chronic Pain. Following NIH chronic pain Research Task Force standards (Deyo et al., 2014), we will utilize the Patient-Reported Outcomes Measurement Information System (PROMIS) (Stone et al., 2016) to assess both pain intensity and pain interference. The PROMISE pain intensity and pain interference items are summed and converted to a T-score for comparison with a normative population. For the current study, and in line

with medical standards, chronic pain was defined as four or more days per week of pain, rated at a severity of 3/10 or greater, for at least three months.

Non-alcohol substance use. In line with recommendations from the CDC (Dowell et al., 2016), opioids use was assessed by asking participants to self-report name and dose (morphine equivalent dose; Svendsen et al., 2011). Other non-alcohol substance was assessed using the Addiction Severity Index Self-Report (McLellan et al., 1992), one of the most widely used measures in the area of substance use (Deane et al., 2013), which assessed use of illicit substances, as well as problems associated with substance use, treatment received, family history, and legal problems related to substance use. It has demonstrated adequate reliability and validity in past work (Leonhard et al., 2000; Mäkelä, 2004) and assesses past-month substance use.

Data Analytic Strategy

A qualitative approach was employed to illicit feedback for how to improve the PFI. Qualitative data analysis were guided by the Systematic and Reflexive Interviewing and Reporting (SRIR) method (Loubere, 2017). The interviewer and lead author listened to each audio-recording individually and outlined important topic areas discussed during the interview. The interviewer and lead author then engaged in a reflexive dialogue session to discuss their impressions of the interview and emerging topic areas. Audio-recordings were played during the reflexive dialogue session and notes written during the interview were reviewed. Themes that emerged across several interviewers were discussed and documented. Audio-transcriptions were not used as part of the qualitative data analysis because of the widely recognized potential for loss of meaning and interpretation bias inherent to transcribed audio-files (Markle et al., 2011). Finally, the PFI was refined based

on data collected during the pilot study and expert opinion.

RESULTS

Interview Analysis

All nine participants included in the qualitative interviews had viable audio recordings and were all discussed in the interview analysis. The first group of participants included the first five individuals, and the second group of participants included four individuals.

Regarding the general presentation, most participants reported the initial version of the feedback to be long and wordy and overall wanted more graphics and interactive elements rather than text. Specific to the alcohol content, in general, participants reported the alcohol, alcohol-pain, and alcohol-opioid content to be engaging, and increased their knowledge in these domains. Participants also reported enjoying the information about the protective behavioral strategies. Some participants indicated that the focus of the PFI appeared to be centered on stopping drinking, and many would have preferred language and content related to reducing drinking. Additionally, since using opioids was not required to enroll in the study, some participants did not find the way the information was presented was relevant to their situation. Regarding the pain content, participants found the pain content to be relevant, but wanted more instruction on how to conduct graded pain exposure on their own following the PFI. Additionally, one participant indicated that tailoring feedback to specific pain location would be helpful. Because the information on pain-related anxiety and its relation to alcohol was novel to most participants, little feedback was provided on how to improve this portion of the PFI. Participants overall reported that the information was clearly presented and that the exercises were modeled clearly, although some participants reported that they were less likely or unlikely to use

the exercises outside of the intervention.

PFI Refinement

Guided by the collected qualitative data, the PFI was refined twice, once following the first five participants, and again following the final four participants. Specifically, the amount of text was reduced and additional graphics and interactive elements were added. Additionally, the opioid content was modified to provide general, rather than specific information about the interaction of alcohol and opioids, given that not all participants were taking opioids. Additional information was added to provide instructions for using the pain-anxiety reducing exercises at home. Additionally, all wording was simplified to an 8th grade reading level, and the refined PFI was strategically testing in a randomized controlled trial.

RANDOMIZED CONTROLLED TRIAL

METHOD

Participants

Participants were n=118 (57.3% male, $M_{age} = 35.24$, $sd = 11.90$) were hazardous drinkers with chronic pain recruited from the community to participate in a randomized controlled trial testing the efficacy of a computer-delivered treatment to reduce alcohol use in the context of pain. Eligibility criteria for the study include 1) ≥ 21 years of age, 2) current hazardous drinking pattern evinced by elevated AUDIT score (≥ 8 for males and ≥ 7 for females), 3) current chronic pain (4 or more days per week of pain, rated at a severity of 3/10 or greater, for at least three months), and fluency in English. Exclusion criteria include 1) concurrent substance or alcohol use treatment, 2) psychotic/thought disorder, and 3) imminent risk of suicidality. See Figure 1 for consort.

The sample reported the following race/ethnicities: 44.4% White, 51.3% Black, 1.7% Asian, 0.9% Native Hawaiian or Pacific Islander, 1.7% other, and 11.1% of the sample reported Hispanic ethnicity. Approximately half (47.9%) of the sample reported being currently single, 32.5% married, 12.0% living with a partner, and 7.7% divorced, separated, or widowed. Over half (70.9%) of the sample reported graduating college or graduate school, 13.7% reported completing some college, 14.5% graduated high school, and 0.9% completed some high school. In terms of current employment, 57.3% reported full time employment, 28.2% reported part time employment, 7.7% reported other employment status, and 6.8% reported being dependent on another person or a recipient of public or private assistance. Approximately 25% of the sample reported physical illness as a limitation for employment.

