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Development and Preliminary Testing of a Promotora-Delivered, Spanish Language, Counseling Intervention for Heavy Drinking among Male, Latino Day Laborers

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ABSTRACT

This study developed and then tested the feasibility, acceptability and initial efficacy of a 3-session, culturally adapted, intervention combining motivational enhancement therapy (MET) and strengths-based case management (SBCM) delivered by promotoras in Spanish to reduce heavy drinking among male, Latino day laborers. A pilot two-group randomized trial (N = 29) was conducted to evaluate the initial efficacy of MET/SBCM compared to brief feedback (BF). Alcohol-related measures were assessed at 6, 12 and 18 weeks after baseline. Most intervention group participants (12/14) attended all counseling sessions and most participants (25/29) remained in the study at 18 weeks. Alcohol-related measures improved in both groups over time with no statistically significant differences observed at any of the time points. However, the comparative effect size of MET/SBCM on weekly drinking was in the large range at 6-weeks and in the moderate range at 12-weeks. Post-hoc analyses identified a statistically significant reduction in number of drinks over time for participants in the intervention group but not for control group participants. Despite the extreme vulnerability of the population, most participants completed all sessions of MET/SBCM and reported high satisfaction with the intervention. We feel our community partnership facilitated these successes. Additional studies of community-partnered and culturally adapted interventions are needed to reduce heavy drinking among the growing population of Latinos in the U.S.

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1. Introduction

In 2012, Latinos, the fastest growing ethnic group, comprised 17% of the U.S. population (U.S. Census Bureau, 2013). Compared to Whites, Latinos are more likely to have low education levels, live in poverty, and be uninsured (Caetano & Clark, 2000; Mulia, Ye, Zemore, & Greenfield, 2008). Latino men often engage in a pattern of low frequency but high levels of drinking per occasion (Alvarez & Ruiz, 2001; Daniel-Ulloa et al., 2014; Kissinger et al., 2013; Ornelas, Eng, & Perreira, 2011).

Studies evaluating therapies to reduce drinking among diverse samples, including Latinos, have largely found no racial/ethnic differences in outcomes (Arroyo, Miller, & Tonigan, 2003; Arroyo, Westerberg, & Tonigan, 1998; Field, Caetano, Harris, Frankowski, & Roudsari, 2010; Roudsari, Caetano, Frankowski, & Field, 2009; Tonigan, 2003). Of note, most of the Latino participants in these studies were English-speaking. In fact, nearly one third of the Latino population are monolingual or have limited English proficiency (U.S. Census Bureau, 2004) and are under-represented in clinical and research samples (Wells, Klap, Koike, & Sherbourne, 2001). There is some evidence that adapting behavioral interventions to include Latinos’ cultural practices and particular stressors improves outcomes including treatment engagement and reduced substance use (Carroll et al., 2009; Field & Caetano, 2010; Lee, Colby, et al., 2013; Lee, López, et al., 2013; Santa Ana et al., 2009).

Motivational enhancement therapy (MET) is a systematic intervention to promote positive change in addictive behavior by providing personalized feedback, using motivation-enhancing interviewing techniques, and setting personal goals (Miller, Zweben, DiClemente, & Rychtarik, 1992). The MET approach has proven to be an effective treatment for reducing alcohol consumption among excessive drinkers (Vasilaki, Hosier, & Cox, 2006) and has been used by non-specialists in substance abuse treatment (Dunn, Deroo, & Rivara, 2001). Through its non-confrontational approach, MET focuses on fostering engagement and retention in treatment, thereby addressing an important health...
disparity issue among monolingual Spanish speaking substance abusers (Carroll et al., 2009; Santa Ana et al., 2009). Strengths based case management (SBCM), also used among those with alcohol use disorders (AUDs), (Barry, Zeber, Blow, & Valenstein, 2003; Siegal, 1998) includes a process for setting and negotiating goals and uses informal resources (e.g., family, church) and formal resources (e.g., linkages to services) to address social needs and to make positive change. An approach combining MET and SBCM may be particularly useful for monolingual, socially disadvantaged, Latinos who are heavy drinkers.

