Does the use of alcohol to treat pain affect drinking reduction among women with HIV enrolled in a randomized placebo-controlled clinical trial of naltrexone?

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Abstract

Background: Many women living with HIV (WLWH) experience pain. Alcohol use with the intent to treat pain could lead to hazardous drinking and difficulty in reducing drinking. Naltrexone acts on opioid receptors important for pain regulation and has shown promise in treating alcohol use disorder. In this secondary analysis of a randomized double-blind placebo-controlled naltrexone clinical trial, the goals were to 1) Assess alcohol reduction between those who did and did not drink to treat pain and 2) Further examine differences in alcohol reduction by both drinking intention and treatment arm.

Methods: WLWH (N=194, mean age 48.3 years, 83% non-Hispanic Black, 11% Hispanic) with hazardous drinking (>7 drinks/week) were randomized to 50mg naltrexone or placebo for four months. Study visits occurred at baseline, 2-months, 4-months, and 7-months (post-treatment). Drinks/week was measured using Timeline Follow Back. Use of alcohol to treat pain was self-reported. Participants were categorized as using alcohol to treat pain or not and in the naltrexone or placebo group. Chi-square, t-test, MANOVA, and sequential mixed effects models were used to determine group differences in demographic factors, mean/drinks per week, and percent change in mean drinks/week at baseline and each follow-up.

Results: There was a consistent decrease in drinking throughout the study. There was not a significant difference in mean drinks/week at any point in the study between those who did and did not use alcohol to treat pain. When considering treatment arm, at 2-months only those who did not use alcohol to treat pain in the naltrexone group had a significantly lower mean drinks/week than the other groups (p=0.007); all groups had similar decreases in drinking from 4-months onward.

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Conclusion: In the naltrexone group, WLWH who drank to treat pain had a slower alcohol reduction than WLWH who did not drink to treat pain. If these findings are replicated, alcohol treatment guidelines might consider addressing pain to provide more impactful care.

Keywords

alcohol; pain; naltrexone; women; HIV

Introduction

Pain is a common condition experienced by many individuals with up to 20% of Americans experiencing chronic pain and 10% experiencing high-impact chronic pain (Dahlhamer *et al.*, 2018). People with pain use a variety of methods to treat or cope with it. Alcohol use has been reported among people living with severe pain and is commonly reported as a method to cope with pain-related symptoms (Alford *et al.*, 2016; Brennan *et al.*, 2005; Riley & King, 2009). There are biological mechanisms to substantiate an acute analgesic effect post-alcohol use (Apkarian *et al.*, 2013; Egli *et al.*, 2012; Neddenriep *et al.*, 2019; Thompson *et al.*, 2017). However, individuals who use alcohol to treat pain are more likely to experience greater pain frequency (Riley & King, 2009). Ferguson et al. established a mechanistic model with pain as an antecedent to substance use as a coping response (Ferguson *et al.*, 2021). If people find that alcohol use reduces pain, they might begin drinking at unhealthy levels to feel those effects. Moreover, it is possible that the expectation of pain relief from alcohol can lead to heavier drinking (LaRowe *et al.*, 2021a, LaRowe *et al.*, 2021b).

There is evidence that drinking to treat pain could lead to hazardous alcohol use. The amount of alcohol needed to experience analgesic effects is greater than recommended drinking levels (Thompson *et al.*, 2017). Other researchers have found that individuals with high-intensity chronic pain consume more alcohol, had more hazardous drinking patterns, and had greater severity of alcohol withdrawal symptoms than those with low-intensity pain (Nieto *et al.*, 2021) and that, among those with any recent heavy alcohol use, over one-third drank to treat pain (Alford *et al.*, 2016). Additionally, experimental studies have found that participants who undergo experimental pain induction subsequently report greater urge to drink and greater intention to consume alcohol (Moskal *et al.*, 2018). Substance use to manage pain may create a positive feedback loop resulting in further exacerbation of pain symptoms and thus require a further increase in substance use (Ditre *et al.*, 2019). Therefore, those who have pain and who use alcohol to treat their pain might find it difficult to reduce their alcohol use.