In terms of alcohol use, participants reported an average AUDIT score of 23.60 ($sd = 8.73$) indicating a high level of hazardous drinking, and reported an average of 5.67 ($sd = 5.04$) daily drinks over a period of 4.26 ($sd = 3.41$) hours. For all participants, between baseline and 2-week follow up, participants reporting drinking an average of 0.38 ($sd = 3.38$) fewer drinks per day, reported drinking an average of 0.40 ($sd = 2.43$) fewer drinks per day between 2-week and 4-week follow up, and reported drinking an average of 0.95 ($sd = 5.18$) fewer drinks per day from baseline to 4-week follow up. Approximately half (47.9%) of the sample reported currently taking opioids for pain, and in terms of other past 30-day substance use, 6.8% reported using heroin, 9.5% reported using methadone (not prescribed), 33.3% other opioids, 6.0% barbiturates, 14.5% sedatives, 11.2% cocaine, 9.4% amphetamines, 44.4% cannabis, 43.2% tobacco, and 8.6% hallucinogens.

In terms of pain experience, participants reported experiencing pain for an average of 5.81 ($sd = 1.21$) days per week, at an intensity of 7.44 ($sd = 1.61$)/10, for a total of 3 years and 9 months in duration ($sd = 7$ years and 2 months). Participants indicated the following locations for their pain (some participants selected more than one location): 8.5% head/neck, 14.4% shoulders, 8.5% chest, 12.7% pelvis/hips/groin, 15.3% right leg, 17.8% left leg, 10.2% ankles/feet, 11.0% right arm/hand, 11.9% left arm/hand, 36.4% upper back, 26.3% lower back, and 18.6% back of legs. Mean PASS-20 score for the sample was 67.58 ($sd = 15.25$).

Study Design and Procedures

This randomized controlled trial employed a longitudinal experimental design and involved three appointments following the online screener: 1) baseline appointment consisting of a pre-intervention assessment, one session computer-delivered intervention (PFI vs. health information control), and a post-intervention assessment, 2) a 2-week post baseline follow up, and 3) a 4-week post-baseline follow-up. Participants were recruited via community posting and online sites (e.g. craigslist, ResearchMatch). Interested participants completed the online screener and provided their contact information. Eligible participants who were willing to participate were scheduled for a baseline appointment and provided with a personalized survey link, wherein full eligibility was confirmed. Given the online nature of the study, a number of validation metrics were included to ensure that participants were providing truthful information. Specifically, along with eligibility criteria as highlighted previously, all responses from the baseline survey were required to match the information provided on the screener, including information about alcohol use, chronic pain status, contact information, as

well as location (I.P. address verified). Participants who were eligible based on the study criteria but did not pass the validation checks were not eligible to continue the study.

At the beginning of the baseline appointment, a trained researcher obtained informed consent from each participant and verified eligibility criteria and completed a brief interview assessment. Then the participant was provided with a unique link for the study, where they would complete the pre-intervention self-report assessment.

Participants who continued to meet eligibility criteria were randomized (1:1) to either 1) the PFI or 2) health information control. After completing the assigned intervention, participants completed a post-intervention questionnaire, and were scheduled for their 2-week and 4-week follow up appointments. The follow up appointments consisted of an online survey, sent via personalized link, and lasted approximately 20 minutes.

Participants were compensated \$30 for completing the baseline appointment, \$10 for completing the 2-week follow up appointment, and \$20 for completing the 4-week follow up appointment.

Interventions

Personalized Feedback Intervention. The refined PFI described in the pilot study above was tested in the randomized controlled trial. Briefly, the PFI included personalized feedback on alcohol use quantity and frequency for individuals with chronic pain, information about BAC and time until BAC returns to 0, protective behavioral strategies, and outcome expectancies. The PFI also provided novel psychoeducation on the relationship between pain-alcohol, pain-alcohol-opioids, and pain-related anxiety, and provided strategies to reduce pain-related anxiety. Similar to

the pilot study, information provided in the pre-intervention survey was used to create the personalized feedback content. The PFI required approximately 30 minutes to complete.

Health Information Control. Participants randomized to the health information control group were not provided any content on alcohol or pain, rather they were provided general health information. As an example, they were provided information on diet, dental hygiene, and sleep, and similar to the PFI, were provided with interactive elements regarding the information provided. No personalized feedback or pain-related anxiety information was presented as part of the control. The control required approximately 20 minutes to complete.

Measures

Demographic Variables. Participants completed the same demographic questionnaire as presented previously, as well as the Brief Symptom Inventory (Derogatis & Melisaratos, 1983).

Drinking History. Drinking history was assessed as described previously in the pilot study.

Chronic Pain. As reported earlier in the pilot study, and following NIH chronic pain Research Task Force standards (Deyo et al., 2014), participants completed the Patient-Reported Outcomes Measurement Information System (PROMIS) assessing pain intensity and pain interference (Stone et al., 2016). The Brief Pain Inventory has shown strong reliability and validity among pain samples (Kapstad et al., 2010).

Non-alcohol substance use. In line with recommendations from the CDC (Dowell et al., 2016), participants provided information on opioid name and dose (morphine

equivalent dose; Svendsen et al., 2011). Non-alcohol substance use was assessed using the Addiction Severity Index Self-Report (McLellan et al., 1992), one of the most widely used measures in the area of substance use (Deane et al., 2013). It has demonstrated adequate reliability and validity in past work (Leonhard et al., 2000; Mäkelä, 2004) and assessed past-month substance use.

Motivation to Reduce Drinking. Motivation to reduce drinking was assessed with a visual analog contemplation ladder that is rooted in the stages of change (Prochaska et al., 1992) and provides a single continuous metric of motivation and readiness to reduce drinking (Hogue et al., 2010; Slavet et al., 2006). Specifically, it assesses degree of importance, confidence, and readiness to stop drinking, summed to a total score. It has demonstrated evidence of reliability/validity (Harris et al., 2008) and has been shown to correlate with multidimensional stages of change of intention to use alcohol (LaBrie et al., 2005). Motivation to reduce drinking was included primary post-intervention assessment outcome, as well as at 2-week and 4-week follow up as a potential mediator.