Cultural adaptation takes into consideration the social and cultural contexts of the client, (Lee, López, et al., 2013; Lee et al., 2011; Santiago-Rivera, Arredondo, & Gallardo-Cooper, 2001; Sue & Sue, 2003) and may improve the effectiveness of interventions addressing unhealthy behaviors in immigrant populations. These populations may experience minority stress due to discrimination, poverty, low social status limited social support and low education attainment (Lee, López, et al., 2013). One type of cultural adaptation is the use of promotoras, or community health workers to deliver culturally-adapted behavior change interventions (Institute of Medicine, 2000; Rhodes, Foley, Zometa, & Bloom, 2007). Promotores have sociodemographic characteristics in common with the populations they serve, understand community social networks and health needs and recognize and incorporate culture to promote health within their communities. Partnering with community-based organizations for research is another means of cultural adaptation that enhances the relevance of research in community, improves recruitment, generates professional competence in community, improve outcomes and sustainability and addresses disparities more effectively through improving professional capacity and competence, outcomes and sustainability of interventions in community (Institute of Medicine, 2000; Jagosh et al., 2012; Wallerstein & Duran, 2010; Zerhouni, 2005).

The population of day laborers may be particularly well-suited for a culturally adapted intervention to reduce heavy drinking. Day laborers are usually socially and economically disadvantaged, Spanish speaking, immigrant, Latino men, who may be at high risk for unhealthy drinking given their stressors including discrimination, undocumented status, language barriers, low income, low acculturation, under employment and isolation from their families (Galvan, Wohl, Carlos, & Chen, 2015; Valenzuela, 2002, 2003). Indeed, a number of studies have identified heavy drinking as a problem in this population (Organista & Kubo, 2005; Ornelas et al., 2011; Worby & Organista, 2007, 2013; Worby et al., 2014).

We developed and then tested the feasibility, acceptability and initial efficacy of a culturally adapted, combined MET and SBCM intervention delivered by promotoras in Spanish to reduce heavy drinking among male, Latino day laborers. Standard MET session content (e.g., structured feedback, decision rulers, and exploration of positive and negative aspects of drinking) was combined with elements of SBCM that included identification of service needs, identification of barriers to services, and drawing on personal strengths and available resources to achieve personal goals. We built on prior work utilizing MET and SBCM to address alcohol problems and aimed to make it more relevant to Latinos by conducting the project in Spanish and partnering with a community-based organization, Instituto de Educación Popular del Sur de California (IDEPSCA). IDEPSCA operates job centers and has a program that utilizes volunteer promotoras to address the health needs of day laborers in Los Angeles. In partnership with IDEPSCA and their volunteer promotoras, we refined our research questions, developed, and implemented a research plan to ensure we were addressing their community’s needs, and developed a potentially sustainable program.

2. Method

2.1. Study design

The study occurred in three phases. First, we developed a culturally adapted MET/SBCM Spanish language intervention and trained volunteer promotoras at IDEPSCA to deliver it. Second, we conducted an uncontrolled pilot study (N = 3) using the developed intervention among heavy drinking, male Latino day laborers to gather data on the utility and feasibility of the study methods. Third, after making refinements, we conducted a pilot two-group randomized trial (N = 29) to evaluate the initial efficacy of MET/SBCM compared to brief feedback (BF) among heavy drinking, male, Latino, day laborers. The Institutional Review Board of the University of California at Los Angeles approved this study.

2.2. Phase 1: Developing the MET/SBCM intervention

We combined aspects of MET and SBCM to develop a 3 session, manualized series to be delivered in 1–2 week intervals by promotoras. The sessions were designed to last 45–55 minutes and structured to provide feedback to the participants about their risks associated with alcohol use and to help them identify barriers and motivators to change. The sessions also aimed to increase participants’ self-efficacy to change through goal setting and linkages to medical, mental and social services as needed.

Once we shared the manualized intervention with the promotoras, they suggested adaptations to expand the focus of the intervention from the individual’s broader cultural and social context and how that might affect their drinking behavior (Lee, Colby, et al., 2013; Lee, López, et al., 2013). Farts of the counseling approach included cultural values such as familialism, and machismo as well as social stressors more common in recently immigrated persons such as acculturation stress, discrimination and poverty. At the recommendation of the promotoras, changes were made to the manual to further address Latino cultural values and particular stressors the day laborers face. For example, the manual was revised to emphasize the partnership between the promotor and the study participant in helping the participant make change. We also implemented the promotoras’ suggestion that we employ visual aids to enhance the participants’ understanding of the effects of alcohol on the body (i.e., a poster depicting cirrhosis and testicular atrophy, and a cartoon depicting increasingly higher blood alcohol levels on the body).

