Screening and Brief Intervention for Drug Use in Primary Care: The ASPIRE Randomized Clinical Trial

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**IMPORTANCE** The United States has invested substantially in screening and brief intervention for illicit drug use and prescription drug misuse, based in part on evidence of efficacy for unhealthy alcohol use. However, it is not a recommended universal preventive service in primary care because of lack of evidence of efficacy.

**OBJECTIVE** To test the efficacy of 2 brief counseling interventions for unhealthy drug use (any illicit drug use or prescription drug misuse)—a brief negotiated interview (BNI) and an adaptation of motivational interviewing (MOTIV)—compared with no brief intervention.

**DESIGN, SETTING, AND PARTICIPANTS** This 3-group randomized trial took place at an urban hospital-based primary care internal medicine practice; 528 adult primary care patients with drug use (Alcohol, Smoking, and Substance Involvement Screening Test [ASSIST] substance-specific scores of ≥4) were identified by screening between June 2009 and January 2012 in Boston, Massachusetts.

**INTERVENTIONS** Two interventions were tested: the BNI is a 10- to 15-minute structured interview conducted by health educators; the MOTIV is a 30- to 45-minute intervention based on motivational interviewing with a 20- to 30-minute booster conducted by master’s-level counselors. All study participants received a written list of substance use disorder treatment and mutual help resources.

**MAIN OUTCOMES AND MEASURES** Primary outcome was number of days of use in the past 30 days of the self-identified main drug as determined by a validated calendar method at 6 months. Secondary outcomes included other self-reported measures of drug use, drug use according to hair testing, ASSIST scores (severity), drug use consequences, unsafe sex, mutual help meeting attendance, and health care utilization.

**RESULTS** At baseline, 63% of participants reported their main drug was marijuana, 19% cocaine, and 17% opioids. At 6 months, 98% completed follow-up. Mean adjusted number of days using the main drug at 6 months was 12 for no brief intervention vs 11 for the BNI group (incidence rate ratio [IRR], 0.97; 95% CI, 0.77-1.22) and 12 for the MOTIV group (IRR, 1.05; 95% CI, 0.84-1.32; P = .81 for both comparisons vs no brief intervention). There were also no significant effects of BNI or MOTIV on any other outcome or in analyses stratified by main drug or drug use severity.

**CONCLUSIONS AND RELEVANCE** Brief intervention did not have efficacy for decreasing unhealthy drug use in primary care patients identified by screening. These results do not support widespread implementation of illicit drug use and prescription drug misuse screening and brief intervention.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT00876941

Screening and brief intervention (SBI) for unhealthy alcohol use is among the most efficacious and cost-effective of preventive services; systematic reviews support their recommendation by the US Preventive Services Task Force (USPSTF). Based in part on extrapolation from these data, the United States has invested heavily over the past decade to disseminate and implement SBI for alcohol and other drugs.2-3 Federal health agencies encourage SBI for illicit drug use and prescription drug misuse.4-5

A commonly implemented model is a single-session intervention delivered by trained health educators for patients across a range of severity from risky use through severe disorders.6 Yet the best evidence for efficacy for addressing unhealthy alcohol use is by multicontact intervention by primary care physicians.7 And the USPSTF concluded that the evidence was insufficient to recommend SBI for unhealthy drug use.8 That same year, based in part on efficacy for unhealthy alcohol use and on results of preliminary studies for drug use,9 the National Institute on Drug Abuse (NIDA) called for research on drug SBI efficacy.10-11

The objective of our study was to test the efficacy and effectiveness of 2 brief interventions for “unhealthy drug use,” defined as illicit drug use or addictive prescription drug misuse (without a prescription or more than prescribed), among primary care patients identified by screening.

Methods

The Assessing Screening Plus Brief Intervention’s Resulting Efficacy to Stop Drug Use (ASPIRE) study was a 3-group randomized trial that tested the efficacy of 2 brief interventions for unhealthy drug use—a brief negotiated interview (BNI) and an adaptation of motivational interviewing (MOTIV)—compared with no brief intervention in primary care patients identified by screening as using illicit or misusing prescription drugs. (See trial protocol in Supplement 1.)

Participants

Health educators employed by the hospital in a federally funded Screening, Brief Intervention, Referral, and Treatment (SBIRT) program6 screened all patients not previously screened in the past year at an urban academic hospital-based primary care clinic (a clinical program in existence prior to ASPIRE study implementation). During the ASPIRE study, health educators and research assistants trained in that same role screened patients for past 3-month unhealthy drug use by asking the second item of the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)13 with minor modifications for local relevance (eg, mention of Klonopin, not Serepax as an example of a sedative and Ritalin as an example of a stimulant). Patients screened positive by the health educators were referred immediately to research assistants. Research assistants completed further screening for study eligibility. Patients were screened at the time of clinic visits in private clinic space.

