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Effectiveness of a Peer-Supported Digital Brief Intervention: Reducing Alcohol Use & Related Harms in Young Adults with Histories of Interpersonal Trauma

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EFFECTIVENESS OF A PEER-SUPPORTED DIGITAL BRIEF INTERVENTION: REDUCING ALCOHOL USE AND RELATED HARMS IN YOUNG ADULTS WITH HISTORIES OF INTERPERSONAL TRAUMA

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ABSTRACT

EFFECTIVENESS OF A PEER-SUPPORTED DIGITAL BRIEF INTERVENTION: REDUCING ALCOHOL USE AND RELATED HARMS IN YOUNG ADULTS WITH HISTORIES OF TRAUMA

Alcohol is the most frequently used substance in the United States, and young adults ages 18-25 have the highest rates of heavy alcohol use. Heavy and persistent alcohol use is associated with a host of negative outcomes in young adults, including poor mental health, lower life satisfaction, cognitive impairments, poor academic performance, increased risk for motor vehicle accidents, and substance use disorders. Brief interventions (BI) are low-resource, short-term interventions designed to reduce problematic substance use and mitigate the substantial harms posed by heavy and persistent use of substances such as alcohol. BIs have limited effectiveness in trauma survivors despite trauma survivors being at increased risk of substance-related problems. The purpose of the current study was to determine whether a trauma-informed and peer-supported digital brief intervention in a sample of heavy alcohol-using young adults with histories of interpersonal trauma was feasible and effective. The trauma-informed brief intervention was found to be feasible and satisfactory to most participants. Additionally, significant reductions in alcohol use, alcohol-related problems, and mental health-related problems were found. Moving forward, it is important to further investigate these findings in a larger, more diverse sample with multiple control conditions. Identifying the underlying mechanisms of change that worked in this study is imperative to effectively help heavy alcohol-using individuals with interpersonal trauma while using minimal resources compared to traditional treatments.

Keywords: alcohol, brief intervention, substance use, trauma, young adults

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Introduction

Over 22 million people in the United States meet the criteria for Alcohol Use Disorder, yet less than eight percent of individuals with an alcohol use disorder received any type of treatment in the past year (SAMHSA, 2021). Severe alcohol use disorder is also most prevalent in the lowest income level, limiting treatment access for those who need it most (Grant et al., 2015). Thus, not only is widespread treatment for alcohol use needed, but accessible, low-cost preventative efforts are critical to mitigating alcohol-use-related harms. The purpose of the current study is to determine whether a trauma-informed and peer-supported digital brief intervention in a sample of heavy alcohol-using young adults with histories of interpersonal trauma is feasible and effective. The following sections will provide an overview of alcohol use in young adults and the use of brief interventions as tools for mitigating substance-related harms.

Heavy Alcohol Use

Heavy alcohol use as defined by the National Institute on Alcohol Abuse and Alcoholism is consuming four or more drinks in a day or eight or more drinks per week for women and consuming five or more drinks in a day or 15 or more drinks per week for men. Young adults (i.e., individuals ages 18–25) have the highest rates of heavy alcohol use of any age group (Johnston et al., 2020). Heavy alcohol use in young adulthood is associated with a host of negative outcomes including poor mental health, lower life satisfaction, cognitive impairments, poor academic performance, increased risk for motor vehicle accidents, and substance use disorders (Bonomo et al., 2001; Volkow et al., 2014). Knight and colleagues (2002) found that many college students who consume alcohol experience negative alcohol-related consequences, such as physical illness, academic impairment, and causing damage to others. Some harms associated with heavy or hazardous drinking specifically in college students include injuries from

vehicle crashes, drunk driving arrests, assault, sexual abuse, health problems, and alcohol use disorder (Samson & Tanner-Smith, 2015). Young adults are a particularly vulnerable population because the typical age of onset of alcohol use disorders is between 18 and 29 years old (Grant et al., 2015). Additionally, data shows that college student young adults are more likely to engage in alcohol use and have higher rates of binge drinking compared to non-college young adults (SAMHSA, 2020). Thus, college students are a relevant sample for alcohol prevention and intervention programs.

Brief Interventions

Brief interventions (BI) for alcohol focus on personalized feedback to identify the consequences of alcohol use, correct faulty normative beliefs, and to increase motivation to change (Teeters et al., 2018). Brief alcohol interventions are most often used for college students engaging in heavy drinking and are also often utilized as a clinical tool in medical settings (McDevitt-Murphy et al., 2014). Although there is substantial variation in their implementation, traditional BIs are one- to two-session clinician-delivered interventions. A traditional brief intervention includes personalized feedback on the individual's use of substances, plus there may be a motivational interviewing (MI) component that explores a person's motivations for changing their substance use patterns. Beyer and colleagues (2022) reported that the structure of a brief alcohol intervention can include personalized feedback on alcohol consumption, comparative population norms, information and guidance about reducing consumption, counseling techniques to explore what drinking means to them, and counseling techniques to explore how to reduce drinking. Field and colleagues (2014) supported this by examining the efficacy of the brief intervention strategies (e.g., brief advice, brief motivational intervention, and brief motivational intervention plus a telephone booster using personalized feedback) that

address heavy drinking among injured patients at trauma care centers. They found that BIs based on MI with the telephone booster and using personalized feedback achieved the most significant reductions in alcohol intake compared to just brief advice or just brief MI. This suggests that utilizing strategies (such as MI, personalized feedback, and a telephone booster) in combination with traditional BIs can have a significant benefit.

Considerable research supports the use of BIs for reducing heavy drinking. Wilk and colleagues (1997) found that heavy drinkers who received a BI were twice as likely as heavy drinkers who received no intervention to lower their alcohol consumption at six- and 12-months post-intervention. Additionally, Tanner-Smith and Risser (2016) found in their meta-analysis examining the effectiveness of brief alcohol interventions in adolescents and young adults that brief alcohol interventions led to significant, albeit modest, reductions in self-reported alcohol use. Relatedly, Smedslund and colleagues (2017) found significant short-term reductions in alcohol consumption utilizing computerized BIs but found no significant long-term effects in their meta-analysis looking at the effects of BIs on substance use. Additionally, Ghosh and colleagues (2022) found in their meta-analysis that a single session of brief alcohol intervention yielded a significant positive effect in reducing alcohol use at three months, but those results did not persist when assessed at the six and 12-month follow-ups. These findings are consistent with previous literature finding nonsignificant intervention effects 12 months post-intervention (Carey et al., 2007; Samson & Tanner-Smith, 2015; Smedslund et al., 2011). Thus, the literature supports the use of BIs for reducing heavy drinking in the short-term, but the utility of BIs for long-term reductions in drinking overall is limited.

BIs vary significantly in their components; however, one common element of brief alcohol interventions is motivational interviewing (MI; Miller & Rollnick, 2013). According to

McDevitt-Murphy and colleagues (2014), motivational interviewing can be defined as "a counseling style characterized by a non-judgmental stance that aims to increase participants' motivation to make positive changes" (p. 2). Samson and Tanner-Smith (2015) in their meta-analysis found MI to be especially helpful in addressing alcohol consumption in identified heavy or hazardous drinkers. However, automated personalized feedback interventions without motivational interviewing elements have demonstrated effectiveness in decreasing alcohol use and related issues among emerging adults (McDevitt-Murphy et al., 2014; Miller & Rollnick, 2013). Despite the potential benefits of MI, a recent study questioned whether MI actually increases motivation to change. Tan and colleagues (2023) studied motivation for change in drinking among college students and found group-based MI with motivation-targeted content to have a significant increase in motivation for change compared to controls. However, they found that individual brief MIs did not show increased motivation for change. Thus, while MI may be helpful as a component in BIs, it is not clear that it is because it enhances motivation.