The opiate receptor is a biological mechanism that could link alcohol and pain (Egli *et al.*, 2012). Naltrexone is an opioid antagonist traditionally used to treat opiate use disorders but has shown promise in treating alcohol use disorder (Anton, 2008). Past research has investigated the use of naltrexone to independently treat alcohol (Cook *et al.*, 2019) or pain (Younger *et al.*, 2014), but less is known about the potential to dually treat alcohol and pain among those who drink to treat pain. A randomized clinical trial of people living with HIV (PLWH) who had chronic pain and heavy drinking patterns found low-dose naltrexone

(4.5mg) was well-tolerated and provided a basis for repeated studies looking at the potential for naltrexone to dually treat both conditions (Bendiks *et al.,* 2021). The treatment of pain by means other than alcohol use could encourage people who drink to treat pain to reduce their alcohol use, but those with hazardous alcohol use or alcohol use disorder will still likely need assistance in reducing their alcohol use. Treatments that target both pain and alcohol use should be further investigated for effectiveness and feasibility.

Prior studies have found that women have a higher prevalence of chronic pain than their male counterparts (22% vs 19%) (Fillingim *et al.*, 2009; Zelaya *et al.*, 2020). Women may also experience greater pain intensity across multiple physical sites (Jiménez-Trujillo *et al.*, 2019) and are more frequently diagnosed with common pain conditions like fibromyalgia (Yunus, 2001), migraine (Buse *et al.*, 2013), and irritable bowel disease (Sandler, 1990), in addition to the experience of sex-specific pain conditions like endometriosis (Maddern *et al.*, 2020). Studies have found that women living with HIV (WLWH) tend to have a higher prevalence of pain than women in the general population. Pereira et al. found that 70% of WLWH reported experiencing pain beyond what is normally expected (e.g., pain from minor headaches, sprains, toothaches) and that women were 79% more likely than men living with HIV to report pain (Pereira *et al.*, 2019). Sabin et al., found that 53% of WLWH reported experiencing moderate to severe pain (Sabin *et al.*, 2021). Little is known about the use of alcohol to treat pain among WLWH.

Hazardous alcohol use is a common problem among PLWH and is associated with negative HIV-related health consequences such as reduced viral suppression and reduced antiretroviral medication adherence (Berg et al., 2009; Cook et al., 2017). In a study of men over 50 years of age living with HIV and chronic pain, alcohol use disorder was significantly associated with missing HIV care appointments (Taylor *et al.,* 2023). Past research has found that WLWH experience poorer HIV care outcomes as drinking level increases (Matson *et al.*, 2018). A secondary analysis of a randomized clinical trial in St. Petersburg, Russia found that pain that interfered with daily life was associated with greater odds of risky drinking among a cohort of people with HIV (Tsui *et al.,* 2014). Another study of PLWH with chronic pain on long-term opioid therapy found that hazardous alcohol use was significantly associated with higher interference of pain in daily life (Ngo *et al.*, 2021). Additionally, pain is associated with many negative HIV clinical outcomes, including lower antiretroviral (ART) adherence (Surratt *et al.*, 2015; Willoughby *al.*, 2021), clinic visit utilization (Merlin *et al.*, 2013a; Safo *et al.*, 2017), physical function (Merlin *et al.*, 2013b), and mental health (Mann *et al.*, 2016; Merlin *et al.*, 2012). Finding ways to better address hazardous alcohol use and pain among PLWH and specific subgroups that might be disproportionately impacted such as PLWH has the potential to improve their HIV-related and overall health outcomes.

Previous work by the research team found, in a clinical trial looking at alcohol reduction among WLWH with hazardous drinking, naltrexone was more effective than placebo in reducing alcohol use within 2 months, but at subsequent follow-ups there were no statistically significant differences in drinking levels between the placebo and treatment groups (Cook *et al.,* 2019). In this secondary analysis of existing data, our goal was to examine the effect of drinking with the intention of treating pain on alcohol reduction

success in a naltrexone clinical trial. Our aims were to 1) assess the reduction of alcohol use over time between those who used alcohol to treat pain and those who did not, and 2) determine whether there were differences in alcohol reduction between those who used alcohol to treat pain and those who did not by treatment arm (i.e., naltrexone vs placebo). We hypothesized that WLWH using alcohol to treat pain would have less reduction in their drinking throughout the clinical trial, and that the use of alcohol to treat pain would moderate the effect of naltrexone in helping WLWH reduce their drinking.