The sessions covered following items:

- **Session 1** 1) overview of the intervention; 2) review baseline assessments of health, substance use, service needs (e.g., job services, housing assistance, medical services); 3) identify future goals for health, activities, relationships, finances and other; 4) provide personalized feedback/education based on baseline assessments; 5) discuss pros and cons for change 6) assess important, readiness and confidence to change and barriers and facilitators to change; and 7) set health and drinking goals to be attained, identify reasons for setting goals, steps to be taken and services to be sought to reach goals.

- **Session 2** 1) Review progress in meeting goals; 2) review barriers and facilitators to meeting goals; 3) review personal strengths; 4) set health and drinking goals; identify barriers to meeting goals, identify steps needed to reach goals and services to be sought to help reach goals.

- **Session 3** 1) Review barriers and facilitators to meeting goals and review progress in meeting goals; 2) identify barriers to achieving goals; 3) identify reasons to continue working on health and drinking goals.

2.3. Training promotoras to deliver the MET/SBCM intervention and adherence

The volunteer promotoras were all primarily Spanish-speaking Latina women immigrants. They had a range of 3–8 years of experience as health promoters. Once the manualized intervention was developed,
over a 2 day period (total of 16 hours), our bilingual study psychologists (VB and LR) trained four promotoras to deliver it by presenting background on unhealthy drinking in Latinos, reviewing the manual, and observing staged role play of a promotora with a day laborer. Training continued via biweekly supervision of promotoras by a Spanish-speaking study psychologist (VB) with continued role play and review of audiotaped interactions with study participants during both the uncontrolled study and randomized trial.

Two bilingual study psychologists (VB and LR) assessed intervention fidelity during the uncontrolled phase of the study by independently reviewing and rating 8 tapes from 4 promotoras using two validated measures, the Global Rating of Motivational Interviewing Therapists (GROMIT) (Moyer, 2004), and a fidelity scale used in a prior trial of substance abuse treatment using SBCM (Marty, Rapp, & Carlson, 2001, Rapp et al., 2008). In the fidelity scales we substituted the word “promotora” for the word “therapist”. Examples of questions on the GROMIT are: “The promotora showed an understanding of the client’s point of view,” and “The promotora showed confidence in the client’s ability to make changes”. Examples of questions to assess fidelity of SBCM are: “The promotora encourages and promotes identification of past and present strengths, including abilities, achievements, interests and resources” and “The personal plan uses the involvement of community supports (e.g., family, community members) and/or community resources (e.g., health and welfare agencies, support groups)”. Intraclass correlation coefficients (ICC) (Shrout & Fleiss, 1979) were used to measure inter-rater reliability. The ICC estimates for ratings were acceptable for both the GROMIT (mean ICC = 0.90) and the SBCM fidelity measure (mean ICC = 0.78). Eight sessions were rated for fidelity (5 double-coded sessions and 3 single-coded sessions). An average rating of 4 or greater on a 5-point fidelity scale was required to meet criteria for acceptable fidelity. This criterion was met for all eight sessions using the GROMIT and five (62.5%) using the SBCM fidelity measure. Prior to the controlled study, the promotoras were counseled by the study psychologists reviewing the tapes to ensure that they were proficient in MET/SBCM.

2.4. Phase 2: Uncontrolled pilot study and Phase 3: Controlled pilot study

Phase 2 had a pre-post-study design and Phase 3 had a randomized controlled study design. Aside from differing study designs, the two study phases had minor differences. Based on feedback from the promotoras, in Phase 3, payment was provided to intervention participants to attend the MET/SBCM sessions to facilitate study engagement and retention and more efforts were made to meet participants in locations at times convenient for them to complete study assessments. The promotoras also suggested adjustments to the MET/SBCM sessions to enhance cultural adaptation. In the rest of the paper we provide detailed description of Phase 3 only.

3. Control group condition

The control group condition was customized brief feedback (BF) administered once by a trained, Spanish speaking research assistant immediately after the baseline assessment. BF was based on the participant’s responses to the baseline assessment and included information about where to seek services if requested (i.e., locations of low cost health centers or bilingual Alcohol Anonymous meetings).