Intention to Reduce Drinking. This measure includes three items that assess intention to drink over the next 30 days (i.e., I plan to - I intend to - I want to - drink alcohol in the next month; baseline, post-test, 2 week, 1month)(Glanton & Wulfert, 2013). Items are rated on a 5-point Likert scale ranging from “definitely do NOT intend” to “definitely DO intend”, with higher scores indicating greater intent, and are summed to create a total score. The intention to drink measure has demonstrated excellent reliability in past work (Glanton & Wulfert, 2013), as well as in the current sample ($\alpha = 0.97$). Intention to reduce drinking was included as a primary post-intervention outcome, as well as at 2-week and 4-week follow up as a potential mediator.

Expectancies for Alcohol Coping. Expectations for pain coping/reduction via drinking will be assessed using the measure of Expectancies for Alcohol Analgesia (EAA; LaRowe et al., 2021), which consists of five face-valid items (e.g., Drinking alcohol would ease my pain) that are rated on a scale ranging from 0 (completely unlikely) to 9 (completely likely) that are summed to create a total score. The EAA was included as a primary post-intervention outcome, and included at 2-week and 4-week follow up as a potential mediator.

Pain-Related Anxiety. Pain-related anxiety was assessed using the short form of the Pain Anxiety Symptoms Scale (PASS-20; McCracken & Dhingra, 2002) is a 20-item self-report scale assessing anxiety symptoms in response to pain on a 6-point Likert scale ranging from 0 (*Never*) to 5 (*Always*). The scale yields a total score, which has established strong psychometric properties (Roelofs et al., 2004) and measurement invariance (Rogers et al., 2020). In the current study, pain-related anxiety was a primary outcome at 2-week and 4-week follow up, as well as a proposed mediator of treatment change of 4-week follow up.

Alcohol-Opioid Co-Use Attitudes/Intentions (AOAI). The AOAI consists of ten items (adapted from a measure of smoking attitudes) that assess the level of agreement with attitudes towards drinking alcohol while taking prescription opioids (ranging from 1 strongly disagree to 5 strongly agree; Haddad & Malak, 2002), and summed to create a total score. The AOAI will serve as a primary post-intervention outcome.

Data Analytic Strategy

Baseline demographics, drinking, and pain variables were compared across groups, and correlations among baseline variables was examined. Variables that differed

across PA-PFI and health information control participants were included as covariates in analyses. Multiple regression models were conducted to evaluate the effects of treatment (0 = control, 1 = PA-PFI) on intention to reduce drinking, motivation to reduce drinking, expectancies for alcohol analgesia/pain coping, and knowledge of adverse pain-alcohol-opioid interrelations. Additionally, multiple regression analyses were conducted to examine difference in daily average drinks consumed at each time point. Difference between baseline and 2-week follow up (skewness = 3.62, kurtosis = 38.46), and 2-week follow up and 4-week follow up (skewness = 1.28, kurtosis = 14.78) were outside the range of normal; visual inspection of the data identified 3 outliers for each variable. Identified outliers were replaced with next highest value, after which the variables were within the range of normal (baseline-2week: skewness = 1.13, kurtosis = 2.45; 2week-4week: skewness = -0.09, kurtosis = 2.25).

Latent growth models (LGM) were used to model linear trajectories of change in outcomes and evaluate the impact of treatment (PA-PFI vs. health information control) on outcomes (number of drinks consumed, pain-related anxiety, intention and motivation to reduce drinking, and expectancies for alcohol analgesia) from baseline to 4-week follow up. Treatment condition (0 = control, 1 = PA-PFI) was included as a predictor of the intercept and slope parameters in the conditional model. All analyses were conducted with Mplus version 8 (Muthén & Muthén, 2017), and evaluation of LGM model fit was examined using and fit statistics, including the χ^2 based fit statistics, the comparative fit index (CFI), root mean square error of approximation (RMSEA), and the Tucker-Lewis Index (TLI). To better understand the potential reproducibility of our findings, conclusions were based on both statistical significance and the magnitude of associated

effect sizes (*Cohen's D*).

To assess the presence of potential mediators of treatment effects on outcomes, similar modeling procedures were used to test change in motivation/intention to reduce drinking, expectancies for pain-coping/reduction via drinking/great knowledge of alcohol-opioid relations and pain-related anxiety as mediators of drinking outcomes. After conducting univariate LGM to explore changes in the putative mediators as a function of treatment condition, we conducted a series of parallel process LGMs, correlating slope and intercept factors of the primary outcome and mediator, to examine how changes in the mechanisms relate to changes in primary follow-up outcomes (at 2 week and 4 week follow up). The effects of changes in the mechanisms of change on the outcomes were examined by specifying the slope factor for each potential mechanism as a predictor of the slope factor for each outcome. The indirect effects of condition on outcomes via the hypothesized mechanisms was evaluated by bootstrapped confidence intervals using the MODEL indirect command in MPlus. Further, given the purported interaction effect of sex, a dummy coded variable (0=female, 1=male) was included as an additional predictor of slope in the LGM parallel process model.