Methods

Study Sample and Procedures:

This is a secondary analysis of de-identified longitudinal data from a randomized double-blinded clinical trial of naltrexone vs. placebo among WLWH with hazardous alcohol use. Details of the original study have been published (Cook *et al.*, 2019) and are described at ClinicalTrials.gov (NCT01625091), but in brief, women were eligible if: they were diagnosed with HIV, were assigned female at birth, were 18 years of age or older, were not currently pregnant/breastfeeding or using opioids, were able to commit to follow-ups, reported hazardous drinking by National Institute on Alcohol Abuse and Alcoholism designation (>7 drinks/week for women or >3 drinks/occasion) (National Institute on Alcohol Abuse and Alcoholism, 2022), and were willing to take a medication to reduce drinking. The final enrolled sample was 194 WLWH (mean age 48.3 years, 83% non-Hispanic Black, 11% Hispanic). WLWH with and without pain are included in this sample.

Naltrexone was chosen due to its mechanism of action as an opioid antagonist, ease of administration (once daily), evidence that it is generally well-tolerated, and preliminary data supporting alcohol reduction (Garbutt, 2010; Jonas *et al.*, 2014; Maisel *et al.*, 2013; Tidey *et al.*, 2008). Women were randomized to take 50mg naltrexone or placebo daily for 4 months in an approximate 1:1 allocation, with 96 (50%) participants assigned to naltrexone and 98 (51%) to placebo. A final follow-up post-treatment was scheduled at 7 months. Outcomes were assessed at baseline, 2 months, 4 months, and 7 months follow-up and included alcohol consumption and HIV-related outcomes. Most participants (n=166, [86%]) completed all follow-up assessments.

All participants provided informed consent prior to study enrollment. Data are available through a formal concept submission and review system.

Measures:

For this study, general current pain was measured using five questions from the short-form Brief Pain Inventory (BPI) severity subscale (Cleeland *et al.*, 1991), modified to ask about past week pain rather than pain today. The first question asked if the participant had any experiences with pain, other than minor everyday pain such as a headache, in the past week. If the participant answered "yes," they were given an additional 4 questions assessing, on a scale of 0–10 with 0 being "no pain" and 10 being "pain as bad as you can imagine": the pain at its worst, the pain at its least, average pain, and current pain. The pain severity score used for this study was calculated as the arithmetic mean of these four items, ranging from

0–10. This score was categorized as follows, as established in previous literature: 0=no pain, greater than 0 and up to 4=mild pain, greater than 4 and up to 6=moderate pain, greater than 6=severe pain (Cleeland *et al.*, 1991; Kapstad *et al.*, 2008; Serlin *et al.*, 1995). Participants reporting pain were also asked about their use of alcohol to treat pain with the following question: "In the past week, did you drink any alcoholic beverage, including beer or wine (and liquor), to treat your pain?" Those who said "yes" were classified as using alcohol to treat their pain. Those that reported no pain were categorized as not using alcohol to treat pain. Perceived relief of pain treated by alcohol was self-reported on a numerical scale (0=no relief to 10=complete relief) by those who reported using alcohol to treat pain.

Self-reported number of drinks in the past 30 days was measured using Timeline Follow Back (TLFB). Average number of drinks/week was calculated at each follow-up. The Alcohol Use Disorder Identification Test (AUDIT) was used to determine hazardous drinking and behaviors with a score of 16 or greater indicating a high level of alcohol-related problems and possible alcohol use disorder (AUD) (Babor *et al.,* 2001; Saunders *et al.,* 1993). The Short Inventory of Problems (SIP) identified alcohol-related problems associated with an AUD (Miller *et al.,* 1995). Change in drinking was calculated as change in mean drinks/week as well as percent reduction in mean drinks/week to control for differences in baseline drinking. Percent change in alcohol use from baseline to subsequent timepoints was calculated by subtracting the mean drinks/week reported at the follow-up timepoints from the baseline reported mean number of drinks/week and divided by the baseline mean drinks/week.

Analysis:

Differences in baseline characteristics between those who did and did not use alcohol to treat pain were determined using chi-square for categorical variables and t-test for continuous variables. Significant differences in mean drinks/week and percent change in mean drinks/week between those who did and did not drink to treat pain at specific timepoints were determined via t-test. All analyses were completed using SAS 9.4 (SAS Institute, 2013).

To assess differences in percent reduction in alcohol over time by use of alcohol to treat pain, sequential mixed effects models with fixed (between-group) and random (within-group) intercepts and slopes were conducted. First, models were compared with different potential variance-covariance structures of the repeated measures to determine the structure with the best model fit and least degrees of freedom. Autoregressive heterogenous was the final chosen structure. Second, we specified time as a fixed effect and if significant, modeled time as a random effect. Third, with time modeled, we specified drinking to treat pain as an independent fixed effect. Fourth, we specified a fixed interaction between time and drinking to treat pain. This analysis was repeated to examine differences in percent reduction in mean drinks/week between those with and without pain to determine if pain, rather than drinking to treat pain, had an effect on drinking reduction.