3.1. Study participants and randomization and remuneration

Between October and December 2012, 66 participants were contacted by distributing flyers at public places where day laborers look for work. Promotoras helped to develop trust between the UCLA study staff and the day laborers to facilitate recruitment. Interested persons (N = 54) spoke with research staff on site to determine if they met the following inclusion criteria: 1) Latino ethnicity; 2) aged 21 years or older 3) speak Spanish 4) report consuming more than 14 drinks per week or more than 4 drinks at least twice per week (exceeding low risk drinking limits per the National Institutes of Health); 5) not currently in treatment for an alcohol or substance disorder 6) not planning on leaving town in the following 6 months; and 7) have a telephone number that may be used to make contact. Those meeting all criteria (N = 31) were invited to participate. Those who agreed (N = 29), were administered informed consent and a baseline survey and were randomly assigned to receive BF (n = 15) or the MET/SBCM intervention (n = 14). Randomization was done by research staff who used consecutively numbered, sealed envelopes containing assignment information using a computer-generated set of random numbers to select permuted blocks of 2 and 4. Within each block, equal numbers were assigned to intervention or control groups. Participants were remunerated for their time via gift cards: baseline $15, 6 weeks $20, 12 weeks $25, 18 weeks $40 (total amount up to $100). In phase 2 of the study we learned that participants would not attend MET/SBCM sessions if they were not remunerated for their time. Therefore participants in the intervention group were also given $20 for each session they attended with a promotora (total amount up to an additional $60). To enhance timely completion of assessments, all participants could participate in a lottery to receive a gift card ranging in value from $5 to $40 for completing study assessments within 2 weeks of each follow up due date.

4. Post-assessment baseline procedures

Once the assessments were completed, the research assistant gave all study participants a calendar with dates for the follow up assessments and the payment schedule. Those in the intervention group were also given an explanation of what to expect over the three sessions, were scheduled to attend the first session, and given contact information for the promotora.

4.1. MET/SBCM procedures

Prior to the first meeting, scheduled within 2 weeks after baseline, the promotora reviewed the baseline assessment data. At the first meeting, she asked permission to audio record the meeting, and delivered the three sessions over a 6 week period.

4.2. Assessments and follow-up

All participants were interviewed by research assistants to complete assessments. Measures available in Spanish language were used when possible and/or English language versions were translated into Spanish. These translations were checked for accuracy and appropriateness by the promotoras. Baseline questionnaires assessed demographic, health-related and alcohol consumption characteristics including age, country of birth, immigration status, education, marital status, living arrangement, and years as a day laborer, English language proficiency items from the Bicultural Involvement Questionnaire-Short Version (Guro, Suarez-Morales, Schwartz, & Szapocznik, 2009), size of social network (Sherbourne & Stewart, 1991), self-rated health (both mental and physical-ranging from 0 = dying to 10 = perfect), SF-12 version 2 mental and physical health composite scores (Gandek et al., 1998; Ware, Kosinski, & Keller, 1996), depression (PHQ-8) (score ranging from 0 to 24 and >=10 signals moderate to severe depressive disorder) (Kroenke, Spitzer, & Williams, 2001), number of drinks consumed per week, frequency of drinking wine or more drinks on one occasion in the past month, alcohol problems using the Alcohol Use Disorders Identification Test (AUDIT) (score ranging from 0 to 40 and > 8 indicates harmful drinking) (Bohn, Babor, & Kranzler, 1995; Medina-Mora, Carreno, & De la Fuente, 1998; Reinert & Allen, 2007) and barriers and facilitators to reducing drinking.
Follow-up assessments were made in person at 6-, 12- and 18-weeks after baseline and included the AUDIT and alcohol consumption. At 18-weeks, participants were asked if they had any suggestions for change to enhance the study and if they enjoyed participating in the study. Participant follow-up concluded April 2013. Of the 29 participants enrolled (14 intervention, 15 control), 25 were assessed at 6 weeks, 24 were assessed at 12 weeks and 25 remained at 18 weeks (12 intervention, 13 control) (86% retention). Of the 14 persons assigned to the intervention group, 12 attended all sessions with the promotor (86%), 1 attended two sessions and 1 did not attend any sessions.