Eligibility criteria were (1) age 18 years or older; (2) arrived for a visit with a primary care clinician; and (3) substance-specific ASSIST score 4 or greater, which means drug use weekly or more in the past 3 months or less frequent use but with a consequence.13 Exclusion criteria were (1) inability to provide contact information for 2 persons; (2) inability to interview and consent in English; (3) unwilling or unable to participate in follow-up; (4) pregnancy (self-report); (5) brief intervention by preexisting SBIRT program in past 3 months; or (6) participation in on-site addiction treatment program.

Participants provided written informed consent and received compensation for study assessments. The institutional review board approved the study, including follow-up of incarcerated participants, and we obtained a certificate of confidentiality from the National Institutes of Health.

Assessments

At study entry, we assessed the following by in-person interview: demographics, tobacco use, ASSIST alcohol and drug items,13 the participant’s main drug (“Which substance used in the past month concerns you most?”), Timeline Followback (TLFB) for the main drug (a validated calendar method that determines drug use on each day in the past month),14 3 items assessing past-month drinking,15 the short form Composite International Diagnostic Interview for drug dependence,16 the 15-item Short Inventory of Problems-Drugs (SIP-D),17 stage of readiness to change,18 HIV sex and drug risk behaviors19-20 using audio-assisted computer self-interview, depression (Patient Health Questionnaire [PHQ-9]),21 the Overall Anxiety Severity and Impairment Scale (OASIS),22 health status (EuroQol),23 and health care utilization and mutual help meeting attendance (Form 90 Alcohol Intake Revised-Economic Development [AIR/ED]).24 Medical diagnoses were recorded from the electronic record (Table 1).25-28 Hair samples providing a 90-day window of use were tested for drugs by enzyme-linked immunosorbent assay and gas chromatography-mass spectrometry (Psychomedics). Assessments were repeated 6 months later. At 6 weeks, we asked the TLFB for the main drug and SIP-D (30-day time frames) and utilization and mutual help items since study entry by telephone.

Randomization, Interventions, and Control

After the baseline assessment, the data coordinating center randomly assigned participants (1:1:1) to receive BNI, MOTIV, or no brief intervention via a central secure website using random permuted blocks of size 3 and 6 stratified by drug dependence and main drug.

Interventions were audio-recorded. Results of screening (risky use or likely disorder) and any interest in a referral were communicated to the primary care clinician via the electronic medical record. Counselors prepared by reviewing ASSIST results. Those providing the MOTIV also reviewed medical records and additional assessment responses.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Entry (n = 528)</th>
<th>6 Months (n = 517)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%)</td>
<td>Overall</td>
<td>369 (69.9)</td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td>Overall</td>
<td>357 (68.8)</td>
</tr>
<tr>
<td>Black</td>
<td>Overall</td>
<td>116 (68.2)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>Overall</td>
<td>18 (10.6)</td>
</tr>
<tr>
<td>White</td>
<td>Overall</td>
<td>32 (18.8)</td>
</tr>
<tr>
<td>Other</td>
<td>Overall</td>
<td>4 (2.4)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>Overall</td>
<td>41.3 (12)</td>
</tr>
<tr>
<td>High school graduate or equivalent, No. (%)</td>
<td>Overall</td>
<td>369 (69.9)</td>
</tr>
<tr>
<td>Health insurance, No. (%)</td>
<td>Overall</td>
<td>69 (13.1)</td>
</tr>
<tr>
<td>Any substance use–related health condition, No. (%)</td>
<td>Overall</td>
<td>450 (85.2)</td>
</tr>
<tr>
<td>Comorbid illnesses (most common), No. (%)</td>
<td>Overall</td>
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</tr>
<tr>
<td>Hypertension</td>
<td>Overall</td>
<td>149 (28.2)</td>
</tr>
<tr>
<td>Skin disorders</td>
<td>Overall</td>
<td>146 (27.7)</td>
</tr>
<tr>
<td>Health-related quality of life, mean (SD)</td>
<td>Overall</td>
<td>70.3 (20.4)</td>
</tr>
<tr>
<td>ED visit past 3 mo, No. (%)</td>
<td>Overall</td>
<td>189 (35.8)</td>
</tr>
<tr>
<td>Hospitalization past 3 mo, No. (%)</td>
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<td>Hospitalization, addiction or mental health related past 3 mo, No. (%)</td>
<td>Overall</td>
<td>29 (5.5)</td>
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<tr>
<td>ED visit for addiction or mental health past 3 mo, No. (%)</td>
<td>Overall</td>
<td>47 (8.9)</td>
</tr>
<tr>
<td>Mutual help group participation past 3 mo, No. (%)</td>
<td>Overall</td>
<td>93 (17.6)</td>
</tr>
<tr>
<td>Residential stay for addiction or mental health past 3 mo, No. (%)</td>
<td>Overall</td>
<td>43 (8.1)</td>
</tr>
<tr>
<td>Outpatient addiction or mental health treatment or counseling past 3 mo, No. (%)</td>
<td>Overall</td>
<td>119 (22.6)</td>
</tr>
</tbody>
</table>

Abbreviations: BNI, brief negotiated interview; ED, emergency department; MOTIV, adaptation of motivational interviewing; OASIS, Overall Anxiety Severity and Impairment Scale; PHQ-9, Patient Health Questionnaire.