In a final exploratory analysis, we created a new variable combining the use of alcohol to treat pain with treatment group, creating four groups: 1) used alcohol to treat pain, randomized to naltrexone; 2) used alcohol to treat pain, randomized to placebo; 3) did not use alcohol to treat pain, randomized to naltrexone; and 4) did not use alcohol to treat

pain, randomized to placebo. MANOVA was used to determine significant differences in mean drinks/week and percent change in mean drinks/week between the four groups, and sequential mixed effects models using previously described methods were created to assess differences in percent change in mean drinks/week over time between the four groups.

Individuals with missing drinking data were excluded at those timepoints.

Results

Study Baseline Characteristics:

Eighty-two participants of the 194 total (42%) reported having any pain. Of those with any pain, 16% had mild pain, 32% had moderate, and 52% had severe pain. Of those with any pain, 59 (72%) used alcohol to treat pain in the past week. The median pain relief provided by alcohol was 6 out of 10 (mean=6.4).

Comparing baseline characteristics between those who did and did not drink to treat pain, there were significant differences by race/ethnicity (p=0.020), baseline AUDIT score (p=0.010), and baseline SIP score (p=0.017) only (see Table 1). Participants who used alcohol to drink pain had a higher mean SIP score, indicating higher instance of alcohol-related problems. Those who drank to treat pain and those who did not drink to treat pain had similar baseline mean drinks consumed per week (62.7 vs 68.0, t=0.35, p=0.725).

In the naltrexone group (n=96), 67 (70%) did not use alcohol to treat pain (Group 1) and 29 (30%) used alcohol to treat pain (Group 2). In the placebo group (n=98), 68 (69%) did not use alcohol to treat pain (Group 3) and 30 (31%) used alcohol to treat pain and were in the placebo group (Group 4). The mean number of drinks/week over time are shown in Figure 1a. Baseline differences in drinking between the four groups were not significant (F=1.06, p=0.543). Retention at each timepoint by each of these groups can be seen in Table 2.

Longitudinal Findings:

There were no significant differences in mean drinks/week or the percent change in mean drinks/week by use of alcohol to treat pain at any of the follow-ups. At 2 months, those who used alcohol to treat pain had a mean of 27 drinks/week while those who did not use alcohol to treat pain had a mean of 17 drinks/week (t=−1.68, p=0.095). At 4 months, the last session at which naltrexone was administered, those who used alcohol to treat pain had a mean of 16 drinks/week compared with 14 drinks/week for those who did not use alcohol to treat pain (t=−0.56, p=0.579). Finally, at 7 months, after the end of the intervention, both groups had a weekly average of 9 drinks (t=0.15, p=0.883). Further, those who drank to treat pain had nearly the same percent change as those who did not drink to treat pain (−80.4% and −81.1%, respectively, t=−0.10, p=0.917) by the end of the study. The mixed effects models confirmed that drinking to treat pain did not have a significant fixed effect, and there was also not a significant random effect of drinking to treat pain on percent change in drinking at follow-ups; this provides further support that there were no significant differences in alcohol reduction by drinking to treat pain.

Treatment Arm Results:

When considering treatment group assignment, all groups had consistent decreases in the mean number of drinks/week at each time point throughout the study. Overall, there was a significant difference in terms of reduction in mean drinks/week (F=1.21, p=0.046) and in percent change in mean drinks/week (F=1.45, p=0.002) between the 4 groups. When looking at specific timepoints, at 2 months only there was a significant difference between the four groups in mean drinks/week (F=1.99, p=0.007). There was also a corresponding significant difference in percent change at this timepoint only (F=2.03, p=0.011); see Figure 1b. At 2 months, those in Group 4 (used alcohol for pain/placebo) had the highest mean drinks/week at 28.7 drinks, followed by those in Group 2 (used alcohol for pain/naltrexone) at 25.0 drinks/week, then those in the Group 3 (no alcohol for pain/placebo) at 23.6 drinks/week, all similar, while those in the Group 1 (no alcohol for pain/naltrexone) had the lowest at 10.5 drinks/week, statistically significantly different from the other groups. There were no significant differences between groups at 4 months (F=1.12, p=0.317) or 7 months (F=0.96, p=0.566). The mixed effects models showed a significant fixed effect of time (F=15.24, p<0.001) on percent change in drinks/week as well as a significant fixed interaction effect between time and group membership (F=3.04, p=0.007), providing further support that there were general differences in the speed of alcohol reduction by group membership.

