Screening and brief intervention for lower-risk drug use in primary care: A pilot randomized trial

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Abstract

Aims: The efficacy of screening and brief intervention for lower-risk drug use is unknown. This pilot study tested the efficacy of two brief interventions (BIs) for drug use compared to no BI in primary care patients with lower-risk drug use identified by screening.

Methods: We randomly assigned participants identified by screening with Alcohol Smoking and Substance Involvement Screening Test (ASSIST) drug specific scores of 2 or 3 to: no BI, a brief negotiated interview (BNI), or an adaptation of motivational interviewing (MOTIV). Primary outcome was number of days use of main drug in the past 30 as determined by validated calendar method at 6 months. Analyses were performed using negative binomial regression adjusted for baseline use and main drug.

Results: Of 142 eligible adults, 61(43%) consented and were randomized. Participant characteristics were: mean age 41; 54% male; 77% black. Main drug was cannabis 70%, cocaine 15%, prescription opioid 10%; 7% reported injection drug use and mean days use of main drug (of 30) was 3.4. At 6 months, 93% completed follow-up and adjusted mean days use of main drug were 6.4 (no BI) vs 2.1 (BNI) (incidence rate ratio, IRR 0.33[0.15-0.74]) and 2.3 (MOTIV) (IRR 0.36[0.15-0.85]).

Conclusions: BI appears to have efficacy for preventing an increase in drug use in primary care patients with lower-risk use identified by screening. These findings raise the potential that less severe patterns of drug use in primary care may be uniquely amenable to brief intervention and warrant replication.

Keywords: Screening and brief intervention; brief negotiated interview; motivational interviewing; lower-risk drug use; randomized trial

1. Introduction

Drug use is prevalent in the United States: in 2018, 53.2 million people reported past year use of a drug (not including tobacco and alcohol), and 8.1 million met the diagnostic criteria for a substance use disorder (Substance Abuse and Mental Health Services Administration, 2019). Those using a drug but not meeting the criteria for a substance use disorder, i.e. those with lower-risk use of drugs, are also at risk of health consequences. Individuals with lower-risk use of drugs can experience impaired judgment, increased sex drive and increased unsafe injection and sex practices (Hudgins et al., 1995; Raj et al., 2007). These risks can lead to the transmission of infectious diseases like human immunodeficiency virus or the development of medical complications such as myocardial infarction, accidents, and trauma (Degenhardt and Hall, 2012). Less risky use of drugs may lead to the development of a substance use disorder. The ability to decrease drug use through early intervention could thus prevent increases in risky behaviors and improve health outcomes. These interventions are well served to occur in primary care (PC) settings, as those with lower-risk drug use are unlikely to seek specialized treatment.

Reliable methods that identify and treat lower-risk drug use are limited, as interventions have primarily focused on individuals with a substance use disorder. Screening and brief intervention (SBI) has been shown to be efficacious and cost-effective for PC patients with unhealthy alcohol use including risky use without an alcohol use disorder (Kaner et al., 2018), but SBI trials for drug use have been unable to show consistent large effects. In trials assessing SBI for drug use across healthcare settings, there was no effect found in safety-net PC settings (Roy-Byrne et al., 2014), no effect in general hospital patients with problematic use of prescription drugs (Otto et al., 2009), no effect in the American site of an international trial (Humeniuk et al., 2012), and no effect in an urban hospital safety-net PC setting (Saitz et al., 2014). There have been modest findings of decreased use in a randomized trial of an intervention that included a standardized video doctor in community health centers (Gelberg et al., 2015) and increased likelihood of receiving treatment for a substance use disorder after a BI in an observational study (Krupski et al., 2010). There are mixed findings with respect to BI efficacy in the ED: BI showed reductions in number of days using any drug among adults in a low-income urban ED setting (Blow et al., 2017) and increased abstinence rates from cocaine and heroin in patients recruited at walk-in clinics at an urban hospital (Bernstein et al., 2005) but a multisite BI study had null results (Bogenschutz et al., 2014). Among

post-partum women, two trials have shown short term efficacy of an electronic BI (Ondersma et al., 2007; Ondersma et al., 2014). The US Preventive Services Task Force has posted a draft recommendation for comment that recommends screening for illicit drug use in adults, when services for accurate diagnosis and effective treatment can be offered. However, trials to date have generally included a spectrum of unhealthy drug use from risky use through disorder but excluded those with use that is lower risk. Thus, the efficacy of SBI for lower-risk drug use is unknown.