* Race was assessed by patient self-report to describe the sample and because it is required of NIH-funded studies and for reporting to the institutional review board. Classifications were black or African American, white, Asian, Alaska native, Native Hawaiian/other Pacific Islander, American Indian, and none. Hispanic or Latino ethnicity was asked separately. In this table, those reporting Hispanic and black are categorized as black; those categorized as white or other do not include those reporting Hispanic ethnicity.

* Includes diagnostic codes from electronic medical records at the medical center within 90 days prior to study entry. Diagnoses were selected based on published literature (see Methods). Examples include chronic obstructive pulmonary disease, hypertension, injuries, depression, cirrhosis, HIV, hepatitis C, cellulitis, and drug-induced mental disorders (full listing available on request).
The BNI was a single 10- to 15-minute structured interview conducted by health educators, all of whom had at least completed high school or the equivalent and had human services experience or a bachelor’s degree. The BNI uses some features of motivational interviewing and includes feedback, review of the “pros and cons” of use, and development of a plan for change.

The MOTIV group received 30 to 45 minutes of motivational interviewing with an offered 20- to 30-minute booster follow-up session conducted by counselors who had a master’s degree. The MOTIV program was less structured than BNI and included eliciting possible links between drug use and health concerns, heightening discrepancies between negative drug use outcomes and valued goals, enhancing self-efficacy about behavior change, and providing options for change.

Both interventions focused on the participant’s main drug but addressed alcohol and other drugs if they emerged as relevant; alcohol was a substance of concern for only 15%. There were 14 BNI and 4 MOTIV counselors. Intervention fidelity was assessed by coding all audible intervention recordings using the Motivational Interviewing Treatment Integrity (MITI) instrument and an instrument developed for this study. Scores on these rating scales suggested that interventionists used a motivational interviewing style for both interventions (although minimally so for BNI) and adequately delivered the interventions. Ratings on the study-specific measure indicated discriminability between the study interventions. Details about the interventions appear in the eMethods in Supplement 2.

Participants assigned to the control group received no brief intervention. All participants, both intervention and control, were given information on how to contact Alcoholics Anonymous, Narcotics Anonymous, the hospital behavioral health clinic and emergency team, a state hotline, a city triage line, and websites for alcohol and drug screening.

Outcomes
The primary outcome was percentage of days using the main drug determined at study entry, assessed at 6 months using the 30-day TLFB. The distribution of the primary outcome was nonnormal even after attempts at transforming the data (eg, log transformation); thus, we analyzed the number of days of use as count data. At 6 weeks, days using the main drug and using the main drug more than once (in the past 30 days), SIP-D, and self-reported health utilization were secondary outcomes, as were, at 6 months, the following: number of days using the main drug more than once (in past 90 days), any drug use, any drug or heavy alcohol use (>3 standard drinks for women, >4 standard drinks for men in a day), use of ASSIST-specified drugs (marijuana, cocaine, opioids, sedatives, amphetamines, hallucinogens, inhalants), drugs (any, amount, and decreases) by hair testing, any injection drug use, ASSIST scores (main substance specific, substance specific, and global), SIP-D, any unsafe sex and number of times (vaginal or anal intercourse without a condom), and self-reported utilization of health services.

Statistical Analyses
We conducted all analyses on an intention-to-treat basis: participants were analyzed according to randomized assignment regardless of whether they received the intervention. The 2 main comparisons were between each intervention vs control. We corrected for multiple comparisons within each outcome using the Hochberg sequential test procedure. The primary outcome and other count outcomes were analyzed using negative binomial regression models chosen instead of Poisson because of overdispersion in the data (ie, the variance exceeds the mean), adjusting for the randomization stratification variables; baseline value of the outcome; and addiction- or mental health–related outpatient visits (except in the analysis of any outpatient care), the only variable statistically significantly different across groups at baseline.

Dichotomous outcomes were analyzed similarly using logistic regression. When events were sparse, we used Fisher exact test. For the ASSIST outcomes and quantitative hair variables, quantile regression was used because the distributions were nonnormal. Median regression was used in all cases except substance-specific ASSIST scores where computational difficulties arose due to excess zeros; therefore, the 90th quantile was modeled. To describe the magnitudes of association across prespecified subgroups, we stratified analyses by risk for drug dependence (ie, ASSIST substance-specific score for main drug ≥27) and by main drug. To assess potential effect modification, we tested interactions between randomization group and readiness to change, past month heavy drinking episode and substance use–related health condition (and anxiety, depressive symptoms, and pain, post hoc). In post hoc exploratory analysis, we compared receipt of a booster (MOTIV group) vs control using the same analytic methods as for the primary outcome.