4.3. Statistical analyses

Participant characteristics are reported for the total sample and by group as frequencies and means and standard deviations (SD). T-tests and chi square tests were used to compare groups for continuous and categorical variables respectively. Fisher’s exact test was used for categorical variable analyses in cases when the cells had fewer than 5 observations. Effect size estimates were computed from observed partial eta-squared values and then converted to Cohen’s d.

5. Results

5.1. Baseline participant characteristics

Among the 29 participants, average age was 43 years (range 21 to 63 years), most were from Mexico, were undocumented and had worked as a day laborer for several years (Table 1). Most had less than high school education, were never married and did not understand spoken English well. About a third were homeless. About half reported fair or poor health and below average mental and physical health (per SF-12). Participants were equally divided among those reporting no or minimal depression (PHQ-8 score 0–4), mild depression (PHQ-8 score 5–9) and moderate or severe depression (PHQ-8 score 10–24).

At baseline, average amount of weekly drinking per person was more than 44 drinks per week: all reported drinking at least 6 drinks per drinking occasion at least weekly, and had AUDIT scores in the harmful range (score ≥ 8) (Table 1). An average of 2.4 barriers and 2.8 facilitators tochanging drinking were reported by participants. Most common barriers were “the people I spend time with all drink” (n = 14), “the people I spend time with encourage me to drink” (n = 12), and “feeling sad or depressed” (n = 13). Most common facilitators identified were “someone to take me to a program and/or encourage me to stop drinking” (n = 15), “access to help to stop drinking” (n = 12), and “friends sharing information about alcohol’s effects” (n = 13).

5.2. Outcomes

Over time, both groups reduced alcohol intake and improved AUDIT scores (Table 2). Though no statistically significant differences were observed at any of the time points (p > 0.05), at 6 weeks, compared to control, intervention group participants drank less (11 vs. 25 drinks per week) and had lower AUDIT scores (14 vs. 20). The difference between groups in drinks per week at the 6-week follow-up approached a large effect size (d = .77). The differences persisted at 12 weeks (effect size of d = .41 for drinks per week) but diminished at 18 week follow-up when control group participants reduced drinking and AUDIT scores to those similar to the intervention group. Exploratory within-group repeated measures analysis of variance were conducted separately for the intervention and control groups. The results indicated a significant change over time for drinks per week for the intervention group (p < 0.05) but not for the control group (p = 0.29). Post hoc contrasts for the intervention group showed that drinks per week were lower at 6-weeks (p < 0.05) and 12-weeks (p < 0.05) compared to baseline. There was no evidence of an effect on drinks per week at the 18-week follow-up (d = .00). At 6 weeks, both groups reduced drinking from 6 or more drinks weekly or more by about 50% and this remained constant over the rest of the study period. When asked about satisfaction with the treatment and the study, 11 of the 12 participants in the intervention group were satisfied with the treatment and all participants in both study groups were satisfied with the study and had no suggestions to improve it.

6. Discussion

In partnership with the promotoras and staff of a community-based organization serving the needs of day laborers, we developed a
culturally adapted and integrated behavioral intervention and trained promotoras to deliver it with high fidelity. Most respondents (12/14) completed the treatment and were satisfied with it. Early in the course of the study, differences in drinking outcomes appeared to favor those receiving the intervention; however these differences did not remain.

Despite the known challenges of recruiting and retaining ethnic minority participants into treatment studies, we were successful in doing so (Lau, Chang, & Okazaki, 2010). There are several possible reasons why we were able to recruit and retain participants including the 1) partnership with IDEPSCA and its promotoras who knew the population and helped to develop trust between the day laborers and study staff; 2) intervention that was selected and developed with IDEPSCA to address the cultural and social context of the day laborers and delivered in Spanish by promotoras; 3) providing financial incentives for participants to complete assessments and to attend the sessions with promotoras; and 4) facilitating participation by meeting participants in locations and at times convenient to them. Indeed, there is increasing evidence that community partnerred research can improve recruitment, capacity to deliver interventions, health outcomes and sustainability of interventions (Jagosh et al., 2012). Further, promotoras and other types of community health workers have been effective in improving health in communities (Balcazar et al., 2011). Particularly for low income populations, financial incentives and enhancing convenience of participation can improve recruitment and retention rates (Nicholson et al., 2011).

