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Randomized Controlled Trial Demonstrates Efficacy of a Culturally Adapted Behavioral Intervention Delivered in Spanish by Community Health Workers to Reduce Unhealthy Alcohol Use Among Latino/as

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Objective: Latino/as comprise nearly 20% of the US population; 25% report past month binge drinking, and disparities in care persist. Culturally adapted interventions may improve outcomes and access. We tested the efficacy of a culturally adapted behavioral intervention to reduce unhealthy alcohol use, delivered in Spanish to Latino/a adults.

Method: We conducted a parallel, two-group, randomized controlled trial with 12- and 26-week follow-ups to test a 3-session intervention delivered by community health workers (CHWs) from a community-based agency in Los Angeles, California. The intervention combined culturally-adapted Motivational Enhancement Therapy and Strengths Based Case Management (CA-MET/SBCM) and was compared to the "*Rethinking Drinking*" booklet. Participants were 236 non-treatment seeking Latino/a adults who exceeded NIAAA low risk drinking limits. The primary outcome was percentage of heavy drinking days (≥ 5 drinks for men, ≥ 4 drinks for women) in the past 90 days at 26 weeks. Secondary outcomes were average number of drinks per week and alcohol-related problems.

Results: The CA-MET/SBCM group had greater reductions in heavy drinking days and average drinks per week at week 26 compared to the *Rethinking Drinking* group (-21.7 vs -12.9 for percent heavy drinking days; -15.9 vs -9.8 for average drinks per week). At week 12, heavy drinking days were also significantly reduced in the CA-MET/SBCM group (-18.5 vs -10.3).

Conclusions: A culturally adapted behavioral intervention, combining MET and SBCM, delivered by Spanish-speaking CHWs significantly reduced unhealthy alcohol use

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among Latino/as. These results are promising in addressing health disparities, though continued research is essential to further reduce unhealthy drinking and advance health equity for Latino/as.

Introduction

In 2023, Latino/as, the fastest growing racial/ethnic group in the US, comprised 19.5% of the population, with Los Angeles, California having the largest Latino/a population (Census.gov, 2024). Latino/as have increased rates of binge drinking compared to other racial/ethnic groups. Using data from the 2023 National Survey of Drug Use and Health (NSDUH) (SAMSHA, 2023), 26.4% of Latino/as age 21 and older reported past month binge drinking compared to 23.1% of non-Latino/a groups. Further, while their rates of alcohol use disorders match those of non-Latino/a White groups, they experience higher negative consequences (Chartier & Caetano, 2010; Zemore, 2005; Zemore et al., 2016). Latino/as are also less likely to utilize alcohol treatment services due to factors including immigration experiences, stigma, social disadvantage, limited access, and a lack of culturally and linguistically appropriate services (Valdez et al., 2018). These findings highlight the need for broad-reaching strategies to address unhealthy alcohol use among Latino/as, especially for the 25% of US Latino/as who are monolingual or have limited English proficiency (Zong, 2022) and who face greater barriers to care (Timmins, 2002).

Culturally adapted interventions consider language, culture, and context relevant to the recipient's background and may better meet the needs of those from different cultural backgrounds and those who experience health disparities (Bernal et al., 2009). Such adaptations focus on content and delivery of interventions and may include use of study materials in the preferred language of the participants, adjusting materials to reflect cultural norms and delivery of the intervention by community health workers. Such

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adaptations may or may not involve the community directly and are often based on existing cultural knowledge, literature or expert consultation. Indeed, there is a growing, yet limited literature on interventions that have been culturally adapted to address substance use disorders and unhealthy substance use in diverse populations, including Latino/as (Carroll et al., 2009; Field & Caetano, 2010; Lee et al., 2019; Lee, López, et al., 2013; Moore et al., 2016; Ornelas et al., 2019; Santa Ana et al., 2009; Venner et al., 2022).

Community health workers (CHWs) provide culturally and linguistically appropriate health information and linkages to resources (Littlefield & Longacre, 2024; Rhodes et al., 2007). CHWs have sociodemographic characteristics in common with their community (e.g., language, ethnicity, cultural background); understand community social networks and health needs; and recognize and incorporate culture to promote health and health outcomes within their communities. Although, through their work, CHWs have improved health behaviors for various medical conditions (Porterfield et al., 2024; Roland et al., 2017; Steinman et al., 2023) and ethnic matching enhances the effectiveness of brief alcohol interventions for Latino/as (Field & Caetano, 2010), the impact of CHWs on reducing unhealthy alcohol use for Latino/as remains understudied. A scoping review of six studies on this topic (Carson et al., 2023) reported modest impacts on alcohol-related outcomes, most focusing on male participants, having small sample sizes, a single contact with a CHW, and follow-ups of 18 weeks or shorter (Cherpitel et al., 2016; Documet et al., 2020; Moore et al., 2016; Ornelas et al., 2019; V. N. Torres et al., 2020; Vanessa N Torres et al., 2020).

Community-engaged research is a research method that involves community participation. Such participation ranges from consultation, to collaboration, to shared leadership. It aims to improve relevance of the research to communities and facilitate research conduct. When this approach is utilized to culturally adapt a research approach or intervention, it improves cultural relevance and appropriateness (Wallerstein et al., 2019). However, aside from one pilot study (Moore et al., 2016), no community engaged research studies have focused on unhealthy alcohol use.

Motivational Enhancement Therapy (MET) is a behavioral intervention that is based on principles of motivational interviewing (MI) (Miller, 1992). It reduces unhealthy substance use through personalized feedback, motivational-enhancing interviewing techniques, and setting personal goals. Because MET is collaborative, empathetic, and nonconfrontational, it fosters engagement and retention in treatment. These factors have made it particularly suitable for monolingual Spanish speakers, where it has been used in studies to strengthen treatment engagement (Carroll et al., 2009; Moore et al., 2016; Ornelas et al., 2019; Santa Ana et al., 2009). Across these studies, treatment engagement was strong and alcohol outcomes improved. However, no significant differences in alcohol outcomes were observed between MET and the control condition.

Strengths Based Case Management (SBCM) is based on strengths theory to assist individuals set and achieve personal goals with an emphasis on the case manager–patient relationship and patient self-determination (Siegal et al., 1995). SBCM adds an explicit focus on linking clients to services they need to resolve tangible barriers (e.g., access to food, health care) that interfere with their ability to change behavior. Three

meta-analyses (Hesse et al., 2007; Rapp et al., 2014; Vanderplasschen et al., 2019) confirm that case management improves outcomes for substance use treatment, including engagement with services. However, no studies have focused on Latino/as with unhealthy alcohol use, or employed CHWs to deliver SBCM.

