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Representativeness of Patients Enrolled in a Primary Care Clinical Trial for Heavy/Problem Substance Use

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Abstract

Background: The extent to which participants in RCTs resemble their broader target groups is of particular concern when studying stigmatized conditions such as substance use disorders (SUDs). The present study compared patients who enrolled in a 4-arm clinical trial of SBIRT (Screening, Brief Intervention, and Referral to Treatment) to eligible patients who declined study participation.

Methods: Participants were N=1,338 primary care patients who anonymously completed a computer-delivered health survey and screened positive for heavy/problem alcohol or drug use. Those who consented to the RCT (N=713) were compared to those who declined (N=625) on a variety of demographic, substance use, and psychosocial characteristics. Variables significant at $p < 0.20$ in univariate analyses were then examined using multivariate logistic regression to determine their combined effect.

Results: The sample was 60% female and 76% African American, with a mean age of 45.2 years. Patients who consented to participate differed from those who declined on 34 (60%) of the 57 variables studied. The most parsimonious model by multivariate regression found those who consented were older, more likely to be unemployed, endorse prescription drug misuse, problems related to drug use, family history of alcohol problems, trouble falling asleep, and a health professional recommendation to lose weight.

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Author Contributions:

Dr. Svikis (PI), Ondersma (Co-I) and Weaver (Co-I) were all involved in the design and writing of the R01 grant and conduct of the study that followed. Dr. Ondersma developed the computer software used to collect the survey data. Sydney Kelpin was responsible for analyses, interpretation of results, and wrote the manuscript. All authors contributed to editing and revision.

Conclusion: Patients consenting to the RCT reported a greater number and more severe psychosocial and mental health problems than those who declined study participation. If the higher level of risk among study participants was found in other studies as well, it would raise questions regarding the generalizability of RCT results to broader clinic samples.

Keywords

substance use; representativeness; generalizability; SBIRT

INTRODUCTION

Randomized clinical trials (RCTs) are widely regarded as the gold standard for evaluating the efficacy of a treatment for a particular disorder. Conclusions drawn from RCTs, however, are applicable only to the extent that trial participants resemble the patient population of interest.¹ This has been a longstanding issue in clinical research, beginning first with the underrepresentation of women and minorities, resulting in treatment protocols skewed toward a norm of middle-aged, white males. The passing of the National Institutes of Health (NIH) Revitalization Act in 1993 served as the first step to address this issue by establishing guidelines for the inclusion of women and minorities in clinical research.²

Although this movement improved representation of these groups, the disconnect between research and practice was still apparent.³ Stringent inclusion/exclusion criteria have contributed to this disconnect, with treatment outcome studies becoming increasingly restrictive in their enrollment procedures since the 1970's.⁴ In addition, research has shown that persons who volunteer for research studies often differ from those who do not, with African Americans^{5,6} and individuals of low socioeconomic status⁷⁻⁹ being less likely to participate. For substance use disorders (SUDs), it is clear that participants in RCTs of behavioral and pharmacological treatments can and often do differ from those who enter real world community substance abuse treatment programs.¹⁰⁻¹² Such differences may be inevitable given the low rate at which persons with SUDs seek treatment (estimated at 11% of those with a SUD diagnosis).¹³

Primary care may be an ideal setting in which to reach non-treatment seeking persons with SUDs. To identify and provide intervention to such patients, practice guidelines recommend Screening, Brief Intervention and Referral to Treatment (SBIRT) as the treatment of choice.¹⁴ While SBIRT has demonstrated efficacy for heavy, problem drinking,¹⁵ more recent studies targeting other drugs of abuse have yielded mixed results.^{16,17} The issue of sample representativeness in SBIRT research has received little attention. This could have important implications in the event that samples under investigation differ from the target population. Research has shown that greater awareness of problems associated with substance use, severity of use, and psychological comorbidities may help to leverage treatment participation and other help-seeking behaviors.^{18,19}

The present study analyzed anonymous, computer-administered health survey screening data to examine this issue. This study afforded a unique opportunity to compare RCT eligible patients who consented to the clinical trial to those who did not across an array of

demographic, psychosocial and mental health variables. Analyses were exploratory in nature given the lack of information regarding representativeness of SBIRT research participants.

METHODS

Participants

Participants were 1,338 primary care patients who completed an anonymous computer-delivered health survey and met eligibility criteria for an RCT targeting heavy/problem alcohol and/or other drug use. The sample was further divided into those who consented to participate (N=713) and those who did not (N=625). RCT eligibility criteria included: 18 years of age or older; residing in clinic catchment area; able to speak and understand English; not enrolled in substance abuse treatment; and meeting criteria for heavy/problem alcohol and/or drug use. Patients were ineligible for the RCT only if they presented with a serious psychiatric or cognitive impairment that prevented them from providing consent.

