

Screening and brief intervention for drug use in primary care: the ASPIRE randomized trial

Assessing Screening Plus brief Intervention's
Resulting Efficacy to stop drug use

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Funded by NIDA 1 R01 DA025068
with support from SAMHSA.
Clinicaltrials.gov ID NCT00876941

Background

- US Preventive Services Task Force (USPSTF) recommends alcohol **brief intervention (BI)** for primary care patients with unhealthy alcohol use identified by **screening**
- Federal efforts support “SBIRT” dissemination. SBIRT includes Screening and BI, *and* **Referral and Treatment**, for alcohol *and* **other drugs**

Background

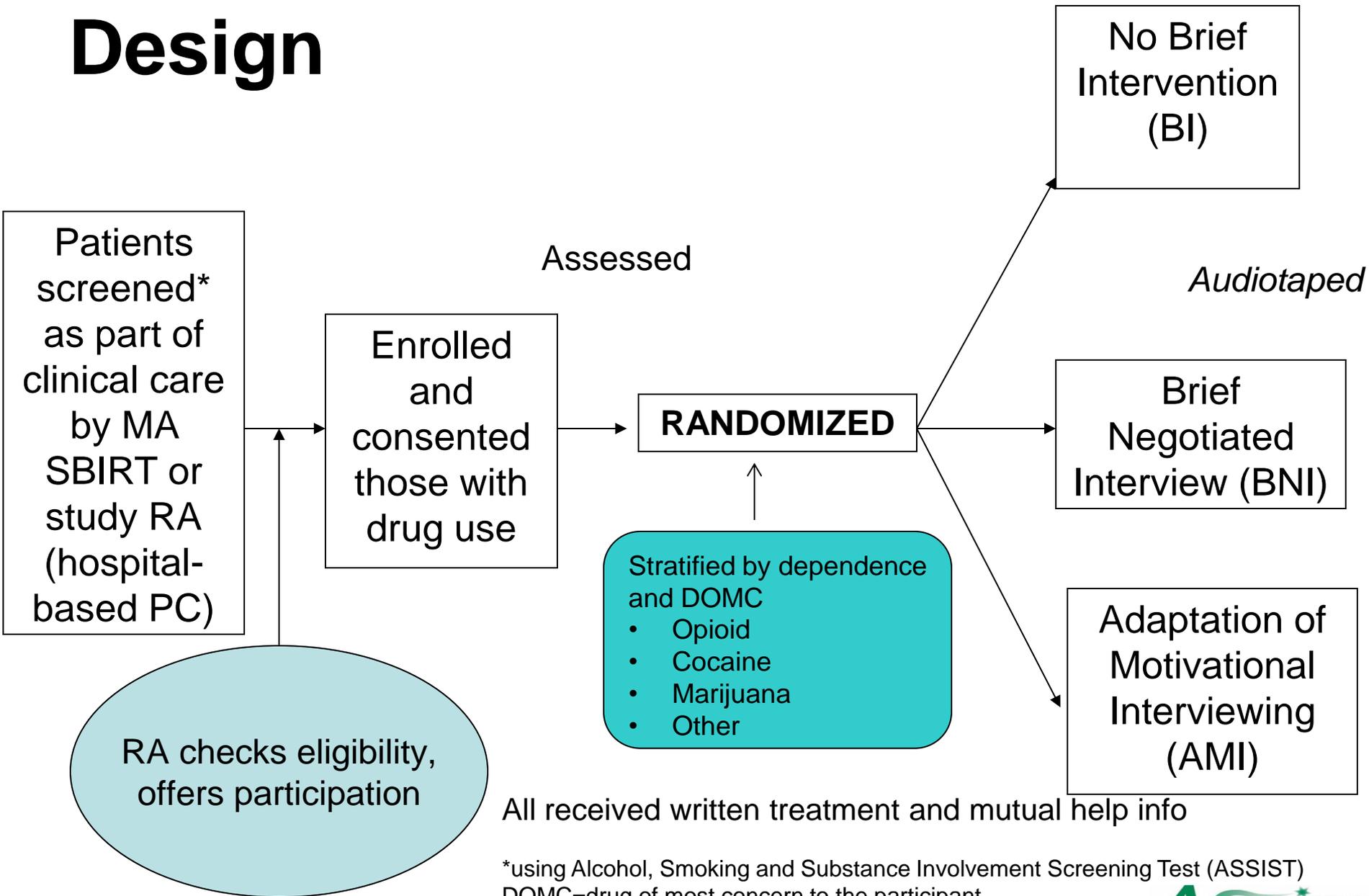
- “The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening adolescents, adults, and pregnant women for illicit drug use.”
(Jan 2008)