Multilevel interventions (e.g., MET combined with SBCM) address health disparities by targeting complex individual needs alongside social, organizational, environmental and policy factors (Paskett et al., 2016). Using a community-engaged research approach and in partnership with a community-based agency, we conducted a randomized 18-week pilot trial to address unhealthy alcohol use among male, Latino day laborers (n=29) (Moore, 2016). The intervention was delivered by CHWs and consisted of three sessions of culturally adapted MET and SBCM and the comparator was brief feedback. (Moore et al., 2016). Though no significant differences were observed between groups, post hoc analyses identified a significant reduction in number of drinks for participants in the intervention group.

Using a randomized controlled trial study design, and a community engaged research approach, this study tested the culturally adapted Motivational Enhancement Therapy and Strengths-Based Case Management (CA-MET/SBCM) intervention to reduce unhealthy drinking in Latino/as, previously piloted in our earlier work (Moore et al., 2016), in a larger, longer duration and adequately powered trial. Conducted with a community-based organization, the trial compared CA-MET/SBCM, delivered by CHWs in Spanish (intervention) to the NIAAA's *Rethinking Drinking* booklet (control). We hypothesized that the intervention would reduce heavy drinking days, weekly alcohol

consumption, and alcohol-related problems at 12- and 26-week follow-ups compared to the control condition.

Method

Study design

We conducted a parallel, two-group, randomized controlled trial to evaluate the efficacy of a culturally adapted intervention to reduce unhealthy alcohol use among Spanish-speaking Latino/a adults. Participants were randomized to receive either a three-session, CHW-delivered intervention combining culturally adapted Motivational Enhancement Therapy and Strengths Base Case Management (CA-MET/SBCM) or the NIAAA's *Rethinking Drinking* booklet (ClinicalTrials.gov; NCT03301064). Participants were assessed at baseline, 12 weeks and 26 weeks after randomization. Outcomes included assessor-blinded, self-reported measures of heavy drinking, number of drinks per week and alcohol-related problems. All study procedures were approved by the participating institutions' Institutional Review Boards.

Community Partner

Our community partner, Providence Health & Services Southern California, serves the health needs of Los Angeles County communities, and provides services to people from low-income, disadvantaged communities. We collaborated with their staff and Community Health Worker Program at two sites in Los Angeles (Van Nuys &

Wilmington) to develop and refine study materials (e.g., recruitment materials and resources), and conduct all study procedures.

Setting, recruitment and enrollment

Staff from Providence and UCLA recruited participants through word of mouth and flyers in English and Spanish language disseminated through: 1) community outreach programs at health fairs, swap meets, churches, job centers, clinics and community centers, 2) staff going to public venues (e.g., work sites, parks), 3) a local newspaper serving the Spanish-speaking community, and 4) Craigslist. Prior to March 17, 2020, all study procedures were completed in person. Beginning March 20, 2020, during the COVID-19 pandemic, all study procedures were conducted via telephone, with recruitment temporarily halted. Recruitment resumed in July 2020 and was performed in outdoor areas following IRB-approved procedures.

Inclusion criteria for participants were: identifying as Latino/a, being age 21 years or older, ability to speak Spanish, and exceeding NIAAA low risk drinking limits (NIAAA) (men: ≥15 drinks per week or ≥5 drinks on an occasion weekly in the past month; women: ≥ 8 drinks per week or ≥4 drinks on an occasion weekly in the past month). Exclusion criteria were: seeking treatment for alcohol problems, receiving any alcohol treatment in the past 30 days, having serious alcohol withdrawal symptoms [Clinical Institute Withdrawal Assessment for Alcohol-Revised (CIWA-Ar) ≥10] (Sullivan et al., 1989) or substantial problems associated with illicit drug use [Drug Abuse Screening Test (DAST-10) ≥6] (Skinner, 1982).

After providing verbal consent to assess eligibility and written informed consent for study participation, participants completed assessments at baseline (60 minutes) and at 12 and 26 weeks (30 minutes each). Participants received $30 gift cards for each assessment and, prior to March 20, 2020, a public transit day pass to offset travel costs. Based on community partner input, to enhance study retention, intervention group participants were additionally compensated for the time spent in each of the intervention sessions: ($50 for the first session and $20 each for each of the next two sessions).

Randomization and Blinding

After providing informed consent and completing the baseline assessment, participants were randomly allocated to study groups using a computerized randomization protocol programmed by an independent statistician. The program used permuted block sizes of 2 and 4, stratified by gender, to ensure a balanced distribution of men and women across groups. Group assignment was concealed until enrollment and baseline procedures were complete, at which point group designation was revealed by research staff. The research staff conducting baseline assignments were not involved in follow-up outcome assessment. Follow-up outcome assessors remained blinded to group assignment.

Study Groups

Rethinking Drinking Group (control)

Immediately after randomization, participants in the *Rethinking Drinking* group received the 2016 *Rethinking Drinking* booklet, now updated (2024 NIAAA), in their preferred language (Spanish or English) immediately after baseline assessment. Although participants were encouraged to read the booklet, research staff did not review the material with them. The booklet has two parts: 1) information on alcohol and related harms and 2) tips, tools and resources for reducing or stopping drinking, including some of the same elements as in the CA-MET/SBCM intervention (e.g., considering pros and cons to change). Participants also received a comprehensive resource list for medical, mental health, substance use and social services created by Providence staff (also provided to the CA-MET/SBCM group). We chose the *Rethinking Drinking* booklet as our comparator because it includes change tools offering equipoise with the intervention. It requires no staff resources to deliver and is a readily available self-help resource that can be easily disseminated.

CA-MET/SBCM Group (intervention)

The CA-MET/SBCM group were offered three manualized sessions (Moore et al., 2016), with an accompanying workbook (Appendix) along with the comprehensive resource list that was also given to the *Rethinking Drinking* group. The sessions were delivered in Spanish every 1-2 weeks by a trained CHW employed by Providence. Sessions were conducted in person prior to March 20, 2020 and by telephone

thereafter. Cultural adaptations included tailoring the delivery and content of the intervention to individual, cultural and social contexts influencing drinking behavior, drawing on work conducted by the study investigators (Barenstein, 2006; Lee et al., 2019; Lee, López, et al., 2013; Lee et al., 2011; Moore et al., 2016). Adaptations addressed factors such as country of origin, family relationships, Latino/a drinking norms, cultural values and immigration- and acculturation-related stressors. CHWs emphasized a collaborative approach and used visual aids to enhance understanding of the physical and cognitive effects of alcohol (e.g., a poster depicting cirrhosis, a cartoon of cognitive effects of increasing blood alcohol levels).

The sessions and workbook were structured to provide participants with feedback on their alcohol use risks and help them identify barriers and motivators to change. The goal was to reduce drinking by promoting self-efficacy to change, setting goals and facilitating access to medical, mental health, substance use disorder and social services.