Duration of Intervention

One variable that varies among current BIs is the duration of the interventions. BIs can be categorized into single-session and multi-session interventions. The duration of each intervention and the total time spent on the intervention varies significantly in the literature. Samson and Tanner-Smith (2015) analyzed 73 studies in which BIs were operationally defined as less than five hours total of contact time and only included single-session interventions. Modest effects for reducing alcohol consumption were found. Moyer and colleagues (2002) defined BIs as interventions lasting no more than four sessions. They found an insignificant effect size in their meta-analysis that compared extended treatment effects to BI treatment effects. This indicates little difference between BIs and more extended treatments. Bendtsen and Bendtsen (2014)

extended their single-session intervention to a four-week multiple-session intervention. They found their single-session alcohol intervention to be feasible and satisfactory among college students. These suggest that single-session BIs may produce similar effects to more extended interventions while requiring fewer resources.

Duration of Treatment Effects

Of note, most single-session BIs do not measure long-term effects, especially past 12 months, calling into question the long-term effects of brief alcohol interventions. Beyer and colleagues (2022) examined non-treatment-seeking heavy drinkers at one-, six-, and 12-months in their meta-analysis. They found significantly decreased alcohol consumption at the six-month follow-up, but no sustained reduced alcohol consumption at the 12-month follow-up. Another example is Stappenbeck and colleagues (2021) who had college women with sexual assault histories complete a brief web-based alcohol reduction intervention, 14 daily diary entries, and one- and six-month follow-up surveys. They found significant short-term reductions in drinking at the one-month follow-up, but no significant reductions at the six-month follow-up. Altogether, more work is needed to extend the limited duration of effects found in brief alcohol interventions.

Method of Delivery

BIs can be delivered through a variety of methods across both modalities and who delivers the intervention. Common modalities include in-person interventions and remote/digital interventions, whereas administrators of BIs can include a variety of persons such as peer-delivered interventions, general practitioner-delivered interventions, clinician-delivered interventions, and nurse-delivered interventions. The most common mode of delivery is in-person with a trained mental health provider; however, peer-delivered interventions show

promise of being a low-cost method of delivery that could increase the accessibility of brief alcohol interventions. Larimer and colleagues (2001) found that fraternity members who received brief alcohol interventions from peers reported similar outcomes to those who received the intervention from professional research staff, suggesting that administrators of BIs do not require advanced professional training.

Digitally delivered BIs are defined as any intervention delivered through a device, which includes text messages and any remote interactions (Beyer et al., 2022). Evidence indicates this modality of BIs is also effective. Stappenbeck and colleagues' (2021) results found that a web-based alcohol intervention resulted in short-term reductions in drinking at their one-month follow-up but did not find significant reduction evidence at their six-month follow-ups. In their meta-analysis, Beyer and colleagues (2022) compared digitally delivered interventions to the effectiveness of BIs delivered in person by a practitioner. They found that short-term practitioner-delivered interventions measured at one- and six-months decreased alcohol consumption more so than digitally delivered BIs. However, when measured at 12 months, there was no significant difference between digitally delivered and practitioner delivered BIs. There was also no significant difference found in the reduction of ‘binge drinking episodes’ between digital, and practitioner delivered BIs. These results suggest that digitally delivered BIs may have less significant results than in-person BIs in the short term, whereas similar effects are observed long term. Regardless, results indicate that greater efforts are needed to improve digital BIs given their utility in increasing dissemination and greater cost effectiveness.

Fjeldsoe and colleagues (2009) suggested that text messages may be a particularly advantageous way to provide brief healthcare interventions as they can be highly personalized to the individual, accessed at any time that suits the individual’s needs, and allow for engagement

and interaction with the intervention. Their meta-analysis examined 14 studies that utilized text-based intervention to promote health-related behavioral changes (e.g., physical activity, nutrition, medication compliance, smoking cessation), 13 of which demonstrated positive behavior changes in participants. Mason and colleagues (2018b) utilized automated personalized text messages focused on emphasizing peer relations for young adults with cannabis use disorders and found significant cannabis use reductions. Text message-based interventions appear to present promising results and typically require fewer resources than practitioner-delivered interventions, but the use of live text messages has been largely unexplored in BIs for substance use.

Trauma History

Although limited, BIs have also been examined in individuals with histories of trauma, with studies showing mixed evidence of effectiveness. Studies that found individuals with trauma to be treatment-resistant include Kurtz and colleagues (2019) who found that their BI significantly reduced substance use, but that the BI was not effective for individuals with trauma-related distress. Similarly, Tanner-Smith and colleagues (2022) found in their meta-analysis that while BIs were effective in general medical settings, no significant effects were observed when delivered in trauma centers. Individuals with post-traumatic stress disorder (PTSD), a trauma-related disorder, are up to 14 times more likely to have a substance use disorder than individuals without PTSD, so this is an especially vulnerable population (Konkolÿ Thege et al., 2017; McCauley et al., 2012).

Notably, few studies have examined BIs in an entirely interpersonal trauma survivor sample, which can be defined as intentionally inflicted harm or injury by another person (Woodward et al., 2015). Stappenbeck and colleagues (2021) examined the effectiveness of a

web-based alcohol intervention on college women with histories of sexual assault and heavy drinking. This study found significant short-term reductions in drinking in the treatment group at the one-month follow-up, and while reductions remained at the six-month follow-up, they were no different from the control condition. However, some studies have found promising results in reducing drinking in adults with histories of trauma in general. McDevitt-Murphy and colleagues (2014) examined Iraq and Afghanistan combat veterans who screened positive for heavy drinking, half of whom met the criteria for PTSD. Participants were randomly assigned to either a BI group just including personalized feedback, or a BI group that received both personalized feedback and a MI counseling session. This study found statistically significant reductions in hazardous drinking in both intervention groups, but the personalized feedback and MI group reported greater reductions in weekly drinking at the six-week follow-up. Additionally, Field and colleagues (2014) examined the efficacy of BI strategies that address heavy drinking among injured patients. This study found that a BI with a telephone booster and using personalized feedback achieved the most significant reductions in alcohol intake compared to brief advice only or brief motivational interviewing. As a whole, studies suggest that BIs for subjects with histories of trauma (who are at higher risk for substance use disorders) may be less effective and require modifications in order to achieve significant improvement.

Coping Motives

One aspect that may make a reduction of substances especially difficult for trauma survivors relates to using substances as a way to cope with negative affect, referred to as the self-medication hypothesis. The self-medication hypothesis posits that individuals may use substances as a means of coping with trauma-induced distress, including conditions such as PTSD, anxiety, or depression (Bountress et al., 2019, Hawn et al., 2020; Kaysen et al., 2007;

Potter et al., 2011). Research indicates that emerging adults with interpersonal trauma are especially likely to use alcohol as a tool to cope with negative emotions (Smith et al., 2021). Bountress and colleagues (2019) explored the relationship between alcohol consumption, interpersonal trauma, and coping motives for trauma-related distress. They found that drinking to cope with trauma-related distress predicted subsequent increases in alcohol consumption. This article suggests the risky behavior model as an explanation, which proposes that individuals with higher levels of alcohol consumption may be at higher risk for future interpersonal trauma. Similarly, Palmisano and colleagues (2021) found that PTSD symptoms were positively associated with alcohol use disorder via attempts to avoid trauma-related distress and that adaptive coping reduced the risk for alcohol use disorder. Thus, enhancing affect regulation may be especially beneficial for trauma survivors. Wycoff and colleagues (2021) found that although individuals were primarily driven to consume alcohol by a desire for subjective relief from negative emotions, they paradoxically reported heightened levels of anxiety and depression following use. This indicates that emphasizing the emotional repercussions of substance use could be valuable for educational purposes. Meinzer and colleagues (2021) found significant reductions in mental health issues (e.g., depression) as a result of an alcohol BI that utilized psychoeducation and brief motivational interviewing. Additionally, Papini and colleagues (2022) examined the efficacy of a traditional brief alcohol intervention in primary care patients with and without depression and found the BI to be significantly helpful in non-depressed patients but found no significant results in depressed patients. Most existing brief interventions do not include adaptive coping strategies for managing these mental health difficulties. As such, the current study aims to bridge this gap.