To confirm whether pain specifically or drinking to treat pain was driving differences in alcohol reduction, we also repeated this analysis while examining the alcohol reduction between those with and without pain. The results were nonsignificant at all timepoints.

Discussion

Among this sample of WLWH who drink heavily, the mean number of drinks/week decreased generally, regardless of use of alcohol to treat pain throughout the course of the trial. In this cohort, 42% of WLWH with hazardous drinking levels reported pain and of those, 72% reported current use of alcohol to treat pain. This aligns with prior studies, which suggests many people with pain use alcohol or other unprescribed substances to treat pain (Alford *et al.*, 2016).

While we did not see a significant association between the use of alcohol to treat pain on the reduction of alcohol use overall, we provide interesting insights from analyses when comparing 4 groups that were categorized by use of alcohol to treat pain and treatment arm. Those assigned to the placebo arm had a similar reduction in drinking between those who used or did not use alcohol to treat pain, with those using alcohol to treat pain having slightly higher alcohol use across all timepoints. Among those in the naltrexone arm, those that did not use alcohol to treat pain featured the sharpest decrease in drinking from baseline to 2-months, with about an 80% reduction; this was significantly different from the other groups. It took an additional 2 months of naltrexone treatment for those who used alcohol to treat pain to reach a similar reduction in drinking (by the 4-month visit). By the end of the study (7-month visit) both naltrexone groups reduced drinking at similar levels, and these levels were similar to those in the placebo group regardless of drinking intention. It is possible that, among the naltrexone group, the difference in success in drinking reduction could have been tempered by drinking to treat pain as those who did not drink to treat

pain had a quicker decline in mean drinks/week, though we are underpowered to draw a more robust conclusion. Using alcohol to treat pain may present an additional barrier to substantially reducing alcohol use during a short period in this population as they could be relying partly on alcohol to manage their pain. These results provide a foundation for further validation studies of naltrexone with a larger sample size, different doses, and perhaps a longer follow-up period, and reinforce the idea that concurrent treatment of pain and hazardous alcohol could be effective among those experiencing both.

All groups maintained their decreases in drinking throughout the trial, even when naltrexone administration finished, and the retention rate was relatively high for both overall sample and across subgroups. This could be attributed more to involvement in a clinical trial rather than naltrexone, especially given that those in the placebo group experienced similar decreases in mean drinks/week. However, it does show promise that motivated individuals with hazardous drinking can experience great success when participating in alcohol reduction interventions.

Alcohol use was reported as a moderately effective pain reliever in this sample, which positively reinforced its use to treat pain. This could create additional challenges in reducing alcohol consumption among those who drink to treat pain, especially since this perceived pain relief conflicts with reports that hazardous drinking is associated with greater pain severity (Zale *et al.*, 2015). The expectation of alcohol's pain-relieving effects has been associated with heavier drinking among people with and without chronic pain (LaRowe *et al.*, 2021a, LaRowe *et al.*, 2021b). This aligns with Ferguson et al.'s mechanistic model which suggests that expectancy of substance-related analgesia is a moderator of the bidirectional pain-to-substance use pathway (Ferguson et al. 2021). To avoid the negative outcomes associated with alcohol as a pain-relief method, we recommend that providers who treat pain thoroughly assess alcohol use in their clients. Unfortunately, prior research has indicated that less than 16% of adults report ever discussing alcohol consumption with their provider (McKnight-Eily *et al.*, 2014). It is also crucial that providers treating clients for alcohol use disorder assess pain, as pain can result in heavy drinking relapse during or after alcohol treatment (Witkiewitz *et al.*, 2015). Past qualitative research among PLWH with chronic pain found that those who indicated using alcohol or other substance to self-manage their pain did not describe it as a highly effective or as their preferred pain management strategy (Merlin *et al.,* 2015). This shows that people who use alcohol to treat their pain might want a strategy to manage pain that does not require alcohol consumption, and working with a provider to address hazardous alcohol use and pain could be the best way to do that.