Before the first session, the CHW reviewed baseline assessment data to tailor feedback. Sessions focused on: 1) identifying health and personal goals and developing discrepancies between goals and current actions; 2) offering feedback on drinking-related risks; 3) providing normative feedback about drinking compared to that of US Latino/as in the participant's age and gender group (Session 1 only); 4) discussing reasons for drinking (e.g., cultural norms, immigration status stress); 5) weighing the pros and cons of drinking and reasons to reduce drinking (e.g., to better provide for the family, improving family relationships); 6) negotiating a plan for reducing drinking and/or

seeking help; 7) recognizing personal strengths in the process of change (e.g., ability to set a goal and follow through); and 8) identifying needed social and health services and exploring potential barriers (e.g., transportation). Participants were encouraged to take ownership of their decisions related to change and follow through with referrals.

Training, Supervision, and Fidelity

Training was modeled on the investigators' research and experience (Barenstein, 2006; Lee, López, et al., 2013; Lee et al., 2011; Moore et al., 2016). Three clinical psychologists (MK, CSL, VB) delivered a two day, 15-hour workshop to two Latina CHWs on the CA-MET/SBCM intervention, focusing on teaching MI using a culturally adapted approach. The CHWs were primarily Spanish-speaking Latina immigrants who had a range of 10-17 years of experience as CHWs (e.g., providing health education and linkages to services) but no previous experience utilizing MI or addressing heavy drinking. The training utilized a collaborative approach, recognizing their expertise and empowering them to use their strengths to enhance relevance of the intervention for participants. The training involved role plays in Spanish and English, practicing MI skills and reviewing the manual and workbook.

Two of the clinical psychologists (VB, CL) initially held weekly supervision meetings with the CHWs, transitioning to bi-weekly meetings during intervention delivery. Supervision entailed addressing any questions the CHWs had and reviewing selected audiotapes to provide feedback on treatment delivery, and monitor adherence to MI principles as well as the culturally adapted elements and delivery of the SBCM content.

During the trial, audiotapes of CHWs' meetings with participants were transcribed and coded for MI fidelity using the Motivational Interviewing Treatment Integrity (MITI-3.1.1) coding manual (Moyers TB, 2010). Two trained MI raters (Lee et al., 2015), with over three years of experience, coded 43 sessions (24% of total sessions). To assess fidelity and provide early feedback, the first 18 sessions were split evenly between the two CHWs conducting the sessions. An additional 25 sessions were randomly selected for coding. Fidelity was assessed using two indicators: a Global Spirit rating and percent MI adherence. MI Global Spirit ratings are computed as the average of global ratings of Evocation, Collaboration and Autonomy/Support. Each of these domains are scored from 1 (low) to 5 (high), where 3.5 is the threshold for beginning proficiency. The average MI Global Spirit rating score was 3.3; just below the threshold of beginning proficiency. MI adherence is assessed as the percentage of adherent versus nonadherent interventions; 90% is the threshold for beginning proficiency. The average percentage of MI adherent interventions was 98%, thus meeting the threshold for beginning proficiency.

Measures

Overview: We utilized three outcomes to assess alcohol-related risk that are common metrics used in clinical trials of unhealthy alcohol use (Witkiewitz et al., 2015). The primary outcome was the percentage of heavy drinking days (≥ 5 drinks for men, ≥ 4 drinks for women) in the past 90 days, measured at 26 weeks using the timeline followback (TLFB) (Sobell & Sobell, 1992). Heavy drinking was chosen as the primary outcome as it increases the likelihood of an alcohol use disorder and other alcohol-

related harms (Dawson et al., 2008). Secondary outcomes were average number of drinks per week measured using the TLFB and alcohol-related problems measured using the Short Inventory of Problems-Revised (SIP-2R) (Goldstein et al., 2023) (Kiluk et al., 2013), with scores ranging from 0 to 45 and with higher scores indicating worse alcohol-related problems. All outcomes were measured at baseline, 12 and 26 weeks. Demographics, health characteristics, past month use of drugs and additional alcohol-related information [self-reported alcohol problems in the past 12 months, family history of drinking problems, and the Alcohol Use Disorders Identification Test (AUDIT)] (Bohn et al., 1995) were collected at baseline. Those having scores of 20 or higher on the AUDIT were advised to seek help and given referrals to specialty treatment; those consuming 28 or more drinks in a week (based on the TLFB) were warned about the risk of alcohol withdrawal if consumption was reduced too quickly.

Demographic variables included age, gender, education level, years of education, marital status, employment status, yearly household income, birth country, years in the United States, and English language proficiency. English language proficiency was ascertained with the question, “How well do you speak English?”. Those responding “Not at all” or “A little” were categorized as monolingual Spanish speakers while those answering “Well” or ”Very well” were categorized as bilingual Spanish speakers.

Other health-related variables used to characterize the sample’s physical and mental health status and drug use included the Short Form Health Survey (SF-12), physical and mental health component summary scores (Ware et al., 1996), the Kessler-6, a measure of general psychological distress (Kessler et al., 2002), and the Patient Health

Questionnaire-8 (PHQ-8) an indicator of depressive symptoms (Kroenke et al., 2009). Scores on the SF-12 physical component score (PCS) and mental component score (MCS) range from 0 to100, with higher scores indicating better health and scores greater than 50 representing above average health status. The Kessler 6 score ranges from 0 to 24 with higher scores indicating greater psychological distress. The PHQ-8 scores range from 0 to12 with the following cut points: normal (0-2), mild (3-5), moderate (6-8) and severe (9-12) depressive symptoms. Drug use was ascertained by asking the frequency of past month use of any of the following: cannabis, cocaine, stimulants, inhalants, sedatives, hallucinogens or opioids (never, less than monthly, monthly, weekly or daily).

Data Analysis

Chi square tests and independent sample t-tests evaluated between-group differences at baseline. These analyses were repeated comparing those lost to follow up with those who completed at least one follow up. Mixed-effects regression models were used to test the effects of the CA-MET/SBCM intervention versus *Rethinking Drinking* for each outcome measure (percentage of heavy drinking days, number of drinks per week, and SIP-2R score). These intention-to-treat (ITT) analyses included all available observations, including those in the CA-MET/SBCM group who did not attend any sessions. Each model included baseline, week 12, and week 26 assessments and considered the main effects of the intervention and time and an intervention-by-time interaction. To account for within-subject correlation, random intercepts and time slopes were specified at the participant level. Time was treated as a categorical variable and

the covariance structure was defined as unstructured. Mixed regression models were fit on all available data using maximum likelihood estimation which allows for valid inference with incomplete data under the assumption of missing at random. Baseline values of age, gender, employment status, SF-12 MCS, PHQ-8, self-reported alcohol problems, and AUDIT score were included as covariates to ensure statistical balance not captured by randomization and to reduce error variance. The hypotheses of interest (between group differences at individual timepoints and within group changes over time) were tested using contrasts with adjusted mean change [95% confidence interval (CI)] reported. Effect sizes were estimated for both within-group and between-group effects using marginal means from the mixed-effects regression models (Morris, 2008).