Limitations of Brief Interventions and Past Research

Despite the benefits and effectiveness of BIs, BIs have several notable limitations. Standard BIs do not typically address mental health issues (e.g., depression, anxiety) that may be driving heavy alcohol use and do not include adaptive coping strategies for managing these difficulties. This is noteworthy given that young adults with interpersonal trauma are more likely than those without trauma to use alcohol as a tool to cope with negative emotions like anxiety and depression (Smith et al., 2021). Additionally, interpersonal trauma survivors have a greater likelihood of experiencing mental health disorders such as PTSD and depression and are also at increased risk of heavy substance use, substance use disorders, and substance-related problems relative to non-interpersonal traumas (Friedman et al., 2022; Kessler et al., 2017). There is a need for additional strategies to increase the reach of substance-related interventions.

Automated, digital interventions have the potential to reach more people than traditional, in-person interventions because they require fewer resources. However, there are some considerable problems with digital interventions including lack of motivation/engagement, lack of human interaction elements, and higher attrition (Kazemi et al., 2017). Engagement issues in digital BIs may be due to a lack of human interaction that could potentially be augmented by the incorporation of peer coaching. Mohr and colleagues (2011) proposed that the supportive accountability aspect of peer support/coaching can increase goal adherence because it can serve as a performance monitor and can increase social support. Relatedly, Tevyaw and colleagues (2007) found that having a friend attend an in-person BI resulted in greater reductions in alcohol use than attending a BI alone. This suggests that adding a peer coaching element to digital BIs could strengthen their effects, especially when considering that traditional BIs do not include follow-up sessions to promote continued substance use reduction. As such, text messaging with a

peer coach represents a viable, low-cost way of incorporating human support that can augment automated, mobile-delivered BIs.

Rationale

BIs have become increasingly accessible through digital means. Therefore, BIs can have a monumental impact on the accessibility of treatment for risky or heavy alcohol use. This is especially important for young adults because of the potential of preventative and harm reduction measures like BIs to mitigate more severe alcohol-related consequences. Digital BIs augmented with peer support offer promise in being a low-cost low resource method of intervention that may overcome traditional limitations of digital BIs, particularly for vulnerable groups such as young adults with interpersonal trauma. However, studies have yet to examine this area of investigation. This data comes from a larger ongoing randomized controlled trial with two control conditions. For this study, only pre-to-post data from the intervention condition was examined. The purpose of the current study was to pilot a novel trauma-informed and peer-supported digital BI for young adults with interpersonal trauma.

Hypotheses

Hypotheses examined the feasibility, acceptability, and pre- to post-change of a peer-supported and trauma-informed digital brief alcohol intervention on young adults with histories of interpersonal trauma. Feasibility was examined via dropout rates, and acceptability was examined via participant feedback regarding the BI. Pre- to post-change was examined by looking at changes in substance use and psychological distress from baseline to follow-up. The first hypothesis was 1) the BI would exhibit relatively low levels of dropout (<30%) at the three-month follow-up. Completion rates exceeding 70% were deemed indicative of acceptable feasibility via past studies standards. Although dropout has varied significantly across behavioral

health interventions, this represents a modal rate of dropout that is consistent with prior BIs (Bendtsen, 2013; Bendtsen & Bendtsen, 2014; Bewick et al., 2008; Fjeldsoe et al., 2009; Lee et al., 2021; Rodgers, 2005). It was also hypothesized that 2) the BI would be perceived by participants as satisfactory, relevant, helpful, and a low burden. The final hypothesis was that 3) the BI would be associated with significant reductions in alcohol use, alcohol-related problems, substance-related coping, anxiety, stress, and depression at three-month follow-up.

Method

Participants

Participants were 34 young adults at a midwestern university. The mean age of participants was 19.7 (SD = 1.47). The sample was predominantly Caucasian (85.3%), followed by African American (11.8%), Hispanic or Latinx (11.8%), and Native American (2.9%). The sample was mostly female (85.3%) followed by male (14.7%). The sample was also predominantly made up of people who identified as straight (76.5%), followed by bisexual (20.6%), and pansexual (2.9%). The sample mostly consisted of non-Fraternity/Sorority members (70.6%). Participants were recruited on a volunteer basis through a variety of campus methods including an online university-based study pool and campus flyers containing a link to a screener survey.

Approximately 500 potential participants were screened for the ongoing randomized clinical trial and completed a brief 15-minute online survey assessing inclusion criteria to determine eligibility for the study. Inclusion criteria for participants included: 1) Ages 18 to 25 2) part-time or full-time college student 3) ability to speak and understand English 4) lifetime history of interpersonal trauma exposure (i.e., exposure to violence; childhood/adulthood physical or sexual assault, abuse, combat exposure, the victim of kidnapping, or the violent death

of a loved one) 5) heavy alcohol use (i.e., two or more past-month heavy drinking episodes; which is four or more standard drinks for woman and five or more standard drinks for men). Participants were rewarded with psychology subject pool credit after completing the screening survey and received a $20 Amazon gift card for completing the baseline and three-month assessment. The informed consent document stated that participants were able to withdraw from the study at any time without penalty. Participants were informed that their responses were confidential and were only accessible to study staff.

Procedure

Participants were recruited from Western Kentucky University. Participants were recruited through the psychology subject pool or via flyers and took the screening survey on a computer or cell phone via Qualtrics. Participants volunteered to complete the screening survey online after reviewing the consent form. Once participants signed up for the study, they were redirected to a survey administered via Qualtrics. The survey took approximately 15 minutes to complete.

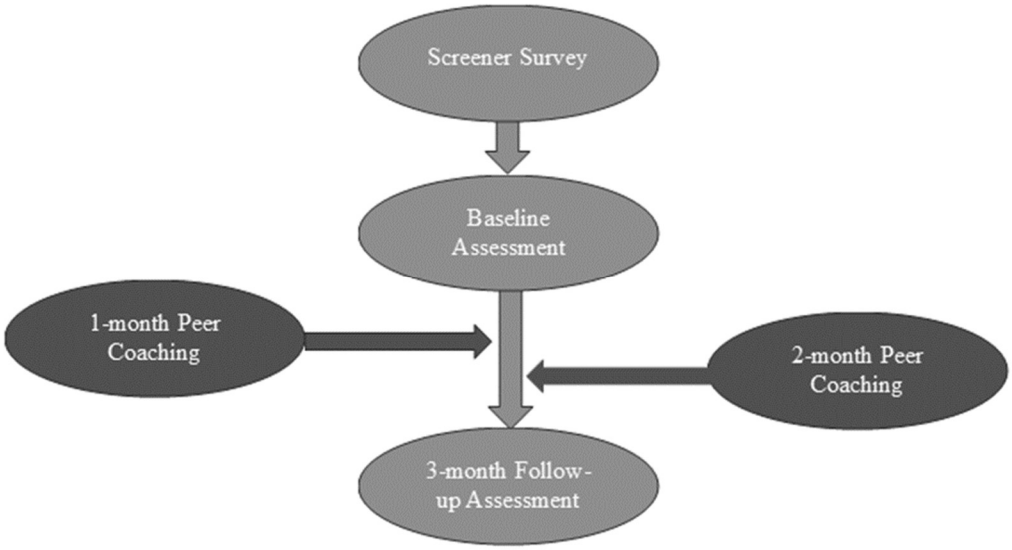
Once the subject took the screening survey the study staff checked Qualtrics and contacted eligible participants through text, confirming interest in the study and then sending another Qualtrics link to the baseline study. The participants then took the baseline survey, where they completed a variety of measures assessing mental health, trauma history, alcohol use motives, alcohol-related problems, PTSD, and demographic information. Similar measures were re-administered three months later. Following completion of the initial round of assessment measures at baseline, participants immediately received the trauma-informed BI. The BI consisted of personalized feedback (a personalized substance use profile, information on peer norms, prior substance-related consequences experienced by the participant, practical costs, and