Heavy/problem alcohol use was defined by 1) CAGE score ≥ 2 (men) or T-ACE score ≥ 2 (women) and self-report consumption of > 14 drinks/week (men) or > 7 drinks/week (women) in the past 30 days; or 2) Self-reported consumption of 5 or more drinks (men) or 4 or more drinks (women) on at least two occasions in the past 30 days.

Heavy/problem drug use was defined by: 1) CAGE-AID (adapted to include drugs) ≥ 1 plus recent drug use (past 30 days); 2) illicit drug use 2 or more days/week (past 30 days) and/or; 3) misuse of prescribed medications on at least 2 occasions in the past 30 days.

Design and Procedures

Patients were recruited from the waiting room of an urban primary care and gynecologic clinic to participate in an anonymous patient health survey. Those providing verbal consent completed the 15–20 minute survey. An intervention authoring tool, developed for previous work,^{20,21} was used to design and deliver the survey. This software used a tablet PC and presented all information aurally and visually. Participants were guided through the survey by a three-dimensional cartoon character who read each question aloud and sought to keep participants engaged in the survey process. All subjects received a \$10 gift card for completing the survey. In addition, survey participants who met heavy/problem substance use criteria were informed of their eligibility for a 4-arm clinical trial of SBIRT. They were told that for those who consented, participation would begin that same day, would end after a 6-month follow-up assessment, and that they would be compensated a total of \$140 for their time and effort. All study procedures were approved by the University's Institutional Review Board. The present study examined anonymous survey data for eligible patients who either did or did not provide informed consent for RCT participation.

Measures

The survey collected information about a variety of health behaviors and psychosocial issues, including substance use and problems, using standardized measures when available. The present study analyzed survey data from the following domains:

Demographics.—Demographic variables included age, race, education, employment, marital status, and insurance coverage.

Health Behaviors.—Items about general health, including physical activity and diet.

Tobacco Use.—Questions focused on current (yes/no) and lifetime use (number of cigarettes smoked: 0, 1–99, or 100).

Physical Health.—Participants reported on lifetime diagnoses of medical conditions (e.g., arthritis, hepatitis, heart disease).

Emotional Health.—Depressive symptoms were assessed with the Patient Health Questionnaire (PHQ-9)²² and anxiety symptoms were measured using the Generalized Anxiety Disorder Screener (GAD-7).²³

Sleep.—Sleep behavior was assessed using items from the Insomnia Severity Index.²⁴ The use of prescription medications for sleep was assessed with an item from the Pittsburgh Sleep Quality Index (PSQI).²⁵

Alcohol Use and Problems.—Quantity and frequency of recent alcohol use (past 30 days) was assessed, as well as binge drinking. NIAAA guidelines were used to define heavy drinking (>7 drinks per week for women and >14 drinks per week for men), and binge drinking (4 drinks on a single occasion for women and 5 drinks on a single occasion for men).²⁶

T-ACE.—Risky drinking in women was assessed using the T-ACE screen (acronym for Tolerance, Annoyed when others express concern, Cut down on drinking, Eye-Opener).²⁷ The present study used a cut-point of 2 to predict risky drinking.

CAGE.—For males, the alcohol CAGE was used to detect problem drinking (acronym for Cut down drinking, Annoyed when others express concern, Guilty, Eye-Opener).²⁸ A cut-off of 2 was used as an indication of problem drinking.

Recreational/Illicit Use and Problems.—The CAGE-AID (adapted for use of other drugs) was used,²⁹ with a cut-off of 1 indicating problem substance use.

Prescription Misuse.—Participants were asked if they had misused any of their medications in the past 30 days, with prescription misuse defined as taking more pills than prescribed, taking pills more often than prescribed, using medication prescribed for someone else, or getting the same medication from more than one doctor.

Family History of Alcohol and Drug Problems.—Participants reported on alcohol and drug problems in parents and grandparents and whether they currently lived with someone having alcohol or drug problems.³⁰

Partner Violence Screen.—The 3-item Partner Violence Screen assessed physical partner violence and perceived safety.³¹

Data Analysis

Univariate logistic regression was used to identify correlates of study participation, sampling from such domains as alcohol and smoking, other drug use, family history of substance use, medical conditions, sleep, health behaviors, and other risk factors. Significance was set at 0.05 for all univariate analyses; however, any variables reaching a significance level of <0.20 , along with basic demographic variables, were subsequently included in a multivariate logistic regression model to examine their effect in combination. When multiple items from the same domain reached significance, only one predictor was selected for inclusion in the multivariate analysis to avoid multicollinearity.