Aim

- To test the efficacy of brief intervention for drug use among primary care patients identified by screening

Design



*using Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)
DOMC=drug of most concern to the participant

Eligibility

- Adults (18 years or older)
- Arrived for a visit with primary care clinician
- No BI by MA SBIRT program in past 3 months
- 2 contact persons (for follow-up efforts)
- Willing/able to return for research interviews
- Not pregnant
- Able to interview and consent in English
- NOT participating in on-site buprenorphine program
- **ASSIST drug-specific involvement score ≥ 4**
 - Score means 'weekly or more,' or less frequent use but with a consequence

ASSIST = Alcohol, Smoking and Substance Involvement Screening Test

Interventions

Brief negotiated interview (BNI)	Adaptation of motivational interviewing (AMI)
More structured	Less structured
Feedback, pros and cons, readiness to change, advice/goal setting	Motivational interviewing (includes advice, goal setting)
Health promotion advocate/HS grad	Masters trained psychologist
Didactic and experiential training	Same but with confirmation of proficiency using coded audio recordings
One 10-15 minute interview	One 30-45 minute interview Offer of 2 nd (“booster”) session
Results of screening and BI communicated to PCP	
1-hour a week with supervisor: job performance and cases; observation	1.5-hours a week with supervisor; review of coded audio recordings

Outcomes (6 weeks, 6 months)

- Primary outcome (Timeline Follow-back method (TLFB))
 - # days use of the DOMC in the past 30 days at 6 months
- Secondary outcomes
 - Other drug use measures
 - Number of days heavy use (2 or more times in a day) (TLFB)
 - Abstinence (TLFB)
 - Drug use other than DOMC (ASSIST)
 - Drug use by hair testing (qualitative and quantitative)
 - Global ASSIST scores
 - Drug use consequences (Short Inventory of Problems-D)
 - HIV risk behaviors (sex and drug, assessed by ACASI)
 - Receipt of substance dependence treatment for those with dependence (self report, confirmed with state data)
 - Cost, healthcare utilization, overall health

Analysis

- Negative binomial regression models
 - adjusted for multiple comparisons (Hochberg procedure) and
 - baseline value of outcome
 - drug dependence
 - DOMC
 - outpatient treatment or counseling (not ED) for alcohol, drug abuse or mental health*

*differed at baseline

DOMC=drug of most concern to the participant

**Total approached for study screening:
1,504 with any drug use identified by screening**

**Total undergoing study screening:
1,287/1,504 (86%)**

Of ineligibles, 78%,
unwilling/unable to
return, 8% no
contacts, 9%
incomplete ASSIST