standard protective behavioral strategies to limit substance-related risk) along with psychoeducation about alcohol use. Additionally, participants were provided with a series of evidence-based coping strategies (e.g., mindfulness meditation, physical exercise, breathing relaxation, self-compassion, expressive writing, and challenging negative thoughts) to help manage trauma-related distress as well as information about the link between trauma and substance use. Participants were then asked to set an alcohol-use-related goal, identify the coping strategy they preferred, and set a reasonable goal for practicing it. In the ongoing randomized clinical trial, Qualtrics randomly assigned participants to one of three conditions (the control condition, the standard BI condition, and the augmented BI condition). The current study only focused on the augmented BI condition, which is the only condition that utilized peer coaching. Participants were then informed that they were assigned a trained peer coach from the research team who would reach out to them through text at the appropriate time points, see Figure 1 for reference.

Participants were then contacted three months from the baseline survey completion date to take the follow-up survey. Participants were sent a $20 Amazon gift card for completion of each baseline and three-month survey. Participants received text messages from a peer coach one and two months following the baseline session. See Figure 1 for an overview of the procedures. For the ongoing randomized clinical trial participants completed the baseline, three-month, and six-month surveys; as well as texted with a peer coach at one, two, four, and five months post-baseline survey. Preliminary data past the three-month survey was not yet available due to the ongoing nature of this study.

Figure 1

Intervention Timepoints



Peer Coaching

Peer coaches were graduate or undergraduate research assistants from the principal investigator's research laboratory. Peer coaches were trained in motivational interviewing techniques and certified before serving as peer coaches. The certification process involved practice sessions with existing peer coaches and a final certification session with the principal investigator. Peer coaches were not allowed to work with participants that they knew previously. Peer coaching assessed current stress levels and stressors, how achievement of alcohol consumption goals have progressed, the challenges to implementing desired substance use changes, provided support to participants regarding successes or failures in attempted change, re-evaluated substance use and stress management goals, and re-directed participants to the coping strategies presented at baseline. See Table 1 for a fictional example peer coach text exchange.

Table 1

Fictional Peer Coaching Exchange Example

Peer Coach	Participant
Hey [participant name], this is [peer coach name] from the Health and Wellness Project at WKU. You completed a	Yes, it is

survey for us a month ago, and I wanted to take a couple of minutes to check in with you via text. Is now still an ok time for a quick 15-minute check in?	
Great! I'm a research assistant and fellow student at WKU and I'll be working with you as your peer coach. My role is to check in with you periodically over the next 5 months. I'll ask about your current stress and review the goals you set in the survey you completed last month. Each check in will take about 15 minutes. Do you have any questions about my role as your peer coach?	No, not that I can think of
Ok, let's start by going over your stress. If you were to rate your stress levels over the past month on a 0 (not at all) to 10 scale (extreme stress), what number would you give?	I'd say about a 5
Ok, sounds like you have been experiencing some stress over the past month. What's been your major sources of stress over the past month?	End of the semester school stuff and sorority stuff
That's understandable, the end of the semester is making everything really stressful but I hope it gets better for you!	Thanks
Let's talk about the stress management strategies we sent you. In the survey you took last month you set a goal to practice exercising 3 times a week or more. How did that go?	It was good, I was able to go 3 or more days a week
That's great! Really glad to hear you were able to practice it. Nice job! We'd like you to keep practicing these strategies over the next month. Which of the exercises that we gave you (mindfulness meditation, physical exercise, breathing retraining, self-compassion, expressive writing, or challenging your negative thoughts) would you be most interested in doing this next month? You can review the strategies if needed by going to the provided link	mindfulness meditation
Sounds good. How often do you think you could realistically practice mindfulness meditation?	I'd say 2-3 times a week
Ok, great. I'll check in next month to see how that went. I want to quickly review some other potential goals we asked you about last month.	Ok
At the time, you weren't interested in setting any goals related to your alcohol use. Would you like to set any goals for this now?	Ya, I'd like to limit my drinking to just on the weekends
Okay, great! What would be the benefit of reaching this goal?	I'd have more free time during the week to do schoolwork and keep up my grades
Ok, that sounds great! I'll make a note to ask you how this went when I check in next month. Thanks for checking in with me today. To summarize, your goals for the next month are to practice mindfulness meditation 2-3 times a week and to limit your drinking to weekends only. You can access these stress management tools by going to the provided link.	Thanks

I'll reach out in a month to check back in with you. Thanks for your time!	

Measures

Demographics. For the baseline survey participants completed a brief demographics measure assessing age, ethnicity, gender, sexual orientation, and fraternity or sorority status.

Dropout. The percentage of participants that dropped out from the intervention was calculated by non-response at each time point.

Alcohol Use. For the screening survey subjects reported frequency and quantity of alcohol use over the past month. Only subjects who had reported heavy alcohol use (i.e., two or more past-month heavy drinking episodes, which is four or more standard drinks for women and five or more standard drinks for men) on this measure were eligible for the study.

Daily Drinking Questionnaire. For the baseline and three-month surveys, subjects reported frequency and quantity of alcohol use over the past month using the Daily Drinking Questionnaire (Collins et al., 1985). Subjects were asked to estimate the number of drinks consumed each day of the week over the past month. Participants were also asked how many times over the past month have they had four or more drinks if female or five or more drinks if male (constitutes binge drinking).

The Brief Young Adult Alcohol Consequences Questionnaire. To assess alcohol-related consequences, participants answered 24 items about their alcohol consumption over the past 30 days (B-YAACQ; Kahler et al., 2005; Kahler et al., 2008). Participants took this measure for the baseline and three-month surveys. This is a series of yes or no items that are summed to create a total score of alcohol-related problems. Higher scores indicate more alcohol consequences experienced. The BYAACQ showed strong internal consistency and reliability in past research (Kahler et al., 2005). In the current study, the internal consistencies of the B-YAACQ was $\alpha =$

.92 and α = .89 for the baseline and three-month follow-up, which indicates excellent and good internal consistency respectively.

Brief-Coping Orientation to Problems Experienced Inventory. Participants completed the Brief-Coping Orientation to Problems Experienced Inventory (Brief-COPE; Carver, 1997) during the baseline and three-month surveys. This scale consists of 28 items that make up 14 subscales. Each of the subscales contains two items. This is the brief version of the original 60-item version. Items are answered on a four-point Likert scale with answers ranging from one- "I usually don't do this at all" to four- "I usually do this a lot." For this study, only the subscale of substance use (using alcohol in reaction to stress) was used. Higher scores indicate more avoidance coping. The reliability (internal consistency) of the Brief-COPE in past research was excellent α = .90 for the substance use scale (Carver, 1997). In the current study, the internal consistency for the baseline Brief-COPE substance use subscale was α = .97, which indicates excellent reliability. The internal consistency of the three-month follow-up Brief-COPE substance use subscale was α = .88, which indicates good reliability.