Our findings should be considered with several limitations. First, this is a post-hoc secondary analysis from a completed clinical trial. Due to the sample size, this study may be underpowered to determine differences in effect sizes between groups of drinking to treat pain and treatment arm. The study also experienced an overall attrition rate of 14%, and those who left the study could have been different from those who remained. An additional study with a larger sample size should be completed to confirm our findings on the potential for naltrexone as an effective treatment for those experiencing pain and hazardous alcohol use. Larger studies can also use multivariable models in their analyses to control for

covariates and pain severity, which was not done in this study. Second, drinks/week were self-reported; though data were collected with standardized TLFB and all research assistants involved with data collection were well-trained, there is the possibility of recall or social desirability bias leading to under-reporting. Third, our study was limited by a relatively short post-intervention follow-up (3 months after the end of naltrexone/placebo). Future studies of long-term efficacy are warranted. Fourth, we cannot distinguish between chronic and episodic pain or pain site. However, we expect the use of alcohol to treat pain is more likely among those with chronic pain compared to episodic pain – nonetheless we cannot confirm this with the current study. Pain was also measured only at baseline, so we do not have data on changes in pain throughout the study. Questions on other important measures of the impact of pain on daily life, such as pain interference and pain catastrophizing, were not included in the survey, but could add additional insights in future studies on this topic. Finally, there are mixed findings in the literature regarding the use of naltrexone for pain management. Most past studies on the subject have been done with low-dose naltrexone, not the 50mg dose used in this study. Additional studies stemming from this research should examine the effect of different naltrexone doses on drinking reduction and pain.

We hope our results provide preliminary support for future examinations of naltrexone as a dual treatment of alcohol and pain. Further, our work suggests that the treatment of alcohol use (regardless of mode) could be bolstered by treatment of pain when patients report the intent of alcohol use to manage pain.

Conclusion

Motivations for drinking could greatly impact the willingness or the ability of someone to reduce their drinking, and this might be especially true if someone is drinking alcohol to treat their pain. Pain and drinking to treat pain were common among this sample of WLWH with hazardous drinking patterns. Though these findings should be considered in light of the study's limitations, in this analysis, WLWH in the alcohol to treat pain/naltrexone group had significantly worse initial success in alcohol reduction compared with the no alcohol to treat pain/naltrexone group, but this difference was not present at 4 months or post-treatment. This study provides preliminary data about the effectiveness of naltrexone to treat co-occurring hazardous alcohol use and pain that can be tested further in future research. If these findings are replicated in other studies, alcohol treatment guidelines might consider dually addressing pain and alcohol use. This could provide targeted, and potentially more effective, care for patients experiencing pain and hazardous alcohol use patterns.
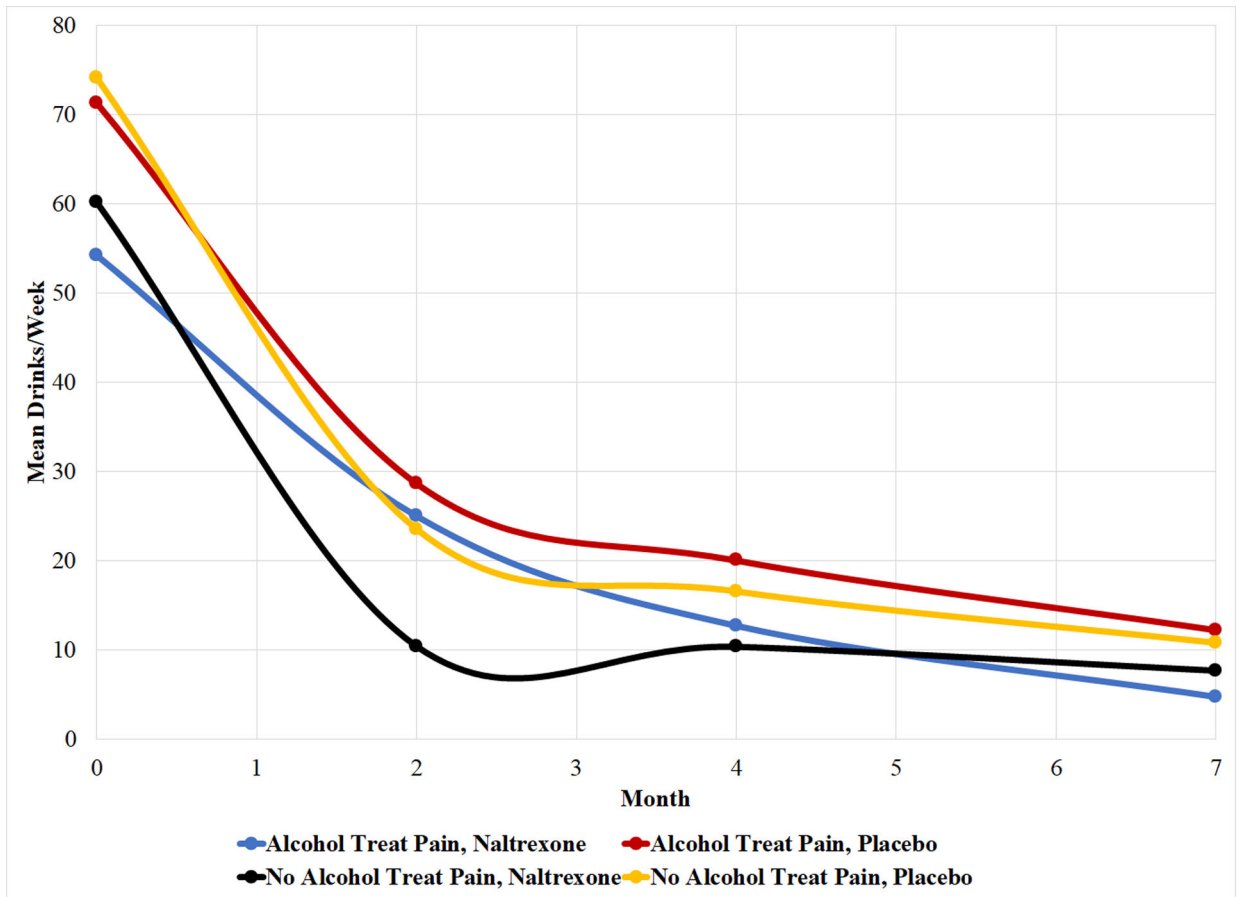
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1a.