Only observed data were used in the primary analysis; missing data were not imputed. However, results were confirmed using multiple imputation analysis (in 20 generated data sets) to account for missing data for the primary outcome. Variables used for imputation were age, sex, and the variables in the primary analysis. The study was initially designed to have 80% power, but because of feasibility, we enrolled a sample for 90% power to detect an absolute difference of 14.7% in percentage of days with drug use in a sample of 528 participants, assuming 10% loss to follow-up and using 2-sided tests and an overall α of .05 (for power calculations, the primary pairwise comparisons of each intervention vs control was set at α = .025). Thus, the study was powered to detect intervention effects among the full sample but not for subgroup analyses, which were conducted for exploratory purposes. All statistical analyses were performed using SAS version 9.2 (SAS Institute).

Results
Study participants were enrolled June 1, 2009, to January 31, 2012, and follow-up continued until October 2012. During study enrollment, 25 302 SBIRT clinical program screenings for drug use were done in primary care, and 2624 patients (10%) were
positive for any use in the past 3 months. When research staff were in clinic, 1504 patients were potentially available for study screening, 1287 completed eligibility screening, and 876 were eligible (Figure). Of those eligible, 528 (60%) were randomized. Compared with those eligible who did not enroll, patients who enrolled in the study were more likely to be black (68% vs 60%), less likely to report marijuana as their main drug (63% vs 80%), and more likely to use cocaine (26% vs 12%) and opioids (24% vs 16%); they had higher global and main drug ASSIST scores (median, 15 vs 12 and 15 vs 11, respectively); and

Figure. Enrollment and Follow-up Flow Diagram for ASPIRE Study of Brief Interventions for Unhealthy Drug Use

- 1504 Individuals potentially available for screening
- 217 Not screened
  - 117 Not interested
    - 7 Patient says not enough time
    - 2 Research assistants not available
  - 14 Timing conflict (eg, with clinical care)
  - 11 Language
  - 13 Health educator referred to doctor
  - 40 Health educator did not refer to research staff
  - 13 Other
- 1287 Screened
- 411 Excluded
  - 12 Not fluent in English
  - 2 Pregnant
  - 209 Unwilling or unable to return for research visits
  - 21 Could not provide contacts for 2 people
  - 167 Substance-specific ASSIST score not ≥4
- 876 Eligible
- 347 Declined participation
  - 20 Refused due to timing
  - 89 Not interested
    - 1 Personal problems
    - 2 Too ill
    - 1 Unknown reasons
    - 1 Questions too personal
  - 226 Unspecified reason
    - 1 Did not complete consent/authorization
    - 1 Data collection technical problem
    - 1 Research staff determined too ill
    - 2 Research staff determined not understanding
    - 2 Discretion of research staff (other reason)
- 529 Enrolled
  - 1 Excluded (withdrawal before randomization)
  - 528 Randomized
  - 177 Randomized to receive MOTIV
    - 177 Received MOTIV as randomized
  - 174 Randomized to receive BNI
    - 174 Received BNI as randomized
  - 176 Completed 6-wk follow-up
    - 1 Died
  - 172 Completed 6-wk follow-up
    - 2 Unable to be contacted
  - 169 Completed 6-mo follow-up
    - 3 Withdraw
    - 2 Unable to be contacted
  - 173 Completed 6-mo follow-up
    - 1 Died
    - 2 Unable to be contacted
  - 169 Included in primary analysis
    - 5 Excluded
      - 3 Withdraw
      - 2 Unable to be contacted
  - 173 Included in primary analysis
    - 4 Excluded
    - 2 Died
    - 2 Unable to be contacted
  - 175 Included in primary analysis
    - 2 Excluded (unable to be contacted)

ASSIST indicates Alcohol, Smoking, and Substance Involvement Screening Test, BNI, brief negotiated interview; MOTIV, an adaptation of motivational interviewing.
they were more likely to have ASSIST scores of 27 or greater (18% vs 7%) and to use more than 1 drug (32% vs 17%).

Of those randomized, 525 of 528 participants (99%) had 6-week follow-up data and 517 of 528 (98%) had 6-month follow-up data; there were no significant differences in follow-up between groups. Baseline characteristics (Table 1, Table 2, and Table 3) were similar across randomization groups except for past outpatient addiction or mental health treatment. At study entry, the mean (SD) number of days using the main drug was 14.4 (11.5) and the median was 12 (interquartile range [IQR], 3-27); at 6 weeks, the mean (SD) was 12.3 (11.9) days and median, 8 (IQR, 1-26); and at 6 months, the mean (SD) was 14.0 (12.2) days and the median, 11 (IQR, 2-29). Almost all baseline hair samples tested positive for drugs at baseline (Table 3).

All participants received their assigned intervention. One assigned to the control group received a BNI, 158 of 351 participants (45%) received a referral to addiction treatment services, and 54 of 177 participants (31%) received a MOTIV booster session.

**Main Results**

For the primary outcome (Table 4), there were no significant differences between the BNI or MOTIV group and the control group (adjusted mean days using the main drug at 6 months, 11 and 12 vs 12, respectively; BNI adjusted incidence rate ratio [aIRR], 0.97; 95% CI, 0.77-1.22; MOTIV aIRR, 1.05; 95% CI, 0.84-1.32). Similarly, in analyses stratified separately by main drug and risk for drug dependence, there were no significant differences between the intervention groups and the control group. There was no significant interaction between randomization group and either readiness to change (P = .61), any heavy drinking day in the past month (P = .94), or substance-related health condition (P = .17) on the primary outcome, number of days (in the past 30 days) using the main drug. Receipt of a MOTIV booster session, compared with no brief intervention, also had no significant effect on the primary outcome (aIRR, 0.96; 95% CI, 0.68-1.34). Results of the multiple imputation analysis were consistent with the main analysis.