Peer Coach Perceptions. For the three-month assessment, participants were asked to report their perceptions of the peer coaching exchanges. This scale consists of eight items; these items measure motivation, comfort, support, satisfaction, helpfulness, feeling impersonal, annoyance, and burdensomeness of the intervention. Statements include items such as "I felt supported by my peer coach" or "I was annoyed by the text messaging exchanges with my peer coach." These items were answered on a seven-point Likert scale ranging from "Strongly Disagree" to "Strongly Agree."

Brief Intervention Perceptions. For the three-month assessment, participants were asked to report their perceptions of the brief intervention and personalized feedback. This scale consists

of seven items; these items measure attention, satisfaction, helpfulness, personal relevance, burdensomeness, likelihood of utilizing stress management strategies, and confidence in coping with stress. Statements include items such as "I paid close attention to the information presented today" and "I found it a burden to complete today's session." These items were answered on a seven-point Likert scale ranging from "Strongly Disagree" to "Strongly Agree."

Depression-Anxiety Stress Scale. For the baseline and three-month surveys, participants rated their depression, anxiety, and stress symptoms over the past week using the Depression, Anxiety, and Stress Scale (DASS-21; Henry & Crawford, 2005; Lovibond & Lovibond, 1995). This scale consists of 21 items broken into the three seven-item subscales of depression, anxiety, and stress. This scale is the shortened version of the original 42-item Depression Anxiety Stress Scale (DASS; Lovibond & Lovibond, 1995). The items are answered on a four-point Likert scale ranging from "Did not apply to me at all" to "Applied to me very much, or most of the time." The reliability (internal consistencies) of the DASS-21 depression, anxiety, stress, and total scales in past studies was $\alpha = .88$, $\alpha = .82$, $\alpha = .90$, and $\alpha = .93$ respectively (Henry & Crawford, 2005). For the current study, the internal consistencies of the baseline DASS-21 depression, anxiety, stress, and total scales were $\alpha = .92$, $\alpha = .86$, $\alpha = .83$, and $\alpha = .94$ respectively. The internal consistencies of the DASS-21 depression, anxiety, stress, and total scales at the three-month follow-up were $\alpha = .91$, $\alpha = .84$, $\alpha = .84$, and $\alpha = .95$ respectively. These indicate good internal consistency.

Life Events Checklist for DSM-5. To assess interpersonal trauma exposure, participants completed the Life Events Checklist for DSM-5 (LEC-5; Grey et al., 2004; Weathers et al., 2013). This measure is designed to evaluate whether a person has experienced or witnessed a number of potentially traumatic events, such as physical assault, sexual assault, combat or

exposure to a war zone, life-threatening illness or injury, and/or natural disasters. Participants select from various levels of exposure to each of the 16 events listed, based on a six-point nominal scale: “Happened to me,” “Witnessed it,” “Learned about it,” “Part of my job,” “Not sure,” “Doesn't apply.” Participants may select multiple levels of exposure to the same trauma type. Participants had to endorse exposure to at least one interpersonal trauma event on the LEC-5 to be eligible for the study. At the three-month follow-up, the measure assessed trauma exposure since the previous assessment period.

Data Analysis

To determine the validity of the data, participants’ responses were visually screened and data was examined for issues related to univariate and multivariate outliers prior to analyses. To test hypothesis one (i.e., the feasibility of the intervention) proportions were calculated to determine dropout. To test hypothesis two (the acceptability of the intervention) participant ratings of satisfaction, helpfulness, relevance, and burdensomeness of the intervention were examined. Negative or mostly neutral ratings indicated low acceptability of the intervention. While mostly positive ratings indicated overall intervention acceptability. To determine changes in alcohol use, alcohol problems, coping, and mental health outcomes (e.g., depression, anxiety, stress) dependent samples t-tests were conducted. This tested hypothesis three, the pre- to post-change of the intervention, and determined if any significant changes in alcohol use, alcohol problems, and/or mental health outcomes occurred between the time points of baseline and three months. For the dependent samples t-tests, the effect size was calculated using hedges g. For reference, small, medium, and large effects would be (e.g., .2, .5, .8) (Cohen, 1988). This is an ongoing study, so this data is preliminary.

Results

Data Cleaning

Data from the current project is considered preliminary as data collection is ongoing. Participants' responses underwent visual screening as an initial check of data validity. Univariate and multivariate outliers were also examined but given the within-person focus of the analyses, no participant data was removed. See Table 2 for sample demographic information.

Table 2

Sample Descriptors

	Overall Sample (n = 34)
Age (years)	19.70 (1.47)
Ethnicity/Race [a]	
Caucasian	85.3%
African American	11.8%
Hispanic or Latinx	11.8%
Native American	2.9%
Gender	
Female	85.3%
Male	14.7%
Sexual Orientation	
Straight	76.5%
Bisexual	20.6%
Pansexual	2.9%
Fraternity/Sorority	
Non-Member	70.6%
Member	29.4%

Note. Numbers in parentheses represent the standard deviation.

[a] Ethnicity/race sums to over 100% due to participants endorsing multiple ethnicities/races.

Feasibility

It was hypothesized that the BI would exhibit relatively low levels of dropout (<30%) at the three-month follow-up. Dropout rates were assessed through proportions. Completion rates exceeding 70% were deemed indicative of acceptable feasibility via past studies standards

(Bendtsen, 2013; Bendtsen & Bendtsen, 2014; Bewick et al., 2008; Fjeldsoe et al., 2009; Lee et al., 2021; Rodgers, 2005). For the current study dropout/completion rates were calculated for each time point including the one- and two-month peer coaching time points and the three-month assessment follow-up. Completion rates were generally high for all time points. The completion rates were 76% (26/34) and 74% (25/34) for the one and two-month peer coaching appointments, respectively. The total retention across both coaching points was 75% (51/68). Response rates were also high for the three-month assessment at 71% (24/34). An independent samples t-test was run to test if any demographic variables predicted dropout. No demographic variables were significantly associated with dropout.