Possible reasons for none of the drinking outcomes being statistically different between the two study groups include small sample size and a possible contamination effect. The group of day laborers at the study sites is cohesive and our study staff informed us that some of the control group participants were aware of the intervention being conducted with others in the group of day laborers. Despite possible contamination, we observed some differences favoring the intervention group at 6 and 12 weeks for average number of drinks per week and AUDIT outcomes were statistically significant between groups are: 1) brief feedback may be as effective as the MET/SBCM intervention beyond a 3-month timeframe; and 2) the intervention was promising but more prolonged intervention may be needed to sustain benefits.

Compared with other studies addressing heavy alcohol use among Latino adults that improved alcohol-related outcomes between groups (Carroll et al., 2009; Lee, López, et al., 2013), our study population was more socially disadvantaged. This extreme vulnerability may have limited the efficacy of the study intervention, and our counseling intervention without direct service provision may have been inadequate to reduce heavy drinking behaviors. Also because of the study population’s low income, we had to provide financial incentives to attend sessions with the promotoras, thereby limiting the sustainability of such an intervention for IDEPSCA.

A possible study limitation is that participants were recruited from Los Angeles and so participants were primarily from Mexico and may not represent other Latinos. Because the study did not use a dismantling design another limitation is that intervention effects cannot be specifically linked to either MET or SBCM.

We are aware of another study that developed, but has yet to test, a brief intervention for Latino day laborers (Ornelas, Allen, Vaughan, Williams, & Negi, 2015) and another testing a culturally adapted approach to address heavy drinking in Latinos (Lee, López, et al., 2013) but the present study is the first we know of to test a culturally adapted, behavioral intervention to reduce heavy drinking in disadvantaged Latino men, employing promotoras, and in partnership with a community based agency serving them. Additional studies of community-based, culturally adapted interventions, including those employing promotoras, to reduce heavy drinking are needed to address this important public health concern among the growing population of Latinos in the U.S.

### Table 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drinks per week, mean (SD)</td>
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</tr>
<tr>
<td>6-week</td>
<td>18.67 (20.89)</td>
<td>11.35 (9.63)</td>
<td>25.42 (26.17)</td>
</tr>
<tr>
<td>12-week</td>
<td>13.39 (27.26)</td>
<td>6.70 (8.67)</td>
<td>19.04 (35.87)</td>
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<td>18-week</td>
<td>12.45 (14.97)</td>
<td>11.48 (15.55)</td>
<td>13.35 (14.99)</td>
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<td>AUDIT Score, 0 to 40, mean (SD)</td>
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<td></td>
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<tr>
<td>6-week</td>
<td>16.92 (8.73)</td>
<td>13.67 (7.80)</td>
<td>19.92 (8.74)</td>
</tr>
<tr>
<td>12-week</td>
<td>13.39 (27.26)</td>
<td>10.18 (9.21)</td>
<td>16.08 (11.21)</td>
</tr>
<tr>
<td>18-week</td>
<td>13.28 (9.75)</td>
<td>13.25 (9.16)</td>
<td>13.31 (10.65)</td>
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<td>Harmful drinking (AUDIT &gt; = 8), n (%)</td>
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<tr>
<td>6-week</td>
<td>21 (84)</td>
<td>9 (75)</td>
<td>12 (92)</td>
</tr>
<tr>
<td>12-week</td>
<td>16 (67)</td>
<td>6 (55)</td>
<td>10 (77)</td>
</tr>
<tr>
<td>18-week</td>
<td>17 (68)</td>
<td>8 (67)</td>
<td>9 (69)</td>
</tr>
<tr>
<td>Binge drinking (&gt;= 6 drinks), weekly or more, n (%)</td>
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<td></td>
</tr>
<tr>
<td>6-week</td>
<td>13 (52)</td>
<td>6 (50)</td>
<td>7 (54)</td>
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<tr>
<td>12-week</td>
<td>12 (50)</td>
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</tr>
<tr>
<td>18-week</td>
<td>13 (52)</td>
<td>6 (50)</td>
<td>7 (54)</td>
</tr>
</tbody>
</table>

**Abbreviations:** SD, standard deviation. No p-values comparing intervention and control groups exceeded 0.05. Data are presented as no. (%) unless otherwise indicated. Fisher’s exact test was used for this analysis.

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