A multivariate logistic regression model, with backward elimination, was used to identify the most parsimonious model of predictors of research participation. The final model was achieved by eliminating covariates, one by one, that were not significant at the 0.05 level. The Hosmer Lemeshow test was used to check goodness-of-fit of the logistic regression, as well as the R-squared value to determine how much of the variance in research participation was explained by the model.

RESULTS

Demographic characteristics of patients who consented and those who declined study participation are summarized in Table 1. The two groups were similar in age, gender, race and education. They differed on employment and health insurance type, with those who consented being more likely to be unemployed and those who declined being more likely to have private insurance. The two groups also differed on marital status.

Other, non-demographic correlates of study participation identified with univariate logistic regression are summarized in Table 2. Of the 57 variables examined, group differences were found for 60% at either the $p<0.05$ ($N=10$) or $p<0.01$ ($N=24$) level. An additional 11% ($N=6$) were significant at $p<0.20$.

For the substance use variables, patients who consented to the RCT were more likely than those who declined to report recent drug use, more days of recent use, and screen CAGE positive for drug problems. Those who consented were also more likely to report recent prescription drug misuse compared to patients who declined, with differences for three of the four misuse items. Binge drinking was the only variable more prevalent among those who declined participation as compared to those who enrolled in the study, but this pattern was found only for males. Patients who consented were more likely than those who declined participation to report family history of alcohol problems in parents and grandparents across all four categories of relatives. A similar pattern was found for other drug use in fathers.

Patients who consented to the RCT were also more likely than those who declined participation to report poor sleep quality, trouble falling asleep, trouble staying asleep, and the use of sleep medications. The two groups differed on all of the surveyed mental health

conditions, with those who consented more likely to report anxiety, depression, migraines, and chronic pain. Lastly, patients who consented were more likely than those who declined RCT participation to report: physical violence; a previous partner making them feel unsafe; and living with someone who currently had a drug problem.

Multivariate Analysis

Variables examined in the multivariate logistic regression are summarized in Table 3. The backward elimination included 29 iterations before arriving at the parsimonious model of predictors of research participation. As shown in Table 3, older individuals who were unemployed or on disability, reported taking their medications more often than prescribed, CAGE-AID positive for drugs, at least one grandmother with an alcohol problem, trouble falling asleep (past 30 days), health professional recommendation to lose weight, and feeling unsafe due to a previous partner were all associated with consenting to participate in the SBIRT RCT. Participants declining study participation were more likely to have high school education and be employed or retired. The model as a whole explained between 7.2% (Cox & Snell R Square) and 9.6% (Nagelkerke R Square) of the variance of subjects, and correctly classified 59.2% of cases.

DISCUSSION

The present study provides benchmark data on sample representativeness, highlighting baseline differences between patients who consented and those who declined study participation. While the two groups were similar for most demographic measures, they differed on domains ranging from emotional health and substance use to sleep disturbances and violence risk. More importantly, in all cases but one, those who consented reported greater symptom severity than those who did not.

The association between substance use severity and consent to the SBIRT RCT may reflect real group differences, with higher severity aiding recognitions of a need for help, and therefore more interest in SBIRT.^{18,32,33} Alternatively, persons declining study participation may be minimizing substance-related problem severity, with less interest in SBIRT. Since alcohol severity was unrelated to consent, perhaps social stigma contributed to the minimizing of illicit drug use by those not interested in RCT participation.¹⁸

Patients consenting to the RCT also endorsed a range of mental health conditions and greater sleep disturbance than those who chose not to participate. This finding may reflect the association between help-seeking and medical comorbidity.^{19,34} Greater awareness of the need for help among clients with comorbidities might make them more motivated to seek services, including those provided through a clinical trial. Further, the observed pattern of sleep disturbances may be even more salient within this population, given the overlap between insomnia and self medication with alcohol, other drugs, and over-the-counter medications.^{35,36,37}

Contrary to previous reports that low SES was negatively associated with research participation,³⁸ patients consenting to the RCT were more likely to be unemployed or on disability and less likely to have private insurance. Present study findings might differ

because the recruitment site serves predominantly low-income, ethnic minorities. Nonetheless, our data illustrate the link between private insurance and likelihood of being employed, which could result in less time available to participate in research. The present study required a considerable time commitment, including staying for the SBIRT intervention and three follow-up visits. Lastly, the financial incentives for study participants, while modest (\$140 total), may also have contributed to the observed demographic pattern.