Acceptability

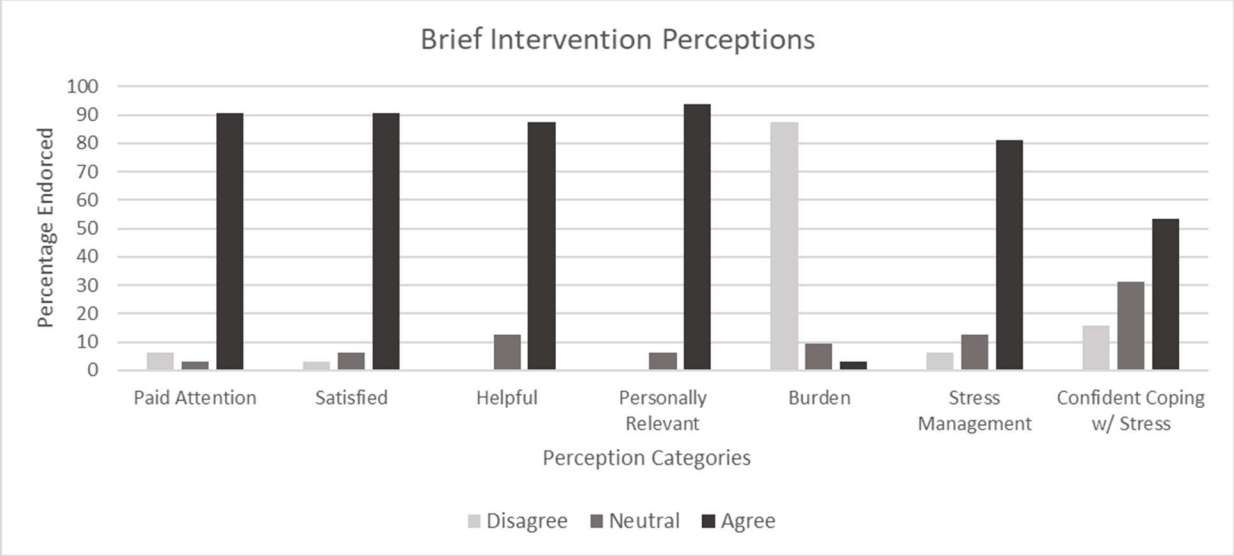
Perceptions of Brief Intervention

It was hypothesized that the BI would be perceived by participants as satisfactory, relevant, helpful, and a low burden. Frequency counts were examined to evaluate the acceptability of the intervention via examination of the proportion of individuals who agreed, disagreed, or were neutral towards a variety of statements about the intervention. See Figure 2 for reference. For the current study, 90.6% of participants agreed that they were satisfied with their personalized feedback, 6.3% reported feeling neutral, and 3.1% disagreed that they were satisfied with their personalized feedback. When reporting whether they found the brief intervention helpful, 87.5% agreed, 12.5% were neutral, and no participants disagreed. When asked whether they found the brief intervention to be a burden 3.1% agreed that it was a burden to complete, 9.4% were neutral, and 87.5% disagreed that it was a burden to complete the intervention. When asked whether the information presented in the brief intervention made them

feel more confident in their ability to cope with their stress, 15.7% of participants disagreed, 31.3% were neutral, and 53.2% of participants agreed.

Figure 2

Brief Intervention Perceptions



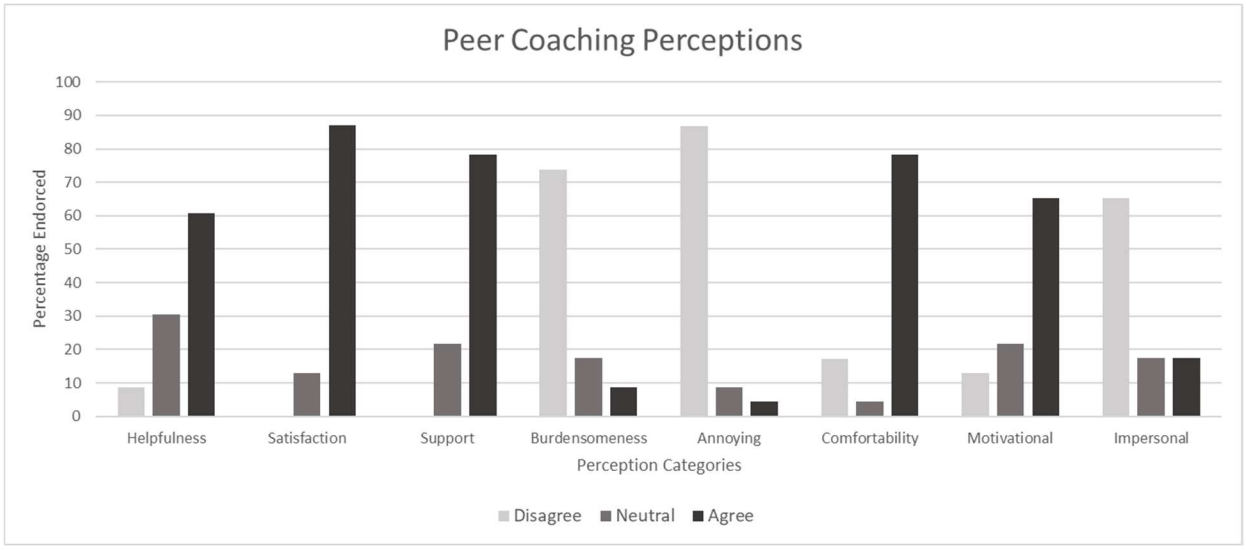
Perceptions of Peer Coaching

Similarly, frequency counts were also used to examine the acceptability of the peer coaching aspect of the intervention via examination of the proportion of individuals who agreed, disagreed, or were neutral. See Figure 3 for reference. For the current study, 60.8% of participants agreed that they found the peer coaching appointment helpful, 30.4% reported feeling neutral, and 8.7% disagreed that the intervention was helpful. When reporting satisfaction, 87% of participants agreed that they were satisfied with the intervention, 13% were neutral, and no participants disagreed with the statement that the intervention was helpful. When asked whether they felt supported by their peer coach, 78.2% of participants agreed, 21.7% were neutral, and no participants disagreed. When asked whether the intervention motivated them to

make positive changes, 65.2% of participants agreed that it did, 21.7% of participants were neutral, and 13% disagreed. Additionally, when asked whether they found the intervention burdensome, 73.9% of participants reported that it was not burdensome, 17.4% were neutral, and 8.7% reported some feelings of burdensomeness. When asked if participants found the intervention annoying 86.9% disagreed that it was annoying, 8.7% were neutral, and 4.3% reported annoyance. Finally, when asked if the peer coach interactions felt impersonal 65.2% disagreed, 17.4% were neutral, and 17.4% agreed that the intervention felt impersonal. Overall, these results indicate generally positive perceptions of the acceptability of the intervention.

Figure 3

Peer Coaching Perceptions



Changes from Baseline to 3-Month Follow-Up

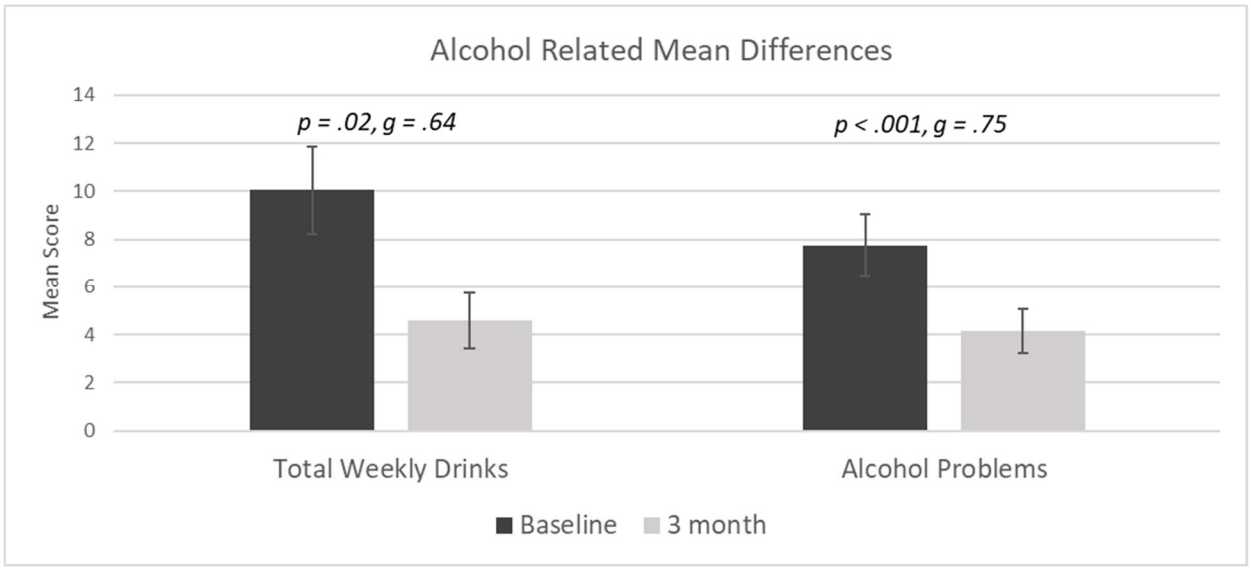
Alcohol-Related Outcomes

It was hypothesized that the BI would be associated with significant reductions in alcohol use, alcohol-related problems, substance-related coping, anxiety, stress, and depression at the

three-month follow-up. Results found that there was a significant decrease in total weekly drinks from baseline (M = 10.0, SD = 8.8) to three-month (M = 4.6, SD = 5.7), $t(23) = 3.25$, $p = .002$, Hedges $g = .64$, and there was also a significant decrease in alcohol-related problems from baseline (M = 7.8, SD = 6.2) to three-month (M = 4.2, SD = 4.5), $t(23) = 3.78$, $p < .001$, Hedges $g = .75$.