Mean Drinks/Week by Month Among 4 Groups of Women Living With HIV. Group differences are statistically significant at 2 months (F=1.99, p=0.007) but not at Baseline (F=1.06, p=0.543), 4 months (F=1.12, p=0.317), or 7 months (F=0.96, p=0.566).
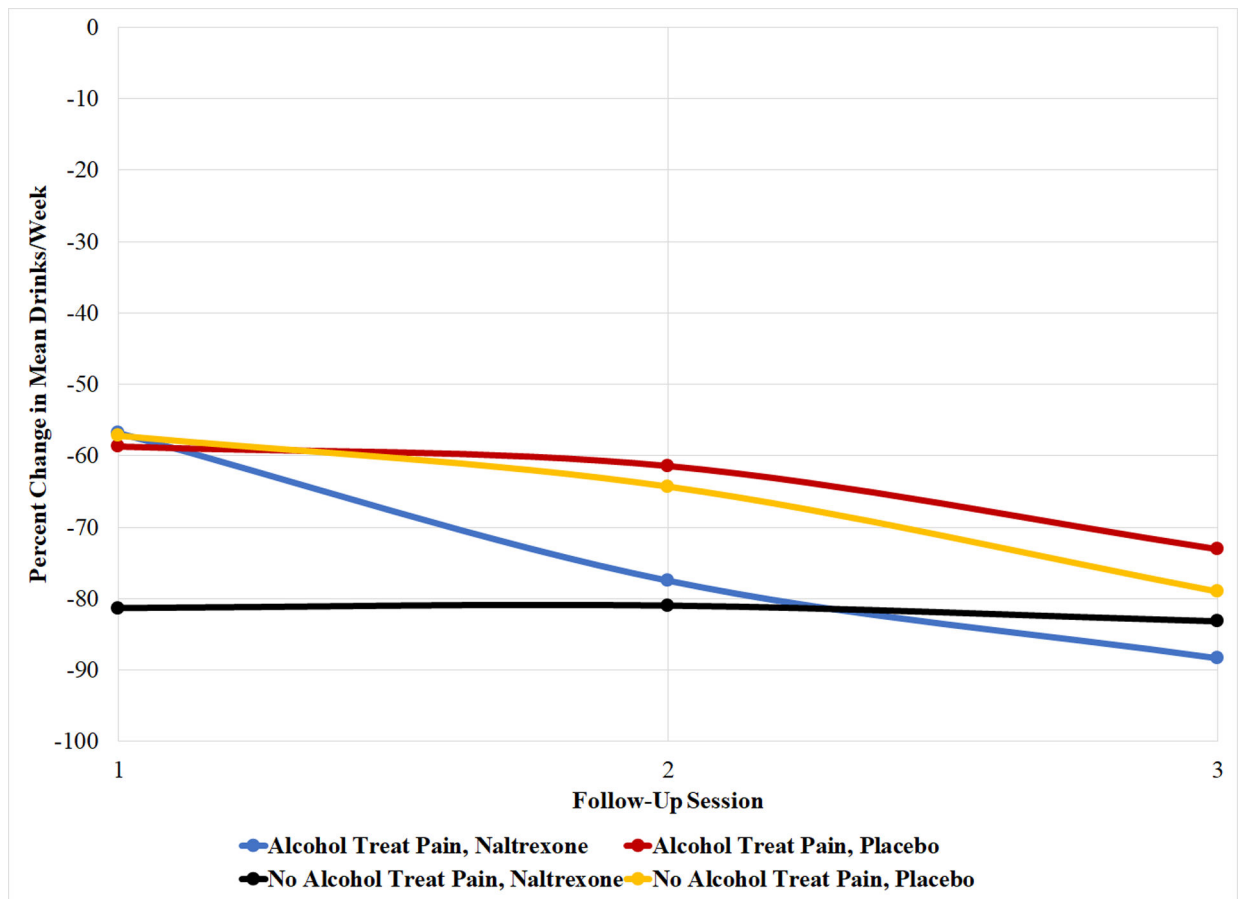
1b.