**Other Drug Use Measures and 6-Week Results**

There were no significant differences at 6 months overall (eTable 1 in Supplement 2) or in analyses stratified by main drug or by risk for drug dependence (eTable 2 in Supplement 2) in any drug use, any heavy alcohol or drug use, ASSIST substance-specific score for the main drug, global ASSIST score, 1 or more days using the main drug, and days using the main drug (in the past 90 days). There were no differences overall (eTable 1) or in analyses stratified by main drug or by risk for drug dependence (eTable 2) in use of ASSIST specified drugs. At 6 weeks, there were also no significant differences between groups overall and in analyses stratified by main drug or risk for drug dependence (eTable 3 in Supplement 2).

**Hair Testing**

There were no significant differences in the proportions of participants testing positive for use of any of the drugs listed in Table 3 (BNI, 95%; MOTIV, 93%; control, 91%) at 6 months (BNI odds ratio [OR], 1.65; 95% CI, 0.64-4.23; MOTIV OR, 1.25; 95% CI, 0.52-3.00) (eTable 4 in Supplement 2). Similarly, there were no significant differences between groups in detection of cocaine or benzoylecgonine, opioids, or carboxy-tetrahydrocannabinol. In sensitivity analyses (missing values assumed positive), there were also no significant differences. There were no significant group differences in concentrations of or decreases in drugs (quantitative hair testing).

**Drug Use Consequences and Health Care Utilization (Including Addiction Treatment)**

There were no significant between-group differences overall (eTable 1) or in stratified analyses at 6 weeks (eTable 3) or 6 months (eTable 2) in drug use consequences (SIP-D), injection drug use, unsafe sex, health care utilization (hospitalizations and emergency department visits, overall or for addiction or mental health reasons), or mutual help group attendance.

**Discussion**

This study is among the first to test the efficacy of SBI for illicit drug use and prescription drug misuse in adults in primary care. In patients identified by screening, neither a BNI nor a MOTIV had efficacy for decreasing drug use as assessed by numerous self-report and biological measures, drug use consequences, addiction or mental health care utilization, mutual help meeting attendance, or other health care utilization. In the primary analyses, the point estimate for days using the main drug was generally higher in the MOTIV group compared with the control group, raising the possibility of harm, although not statistically significant and not a hypothesized effect. The lack of effect was consistent regardless of drug used, severity, alcohol use, readiness to change, or presence of a substance-related health condition. More than 90% of participants still had laboratory evidence of drug use at the 6-month follow-up.

Brief intervention trials to address illicit drug use and prescription drug misuse are critical before widespread implementation that assumes efficacy. Although motivational interventions are often effective among people seeking help,33 efficacy among patients identified by screening (eg, for risky alcohol use) may not translate to reductions in drug use. The approach is the same as that proven efficacious for alcohol. Patients with marijuana use or risky alcohol use who are unaware of any consequences are motivated to make changes when they, as a result of counseling, perceive risks that are inconsistent with their values and behaviors. This change occurs even if before counseling they perceive no obvious risks, which is likely the case for many with low levels of risky alcohol or marijuana use. For those with consequences (eg, recurrent injury related to alcohol intoxication, job loss due to poor performance related to marijuana use), these problems serve as a starting point for discussion.
Table 2. Drug Use Among Primary Care Patients With Unhealthy Drug Use Identified by Screening