The objective of the current study was to test the efficacy of two BIs for lower-risk drug use compared to no BI, among PC patients identified by universal screening. An exploratory aim was to assess whether effects differed by main drug of concern.

2. Methods

2.1 Trial design:

We conducted a pilot parallel-group individually randomized controlled trial with 3 arms: a brief negotiated interview (BNI), an adaptation of motivational interviewing (MOTIV) or no BI (control condition). Follow-up was at 6 months. We randomized participants after the baseline assessment. The data coordinating center randomly assigned participants via a central secure website. Research assistants entered information in on subject ID and stratification factors. The randomization list was generated ahead of time based on the blocking and stratification specifics using SAS (1-1-1 randomization, with permuted blocks of size 3 and 6, stratified by drug dependence and main drug). After entering in the required information, the electronic system then generated the randomized assignment to the research assistant via a central secure website. Research assistants, blinded to group allocation, conducted the assessments during in-person interviews, repeated at 6 months.

We recruited participants between June 2009 and January 2012 at a PC clinic at an urban medical center in Boston, Massachusetts, USA. Eligibility criteria were: 1.) age >=18; 2.) attending for a PC visit; 3.) positive screen for lower-risk drug use; 4.) fluency in English or Spanish; 5.) providing at least two contacts and being able to return for the 6-month assessment; 6.) being able to be interviewed by trained research staff. Exclusion criteria were: 1.) pregnancy; 2.) having received a previous BI by a trained health educator in the past 3 months.

Trained personnel conducted screening for past 3-month unhealthy drug use (illicit drug use (including cannabis, which use was illegal in Massachusetts at the time of the study) or prescription medication misuse) by asking the second item of the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)(Henry-Edwards et al., 2003) and, for those reporting any use (score of at least 2), the remaining items. The main eligibility criterion was a lower-risk drug use, defined as a drug-specific involvement score of 2 or 3 (i.e. : participants had to have an ASSIST score of 2-3 on the drug specific score, which means that they could have had more than one drug but had to be low risk on any drug they used). At study entry, we assessed demographics. We assessed the participant's main drug by asking them to report the substance used in the past month that concerned them the most. There was no exclusion based on type of drug used.

Participants provided written informed consent. They received compensation for study assessments (baseline study procedures: $50, six-month follow-up study procedures: $75). The institutional review board approved the study, and we obtained a certificate of confidentiality from the National Institutes of Health.

2.2 Measures:

Outcomes: The primary outcome was the number of days of use of main drug in past 30 days at 6-months, measured with the Timeline Followback (TLFB)(Sobell and Sobell, 1992). Secondary outcome was drug use consequences at 6-months measured by the Short Inventory of Problems–Drugs (SIP-D)(Alterman et al., 2009). In addition, we conducted hair analyses for the presence of cocaine, benzoylecgonine, carboxy-tetrahydrocannabinol, codeine, morphine, 6-monoacetylmorphine, oxycodone, hydrocodone, and hydromorphone.

2.3 Interventions:

Brief Negotiated Interview (BNI): specially trained health educators conducted the BNI. It was a single 10- to 15-minute structured interview using features of motivational interviewing and comprised feedback, review of the "pros and cons" of use, and negotiating a plan for change based on the patients readiness.

Adaptation of motivational interviewing (MOTIV): master-level counselors conducted MOTIV. It was a 30- to 45-minute session of motivational interviewing. Counselors offered an additional 20- to 30-minute booster session. MOTIV was less structured than BNI. It included eliciting potential 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 substance reported by the participant as the main drug.

Participants assigned to the control group received no intervention.