We repeated the mixed effects regression analyses with per-protocol (PP) analyses that included all participants in the CA-MET/SBCM group who completed at least one session as well as all participants in the *Rethinking Drinking* group.

To address the robustness of the missing at random assumption, sensitivity analyses were conducted using multiple imputation to generate 20 datasets of complete data. Baseline characteristics and all available outcome data were included in the multiple imputation model. Each of the imputed datasets generated using PROC MI (seed=0725) were analysed using the mixed effects regression models described above and estimates and 95% CIs were pooled using PROC MIANALYZE. The relative efficiency for all imputed variables was >0.987. Data were analysed using SAS 9.4 (Cary, NC, USA).

Results

Participant Flow

Participant flow, reasons for exclusion, group assignment and retention are presented in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Figure 1). Between June 2018 and July 2021, 1237 persons were assessed for eligibility. Of this number, 237 of them (19%) met eligibility criteria. All 237 completed the consent process, baseline assessment and were randomized: 117 to the CA-MET/SBCM group and 120 to the *Rethinking Drinking* group. One person in the *Rethinking Drinking* group was later found to have received the CA-MET/SBCM intervention and was dropped from analyses, leaving 119 persons in the *Rethinking Drinking* group. Of those randomized to the CA-MET/SBCM group, 74 (63%) participated in at least one of the CA-MET/SBCM sessions and 44% (n= 51) completed all three sessions. At 26-weeks, overall loss to follow-up was 23.7%; and was nearly identical in the two groups (23.1% CA-MET/SBCM; 24.3% *Rethinking Drinking*). All participants who came to a follow up visit had complete data for all three alcohol outcomes.

Baseline Characteristics

The average age of the sample was 41.78 years with 66% male (Table 1). Educational level ranged from no formal education to beyond college with a mean of 11.1 years. Most participants were never married, employed and had low incomes (76% earning under $40,000 per year). Sixty-nine percent were born outside of the United States,

43% were born in Mexico, and participants averaged 27.5 years living in the US with 56% categorized as bilingual and 44% categorized as monolingual. The mean SF-12 PCS and MCS scores indicated somewhat below average health status. The average Kessler 6 scores were 7.1, representing no or low psychological distress, and the average PHQ-8 score was 6.9 corresponding to moderate depression. Self-reported drug use and alcohol use were reported by 39% each, and 72% had a family history of drinking problems. The mean AUDIT score was 16. 2 indicating a high risk of a moderate-severe alcohol use disorder. Comparability analyses between the CA-MET/SBCM and *Rethinking Drinking* groups showed significant differences in the percentage of persons employed, SF-12 MCS scores, PHQ-8 scores, self-report of alcohol problems, and AUDIT scores. Compared to those lost to follow up (n=34), those who completed at least one follow up (n=202) had more years of education (11.4 vs 9.1), lived in the US longer (28.2 vs 23.7 years), and were less likely to self-report an alcohol problem (35% vs 62%) or a drug use problem (35% vs 59%). They also had a lower percentage of heavy drinking days (30.5 vs 42.3) and average drinks per week (21.8 vs 34. 5) (Supplemental Table A).

Outcomes

The primary outcome, percentage of heavy drinking days in the past 90 days, and a secondary outcome, average number of drinks per week, were significantly reduced in the CA-MET/SBCM group compared to the *Rethinking Drinking* group at week 26 (-21.7 vs -12.9 for heavy drinking days and -15.9 vs -9.8 for drinks per week) (Table 2, Supplemental Figure A). The percentage of heavy drinking days was also significantly

reduced in the CA-MET/SBCM group at week 12 compared to the *Rethinking Drinking* group (-18.5 vs -10.3). The percentage of heavy drinking days, average number of drinks per week, and SIP-2R scores decreased significantly from baseline to week 12 and week 26 within both groups. Between group effect sizes were all in the small to medium size range (Table 2). The model statistics for the ITT analysis showed an overall significant treatment by time interaction for percentage heavy drinking days ($p=0.038$) and a significant time effect for all outcomes ($p<.001$) (Supplemental Table B).

In the PP analyses (Supplemental Table C), including only those who completed at least one session in the CA-MET/SBCM group, we observed largely comparable between group differences compared to the ITT analyses. The percentage of heavy drinking days and the average number of drinks per week were significantly reduced in the CA-MET/SBCM group compared to the *Rethinking Drinking* group at both weeks 12 and 26 and the SIP-2R was significantly reduced compared to the *Rethinking Drinking* group at 26 weeks. Larger reductions were also observed for all alcohol outcomes within the CA-MET/SBCM group. The multiple imputation sensitivity analyses (Supplemental Table D) show a similar pattern of results as in the main analyses.

Discussion

This study was conducted in partnership with a community-based organization serving the needs of lower income communities in Los Angeles. We trained their CHWs to deliver a multilevel, culturally adapted, Spanish language intervention combining MET

and SBCM to address unhealthy alcohol use in Latino/as who, on average, reported a high risk of moderate-severe alcohol use disorder. Compared to *Rethinking Drinking*, a booklet providing education, tools and resources to reduce unhealthy drinking (NIAAA, 2024), the CA-MET/SBCM group showed greater reductions in percentage of heavy drinking days and average number of drinks per week at 26 weeks. This finding occurred despite the baseline differences in groups indicating increased vulnerability in the CA-MET/SBCM group (e.g., lower employment, worse mental health and higher alcohol-related risks). Compared to participants lost to follow up, those who remained in the study had more favorable alcohol use characteristics at baseline (e.g., fewer heavy drinking days and lower average drinks per week). This limits generalizability and might have overestimated the intervention's effectiveness; however, multiple imputation was employed to mitigate any potential bias introduced by differential attrition. In within group analyses, both the CA-MET/SBCM group and the *Rethinking Drinking* group showed improvements in all outcomes over time. Possible reasons for this include assessment reactivity (McCambridge & Kypri, 2011) and regression to the mean (McCambridge et al., 2014). Other factors that may explain the within group improvements observed in the study-conducted during the COVID pandemic-include participants' potentially having reduced disposable income,(Krogstad JM, 2020) and increased access to virtual support (Palzes et al., 2022). Despite these factors, the differences between groups support the conclusion that CA-MET/SBCM had a greater effect than the *Rethinking Drinking* booklet. The PP analysis confirmed these findings. Greater between group differences may have been seen had we chosen a comparator condition that did not include tools and resources to address unhealthy drinking.

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Further, comparison of the CA-MET/SBCM condition to a less active control condition (e.g., assessment only, or educational materials) might have revealed larger between group differences.