**Of those screened, total eligible:
876/1,287 (68%)**

**Consented:
529/876(60%)**

**Randomized:
528/529 (99.8%)**

**No BI group
177**

**BNI group
174**

**AMI group
177**

**Follow-up at 6 weeks:
525/528 (99%)**

1/528 due to death
2/528 loss to FU

**Followed up at 6 months:
517/528 (98%)**

3/528 due to death
8/528 loss to FU

Baseline Characteristics

<i>Race/ethnicity</i>		
Black or African American	<i>n (%)</i>	357 (69)
Hispanic or Latino	<i>n (%)</i>	50 (10)
White	<i>n (%)</i>	105 (20)
Mean age (SD)	<i>years</i>	41 (12)
Male	<i>n (%)</i>	369 (70)
1+ nights in shelter <u>OR</u> on street in past 3 months	<i>n (%)</i>	88 (17)
High school graduate or higher	<i>n (%)</i>	369 (70)
Never married	<i>n (%)</i>	370 (63)
PHQ-9 score ≥ 10 (mod to severe depressive symptoms)	<i>n (%)</i>	189 (36)
OASIS score ≥ 8 (clinically significant anxiety)	<i>n (%)</i>	176 (33)
Outpatient (not ED) treatment or counseling during past 3 months for alcohol, drugs or mental health*	<i>n (%)</i>	119 (23)

*No BI-17%, BNI-19%, AMI-32%, $p=0.002$

No other significant differences in baseline characteristics

Baseline Characteristics: Drug and Alcohol Use

<i>DRUG USE:</i>		
<i>Drug of Most Concern (DOMC)</i>		
Opioids	<i>n (%)</i>	90 (17)
Prescription Opioids	<i>n (%)</i>	58 (11)
Cocaine	<i>n (%)</i>	98 (19)
Marijuana	<i>n (%)</i>	331 (63)
Days Use of DOMC (in past 30)	Mean (SD)	14 (11)
Injected Drugs (past 3 Months)	<i>n (%)</i>	63 (12)
Use of more than 1 drug in past three months	<i>n (%)</i>	165 (31)
Misuse of any RX drug in past three months	<i>n (%)</i>	112 (21)
ASSIST Score ≥ 27	<i>n (%)</i>	97 (18)
Tobacco use (past year)	<i>n (%)</i>	403 (76)
<i>ALCOHOL USE:</i>		
Any heavy drinking days in past month (Women 4+ drinks/day, Men 5+ drinks/day)	<i>n (%)</i>	114 (22)
Number of heavy drinking days in the past 30	Median (IQR)	0 (0-4)



Fidelity of the Intervention

- 40% sample of recordings were coded using both the MITI and an ASPIRE-study-developed instrument
 - Both had scores consistent with proficiency

MITI – Motivational Interviewing Treatment Integrity

Results: Primary outcome (6 mo)

Days Used DOMC in past 30 days

		No BI	BNI	AMI	BNI vs. no BI		AMI vs. no BI	
	N	Adjusted Means			IRR (95% CI)	p- value**	IRR (95% CI)	p- value**
Days used DOMC*	516	11.52	11.19	12.10	0.97 (0.77,1.22)	0.81	1.05 (0.84,1.32)	0.81

* Model adjusted for DOMC, number of days used DOMC in past 30, drug dependence, and outpatient treatment or counseling during past 3 months for alcohol, drugs or mental health

**p-values adjusted for multiple comparisons using the Hochberg procedure

Results: # Days Used DOMC in past 30 days, stratified by DOMC (6 mo)

		No BI	BNI	AMI	BNI vs. No BI		AMI vs. No BI	
	N	Adjusted Means			IRR (95% CI)	p- value**	IRR (95% CI)	p-value**
Opioids								
Days used DOMC	88	7.59	6.43	7.41	0.85 (0.35,2.07)	0.96	0.98 (0.41,2.34)	0.96
Cocaine								
Days used DOMC	97	4.97	5.71	7.17	1.15 (0.62,2.14)	0.66	1.44 (0.78,2.65)	0.48
Marijuana								
Days used DOMC	322	16.70	16.72	17.11	1.00 (0.80,1.25)	0.99	1.02 (0.82,1.28)	0.99

* Model adjusted for DOMC, number of days used DOMC in past 30, drug dependence, and outpatient treatment or counseling during past 3 months for alcohol, drugs or mental health