2.4 Analyses:

The main comparisons were between each intervention compared to no BI. For the outcomes number of days of use of main drug and drug use consequences, we assessed intervention effects with negative binomial regression models, adjusted for baseline use and main drug. We used the negative binomial model to allow for overdispersion in the data. In addition, we conducted exploratory analyses stratified by main drug. Given the prevalence of main drug, analyses were stratified by: cannabis as main drug, cocaine, opioids and other as main drug. For the binary outcomes, any main drug use at follow-up based on hair analyses, we used logistic regression models, adjusted for baseline use and main drug. All subjects were analyzed according to randomized group. We performed analyses using SAS version 9.2 (SAS Institute).

3. Results

We randomized 61 participants to the control (n=19), BNI (n=23), and MOTIV (n=19) groups. A CONSORT diagram is presented in Figure 1. Mean age was 41, 54% were male, 77% were black or African American, 16% white, 5% Hispanic or Latino. Main drug used was cannabis (70%), cocaine (15%), prescription opioids (10%) and other (5%). There was no exclusion based on type of drugs used but no participants with lower-risk drug use reported using opioids other than prescription opioids. Mean (SD) number of days of use of main drug over the past 30 days was 3.4(5.1); 7% reported injection drug use in the past 3 months and 25% using more than one drug; 74% had an ASSIST score of 2 and 26% a score of 3. Half (49%) reported any heavy drinking days in the past month (defined as >=4 drinks in a day for women, >=5 for men). Mean SIP-D score was 3.8(7.2), indicating a low level of problems; readiness to change drug use assessment indicated that 48% of participants were in pre-contemplation, 10% in contemplation, 16% in determination and 26% in action (Heather et al., 2008).

At 6 months, 93% (57/61) completed follow-up. Participants in the BNI and MOTIV group reported significantly less days of use of main drug compared to those in the control group. When stratified by main drug, directions of associations remained similar, but results were statistically significant only for the main drug "cocaine, opioids and other", when BNI was compared to control. With respect to drug use related problems, there were no significant differences between groups, including when stratified by main drug. Detailed results are presented in Table 1. Prevalence of identification of any main drug use at follow-up in hair analyses was 72% in the control group, 53% in BNI and 62% in MOTIV with adjusted odds ratio of a detectable hair level of main drug at follow-up, compared to control, of 0.33 (0.03, 2.46), p=0.8, for BNI and 0.59 (0.06, 5.17), p=0.9, for MOTIV.

4. Discussion

This pilot study suggests that BNI and MOTIV have efficacy for preventing an increase in drug use in PC patients with lower-risk drug use. At six months, those who received either intervention reported decreases in number of days of use while those in the control group reported an increase. These results were consistent with findings from the hair testing, although the hair results lacked statistical significance. We did not detect an effect on drug use-related problems. This was not surprising, considering that problem scores were low at entry. This may reflect lowered risky behaviors associated with lower risk drug use.

Additional analyses were conducted to explore whether effects differed by main drug. When stratified by main drug, there were no significant differences for days of cannabis use, even though direction and magnitude of associations were similar. There was a significant effect of BNI, but not MOTIV, on days of use of cocaine, opioids and other drugs.

This study offers important insight into our understanding of BI and their role in preventing and reducing drug use. Research has shown PC to be an important setting for reducing risky substance use, notably unhealthy alcohol use (Kaner et al., 2018). It may be an important setting for reaching those with lower-risk use of drugs, and BI may improve patient outcomes and decrease the risk of individuals developing a substance use disorder.

These findings are consistent with other PC-based BI studies on drug use showing intervention efficacy on use or problems (Bernstein et al., 2005; Gelberg et al., 2015; Walton et al., 2013a; Walton et al., 2013b). Nevertheless, several

other studies reported no effect of BI (Humeniuk et al., 2012; Roy-Byrne et al., 2014; Saitz et al., 2014). Differences between studies might be explained by the drug use severity: it may be that BI for drug tend to be efficacious among individuals with lower-risk use or to prevent use (Walton et al., 2013b). Or differences might be related to the BI content or format: one of the effective interventions incorporated a video intervention and one computer-based intervention (Gelberg et al., 2015; Walton et al., 2013a). In the present study, the most often identified main drug was cannabis. The same was observed for higher-risk drug use (Saitz et al., 2014). Evidence for efficacy of brief interventions for cannabis use in health care settings among patients identified by screening is questioned, as a recent meta-analysis did not identify reductions in cannabis-specific ASSIST scores on number of days of cannabis use following a brief intervention (Imtiaz et al., 2020).). Compared to the studies included in the meta-analysis, the current study informs us regarding the efficacy of an intervention targeting lower-risk use.