Cost, scalability and sustainability are important considerations when evaluating interventions. Both the CA-MET/SBCM intervention and the *Rethinking Drinking* booklet reduced drinking outcomes, but the CA-MET/SBCM intervention has higher upfront costs due to training, staffing and time required for personalized engagement. However, this intervention may yield more substantial and lasting behavior change through culturally-tailored support and relationship-building. In contrast, the *Rethinking Drinking* booklet is a low-cost, easily scalable option that can be widely distributed, making it attractive for large populations or resource-limited settings. But its sustainability and long-term impact may be limited by low engagement and a lack of personalization. A potential strategy for addressing unhealthy alcohol use in Latinos could entail broadly disseminating the Rethinking Drinking booklet (e.g., through community-based organizations) while offering the CA/MET/SBCM intervention to those who need additional support. This tiered approach would need to be tested to confirm its effectiveness.

At 12 weeks, heavy drinking days, but not average number of drinks per week, was significantly reduced between groups. As a result of the intervention, those who engaged in heavy drinking may have become more aware of its heightened risks and been motivated to reduce heavy drinking more than reducing average number of drinks. No between group differences were observed in the SIP-2R score at 12 or 26 weeks. At

baseline, this score indicated a moderate level of alcohol-related problems in both groups with reductions in both groups over time. A longer follow up period or a more intensive intervention may be needed to observe a difference between groups.

Despite the study occurring during the COVID-19 pandemic, 63% of the CA-MET/SBCM group completed at least one session. This is compared to rates ranging from 75% to 92% in other community-based studies among Latino populations (Lee et al., 2016; Moore et al., 2016; Ornelas et al., 2019).

Other randomized trials addressing heavy drinking in non-treatment seeking, Latino/a adults, employing CHWs and/or delivered in Spanish and English have had mixed outcomes (Cherpitel et al., 2016; Field & Caetano, 2010; Lee, Colby, et al., 2013; Lee et al., 2019; Moore et al., 2016; Ornelas et al., 2019; Vaca et al., 2023). Three prior studies conducted in emergency departments with Latino/as experiencing unhealthy drinking demonstrated positive outcomes for a number of drinking measures at 12-months (Cherpitel et al., 2016; Field et al., 2010; Vaca et al., 2023). The interventions tested in these studies included brief MI delivered by CHWs (Cherpitel et al., 2016; Moore et al., 2016; Ornelas et al., 2019), brief intervention delivered by primarily Latino/a, Spanish speaking clinicians (Field & Caetano, 2010; Field et al., 2010; Lee et al., 2019; Lee, López, et al., 2013), and an automated bilingual computerized alcohol screening and intervention digital health tool (Vaca et al., 2023).

Culturally adapted brief interventions for unhealthy alcohol use in Latino/a populations have shown limited success (Lee et al., 2019; Lee, López, et al., 2013; Moore et al.,

2016; Ornelas et al., 2019). Two randomized clinical trials compared a single session of the Culturally Adapted Motivational Interview (CAMI) (Lee et al., 2016; Lee, Colby, et al., 2013; Lee et al., 2019; Lee et al., 2006; Lee, López, et al., 2013) to unadapted MI among Latino/as exceeding low risk drinking guidelines. In the first study (n=58), the CAMI group had significantly greater reductions in alcohol-related consequences at 2-month follow up, with no differences in drinking outcomes at 6 months (Lee, López, et al., 2013). In the second study (n=296), those in the CAMI group who reported high levels of discrimination and stigma, reported significantly greater decreases in alcohol related harms at 3-months, but no differences were observed at 12-months (Lee et al., 2019). Ornelas et al. randomized 121 Latino day laborers with unhealthy alcohol use to receive a 30-minute culturally adapted brief intervention and referral to services delivered by a CHW (Ornelas et al., 2019) or to receive information about local substance use treatment services. This study found no differences between groups at 8-week follow-up. In partnership with a community-based day labor organization, Moore et al. randomized 29 Latino day laborers, to receive CA-MET/SBCM delivered by CHWs in Spanish, compared to brief feedback (Moore et al., 2016) and found no differences between groups at 18-week follow up. Aside from this study, none of these interventions have been conducted in partnership with a community-based organization, nor combined MET and SBCM.

One intention of our work was to create a sustainable approach for community-based organizations to reduce unhealthy alcohol use among Spanish-speaking Latino/as using CHWs. CHWs are less costly than behavioral health care professionals (e.g., social

workers and psychologists) and, with training, CHWs in this study were able to deliver the intervention and improve unhealthy drinking, despite nonoptimal performance on one of the fidelity measures. Though more research is needed, this approach has promise. While this study was not designed to test this, exploratory post-hoc analyses suggest that delivering the CA-MET/SBCM intervention by telephone during the COVID-19 pandemic may be as effective as in-person delivery, warranting further study of this approach to address unhealthy drinking in Latino/a populations.

The findings of this study should be considered in light of its limitations. First, financial incentives for CA-MET/SBCM participants, and compensation to our community partner and their CHWs for their time, limit the study's sustainability and generalizability. Additionally, differences in study engagement may have resulted from the lower compensation provided to those in the *Rethinking Drinking* group compared to those in the CA-MET/SBCM group. However, we did not observe differences in study engagement between groups. Further, limitations in fidelity included no assessment of reliability for the MITI 3.1.1., and no formal measure of SBCM or of the cultural adaptations, though these adaptations were reviewed and discussed during supervision of the CHWs. We also relied on self-report of drinking behavior without inclusion of biological markers of alcohol use. Finally, although we did not conduct mediation analyses for this manuscript, we have the relevant data and plan to explore these analyses in a subsequent publication.

Conclusions: In this randomized controlled trial, conducted with a community-based organization and its Spanish-speaking CHWs, the multilevel CA-MET/SBCM

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intervention effectively reduced unhealthy alcohol use among mono- and bilingual Spanish-speaking Latino/as. The intervention utilized a version of MET relevant to Latino/as and employed SBCM to aid participants in making behavioral change and linking them to services. To our knowledge, this is the first study to use this combination of components and positively impact unhealthy alcohol use in a Latino population. Though this study is a promising beginning, additional studies are needed to establish sustainable, scalable and effective models for training and delivering behavioral interventions to reduce unhealthy alcohol use and reduce alcohol-related health disparities in Latino/as.