Percent Change in Mean Drinks/Week by Follow-Up Session Among 4 Groups of Women Living With HIV. Follow-Up session 1 was at 2 months, follow-up session 2 was at 4 months, and follow-up session 3 was at 7 months. Group differences are statistically significant at Follow-Up 1 (F=2.03, p=0.011) but not Follow-Up 2 (F=1.07, p=0.399) or Follow-Up 3 (F=0.98, p=0.539).

Table 1:

Study Participant Demographics by Use of Alcohol to Treat Pain

	Used Alcohol to Treat Pain (n=59)	Did Not Use Alcohol to Treat Pain (n=135)	Test Statistic and P-Value
Mean Age (Standard Deviation)	*48.5 (8.7)*	*48.3 (8.7)*	*t=−0.17 p=0.865*
Mean SIP Score (Standard Deviation)	*15.8 (11.8)*	*11.7 (10.6)*	*t=−2.41 p=0.017*
Race/Ethnicity			
Hispanic	12 (20.3%)	10 (7.4%)	χ^2=9.86 p=0.020
Black/African American	43 (72.9%)	118 (87.4%)	
White	4 (6.8%)	4 (3.0%)	
Other	0 (0.0%)	3 (2.2%)	
Education			
Less than High School	29 (49.2%)	55 (40.7%)	χ^2=1.83 p=0.277
High School or Greater	30 (51.8%)	80 (59.3%)	
Current Employment			
Employed	5 (8.5%)	15 (11.1%)	χ^2=0.31 p=0.579
Unemployed	54 (91.5%)	120 (88.9%)	
Marital Status			
Married/Living with Partner	48 (81.4%)	115 (85.2%)	χ^2=0.45 p=0.503
Single/Separated/Divorced/Widowed	11 (18.6%)	20 (14.8%)	
AUDIT Scores			
0–7	4 (6.8%)	19 (14.1%)	χ^2=11.41 p=0.010
8–15	22 (37.3%)	54 (40.0%)	
16–19	4 (6.8%)	25 (18.5%)	
20	29 (49.2%)	37 (27.4%)	

Table 2:

Study Retention by Drinking Intention and Treatment Arm

	Group 1 No Alcohol Treat Pain, Naltrexone (n=67)	Group 2 Alcohol Treat Pain, Naltrexone (n=29)	Group 3 No Alcohol Treat Pain, Placebo (n=68)	Group 4 Alcohol Treat Pain, Placebo (n=30)	Total (N=194)
2 Months	63 (94.0%)	27 (93.1%)	64 (94.1%)	29 (96.7%)	183 (94.3%)
4 Months	58 (86.6%)	27 (93.1%)	59 (86.8%)	28 (93.3%)	172 (88.7%)
7 Months	56 (83.6%)	25 (86.2%)	58 (85.3%)	27 (90.0%)	166 (85.6%)