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Entry (n = 528)</th>
<th>6 Months (n = 517)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>BNI</td>
</tr>
<tr>
<td>Substance Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main drug, No., (%)</td>
<td>90 (17.1)</td>
<td>30 (5.7)</td>
</tr>
<tr>
<td>Opioid (includes heroin, prescription, and others)</td>
<td>31 (17.8)</td>
<td>8 (5.7)</td>
</tr>
<tr>
<td>Prescription opioid only</td>
<td>28 (15.8)</td>
<td>10 (5.7)</td>
</tr>
<tr>
<td>Cocaine</td>
<td>31 (17.5)</td>
<td>12 (6.8)</td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIDI-SF positive&lt;sup&gt;b&lt;/sup&gt;</td>
<td>100 (100)</td>
<td>100 (100)</td>
</tr>
<tr>
<td>Tobacco use past year</td>
<td>63 (12.1)</td>
<td>26 (14.9)</td>
</tr>
<tr>
<td>Days using main drug past 30 d</td>
<td>14.4 (11.5)</td>
<td>15.1 (11.7)</td>
</tr>
<tr>
<td>Days ≥ 1 time using main drug past 30 d</td>
<td>5.0 (0.0-18.0)</td>
<td>5.5 (0.0-21.0)</td>
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<tr>
<td>Use of &gt;1 drug past 90 d, No. (%)</td>
<td>9.8 (11.1)</td>
<td>10.5 (11.1)</td>
</tr>
<tr>
<td>Injection drug use past 3 mo, No. (%)</td>
<td>63 (12.1)</td>
<td>26 (14.9)</td>
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<tr>
<td>Misuse any prescription drug past 90 d, No. (%)</td>
<td>112 (22.2)</td>
<td>37 (21.3)</td>
</tr>
<tr>
<td>Any heavy drinking past month, No. (%)</td>
<td>254 (48.1)</td>
<td>81 (46.2)</td>
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<tr>
<td>Tobacco use past year</td>
<td></td>
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<tr>
<td>No. of heavy drinking days past month</td>
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<td>0.0 (0.0-4.0)</td>
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<tr>
<td>Tobacco use past year</td>
<td>4.5 (8.0)</td>
<td>4.2 (7.9)</td>
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<tr>
<td>ASSIST Scores&lt;sup&gt;c&lt;/sup&gt;</td>
<td>97 (18.4)</td>
<td>29 (16.7)</td>
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<tr>
<td>Substance-specific score</td>
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<td></td>
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<tr>
<td>Main drug, median (IQR)</td>
<td>15.0 (9.0-23.0)</td>
<td>14.0 (9.0-23.0)</td>
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<tr>
<td>Opioid, median (IQR)</td>
<td>0.0 (0.0-0.0)</td>
<td>0.0 (0.0-0.0)</td>
</tr>
<tr>
<td>Cocaine, median (IQR)</td>
<td>4.8 (10.6)</td>
<td>4.8 (10.7)</td>
</tr>
<tr>
<td>Marijuana, median (IQR)</td>
<td>0.0 (0.0-2.0)</td>
<td>0.0 (0.0-2.0)</td>
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<tr>
<td>Mean (SD)</td>
<td>11.1 (8.8)</td>
<td>10.5 (8.6)</td>
</tr>
<tr>
<td>Global ASSIST score</td>
<td>15.0 (10.0-29.0)</td>
<td>15.0 (10.0-27.0)</td>
</tr>
</tbody>
</table>

Abbreviations: ASSIST, Alcohol, Smoking, and Substance Involvement Screening Test; BNI, brief negotiated interview; CIDI-SF, Composite International Diagnostic Interview Short Form; IQR, interquartile range; MOTIV, adaptation of motivational interviewing.

<sup>a</sup> Based on a memo from Kessler R, the CIDI-SF was only provisionally validated and should not be interpreted as diagnostic without a clinical interview (http://www.hcp.med.harvard.edu/wmhcidi/ftpdir_public/CIDI-SF%20memo.pdf). In this study, it served as a severity marker stratification variable; the ASSIST is a better validated tool to determine actual current severity.
<sup>b</sup> Substance-specific scores range from 0-39; global drug score ranges from 0-273; in both cases, higher score is riskier use/greater severity.
Table 3. Drug Use Consequences, Readiness to Change, and Hair Testing Among Patients With Unhealthy Drug Use Identified by Screening

<table>
<thead>
<tr>
<th>Drug Test Quantitative Values, ng/mL</th>
<th>Overall (n = 528)</th>
<th>BNI</th>
<th>MOTIV</th>
<th>Control</th>
<th>Overall (n = 517)</th>
<th>BNI</th>
<th>MOTIV</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hair Testing Readiness, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precontemplation</td>
<td>108 (20.5)</td>
<td>34</td>
<td>19.5</td>
<td>35 (19.8)</td>
<td>39 (22.0)</td>
<td>108 (20.5)</td>
<td>34</td>
<td>19.5</td>
</tr>
<tr>
<td>Contemplation</td>
<td>111 (21.0)</td>
<td>34</td>
<td>19.5</td>
<td>42 (23.7)</td>
<td>35 (19.8)</td>
<td>111 (21.0)</td>
<td>34</td>
<td>19.5</td>
</tr>
<tr>
<td>Determination</td>
<td>45 (8.5)</td>
<td>19</td>
<td>10.9</td>
<td>13 (7.3)</td>
<td>13 (7.3)</td>
<td>45 (8.5)</td>
<td>19</td>
<td>10.9</td>
</tr>
<tr>
<td>Action</td>
<td>264 (50.0)</td>
<td>87</td>
<td>50.0</td>
<td>87 (49.2)</td>
<td>90 (50.9)</td>
<td>264 (50.0)</td>
<td>87</td>
<td>50.0</td>
</tr>
<tr>
<td><strong>Hair Testing, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any drug use</td>
<td>475 (96.2)</td>
<td>160</td>
<td>97.0</td>
<td>158 (95.8)</td>
<td>157 (95.7)</td>
<td>475 (96.2)</td>
<td>160</td>
<td>97.0</td>
</tr>
<tr>
<td>Any drug use (missing as positive)</td>
<td>490 (96.3)</td>
<td>164</td>
<td>97.0</td>
<td>163 (95.9)</td>
<td>163 (95.9)</td>
<td>490 (96.3)</td>
<td>164</td>
<td>97.0</td>
</tr>
<tr>
<td>Any opioids</td>
<td>86 (18.4)</td>
<td>34</td>
<td>22.2</td>
<td>33 (20.9)</td>
<td>67 (15.3)</td>
<td>86 (18.4)</td>
<td>34</td>
<td>22.2</td>
</tr>
<tr>
<td>Any cocaine or benzoylecgonine</td>
<td>249 (53.4)</td>
<td>81</td>
<td>52.9</td>
<td>79 (50.6)</td>
<td>70 (49.3)</td>
<td>249 (53.4)</td>
<td>81</td>
<td>52.9</td>
</tr>
<tr>
<td>Any carboxy-tetrahydrocannabinol</td>
<td>366 (75.6)</td>
<td>120</td>
<td>75.9</td>
<td>125 (77.2)</td>
<td>121 (73.8)</td>
<td>366 (75.6)</td>
<td>120</td>
<td>75.9</td>
</tr>
</tbody>
</table>