Table 1. Baseline Characteristics of Study Participants, N (%) or Mean (SD)

	All (N=236)	CA-MET/SBCM (N=117)	*Rethinking Drinking* (N=119)	p-value
Age	41.8 (13.7)	42.4 (14.1)	41.2 (13.4)	.485
Male	155 (66%)	78 (67%)	77 (65%)	.751
Education Level				.832
Less than HS	56 (24%)	28 (24%)	28 (24%)	
Some or Complete HS	93 (39%)	48 (41%)	45 (38%)	
Some College or More	87 (37%)	41 (35%)	46 (39%)	
Years of Education	11.1 (4.3)	10.9 (4.2)	11.2 (4.3)	.653
Marital Status				.525
Never Married	147 (62%)	72 (62%)	75 (63%)	
Married	47 (20%)	25 (21%)	22 (18%)	
Divorced/Separated	40 (17%)	20 (17%)	20 (17%)	
Widowed	2 (1%)	0 (0%)	2 (2%)	
Employed	147 (62%)	65 (56%)	82 (69%)	.034
Yearly Household Income				.140
< $9,999	65 (28%)	37 (32%)	28 (24%)	
$10,000-$19,999	72 (31%)	39 (33%)	33 (28%)	
$20,000-$39,999	44 (19%)	16 (14%)	28 (24%)	
$40,000+	55 (23%)	25 (21%)	30 (25%)	
Birth Country				.717
US	74 (31%)	33 (28%)	41 (35%)	
Mexico	101 (43%)	55 (47%)	46 (39%)	
El Salvador	21 (9%)	11 (9%)	10 (8%)	
Guatemala	20 (8%)	8 (7%)	12 (10%)	
Honduras	3 (1%)	1 (1%)	2 (2%)	
Other	17 (7%)	9 (8%)	8 (7%)	
Years in US	27.5 (11.7)	28.9 (11.8)	26.2 (11.4)	.077
Speak English well/very well	132 (56%)	68 (58%)	64 (54%)	.502
SF-12[a] Score				
PCS-12[b]	47.4 (9.0)	46.8 (8.7)	48.0 (9.3)	.314
MCS-12[c]	45.9 (11.7)	43.8 (11.5)	47.9 (11.6)	.008
Kessler-6 Score	7.1 (5.8)	7.7 (6.2)	6.4 (5.3)	.100
PHQ-8[d] Score	6.9 (5.6)	7.6 (5.9)	6.2 (5.3)	.051
Self-Report Drug Use	91 (39%)	46 (39%)	45 (38%)	.813
Self-Report Alcohol Problems	92 (39%)	54 (46%)	38 (31%)	.025
Family Hx of Drinking Problem	170 (72%)	89 (76%)	81 (68%)	.171
AUDIT[e] score	16.2 (8.0)	17.8 (8.3)	14.5 (7.4)	.002
AUDIT[e] Risk Category				.001
≤ 7	28 (12%)	9 (8%)	19 (16%)	
8-14	82 (35%)	37 (32%)	45 (38%)	

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15-19	50 (21%)	19 (16%)	31 (26%)
≥ 20	**76 (32%)**	**52 (44%)**	**24 (20%)**

[a]Short Form-12; [b]Physical Component Score; [c]Mental Component Score; [d]Patient Health Questionnaire-8; [e]Alcohol Use Disorders Identification Test

Table 2. Intent-to-Treat (ITT) Treatment Effects estimated from Mixed Effects Models[a]

	CA-MET/SBCM (N=117)			*Rethinking Drinking* (N=119)			Difference		
	Mean (95% CI)	**Within group p-value**	**Within group effect size**	**Mean (95% CI)**	**Within group p-value**	**Within group effect size**	**Mean Diff (95% CI)**	**Between group p-value**	**Between group effect size**
% Heavy Drinking Days									
Week 0	35.0 (30.5, 39.5)			30.6 (26.1,			4.4 (-1.9, 10.7)	.169	
Week 0-Week 12	-18.5 (-23.8, -	<.001	-0.78	-10.3 (-15.6, -	<.001	-0.43	-8.2 (-15.6, -0.7)	.032	-0.29
Week 0-Week 26	-21.7 (-26.7, -	<.001	-0.96	-12.9 (-17.8, -	<.001	-0.56	-8.9 (-15.8, -1.9)	.013	-0.32
Average Drinks/Week									
Week 0	25.7 (22.2, 29.1)			22.6 (19.1,			3.0 (-1.9, 7.9)	.224	
Week 0-Week 12	-12.8 (-16.8, -8.9)	<.001	-0.76	-8.1 (-12.0, -	<.001	-0.47	-4.8 (-10.3, 0.81)	.094	-0.23
Week 0-Week 26	-15.9 (-19.7, -	<.001	-1.01	-9.8 (-13.7, -	<.001	-0.62	-6.0 (-11.4, -0.6)	.029	-0.29
SIP-2R[b] Score									
Week 0	11.7 (10.5, 12.9)			12.7 (11.5,			-1.0 (-2.7, 0.6)	.224	
Week 0-Week 12	-3.7 (-5.5, -1.9)	<.001	-0.46	-2.8 (-4.6, -1.0)	.003	-0.34	-0.9 (-3.5, 1.7)	.505	-0.09
Week 0-Week 26	-6.3 (-8.1, -4.4)	<.001	-0.80	-3.8 (-5.7, -2.0)	<.001	-0.48	-2.4 (-5.0, 0.2)	.066	-0.24

[a]Models are adjusted for age, gender, employment status, SF-12 MCS, PHQ-8 score, self-report alcohol problems, and baseline AUDIT scores.