Figure 4

Alcohol Outcomes

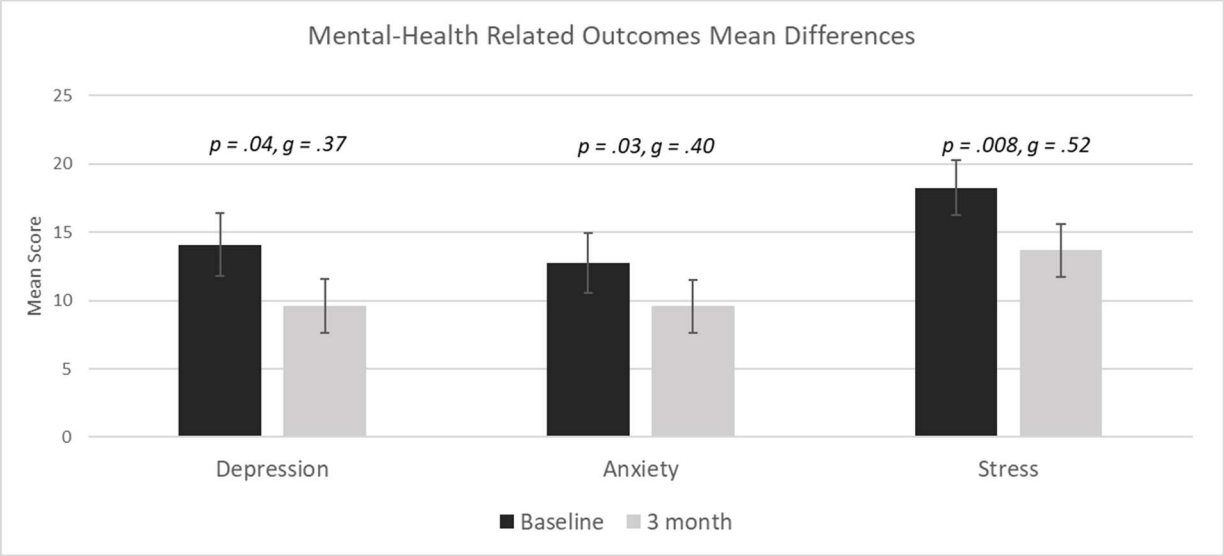


Mental Health Related Outcomes

There was also a significant decrease in symptoms of depression from baseline (M = 14.1, SD = 11.3) to three-month follow-up (M = 9.6, SD = 9.7), $t(23) = 1.85$, $p = .04$, Hedges $g = .37$, a significant decrease in symptoms of anxiety from baseline (M = 12.8, SD = 10.7) to three-month follow-up (M = 9.6, SD = 9.4), $t(23) = 1.96$, $p = .03$, Hedges $g = .40$, and a significant decrease in stress from baseline (M = 18.3, SD = 9.9) to three-month follow-up (M = 13.7, SD = 9.3), $t(23) = 2.61$, $p = .008$, Hedges $g = .52$. See Figure 5 for reference.

Figure 5

Mental-Health Related Outcomes



Coping Related Outcomes

There was a significant decrease in substance use-related coping from baseline (M = 3.9, SD = 2.1) to three-month follow-up (M = 2.7, SD = 1.3), $t(22) = 2.75$, $p = .006$, Hedges $g = .55$.

Discussion

The purpose of the current study was to find an effective, low-resource intervention for young adult college students with interpersonal trauma who have histories of heavy drinking. More specifically, the purpose of this study was to examine the acceptability, feasibility, and effectiveness of a text-based brief alcohol intervention augmented with peer support and coping strategies in a young adult population with histories of heavy drinking and interpersonal trauma. This study also aimed to help these individuals set goals to decrease and control their drinking to promote healthier outcomes. Initial findings suggest the intervention is feasible, acceptable, and

effective at reducing alcohol use and related problems as well as symptoms of depression, anxiety, and stress among a small sample of college students.

Research shows that young adults with histories of interpersonal trauma are more likely than those without trauma to use alcohol as a tool to cope with negative emotions like anxiety and depression (Smith et al., 2021). Additionally, interpersonal trauma survivors have a greater likelihood of experiencing mental health disorders such as PTSD and depression and are also at increased risk of heavy substance use, substance use disorders, and substance-related problems relative to non-interpersonal traumas (Friedman et al., 2022; Kessler et al., 2017). Standard BIs do not address the mental health issues (e.g., depression, anxiety) that may be driving heavy alcohol use and do not include adaptive coping strategies for managing these difficulties. There are also considerable problems with digital interventions including lack of motivation or engagement, lack of human interaction elements, and higher attrition (Kazemi et al., 2017). Given the lack of effectiveness of BIs among heavy alcohol-using young adults with histories of interpersonal trauma, additional interventions are needed to reach this population. This led our research team to develop and evaluate this trauma-informed, peer-supported brief intervention. This study is preliminary data from a larger ongoing pilot study so results should be interpreted with caution.

Findings and Implications

The current study had a 29% dropout rate, which indicates acceptable feasibility and is consistent with past studies using similar approaches (Bendtsen, 2013; Bendtsen & Bendtsen, 2014; Bewick et al., 2008; Fjeldsoe et al., 2009; Lee et al., 2021; Rodgers, 2005). This supports hypothesis one that the BI would exhibit relatively low levels of dropout (<30%) at the three-month follow-up. Notably, this intervention was found to be viable via a relatively low dropout

rate comparable to other studies. Digital interventions are often found to have problems with lack of motivation and engagement as well as higher attrition in past research (Kazemi et al., 2017). These preliminary findings show that digital-delivered BIs, which are less resource-intensive than traditional BIs and allow for greater dissemination and uptake, are feasible among a population of interpersonal trauma survivors. In past studies, BIs have been significantly less effective in trauma survivors than in non-trauma survivors (Kurtz et al., 2019). Thus, augmenting alcohol BIs with peer support and coping mechanisms to address mental health issues shows promise in this typically treatment-resistant population.

Additionally, the majority of participants found the peer coach intervention to be helpful and were satisfied with it. Overall, the majority of participants had positive impressions of both the personalized feedback component of the intervention as well as the peer coaching sessions. This supports hypothesis two that the BI would be perceived by participants as satisfactory, relevant, helpful, and a low burden. The brief intervention was perceived by participants as satisfactory, relevant, helpful, and a low burden. This indicates that our sample of college student young adults with histories of heavy drinking and interpersonal trauma responded positively to a digital BI augmented with peer support and personalized feedback. This is notable because no prior brief interventions have utilized peer coaching via text message. Although peers have been used in some previous studies, peer coaching via mobile phones offer a novel, feasible way of reaching a wide variety of participants without requiring trained clinicians (Larimer et al., 2001). Utilizing trained peers (who have no previous relationship with the participant) may also make participants feel more comfortable and accepted than if a clinician or authority figure were asking about their alcohol use. The added layer of anonymity due to being entirely digital may also make participants feel more comfortable being honest about their alcohol use. This

anonymity is important because alcohol use is a taboo topic for many individuals, especially college students ages 18 to 20 who may fear legal repercussions of underage drinking (Smedslund et al., 2017). Additionally, interactive live text messages vary from automated text messages, which have been used in previous BIs (Mason et al., 2018a; Mason et al., 2018b). Interactive text messages ideally offer a human element that automated messages lack. Positive perceptions of the current study do indicate promise because the majority of participants reported that the peer coaching exchanges did not feel impersonal, despite the structured nature of the exchanges.