**p-values adjusted for multiple comparisons using the Hochberg procedure

Results: # Days Used DOMC in past 30 days stratified by baseline ASSIST score ≥ 27 (6 mo)

		No BI	BNI	AMI	BNI vs. No BI		AMI vs. No BI	
	N	Adjusted Means			IRR (95% CI)	p- value**	IRR (95% CI)	p- value**
ASSIST < 27								
Days used DOMC	423	11.47	11.10	11.72	0.97 (0.76,1.23)	0.86	1.02 (0.80,1.30)	0.86
ASSIST ≥ 27								
Days used DOMC	93	10.58	10.74	12.62	1.01 (0.52,1.98)	0.97	1.19 (0.63,2.26)	0.97

* Model adjusted for DOMC, number of days used DOMC in past 30, drug dependence, and outpatient treatment or counseling during past 3 months for alcohol, drugs or mental health

**p-values adjusted for multiple comparisons using the Hochberg procedure



Results: Secondary outcomes

- There were also no significant differences between groups in analyses
 - overall and stratified by DOMC and ASSIST score
- Primary outcome at 6 weeks
- At 6 weeks and 6 months
 - heavy drug use (2 or more times per day)
 - drug use consequences (SIP)
 - HIV risk behaviors



Limitations

- Effectiveness design choices
 - No exclusions for heavy drinking, multiple drug use, drug dependence, comorbidity
- Applicability beyond urban hospital-based primary care
- Observed results unlikely due to: regression to mean, assessment effects, loss to follow-up, severity/drug, fidelity, power

Conclusions

- BNI and AMI did not have efficacy for decreasing drug use or drug use consequences in primary care patients identified by screening
 - Future analyses will examine additional outcomes (e.g. hair toxicology, receipt of substance abuse treatment, health care utilization, and cost)



Implications

- If other trials yield consistent results, widespread implementation of drug SBIRT should be reconsidered
 - Negative studies in the SBIRT literature should not be assumed to be due to methodological limitations
 - Research (and clinical practice) should focus on alternative ways to address drug use and consequences in primary care settings



Interventions

Brief negotiated interview (BNI)	Adaptation of motivational interviewing (AMI)
More structured	Less structured
Preparation: review of ASSIST Content: feedback, pros and cons, readiness to change, advice (and goal, e.g. cut down/quit/refer)	Preparation: review of ASSIST, drug and alcohol consequences, dependence symptoms, and medical record Content: Motivational interviewing (including goal, e.g. cut down/quit/refer, as appropriate)
Health promotion advocate/health educator, High school graduate or equivalent (minimum)	Masters trained psychologist
Didactic and experiential training	Didactic and experiential; confirmation of proficiency using coded audio recordings
One 10-15 minute interview	One 30-45 minute interview Offer of 2 nd (“booster”) session
Results of screening and BI communicated to PCP	
1-hour a week with supervisor: job performance and cases; observation	1.5-hours a week with supervisor; review of coded audio recordings

Fidelity of the Intervention

- Recordings of a 40% sub-sample were coded using both the MITI and an ASPIRE-study-developed instrument
 - 20% of the sub-sample double coded
 - Global MITI Spirit [1-5] (proficient ≥ 3.5)
 - BNI=3.59 (0.76) AMI=4.65 (0.49)
 - ASPIRE [1-5] (proficient ≥ 3.0)
 - BNI = 2.53 (0.69) AMI = 3.64 (0.73)

MITI – Motivational Interviewing Treatment Integrity

Spirit – mean score of a composite of interactional style central to MI

ASPIRE – mean score for the specific components of each intervention

Objectives

- Identify patients with drug use by screening in a large hospital-based primary care practice
- Enroll screen-positive subjects
- Randomly assign subjects to 1 of 3 groups:
 1. No BI
 2. Brief negotiated interview (BNI)
 3. Adaptation of motivational interviewing (AMI)
- All received treatment and mutual help info
- Assess all subjects at study entry and 6 months later