Abbreviations: BNI, brief negotiated interview; IQR, interquartile range; MOTIV, adaptation of motivational interviewing; SIP-D, Short Inventory of Problems-Modified for Drug Use.

* Ranges from 0-45; higher score means more consequences.

** Of 528 participants, 509 provided a sample, but 5 were insufficient for any testing, and 10 were insufficient for confirmatory testing. Thus, 494 provided a sufficient sample for complete testing. At 6 mo, 485 provided a sample, but for 19 it was insufficient for any testing, and 10 were insufficient for confirmatory testing. Thus, 455 provided a sufficient sample for complete testing. Sample size for any drug use (with missing coded as positive), baseline was 509; 6 mo, 485; any opioids, baseline, 467; 6 mo, 412; any cocaine/benzoylecgonine, baseline, 466, 6 mo, 405; any carboxy-tetrahydrocannabinol, baseline, 484; 6 mo, 439.

* Only completed when substance in question was confirmed and testing possible. For codeine, number tested was 57 at baseline and 39 at follow-up. For remaining drugs, numbers tested were, respectively: morphine, 62 and 39; oxycodone, 45 and 35; hydrocodone, 24 and 22; hydromorphone, 38 and 23; cocaine, 249 and 199; benzoylecgonine, 196 and 183; carboxy-tetrahydrocannabinol, 366 and 328.

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More than half of our participants with marijuana use reported consequences. One might think intervention would have a better chance of efficacy given a “teachable moment” (eg, being aware of a related consequence). On the other hand, such patients are already aware of consequences and have not changed on their own (having missed a “learnable moment”), so it isn’t a given that counseling would be more successful for them. As for those with an alcohol use disorder and for those with likely drug dependence (1 in 5 of our participants), the goal of brief intervention is to link them with further treatment, again building on their recognizing risks and harms that tip the balance toward change.

Despite the potential for benefit with this approach, drug use differs from unhealthy alcohol use in that it is often illegal and socially unacceptable, and is diverse—from occasional marijuana use, which was illegal during this study, to numerous daily heroin injections. Prescription drug misuse is particularly complex, with diagnostic confusion between misuse for symptoms (eg, pain, anxiety), euphoria-seeking, and drug diversion. Brief counseling may simply be inadequate to address these complexities, even as an initial strategy.

Our findings are consistent with the few published efficacy studies of brief intervention for illicit drug use among patients identified opportunistically in other health settings. Observational studies found reductions in drug use after SBI, but these are likely due to regression to the mean and other exposures. In one pediatric emergency department randomized trial, brief intervention was associated with less marijuana use. In a general hospital, a brief intervention reduced psychoactive drug use, although it did not affect addiction treatment utilization. In an international trial in varied sites (eg, dental, sexually transmitted
disease clinics), brief intervention was associated with a very small difference in a self-report drug use and problem score, with effects for marijuana and stimulants but not opioids and not in US participants.\(^4\) In an emergency department trial, there were no differences in self report of use, addiction severity, or hair test abstinence, although 58% of the sample was lost to follow-up.\(^4\) Four other randomized trials have been registered (NCT01942811, NCT01942876, NCT00877331, NCT01207791).

The ASPIRE study has a number of strengths. It is among the largest trials. We used biochemical corroboration of drug use and research staff assessed outcomes, minimizing social desirability bias. Follow-up was high. We tested feasible interventions in a real-world setting with few participant exclusion criteria. We did not exclude participants with dependence because in clinical practice they cannot be excluded and some studies suggest efficacy in these groups.\(^4,43\) Counselors referred patients with dependence to treatment, and results suggest no difference in intervention effects between this subgroup and participants with lower severity. Primary care clinicians were given screening results and other information, but they did not perform the study interventions because we wanted to test interventions that might be feasible to adopt broadly (eg, in federal programs,\(^3,6\) under health reform\(^4\)).