This study has several limitations. It only analyzed individuals with lower-risk use, which was a small percentage of those using drugs who go to PC, and for those with higher risk use, no intervention effect was detected (Saitz et al., 2014). Half of those screened were eligible, which limited the sample size and thus analyses were likely underpowered to detect differences within subgroups. The proportion eligible who enrolled was modest and lower than it was for those with more severe drug use included in a larger trial (Saitz et al., 2014). So generalizability to all with lower-risk drug use may be limited, and it may inform on the difficulty to reach patients with lower-risk use. Further, this study was conducted at an urban safety-net hospital, and findings require replication to determine generalizability beyond urban hospital-based PC. Nevertheless, it gives valuable information on who might respond or not respond to a BI.

Our study has notable strengths: the follow-up rate was high, the interventions were delivered as intended and the outcomes measures included biological testing. One limitation of many BI trials is the absence of a biological measure, relying solely on self-report to assess intervention efficacy, with a significant risk of social desirability bias. In this study, biological measures were in line with self-reported use suggesting that the reported differences in drug use between group may not be solely attributed to social desirability.

In conclusion, although warranting further replication in a larger trial, our exploratory results suggest that less severe patterns of drug use in primary care may be uniquely amenable to brief interventions. Lower-risk drug use may be seen

as less important a target of screening than alcohol and tobacco, or higher risk drug use or screening for drugs other than cannabis. Nevertheless, cannabis use is not risk free (Abrams, 2018), and for primary care patients who typically have comorbid conditions, addressing any drug use can be important to reduce risk.

Conflict of interest:

Debbie Cheng serves on Data Safety Monitoring Boards for Janssen Research & Development.

The other authors have no conflicts of interest to report.

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Figure 1. Study CONSORT (CONsolidated Standards of Reporting Trials) enrollment and follow-up diagram

Legend: MOTIV: adaptation of motivational interviewing, BNI: brief negotiated interview

Table 1: Number of days used of main drug in past 30 days and Drug Use Consequences (SIP-D) at 6-month follow-up (adjusted)

Main analysis

		No BI	BNI	MOTIV	BNI vs. no BI		MOTIV vs. no BI	
	N	Adjusted Means			IRR (95% CI)	p-value	IRR (95% CI)	p-value
Days used main drug[++]	57	6.4	2.1	2.3	0.33 (0.15,0.74)	0.01	0.36 (0.15,0.85)	0.02
SIP-D[+++]	57	1.7	1.8	0.5	1.05 (0.20, 5.60)	0.96	0.31 (0.05, 1.92)	0.41

Exploratory analyses stratified by main drug

		No BI	BNI	MOTIV	BNI vs. no BI		MOTIV vs. no BI	
	N	Adjusted Means			IRR (95% CI)	p-value	IRR (95% CI)	p-value
Days used main drug[‡] Cocaine, Opioids[§], and Other	17	2.3	0.3	1.9	0.12 (0.03,0.43)	0.003	0.81 (0.17,3.91)	0.79
Days used main drug[‡] Cannabis	40	7.4	3.6	3.1	0.49 (0.19,1.25)	0.13	0.42 (0.15,1.14)	0.13
SIP-D[†] main drug Cocaine, Opioids[§], and Other	17	6.9	2.9	2.1	0.41 (0.04, 4.13)	0.45	0.30 (0.02, 3.63)	0.45
SIP-D[†] main drug Cannabis	40	0.45	0.48	0.39	1.07 (0.10, 11.33)	0.96	0.80 (0.05, 12.46)	0.96

BI: brief intervention, BNI: brief negotiated interview, MOTIV: adaptation of motivational interviewing

[++]Model adjusted for the following baseline covariates: # days main drug use in past 30 days and main drug

[+++]Model adjusted for the following baseline covariates: SIP-D and main drug

[‡]Model adjusted for the following baseline covariates: # days main drug use in past 30 days

[†]Model adjusted for the following baseline covariates: SIP-D

[§]Opioid use does not include heroin

SIP-D=Short Inventory of Problems, Drug

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