While the multivariate model was statistically significant, clinical significance is not known. At one level, the model only accounted for a limited amount of the variance (7.2%–9.6%). On the other hand, all non-demographic variables in the model showed patients who consented to the RCT to be more at-risk compared to those who declined. These findings are consistent with similar patterns found in clinical practice, with selective implementation of brief alcohol interventions in primary care based on interpersonal factors of the patients and practitioners.³⁹ Thus, future research further exploring these differences and clinical implications is warranted.

Limitations

First, this was a secondary analysis of existing data and limited to variables in the RCT screener. Further, despite efforts to mask the primary purpose of the screener, it relied solely on self-report information. Second, measures were administered by computer tablet, a method associated with greater self-disclosure.⁴⁰ Findings may not generalize to clinical practice; however, research has shown that mode of assessment administration does not affect validity of measures.^{41,42} Third, the number of univariate analyses performed increased the probability of Type I error. This was justified, however, given the paucity of data on sample representativeness in the target population and primary care setting. Fourth, the sample was predominantly low-income, ethnic minority patients, limiting the generalizability of study findings. Lastly, participants completed the computerized health survey prior to being offered research participation, which may have resulted in practical issues influencing their ability to consent to the RCT (e.g., cumulative time for research at one visit).

Conclusion

The present study demonstrated that patients with heavy/problem substance use who volunteer for a SUD intervention reported a larger number and more severe problems across the many domains surveyed. While group differences were statistically significant, clinical significance remains to be seen. Nonetheless, study findings support a need to better understand representativeness of patients who volunteer for SBIRT and brief intervention research trials to determine whether differences are associated with variability in treatment outcomes.

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Table 1.

Demographic Characteristics

Variable	Patients providing consent (N=713)	Patients declining consent (N=625)	P value
Age (years)	45.3 (10.8)	45.1 (11.7)	0.79
Gender (% Male)	39% (281)	41% (254)	0.66
Race			0.59
Black	77% (547)	75% (466)	
White	19% (136)	20% (127)	
Other	4% (30)	5% (32)	
<i>Education</i>			<i>0.08</i>
Less than high school	26% (139)	30% (143)	
Grade 12 or GED	39% (212)	41% (193)	
Some college and beyond	36% (195)	30% (141)	
<i>Employment Status</i>			<i>0.001*</i>
Full Time	11% (63)	18% (88)	
Part Time	14% (77)	16% (76)	
On disability	18% (103)	16% (78)	
Unemployed	51% (284)	41% (200)	
Retired	3% (17)	6% (28)	
Student	3% (16)	4% (17)	
<i>Health Insurance</i>			<i>0.009*</i>
Private Insurance	6% (33)	11% (53)	
VCC	71% (396)	64% (310)	
Medicare	8% (44)	8% (37)	
Medicaid	10% (57)	9% (44)	
Uninsured	5% (30)	9% (42)	
<i>Marital Status</i>			<i>0.04*</i>
Single	45% (250)	51% (246)	
In a relationship	18% (100)	16% (79)	
Married	13% (72)	15% (74)	
Divorced	21% (119)	15% (71)	
Widowed	3% (19)	3% (16)	

Variables eligible for inclusion in the multivariate analysis are shown in italics.