RESULTS

Screening, Randomization, and Attrition. One thousand, two hundred, and 8 individuals completed the online pre-screening survey. Of those individuals, 306 were found to be eligible and provided the opportunity to participate in the baseline assessment. One hundred and sixty-two individuals attended/completed the baseline appointment, and after assessing eligibility, 118 individuals were found eligible for the current study (see Figure 1 for consort). Participants eligible and ineligible for the larger study did not differ

on age ($t(113) = -0.86, p = .39$), sex ($\chi^2(1) = 0.13, p = .72$), nor income ($\chi^2(5) = 11.32, p = .18$). A significant association between eligibility status, ethnicity ($\chi^2(1) = 10.31, p = .001$), and race ($\chi^2(5) = 29.20, p < .001$) emerged, such that fewer individuals identifying as Hispanic/Latino who were screened were found ineligible, and that fewer individuals identifying as Black who were screened were found ineligible.

The final sample included 118 individuals with chronic pain reporting hazardous drinking, with 58 (50%) being randomized to PA-PFI and 58 (50%) being randomized to the health information control. Participants randomized to each study condition did not differ on sex ($\chi^2(1) = 1.09, p = .30$), race ($\chi^2(4) = 2.75, p = .60$), ethnicity ($\chi^2(1) = 2.07, p = .15$), income ($\chi^2(8) = 6.58, p = .58$), education ($\chi^2(4) = 2.28, p = .68$), or marital status ($\chi^2(5) = 2.51, p = .78$). Regarding drinking and pain variables, no differences emerged between those randomized to the PA-PFI and those in the health information control. Mean differences are presented in Table 1.

In terms of attrition, there were no differences between those randomized to the PA-PFI and the health-information control on drop out at the 2-week ($\chi^2(1) = 0.894, p = 0.34$) and 4-week ($\chi^2(1) = 0.00, p = .59$) follow up assessments. Additionally, examining baseline AUDIT scores as predictors of dropout, there was no significant association for the 2-week ($OR = 0.987, p = 0.649$) and 4-week ($OR = 0.984, p = 0.552$) follow up assessments.

Baseline Bivariate Correlations. See Table 2 for full correlation matrix. In general, AUDIT score was significantly correlated with intention to reduce drinking ($r = 0.29$), motivation to reduce drinking ($r = 0.36$), expectancies for alcohol analgesia ($r =$

0.29), and pain-related anxiety ($r = 0.41$). Additionally, PASS-20 total score was significantly correlated with age, and all alcohol and pain outcomes.

Post Intervention Outcomes. At post-intervention, there were no group significant group differences between those randomized to PA-PFI and health information control in intentions to reduce drinking ($b = 1.58$ (95% CI [-0.19, 3.35]), $se = 0.90$, $p = 0.08$, *Cohen's D* = -0.33) or motivation to reduce drinking ($b = 2.31$ (95% CI [-0.55, 5.16]), $se = 1.44$, $p = 0.11$, *Cohen's D* = -0.30), but means for the PA-PFI group were higher than the health information control group. Additionally, there were no group differences in knowledge regarding adverse pain-alcohol-opioid interrelations ($b = -0.91$ (95% CI [-3.77, 1.96]), $se = 1.44$, $p = 0.53$, *Cohen's D* = .12). However, there was a significant group difference in expectancies for alcohol analgesia ($b = -6.46$ (95% CI [-11.17, -1.76]), $se = 2.38$, $p = 0.008$, *Cohen's D* = 0.51), such that compared to the health information control, the PA-PFI group had lower expectancies for alcohol analgesia at post-intervention (see Table 3).

2-week and 4-week follow up outcomes. At 2-week follow up, there were no significant differences between those randomized to PA-PFI or health information control on past 2 weeks average number of drinks ($b = -0.25$ (95% CI [-1.45, 0.96]), $se = 0.60$, $p = 0.69$, *Cohen's D* = 0.09), with mean differences indicating those randomized to PA-PFI reported drinking fewer drinks at 2-week follow up. Further, there were no group differences between those randomized to PA-PFI and health information control on PASS-20 total score ($b = -2.61$ (95% CI [-11.01, 5.79]), $se = 4.23$, $p = 0.54$, *Cohen's D* = 0.13), with group mean differences indicating that those randomized to PA-PFI reported

lower mean PASS-20 scores than those randomized to health information control (see Table 1 and Table 3).

Similarly, for the 4-week follow up outcomes, there were no differences between those randomized to PA-PFI and health information control on past 2 weeks average number of drinks ($b = 0.02$ (95% CI [-1.33, 1.37]), $se = 0.68$, $p = 0.98$, *Cohen's D* = -0.01). Additionally, there were no group differences between 4-week PASS-20 total scores ($b = 0.28$ (95% CI [-8.37, 8.93]), $se = 4.36$, $p = 0.95$, *Cohen's D* = -0.13).

Univariate Latent Growth Curve Models. Univariate latent growth curve models were used to examine treatment by time interactions on drinking and proposed mediator outcomes. For average number of drinks, latent growth models showed excellent model fit ($\chi^2(1) = 0.01$, $p > 0.05$, RMSEA < 0.001, CFI = 1.00, TLI = 1.00) and found that drinking reduced from baseline to 4-week follow up ($b = -0.95$, $se = 0.48$, $p = 0.048$). Including randomization condition in the model showed there was no effect on treatment condition on longitudinal drinking outcomes ($b = 1.04$, $se = 1.11$, $p = 0.35$; see Table 4).

In terms of pain-related anxiety (PASS-20 total score), latent growth curve models showed excellent model fit ($\chi^2(2) = 0.18$, $p > 0.05$, RMSEA < 0.001, CFI = 1.00, TLI = 1.02), and results indicated that pain-related anxiety decreased longitudinally across the study ($b = -4.001$, $se = 0.90$, $p < 0.001$). After including treatment condition in the model, there was no significant effect on slope of PASS-20 scores ($b = 0.87$, $se = 1.11$, $p = 0.35$; see Table 5).