[b]SIP-2R = Short Inventory of Problems-Revised

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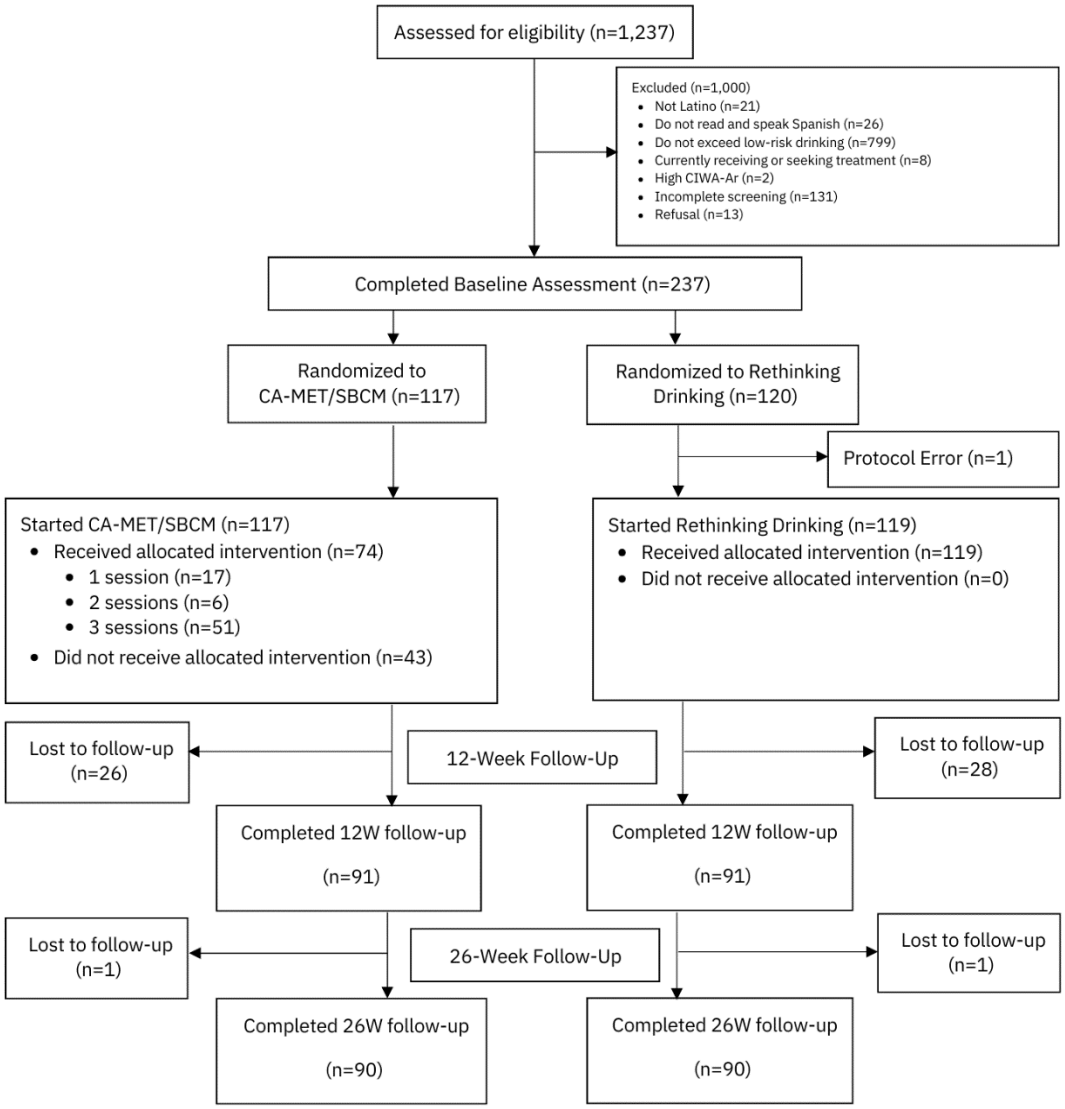
Figure 1. Study CONSORT Diagram



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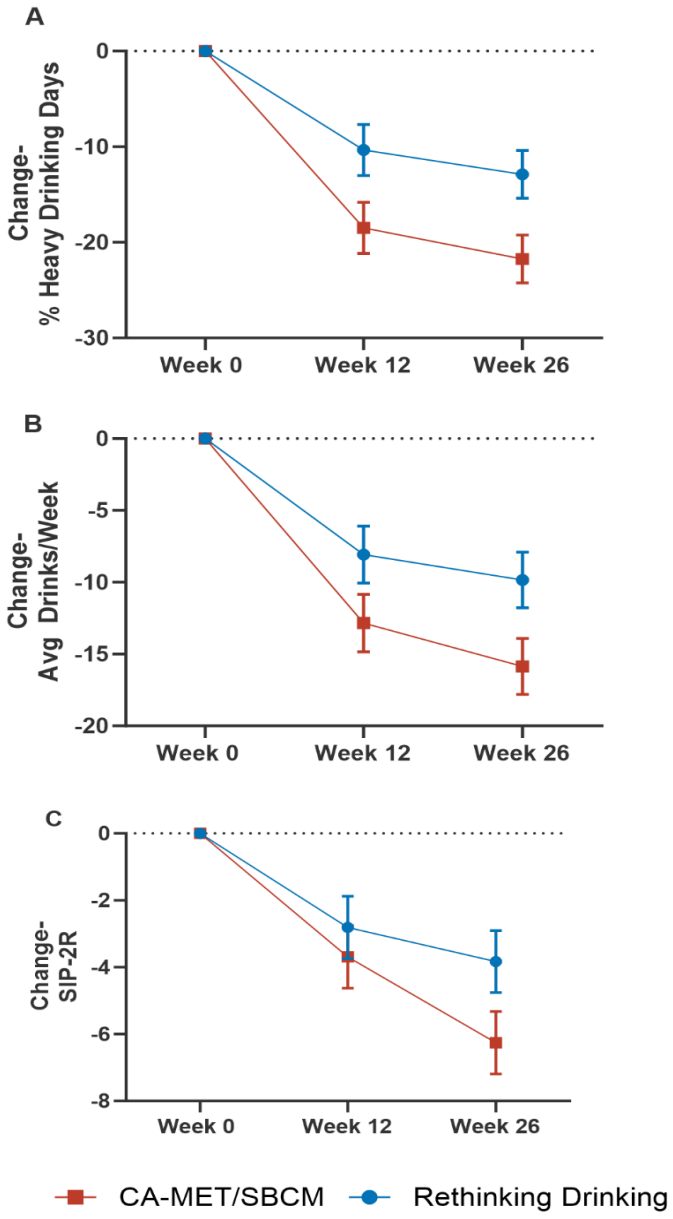
Supplemental Material

Supplemental Figure A. Change (mean (SE)) in A) % Heavy Drinking Days, B) Average Drinks/Week, and C) SIP-2R



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Supplemental Table A. Baseline Characteristics of Participants by follow-up status, N (%) or Mean (SD)

	Lost to Follow-Up (N=34)	Completed at least 1 Follow-Up (N=202)	p-value
Age	40.5 (12.5)	42.0 (13.9)	.558
Male	27 (79%)	128 (64%)	.068
Education Level			.033
Less than HS	12 (35%)	44 (22%)	
Some or Complete HS	16 (47%)	77 (38%)	
Some College or More	6 (18%)	81 (40%)	
Years of Education	9.1 (4.8)	11.4 (4.1)	.004
Marital Status			.747
Never Married	22 (65%)	125 (62%)	
Married	5 (15%)	42 (21%)	
Divorced/Separated	7 (21%)	33 (16%)	
Widowed	0 (0%)	2 (1%)	
Employed	21 (62%)	126 (62%)	.946
Yearly Household Income			.533
< $9,999	12 (35%)	53 (26%)	
$10,000-$19,999	11 (32%)	61 (30%)	
$20,000-$39,999	6 (18%)	38 (19%)	
$40,000+	5 (15%)	50 (25%)	
Birth Country			.186
US	8 (24%)	66 (33%)	
Mexico	14 (41%)	87 (43%)	
El Salvador	7 (21%)	14 (7%)	
Guatemala	3 (9%)	17 (8%)	
Honduras	0 (0%)	3 (1%)	
Other	2 (6%)	15 (7%)	
Years in US	23.7 (12.6)	28.2 (11.4)	.038
Speak English well/very well	15 (44%)	117 (58%)	.134
SF-12[a] Score			
PCS-12[b]	47.5 (8.5)	47.4 (9.1)	.952
MCS-12[c]	44.7 (13.5)	46.1 (11.4)	.519
Kessler-6 Score	7.4 (6.3)	7.0 (5.8)	.677
PHQ-8[d] Score	6.9 (6.2)	6.9 (5.5)	.954
Self-Report Drug Use	20 (59%)	71 (35%)	.009
Self-Report Alcohol Problems	21 (62%)	71 (35%)	.003
Family Hx of Drinking Problem	23 (68%)	147 (73%)	.538
AUDIT[e] score	18.4 (8.0)	15.8 (8.0)	.079
AUDIT[e] Risk Category			.218
≤ 7	2 (6%)	26 (13%)	
8-14	9 (26%)	73 (36%)	