Table 2.Variables with Significant Differences at $p < 0.20$

Variable	Patients providing consent (N=713)	Patients declining consent (N=625)	Multivariate Regression
Binge Drinking (Overall) **	71% (503)	78% (484)	X
<i>Binge Drinking (Males only) **</i>	<i>72% (202/281)</i>	<i>83% (211/254)</i>	
Rec. Drug Use (past 30 days) **	36% (258)	26% (161)	X
CAGE-AID Positive **	29% (209)	17% (108)	X
Rec. Drug Use (# days in past 30) **	5.09 (9.71)	3.52 (8.33)	X
<i>Rec. Drug Use (days/week) **</i>	<i>1.39 (2.35)</i>	<i>1.01 (2.10)</i>	
Rx Drug Misuse **	27% (190)	17% (108)	X
Rx Misuse: More pills than prescribed **	16% (113)	10% (63)	X
Rx Misuse: More often than prescribed **	12% (85)	6% (40)	X
Rx Misuse: Used someone else's Rx **	13% (91)	7% (42)	X
Alcohol Use: Mother **	21% (150)	15% (94)	X
Alcohol Use: Father *	46% (331)	41% (253)	X
Alcohol Use: Grandmother **	13% (91)	8% (49)	X
Alcohol Use: Grandfather *	20% (140)	15% (96)	X
<i>Parental Density Alcohol Use **</i>			
<i>No history</i>	<i>46% (330)</i>	<i>54% (337)</i>	
<i>One parent</i>	<i>40% (285)</i>	<i>36% (225)</i>	
<i>Both parents</i>	<i>14% (98)</i>	<i>10% (61)</i>	
Drug Use: Father *	15% (109)	11% (68)	X
Drug Use: Grandmother	2% (16)	1% (8)	X
<i>Hepatitis *</i>	<i>14% (98)</i>	<i>10% (64)</i>	
<i>Heart Disease</i>	<i>12% (88)</i>	<i>10% (63)</i>	
<i>High Blood Pressure</i>	<i>55% (392)</i>	<i>51% (320)</i>	
Mean number of medical conditions	1.24 (1.18)	1.14 (1.06)	X
Sleep Quality **			X
Poor	36% (257)	29% (179)	
Fair	40% (288)	39% (244)	
Good	18% (126)	25% (156)	
Very Good	6% (42)	7% (44)	
Trouble falling asleep **	72% (514)	62% (388)	X
Trouble staying asleep *	72% (516)	66% (410)	X

Variable	Patients providing consent (N=713)	Patients declining consent (N=625)	Multivariate Regression
Sleep Aids **			X
None	51% (364)	62% (388)	
Rx Only	30% (216)	25% (155)	
Non-Rx Only	13% (89)	9% (59)	
Both	6% (44)	4% (23)	
Anxiety **	39% (275)	30% (188)	X
Depression **	48% (340)	36% (224)	X
Migraine *	16% (111)	11% (72)	X
Chronic Pain **	37% (267)	31% (193)	X
<i>Mean number of mental health conditions **</i>	<i>1.39 (1.28)</i>	<i>1.08 (1.16)</i>	
Physical violence (past year) *	18% (129)	13% (84)	X
Previous partner make feel unsafe *	9% (62)	5% (29)	X
Living with someone with drug problem *	12% (82)	6% (39)	X
Physical activity (past 30)			X
Rarely	24% (169)	25% (158)	
Light/Moderate	59% (419)	60% (374)	
Min 30 minutes, 5+ days	18% (125)	15% (90)	
Average hours/day sedentary **			X
0–2 hours	34% (244)	40% (247)	
3–5 hours	26% (184)	29% (178)	
6–8 hours	14% (102)	12% (77)	
More than 8 hours	26% (183)	19% (119)	
Health rec. to lose weight **	45% (319)	37% (233)	X

Variables significant at 0.05 are denoted with (*) and variables significant at 0.01 are denoted with (**). All others $p < 0.20$. Variables shown in italics were not included in the model to avoid issues of multicollinearity. Variables included in the multivariate logistic regression are summarized in right column.

Table 3.

Multivariate Logistic Regression

Variable	Estimate	Standard Error	P value	Odds Ratio (95% CI)
Age	0.013	0.007	0.045	1.01 (1.00, 1.03)
Education			0.045	
<i>Less than high school</i>	−0.429	0.176	0.015	0.65 (0.46, 0.92)
<i>Grade 12 or GED</i>	−0.268	0.158	0.089	0.77 (0.56, 1.04)
Employment			0.016	
<i>Full Time</i>	−0.288	0.411	0.484	0.75 (0.34, 1.68)
<i>Part Time</i>	−0.051	0.410	0.902	0.95 (0.43, 2.12)
<i>On disability</i>	0.222	0.416	0.593	1.25 (0.55, 2.82)
<i>Retired</i>	−0.653	0.516	0.206	0.52 (0.19, 1.43)
<i>Unemployed</i>	0.258	0.391	0.510	1.29 (0.60, 2.79)
% Positive CAGE-AID	0.680	0.165	<0.001	1.97 (1.43, 2.73)
Taking prescriptions more often than prescribed	0.535	0.244	0.028	1.71 (1.06, 2.75)
Grandmother had problem with alcohol	0.501	0.228	.028	1.65 (1.06, 2.58)
Trouble falling asleep in past 30 days	0.292	0.141	0.039	1.34 (1.02, 1.77)
Health professional recommendation to lose weight	0.293	0.135	0.030	1.34 (1.03, 1.75)
Previous partner make feel unsafe	0.626	0.291	0.031	1.87 (1.06, 3.31)