In terms of intention and motivation to reduce drinking, latent growth curve models showed good fit for both intention to reduce drinking ($\chi^2(5) = 21.34$, $p < 0.001$, RMSEA = 0.166, CFI = 0.83, TLI = 0.800) as well as motivation ($\chi^2(5) = 9.76$, $p = 0.08$,

RMSEA = 0.090, CFI = 0.96, TLI = 0.95). For intention to reduce drinking, results from the models indicate an overall longitudinal increase in intention to reduce drinking ($b = 0.35$, $se = 0.17$, $p = 0.045$), but there was no effect of including treatment condition in the model ($b = 0.02$, $se = 0.35$, $p = 0.95$; see Table 6). For motivation, latent growth curve models indicated a significant increase in motivation to reduce drinking from baseline to 4-week follow up ($b = 0.98$, $se = 0.21$, $p < 0.001$), but there was no effect of treatment condition ($b = 0.27$, $se = 0.42$, $p = 0.53$; see Table 7).

For expectancies for pain-coping/reduction via drinking (EAA total score), models showed excellent fit ($\chi^2 (5) = 9.77$, $p = 0.09$, RMSEA = 0.09, CFI = 0.94, TLI = 0.92). The intercept parameter for the model was significant ($b = 28.77$, $se = 0.96$, $p < 0.001$), but the slope factor was not ($b = -0.73$, $se = 0.40$, $p = 0.067$), indicating that EAA did not significantly change from baseline to 4-week follow up. Including treatment condition in the model showed no differences between those randomized to PA-PFI and health information control ($b = 0.23$, $se = 0.72$, $p = 0.75$; see Table 8).

Parallel Process Mechanism/Mediation Models. To examine the potential mediating effect of pain-related anxiety, intention/motivation to reduce drinking, and expectancies for alcohol analgesia on the relationship between treatment condition and drinking outcomes, a series of parallel process latent growth curve models were estimated. In examining PASS-20 as a potential mediator, slope of PASS-20 was not related to slope of average drinks throughout the study ($b = -1.39$, $se = 1.23$, $p = 0.26$) and did not mediate the relationship between treatment condition and drinking outcomes ($b = -0.05$, $se = 0.23$, 95% CI [-0.50, 0.40], $p = 0.84$).

In terms of intention to reduce drinking, slope was negatively associated with slope of average drinks throughout the study ($b = -0.75$, $se = 0.22$, $p = 0.001$), such that increase in intention to reduce drinking was associated with decrease in average drinks. However, intention to reduce drinking did not mediate the relationship between treatment condition and drinking outcomes ($b = 0.23$, $se = 0.21$, 95% CI [-0.18, 0.63], $p = 0.28$).

For motivation to reduce drinking, slope was not associated with slope of average drinks throughout the study ($b = 8.39$, $se = 16.88$, $p = 0.62$), and motivation to reduce drinking did not mediate the relationship between treatment condition and drinking outcomes ($b = -0.001$, $se = 0.03$, 95% CI [-0.05, 0.05], $p = 0.96$).

Finally, for expectancies for alcohol analgesia, slope was not associated with slope of average drinks throughout the study ($b = 2.46$, $se = 3.96$, $p = 0.54$), and did not mediate the relationship between treatment condition and drinking outcomes ($b = 0.15$, $se = 0.29$, 95% CI [-0.42, 0.72], $p = 0.62$).

Moderation Analyses. Examining the moderation of treatment condition by sex on average drinking outcomes throughout the study did not yield significant findings to support the moderation ($b = -0.19$, $se = 2.14$, $p = 0.93$).

DISCUSSION

The current study developed and evaluated the efficacy of a novel, brief, computer-delivered personalized feedback intervention (PA-PFI) targeting pain-related anxiety to reduce alcohol use among hazardous drinkers with chronic pain, compared to a computer-delivered health information control treatment. Results from the semi-structured qualitative interviews helped to refine the development of the PA-PFI, but in general highlighted the perceived helpful nature of the content presented. The PA-PFI was then

evaluated in a randomized controlled trial (RCT), and evaluative outcomes of efficacy included average daily drinks prior to each assessment point, increased intention and motivation to reduce drinking, decreased pain-related anxiety, and decrease expectancies for alcohol analgesia/pain coping, as well as trajectories of all these variables assessed at pre-intervention baseline, post-intervention, 2-week follow up, and 4-week follow up. Results from the RCT indicated equivalence of PA-PFI and health information control on all outcomes, with reductions in alcohol and pain variables observed across both conditions. However, examining mean differences and effect sizes provides some evidence that the two conditions may differentially impact drinking behavior through pain variables, such that individuals in the PA-PFI condition reported lower mean levels of pain-related anxiety and expectancies for alcohol analgesia, and higher mean levels of intention and motivation to reduce drinking. While these differences did not reach the values of statistical significance, it is possible that, with greater power, these differences may emerge as significant. It is also important to note, that while there were no treatment differences, increased intention to reduce drinking was associated with decreased alcohol use over the course of the study, highlighting the importance of intention in reducing alcohol use (Hettinga et al., 2005).