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	15-19	11 (32%)	39 (19%)
	≥ 20	**12 (35%)**	**64 (32%)**

[a]Short Form-12; [b]Physical Component Score; [c]Mental Component Score; [d]Patient Health Questionnaire-8; [e]Alcohol Use Disorders Identification Test

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Supplemental Table B. Model Effects

	% Heavy Drinking Days		Average Drinks/Week		SIP-2R[a] Score	
	***F* (df)**	***p***	***F* (df)**	***p***	***F* (df)**	***p***
Treatment Main Effect	0.37 (227)	.544	0.17 (227)	.679	6.89 (227)	.009
Time Main Effect	48.38 (358)	<.001	44.81 (358)	<.001	29.41 (356)	<.001
Treatment x Time interaction	3.31 (358)	.038	2.50 (358)	.083	2.03 (356)	.132

[a]SIP-2R = Short Inventory of Problems-Revised

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Supplemental Table C. Per-Protocol (PP) Treatment Effects estimated from Mixed Effects Models[a]

	CA-MET/SBCM (N=74)[c]			*Rethinking Drinking* (N=119)[c]			Difference		
	Mean (95% CI)	Within group p-value	Within group Effect Size	Mean (95% CI)	Within group p-value	Within group Effect Size	Mean Diff (95% CI)	Between group p-value	Between group Effect Size
% Heavy Drinking Days									
Week 0	34.7 (29.1, 40.4)			30.8 (26.3, 35.3)			3.9 (-3.2, 10.9)	.281	
Week 0-Week 12	-19.3 (-25.9, -	<.001	-0.83	-10.3 (-15.6, -5.0)	<.001	-0.43	-9.0 (-17.5, -0.5)	.038	-0.31
Week 0-Week 26	-25.0 (-31.2, -	<.001	-1.16	-12.9 (-17.9, -7.9)	<.001	-0.57	-12.1 (-20.1, -4.1)	.003	-0.42
Average Drinks/Week									
Week 0	26.0 (21.6, 30.5)			22.3 (18.8, 25.9)			3.7 (-2.0, 9.3)	.199	
Week 0-Week 12	-14.7 (-19.6, -9.9)	<.001	-0.90	-8.0 (-11.9, -4.2)	<.001	-0.48	-6.7 (-12.9, -0.5)	.033	-0.31
Week 0-Week 26	-17.8 (-22.6, -	<.001	-1.14	-9.8 (-13.6, -6.0)	<.001	-0.61	-8.0 (-14.1, -1.9)	.011	-0.37
SIP-2R[b] Score									
Week 0	12.3 (10.8, 13.9)			12.4 (11.1, 13.7)			-0.1 (-2.1, 1.9)	.923	
Week 0-Week 12	-5.5 (-7.8, -3.2)	<.001	-0.68	-2.8 (-4.7, -1.0)	.003	-0.46	-2.6 (-5.6, 0.3)	.079	-0.25
Week 0-Week 26	-7.8 (-10.0, -5.6)	<.001	-1.01	-3.8 (-5.6, -2.0)	<.001	-0.33	-4.0 (-6.8, -1.2)	.006	-0.37

[a]Models are adjusted for age, gender, employment status, SF-12 MCS, PHQ-8 score, self-report alcohol problems, and baseline AUDIT scores.

[b]SIP-2R = Short Inventory of Problems-Revised

[c]Week 12: CA-MET/SBCM N=62, Rethinking Drinking N=91; Week 26: CA-MET/SBCM N=63, Rethinking Drinking N=90

Supplemental Table D. Multiple Imputation Sensitivity Analysis: Intent-to-treat (ITT) Treatment Effects estimated from Mixed Effects Models[a]

	CA-MET/SBCM (N=117)			*Rethinking Drinking* (N=119)			Difference		
	Mean (95% CI)	Within group p-value	Within group Effect Size	Mean (95% CI)	Within group p-value	Within group Effect Size	Mean Diff (95% CI)	Between group p-value	Between group Effect Size
% Heavy Drinking Days									
Week 0	35.2 (30.8, 39.7)			30.7 (26.2, 35.2)			4.5 (-1.7, 10.8)	.156	
Week 0-Week 12	-18.5 (-23.7, -	<.001	-0.78	-10.7 (-16.1, -5.3)	<.001	-0.44	-7.8 (-15.2, -0.3)	.041	-0.28
Week 0-Week 26	-21.1 (-26.2, -	<.001	-0.92	-13.4 (-18.2, -8.5)	<.001	-0.58	-7.8 (-14.7, -0.9)	.027	-0.28
Average Drinks/Week									
Week 0	25.8 (22.3, 29.3)			22.6 (19.1, 26.2)			3.2 (-1.7, 8.1)	.205	
Week 0-Week 12	-12.8 (-16.7, -8.9)	<.001	-0.76	-8.5 (-12.1, -4.0)	<.001	-0.46	-4.8 (-10.3, 0.8)	.092	-0.23
Week 0-Week 26	-15.7 (-19.6, -	<.001	-1.00	-10.2 (-14.0, -6.3)	<.001	-0.63	-5.5 (-10.9, -0.1)	.045	-0.26
SIP-2R[b] Score									
Week 0	11.9 (10.7, 13.1)			12.8 (11.5, 14.0)			-0.9 (-2.5, 0.8)	.505	
Week 0-Week 12	-3.8 (-5.7, -2.0)	<.001	-0.48	-3.0 (-4.8, -1.2)	.001	-0.37	-0.9 (-3.4, 1.7)	.436	-0.08

	CA-MET/SBCM (N=117)			*Rethinking Drinking* (N=119)			Difference		
Week 0-Week 26	-6.5 (-8.3, -4.7)	<.001	-0.85	-4.3 (-6.2, -2.3)	<.001	-0.51	-2.2 (-4.8, 0.4)	.099	-0.22

[a]Models are adjusted for age, gender, employment status, SF-12 MCS, PHQ-8 score, self-report alcohol problems, and baseline AUDIT scores.

[b]SIP-2R = Short Inventory of Problems-Revised