The negative results obtained in this study are unlikely to be due to regression to the mean or assessment reactivity because drug use did not decrease. Several randomized trials of intervention vs none have not detected assessment effects.\(^45-47\) Power, at more than 90% for modest effects, is similarly unlikely to be responsible for the findings in the overall sample. Although the study was not adequately powered for subgroup analyses, observed effect sizes were close to null and of clinically unimportant magnitude (for the full sample and the majority of secondary analyses) even if they had been significant.

Methodological features should be considered in interpreting the results. The design had features of effectiveness studies (few exclusions, feasible training). The BNI, delivered by an existing SBIRT program, was characterized by less fidelity to its components than was the MOTIV, yielding a test of efficacy for the MOTIV and of effectiveness for the BNI. However, the BNI was implemented in an ideal practice context: trainers included its original developers and the BNI was grant-funded with more hours of training and supervision than would be likely elsewhere. Counseling sessions were audiotaped, which does not occur in routine practice. Participants were compensated when they completed follow-up interviews. Because patients who did not enroll in the study were more likely to report marijuana as their main drug and appeared to be even less severe than our participants (lower ASSIST scores), we cannot say whether our results would apply to them, although it seems unlikely that brief intervention would be more effective in such a group. Furthermore, our findings may not be generalizable beyond the urban primary care setting.

Given strong prior belief in the efficacy of SBI for drug use, future trials could focus on drug subgroups (eg, marijuana, heroin, prescription drug) for which interventions, to be effective, may need to differ. We performed post hoc additional subgroup analyses among those who reported heavy drinking and marijuana use, heavy drinking and cocaine use, and all 3. In analyses overall and stratified by an ASSIST score of 27 or greater, we found no evidence of effect on total ASSIST score, marijuana- and cocaine-specific scores, or heavy drinking days. We also found no intervention effects among subgroups without dependence risk (ASSIST scores 4-15, 16-26) or subgroups based on frequency of use (≥5 vs <5 days of the main drug). Although it might be reasonable to consider the design and testing of interventions for such subgroups, our findings suggest the ones we tested would not be effective.

There were also no significant interactions between group assignment and anxiety symptoms, depression symptoms, or pain. We also tested whether daily marijuana users benefitted from intervention and found no significant effects. Among a subgroup of 23 participants who also had marijuana consequences and ASSIST scores of 27 or greater, MOTIV was associated with fewer days of marijuana use (mean, 8 vs 20 for BNI, 21 for control; \(P = .06\)), but given numerous analyses, this should be viewed as hypothesis generating at most. Trials could also test having the primary care clinician as the interventionist, a multicontact (>2) intervention, a multicomponent intervention (eg, several clinicians, electronic), and interventions that address multiple risk behaviors. Combined prespecified outcomes (eg, cocaine and alcohol use) could be used. Trials could also have more exclusion criteria, even greater attention to fidelity than was given for the BNI in our trial, and a focus on suburban populations. But such efficacy designs and reliance on primary care clinicians as counselors are strategies unlikely to yield practices that achieve widespread implementation.

Based on the current literature and our findings, brief intervention for unhealthy drug use in primary care patients identified by screening appears unlikely to be effective for decreasing drug use or consequences. Guideline development groups for primary care preventive services should consider these results. There are other reasons to identify and address drug use in primary care settings (eg, to make appropriate diagnoses, for safer prescribing) but if other trials yield consistent results, widespread implementation of drug SBIRT, the goal of which is reduction of use or consequences, should be reconsidered. Both clinicians and researchers should look beyond screening and brief intervention—and perhaps to lengthier and more complex longitudinal care management strategies—as the main solution to addressing illicit drug use and prescription drug misuse in primary care patients.

Conclusions

Brief intervention did not have efficacy for decreasing unhealthy drug use in primary care patients identified by screening. These results do not support widespread implementation of illicit drug use and prescription drug misuse screening and brief intervention.
ARTICLE INFORMATION

Author Contributions: Dr Saitz had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Saitz, Palfai, Cheng, Alford, Bernstein, Meli, Samet.

Acquisition, analysis, or interpretation of data: Saitz, Palfai, Cheng, Alford, Bernstein, Lloyd-Travaglini, Meli, Chaisson, Samet.

Drafting of the manuscript: Saitz, Palfai.

Critical revision of the manuscript for important intellectual content: Saitz, Palfai, Cheng, Alford, Bernstein, Lloyd-Travaglini, Meli, Chaisson, Samet.

Statistical analysis: Saitz, Cheng, Bernstein, Lloyd-Travaglini.

Obtained funding: Saitz, Bernstein, Meli, Samet.

Administrative, technical, or material support: Saitz, Alford, Bernstein, Meli, Chaisson.

Study supervision: Saitz, Palfai, Alford, Meli, Chaisson.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Saitz reported receiving grants from the National Institutes of Health (NIH), having consulted as editor to BMJ, having received speaking fees from academic and governmental institutions and professional societies often concerning the evidence related to addressing substance use in health settings, and having consulted as an expert witness on alcohol and drug topics. Dr Cheng reported having served on data monitoring committees for Johnson & Johnson/Janssen and having received grants from the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration (SAMHSA). Ms Lloyd-Travaglini reported having received grants from NIH. No other disclosures were reported.

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