Importantly, the relationship between alcohol and pain is complex, where research suggests a bi-directional relationship (Zale et al., 2015). This may have a direct impact on the ability to reduce alcohol use in a minimal contact treatment (e.g. computer-delivered, single-session intervention) for a number of potential reasons. First, pain has been empirically identified as a motivator for alcohol consumption (Ditre et al., 2023) which is likely associated with alcohol-related pain reduction (Scott et al., 2018). On the contrary,

consistent alcohol consumption in the context of chronic pain has been consistently associated with alcohol-induced hyperalgesia, or greater pain experience (Robins et al., 2019), which motivates more, rather than less alcohol consumption (or other substance use) to reduce pain; this effect is further exacerbated if there has been a delay in chronic pain treatment, or pain has historically been undertreated (Boissoneault et al., 2018). In considering the results of the current study in line with this research, the likely increased pain the resulted from reduction in alcohol use in the context of chronic pain may have been enough to motivate either increased drinking, or no change from baseline. Of course, all participants did evince a reduction in drinking throughout the study (albeit small effect size), but the effect of targeting pain-related anxiety was not robust for the PA-PFI group.

It is also important to consider the elements included in the PA-PFI that were specifically designed to target pain-related anxiety, and how these may have played a role in the outcomes. First, a mindfulness exercise was provided to participants, as there has been a strong link between increased mindfulness, increased pain acceptance, and decreased pain-related fear and anxiety (Andersen & Vægter, 2016; Cho et al., 2010; Curtin & Norris, 2017; Jay et al., 2016; Schütze et al., 2010). Yet, in examining the trials that have evaluated the efficacy of a mindfulness-based intervention for pain and pain-related variables, such as fear, catastrophizing, and anxiety, most interventions have lasted for at least 10-16 weeks (Cusens et al., 2010; Jay et al., 2016), but the mindfulness intervention included in the PA-PFI lasted a few minutes. Participants were given instructions to continue practicing mindfulness after the initial appointment, but given that the longest follow-up appointment was 4-weeks, even for those who practiced regularly, the full effect of mindfulness on pain-related anxiety reduction may not have been fully

evident. Similarly, graded pain exposure has significant research support in reducing pain-related anxiety and increasing function (Vlaeyen et al., 2002), but the research typically indicates graded exposure to be done over multiple sessions, rather than 1 (López-de-Uralde-Villanueva et al., 2016; Macedo et al., 2010). Additionally, the graded exposure exercises in the PA-PFI were self-guided. While there has been efficacy for self-guided exposure exercises, it appears that therapist-guided exposures tend to produce quicker and larger effects, and therefore repeated practice of exposure is warranted. It is therefore possible that effects would not emerge in the timeline observed (Lindner et al., 2019; Voderholzer et al., 2020).

It is also worth considering the dose of treatment specifically targeting pain-related anxiety, given that this is a brief, single-session intervention. One previous study in a primary care setting found efficacy for a single-session intervention to reduce alcohol use, and did not find any additional benefit for including more intervention sessions (Kypri et al., 2008). However, this study did not use this brief intervention among individuals with chronic illness, which may provide an additional layer of treatment complexity. Brief intervention work aimed at improving self-management among individuals with diabetes, IBS, and chronic widespread pain, found that single-session interventions were helpful, but booster sessions may be required for sustained effect (Nes et al., 2013). In one recent study testing a PFI to reduce cigarette smoking and analgesic use among persons living with HIV and AIDS, authors found efficacy for a single-session intervention, but also found that the intervention appeared to exhibit the strongest effects for the heaviest substance users (Ditre et al., 2019). Therefore, in relation to the population in the current

study, it is possible that a greater dose of the intervention would lead to the hypothesized effects.

It is also noteworthy that while expected changes in the hypothesized mediators was observed, these effects did not mediate treatment change. Additionally, it is important to note that analyses were run because they were pre-determined and registered, but there was no statistical indication for mediation. It was, however, important to examine potential mechanisms of change regardless of intervention condition. Given the points mentioned above, it is possible that the primary hypothesized mechanism, pain-related anxiety, did not receive a large enough dose of the treatment to exhibit an effect that would rise to the level of a mediator. Future replication in this area is needed.

However, despite the lack of treatment-specific associations observed in the current study, it is important not to undermine that reductions in alcohol use and pain variables were seen across the board. In considering these findings, it is also worth discussing the power of the health information control. This control condition was specifically designed to include non-alcohol or pain-related information, yet the effects were still seen. It is possible that given the large quantity of questionnaires focused on pain and alcohol for all participants regardless of randomization, that participants may have been focusing on their drinking despite the content of the intervention. Further, it is also possible that, given that the content of the health information control condition was about health behaviors generally (which may or may not be associated with drinking and other substance use), that it could have prompted participants to consider how drinking and pain may have impacted engagement in these behaviors (diet, sleep, dental), which

may have prompted behavior change. It is important to pursue additional avenues of research with other control conditions to further tease apart these effects.

These findings are generally consistent with past work showing that computer-based interventions are important in reducing hazardous alcohol use (Bien et al., 1993; Ghosh et al., 2022; M. B. Miller et al., 2013; Neighbors et al., 2004; Rubin et al., 2022). One recent study found similar findings to the current study, such that there were no differences on alcohol consumption variables between those randomized to a computer-based brief intervention compared to treatment as usual, but those receiving the computerized treatment reported lower alcohol-related negative consequences. This follows past work highlighting the importance of harm reduction in reducing the negative impact and increasing function in the context of hazardous alcohol use and alcohol use disorder (Charlet & Heinz, 2017; Marlatt & Witkiewitz, 2002), and therefore, the knowledge that the participants in this study were there to test a potential treatment to reduce alcohol use in the context of chronic pain may have, in fact, been enough to jump start change processes.