However, there was still a portion of participants that appeared to have neutral or unsatisfactory perceptions of the intervention and peer coaching. This could be participants who did not engage as much with the intervention as others or who did not complete the one- or two-month peer coaching sessions. This is not unsurprising given that engagement in digital interventions is often more limited than in face-to-face modalities (Kazemi et al., 2017). Some participants may have felt the intervention was impersonal because it lacked face-to-face interaction. However, digital means provide the advantage of allowing for greater dissemination of the intervention. Altogether, more research is needed to understand what specific factors of the intervention that participants found helpful and how this intervention can be modified to improve engagement and satisfaction.

Additionally, this study found significant reductions in alcohol use, alcohol-related problems, substance-related coping, anxiety, stress, and depression from baseline to three-month follow-up. This supports hypothesis three that the BI would be associated with significant reductions in alcohol use, alcohol-related problems, substance-related coping, anxiety, stress, and depression at three-month follow-up. Notably, participant's alcohol use and alcohol-use-related

problems decreased because heavy drinking is associated with numerous harmful outcomes (e.g. poor mental health, lower life satisfaction, cognitive impairments, poor academic performance, increased risk for motor vehicle accidents, and substance use disorders) and college students with interpersonal trauma are an especially vulnerable population (Bonomo et al., 2001; Volkow et al., 2014). Interpersonal trauma survivors are also a population that traditional BIs do not typically work well for in the literature (Kurtz et al., 2019). Integration of coping motives and peer support with this vulnerable sample may have aided this intervention in significantly reducing alcohol consumption and alcohol-related problems. However, personalized feedback is also a common component of brief interventions that has demonstrated utility in reducing substance use, so this factor likely also contributed (Beyer et al., 2022). Additionally, participants' mental health outcomes improved from pre- to post-intervention. This could have been due to both the decreased alcohol intake and the implementation of stress management strategies promoted in the intervention. Regardless, this study is notable in that improvements were noted in both substance and mental health-related outcomes. Most studies to date target one type of issue or the other, but mental health issues, such as anxiety, depression, and PTSD are highly comorbid with alcohol and substance use disorders, especially in trauma survivors (SAMHSA, 2021). Despite the improvements in alcohol use, alcohol-related problems, and mental health issues, it is unclear what element of the intervention was an important mechanism of change in this sample. This indicates that additional research in an interpersonal trauma survivor sample is needed comparing this intervention to traditional BIs, which lack features such as peer support and emotion regulation strategies.

Limitations

Despite the merits of this study, there were a number of limitations. This study's small sample size (N = 34) hinders the study's generalizability and the conclusions that can be drawn. Additionally, the sample was predominantly white and female, also affecting the study's generalizability. It is important to investigate this intervention in a more diverse sample, such as older adults or racial and ethnic minorities. Another limitation of the present study is there is no control group to compare results to. It is important to see how these results would compare to other interventions such as standard BIs to determine whether it is more effective than standard care. This would elucidate whether the added components of the intervention including peer coaching and coping strategies have additional benefit. Additionally, the follow-up period in the current intervention was rather limited at just three months post-intervention. Given traditional BIs limited duration of effectiveness in the literature (Beyer et al., 2022; Stappenbeck et al., 2021), a more protracted intervention and follow-up period is needed to determine whether effectiveness wanes over time.

Future Directions

This study points to a number of possible future directions. For example, future studies could include utilizing a more rigorous comparison to a standard brief intervention, and/or individuals given no intervention. This would help decipher both the mechanisms of change and whether the significant results are due to intervention or are simply due to the effect of time. Administering a follow-up survey longer after the final intervention could also help test the duration of treatment effects. It is also important to investigate why some individuals did not find the intervention helpful or beneficial. Although the intervention had overall high acceptability, not all individuals had positive perceptions of the intervention. Qualitative interviews or focus groups may be a useful approach in identifying which aspects of the intervention were helpful as

well as why some individuals did not appear to respond positively to the intervention. Additionally, intentionally recruiting a more diverse sample in the future could also increase generalizability. Given the limited long-term effectiveness of alcohol BIs, utilizing more intervention sessions over a longer period of time could potentially extend the effectiveness.

Future studies could also benefit from utilizing this augmented BI in individuals who use cannabis, as past research suggests BIs are not effective for reducing frequency of cannabis use (Halladay et al., 2019; Tanner-Smith et al., 2022). Co-use of alcohol and cannabis use is highly prevalent among college student young adults (Schulenberg et al., 2019). Cannabis use is also associated with many negative outcomes (e.g. poor mental health, lower life satisfaction, cognitive impairment, poor academic performance, increased risk for motor vehicle accidents, and substance use disorders) and thus warrants additional investigation into how to increase the effectiveness of BIs for cannabis users (Bonomo et al., 2001; Volkow et al., 2014). As such, this intervention may also hold utility in non-trauma-exposed populations of substance users and could be easily modified for implementation in cannabis users. Furthermore, additional investigations could compare whether the intervention is more effective in trauma vs. non-trauma samples to demonstrate its broad utility.

Conclusions

Alcohol BIs have restricted effectiveness in populations with trauma (Kurtz et al., 2019; Tanner-Smith et al., 2022) and limited research has been conducted on entirely interpersonal trauma survivors (Stappenbeck et al., 2021). Additionally, college student young adults are at a higher risk for both heavy drinking and experiencing interpersonal trauma (Friedman et al., 2021; Smith et al., 2021). Thus, it is imperative to augment existing BIs to work effectively in young adult college students with histories of interpersonal trauma and heavy drinking while also

keeping treatment accessible and feasible through means that use minimal resources. The current study found promising preliminary results that suggest a text-message-based alcohol BI augmented with peer support can be feasible, acceptable, and effective among this population. This study points to fruitful ways to adapt existing interventions to potentially improve and extend the duration of their effectiveness. Although more work is needed to determine the utility of the current intervention to existing alternatives, this study holds promise for moving the field of brief interventions forward to reach at-risk populations and bolster prevention efforts for trauma-exposed substance users.

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APPENDIX A

IRB Approval

INSTITUTIONAL REVIEW BOARD
OFFICE OF RESEARCH INTEGRITY

DATE:	September 27, 2023
TO:	Matt Woodward, Ph.D.
FROM:	Western Kentucky University (WKU) IRB
PROJECT TITLE:	[1839376-6] A Randomized Controlled Trial of a Trauma-Informed and Peer-Supported Mobile Brief Intervention for Alcohol and Cannabis Users with Interpersonal Trauma
REFERENCE #:	IRB# 22-132
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	September 27, 2023
EXPIRATION DATE:	October 26, 2024
REVIEW TYPE:	Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The Western Kentucky University (WKU) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a *signed/implied* consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

This project has been determined to be a MINIMAL RISK project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of October 26, 2024.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Robin Pyles at (270) 745-3360 or Robin.Pyles@wku.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Western Kentucky University (WKU) IRB's records.

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