Current data provide preliminary evidence for the utility of a PFI to encourage behavior change related to alcohol use by addressing pain-related anxiety among hazardous drinkers with chronic pain. The effects observed, however, were limited in magnitude and statistical significance. Yet, the “signal” that was observed (i.e. mean differences) in this small RCT provides a strong rationale for continued work in this domain. Theoretically with a better-powered RCT, and a PFI with a greater dose of treatment, PA-PFI may lead to greater reduction in alcohol use through reductions in pain-related anxiety, or, at the very least, would specifically lead to increased motivation to

reduce or stop drinking. It is also possible that, as an exploratory approach, Bayesian analytic approaches, that focus more on confidence intervals than frequentist statistics and statistical significance, may show efficacy of the intervention despite power. Additionally, by encouraging continued, longer-term practice of pain-anxiety reduction techniques, particularly self-guided, individuals may receive a dual benefit of finding it easier to reduce alcohol use as well as improve pain-related function.

Clinically, the findings support that brief, single session treatments for hazardous alcohol use in the context of chronic pain can help facilitate drinking reduction. Overall, both treatment conditions evinced reductions in drinking. Given that alcohol reduction, rather than cessation, is the optimal outcome for best health for many individuals (Ng Fat et al., 2015), a PFI may be a clinically useful tool to help individuals reach this goal. While the results of the current study did not reach statistical significance, continuing research with the PA-PFI offers a potentially cost and time effective solution to reach a highly vulnerable population. An important next step in the clinical examination of this treatment is to continue testing with a larger sample and dose, and to evaluate the effectiveness when implemented in a point-of-care setting, such as a pain or primary care clinic.

Several limitations of the current investigation warrant comment. First, while both the PA-PFI and health information control conditions were interactive, only one of the interventions contained alcohol content, and thus it is unclear which parts of either intervention may have had an effect on the observed outcomes. A dismantling study would be particularly useful to identify key elements that are responsible for promoting the greatest change. Second, the current study relied on retrospective recall for most of the

drinking assessment. While the measures included in the current study were previously shown to be valid and reliable (Carey et al., 2004; Sobell & Sobell, 1992), it is possible these estimates were biased most by current use. The results from the study are an important first glance into drinking behavior among hazardous drinkers with chronic pain, but more sophisticated assessment methods, including real-time monitoring of drinking with ecological momentary assessment, may provide more accurate data regarding drinking behavior. Further and related, due to having to move the study to a virtual format, we were not able to biochemically verify drinking status, which would also be an important step in replication. Third, the sample was relatively small and followed for a short period of time. Therefore, some of the statistical tests employed in the current study may have been underpowered to detect effects. Replication and extension of the findings in a larger cohort with a longer follow up window is warranted. Finally, while close in time, time to completed varied across treatment conditions, and future would should examined a better time-matched control to account for a potential confound of time and effort engagement.

Overall, the present investigation provides descriptive, but not statistical evidence for the efficacy of a single-session, computer-delivered PFI targeting pain-related anxiety to reduce alcohol use among hazardous drinkers with chronic pain. Further, the treatment appeared to engaged and move the proposed mediators, suggesting that, at least on a small scale, the intended targets were reached. Future work would benefit from continuing to explore and refine the PFI dose and components, as well as continue to explore and identify mechanisms that may support drinking reduction (and long-term sustained effect) in this vulnerable population.

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Table 1.

Comparison of Baseline Demographic, Alcohol, and Pain Variables across PA-PFI and Health Information Control Conditions.

Baseline Variables	Overall		PA-PFI		Control		<i>p-value</i>
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	
Age	35.24	11.90	35.49	12.44	34.74	11.32	>0.05
Income	5.48	2.32	5.58	2.14	5.41	2.44	>0.05
Education	2.24	1.09	2.22	0.99	2.25	1.15	>0.05
AUDIT Total	23.60	8.73	22.86	8.99	24.21	8.37	>0.05
TLFB Avg. Drinks	3.67	4.45	3.12	2.38	4.05	5.40	>0.05
Days with Pain	5.81	1.21	5.81	1.22	5.83	1.20	>0.05
Pain Intensity	7.44	1.61	7.41	1.45	7.45	1.77	>0.05
Pain Duration	44.80	86.81	35.59	65.90	52.55	101.88	>0.05
PASS-20	64.12	19.89	65.46	15.90	62.91	22.93	>0.05
IRD	8.92	4.75	9.41	4.45	8.30	4.67	>0.05
MI	18.10	7.29	18.03	6.44	18.17	8.11	>0.05
EAA	29.13	10.22	27.42	11.42	30.86	8.60	>0.05

Note: AUDIT: Alcohol Use Disorders Identified Test; TLFB Avg. Drink: Timeline Follow Back Baseline Past 4 weeks average drinks; Pain intensity out of 10; Pain duration in months; PASS-20: Pain Anxiety Symptoms Scale – 20; IRD: Intentions to Reduce Drinking; MI: Motivation to Reduce Drinking; EAA: Expectancies for Alcohol Analgesia/Coping. Education coded from 1 (graduate school) to 7 (less than 7 years of school); Income coded from 1 (<\$5,000/year) to 8 (>\$75,000/year).

Table 2.
Baseline Bivariate Correlations among Study Variables

	1.	2.	3.	4.	5.	6.	7.	8.	9.
1. Age	-								
2. Sex	-.341**	-							
3. AUDIT Score	-.463**	.215*	-						
4. TLFB Average Drink	-0.018	0.108	0.134	-					
5. IRD	-.205*	.217*	.286**	-0.078	-				
6. MI	-.335**	0.172	.356**	-0.059	.623**	-			
7. EAA	-.313**	.193*	.286**	-0.005	-0.006	-0.009	-		
8. PROMIS Pain Intensity	-0.120	0.023	0.133	0.032	0.066	.183*	.339**	-	
9. PROMIS Pain Interference	0.039	-.218*	0.159	-0.149	0.067	0.063	.260**	.603**	-
10. PASS-20 Total	-.323**	0.043	.407**	-0.073	.226*	.307**	.368**	.450**	.551**

Note. ** $p < 0.01$, * $p < 0.05$. $N = 118$. AUDIT: Alcohol Use Disorders Identification Test, TLFB: Timeline Follow Back, IRD: Intentions to Reduce Drinking, MI: Motivation to Reduce Drinking, EAA: Expectancies for Alcohol Analgesia/Pain Coping, PROMIS Pain Intensity/Interference: T-scores, PASS-20: Pain Anxiety Symptoms Scale 20.

Table 3.

Average drinks, PASS-20 total score, Intention to Reduce Drinking Total Score, Motivation to Reduce Drinking, and Expectancies for Alcohol Analgesia across Conditions at Follow-Ups

<i>PA-PFI</i>	Post Intervention		2-week Follow Up		4-week Follow Up	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
Avg. Drinks	-	-	3.09	2.43	2.80	3.68
PASS-20	-	-	60.48	19.88	58.28	20.35
IRD	11.39	4.72	9.84	4.43	10.77	4.57
MI	21.17	6.73	19.86	6.23	21.47	5.98
EAA	22.41	14.63	25.56	12.00	24.87	12.38
<i>Control</i>						
Avg. Drinks	-	-	3.33	3.33	2.78	2.74
PASS-20	-	-	63.09	21.57	58.00	21.85
IRD	9.81	4.96	9.70	4.78	9.40	4.89
MI	18.86	8.75	20.85	7.21	21.09	7.30
EAA	28.87	10.46	30.59	10.41	28.00	12.34

Note: PA-PFI: Personalized Feedback Intervention, PASS-20: Pain Anxiety Symptoms Scale – 20, IRD: Intentions to Reduce Drinking, MI: Motivation to Reduce Drinking, EAA: Expectancies for Alcohol Analgesia/Pain Coping.

Table 4.

Latent Growth Curve Parameters for Average Drinks from Pre-Intervention TLFB Interview to 4-week follow up Predicted by Treatment Condition.

Avg. Drinks Model Parameters	B	p-value
Intercept	3.71	<0.001
Intercept Variance	14.06	0.19
Slope	-0.95	0.048
Slope Variance	17.11	0.18
Covariate Effects (Intercept)	B	p-value
Treatment Condition	-1.05	0.20
Covariate Effects (Slope)	B	p-value
Treatment Condition	1.04	0.35

Note: Avg. Drinks from Timeline Follow Back Interview. Treatment condition coded at 0 = Health Information Control, 1 = Personalized Feedback Intervention.

Table 5.

Latent Growth Curve Parameters for PASS-20 Total Score from Pre-Intervention to 4-week follow up Predicted by Treatment Condition.

PASS-20 Model Parameters	B	p-value
Intercept	65.69	<0.001
Intercept Variance	312.27	<0.001
Slope	-4.00	<0.001
Slope Variance	67.62	<0.001
Covariate Effects (Intercept)	B	p-value
Treatment Condition	-0.69	0.84
Covariate Effects (Slope)	B	p-value
Treatment Condition	0.87	0.63

Note: PASS-20: Pain Anxiety Symptoms Scale-20. Treatment condition coded at 0 = Health Information Control, 1 = Personalized Feedback Intervention.

Table 6.

Latent Growth Curve Parameters for IRD Total Score from Pre-Intervention to 4-week follow up Predicted by Treatment Condition.

<i>IRD Model Parameters</i>	<i>B</i>	<i>p-value</i>
Intercept	9.25	<0.001
Intercept Variance	17.08	<0.001
Slope	0.35	0.045
Slope Variance	1.87	0.005
<i>Covariate Effects (Intercept)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	1.23	0.15
<i>Covariate Effects (Slope)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	0.02	0.95

Note: IRD: Intentions to Reduce Drinking. Treatment condition coded at 0 = Health Information Control, 1 = Personalized Feedback Intervention.

Table 7.

Latent Growth Curve Parameters for MI Total Score from Pre-Intervention to 4-week follow up Predicted by Treatment Condition.

<i>MI Model Parameters</i>	<i>B</i>	<i>p-value</i>
Intercept	18.21	<0.001
Intercept Variance	49.12	<0.001
Slope	0.98	<0.001
Slope Variance	3.87	0.001
<i>Covariate Effects (Intercept)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	0.07	0.96
<i>Covariate Effects (Slope)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	0.27	0.53

Note: MI: Motivation to Reduce Drinking. Treatment condition coded at 0 = Health Information Control, 1 = Personalized Feedback Intervention.

Table 8.

Latent Growth Curve Parameters for EAA Total Score from Pre-Intervention to 4-week follow up Predicted by Treatment Condition.

<i>EAA Model Parameters</i>	<i>B</i>	<i>p-value</i>
Intercept	28.77	<0.001
Intercept Variance	80.50	<0.001
Slope	-0.73	0.067
Slope Variance	9.07	0.02
<i>Covariate Effects (Intercept)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	-9.98	0.03
<i>Covariate Effects (Slope)</i>	<i>B</i>	<i>p-value</i>
Treatment Condition	0.23	0.75

Note: EAA: Expectancies for Alcohol Analgesia/Pain Coping. Treatment condition coded at 0 = Health Information Control, 1 = Personalized Feedback Intervention.

Figure 1. Study Consort

